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No. 80264-5

(~~Thurston County~~ Superior Court No. 04-2-01506-2)

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

UNIVERSITY OF WASHINGTON MEDICAL CENTER,

Respondent,

vs.

WASHINGTON STATE DEPARTMENT OF HEALTH

and

SWEDISH MEDICAL CENTER,

Appellants

SWEDISH'S APPENDIX OF RECORD

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Swedish Health Services
d/b/a Swedish Medical Center

University of Washington Medical Center
v.
Washington State Department of Health
and
Swedish Medical Center

Washington Supreme Court
No. 80264-5

Swedish's Appendix of Record

Exhibit	Record	Document
A	CP 961-970	Superior Court's Order Granting Petition for Judicial Review and Reversing Award of Certificate of Need No. 1288 (11 May 2007)
B	AR (Remand) 1906-1914	Department of Health's (Health Law Judge's) Final Order on Remand (15 August 2006)
C	AR 994-1019	Department of Health's (Health Law Judge's) Final Order (23 August 2005)
D	AR 1796-1816	Department of Health's (Certificate of Need Program's) Evaluation (17 June 2004) and Issuance of CN to Swedish (30 June 2004)
E	AR (Remand) 286-289	HLJ's Evidentiary Ruling (13 April 2006)
F	AR 1628-1795	Swedish's Rebuttal Statement (24 November 2003)
G	AR 3788-3793; AR 3807	Excerpts of the testimony of Dr. Rolland Dickson
H	AR 3853-3859	Excerpts of the testimony of Dr. Charles Miller
I	AR 3160-3164; AR 3901-3903	Excerpts of the testimony of Dr. William Marks
J	AR 3819-3820 AR 3832	Excerpts of the testimony of Dr. Marquis Hart

EXHIBIT A

ORIGINAL

☐ EXPEDITE

☒ Hearing is set
Date: 05/11/07
Time: 9:00 a.m.
Judge/Calendar: Tabor

FILED
SUPERIOR COURT
THURSTON COUNTY, WASH
07 MAY 11 AM 10: 34
BETTY J. GOULD, CLERK
BY _____ DEPUTY

SUPERIOR COURT OF WASHINGTON FOR THURSTON COUNTY

UNIVERSITY OF WASHINGTON MEDICAL CENTER, Petitioner, v. WASHINGTON STATE DEPARTMENT OF HEALTH, Respondent.	No. 04-2-01506-2 ORDER GRANTING PETITION FOR JUDICIAL REVIEW AND REVERSING AWARD OF CERTIFICATE OF NEED NO. 1288

This matter came before The Honorable Gary R. Tabor on April 13, 2007, on the University of Washington Medical Center's Second Amended Petition for Judicial Review of the "Final Order on Remand Affirming Findings of Fact, Conclusions of Law and Final Order Dated August 23, 2005" (Agency Order). With this Agency Order, the Department of Health Law Judge had awarded Certificate of Need No. 1288 to Swedish Health Services for a liver transplant program.

The Court considered the records and written submissions of the parties, including: (a) University of Washington Medical Center's Second Amended Petition for Judicial Review or, in the Alternative, Petition for Judicial Review; (b) Brief in Support of University of Washington Medical Center's Second Amended Petition for Review; (c) Response Brief of Swedish Health Services; (d) Department of Health's Trial Brief;

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(e) University of Washington Medical Center's Consolidated Reply Brief in Support of its Second Amended Petition for Judicial Review; (f) Declaration of Sally Gustafson Garratt in Support of UWMC's Reply Brief in Support of Petition for Judicial Review; (g) University of Washington Medical Center's Second Request to Accept Additional Evidence or, in the Alternative, Remand to the Department of Health CON Program to Take Additional Evidence; (h) Supplement to Brief in Support of University of Washington Medical Center's Second Amended Petition for Review and Submission of Supplemental Authority; (i) Response Brief of Swedish in Opposition to UWMC's "Second Request to Accept Additional Evidence or, in the Alternative, Remand to the Department of Health CON Program to Take Additional Evidence"; (j) Department of Health's Memorandum Opposing UWMC Request to Accept Additional Evidence; and (k) University of Washington Medical Center's Consolidated Reply Brief in Support of Its Second Amended Petition for Judicial Review; and the Court further considered the administrative and superior court record herein. Having considered the evidence and hearing arguments of counsel, now, therefore, it is hereby ORDERED AND ADJUDGED THAT:

1. This Court has jurisdiction over the Second Amended Petition for Review pursuant to RCW 34.05.570(3).

2. This Court has the authority pursuant to RCW 34.05.574(1) to (a) affirm the agency action or (b) order an agency to take action required by law, order an agency to exercise discretion required by law, set aside agency action, enjoin or stay the agency action, remand the matter for further proceedings, or enter a declaratory judgment order.

3. The Second Amended Petition for Review is granted, ~~and the appropriate remedy is to set aside the Agency Order.~~ the matter will not be remanded again, instead, the Court is setting aside the agency order. The Agency Order awarding Certificate of Need No. 1288 to Swedish Health Services is reversed for the reasons detailed in the Court's oral decision attached hereto as Exhibit A:

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a. The Agency Order is in violation of constitutional due process provisions and is set aside pursuant to RCW 34.05.570(3)(a);

b. The agency has engaged in unlawful procedure in its decision-making process and has failed to follow the decision-making procedure proscribed by law, and its Agency Order is set aside pursuant to RCW 34.05.570(3)(c);

c. The agency has erroneously interpreted and applied the law, and its Agency Order is set aside pursuant to RCW 34.05.570(3)(d);

d. The Agency Order is arbitrary and capricious and is set aside pursuant to RCW 34.05.570(3)(i);

c. ~~Alternatively, the Agency Order is set aside pursuant to RCW 34.05.570(3)(c), (d), (e), and (i) because it did not properly "consider the application in terms of its impact on existing and proposed institutional training programs for doctors of osteopathic medicine and surgery and medicine at the student, internship, and residency training levels" as required by RCW 70.38.115.~~ Alternatively, the Court stated that Swedish did not in its CON application address any potential impacts on existing or proposed institutional training programs as required by RCW 70.38.115 and/or WAC 246-310-210;

4. The Court stays the effect of the decision for a one-week period to more fully address Swedish's motion for stay.

Dated this 11 day of May, 2007.

The Honorable Gary R. Tabor

Presented by:

BENEDICT GARRATT POND, PLLC

Kathleen D. Benedict, WSBA #07763
Attorneys for Petitioner

Notice of Presentation waived; All objections preserved:
Peter Ehrlichman
for Swedish

Richard A. McCartan
Ass't Attorney General

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IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON

IN AND FOR THE COUNTY OF THURSTON

UNIVERSITY OF WASHINGTON MEDICAL CENTER,	)	
Petitioner,	)	
vs.	)	
WASHINGTON STATE DEPARTMENT OF HEALTH,	)	SUPERIOR COURT NO. 04-2-01506-2
Respondent.	)	

VERBATIM REPORT OF PROCEEDINGS

BE IT REMEMBERED that on April 13, 2007, the above-entitled and numbered cause came on for hearing before JUDGE GARY R. TABOR, Thurston County Superior Court, Olympia, Washington.

Pamela R. Jones, Official Court Reporter
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For the Intervenor: PETER EHRLICHMAN
Attorney at Law
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1 April 13, 2007 Olympia, Washington
2 MORNING SESSION
3 Department 6 Hon. Gary R. Tabor, Presiding
4 APPEARANCES:
For the Petitioner, Sally Gustafson Garratt and
5 Kathleen Benedict, Attorneys at Law; For the
Respondent, Richard A. McCartan, Assistant Attorney
6 General; for the Intervenor, Peter Ehrlichman,
Attorney at Law
7
8 Pamela R. Jones, Official Reporter
9 * * * * *
10 THE COURT: I wish I had a magic wand.
11 I'd like to wave a magic wand and go back in time
12 and fix what I see is a real mess. That's not my
13 job and I don't have a magic wand, and I've got to
14 rule according to what I understand the posture of
15 the matter before me is.
16 Previously I've said I'm not going to go there
17 because this isn't appropriate under this particular
18 context, and that was several times dealing with
19 particular motions that were made that really would
20 have required me to go into the record and spend
21 hours and hours understanding the record before I
22 made a ruling. That's the reason we have a Local
23 Civil Rule 56 that says here in Thurston County we
24 get plenty of administrative law appeals and we do
25 not normally entertain motions, certainly not

1 summary judgment motions, that require a
2 consideration of the record before ruling.
3 What is before me today is a proceeding that is
4 very convoluted. It started a number of years ago
5 and I have heard arguments in a number of contexts,
6 but at one point I did remand the matter indicating
7 that I believe that evidence was wrongfully withheld
8 from consideration at the administrative level and
9 it needed to be considered. Now when I say "it," I
10 did, I acknowledge, say I'm not going to rule on
11 what the scope of that is; that will be for someone
12 below to look at. I then indicated that I wasn't
13 even going to say that it went back to the
14 administrative law judge or it went back to the
15 Department of Health for a new C of N hearing or
16 public input. Now the DaVita case has provided this
17 Court with valuable insight, in my opinion, about
18 some of the issues surrounding these types of
19 Certificate of Need matters. Whether or not I would
20 have anticipated that is not really the issue, and
21 whether or not the administrative law judge would
22 have anticipated that is not the issue either.
23 It is not my position to point fingers or to
24 tell anybody, well, this is my decision and you
25 should have listened to it in the first place. I

1 will tell you, candidly, that it was very
2 interesting for me to read in the remarks that were
3 made by people about what I did or what I meant, and
4 that wasn't just the administrative law judge, it
5 was counsel, too. And everybody liked to second
6 guess me and tell me what I was going to do about a
7 matter that was coming up, more than likely, or why
8 I had done a particular thing. That's not really at
9 issue here either. I want to get to the point.
10 I'm not remanding this matter today, but I am
11 reversing the administrative law judge as to the
12 granting of the Certificate of Need. In doing so,
13 I'll flesh out in a few moments what I believe are
14 errors that cannot be corrected, and I'm simply not
15 going to try to go back and say here's the way to do
16 it right the third time. On the other hand, it's
17 not my place to indicate whether or not there is to
18 be a new application for Certificate of Need by
19 Swedish and how that battle would be fought.
20 In any event, by saying that I am not remanding
21 the matter, one of the difficulties that apparently
22 existed is people weren't sure of what I meant when
23 I said evidence should be taken. If you will recall
24 after my oral ruling on remand, and there was a
25 request to clarify what I meant, the request was did

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1 I mean that the evidence that was presented by
2 University of Washington in their briefing should be
3 admitted; was I saying that Swedish and/or the
4 Department of Health should have the opportunity of
5 responding to that; what would the rules be as far
6 as would there then be a further rebuttal? I simply
7 indicated that I was leaving that to the discretion
8 of the courts below except to say that fairness
9 would say if there's additional information
10 considered, the other side should also have the
11 opportunity of responding to that, but I did not
12 tell anyone how to conduct their business. On the
13 other hand, that does not absolve my responsibility
14 here today to review what was done and determine
15 whether or not it complied with the law.
16 I recognize that reasonable minds can often
17 differ. If I've made a mistake, then perhaps a
18 higher court can look at this and determine whether
19 or not they agree that I made a mistake or uphold
20 me, but that's up to the parties and I'm not going
21 to consider the fact that a higher court may look at
22 this for anything other than that's the right of the
23 parties. But I'm ruling today not based on any
24 anticipation of how anybody else might look at this,
25 but, rather, the way I see things.

1 Under RCW 34.05.574 I'm told that my job is not
2 to undertake to exercise the discretion that the
3 legislature has placed in the agency. My job is to
4 assure that the agency exercised its discretion in
5 accordance with the law, but, in doing that, I have
6 a number of options. I can affirm or overrule the
7 agency action, I can order the agency to do
8 something that I believe the law requires, I can set
9 aside or, I should say, remand the matter for
10 further proceedings, or, in certain cases, issue a
11 declaratory judgment.
12 I believe that I am required in this particular
13 case to deny the Certificate of Need based upon,
14 first of all, a violation of constitutional rights
15 as far as the University of Washington Medical
16 Center and due process. Many of things that I have
17 to say about due process I've already said before,
18 and, that is, that when there is new information, a
19 party should have the right to respond to that new
20 information. When I previously held that the
21 administrative law judge erred in saying you didn't
22 ask for reconsideration at the agency public hearing
23 or CON level, and because you didn't, University of
24 Washington, you didn't get to put it in. And I said
25 there's no requirement that there be request for

1 reconsideration. That's the reason that I remanded
2 this matter.
3 I indicated that it could be heard either by the
4 agency or by the administrative law judge and it was
5 totally up to her, but, in hindsight, the
6 administrative law judge chose, in my opinion, to
7 keep this matter before her and not remand it to the
8 Department for further public input because to do so
9 would open the record that she didn't want open.
10 She then set an artificial deadline which was to be
11 December 31st of 2003, which was some 30-plus days
12 after the close of the record. My recollection is
13 that record at the public hearing of the Department
14 of Health closed in early November 2003, and then
15 there was a time given for rebuttal briefs and
16 that's when the issue arose as to Swedish allegedly
17 putting in new information in the rebuttal. The
18 rebuttal for both Swedish and the University of
19 Washington was due on the same day, November the
20 24th. By then setting at the second hearing or at
21 the remand an artificial cutoff of December 31st,
22 2003, Judge Caner candidly said I don't agree with
23 Judge Tabor but I'll follow his order; nevertheless,
24 I'm going to impose this cutoff date.
25 If that cutoff date was set in concrete, why

1 wasn't it mentioned at the time that the matter was
2 originally denied? This artificial date, in this
3 Court's opinion, would be a violation of due process
4 even had the Court of Appeals Division 2 not
5 recently spoken in DaVita. And I do put some stock
6 in what DaVita has to say about the scope of the
7 hearing and the role of the hearings officer and
8 this being a de novo hearing, and I'll speak more
9 about that in a moment, but I also have spent
10 considerable time trying to understand on my own
11 certain other statutes that deal with hearings.
12 I've already, in a question I had for
13 Mr. McCartan, spoken before about RCW 34.05.449.
14 Subparagraph(2) there specifically says that at this
15 hearing, "The presiding officer shall afford all
16 parties the opportunity to respond, present evidence
17 and argument, conduct cross-examination, and submit
18 rebuttal evidence." It then goes on to say, "except
19 as restricted by a limited grant of intervention or
20 by the prehearing order."
21 Well, I'm not going to go into great detail to
22 solve everybody's problems about, well, doesn't that
23 create then a -- I think somebody called it a
24 revolving door, that people would not present
25 evidence at the public hearing so that they could

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1 hold it close to the vest. I would submit that
2 those kinds of things can be dealt with with orders
3 regarding discovery, if nothing else, about what
4 kind of information has to be provided to the other
5 side before it can be presented. That's simply
6 basic common sense, in this Court's opinion. But
7 section 449 clearly speaks to the need to provide
8 the opportunity to present information which could
9 either be presented by a party in their case in
10 chief, if you will, or assist in the
11 cross-examination of the witnesses of the other
12 side, or in submitting rebuttal argument.
13 There's another statute that I wanted to refer
14 to and that's RCW 34.05.461. I'm looking at
15 subparagraph (4). "Findings of fact shall be based
16 exclusively on the evidence of record in the
17 adjudicative proceeding" -- and I am highlighting in
18 the adjudicative proceeding. It doesn't say based
19 on the record at the public input below -- "and on
20 matters officially noticed in that proceeding."
21 It then goes on to say, "Findings shall be based
22 on the kind of evidence on which reasonably prudent
23 persons are accustomed to rely."
24 Here's the common sense concern that's led me to
25 my decision here today. I'm not going to go into

1 any kind of speculation or subjective indication of
2 how I might evaluate the evidence. I am saying the
3 evidence was not, in fairness, before the trier of
4 fact because of artificial rules. If, for instance,
5 someone states that as of right now, as of this
6 year, a particular fact exists which causes us to
7 believe that in coming years, that is, predicting
8 the future, certain things are going to happen, and
9 a period of time passes before a court actually
10 considers that evidence. Would it be common sense,
11 would it be reasonable for a trier of fact to say
12 I'm going to consider information that has developed
13 since the time that this was made as to whether or
14 not that trend that was projected is, in fact, being
15 carried out? Can there be cutoffs? Certainly,
16 there can, but not an artificial cutoff such as in
17 this case. So I've addressed 34.05.570(3)(a)
18 dealing with a violation of a constitutional
19 provision.
20 I believe that subparagraph (c) also applies.
21 "The agency engaged in unlawful procedure or
22 decision-making process." In this particular case,
23 that artificial standard and that absolute
24 prohibition about exceeding or presenting anything
25 that occurred after December 31st, 2003, was a

1 mistake. Now, I will acknowledge, as Mr. Ehrlichman
2 has argued, that there was some equivocation as to
3 whether or not there might be a procedure for
4 something being considered if it impacted the
5 evidence that fell within that time period. But in
6 practice, it's clear from the record that witnesses
7 were prohibited from even stating the title of
8 particular documents. It was clear that there were
9 documents that had been admitted in the first
10 hearing that were excised because they contained
11 information that was beyond that date.
12 Now, I will say that I was disturbed, I think
13 that's an accurate statement of my concern, as I
14 read the record of the second remand hearing, the
15 one that was supposed to last three days that only
16 lasted a day. It's not my place as a judge when
17 people appear before me, and it would not be my
18 place today in reviewing that, to tell attorneys
19 what they should or should not have done. But that
20 whole hearing was an embarrassment, as far as I'm
21 concerned, with all the objections that were being
22 made and all the back and forth, attorneys
23 addressing one another instead of the court, and
24 tactics.
25 I'm not sure of why particular parties had

1 particular tactics. I wouldn't have done it that
2 way. I would have suggested that the University of
3 Washington attempt to make more of a record of how
4 that information was relevant, even though it was
5 something that the judge had said is beyond the date
6 so you can't consider with specific statements.
7 It's relevant because it affects consideration of
8 evidence that's before you. I think you were trying
9 to do that to me here today when you were arguing.
10 I think that should have been done at the time.
11 Then as to Swedish and, to a lesser extent, the
12 Department of Health, what is so concerning about
13 this other information, if it can be so easily
14 rebutted, why not get it out and decide the matter
15 based upon all the evidence? If there's evidence
16 that's years too late, then the argument would be
17 that it shouldn't be given any weight. If there's
18 evidence that a statistic that was cited before is
19 wrong, then a party would have to concede that's
20 wrong but that doesn't make any difference, and
21 argue that.
22 But, instead, we've gone through this artificial
23 procedure, in my opinion, saying none of that should
24 be considered, we want you to decide this case based
25 upon the evidence presented at the time of the

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1 public hearing and nothing else. I guess saying
2 "nothing else" is unfair because there were
3 witnesses that were offered. But there were
4 artificial restrictions, and even today I was
5 hearing argument that once the record closed you
6 can't develop any new information. I simply think
7 that's not the case.
8 And so as to 34.05.570(3)(d), the agency has
9 erroneously interpreted or applied the law, I
10 believe, that applies in this case, putting on that
11 artificial restriction.
12 And finally as to subparagraph (i), the order is
13 arbitrary and capricious. I just said a moment ago
14 that reasonable minds can differ, and often when I'm
15 called upon to decide whether something is arbitrary
16 and capricious, I say my understanding of that
17 concept is that no person could possibly have taken
18 that position, so arbitrary and capricious is a very
19 high standard. In this particular case, however, I
20 believe that the decision by the administrative law
21 judge setting an artificial deadline, not allowing
22 anything beyond that deadline was, indeed, arbitrary
23 and capricious. I find absolutely no justification
24 for that under the rules that existed before DaVita.
25 Now let me say a few things about DaVita. Had I

1 been aware of how Division 2 was going to interpret
2 the law, and perhaps had I spent more time looking
3 at the law and the rules myself I would not have
4 remanded the matter before with the idea that it
5 would either be before the administrative law judge
6 or before the Department of Health. I would have
7 simply said there's to be a hearing and the hearing
8 below is to be conducted based upon evidence that's
9 relevant regarding the CON at the time the hearing
10 is held. Because what is a trial but a search for
11 the truth? And what's the truth? Well, the truth
12 yesterday may give way to the realities of today. I
13 don't know.
14 Now, in saying all that, I think I've already
15 indicated that I am not at this point saying whether
16 the University of Washington should be the only
17 liver transplant program for adults in the state of
18 Washington. I'm not saying that Swedish Hospital
19 should not be granted a Certificate of Need. I
20 don't know. That's going to have to be determined
21 under proper procedures.
22 And finally, previously when I granted the
23 remand there was an issue about a stay of the CON.
24 That's not an issue any longer as far as this
25 Court's concerned. There was a CON before. I

1 didn't overturn the CON, I simply said there needs
2 to be a new procedure, and I stayed the matter for
3 awhile and, as you recall, I then lifted the stay.
4 There is no necessity to address the idea of a stay
5 at all, as far as this Court is concerned, now
6 unless I'm missing something. So I don't have a
7 vision that tells me -- I used to say I don't have a
8 crystal ball but my reporter gave me a crystal ball
9 here at Christmas so I do have a crystal ball, I
10 just don't know how to read it. But I don't have a
11 vision for the future that knows what's going to
12 happen.
13 Is this matter going up on appeal? Is this
14 matter going to be dealt with with a new request for
15 a Certificate of Need? I don't know and it's not
16 for me to really speculate about that one way or the
17 other. I've ruled as I believe the evidence
18 requires.
19 I just want to speak about two other things, and
20 this may be dicta. The first is whether or not the
21 Certificate of Need portion of the application
22 dealing with the affects on the teaching program at
23 the University of Washington was properly addressed.
24 I've heard arguments on both sides. The reason I
25 think it's dicta is because since I'm denying the

1 CON at this point, whether or not that will be
2 presented in the future is up to the parties, I
3 guess, but I wanted to say that in looking at the
4 statute and the WAC, the statute that deals with
5 this is RCW 70.38.115. In that particular statute
6 at subparagraph (2)(d) it says, "The department
7 shall consider the application in terms of its
8 impact on existing and proposed institutional
9 training programs," et cetera, et cetera. The WAC
10 that deals with that is 246-310-210. And when one
11 reads about that, it seems to say that the applicant
12 would need to address that if they were asking for a
13 program that dealt with training programs. The
14 problem that I have with the way things came down is
15 the statute seems to be more specific than the WAC
16 and I think takes priority, and Swedish did not
17 choose to address that at all by saying
18 nonapplicable, N/A. There may have been some
19 testimony presented about that, but it wasn't in the
20 application. And the important thing, as I see it,
21 the applicant, Swedish, has the burden of showing
22 that they've met all the requirements showing need
23 under the various WACs or statutes.
24 Finally, just one other area, that's as to --
25 MR. ERLICHMAN: Excuse me, Your Honor.

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1 I don't mean to interrupt. I didn't quite
2 understand the point. Are you saying in dicta that
3 you do not believe that the record as it was
4 ultimately developed at the hearing addressed this
5 issue?
6 THE COURT: I don't think it properly
7 addressed it. I realize there was some information
8 there, but I think the burden was upon Swedish to go
9 forward, not upon the University of Washington, to
10 show that there was a problem. In any event, that's
11 dicta because we're not -- we didn't ever get there.
12 The final thing I wanted to address, and excuse
13 me for jumping around in my notes, just to let you
14 know how I looked at things here. It's as to the
15 issue regarding the request for disqualification of
16 the administrative law judge. I've already said
17 once before and I noticed that Judge Caner mentioned
18 that. Also, that as judges or administrative law
19 judges we have to have thick skins. But it's also
20 true that simply because someone rules in a way that
21 a party doesn't agree with doesn't mean that that
22 person is disqualified or prejudiced, and the
23 request for disqualification was not timely in this
24 particular case, nor was it well taken, in my
25 opinion.

1 Now, in hindsight, was Judge Caner wrong? I
2 already said I think she was. But I don't think
3 that she was in a position to simply step back when
4 there was a request by the University of Washington
5 for disqualification. I realize that's dicta as
6 well, in this particular case. And again, I'm not
7 going to predict whether Judge Caner will have
8 anything to do with this matter in the future, nor
9 am I indicating one way or the other.
10 There was a case here recently in which the
11 Court of Appeals indicated that a particular
12 Superior Court Judge should not have anything to do
13 with the matter when it was sent back to the judge.
14 I found that troubling and unprecedented. I'm not
15 making any kind of ruling about Judge Caner's
16 ability to hear this matter in the future. I told
17 you I think she was wrong, but that's as far as I'm
18 going.
19 Now, I know I've said lots of things. Let me
20 inquire if there are specific questions about my
21 rulings.
22 Mr. Ehrlichman?
23 MR. EHRLICHMAN: Is the Court making a
24 finding with respect to whether or not the
25 University of Washington was given an opportunity to

1 be heard at the remand hearing as to Swedish's
2 rebuttal statement? And, if so, could you address
3 what you pointed out which, at some point in this
4 proceeding, that they had listed 17 witnesses,
5 elected only to call two, in a hearing that was
6 scheduled for three days and ended up taking only a
7 couple of hours? Is the Court making a
8 determination as to whether or not the opportunity
9 to be heard was provided to the University of
10 Washington in that remand setting?
11 THE COURT: Well, I'll make that short
12 and sweet. I'm saying that the University of
13 Washington did not have the opportunity to respond
14 based upon Judge Caner's prehearing ruling that set
15 an artificial date that I've already said I believe
16 was totally inappropriate. That's all I'm going to
17 say about that.
18 Any other questions? All right. I thank
19 everybody for their efforts. I'm sure that an order
20 will be prepared, circulated, and presented.
21 MS. BENEDICT: Your Honor, may I ask,
22 would you like findings included with that order?
23 THE COURT: I've often said in
24 administrative law review I think what I've said is
25 on the record. And I don't think it's necessary

1 that specific findings and conclusions be issued in
2 writing, but that's my own style, I guess. I'll
3 leave it to the parties. You can argue whatever you
4 wish as to the form of the final order.
5 MS. BENEDICT: Thank you, Your Honor.
6 THE COURT: We be in recess.
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SCANNED

CERTIFICATE OF REPORTER

STATE OF WASHINGTON)
COUNTY OF THURSTON)

I, PAMELA R. JONES, RMR, Official Reporter of the Superior Court of the State of Washington, in and for the County of Thurston, do hereby certify:

That I was authorized to and did stenographically report the foregoing proceedings held in the above-entitled matter, as designated by Counsel to be included in the transcript, and that the transcript is a true and complete record of my stenographic notes.

Dated this the 19th day of April, 2007.

PAMELA R. JONES, RMR
Official Court Reporter
Certificate No. 2154

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SCANNED

0-000000970

EXHIBIT B

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In Re: Certificate of Need Application of:	)	Docket No. 04-07-C-2005CN
	)	
SWEDISH MEDICAL CENTER	)	FINAL ORDER ON REMAND
	)	AFFIRMING FINDINGS OF FACT,
	)	CONCLUSIONS OF LAW AND
	)	FINAL ORDER DATED
	)	AUGUST 23, 2005
	)	

APPEARANCES:

Petitioner, University of Washington Medical Center by
Benedict & Garratt, PLLC, per
Kathleen Benedict and Sally Garratt, Attorneys at Law

Intervener, Swedish Medical Center, by
Dorsey & Whitney, LLP, per
Peter Ehrlichman and Brian Grimm, Attorneys at Law

Respondent, Department of Health Certificate of Need Program, by
Office of the Attorney General, per
Richard A. McCartan, Assistant Attorney General

PRESIDING OFFICER: Zimmie Caner, Health Law Judge

Pursuant to a remand order issued by Thurston County Superior Court, a hearing was held on June 6, 2006. The August 23, 2003 Findings of Fact, Conclusions of Law and Final Order is affirmed.

I. PROCEDURAL BACKGROUND

1.1 On June 11, 2003, Swedish Medical Center (Swedish) submitted its application to the Department of Health Certificate of Need Program's (Program) for a liver transplant program. The University of Washington Medical Center's (University)

requested a copy of the application and any other information submitted to Program regarding the Swedish application.

1.2 On July 30, 2003, the University requested a public hearing regarding Swedish's application. Prior to and during the public hearing, the University and other interested parties submitted written comments and documents regarding the Swedish application. During the November 6, 2003 public hearing, the University and Swedish presented testimony and documents. On November 24, 2003, pursuant to WAC 246-310-160(1)(a), the University and Swedish submitted rebuttal documents to oral and written information submitted during the public hearing. Swedish raised a new theory within its rebuttal statement regarding patients falling through the cracks. On November 24, 2003, the rebuttal period ended and Program closed the period for public/party input.

1.3 On June 30, 2004, Program issued Swedish a CN to establish a liver transplant program for adult patients. Pursuant to RCW 70.38.115(10), the University filed a request for an adjudicative proceeding protesting the issuance of this CN.[1]

1.4 During the January 25, 26, 27, February 3 and 4, 2005 administrative hearing before a Health Law Judge (HLJ), the University presented the testimony of six physicians, a health care consultant, and a staff member with United Network for Organ

[1] Prior to the adjudicative appeal, the University participated in the administrative application review process as an "affected party" (defined in WAC 246-130-010) contesting Swedish's application for a liver transplant program CN.

Sharing.[2] Swedish presented the testimony of five physicians, the Program analyst, and the Program manager. Eleven exhibits were admitted two of which included a copy of Program's 1,548 page administrative record (AR) and the transcript of the public hearing regarding Programs' review of the Swedish application.

1.5 During the 2005 adjudicative proceeding, the HLJ concluded that the University failed to exhaust its administrative remedies by its failure to request reconsideration of Program's decision; and that reconsideration was the appropriate procedure to submit additional facts and data in respond to Swedish's November 2003 rebuttal statement.[3] As a result, the HLJ sustained objections regarding the presentation of facts and data that were not a part of the administrative record. During the 2005 administrative hearing, the University made an offer of proof in the form of the proposed exhibits. Swedish made a responding offer of proof.

1.6 On August 23, 2005, the HLJ issued Findings of Fact, Conclusions of Law and Final Order (Final Order) that affirmed Program's approval of Swedish's CN application for a liver transplant program. The HLJ concluded that even if the offers of proof were admitted as evidence, the findings of fact in the Final Order would not

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[2] The University's expert witnesses disagreed with Swedish's theory that patients are falling through the cracks and that Swedish's proposed liver transplant program is needed.

[3] Within 28 days of the Program's decision, any interested or affected person may, for good cause shown, request a public hearing for the purpose of reconsideration" of the decision on a certificate of need application. WAC 246-310-560(1). Good cause for a reconsideration hearing include but is not limited to:

> (i) Significant relevant information not previously considered by the department which, with reasonable diligence, could not have been presented before the department made its decision; ...(iii) Evidence the department materially failed to follow adopted procedures in reaching a decision.

WAC 246-310-560(2)(b).

The HLJ concluded in Prehearing Order No. 4 that subsections (i) and (iii) encompass the University's arguments for a remand and additional hearing; and that the reconsideration procedure is more efficient for all parties consuming less time and expense than pursuing a remand through an adjudicative appeal.

substantially change, and the conclusions of law and order would not be modified. The University appealed this Final Order to Thurston County Superior Court.

1.7 On January 13, 2006, Superior Court Judge Gary R. Tabor held that the HLJ erred. Judge Tabor held that the University did not lose its right to present additional evidence in response to Swedish's rebuttal at the adjudicative proceeding by failing to request reconsideration of Program's decision. In his remand order Judge Tabor outlined the scope of the remand:

> (5) The offer of proof submitted in the administrative proceeding below informed the court of the substance of the excluded testimony but does not go into sufficient detail to substitute for the testimony itself. Therefore, the administrative proceeding must be reopened in order to receive the information in the form of additional testimony.

1.8 During a March 2006 status conference and in Post-Hearing Order No. 1, the HLJ ruled that the evidence will be presented in the following order during the remand hearing;

1. The University may submit evidence in response to the Swedish's November 24, 2003 Rebuttal Statement that was submitted to Program.[4]
2. Swedish may submit evidence in response to the University's evidence admitted during the remand hearing.
3. The University may submit evidence in response to Swedish's evidence admitted during the remand hearing.[5]

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[4] The University was not limited to oral testimony although such a limitation could have been issued pursuant to paragraph 5 of Judge Tabor's remand order.
[5] The Program did not request the opportunity to present any evidence

1.9 Under the Washington Administrative Procedures Act (APA) chapter 34.05 RCW, a HLJ shall provide parties an opportunity to present evidence to the extent necessary for full disclosure of all the relevant facts and issues. RCW 34.05.449(2). The HLJs shall regulate the course of the proceedings in conformity with applicable rules and the prehearing order if any. RCW 34.05.449(1). In doing so the HLJ may restrict a party's opportunity to present evidence. RCW 34.05.449.

1.10 During the March 2006 status conference and in Post Hearing order No 1, the HLJ set a May 5, 2006 deadline for the filing of witness lists and proposed exhibits,[6] and limited the evidence to information that relies on facts and data that existed as of December 31, 2003.[7] This date is approximately five weeks after the rebuttal statements were submitted to Program, and five weeks after Program "closed" the public input stage pursuant to WAC 246-310-160. The public input stage is closed so Program may review and analyze an application with all the information that the applicant, interested parties and the public deem relevant and submit to Program.[8]

1.11 The December 31, 2003 date was selected by the HLJ because it provided the University with an opportunity to respond to the new theory raised in

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[6] Evidence that is not submitted in advance as ordered by the presiding officer should not be admitted in the absence of a "clear showing that the offering party has good cause for his or her failure to produce the evidence sooner, unless it is submitted for impeachment purposes". WAC 10-08-140(2)(a),(b). The purpose of the deadline is to provide the parties with sufficient time to prepare for hearing.

[7] During a May 18, 2006 prehearing conference, the HLJ granted the University a May 18th extension of time to submit additional exhibits that were not filed by the May 5th deadline. The parties were also granted a May 22nd extension of time to present redacted versions of timely filed exhibits (redacting the post 2003 data). The University did not provide good cause for its failure to file a number of its proposed exhibits by the extended deadline.

[8] The remand order did not address whether facts and data that did not exist at the time of Program's record "closure" should be admitted during the remand adjudicative proceeding.

Swedish's November 2003 rebuttal statement, and at the same time set a reasonable date that does not deviate unnecessary far from the closure of the public input stage of the administrative record. If no date was set as the University requested, new information could be submitted that did not exist at the time the Program made its decision. Such a ruling could result in a revolving door of litigation with additional information submitted for the first time during the adjudicative and judicial stages. As a result, applicants and/or interested parties may tactically benefit from postponing the submission of additional facts until the adjudicative or judicial stages. This may be of special advantage when the interested party is a potential competitor who may want additional time to change the manner in which it provides health care. Closure is needed so a revolving door of delayed responses does not unreasonable draw out the process. Late presentation of facts and data would result in an increase number of appeals/remands and delays in the resolution of CN appeals. The purpose of CN adjudicative appeals is not to supplant the certificate of need application review process but to assure that the procedural and substantive rights of the parties were observed and that the factual record supports Program's analysis and decision.[9] The December 31, 2003 cut off date for evidence during the remand hearing is reasonable and consistent with the facts at hand and the CN regulatory framework.[10]

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[9] See page 8 Prehearing Order No. 6, Order on Motion for Partial Summary Judgment In re the Certification of Need Application of Ear, Nose, Throat and Plastic Surgery Association, Inc., Docket No. 00-09-C-1027CN.

[10] The CN applicant has the burden to provide information necessary to grant the requested CN. WAC 246-310-090. Interested parties may comment on the application and parties may provide rebuttal information. WAC 246-310-060, -180. Program shall complete its final review and make its decision on

II. REMAND HEARING

2.1 The remand hearing was scheduled for a three day hearing on June 6-8, 2006.

2.2 On June 6th the University rested after presenting its exhibits and the testimony of Robert Carithers, M.D. and James Perkins, M.D. Their testimony was extremely limited because they stated that they could not dispute the new theory raised in the November 2003 Swedish rebuttal without post 2003 facts and data.

2.3 None of the University's proposed exhibits were admitted because they were not timely filed,[11] contained post 2003 facts and data, and/or lacked proper foundation.

2.4 Swedish did not present any rebuttal evidence due to the limited evidence presented by the University.

2.5 The parties submitted closing arguments through briefs.

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the application within 45 days of the end of the public comment period, unless the public comment period is extended in accordance with the rules. WAC 246-310-160. A party may request reconsideration of the program's decision. WAC 246-310-560. Program's decision to grant or deny an application for a CN must be in writing and include the findings that are the basis of Program's decision. WAC 246-310-490(1).

[11] The University argues in its closing brief that deadlines are not applied in other CN adjudicative proceedings to preclude exhibits, and therefore the University is not being fairly treated. This is not true. This HLJ rejects exhibits that are not timely filed by deadlines set in prehearing orders when a party objects to the admission of the untimely identified exhibit. These deadlines would be meaningless unless so applied, and the failure to reject untimely identified exhibits would place the complying party at a strategic disadvantage.

III. ORDER

The August 23, 2005 Findings of Fact, Conclusions of Law and Final Order that affirmed Program's issuance of Swedish's CN for a liver transplant facility is AFFIRMED.

Dated this 15th day of August, 2006.

ZIMMIE CANER, Health Law Judge
Presiding Office

NOTICE TO PARTIES

Either Party may file a **petition for reconsideration**. RCW 34.05.461(3); 34.05.470. The petition must be filed within 10 days of service of this Order with:

Adjudicative Service Unit
PO Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Certificate of Need Program
PO Box 47852
Olympia, WA 98504-7852

The petition must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration is considered denied 20 days after the petition is filed if the Adjudicative Service Unit has not responded to the petition or served written notice of the date by which action will be taken on the petition.

A petition for judicial review must be filed and served within 30 days after service of this order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed,

however, the 30-day period will begin to run upon the resolution of that petition. RCW 34.05.470(3).

The order remains in effect even if a petition for reconsideration or petition for review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This Order was "served" upon you on the day it was deposited in the United States mail. RCW 34.05.010(19).

EXHIBIT C

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In Re: Certificate of Need Application of:	)	Docket No. 04-07-C-2005CN
	)	
	)	FINDINGS OF FACT,
SWEDISH MEDICAL CENTER	)	CONCLUSIONS OF LAW,
	)	AND FINAL ORDER
	)	

APPEARANCES:

Petitioner, University of Washington Medical Center by
Kathleen D. Benedict, PLLC, per
Kathleen D Benedict, Attorney at Law

Intervener, Swedish Medical Center, by
Bennett, Bigelow & Leedom, per
Stephen I. Pentz, Attorney at Law

Respondent, Department of Health Certificate of Need Program, by
The Office of the Attorney General, per
Richard A. McCartan, Assistant Attorney General

PRESIDING OFFICER: Zimmie Caner, Health Law Judge

This is the University of Washington Medical Center's (the University) appeal of the Department of Health Certificate of Need Program's (the Program) issuance of a certificate of need (CON) to Swedish Medical Center (Swedish) for a liver transplant program. Program Affirmed.

ISSUES

1. Whether Swedish's application contains sufficient information demonstrating that it meets all applicable criteria for a liver transplant program CON.

2. Whether the Program's written analysis contains sufficient information that supports its decision to issue the Swedish liver transplant program CON.

3. Whether a preponderance of evidence supports the University's appeal; that the Swedish CON application does not met the requisite CON criteria, and/or the Program's written analysis does not support the issuance of the Swedish CON.

HEARING

During the hearing on January 25, 26, 27, February 3 and 4, 2005, Swedish presented the testimony of Randall Huyck, CON Program Analyst, Janis Sigman, CON Program Manager, William Marks, M.D., Swedish's Director of Organ Transplant Program and Director of Life Center Northwest, Rolland Dickson, M.D., Mayo Jacksonville Clinic Director of Transplantation Research, Marquis Hart, M.D., University of California San Diego Director of Transplant Program, and Charles M. Miller, M.D., Cleveland Clinic Foundation Transplant Program Director.

The University presented the testimony of: Robert Carithers, M.D., University's Vice Chairman for the Department of Surgery, Jorge Reyes, M.D., University's Division Chief of Transplant Surgery, James Perkins, M.D., the University's Vice Chairman of the Department of Surgery, John Hamm, M.D., Oregon Health & Sciences University Division Chief of Liver and Pancreas Transplantation, Amadeo Marcos, M.D., University of Pittsburgh Transplant Surgery Division Chief, John Fung, M.D., Cleveland Clinic Foundation General Surgery Department Chairman and Transplant Center Director, Sally Aungier, United Network for Organ Sharing (UNOS) Member Services Manager, and Jody Corona, Health Care Consultant.

A copy of the Program's 1,548 page administrative record (AR) regarding the Program's review of the Swedish CON application was admitted as Exhibit 1. Exhibits 2 through 10 were admitted during the hearing.

Pursuant to an agreement of the parties during the hearing, the November 6, 2003 administrative public hearing tapes were transcribed. The transcript was filed and admitted as Exhibit 11 on March 15, 2005. This transcript is a part of the administrative record.

Closing arguments were presented through briefs. The final brief was filed on May 3, 2005. Due to conflicts in schedule, the Health Law Judge issued an order extending the time to issue the final order.

OFFERS OF PROOF

The University filed an offer of proof filed on February 18, 2005 and Swedish filed a responding offer of proof on March 4, 2005.[1] Pursuant to an oral ruling during the

[1] During the hearing, the University moved for reconsideration of the ruling in Prehearing Order No. 4 regarding the admission of new evidence that is not a part of the administrative record. The administrative record was closed on November 24, 2003. After consideration of the University's brief in support of its motion for reconsideration and after consideration of the parties' oral argument, the Health Law Judge denied the motion on the record. The various procedural options for offer of proof were discussed during the hearing, and the parties decided to file written offers of proof pursuant to deadlines set forth by the Health Law Judge.

hearing and pursuant to Prehearing Order No. 4 regarding the closure of the administrative record, the offers of proof are rejected. Even if the offers of proof were admitted, the findings of fact in this order would not substantially change, and the conclusions of law and order would not be modified as a result the consideration of the offers of proof.

I. FINDINGS OF FACT

1.1 Swedish applied to the Program for a CON to establish an adult liver transplant program that would provide liver transplant services, including pre-screening/testing, complete inpatient care and follow-up treatment. The Swedish program would be located in Seattle, Washington where the University's existing transplant program is located. The Program granted Swedish a liver transplant program CON. The University is contesting the Program's decision to grant the CON.

1.2 The Program's written analysis addressed the CON criteria regarding "need", "financial feasibility", "structure and process (quality) of care" and "cost containment" that support the issuance of the Swedish CON. The "need" analysis addresses accessibility of liver transplant care from the University and the potential adverse effects a Swedish liver transplant program would have on the University's clinical, training and research programs.[2]

"Need"

1.3 The University provides adult liver transplant services and Children's Regional Hospital & Medical Center provides pediatric liver transplant services. These facilities work together to coordinate split liver or cut down liver procedures involving

[2] AR 771-780.

both adult and pediatric patients.[3] The University is the only facility providing adult liver transplant services to patients in Washington, Wyoming, Alaska, Montana and Idaho (WWAMI) who do not seek treatment elsewhere.[4] The University is an institution with a good reputation regarding the treatment of patients and the education of medical students and fellows. But, a comparison of statistics regarding population, liver disease/death and transplant rates of the University to other programs indicates that the University is not meeting the needs of Washington or WWAMI region.

1.4 The allocation of donor livers is based upon the severity of the illness. The statistical analysis demonstrates that the University has failed to provide liver transplant services to a sufficient number of sicker patients, or transplant a sufficient total number of patients. These shortcomings are particularly apparent when the University's statistics are compared with similar regions and the University's peer liver transplant programs.[5] There is a need for a second facility in this service area to serve those qualified patients who are not wait-listed or transplanted by the University.

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[3] There are basically four liver transplant procedures; donor liver transplant, a cut down donor liver transplant to fit into a smaller patient, a split donor liver transplant into two patients and live donor transplant, a portion of live donor's liver is transplanted into a patient. The later procedure places a healthy donor at risk, and therefore is done less frequently. The live donor procedure requires two surgical teams, one for the donor and one for the recipient patient, therefore a new program such as Swedish's would not only lack the experience but the staffing levels to conduct such a procedure. It was unclear from the evidence how long before Swedish would perform live donor transplants. The University has only performed one live donor transplant.

[4] Some Washington patients seek treatment from Oregon Health & Sciences University in Portland for insurance or veteran benefit coverage or because they live close to Portland in southwest Washington. WWAMI patients may also seek treatment elsewhere to be close to family/friends, for benefit coverage, or because other facilities have less conservative wait list selection criteria and/or transplantation protocols related to the acceptance of donor livers and matching patients to donor livers.

[5] Peer programs are those with similar size, quality of care and are serving a similar patient population/market. AR 605, 613-622.

1.5 The allocation of donor livers is a critical factor in the needs analysis for Washington and WWAMI. To understand the importance of the "sickest" first treatment standard for liver transplantation and donor liver allocation, one needs to understand its brief history. Prior to the existing donor liver allocation system, donor livers were allocated by length of time that a patient's name was on a wait list. Some patients were placed on waiting lists before they were very sick or before they needed a transplant, resulting in healthier patients receiving transplants first. As a result some sicker wait list patients with a shorter wait list time were dying unnecessarily.

1.6 To solve this problem, the Institute of Medicine recommended in 1999 that liver allocation could be improved with a new allocation system that focuses on the severity of the patient's illness rather than patient's wait list time. In response to this recommendation, the Department of Health & Human Services created the Organ Procurement and Transplantation Network (OPTN) to improve donor organ procurement and to assure fair distribution of organs, primarily based upon medical urgency.[6] OPTN awarded the contract to establish the allocation system and a scientific registry to United Network for Organ Sharing (UNOS).

New allocation system: Model for End-Stage Liver Disease (MELD)

1.7 In February 2002, after careful evaluation and studies predicting mortality related to liver disease, UNOS adopted the Model for End-Stage Liver Disease (MELD). The MELD system is an evidence based system relying on objective lab test results

[6] AR 734.

rather than subjective findings.[7] This system satisfied the recommendation made by the Institute of Medicine and the Department of Health and Human Services that emphasizes disease severity rather than time on wait lists.[8]

1.8 The MELD system generally dictates that the sickest patients on the wait lists are transplanted first, unless the patient's condition deteriorates so much that it is highly likely the patient will die even with a transplant. The transplant program such as the University makes that decision and removes those patients from its list.[9] The question in the case at hand is whether the University is treating/placing the sickest patients on its wait list or is it to some degree "cherry picking" its patients and donor livers? To answer this question one must understand the MELD allocation system.

1.9 The MELD system of allocation is divided into six basic levels pursuant to the severity of the illness (mortality risk) and the location of the patient in relation to the donated liver.[10] In an attempt to maintain fair, current and accurate information regarding the patient's life expectancy without a transplant, the MELD system requires regular reassessment of patients.[11] The reassessment is completed by a review of the patient's new lab test results that may result in a new MELD score and a new place on

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[7] The lab test results used to help calculate the MELD score are the values for Creatinine (kidney function), Bilirubin (liver's bile secretion function) and IRN (liver's blood clotting function).
[8] AR 737 and 560.
[9] AR 560.
[10] Six MELD levels of mortality risk: 1. local "Status 1" patients with a life expectancy less than 7 days without transplant, 2. regional "Status 1" patients, 3. local patients in descending order of mortality risk scores, the probability of pre-transplant death, 4. regional patients in descending order of mortality risk scores, 5. national "Status 1" patients, and 6. national patients in descending order of mortality risk status. AR 560.
[11] The MELD mortality risk status is divided into five tiers for reassessment and transplant priority purposes: 1. Status 1 patients are reassessed every 7 days, 2. Patients with a MELD score 25 or greater are reassessed every 7 days, 3. Patients with a MELD score between 24-18 are reassessed every month, 4. Patients with MELD scores between 18-11 are reassessed every 3 months, and 4. Patients with MELD scores between 10-0 are reassessed every 12 months.

the MELD priority list. These MELD scores are entered into the UNOS system that helps quickly determine the allocation of donor organs pursuant to the MELD system with current information.

1.10 Health care facilities of liver donors notify the local organ procurement organization of donor liver availability and provide the clinical information that is necessary to offer the liver to a transplant facility such as to University. The local organ procurement organization[12] responsible for the distribution of the donor liver contacts the facility with the patient(s) qualified under the MELD system to receive the donated liver. If there is no "Status 1" regional (non-local) patient with priority, the donor liver is offered to the local transplant program such as the University.

1.11 If a local transplant program such as the University rejects the organ, the organ procurement organization goes down the MELD priority list contacting the non local program with the patient(s) next qualified to receive a donor liver under the MELD allocation system. A local liver transplant program uses its discretion/protocols to determine whether a donor liver is an appropriate match to its wait list patient(s) qualified to receive the organ under the MELD system. The local liver transplant program may or may not accept the donated organ after reviewing the information regarding the donor and the donated organ.[13]

1.12 The MELD system provides an objective standard to prioritize patients once they are on the wait list, but the system does not set forth criteria to determine:

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[12] There are approximately 59 organ procurement organizations. Life Center Northwest is the local organ procurement organization for the University.
[13] AR 572.

a. which patients should be placed on the list,

b. which donor livers should be accepted or rejected by a liver transplant program, or

c. which match is appropriate - donor liver to a particular patient on the wait list.

1.13 Within these areas of discretion, the statistical analysis indicates that the University has been too conservative and less innovative in its approach.[14] As a result, healthier patients with lower MELD scores and an insufficient number of patients have been placed on the University's liver transplant wait list, and too many donor livers have been "turned down" by the University.[15] The statistics indicate that the University's conservative approach has under-served patients suffering from end stage liver disease who warrant a place on the wait list and/or patients on the wait list who would be a reasonable recipient of a "rejected" donor liver.[16]

Patient choice/competition

1.14 The University has not performed as many transplants as would be expected considering the rate of liver disease and the population of WWAMI or Washington. A second program is needed for patient choice/competition that will promote innovation and discourage complacency, resulting in the treatment of a higher percentage of sicker patients and better use of donor organs. The Swedish program would provide this needed choice/competition.

1.15 The transplant program uses it discretion to determine whether the donor liver matches the patient's needs. In doing so, the liver's quality and function is

[14] AR 45-48, 618 and testimony of Drs. Marks, Dickson, Hart and Miller.
[15] All but two of the "exported" livers (between 1999- 2002) were successfully transplanted.
[16] AR 614 and the testimony of Drs. Marks, Dickson, Hart and Miller.

evaluated based upon clinical information such as age, fat content/body mass index, cold ischemic time, illicit drug/alcohol use and the cause or the donor's death. The program needs to assess the risk of transplant failure resulting in the need for retransplantation, excessive hardship on the recipient and high post operative recovery cost.

1.16 A program's acceptance standards of donor livers affect the number of patients who receive livers. For example, livers donated after cardiac death were routinely rejected until innovative treatment disclosed that some livers donated after cardiac death could be successfully transplanted. This innovation greatly increased the pool of usable donor organs. The University was slow to respond to this innovation, and therefore deprived patients of transplants with viable livers donated after cardiac death. Dr. Marks, as Director of Life Center Northwest, the local organ procurement organization, was frustrated at the University's slow acceptance of this type of donor liver.

1.17 Medical literature concludes that programs in areas without competing liver transplantation programs treat less sick patients and those programs in areas with competition treat patients at significantly higher MELD scores.[17] Liver transplantation is a relatively new field, therefore innovation is important. "Collegial competition" between two facilities with good reputations such as Swedish and the University will generate

[17] Schaffer, Kulkarni, Harper, Millis & Cronin, The Sickest First? Disparities with Model for End-State Liver Disease-Based Organ Allocation: One Region's Experience, Liver Transpl. 2003:9:1211-1215. This article concludes that competing centers create patient choice, "programs performed transplantation on patients at a significantly higher MELD score than transplant service areas dominated by a single center." The study upon which this article is based included approximately 10% of the nations liver transplants including transplant service areas that had one transplant provider comparing areas with multiple providers. AR 734-738.

better ideas, increase innovation and decrease complacency, therefore improving the quality of care and expanding the organ pool to the point where Washington may start importing more organs than it exports.[18]

1.18 In evaluating patients, the MELD system directs the treatment of the sickest patients first whenever medically practical, whether it is placing a patient on a wait list or matching a patient to a donor liver. The University transplants a higher percentage of patients with lower MELD score patients than its peers.[19] Competition stimulates facilities to be more innovative, provide better care, reach out and treat sicker patients (higher MELD scores). The addition of the Swedish program will provide patients with a choice, and therefore a greater opportunity for the sicker patients to be wait listed and transplanted as intended by the MELD liver allocation system, and recommended by the Institute of Medicine and the Department of Health & Human Services.

Export/import of donor livers

1.19 The University rejected approximately 126 donor livers from 1999 through 2002, 98 of which were elective exports under the MELD system. Approximately 28 were exports for "Status 1" patients, mandatory exports pursuant to the MELD allocation system that is based upon mortality risk.[20] All but 2 of the exported livers were successful upon transplantation.[21] All of these livers would probably not have been

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[18] See AR 22-23, the testimony of Dr Dickson, Day 4 at 49 and Dr. Milller, Day 4 at 115-116.
[19] Despite the fact that the University transplant a higher percentage of patients with lower MELD scores, the University's transplant patient three year survival rate is lower that its peers who treat a higher percentage of sicker patients with higher MELD scores. AR 614 and 617.
[20] See footnote #10.
[21] Statistics regarding transplant success for longer periods of time were not present, because UNOS did not collect that data (other than data regarding transplantation of livers donated after cardiac death).

exported if more patients were on the list, and/or the University used less conservative criteria to accept/match donor livers to patients.[22] A longer wait list provides a larger pool, therefore increasing the probability of a compatibility match of donor liver to patient.

1.20 Life Center Northwest, the local organ procurement organization's export rate is composed of the donor livers rejected by the University[23] and the mandatory MELD export for "Status 1" non local patients.[24] Life Center Northwest's 27% export rate is close to the 25% national average, but that is not a reasonable figure for comparison purposes. Life Center Northwest's export rate should be compared with organ procurement organizations with similarities such as population served and similar programs served. These comparable organ procurement organizations have much lower export rates from approximately 10% to 15%.[25]

Number of Patients on the University's Wait List

1.21 There are an unknown number of patients with undiagnosed liver disease, patients diagnosed but never referred to a transplant center and patients evaluated by a transplant center but not listed for transplantation.[26] Swedish proposes to reach these

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During this period of time more patients on the University wait list may have survived through innovations such as earlier utilization of livers donated after cardiac death. AR 601, 620.

[22] One factor used to analyze the University's conservative, less innovative approach is its retransplantation rate as compared to the University's peer programs; Stanford 13%, University of Pittsburg 13 %, UCLA 13% and Baylor 7%. The national retransplantation rate is 9%. The University's low 2.8% retransplant rate is probably the result the University transplanting more patients with lower MELD scores than its peers transplant. AR 23

[23] Children's may also reject offered donor livers, but no evidence was presented regarding any donor livers Children's may have rejected.

[24] In 2002, only seven of the thirty exported livers were mandatory exports from Life Center Northwest.

[25] These four comparable organ procurement organizations serve the San Francisco Bay area, Los Angeles County, Nebraska and Colorado. AR 621-622.

[26] AR 738.

patients with less conservative, more innovative wait list/treatment protocols, and through outreach/education of patients and heath care providers. Through these methods, Swedish should increase the number of patients who are wait-listed and/or eligible to receive a liver transplant.

1.22 The population, liver disease and deaths statistics indicate that patients in Washington state and WWAMI region are "falling through the cracks".[27] Some patients may choose to be treated elsewhere for family support, veteran/insurance coverage reasons, but the statistics indicate that more patients should be on the University's wait list, and the number of exported livers should not be as large as it is. Patients probably come to Washington as some patients leave to be close to friends or family for support during the transplant process. Therefore, this factor may not be significant in the statistical analysis as the University asserts.

1.23 The average number of residents on wait list per million residents is 60 nationally, 14 in the WWAMI region, 38 in Arizona, 106 in California, 17 in Georgia, 82 in Maryland, 47 in Missouri, 55 in North Carolina, 48 in Tennessee and 46 in Virginia.[28] Washington is comparable to North Carolina with an 8.2 million population. The University serves the WWAMI region that has an 8.8 million population (6 million in Washington alone). North Carolina has a 251 patient wait list, and the University has only 127 patients on its list.[29] As Dr. Dickson stated; "WWAMI region is grossly

[27] AR 605, 608-619, 764-7.
[28] AR 618.
[29] AR 45-8, 618.

underrepresented in persons on the wait list per million residents, falling only below Georgia" [30]

1.24 These comparisons indicate that the University should have many more patients on its wait list. In light of these statistics, Drs. Marks, Miller, Hart and Dickson are more credible and persuasive than the experts presented by the University. The addition of a second program is needed for patient choice/competition that will result in increased innovation, decreased complacency and improved volume and quality of care. Even though the University on average performs transplants on its wait list patients at a faster rate, there should not be such a large discrepancy with its wait list size. A shorter list will result in patients being transplanted faster since the patients do not have as much competition on the shorter list. The wait list size does not dictate the number of transplants, but the longer the wait list the more varied the patients' needs (matching criteria of patient to donor liver). Therefore a longer wait list will probably result in higher use of the available donor livers and a lower donor liver export rate.[31]

1.25 Patients who are turned down by the University and not placed on its wait list can seek care from another facility out-of-state.[32] However, increased cost or lack of

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[30] Day 4 at 44-5. Dr. Dickson's point is supported by indicated by Table 5 at AR 617 that shows the average number of resident on wait list per million residents nationally is 60, 14 in the WWAMI region, 38 in Arizona, 106 in California, 17 in Georgia, 82 in Maryland, 47 in Missouri, 55 in North Carolina, 48 in Tennessee and 46 in Virginia. AR 618.

[31] A number of physicians who refer patients to the University's program find that their patients receive good treatment, and that their patients do not have to seek care elsewhere. A number of those practitioners were trained or closely affiliated with the University. It would be reasonable to conclude that they have similar standards as the University. Letters submitted by these physicians fail to address many of the issues raised by the statistical analysis such as wait list size and MELD scores discrepancies. AR 501-528 and 651-658.

[32] See Dr. Green's testimony at 21 of Exhibit 11 and Dr. Dickson's testimony regarding patients who migrated out of state for liver transplants.

information may result in patients not seeking out-of-state care. As a result these patients may die.

Minimum volume standards

1.26 The University has a fellowship liver transplant education and training program with one fellow. The University argues that its existing transplant volume levels are necessary to maintain quality training and research programs. That argument is asking the health law judge to set new minimum standards for a liver transplant program after expert medical organizations have done so. That would be inappropriate. UNOS and the American Society of Transplant Surgeons (ASTS) are clearly better qualified to determine minimum volumes needed to sustain a fellowship training program.[33]

1.27 In evaluating potential adverse impact on the University's program, one must rely on the minimum standards set by UNOS and ASTS.[34] UNOS and ASTS require a liver transplant training program to perform 50 liver transplants annually and a liver transplant fellow must participate in 45 liver transplants as primary surgeon or as first assistant over a two year period.[35] In light of the number of University transplants, the potential for the increase in the number of transplants, the University's annual transplant volume should remain well above the minimum volumes set by the experts through UNOS and ASTS.

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[33] There are approximately 120 UNOS approved liver transplant programs of which approximately 44 have fellowship training programs.
[34] Even if the University's program were to expand to two fellows, the University would probably perform more than the requisite number of transplants for a training program with the addition of competing transplant program.
[35] AR 943.

1.28 In assessing the potential impact on the University's fellowship training program, one should compare it with other well know peer academic programs. These programs have annual volumes that are comparable or lower than the University.

1.29 There are no minimum volume standards for liver transplant programs without a fellowship training program. One study concludes that transplant outcomes are better at high volume programs but find no clear minimal threshold volume.[36] Another study regarding minimum volume standards concluded that liver transplant programs under 20 transplants a year experienced higher mortality rates, and that the mortality rates varied little when programs performed twenty or more transplant annually.[37] Swedish projects that its new program will be performing 18 transplants during its second year of operation, 32 in its third year, 42 in its fourth year and 48 in its fifth year.[38] Swedish will be soon above 20 transplants a year, and the statistical analysis indicates that the University will remain well above 20 transplants a year.

1.30 To evaluate the potential adverse effect, one needs to review the national and local upward trends in the number of liver transplants, liver disease and population. The University stated that it had an excellent program when its volumes were even lower than the volumes in 2003 and 2004. The University performed approximately 68 transplants in 1998, 67 transplants in 1999, 93 in 2000, 71 in 2001, 79 in 2002, 104 in 2003 and 126 in 2004.[39] The 5 % national annual growth rate in liver transplants during

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[36] AR 1178-1185, Axelrod, Guidinger, McCullough, Liechtman, Punch, Merion, Association of Center Volume with Outcome after Liver and Kidney Transplantation, Am J of Transplantation 1999; 4: 920-7.
[37] AR 780, 1518-1522, Edwards, Roberts, McBride, Schulak, Hunsicker, The Effect of the Volume of Procedures at Transplantation Centers on Mortality After Liver Transplantation, N Engl J Med 199, 341: 2049-53.
[38] AR 36.
[39] Dr. Carithers on direct examination, Day 3 at 19 and AR 70, 1068.

this same period probably will continue. Also, a new program at Swedish will increase the total number of liver transplants through innovation and competition.

1.31 The addition of a new liver transplant program is not a "zero sum game". Any Swedish transplant would not necessarily subtract a transplant from the University's volume. As Dr. Dickson and Dr. Miller explained, more than one program in a service area results in the performance of a greater total number of transplants because competition promotes additional transplants. Additional transplants are the result of competition/innovation because more than one provider determines who qualifies for a transplant, is interested in promoting organ donations, and is available during peak demand within the service area. Therefore, the addition of a second program to this service area will not result in the creation of an unneeded program leading to mediocrity and low volumes for both programs.

Adequate Staffing levels

1.32 Swedish's proposed liver transplant program includes adequate staffing levels for the projected transplant volumes, and clinical care/assessment before and after the transplant. Staffing levels need to take into account the patients who are assessed but who are not placed on a list, and those who are placed on the list but who do not receive a transplant.[40] A liver transplant program requires available staff twenty-four hours a day seven days a week.

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[40] Swedish transplant program started 1993 and presently includes pancreas, kidney, and bone marrow. These programs have demonstrated innovations such as steroid free immunosupression for kidney transplantation, the first facility in the Northwest to offer this protocol. The University now provides this treatment but in a different fashion, therefore offering a patient a choice in care. AR 630-1.

1.33 Swedish's proposal includes a new hepatologist and liver transplant surgeon who will work with the existing staff. UNOS liver transplant program standards require one qualified liver transplant surgeon on site.[41] Swedish's existing transplant program includes three board-certified surgeons[42], a urologist, a nephrologist and six rotating nephrologists. It also includes residents in training, transplant nursing staff with special training and assignments, a transplant pharmacist, a transplant pathologist, a transplant infections disease group, a social worker, a data manager and a research fellow. Some of the existing staff members will work with the new liver transplant program in addition to the existing program since it will be part of the Swedish transplant program.

Financial Feasibility

1.34 Because Swedish will use existing transplant program facility and staff with the addition of two physicians, equipment and training, the initial capital costs are relatively small.[43] Swedish can appropriately finance the proposed liver transplant program from existing Swedish funds and projected income, and the project will not result in an unreasonable impact on the cost and charges for liver transplant health care services.[44] The Swedish program will probably result in an increase in the overall health care costs in Washington, but not as a result of unnecessary duplication. This increase

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[41] Board certified in surgery, urology or osteopathic surgery. AR 779, 943, 947.
[42] UNOS requires a liver transplant program to have one qualified transplant surgeon on site. UNOS qualified transplant surgeon must be board certified by either American Boards of Surgery or Urology, the American Board of Osteopathic Surgery, or their foreign equivalent.) Two of Swedish's transplant surgeons are certified by the American Board of Surgery. AR 779.
[43] Swedish service agreements with the local organ procurement organization, the local blood bank demonstrates its relationships with ancillary and support service providers currently serving other Swedish programs and that it will continue the relationship to support a liver transplant program.
[44] AR 56-66 (pro forma budget and volume/revenue projections), and AR 776-781.

will result from the increased number of Washington residents receiving transplants. Liver transplants on average extends a life by 12 years, therefore the increased costs are not unreasonable.[45]

II. CONCLUSIONS OF LAW

Purpose of the Health Planning & Development Act

2.1 In response to the 1974 National Health Planning and Resources Development Act, the Washington legislature adopted Washington's 1979 Health Planning & Development Act creating the certificate of need program. Chapter 70.38 RCW and St. *Joseph Hospital & Health Care Center v. Department of Health*, 125 Wn2d 733, 735-736 (1995). One of the purposes of the federal and state health care planning acts was to control health care costs. *Id.* Both legislative bodies were concerned that competition in health care "had a tendency to drive health care cost up rather than down, and government therefore needed to restrain marketplace forces. *Id* at 741. The CON regulations are therefore designed in part to control rapid rising health care cost by limiting competition within the health care industry". *Id.*

2.2 The CON statutory scheme protects existing facilities from competition "unless a need for additional services" can be demonstrated. *Id.* at 742. Swedish's CON will meet a public need of increasing number of liver transplants and need for more innovative/less conservative program that will not adversely affect the University's program and may also improve the quality of care at both facilities.

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[45] AR 781.

2.3 The CON statutory requirements limit provider entry into the health care markets so the development of services and resources "should be accomplished in a planned, orderly fashion, consistent with identified priorities and without unnecessary duplication or fragmentation". RCW 70.38.015(2).

2.4 The Department of Health (the Program) is responsible for managing the CON chapter under chapter 70.38 RCW. RCW 70.38.105(1). Certificates of Need shall be issued or denied in accordance with Health Planning & Development Act and the Department rules which establish the review procedures and criteria for the CON program in chapter 246-310 WAC. RCW 70.38.115(1).

2.5 This health planning process must consider the "cost-effectiveness and cost-benefit analysis" and provide accessible health care services "while controlling excessive increases in costs". RCW 70.38.015(1) and (5).

Liver Transplant Programs

2.6 Liver transplantation programs are hospital-based "tertiary services" that are subject to CON review. WAC 246-310-020(1)(d)(i)(D). The Department rules do not set minimum standards for liver transplant facilities, unlike kidney facilities that must perform at least 15 transplants by its fourth year of operation, and must meet the United Network for Organ Sharing (UNOS) requirements for organ sharing. WAC 246-310-260(2)(a)(b). Even though the Department rules are silent on the issue of minimum volumes for liver transplant centers, UNOS and the American Society of Transplant Surgeons (ASTS) have minimum standards/volumes for liver transplant fellowship training programs. It is unreasonable for the CON Program or a Health Law

Judge to create standards that conflict with the well researched standards set by these expert organizations. UNOS and ASTS do not have minimum volume standards for a liver transplant program that does not include a fellowship training program. After review of available literature regarding liver transplant volumes and outcomes, the CON Program reasonably concluded that Swedish and the University would meet minimum volumes that results in good quality of care in their liver transplant programs.[46]

2.7 The general CON criteria apply to a liver transplant program application. An applicant for a CON shall establish that it meets all applicable criteria. WAC 246-10-606. The CON Program then renders a decision whether to grant a CON in a written analysis that must contain sufficient information supporting its decision. RCW 70.38.115(2) and WAC 246-310-200 outline the criteria that the CON Program must address in determining whether it should grant or deny a CON. Those criteria are "need" (WAC 246-310-210), "financial feasibility" (WAC 246-310-220), "structure and process (quality) of care" (WAC 246-310-230), and "cost containment" (WAC 246-310-240). The Program's written analysis contains sufficient information regarding "need", "financial feasibility", "structure and process (quality) of care" and "cost containment" criteria that support the issuance of the Swedish CON. Swedish's application established that it met the requisite criteria.

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[46] AR 780

Need – WAC 246-310-210

2.8 A preponderance of the evidence supports Program's conclusion that there is a need for Swedish's proposed liver transplant facility. As stated in WAC 246-310-210(1):

> The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need... (Emphasis added)

Patient choice may be used under this criteria when evidence demonstrates a public need for a second transplant facility, and when that facility does not adversely affect the existing facility. St. Joseph at 742. There is a need for a second facility. The lack of patient choice resulted in some patients not receiving necessary and proper care or traveling longer distances to obtain care.[47]

2.9 Because The CON Program does not have a rule or established numeric needs projection methodology for liver transplant services, Swedish provided a rational and verifiable analysis of need. Swedish's need analysis examined national and local liver disease/mortality and transplant program statistics, and demonstrated that the existing facility is not meeting the transplant needs of all eligible transplant recipients.

2.10 A preponderance of the evidence supports The CON Program's conclusion that the Swedish program will not have an adverse effect on University's research and training programs. The pertinent part of WAC 246-310-210 states:

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[47] The University cites the *Olympic Peninsula Kidney Center* decision. Docket No. 04-06-C-2003CN (2005). Contrary to the University's argument, the decision held that patient choice is a legitimate CON factor in the review of CON applications whenever there is need and the facilities would provide the patients with a realistic choice. In *Olympic*, the geographic distance between the dialysis facilities in question precluded a realistic patient choice, therefore competition/patient choice was found to be unsupported by the facts, unlike the case at hand.

The determination of need for any project shall be based on the following criteria...
(4) The program will not have an adverse affect on health professional schools and training programs. The assessment of the conformance of the project with this criterion shall include consideration of:
(a) The effect of the means proposed for the delivery of health services on clinical needs of health professional training program in the area in which the services are to be provided; and
(b) If the proposed health services are to be available in a limited number of facilities, the extent to which the health professional schools serving the area will have access to the services for training purposes. (Emphasis added)

2.11 Analysis under subsection (a) indicates that the addition of Swedish's competing program, with different selection criteria and treatment protocols will increase the number of Washington patients on wait lists and the number of liver transplants. Innovation and less conservative protocols will increase the use of the existing donor livers. Population increases and education/recruitment of new donors will increase the overall size of the donor pool. In light of these factors, the literature regarding minimum volume standards and UNOS minimum volume standards, a new Swedish liver transplant program should not have an adverse effect on the University's training or research programs as well as its clinical program. The simple reduction of the total number of transplants is not sufficient evidence of adverse affect in light of UNOS/ASTS standards and the statistical analysis regarding population, liver disease and liver transplants.[48]

[48] University argues that WAC 246-310-210(3) applies. This subsection addresses applications that contain proposed training and/or research programs; therefore it does not apply to the Swedish application. Subsection (4) addresses applications that may affect existing training programs and research programs and therefore subsection (4) applies to the case at hand.

2.12 Subsection (b) does not apply since the University has its own liver transplant program and therefore will not need to have "access to the services for training purposes".

Financial Feasibility – WAC 246-310-220

2.13 A preponderance of the evidence supports the Program's conclusion that Swedish's proposed liver transplant program is "financially feasible" because: 1) the capital and operating project costs can be met; 2) the costs of the project will not result in "an unreasonable impact" on the costs and charges for health care services; and 3) "the project can be appropriately financed." WAC 246-31-220(1)-(3).

2.14 The Swedish program will increase in the overall health care costs in Washington, but not as a result of "unnecessary construction or duplication". WAC 246-210-220(2). This increase will result from an increased number of transplants. This increased cost is not unreasonable, because a liver transplants extends a life by approximately 12 years.[49]

2.15 The initial capital costs are relatively small, and Swedish intends on using existing transplant program facility and staff with the addition of two physicians, equipment and training. Therefore, Program reasonably concluded that Swedish's transplant program "will not have an unreasonable impact" on the heath care costs and charges to the public. WAC 246-310-220(2) and WAC 246-310-240(2)(b).

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[49] AR 781.

Structure and Process (Quality) of Care – WAC 246-310-230

2.16 A preponderance of the evidence supports the Program's conclusion that Swedish's proposed program will foster an "acceptable or improved quality of care" because the Swedish program will have sufficient staff, appropriate relationships with needed ancillary and support services, and "will not result in an unwarranted fragmentation of services". WAC 246-310-230(1)-(5).

2.17 Swedish's liver transplant program will not result in unwarranted fragmentation of services because the University will maintain volumes well above the "low volume standard" associated with higher mortality rates. In addition, a Swedish program should decrease fragmentation because fewer patients will probably travel out of state to receive a liver transplant.

Cost Containment – WAC 246-310-240

2.18 A preponderance of the evidence support Program's conclusion regarding "cost containment." As stated in WAC 246-310-240:

> A determination that a proposed project will foster cost containment shall be based on the following criteria: (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable... (Emphasis added)

A second facility will probably provide services to the types of patients who have been denied access in the past, and provide more "efficient" (not having to travel out of state) or "effective" care (qualified patients not receiving a place on wait list and/or transplants). WAC 246-310-240.

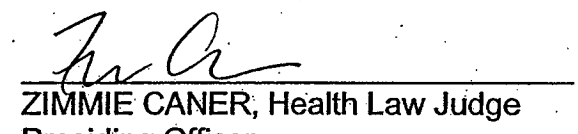
2.19 The party appealing the CON Program decision has the burden of proof in the adjudicative proceeding. The standard of proof is a preponderance of the evidence.

WAC 246-10-606. Evidence should be the kind that "reasonably prudent persons are accustomed to rely in the conduct of their affairs." RCW 34.05.461(4). Sufficient evidence was present to support Program's decision to grant a CON to Swedish for a liver transplant program. University failed to present a preponderance of the evidence that supports its appeal regarding the issuance of the Swedish CON.

III. ORDER

Based on the foregoing findings of fact and conclusions of law, the Program's issuance of Swedish's CON for a liver transplant facility is affirmed.

Dated this 23rd day of August, 2005.



ZIMMIE CANER, Health Law Judge
Presiding Officer

NOTICE TO PARTIES

Either Party may file a **petition for reconsideration**. RCW 34.05.461(3); 34.05.470. The petition must be filed within 10 days of service of this Order with:

Adjudicative Service Unit
PO Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Certificate of Need Program
PO Box 47852
Olympia, WA 98504-7852

The petition must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration is considered denied 20 days after the petition is filed if the Adjudicative Service Unit has not responded to the petition or served written notice of the date by which action will be taken on the petition.

A petition for judicial review must be filed and served within 30 days after service of this order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed, however, the 30-day period will begin to run upon the resolution of that petition. RCW 34.05.470(3).

The order remains in effect even if a petition for reconsideration or petition for review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This Order was "served" upon you on the day it was deposited in the United States mail. RCW 34.05.010(19).

EXHIBIT D

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
PO Box 47852 * Olympia, Washington 98504-7852

June 17, 2004

CERTIFIED MAIL # 7000 1670 0013 5840 9773

Brian Kuske
Vice President, Ambulatory and Ancillary Services
747 Broadway
Seattle, Washington 98122

Dear Mr. Kuske:

The department has completed its review of the Certificate of Need application submitted on behalf of Swedish Health Services proposing to establish a liver transplant program at the First Hill campus of Swedish Medical Center. Enclosed is the written evaluation of the proposal.

For the reasons stated in this evaluation, Swedish Health Services' project is consistent with applicable criteria of the Certificate of Need Program, with the following conditions:

1. Swedish Health Services is approved only to offer adult liver transplant services.

2. Swedish Health Services will provide charity care in compliance with the charity care policies provided in its Certificate of Need application and the requirements of the applicable law. Swedish Health Services will use reasonable efforts to provide charity care in an amount comparable to the average amount of charity care provided by hospitals in the King County region, during the three most recent years. For historical years 2000-2002, these amounts are .75% of total revenue and 1.3% of adjusted revenue. Swedish Health Services will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies and applicable law.

With the conditions stated above, the Department of Health concludes that the proposal satisfies the application criteria. Without this condition, the proposal would not be consistent with applicable Certificate of Need criteria, and a Certificate of Need would be denied.

Please notify the Department of Health within 20 days whether you agree to the condition for your proposal. The Certificate of Need Program does not accept faxed responses to correspondence. Your written response should be sent to the Certificate

of Need Program, 310 Israel Road Southeast, Post Office Box 47852, Olympia, Washington 98504-7852.

Thank you for your cooperation during the review of the application. If you have any questions, please contact Janis Sigman of the Certificate of Need Program at (360) 236-2955.

Sincerely,

Gary Bennett, Director
Facilities and Services Licensing

Enclosure

cc: Office of Health Care Survey

THE DEPARTMENT OF HEALTH'S FINDINGS FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF SWEDISH HEALTH SERVICES, SEATTLE, PROPOSING TO ESTABLISH A LIVER TRANSPLANT PROGRAM

PROJECT DESCRIPTION

Swedish Health Services (SHS) is a private non-profit corporation that provides acute-care hospital services at three campuses in Seattle. SHS also provides Medicare/Medicaid certified home health and hospice services and operates an ambulatory surgery center in Seattle. The three campuses are licensed for a total 1,296 acute care beds and 81 long-term care beds. SHS has grown to be a regional provider of specialized health services, providing adult and pediatric open heart surgery, pancreas, kidney and autologous and allogenic bone marrow transplant, and specialized pediatric services. SHS operates chemical dependency, rehabilitation, pain management, diabetes treatment and education, and sleep diagnostic centers. In addition, SHS operates tumor centers in collaboration with Stevens and Highline Community Hospitals and provides medical services through a group physician practice with nine clinics.

For this project, SHS proposes to establish a liver transplant program as part of developing a comprehensive diagnostic and treatment program for end stage liver disease.

Liver transplantation is used to treat patients suffering from liver failure resulting from liver diseases such as cirrhosis and hepatitis, acute liver failure, hepatocelular carcinoma, and other less common diseases[1]. Adult patients suffering from life-threatening liver failure are prioritized for liver transplant according to the Model for End-Stage Liver Disease (MELD) scoring system. This rating system designates patients with a life expectancy without liver transplant of less than seven days as "Status 1" patients, and all other patients are assigned a MELD score depending on results of laboratory tests for various markers of liver function. The United Network for Organ Sharing (UNOS) operates the Organ Procurement and Transplant Network (OPTN), the body responsible for allocation and distribution of harvested organs. UNOS policy outlines the distribution policy for harvested livers based on status, MELD score, and location relative to the harvested organ. Harvested organs are offered first to local Status 1 patients, then to regional Status 1 patients. If no local regional or Status 1 patients are suitable recipients for an organ, it is then offered to local patients in descending order of MELD score, then to regional patients in descending MELD order. If no local or regional recipients are able to receive the organ, it is then offered to Status 1 patients elsewhere in the nation, followed by other patients, again in descending order. The MELD system is intended to be an equitable and objective method of distributing cadaveric organs based on the severity of illness of the patient, rather than time on waiting lists. Patients' MELD scores are re-evaluated as the patients' conditions change in order to properly reflect the patient's probable survival without a transplant.

As of the writing of this application, over 17,340 patients are awaiting liver transplants in the United States, based on Organ Procurement and Transplantation Network (OPTN) data. Of these patients, 141 are Washington residents.

The total capital expenditure associated with this project is $417,400, and is composed of the fixed and moveable equipment necessary to add liver transplantation to SHS's existing transplant program.

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[1] Robert L. Carithers, Jr., "AASLD Practice Guidelines, "Liver Transplantation, January 2000

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a tertiary health service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(i)(D).

APPLICATION CHRONOLOGY

March 18, 2003	Letter of Intent Submitted
June 11, 2003	Application Submitted • Screening activities and responses
September 17, 2003	Department Begins Review of Application • Public comment period
November 6, 2003	Public Hearing in Bellevue • End of Public Comment on Application
November 24, 2003	Rebuttal Documents Submitted to Department
January 8, 2004	Department's Anticipated Decision Due
June 17, 2004	Department's Actual Decision Date

AFFECTED PARTIES

University of Washington Medical Center, Seattle, and Children's Hospital and Regional Medical Center, Seattle, sought and received affected person status under WAC 246-310-010 during the review of this project.

SOURCE INFORMATION REVIEWED

- Swedish Healthcare's Certificate of Need Application (March 18, 2003)
- Swedish Healthcare's supplemental information (August 21, 2003)
- Comments submitted during public comment period.
- Rebuttal comments from Swedish Healthcare, University of Washington Medical Center, and Children's Hospital and Regional Medical Center (November 24, 2003)
- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (2000, 2001, and 2002 summaries)
- Hospital licensing and survey data provided by the Department of Health's Office of Health Care Survey
- Information and statistics obtained from the following entities:
  - United Network for Organ Sharing
  - Organ Procurement and Transplant Network
  - Scientific Registry of Transplant Recipients
  - Washington State Cancer Registry
  - Department of Health and Human Services
    - Office of Inspector General
    - Center for Medicare and Medicaid Services
  - National Institutes of Health
    - National Cancer Institute
    - National Institute of Diabetes and Digestive and Kidney Diseases
  - American Cancer Society
  - Other sources as referenced in the attached evaluation
  - Other miscellaneous background information documents

CRITERIA EVALUATION

To obtain Certificate of Need approval, SHS must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care; and 246-310-240 (cost containment).[2]

CONCLUSION

For the reasons stated in this evaluation, and with the following conditions, Swedish Health Services is approved to establish a liver transplant program at its First Hill campus:

1. Swedish Health Services is approved only to offer adult liver transplant services.

2. Swedish Health Services will provide charity care in compliance with the charity care policies provided in its Certificate of Need application and the requirements of the applicable law. Swedish Health Services will use reasonable efforts to provide charity care in an amount comparable to the average amount of charity care provided by hospitals in the King County region, during the three most recent years. For historical years 2000-2002, these amounts are .75% of total revenue and 1.3% of adjusted revenue. Swedish Health Services will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies and applicable law.

[2] Each criterion contains certain sub-criteria. The following sub-criteria are not relevant to this project: WAC 246-310-210(3), (5), and (6); WAC 246-310-240(2).

A. Need (WAC 246-310-210)
Based on the source information reviewed, and subject to the conditions on page two of this evaluation, the department determines that the application is consistent with the need criteria in WAC 246-310-210(1) and (2).

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need
SHS is proposing to serve 6 patients in the first year of operation, 18 in the second, and 32 in the third year. By the fifth year of operation, SHS projects an annual volume of 46 transplants and 115 other related non-transplant procedures that will only be conducted at SHS if this project is implemented. These additional procedures consist of hepatotomy, liver biopsy, lesion destruction, aspiration and similar procedures that will be performed by program staff in addition to liver transplants. [Source: SHS application, p12 and Appendix B, p3]

Because the department does not have an established numeric need projection methodology for organ transplant services, it is incumbent upon the applicant to provide a rational and verifiable analysis of need for the service to be provided. In this application, SHS examined national and local rates of liver diseases and liver transplants to attempt to determine whether a need exists for additional liver transplant capacity in Washington.

In its application, SHS estimated that 111 Washington residents either received or should have received, liver transplants in 2001. SHS examined utilization of the two existing liver transplant programs in Washington, University of Washington Medical Center (UWMC) and Children's Regional Hospital and Medical Center (CHRMC), and found that they performed a combined 71 liver transplant operations on Washington residents. SHS then theorized that the remaining 39 eligible patients must have received transplants outside Washington.

SHS also examined the disposition of cadaveric livers recovered by Life Center Northwest (LCNW). In 2002, LCNW recovered 114 livers, of which 30 were exported to transplant programs outside Washington.

From the evidence that fewer Washington patients than expected were receiving liver transplants in Washington and a significant number of organs were being sent outside Washington, SHS deduced that existing programs are not meeting the entire need for liver transplant surgeries in Washington.

SHS bases this assertion on several years' data indicating: 1. There is a growing need for liver transplant services in Washington, 2. Washington residents are leaving the state in order to receive liver transplantation, 3. Existing providers are either unable or unwilling to meet the transplant needs of all eligible liver transplant recipients. Each of these points will be discussed in detail below:

1. SHS contends there is a growing need for liver transplant services in Washington.
Washington currently has two providers of liver transplant services: the University of Washington Medical Center (UWMC) and Children's Hospital and Regional Medical Center (CHRMC). UWMC performs liver transplant procedures on adults, and CHRMC's procedures are limited to pediatric patients. UWMC currently serves as the only adult liver transplant program in the states of Washington, Alaska, Montana, and Idaho (WAMI). From 1993 to 2002, the number of liver transplant procedures for WAMI residents has increased a total of 33%. [source: November 6, 2003 comments by Dr. William Marks]

SHS notes that rates of liver-related diseases in Washington are similar to those of the nation as a whole, but the state's rate of transplants is below the national average. Rates of hepatitis C and hepatocelular carcinomas, frequent indicators of need for liver transplant surgeries, are growing.

Statistics obtained from the Department's Washington State Cancer registry indicate that Washington's age-adjusted rates of incidence and mortality due to cancers of the liver are slightly lower than the nation as a whole, but are increasing. The age-adjusted incidence rate of liver-related cancers in King County and the State of Washington are similar to the national rate.[3,4] Mortality statistics presented by SHS in rebuttal also indicate that the Washington State, WAMI region, and national mortality rates for liver diseases, as computed by the Centers for Disease Control, are similar.

The department finds that as population increases and incidence rates of diseases for which liver transplant is indicated increase, it is reasonable to conclude that the need for liver transplant services can be expected to increase in the future.

2. SHS claims Washington residents are leaving the state in order to receive liver transplant surgeries.

SHS's initial application contended that 39 Washington residents left the state in 2001 to receive liver transplants. Data provided to the department by UWMC and later confirmed by SHS on rebuttal indicates that the actual number of patients receiving transplants outside Washington is considerably smaller - 17. Information provided by SHS indicates, however that in addition to the 17 Washington residents leaving the area for transplants, an additional 17 patients left the remaining states in the WAMI region for liver transplants. [Source: SHS November 24, 2003 rebuttal comments]

UWMC has noted that several factors may explain the out-migration of WAMI area patients. Liver transplant candidates may be required to use hospitals outside Washington due to restrictions by their insurers. WAMI residents who are insured by the Department of Veterans Affairs receive their liver transplants in Oregon. Another major insurer, Aetna, is contracted with and refers its insured to a program outside Washington. Finally, UWMC contends that natural treatment referral patterns may cause patients to leave the state. UWMC noted that residents of Southwest Washington frequently seek medical treatment in Oregon and contended that a similar pattern of referral for transplant services is to be expected. UWMC also noted that transplant candidates may choose the area to be treated where they have families or other support systems to aid in their recovery from surgery. [Source: UWMC November 24, 2003 rebuttal comments]

The department also obtained information from UNOS regarding the number of Washington residents placed on liver transplant waiting lists at all centers and regarding the number of Washington residents receiving transplants in all centers[5]. In each case, the department finds that for the years 1993 through November 2003, between 15% and 33% of all Washington residents on liver transplant waiting lists were listed outside Washington and for the same time period between 11% and 34% of all Washington residents receiving transplants did so outside of Washington. The percentages for each category have decreased from 1993 to present, but the variation from year to year is great enough that the department is unable to conclude that a measurable trend exists.

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[3] Data obtained from Washington State Cancer registry for time period 1997-2001 in aggregate and individual years.
[4] Data obtained from National Cancer Institute SEER*Stat database for time period 1969-2001
[5] Email from Katarina Anderson of UNOS to Randall Huyck dated February 12, 2004, containing tables based on OPTN data as of February 6, 2004

3. SHS claims existing providers are either unable or unwilling to meet the transplant needs of all eligible transplant recipients.

SHS contends that the difference between its estimate of "expected" liver transplant recipients leaving Washington and the actual number of Washington residents obtaining transplants elsewhere is not indicative of a flawed projection methodology, rather that the difference is due to the fact that potential liver treatment candidates are not being identified and listed by UWMC. SHS argues that many of these patients are unwilling or unable to seek transplant services elsewhere due to lack of economic resources and lack of knowledge which might lead them to seek out other programs willing to list them for transplant. As a result, these patients are never listed on any centers' waiting lists and do not receive transplants.

SHS further contends that it is unusual for a region with a population as large as the WAMI area to have only one liver transplant center. As an example, SHS presented the San Francisco, California area, which is similar in population to western Washington and is served by three liver transplant programs. SHS contends that multiple programs in a region lead to increased numbers of transplants due to differing transplant criteria used by different centers. [source: November 6, 2003 comments of William Marks, MD]

SHS contends that the selection criteria used by UWMC to evaluate potential transplant recipients as well as the suitability of harvested organs may be the cause of the region's relatively low rate of liver transplants. SHS presented the argument that the existence of only one transplant center and, therefore, only one set of selection criteria for recipients and donor organs restricts the ability of area residents to obtain needed transplants. SHS noted that San Francisco area hospitals, discussed above, transplant a higher number of patients than UWMC with similar survival rates. Because of the variation in patients' cases, the department concurs that it is reasonable to conclude that multiple centers in an area, each with different admission criteria for their transplant programs, may be able to provide treatment to more patients than a single program.

Another example cited by SHS is the issue of living-donor liver transplants. UNOS data shows that UWMC does not perform living-donor liver transplants on adult patients. SHS also asserted that UWMC leadership has publicly stated that UWMC has no interest in performing living-donor liver transplants.[source: November 6, 2003 comments of William Marks, MD] A study published in early 2003 indicates that adult-to-adult liver transplantation from living donors currently number 5% of liver transplants to adults[6]. Patients with conditions such as liver tumors may not be ill enough to have a MELD score high enough to obtain a timely liver transplant until their cancers have progressed to the point that a transplant may not improve their chances of survival, thus making them unsuitable recipients for scarce organs. With the current provider unwilling to perform living-donor liver transplants, those patients who may be good candidates for this procedure, but with MELD scores or other factors that make them unlikely recipients for cadaveric organs, are not able to obtain this potentially life-saving treatment in Washington.

In response to SHS's contentions that UWMC's transplant protocols may be restricting the number of patients deemed suitable for transplant, UWMC provided statistics demonstrating that patients placed on its program's waiting list are more likely to receive timely transplant than national averages. UWMC also stated that Washington residents use all health services at a lower rate than the nation as a whole, therefore a lower rate of liver transplants than the national average should logically follow[7]. The department concludes that neither of these items, nor any of the other data

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[6] Brown, Robert S. and others, "A Survey of Liver Transplantation from Living Adult Donors in the United States," New England Journal of Medicine, February 27, 2003.

[7] Testimony of Helen Shawcroft, Associate Administrator, UWMC, at 11/06/03 public hearing

presented by UWMC provide a rebuttal to SHS's contention that the liver transplant rate for Washington residents is lower than is to be expected in light of current information about liver disease prevalence in Washington. Further evidence to support SHS's claim that the number of transplants performed on Washington residents might increase if an additional program is approved is contained in Exhibit 10 to SHS's rebuttal comments:

> "Selection criteria for listing and, similarly, reasons for turning down a patient for liver transplantation have always been left to the discretion of the individual transplant program.
>
> "Data suggest that competition among centers in an OPO (or the lack of competition) also might factor into the decision of whether to list and perform transplantation on a patient. Centers with competition perform transplantation on patients at higher MELD scores than centers without competition. Patients often recognize this, and as a result, those considered too sick to undergo transplantation by one center may go to another center willing to perform transplantation on patients with high MELD scores to be listed. Similarly, patients with lower MELD scores listed in a competitive OPO also may get listed in another OPO known to perform transplantation on patients at lower MELD scores with shorter waiting times.[8]"

On the basis of the preceding discussion, the department concludes the existence of competing programs, with differing selection criteria and treatment protocols can reasonably be expected to increase the number of Washington residents added to wait lists for liver transplants. This conclusion does not, however, carry with it the conclusion that more transplants will necessarily occur if more residents are added to wait lists. An increase in the number of transplants actually performed is also dependent upon several factors, among which are: an increase in the number of cadaveric livers harvested; an increase in the overall suitability of harvested livers for transplantation; increased use of living-donor, split-liver, and cut-down liver procedures; and increased willingness to transplant livers previously deemed sub-optimal by existing programs.

Of the factors listed above, the department acknowledges that the first and second, increases in the number and quality of harvested cadaveric organs, are not likely to occur rapidly enough to account for a significant increase in the number of transplants performed, without regard to the number of transplant programs approved. The quantity and quality of harvested organs is entirely dependent upon the ability of an OPO to recruit potential donors well in advance of their demise, as well as to educate and recruit family members of soon-to-be or recently-deceased individuals who may have organs suitable for donation, and then to harvest those organs and rapidly identify appropriate recipients for them. Information reviewed during the course of this evaluation consistently show that the best outcomes for transplant recipients are generally obtained from using high-quality, intact cadaveric organs. The department concludes, however, that the information reviewed indicates that living-donor procedures may benefit patients unable to obtain cadaveric liver transplants. Similarly, the increasingly utilized split-liver and cut-down liver procedures using cadaveric organs expand the pool of potential recipients for an organ by allowing two recipients for portions of one organ (split-liver) or reducing the size of a harvested liver to match a physically smaller recipient (cut-down liver). The department further concludes that some willingness to expand the criteria used to evaluate organs' suitability for transplant, while potentially increasing gross mortality rates for transplant procedures, may result in an increased number of patients actually receiving and surviving liver transplant procedures.

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[8] Schaffer, Randolph L. III, and others, *The Sickest First? Disparities With Model for End-Stage Liver Disease-Based Organ Allocation: One Region's Experience*, Liver Transplantation, Vol 9, No 11 (November), 2003: pp 1211-1215

At issue is whether approval of a liver transplant program at SHS will allow patients to receive liver transplants who would not otherwise be served by the existing program at UWMC. On the basis of the information reviewed, the department concludes that it would, therefore this criterion is met.

Both UWMC and CHRMC observed in comment and rebuttal that the SHS application did not indicate whether SHS intends to perform liver transplant services on pediatric patients. The department agrees that the SHS application does not address the specific needs of pediatric patients, nor does it specifically request approval to perform this service, which would be considered by the department to be a tertiary service separate from adult liver transplant and, therefore, a different application. The department concludes, therefore, that any approval of SHS's request to establish a liver transplant program should be conditional upon SHS offering liver transplant services only to adults.

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.
All residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups currently have access to services at SHS. The addition of liver transplant services to the hospital is not expected to change this access. Additionally, admission policies provided by the applicant demonstrate that patients are admitted to the facility for treatment without regard to age, race, color, religion, sex, national origin, handicap, or sexual preference and will be treated with respect and dignity. [source: SHS application, Appendix D]

For charity care reporting purposes, the OHPDS, divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. SHS is one of 17 hospitals located within the King County Region. According to 2000-2002 charity care data obtained from OHPDS, OHMC has historically provided an average of charity care greater than the King County regional average. SHS's most recent three years percentages of charity care for gross and adjusted revenues range are .53% and .92%, respectively. The 2000-2002 average for the King County Region is .75% for gross revenue and 1.30% for adjusted revenue.[9] [source: OHPDS 2000-2002 charity care summaries] SHS's pro forma financial statements and current charity care policies for the liver transplant program both indicate that the hospital will provide charity care. SHS identified the percentage of charity care to be provided as 1.4% of adjusted revenues. [source: SHS August 21, 2003, supplemental responses and SHS application, p43] Therefore, if this project were approved, the department would conclude that all residents of the service area would have adequate access to the health services at SHS. This sub-criterion is met.

The department concludes that, subject to the conditions on page two of this evaluation, there is reasonable assurance that all residents of the service area will have access to the services proposed by SHS. This sub-criterion is met.

(4) The project will not have an adverse effect on health professional schools and training programs.
This sub-criterion is discussed below in section C. 4.

[9] Harborview Medical Center is subsidized by the state legislature to provide charity care services. Charity care percentages for Harborview make up almost 50% of the total percentages provided in the King County Region. Therefore, for comparison purposes, the department excluded Harborview Medical Center's percentages.

B. Financial Feasibility (WAC 246-310-220)
Based on the source information reviewed and subject to the conditions on page two of this evaluation, the department determines that the applicant has met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.
To analyze short- and long-term financial feasibility of hospital projects and to assess the financial impact of a project on overall facility operations, the department uses financial ratio analysis. The analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios utilized are 1) long-term debt to equity ratio; 2) current assets to current liabilities ratio; 3) assets financed by liabilities ratio; 4) total operating expense to total operating revenue ratio; and 5) debt service coverage ratio. If a project's ratios are within the expected value range, the project can be expected to be financially feasible.

Table V, below, shows the financial ratios that SHS projects in the first three years of operation for the liver transplant program and the Office of Hospital and Patient Data Systems (OHPDS) year 2002 financial ratio guidelines for hospital operations. [source: OHPDS analysis, p3.]

Table V
SHS Liver Transplant Services Projected Financial Ratios

Financial Ratio	OHPDS Guideline		SHS 2002	Year 1	Year 2	Year 3
Long Term Debt to Equity	.572	*Below	0.854	N/A	N/A	N/A
Current Assets/Current Liabilities	1.792	*Above	1.371	N/A	N/A	N/A
Assets Financed by Liabilities	0.459	*Below	0.514	N/A	N/A	N/A
Operating Expense to Operating Revenue	0.975	*Below	.987	1.717	1.206	0.929
Debt Service Coverage	3.494	*Above	3.101	N/A	N/A	N/A

* = a project is considered more feasible if the ratios are above or below the value/guideline as indicated

After reviewing the financial information provided by SHS, staff from OHPDS stated the following:

> "I have also reviewed various ratios that can give a picture of the financial health of the hospital and the project. Swedish Health Services (SHS) Long-Term Debt to Equity Ratio at the end of 2002 is .854 which is worse than the 2002 state average of .572 as calculated by CHS/Hospital and Patient Data. I have also reviewed other ratios that can give a picture of the financial health of the hospital and the project. Important ratios used by Certificate of Need are listed below. The A means it is better if the hospital number is above the State number and B means it is better if the hospital number is below the state number. SHS has a below average showing on financial ratios for the five ratios Certificate of Need usually uses in its analysis. SHS did however generate a positive net income in 2002 and is improving its financial status. In the third year of the CON, the Liver Transplant project itself has better than average ratio for the one ratio that can be calculated. The applicant SHS has the cash and reserves to initiate and sustain this project. The project, when fully implemented will improve the financial standing of SHS.

"Three of the four ratios normally used by CON are not calculated because no debt is associated with this project and a balance sheet was not provided. Review of the financing and ratios show the immediate and long-range operating costs of the project can be met. This criterion is satisfied." [source: OHPDS analysis, p3]

Based on this information, the department concludes that the long-term capital and operating costs of this project can be met.

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

OHPDS also compared the SHS's transplant costs and charges to the available data and determined that they are reasonable. [source: OHPDS analysis, p4] Table VI, below, details the projected revenues and expenses in the first three years of operation of the proposed program.

Table VI
Swedish Liver Transplant Program
Projected Revenue

Rate per Various Items	Year 1	Year 2	Year 3
Transplants	6	18	32
Total Procedures	75	139	225
Gross Revenue	$3,151,813	$7,648,193	$13,151,348
Deductions From Revenue	1,752,896	4382498	6848738
Net Operating Revenue	1,398,917	3,265,695	6,302,610
Operating Expense	2,401,343	3,936,956	5,852,952
Net Profit (Loss)	**$(1,002,426)**	**$(671,261)**	**$449,658**
Operating Revenue per Transplant	$233,153	$181,428	$196,957
Operating Expense per Transplant	400,224	218,720	182,905
Net Profit (Loss) per Transplant	**$(167,071)**	**$(37,292)**	**$14,052**
Operating Revenue per Total Procedures	$18,652	$23,494	$28,012
Operating Expense per Total Procedures	32,018	28,323	26,013
Net Profit (Loss) per Total Procedures	**$(13,366)**	**$(4,829)**	**$1,998**

As previously stated, the capital expenditure for the establishment of the liver transplant program is projected to be $417,400 which includes only the purchase of equipment. After reviewing the capital expenditures and revenue projections, staff from OHPDS stated the following:

"Universities of Washington Medical Center (UWMC) and Children's Hospital and Medical Center (CHMC) have the only Liver Transplant programs currently operating in the state. I looked at 2002 CHARS data for DRG 480 Liver Transplant for cost comparisons.

"The income statement from Swedish shows income and expenses separately for transplants and other surgeries and procedures related to the Liver transplant program. The various results are similar to current providers. This criterion is satisfied." [source: OHPDS analysis, p4]

Based on the information provided above, the department concludes that the cost of the project will not result in an unreasonable impact on the costs and charges for health services within the service area. This sub-criterion is met.

(3) The project can be appropriately financed.
The capital expenditure for the establishment of the liver transplant program is projected to be $417,400 which includes only the purchase of equipment. After reviewing the capital expenditures, staff from OHPDS stated the following:

> "The system indicates it will use reserves (board designated assets) to finance this project. SHS reports $127 million in reserves. The hospital will use approximately .33% of reserves. This project will not adversely impact reserves, or total assets, total liability or the general health of the hospital in a significant way. The use of reserves is very inexpensive. Reserves are accumulated mainly from prior year profits. The only cost would be that the money would not be available for other uses." [source: OHPDS analysis, p4]

As noted above, this project will not adversely affect the hospital's reserves, total assets, total liability, or general financial health. OHPDS staff concluded that SHS has the financial capacity to proceed with this project and that the project is financially feasible. Based on this information, the department concludes that the proposed financing is appropriate, and this sub-criterion is met.

C. Structure and Process (Quality) of Care (WAC 246-310-230)
Based on the source information reviewed, the department determines that the applicant has met the structure and process (quality) of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.
SHS currently operates and staffs an organ transplant program. For implementation of the proposed project, SHS intends to recruit and hire a hepatologist and a liver transplant surgeon. SHS states that it currently has the necessary ancillary and support staff needed for the proposed liver transplant program. The applicant does, however, note that additional training may be necessary to prepare existing program staff for liver procedures.

UWMC stated several concerns in its rebuttal comments. The first of these issues is that "Contrary to Swedish's Testimony, it does not have the infrastructure "already in place" to support a program and it has failed to acknowledge or budget for the required infrastructure." UWMC states that of the three hepatologists identified as members of SHS's staff, two are employed by Pacific Medical Center, which exclusively refers liver patients to UWMC, and the third physician has written the department a letter in opposition to this project. UWMC further states that SHS does not employ any UNOS-approved transplant hepatologists, and has only stated intent to hire one hepatologist. UWMC contrasts this staffing to its own program, which, it states, employs six UNOS-approved liver transplant surgeons.

SHS refutes these staffing claims in its own rebuttal documents. SHS notes that its transplant program is staffed by three full-time board-certified surgeons, one urologist, one full-time nephrologist and six rotating nephrologists. With the addition of the proposed additional surgeon and hepatologist, SHS believes it will employ a sufficient number of properly trained physicians to accommodate the addition of liver procedures to its existing transplant program.

SHS further discuses UWMC's description of its own transplant program, contending the UWMC's combined transplant program (liver, kidney, and pancreas) is actually staffed by "one board-eligible (not board-certified) general surgeon, two urologists trained in liver transplantation at the UW and a newly graduated junior faculty member..." SHS also contends that UW's transplant program employs four hepatologists and an infectious disease doctor, assisted by fellows and other staff.

UNOS liver transplant program standards dated June 27, 2003, state "Each Transplant center must have on site a qualified transplant surgeon. A liver transplant surgeon shall be a physician with an MD or DO degree or equivalent degree...The surgeon shall have and shall maintain current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent." The department notes the Dr. William Marks, the director of SHS's transplant program, Dr. Lisa Florence, the program's assistant director, are both certified by the American Board of Surgery.

The department concludes that, while structural and programmatic differences exist between UWMC's existing program and SHS's proposed program, these differences are not sufficient evidence to conclude that either program is inadequate. On the basis of the information provided by both the applicant and UWMC, the department concludes that the applicant has proposed appropriate and reasonable staffing for the proposed program.

(2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.
SHS notes that the creation of the new program at the existing First Hill facility, few additional ancillary or support services will be required. SHS further notes that it is currently an approved UNOS facility for transplant services and must demonstrate adequate ancillary support to obtain that approval.

In support of the above assertions, SHS provided copies of service agreements between SHS and LifeCenter Northwest and Puget Sound Blood Bank, demonstrating SHS's established relationships with local organ procurement organizations.

The department concludes that there is reasonable assurance that SHS, as the operator of an established organ transplant program, will continue its relationships with ancillary and support services providers currently serving other SHS programs.

(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.
SHS will provide Medicare and Medicaid reimbursed services to the residents of the service area. Within the most recent two years, the Department of Health's Office of Health Care Survey (OHCS), which surveys hospitals within Washington State, has completed one compliance survey for the facilities owned and operated by SHS. SHS's facilities have also been surveyed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The surveys revealed minor non-compliance issues, and SHS submitted acceptable plans of correction. [source: 2001 and 2003 survey data provided by Office of Health Care Survey] Based on SHS's compliance history and recommendations contained in the department's surveys recommending recertification, the department concludes that there is reasonable assurance that SHS would continue to operate in conformance with state and federal regulations with the establishment of the proposed liver transplant program.

In addition, Medicare facility requirements call for approved adult liver transplant centers to perform 12 or more cases per year[10]. The applicant's proposed volumes exceed that standard. This criterion is met.

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[10] Federal Register, Vol 56, No. 71, April 12, 1991

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

UWMC contends that establishment of a liver transplant program at SHS will result in an unwarranted fragmentation of services and will have a detrimental effect on its existing program. UWMC contends that SHS's projected volumes will decrease its ability to perform sufficient numbers of surgeries to train new transplant physicians and perform research in the liver transplant field. UWMC argues that, due to decreased volume, residents of Washington will be left with "two centers of mediocrity." SHS counters these assertions by arguing that based on its need projections; UWMC should be able to continue to increase its liver transplant volume even with a competing program at SHS. If UWMC is able to maintain or increase its transplant volume, no negative impact on training or research can be demonstrated. UNOS standards for liver transplant programs require a training program to perform at least 50 transplants each year[11]. Under the projections contained in this application, SHS expects UWMC to be able to maintain that volume. SHS also notes that it currently participates in training of new physicians and clinical research programs and will continue to do so.

The department also examined available literature regarding liver transplant volumes and outcomes in order to help determine whether some reduction in volume at UWMC would necessarily correlate to worsened outcomes for its patients. A study published in the New England Journal of Medicine in 1999 found that low-volume liver transplant centers experience significantly higher mortality rates than high-volume centers[12]. The authors of that study defined low-volume centers as those performing fewer than 20 procedures per year. This study did not issue conclusions about an optimum size for a transplant program – in fact the data presented in that study showed relatively little effect on outcomes as number of transplants exceeded 20 per year. The department notes that both the applicant and UWMC would be projected to be performing in excess of 20 procedures per year after the second year of the proposed program and would be considered "high-volume" programs. The abstract of another study, published in the June 2004 edition of the American Journal of Transplantation further states that "Transplant outcomes are better at high volume centers; however, there is no clear minimal threshold volume[13]."

SHS further contends that implementation of the proposed program will reduce fragmentation of services that currently exists in the form of transplant-eligible patients not placed on UWMC's waiting list and patients leaving the area to obtain transplants. This concept is discussed in the Need section of this evaluation on page 5 of this evaluation. Based on the discussion above, the department concludes this criterion is met.

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

This criterion is addressed in (3), above.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that the applicant has met the cost containment criteria in WAC 246-310-240.

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[11] UNOS Transplant program standards dated November 21, 2003

[12] Edwards E, Roberts J, McBride M, Schulak J,Hunsicker L, "The Effect of the Volume of Procedures at Transplantation Centers on Mortality After Liver Transplantation," New England Journal of Medicine, Volume 341, Number 27, pp2049-2053.

[13] Axelrod, D, Guidinger M, McCullough K, Leichtman A, Punch J, Merion R, "Association of Center Volume with Outcome After Liver and Kidney Transplantation," Amercian Journal of Transplantation, Volume 4, Issue 6, pp920-927.

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

Given the identified unmet need, the applicant did not explore alternatives to establishing a liver transplant program. The addition of another organ to an existing transplant program represents a relatively small initial capital cost, as noted in the Financial Feasibility section of this evaluation. [source: initial application, p50]

The department notes that, as a consequence of approving this application, overall health care costs in the state may increase. This increase is not, however to be attributed to unnecessary construction or duplication of services. It is likely that, if the applicant's assertions that fewer Washington residents are receiving liver transplants than is optimal, the increased number of transplants provided by addition of a new program will represent an increase in health care costs. The applicant notes on page 42 of the initial application that total charges per transplant exceed $300,000.

A 2002 report by Milliman USA estimated that the average cost for a liver transplant in the US cost $313,600 in 2002, with a cost per-month-per-member (a measurement used to estimate costs to insurance plan members) of $ .53 for recipients under age 65 and $ .27 for older members.[14]

If more transplants occur as a result of this approval, each transplant will result in over $300,000 more in health care expenditures, as well as associated on-going costs for medication and treatment. The Milliman study also found that, with the exception of transplants for ESRD and intestinal failure, the financial costs to insurers are greater for transplants than for alternative treatment. These costs must, however, be weighed against the cost of denying such services to those who need them. Neither the applicant nor the department has conducted an analysis of the costs associated with a patient's inability to obtain needed transplant services. If such a study were to be undertaken, in addition to costs such as treatment of a patient with hepatic failure, societal costs such as lost productivity due to illness, productivity lost due to untimely death, and other quality-of-life and intangible costs should be considered. Such a study during the course of the review of a Certificate of Need application is, however, not appropriate.

A report to Congress by the federal Office of Management and Budget (OMB) claimed that each non-renal (primarily liver, heart, pancreas, and lung) transplant resulted in an average of 12 life-years gained per transplant at a value of $116,000 per life-year.[15] This can be contrasted with the approximate $300,000 estimated cost of a transplant and supporting care, resulting in a clear benefit derived from the procedure.

The department concludes, based on the discussion above, that this criterion is met.

(2) In the case of a project involving construction:

(a) The costs, scope, and methods of construction and energy conservation are reasonable;

This project does not involve any construction.

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

Not applicable. This project does not involve any construction.

---

[14] Hauboldt, Richard H., FSA, and Ortner, Nickolas J., ASA, *2002 Organ and Tissue Transplant Costs and Discussion*, Milliman USA Consultants and Actuaries, http://www.milliman.com/health/publications/research_reports/hrr_07-2002.pdf

[15] Estimates of Total Annual Monetized Costs and Monetized Benefits of Social Regulation as of 1988, found at http://www.whitehouse.gov/omb/inforeg/2000fedreg-charts.pdf

SWEDISH MEDICAL CENTER

RECEIVED
JUN 29 2004
CERTIFICATE OF NEED PROGRAM
DEPARTMENT OF HEALTH

June 28, 2004

Mr. Gary Bennett, Director
Certificate of Need Program
Department of Health
310 Israel Road Southeast
PO Box 47852
Olympia, Washington 98504-7852

Re: Swedish Health Services Liver Transplant Certificate of Need

Dear Mr. Bennett:

We are writing to inform you that we agree to the following conditions as stated in your letter dated June 17, 2004. They are:

1. Swedish Health Services is approved only to offer adult liver transplant services.

2. Swedish Health Services will provide charity care in compliance with the charity care policies provided in its Certificate of Need application and the requirements of the applicable law. Swedish Health Services will use reasonable efforts to provide charity care in an amount comparable to the average amount of charity care provided by hospitals in the King County region, during the three most recent years. For historical years 2000-2002, these amounts are .75% of total revenue and 1.3% of adjusted revenue. Swedish Health Services will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies and applicable law.

We would appreciate your issuance of this Certificate of Need at your earliest convenience, as we are anxious to begin project implementation. Please call me at (206) 215-3000 if you have any questions.

Sincerely,

Brian Kuske
Vice President
Ambulatory and Ancillary Services

747 Broadway
Seattle, WA 98122-4307
(206) 386-6000

Swedish Medical Center/
Ballard Campus

Swedish Medical Center/
First Hill Campus/

Swedish Medical Center/
Providence Campus

Swedish Home Health
& Hospice

www.swedish.org

001813

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
PO Box 47852 * Olympia, Washington 98504-7852

June 30, 2004

CERTIFIED MAIL 7000 1670 0013 5840 9759

Brian Kuske
Vice President, Ambulatory and Ancillary Services
Swedish Medical Center
747 Broadway
Seattle, Washington 98122

Dear Mr. Kuske:

Thank you for your letter of June 28, 2004, accepting the conditions related to the approval of the establishment of an adult liver transplant program at Swedish Medical Center. Enclosed is Certificate of Need #1288.

NOTE: Issuance of this Certificate does not constitute approval under any other local, federal or state statute, implementing rules and regulations. Examples where additional approval may be necessary include, but are not limited to, construction plan approval through the Construction Review Section of the Department of Health, facility licensing/certification through the Department of Social and Health Services or Department of Health, and other federal or local jurisdiction permits.

Note that the date of this letter commences the time for requesting appeals under Washington Administrative Code (WAC) 246-310 unless otherwise specified in rule.

Certificate of Need #1288 has a validity period of two years during which time the project must commence. The validity period may be extended for one six-month period if there has been substantial and continuing progress toward commencement. An extension request must be submitted to the Certificate of Need Program at least 120 days prior to the expiration date of the Certificate of Need. A project may not be commenced after the validity period *(or extended validity period)* has expired.

The statute requires the Certificate of Need Program monitor approved projects through completion, which is accomplished with quarterly progress reports. At least 30 days prior to the progress report's due date, we will mail you a report to complete and return.

Please contact Janis Sigman, Manager of the Certificate of Need Program at (360) 236-2955 if you have any questions or concerns as you proceed with your project.

Sincerely,

Gary Bennett Director
Facilities and Services Licensing

Enclosure

cc: Office of Health Care Survey

Washington State Department of Health

This Certificate is granted under the authority of RCW 70.38. Issuance of this Certificate does not constitute approval under any other local, federal or state statute, implementing rules and regulations. Examples where additional approval may be necessary include, but are not limited to, construction plan approval through the Construction Review Unit of the Department of Health, facility licensing/certification through the Department of Social and Health Services or Department of Health, and other federal or local jurisdiction permits.

Certificate of Need #1288 is issued to:

Legal Name of Applicant:	Swedish Health Services
Address of Applicant:	747 Broadway Seattle, Washington 98122
Type of Service:	Adult Liver Transplant
Facility Name:	Swedish Medical Center
Facility Address:	First Hill Campus 747 Broadway Seattle, Washington 98122

PROJECT APPROVAL IS BASED ON THE DEPARTMENT'S RECORD AND EVALUATION OF JUNE 17, 2004, AND THOSE FINDINGS ARE INCORPORATED.

Description/Services To Be Provided:
This certificate approves the establishment of an adult liver transplant program

Service Area
Washington State

Conditions

1. Swedish Health Services is approved only to offer adult liver transplant services.
2. Swedish Health Services will provide charity care in compliance with the charity care policies provided in its Certificate of Need application and the requirements of the applicable law. Swedish Health Services will use reasonable efforts to provide charity care in an amount comparable to the average amount of charity care provided by hospitals in the King County region, during the three most recent years. For historical years 2000-2002, these amounts are .75% of total revenue and 1.3% of adjusted revenue. Swedish Health Services will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies and applicable law.

Approved Capital Expenditure

Item	
Construction costs	$ 0
Moveable equipment to initiate program	417,000
Architect/Engineering/Consulting Fees	0
Total	**$ 417,000**

This Certificate authorizes commencement of the project from June 30, 2004, to June 30, 2006, unless extended, withdrawn, suspended, or revoked in accordance with applicable sections of the Certificate of Need law and regulations.

Date Issued: June 30, 2004

Gary Bennett, Director
Facilities and Services Licensing

This Certificate is not transferable.

EXHIBIT E

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In re Certificate of Need Application of:	)	**Docket No. 04-07-C-2005CN**
	)	
SWEDISH MEDICAL CENTER,	)	POST-HEARING ORDER NO. 1:
	)	SCHEDULING ORDER PURSUANT
Applicant.	)	TO SUPERIOR COURT REMAND
	)	(Corrects March 30, 2006 Order)

APPEARANCES:

Petitioner, University of Washington Medical Center, by
Benedict & Garratt, per
Kathleen Benedict and Sally Garratt, Attorneys at Law

Intervener, Swedish Medical Center, by
Dorsey & Whitney, per
Brian Grimm and Peter Ehrlichman, Attorneys at Law

Respondent, Department of Health Certificate of Need Program, by
The Office of the Attorney General, per
Richard McCartan, Assistant Attorney General

On March 16 and 22, 2006, status conferences were held to discuss the nature, scope, and schedule of the above entitled case in light of Superior Court Judge Tabor's remand order. The following schedule was set pursuant to his order after the Health Law Judge reviewed the parties' briefs addressing the scope and procedure of this remand.

Judge Tabor granted the University of Washington's (the University) request that new evidence may be submitted but not at the superior court level. Judge Tabor remanded the case to the Department of Health for the submission of additional evidence regarding the University's response to Swedish's Rebuttal Statement submitted to the Certificate of Need Program (the Program) on November 24, 2003.

Judge Tabor ruled that the University "was not required to request reconsideration" of the Program's decision prior to offering additional evidence in response to new information contained in Swedish's November 2003 Rebuttal Statement. In his remand order, Judge Tabor gives the Health Law Judge the discretion to hear the evidence or remand the case to the Program "to hear the information and take the additional testimony." In his oral ruling, Judge Tabor made it clear that he finds that the Health Law Judge has the authority to hear the evidence on remand:

> I think that the administrative judge had the power to hear the information herself had she chosen to do so. So I'm going to remand this and the administrative judge can decide whether or not he or she is going to hear the information, take the additional testimony themselves, or remand it to the Department.

During the 2005 administrative hearing, the Health Law Judge did not allow the University to present evidence in response the Swedish's November 2003 Rebuttal Statement, because the University failed to file a request for reconsideration with the Program. The Health Law Judge did permit the University to make an offer of proof. Judge Tabor stated in his order that:

> (5) The offer of proof submitted in the administrative proceeding below informed the court of the substance of the excluded testimony but does not go into sufficient detail to substitute for the testimony itself. Therefore, the administrative proceeding must be reopened in order to receive the information in the form of additional testimony.

In light of Judge Tabor's oral rulings and written order, the new evidence will be admitted at the adjudicative level, and the case will not be remanded to

//////////

//////////

Program.[1] On remand the University and Swedish will be permitted to present evidence in the following order:

1. University may submit evidence in response to the Swedish's November 24, 2003 Rebuttal Statement submitted to Program.

2. Swedish may submit evidence in rebuttal to evidence submitted by the University in response to the Swedish Rebuttal Statement. Swedish will not be permitted to present evidence in response to the University's Rebuttal Statement submitted to Program on November 24, 2003, because Swedish did not raise this issue at the adjudicative or superior court level.

3. University may submit evidence in rebuttal to the evidence submitted by Swedish in its response.

Program did not request the opportunity to present any evidence, but the opportunity to submit a response to the new evidence in the form of a closing brief after Swedish and the University filed their closing brief. Program's request that it be permitted to file its closing brief after Swedish and the University was denied. Program failed to present adequate grounds upon which it should be provided that advantage over the University and Swedish.

Any evidence submitted by the University or Swedish shall be limited to evidence that existed as of December 31, 2003, which is approximately one month after program closed the record.

The case on remand from Superior Court is scheduled as follows:

Witness lists and proposed exhibits must be filed and served no later than **May 5, 2006.**

---

[1] The parties submitted briefs addressing the nature of the remand, and proposed how the remand should proceed. The University argued for a remand to Program for the submission of new evidence and for a public hearing. Program and Swedish argued that the evidence should be admitted at the adjudicative level.

Motions must be filed and served no later than **May 10, 2006.** Any response must be filed and served no later than **May 17, 2006** and replies no later than **May 19, 2006.**

Prehearing statements must be filed and served no later than **May 15, 2006.** The prehearing conference shall be held at **11:00 a.m. on May 18, 2006.**

If a party or intervener chooses to file a hearing brief, the brief must be filed and served no later than **May 31, 2006.**

The hearing shall be held **June 5-9, 2006, in Kent, Washington.**

Closing argument may be made at the end of the hearing or by brief. Closing briefs must be filed and served no later than **June 16, 2006**, and responsive closing briefs no later than **June 23, 2006.**

Dated this 11th day of April, 2006.

James SHLW FOR

ZIMMIE CANER, Health Law Judge
Presiding Officer

DECLARATION OF SERVICE BY MAIL
I declare that today I served a copy of this document upon the following parties of record:
KATHLEEN BENEDICT, SALLY GARRATT, BRIAN GRIMM, AND PETER EHRLICHMAN; ATTORNEYS AT LAW AND RICHARD MCCARTAN AND PAMELA ANDERSON, ASSISTANT ATTORNEYS GENERAL
by mailing a copy properly addressed with postage prepaid.

DATED AT OLYMPIA, WASHINGTON THIS 13th DAY OF APRIL 2006.

Michelle Singer
Adjudicative Service Unit

cc: **JANIS SIGMAN**

EXHIBIT F

SWEDISH MEDICAL CENTER

November 24, 2003

Randall Huyck, Analyst
Certificate of Need Program
Department of Health
310 Israel Road S.E.
Tumwater, Washington 98501

NOV 2 4 2003

Re: Swedish Health Services Liver Transplant Certificate of Need

Dear Mr. Huyck:

Swedish Health Services is pleased to submit responses in rebuttal to the University of Washington Medical Center and other selected physicians from the state. We categorize the criticisms of our liver transplant certificate of need application into 6 principal classes as they relate to WAC CN review criteria:

WAC 246-310-210(1) Need:
Issue #1: Out-migration

WAC 246-310-230 (C) Structure and Process (Quality) of Care:
Issue #2: UW Liver Transplant Program Quality
Issue # 3: Liver "Export" figures
Issue # 4: Minimum Liver Transplant Volumes

WAC 246-310-220 Financial Feasibility and
WAC 246-310-240 Cost Containment:
Issue # 5: Competition and Choice
Issue #6: Swedish Medical Center Capabilities

Attached is detailed Rebuttal Testimony ("Rebuttal"), which includes detailed responses to the above issues. Following our discussion of the above 6 issues, we will address each principal issue raised in each letter we received from the public hearing testimony. (Appendix A)

The issues we address are complex; we have provided necessary "back-up" information and scientific articles as Exhibits. We also include the names and contact numbers for 3 nationally-recognized liver transplant surgeons. These professors have agreed to be contacted directly by you and to assist you with your analysis according to your needs. These physicians include:

- Byers Shaw, MD, Professor and Chairman, University of Nebraska, Omaha, NE (402) 559-8272
- Carlos Esquivel, MD, PhD, Professor and Chief of Transplantation, Stanford University Medical Center, Palo Alto, CA (650) 498-5689

- Marquis Hart, MD, Professor and Director of Abdominal Transplantation, University of California, San Diego, San Diego, CA (619) 517-3510

Summary and Conclusions of Public Hearing Testimony

We were not surprised at the criticism we received from the University of Washington Medical Center. The UW is doing what it feels it must to protect its market monopoly. Although we expected this, we were surprised at the data the UW claimed was objective, more by what it did not state, rather than by what it did. There are many instances in which its assertions and conclusions are simply wrong. We were also surprised with some of the letters the UW provided in support of its position. Apparently the UW has done a very good job convincing selected individuals that there is no unmet need for a second liver transplant program in Washington—that it very adequately meets all residents' needs, there is an "appropriate" amount of liver organ export from our region, and in fact, it is a "center of excellence." All of these opinions starkly contrast with our liver transplant CN application. However, in our application, we did not provide detail on UW "quality" issues associated with liver transplantation—we had intended to avoid this type of critique. But in the attached Rebuttal testimony, we do address UW quality, principally to correct what we perceive are UW distortions of objective, published performance statistics.

The UW's arguments, and the data used to support them, are fundamentally flawed. The UW provides only selected details of the story, omitting key facts. Below, we summarize the key issues we raise in our Rebuttal for each of the four WAC criteria.

WAC 246-310-210(1) Need:

The UW asserts that because Washington residents are very healthy, there is no unmet need. Further, it asserts there is no out-migration of residents for liver transplantation. However, we find that, in addition to actual out-migration, there is very significant unmet need in terms of residents who simply do not appear on any transplant waiting list. We also know from the Washington Department of Health ("DOH") mortality and disease incidence statistics, that Washington residents are not healthier regarding liver disease than elsewhere in the country. Further, evaluating the number of candidates on transplant waiting lists, in comparison to other transplant centers, the UW list is much too small. This is very concerning. Given our incidence of liver disease, the "short" UW waiting list does not indicate to us a lack of liver disease, but rather that residents with chronic liver failure cannot get on the UW waiting list.

In addition, Washington State has a much higher percentage of Asian and Asian Pacific Islander populations. These ethnic groups have a much higher incidence of hepatitis B and C, and subsequent development of liver cancers, known as hepatocellular carcinomas (HCC). These are the leading reasons for liver transplantation. Since Washington has a high percentage of Asian Americans and Asian Pacific Islander Americans, our state should also have an incidence of liver disease at least comparable

to other states. This, too, is in direct opposition to the UW contention that our residents are somehow healthier than people everywhere else in the nation.

By the size of its waiting list, the UW cannot be identifying these patients. We know the UW transplant list is too low compared to other peer medical centers and compared to what should be expected from a population our size. We have the data to support our contention. We are the only major metropolitan area in the US that is served by a single transplant center. All the data suggest that for a population of 6 million residents in our state and 9 million in the WWAMI region, there should be large numbers of patients requiring liver transplants.

We know residents leave the state for transplants, and we know the UW list is too small. This makes no sense to us. This data reaffirms our contention of unmet need and lack of local access.

WAC 246-310-230 (C) Structure and Process (Quality) of Care:

This issue really concerns quality of the UW's liver transplant program. The UW asserts it is a "center of excellence," and thus, meets our residents' transplant needs. Further, it asserts there is no way Swedish could possibly measure up.

Our evaluation of UNOS data, and we present a significant amount in our Rebuttal, clearly reaches opposite conclusions. The UW performance data, as described by UNOS statistics, is no better, and in many cases is worse, than its peers. It makes no sense for the UW to compare itself to "averages." It should be comparing itself to other academic and teaching institutions such as UCSF, Stanford or UCLA. Measured against its peers, the UW does not perform well. We reach the conclusion that there are opportunities to improve the quality of care with liver transplantation offered to state residents.

UNOS data indicate the UW provides transplants to much less sick patients than its peers. This is confirmed with MELD score data. We present that data, which is unequivocal.

If patients on the UW liver transplant waiting list are not as sick as at peer hospitals, the obvious question is why? It is not that residents suffer less liver disease. The DOH incidence and mortality data confirm this. It is not because Washington residents are out-migrating in large numbers. This leads to the obvious conclusion that there are residents who are sick enough to be on a liver waiting list, and should be on the UW's, but are not—they "fall through the cracks". This is another example of much needed quality improvement in the UW liver transplant program.

The UW liver transplant program does not perform at the level of its peers, other centers of excellence. Given its relatively healthy transplant patient mix, it is of concern that their outcomes are not better.

Also related to quality is the issue of appropriate exportation of liver organs from our region. We argue that export of livers for transplantation elsewhere is much higher than expected, and too high for a population base our size. The UW argues just the opposite and asserts we do not understand allocation rules. This is incorrect. Dr. Marks, our transplant Medical Director, is the Medical Director of LifeCenter Northwest and, in this capacity, he knows the rules and policies regarding donor organ exports. We stand by our contention that the liver export rate for Washington is extremely high.

The UW attempts to appear knowledgeable in Liver Transplant Allocation. However, the facts have been misrepresented. The export rate is 26.3%, when it would be 6.1% if we only exported mandatory Status 1 livers. Comparing itself to the national export rate is a further distortion of the truth. Since not every OPO serves an active liver transplant center, for example, Mississippi, organ procurement organizations ("OPOs") are forced to export livers to other states, thus raising the 'national' export rate.

The UW is simply wrong in suggesting the high liver export rate in Washington is anything but a result of its choices as to which livers to use for transplantation. For the overwhelming majority of livers exported for transplant elsewhere, the UW had the right of first refusal. Over the past 4 years, we have exported 126 organs and virtually all functioned on transplant. Over the same period, 64 UW patients died while waiting for a transplant. This situation is definitely not in the best interest of Washington residents.

The UW makes much of "minimum" volume standards for quality liver transplant programs. It even quotes sources. We have researched these sources, and there are no such standards. One published study found that below average programs tend to perform less than 20 liver transplants per year. However, others have shown some programs that perform less than 20 liver transplants per year have high quality outcomes. The key determinant of quality relates to clinical skills and institutional expertise, not volume. As stated in our CN application, we are committed to program excellence, and will take all necessary steps to insure excellent outcomes, including employment of additional trained experts. Further, Swedish has no intention of performing less than 20 liver transplants per year and it is unlikely that the UW will either.

WAC 246-310-220 Financial Feasibility and
WAC 246-310-240 Cost Containment:

The UW asserts that liver transplantation programs should not face competition, because it will somehow produce market "chaos" and bad outcomes. This is patently not true - competition increases each institution's focus on clinical quality with an added incentive to identify and rectify any weaknesses, so it becomes a premier program. Competition will force the UW liver transplant program to perform at peer standards.

Choice is also very important: with only one liver transplant program, patients are unable to get a second opinion locally when transplantation is ruled out by the UW, yet the UW dismisses choice and the need for second opinions as pointless "consumerism."

Those that have the financial means, out-migrate, and those that do not, die. The DOH data on disease and mortality confirm this.

The UW asserts Swedish does not and cannot know how to properly run an interdisciplinary transplant program. We would simply point to our successful kidney and pancreas transplant program. This truly multi-disciplinary program is the foundation upon which we will build our proposed liver service. Our transplant program is highly sophisticated and its outcomes compare to any in the country, including the UW. We strongly disagree that Swedish would not know how to implement and operate a clinically excellent liver transplant program. This is another example of the UW selectively misreading and distorting our CN application.

We continue to believe that Washington residents would significantly benefit from alternatives with respect to protocols, expertise, and options. Right now, there is no choice, and we know that too few patients are transplanted in our state. This must change. We will offer patients choice and, with complex medical care, choice and alternatives are essential.

On the basis of these findings, which we detail in our Rebuttal, we conclude that the University of Washington has not and does not service the full needs of the residents of the State of Washington. Even if the actual number of persons seeking transplantation outside of the state is less than the number that we predicted, the data support our contention that these potential recipients exist but have been denied access to transplantation by the policies, protocols and practice standards of the UW. Our initial CN application remains valid: the number of Washington State residents eligible for liver transplantation as a life saving procedure is far greater than that portrayed by the UW. There is unmet need and lack of access for Washington residents.

Thus, there is need for a second liver transplant program, and it is in the best interests of Washington residents that Swedish Health Service's application for a liver transplantation program on its First Hill campus be approved.

I would be happy to answer any questions you may have on any of the materials we have provided you.

Sincerely,

Brian Kuske
Vice President, Ambulatory and Ancillary Services

NOV 2 4 2003

Swedish Medical Center
Liver Transplant Program
Rebuttal Testimony
November 24, 2003

Introduction

We have categorized the majority of our responses to comments submitted at the public hearing, November 6, 2003, into 6 principal classes as they relate to WAC CN screening criteria:

WAC 246-310-210(1) Need:
Issue #1: Out-migration

WAC 246-310-230 (C) Structure and Process (Quality) of Care:
Issue #2: UW Liver Transplant Program Quality
Issue # 3: Liver "Export" Figures
Issue # 4: Minimum Liver Transplant Volumes

WAC 246-310-220 Financial Feasibility and
WAC 246-310-240 Cost Containment:
Issue # 5: Competition and Choice
Issue #6: Swedish Medical Center Capabilities

There are also other criticisms of our CN application, which we will address following our discussion of the above 6 issues. These are included in Appendix A. There were 23 letters submitted at the public hearing in opposition to Swedish's Certificate of Need Application. For purposes of our responses, we class them into 3 groups: (1) those written by UW employees, including physicians; (2) those written by physicians either trained by or currently closely affiliated with the UW; and (3) gastroenterologists in the state who have made referrals to the UW liver transplant program. We have tried to avoid redundancy, but since many of the letters read like form letters, there may be some duplication.

WAC 246-310-210(1) Need:
Issue #1: Out-Migration

- We acknowledge our application estimates of out-migration may have been better termed "expected out-migration." We agree UNOS data indicates 17 Washington residents left the state in 2002 for liver transplants.

- If one excludes pediatric cases, about 10%, that leaves 15 patients. If one excludes Southwest Washington patients transplanted in Oregon (3 patients in 2002) this leaves 12 adults out-migrating in 2002. That is a known figure.

- But we return to our original out-migration estimate, 39 patients in 2002. We used national incidence figures for liver transplantation. These are very appropriate figures and to the extent actual 2002 out-migration, 17, is less than the expected 39, the difference must be due to either:

  1. Different incidence of liver disease rates in Washington compared to the US, or
  2. Part of the appropriate recipient population was never identified. These persons with chronic liver disease were never given the opportunity to receive a transplant within Washington and did not have the knowledge and/or resources to seek alternative opinions.

- We think the answer is #2, and, in explaining why, we will refute the first of many UW inaccuracies and misrepresentations.

- As the explanation for why the UW waiting list is less than the national average, Ms. Helen Shawcroft, Associate Administrator, UW, stated in her letter: "... as we are all well aware, WA residents use most medical resources at rates far below national averages. The same is true for liver." (Page 1, Shawcroft letter.)

- Ms. Shawcroft asserts that liver disease is less in Washington in other parts of the country. IF the UW is correct, then the incidence of chronic liver disease should be less than the incidence reported for the country, and other states. Thus, the death rate from chronic liver disease in Washington State should be less than it is in the rest of the country and other states.

- IF, as Swedish contends, the population of Washington State is under-served, then the reported deaths due to chronic liver disease for Washington State should be at an equivalent rate to the country and other states.

- The most recent Center for Disease Control (CDC) data clearly demonstrate that Washington residents have about the same death rate from liver disease as other states, and Washington death rates for liver disease exceed those for the nation. Washington residents are not healthier with respect to mortality from liver disease. (Table 1.)

Table 1
Total Mortality Statistics, by State, by Principal Disease/Illness Type, 1999

		Total Number of Deaths	Liver Disease
Washington	Number	43,865	532
	% of Total	100.0%	**1.2%**
Alaska	Number	2,708	46
	% of Total		**1.7%**
Idaho	Number	9,579	88
	% of Total		**0.9%**
Montana	Number	8,128	91
	% of Total		**1.1%**
Wyoming	Number	4,042	49
	% of Total	–	**1.2%**
WWAMI Total		68,322	**806**
			1.2%
Other State Data			
California	Number	229,380	3,572
	% of Total		**1.6%**
Oregon	Number	29,422	306
	% of Total		**1.0%**
Hawaii	Number	8,270	NA
	% of Total		
Colorado	Number	27,114	391
	% of Total		**1.4%**
Florida	Number	163,224	2,029
	% of Total		**1.2%**
New York	Number	159,927	1,574
	% of Total		**1.0%**
Missouri	Number	55,931	428
	% of Total		**0.8%**
Illinois	Number	108,436	1,095
	% of Total		**1.0%**
United States	Number	2,391,399	26,259
	% of Total		**1.1%**

Note: This is most recent compilation of data across major diseases/illnesses, across all states.
Source: Center for Disease Control website, accessed November 17, 2003.

- Further, we are concerned that the liver tumor population is underserved. There is a significant body of literature on Asian Americans that documents this ethnic group's particular susceptibility to Hepatitis B and C and subsequent development of liver cancers, known as hepatocellular carcinoma (HCC). These are the leading reasons for liver transplantation. Given that Asians have a higher incidence of these diseases than non-Asians, areas where there is a higher concentration of Asian Americans will have a higher incidence of liver disease and liver tumors,

other things being equal. Washington State has a large number of Asian Americans.

- It is estimated that 1.2 million, or 1 in 10, Asian Americans are chronically infected with hepatitis B virus. (Nguyen and Keefe, Reviews in Gastroent Disorders 2003, 3(3):125-134) (Exhibit 1). Further, cancer, another indication for liver transplantation, is also higher in Asian Americans, and the risk of cancer developing in Hepatitis B infected persons is significantly greater for Asians and Asian Pacific Islanders than in other groups.

- For most persons with Hepatitis C ("HCV"), the risk for developing hepatocellular carcinoma (HCC) without chronic liver damage (cirrhosis) is small, but the annual incidence of developing HCC in patients with cirrhosis is up to 8% in Asians (vs 4% in non-Asians). (Nguyen and Keefe, Reviews in Gastroent Disorders 2003, 3(3):125-134)

- In Washington State, there are 322,335 Asians and 23,953 Asian Pacific Islanders (5.9% of the population). In the US, the comparable figure for this ethnic group is 3.7%. In the remaining WWAMI states, there are an additional 41,234 residents in this ethnic group. Total WWAMI Asian population is 387,522 residents (4.5% of the WWAMI total population of 8,717,201 residents) (Census 2000, US Census Bureau, American FactFinder, accessed 10/20/03). This does not include Asian mixed race.

- Based on the racial breakdown of Washington, we would also expect more liver disease in Washington, not less than the national average.

- Another example of under-service is derived from the fact that the UW has continued to defend its position that living donor liver transplantation is not necessary. At educational symposia this fall (2003), Dr. Perkins, the chief of the UW liver program, stated that there is no need for living donor liver transplantation as there are enough livers to fulfill the needs for liver transplantation of Washington residents.

- Under the current MELD listing system, discussed below, this can only be true if patients with tumors are not transplanted or if their list of patients contains so many individuals with low MELD scores that persons with liver tumors have an equal chance for cadaver organs as those with chronic liver disease.

- If the UW is transplanting a significant number of persons with liver tumors then they are not listing a significant number of sicker patients with chronic liver disease. If the UW is not transplanting a significant number of persons with liver tumors then the Asian American population is being ignored since they do not perform living donor liver transplantation and they do not apparently refer these persons to centers of excellence that do perform these procedures.

- We assumed that, as part of excellent medical practice, patients who could not be cared for locally would have been directed to seek alternative therapy at centers outside of our region. It is now clear that this population would have to be self-directed and that only a minority of Washington residents turned down for transplant at the UW are able or knowledgeable enough to seek a second opinion elsewhere.

- The data support our contention that there is a large underserved population in Washington State and the WWAMI region that does not get on the UW transplant wait list, and/or is unable to access transplant services out of state. Given Washington State's significant incidence of chronic liver disease, primary liver tumors, at risk population and annual mortality from chronic liver disease, how else can one explain the difference between actual and expected out migration?

- Why don't Washington residents who do not qualify for a liver transplant at the UW just seek a second opinion elsewhere? There are 3 main reasons:

  1. It is very costly. Liver transplant itself is very costly, but to add costs of travel and lodging for the patient and family members makes this life saving procedure even more out of reach for many individuals.
  2. It requires time, energy, and the ability to evaluate and choose alternatives. Patients need to research other liver transplant centers outside of their state of residence and make the best decision given the information available to them.
  3. It requires making hard choices with little medical support, either emotional or clinical. Liver transplantation is very complex, and patients and their families often times do not have a physician available to help guide them in making the decision that is right for them, especially if they have been turned down by their local transplant center to be a transplant candidate.

- The UW referring physicians also give us reason to believe that some WA residents who may have benefited from transplant were denied without the opportunity to obtain a second opinion locally. Dr. Read, Seattle Gastroenterology Associates, in her November 3, 2003 letter regarding the only patient that she follows who was transplanted out of state, stated "... this patient was denied a transplant at the University of Washington because of two separately documented instances of active drinking. This patient found a <u>very</u> newly established program that was actively seeking patients, and underwent transplant there. Given the limited availability of liver donors for transplantation, I believe the University of Washington made the best decision in this patient's case. Although this patient will be counted in the statistics for 'out migration,' his case does not reflect 'an unmet need for transplants' within the state of Washington."

- We beg to differ. This is absolutely a reflection of the unmet need for liver transplant in Washington State. It is obvious this patient benefited from a successful liver transplant elsewhere, one he could have received in his own state.

Dr. Read appears willing to deny patient access in the face of successful outcomes. She did not refer her patient elsewhere. The UW said "no," and so she accepted this pronouncement without regard to her patient's desire to seek an alternative opinion, revealing an attitude consistent with that of Dr. Perkins and others at the UW that allows patients no alternatives. This is of great concern, and confirms our position that the UW program is too conservative in accepting patients into its program.

- We also heard from Mr. Metcalf at the public hearing. He stated his daughter was forced to go out of state for a transplant. He also provided Swedish with additional rebuttal points after hearing public testimony from the UW. These points center on his perception of restrictive protocols and consequent lack of access. (Exhibit 2) We also heard from other patients who had virtually identical experiences. Unfortunately, they elected not to provide public testimony.

- In addition to the UNDERserved population in Washington, there is the issue of the UNserved, those patients who never get a chance for liver transplantation because they are kept unaware of alternatives that may be available to them. Washington DOH Mortality statistics for the year 2002 indicate there were 8.7 deaths attributed to liver disease per 100,000 population (Exhibit 3). Based on a population of roughly 6 million in the state in 2002, this equates to 527 deaths for state residents from liver disease.

- In the age group 45-54, 2002 DOH data documents that there were 131 liver disease deaths in 2002 (Exhibit 3). Theoretically, this is within a relatively young age group who would greatly benefit from liver transplantation and the age group that would otherwise be one of the most healthy candidate pools. If, for the sake of argument, we allow that as much as 50% of this group would have co-morbidities, e.g. AIDS, or they had untreatable alcoholism, which would disqualify them as transplant candidates, this reduces the 131 figure above to 60. This represents just one group of people who died from chronic liver disease at a relatively young age that is very appropriate for receiving a lifesaving liver transplant.

- The problem was even more stunning in 2001. That year, Washington DOH data indicate 571 persons died of chronic liver disease, 68 of whom were aged 35-44 and 163 of whom were aged 45-54 (Exhibit 4). As of August 31, 2003, 72% of liver transplant recipients on the UNOS registry were between the ages of 35-54.

- Deaths attributed to liver cancers (HCC) are not included in the above groups. Including deaths from liver cancers would increase the death toll due to liver disease.

- Looking at the UW wait list mortality statistics, there were 4 patients who died in 2002 and 18 in 2001. Clearly, the 131 deaths for 2002 within the age group 45-54, and the 231 (68+163) deaths for ages 35-54 in 2001 were not persons who died while awaiting a liver on the UW liver transplant waiting list. Even if we allow that

50% of these persons would not have qualified for transplantation at any liver transplant center because of medical or social problems, this still leaves a very large number of persons who were not given the opportunity for a liver transplant in Washington. The question is, why?

- We believe the UW employs very conservative liver candidate acceptance standards, thereby excluding large numbers of people who would otherwise be candidates for transplantation but instead, are allowed to die without options. The UW may have a variety of reasons for employing the selection criteria that it does. We are not in question of their motivation. We do question their choices and their role as the court of last and only opinion for the residents of Washington State.

- The data clearly show a large population with unmet needs, which gets to the heart of the access issue. The data tell us that in addition to the UW transplant figures, and the UNOS out-migration reports, there are anywhere from 50 -100 transplant candidates per year that are currently "falling through the cracks"— persons who are not considered candidates. These data explain why our 2002 estimate of 39 residents out-migrating in our original CN application is so different from the actual figure of 17 we obtained from UNOS and in fact, is likely a conservative estimate of the unserved potential.

- As the sole provider of liver transplantation for Washington State, the responsibility for educating the state's referring medical community and residents about liver transplantation and options falls squarely on the shoulders of the UW. The data demonstrate that the UW is not adequately meeting this responsibility. This is, in part, why Washington State residents are currently under- and unserved.

In summary, death from liver disease in Washington is actually slightly higher than the national average. Since Washington has very large Asian and Asian Pacific Islander populations who have a greater incidence of Hepatitis B and Hepatitis C, this is a reasonable expectation. With its current selection criteria, the UW does not capture a significant number of patients with chronic liver disease on its liver transplant waiting list. Apparently, only some Washington residents with chronic liver disease leave the State (out-migrate) for liver transplantation.

The reasons that more Washington residents with chronic liver disease do not leave the State for liver transplantation are likely to be multiple:

1. **They are not recognized because the selection process is conservative**
2. **They do not believe there is a reason to challenge the opinion of their doctor or liver transplant experts**
3. **They are unable to take advantage of alternative possibilities because they lack the knowledge and/or resources for how to proceed.**

Over 500 Washington residents die each year from liver disease, but less than 20 of these deaths occur in patients awaiting liver transplantation on the UW waiting list. This does not include deaths from liver cancer in patients who do not have the option for living donation, a procedure the UW states it does not feel the need to provide. (We discuss this issue in our "choice" discussion, below).

We conclude the UW liver transplant program does not adequately serve the needs of Washington State residents with chronic liver disease. There is clearly unmet need and lack of appropriate access. Washington residents would be better served with an additional liver transplant program.

WAC 246-310-230 (C) Structure and Process (Quality) of Care: Issue #2: UW Liver Transplant Program Quality

- The UW relies upon UNOS data when it compares itself to national average figures. From this comparison, the UW concludes that Swedish's characterization of the UW program is wrong.

- Quotes from Ms. Kathleen Sellick, UW Executive Director, include the following: "...published data speaks for itself: The wait time for transplant at UWMC, UWMC's retransplant rate and UWMC's mortality rate are far superior to national averages...because of the documented and proven quality of UWMC's program, Washington residents are best served by remaining in Washington." (Sellick letter, page 2). She also asserts: "...a review of published UNOS data demonstrates that UWMC's program is one of the most efficient, best performing liver transplant programs in the nation." (Sellick letter, page 2).

- We, too, are very familiar with UNOS data. Since the UW uses it to support its image of high quality, we will use this same data to paint a different interpretation of the UW liver transplant program's quality. We will do this by comparing the UW to 'like institutions,' not the "national average." Frankly, we are a little surprised, given the UW repeatedly refers to itself as a "center of excellence" that it does not make the effort to compare itself to other recognized centers of excellence for liver transplant.

- The UW may perform better than the 'national average' but that is not the way to determine quality within a program. Many of the liver transplant programs that make up the national total do not have significant volumes, nor do they transplant more complicated and sicker patients. Quality assessment must include comparing the UW transplant program to 'peer programs.'

- Compared to its peers, UNOS data demonstrates the UW is average, at best. Its 3-year patient survival is worse than expected and worse than at peer centers. It is of little benefit to compare UW liver transplant statistics to other Region 6 programs, which the UW does, but these programs too, are average.

- Specifically, we will demonstrate with UNOS data:

1. Compared to its peers, the UW does not transplant sick or very sick patients. This is better understood when one evaluates the morbidity of UW transplant candidates on its waiting list. Very sick patients do not make the UW wait list in significant numbers. Please see Figures 1 and 2, Table 2, and the discussion of MELD scores below. This is very important, and helps explain why the outcomes for the UW can only be considered average.

2. Significant numbers of sick patients are not on its waiting list, therefore, the UW does not transplant them. By not transplanting sicker patients (those most in need), it is not surprising the UW has "high" success rates at one-month post transplant. However, with regard to more important outcomes, the 1-year survival is as expected, but its 3 year survival statistics are worse than expected.

3. Compared to its peers, the UW graft and patient survival rates are at best, average. UW boasts about its one-month post-transplant graft survival rate (Table 3), but their outcomes are not statistically different from what is expected. Given their healthier transplant population and their history of only using livers of outstanding quality for transplantation (this issue is further addressed below with regard to their judgment about what constitutes a transplantable liver) it is surprising their outcomes are not above average, as are the outcomes for some of their peers. Despite using livers of outstanding quality and transplanting them into patients who are relatively healthy, the UW's actual 3-year patient survival rate is statistically significantly less the expected, and much lower than 3-year survival rates at any medical center listed in Table 4. This is a very important statistical finding, one ignored by the UW.

4. The UW liver transplant wait list consists of about 127 patients. This number is low for a program that boasts coverage of not only Washington but also the WWAMI region, which consists of 6 million and 9 million residents, respectively, as of July 2002. Based on peer comparisons, we would have expected the UW wait list to be at least twice as large as it is. Given a small list, it is not surprising that the UW time to transplant is relatively fast. **The real issue is the short list.** This will be further explained below.

5. The UW raves that it has low mortality rates while candidates are on its wait list. We agree–UNOS data does indicate this, but the important point is that transplant candidates on the UW wait list are much less sick, as a group, than at peer institutions. The MELD scores in Figures 1 and 2 and Table 2 verify this. With a small wait list and relatively less sick patients, we would be surprised if UW's mortality rates were not low. This is discussed further, in the MELD score discussion below.

Definition of Appropriate Peer Group

- The appropriate peer group for the UW is higher volume teaching hospitals in the western states. Peers should include:
  - UCSF
  - UCLA
  - Stanford
  - CPMC (a private teaching hospital)
  - University Hospital, Colorado

Comparison of MELD scores

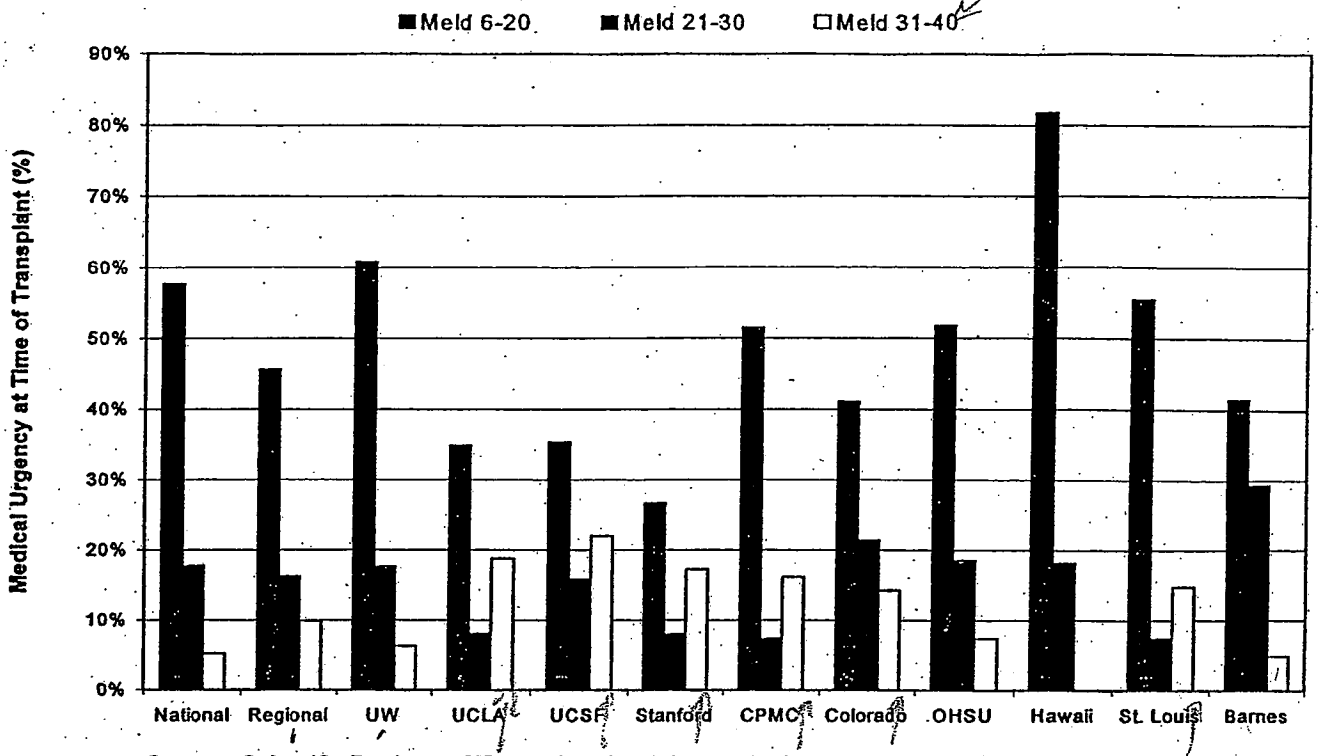
- MELD (model for end-stage liver disease) is a scoring system that defines the risk of dying from liver disease with only medical therapy. This is the risk of dying without a liver transplant while waiting on the list. UNOS mandates that livers be transplanted to the sickest persons on a waiting list first (those with the highest scores); this is because of the proven utility of liver transplantation. The liver transplant community migrated to the MELD system for determining who should receive a liver transplant in the year 2000.

- The MELD score can be used to determine the severity of illness of a transplant center's list of patients, and likewise, the MELD score of a center's recipients can be used to determine the severity of illness of the patients that it transplants.

- The UW contends that persons in Washington and the Pacific Northwest are just not as ill as in other parts of the country. The data we presented above refute that claim when it comes to liver disease, and the data we present here demonstrate the UW selectively excludes sicker patients from being liver transplant candidates. It either does this directly by exclusion through its candidate evaluation and protocols, or indirectly by not appropriately educating the public and referring physicians. Either way, compared to its peer centers, sicker people (MELD 31-40) do not appear on the UW list in appreciable numbers.

- Figures 1 and 2 represent MELD statistics for the UW, UCLA, UCSF, Stanford, CPMC, University of Colorado, OHSU, Hawaii, St. Louis, Barnes Jewish, region 6 and the nation. If one remembers the higher the MELD score, the sicker the candidate, then by observing the lighter bar across the different hospitals, one cannot help but notice that the UW has the lowest percentage of its patients in the MELD group 31-40 of any hospital listed on the graph, except Hawaii, OHSU, and the nation-as-a-whole. Barnes Jewish, in St. Louis, also has a small percentage of MELD 31-40 patients, but a much larger number of MELD 21-30. In addition, St. Louis has a second liver transplant center (St. Louis University) that transplants a larger number of MELD 31-40 patients, The UW has 61% of its patients in the MELD class 6-20 range, the highest presented on the graph, of any hospital

Figure 1
C. ...veric Organ Donor Liver Transpla...



Source: Scientific Registry of Transplant Recipients. Patients transplanted between 01/01/2000 and 06/30/2002 for 1 month and 1 year and 01/01/1998 for 3-year cohort.

except Hawaii, which is the state with the lowest per capita incidence of deaths from chronic liver disease in the nation. The UW even exceeds the national average for the number of low MELD score patients that it transplants.

- These statistics are totally inconsistent with the UW's assertion that its transplanted patients are comparable to other centers—its patients are simply not as sick. This has important implications regarding many of the UW's other claims, as well. It is particularly important with respect to UW survival statistics, and its performance compared to its peers.

- To paraphrase Ms Sellick, the data says it all. The UW patients are less sick, with a higher percentage of low MELD score patients in the 6-20 range, than those of all of its peers. The only center with a higher percentage of healthy individuals being transplanted is Hawaii, which is a relatively small center, and not considered a center of excellence. Although Barnes-Jewish of St. Louis has a smaller percentage of high MELD score transplant patients, it also has a much larger number of patients with MELD scores in the 21-30 range, than the UW. Barnes-Jewish also has more Status 1 patients (Figure 2) than the UW. And, the residents of Missouri (population 5.7 million in 2001) are served by both Barnes-Jewish and St. Louis transplant centers and St Louis University lists many more MELD 31-40 patients.

- Table 2 presents this same MELD data, but in tabular form, limited to the UW and its peers. It also contains information of "Status 1" patients. "Status 1" means that a potential liver recipient has a very acute problem (not chronic) and is not

expected to survive more than a brief period. Just as MELD 31-40 patients are those patients in greatest risk of dying from chronic disease, Status 1 patients are the high risk, acute population.

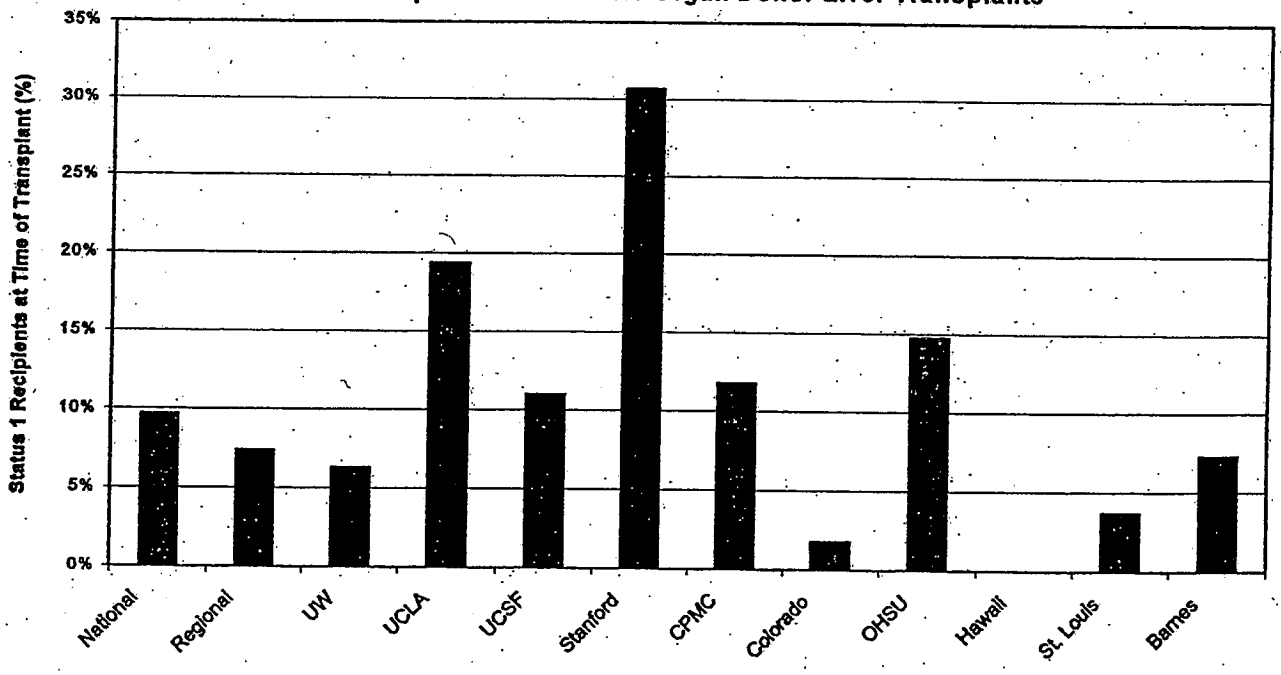
Table 2
MELD Scores (Risk of Mortality) at Time of Transplant (%)
UW Compared to Peers

	UW	UCLA	UCSF	Stanford	CPMC	U Colorado
MELD 6-10	8.9	12.9	15.9	4.0	26.5	14.3
MELD 11-20	51.9	22.0	19.5	22.7	25.0	26.8
MELD 21-30	17.7	8.1	15.9	8.0	7.4	21.4
MELD 31-40	6.3	18.8	22.0	17.3	16.2	14.3
Status 1	6.3	19.4	11.0	30.7	11.8	1.8

Source: Scientific Registry of Transplant Recipients. Patients transplanted between 01/01/2000 and 06/30/2002.

- Higher percentages of MELD 31-40 and Status 1 patients indicate a higher percentage of sicker patients (most likely to die without a liver transplant) at those institutions. UW MELD scores are significantly lower than those reported for its peer centers of excellence. In fact, the UW has essentially the lowest percentage of MELD 31-40 and Status 1 patients when compared to its peers.

Figure 2
Status 1 Recipient of Cadaveric Organ Donor Liver Transplants



Source: Scientific Registry of Transplant Recipients. Patients transplanted between 01/01/2000 and 06/30/2002 for 1 month and 1 year and 01/01/1998 for 3-year cohort.

- Figure 2 further validates that the UW is transplanting healthier patients in comparison to its peers. While St. Louis and Colorado transplant a smaller percentage of Status 1 patients, when you also look at Figure 1, both institutions transplant a much higher percentage of MELD 21-40 patients, a much sicker population than the UW.

- In relation to Ms. Sellick's claim that the UW is better than the national average, we show in Figure 2 not only is the UW well below its peers, the UW has a lower percentage of Status 1 patients than the national or regional averages. The UW performs worse, not better.

Retransplant Rate

- The UW argues that its low retransplant rate is a sign of excellence. To the contrary, the UW rate is a reflection of using excellent livers that are transplanted into relatively healthy candidates. The expected graft and patient survival figures are high compared to other groups because as noted, the UW transplants good livers into relatively well persons. That is what the "expected" figure represents -- it adjusts for acuity. However, the actual survival figures are not statistically different from expected, except 3 year patient survival is statistically worse than expected at the UW.

- Thus, the UW low retransplant rate is not a sign of technical excellence, but an expected statistic. The surprise is that their patient survival rates are not better.

Graft Survival Rates

- Statistical significance should be used to denote a mathematical finding. The UW often used the term incorrectly in its testimony. Survival rates and their significance are determined by comparing actual outcomes at each institution with the expected outcomes for that institution, given the patient mix. This comparison is important because the expected statistic "normalizes" the hospital's data for its patient mix, and other variables such as the quality of the organs it accepts. This allows comparison with the performance at other centers.

- Centers where the term "statistically higher" appears are performing better than would be expected, given their patient mix, while centers where the term "statistically lower" appears are performing worse than would be expected, given their patient mix. Statistical significance is important because it allows one to determine if the difference in outcomes is due to random chance or the difference is statistically meaningful. For example, in Table 3, looking a 1-month graft survival, the UW actual rate, 95.6, is 2.7 points higher than its expected value, 92.9. Table 3 indicates this difference is not statistically significant, i.e., the 2.7 difference is due to random chance, and not a statistically meaningful difference.

- The most important finding from Table 3 is with 3-year graft survival rates. First, the UW actual graft survival is not statistically significantly different from expected, and second, the UW's actual graft survival is worse than all other centers except UCLA. These data indicate the UW graft survival is no better than its peers. In fact, the UW's one and three years graft survival is worse than several of its peer institutions.

Table 3
Deceased Donor Liver Transplant Graft Survival
UW Compared to Peers

	1 Month			1 Year			3 Year		
	Actual	Expected	Statistically Significant	Actual	Expected	Statistically Significant	Actual	Expected	Statistically Significant
UW	95.6	92.9	No	86.8	85.4	No	70.3	75.6	No
UCLA	86.1	90.1	Statistically Lower	74.4	78.2	No	67.5	71.0	No
UCSF	94.5	91.4	No	87.4	79.6	Statistically Higher	79.2	71.2	Statistically Higher
Stanford	87.2	91.1	No	81.5	81.2	No	72.5	74.1	No
CPMC	96.2	91.0	Statistically Higher	92.7	79.4	Statistically Higher	80.9	71.9	Statistically Higher
U Colorado	99.3	93.6	Statistically Higher	93.3	85.9	Statistically Higher	81.2	75.4	No

Source: Scientific Registry of Transplant Recipients. Patients transplanted between 01/01/2000 and 06/30/2002.

Patient Survival

- Table 4 provides patient survival statistics for one month, one year and three years for the UW and peer centers. Graft survival statistics are important, but it goes without saying that what matters is patient survival. Notice that the UW does not perform any better than its peers, except Stanford and UCLA at one month.

- At 3 years, there are two key findings from Table 4: First the UW performs statistically significantly lower than expected, which is to say its actual outcomes are statistically worse than would be expected from random chance. Second, its actual 3-year patient survival rate is much below any peer medical center in Table 4. This trend is not one expected for a "center of excellence," particularly given its relatively less sick transplant patients

- The UW makes much mention of its superiority compared to UCLA—this is worth examining. In comparing UCLA and UW, at one month, actual and expected rates at both hospitals are virtually the same. At one year, survival rates are higher at the UW than at UCLA, but both hospitals are performing at their expected values. This is important because that is what adjusts for patient acuity. At 3 years, the UW is performing worse than expected and this is statistically significant, and further, its actual survival rate is well below UCLA. We suggest the UW is not better at all, particularly if we care about long term patient survival.

Table 4
Deceased Donor Liver Transplant Patient Survival
UW Compared to Peers

	1 Month			1 Year			3 Year		
	Actual	Expected	Statistically Significant	Actual	Expected	Statistically Significant	Actual	Expected	Statistically Significant
UW	96.6	95.8	No	90.1	89.2	No	71.4	80.4	Statistically Lower
UCLA	95.2	94.3	No	83.7	84.1	No	76.1	76.4	No
UCSF	97.4	95.1	No	90.7	84.7	No	83.0	77.3	No
Stanford	88.5	95.2	Statistically Lower	84.6	87.5	No	77.0	79.8	No
CPMC	96.1	94.2	No	91.9	82.7	Statistically Higher	82.1	75.1	No
U Colorado	99.2	96.4	No	94.3	90.2	No	87.7	81.9	No

Source: Scientific Registry of Transplant Recipients. Patients transplanted between 01/01/2000 and 06/30/2002.

Transplant Wait List

- The size of the liver transplant wait list directly relates to patient access for liver transplantation. Smaller lists indicate fewer patients deemed "eligible candidates" by their transplant institution.

- The UW wait list is much too small. There is no way to "prove" this, but we can compare its size with what would normally be expected.

- Based on current UNOS data, there are 17,246 persons on waiting lists in the US, as a whole (UNOS website, accessed November 17, 2003). With a US population of 292 million persons, this translates into a "rate" of 5,9 persons on a liver transplant waiting list per 100,000 residents, or 59 per million.

- Given that Washington's 2003 population is about 6 million residents, using the US rate of transplant waiting list candidates of 5.9 persons per 100,000 residents, this yields a figure of 354 persons—the number of Washington State residents we would have expected to be liver transplant waiting list candidates in our state.

- We have demonstrated elsewhere that mortality associated with liver disease in our state is comparable to other states, and actually above the national average. Thus it is reasonable to use the national rate of 5.9 persons per 100,000 residents to estimate the expected size of the transplant waiting list.

- The UW list is about 127 persons (UNOS website, accessed November 10, 2003). The difference, 227 (354-127) is very large, too large for random chance. This validates our contention there is a large underserved/unserved liver transplant population in Washington—people who never make it onto the UW wait list.

- As another comparison of the size of the UW wait list for liver transplants, we provide Table 6 below, which provides wait list data for selected states, some in the east, some in the west, some much smaller than Washington/WAMI, and some larger:

- When we compare the listing rate (patients on liver transplant waiting list per 1 million resident population) for the nation and for a number of other states, it is clear that the UW listing rate is woefully inadequate, In fact the only state the UW listing rate compares to is Georgia.

Table 5
Number of Persons on Liver Transplant Wait lists, and Rate per Million Residents, By State, for Selected States and the U.S., 2002

Geographic Region	Persons on Liver Transplant Waiting List	2002 Population (Millions)	Number of Persons on Wait List Per Million Residents
United States	**17,567**	**292**	**60**
WA/WWAMI	**127**	**8.8**	**14**
Arizona	203	5.3	38
California	3,563	33.5	106
Georgia	**140**	**8.4**	**17**
Maryland	443	5.4	82
Mass/New England	1,091	12.0	78
Missouri	269	5.6	47
North Carolina	451	8.2	55
Tennessee	277	5.8	48
Virginia	331	7.2	46

Sources: www.ustransplant.org for wait list statistics, and US Bureau of Census for population statistics. See their website.

Time to Transplant

- The UW lauds itself on its rapid time to transplant. However, this is not at all surprising, given the small size of its waiting list, and the availability of local donor organs?

In summary, the UW liver transplant program performs below its peers in multiple key quality indicators:

1. **UW does not transplant sick patients relative to its peer institutions.**
2. **The UW does not list sicker patients in significant numbers.**
3. **The UW does not list patients at an expected rate. This is especially true given that the number of persons with chronic liver disease in Washington State and the WWAMI region is as great or greater than the nation as a whole and other states.**

4. The UW wait list is very small in size – again because the UW denies access to patients most in need of a liver transplant
5. The UW outcomes are no better than its peers and in fact tend to have worse outcomes over time. The three-year patient survival rate is below all peer medical centers listed in Table 4.
6. The UW is the only hospital listed in Table 4 (Patient Survival) that performs worse than expected in a statistically significant fashion although several of its peer institutions perform statistically better than expected This emphasizes the UW's poor performance compared to its peers and its own misrepresentation of its quality.
7. The outcomes at UW are lower than expected, even though it selectively picks its patients and organs in efforts to insure success.

Ms. Sellick, UW's Executive Director, is correct--the data speak for themselves. The UNOS data, as presented by the UW employees in their testimony and written comments, has been misrepresented by them. As Dr. Marks stated at the hearing, the UW should be congratulated for its contributions to establishing liver transplantation in Washington State. It accomplishments should not be diminished or overlooked. However, the UW has not performed at the level it claims, and it has not served the complete needs of the chronic liver failure and liver tumor populations of Washington State and the WWAMI region.

The UW should be listing and transplanting patients with higher MELD scores, those most in need of a life saving liver transplant, as is UNOS policy. Those patients exist but are not recognized by the UW. This population must either out-migrate, if they have the means, or die without options. Given its relatively healthy transplant patient mix, it is of great concern that the UW outcomes are not better.

In essence, UNOS data confirm that the UW liver transplant program is not performing at the level of its peers, other centers of excellence. At best it is an average institution. Passable performance is not what the residents of Washington and the WWAMI deserve from the only organization providing liver transplantation. We believe there are many opportunities to improve quality, which directly pertains to our conformance to WAC 246-310-230.

WAC 246-310-230 (C) Structure and Process (Quality) of Care: Issue # 3: Liver "Export" figures

- Ms. Sellick argues in her letter that "...Swedish's contention that the fact that liver donor organs are routinely being exported to other states ...demonstrates its fundamental lack of knowledge of the intent and purpose of the 1984 National Organ Transplant Act...published data documents that Washington's rate of

retention and use of local donors is actually higher than the national average demonstrating UWMC's excellence and commitment to accessing the organs we need to serve Washington residents." (Sellick letter, page 2).

- We strongly disagree with Ms. Sellick. UNOS policy 3.0 (Organ Distribution), subsection 3.6 (liver allocation) has been misrepresented. This policy states that local Status 1 patients (acutely ill persons unlikely to survive 7 days without a liver transplant) have priority. If no Local Status 1 patient is available then Regional Status 1 candidates have next priority. If no Regional Status 1 patients are available then local liver transplant programs have priority over all other centers for donated livers. These livers are to be allocated according to the risk of mortality (MELD) score. (Please see Adult Donor Liver Allocation Algorithm below and Exhibit 4.) Since the UW is the only local liver transplant program served by the OPO, it has the right of first refusal for all non-Status 1 livers procured by LifeCenter Northwest.

- **Adult Donor Liver Allocation Algorithm**

  Local

  1. Status 1 Patients in descending point order (longest waiting time first)

  Regional

  2. Status 1 patients in descending point order (longest waiting time first)

  Local

  3. All other patients in descending order of mortality risk scores

  Regional

  4. All other patients in descending order of mortality risk scores

  National

  5. Status 1 patients in descending point order (longest waiting time first)
  6. All other patients in descending order of mortality risk scores

- Based on 1999-2002 LifeCenter Northwest data, which we have cited, we know first hand, that, over this period, on average, 28 livers were exported each year. We also know from UNOS data over the same period, that 64 patients on the UW wait list expired while waiting for a liver transplant.

- We stand by our contention that our local export rate for livers is high. This high export rate is a direct result of UW transplant surgeons deeming these livers unsuitable for transplant, when in fact virtually all exported livers were successfully transplanted.

- Dr. Marks, as the Medical Director of the OPO and the medical advisor-elect of AOPO, the national organization of organ procurement organizations, fully understands the requirements as well as the mission of the organ procurement organization. Dr. Marks clearly understands the requirements for organ sharing.

- The UW knows full well that Dr. Marks, as the Medical Director of the OPO, together with the OPO administration, has worked, and continues to work, to

assure that the UW and its patients have access to all available transplantable livers. They have worked for years to inform the UW team of rates of procurement, reasons for turn down, results of transplanted organs at other centers in the hope that through repeated contact, the UW might use all available transplantable organs.

- The OPO placed livers with regional Status 1 and pediatric Status 1 candidates as required, and offered all remaining organs to the UW with right of first refusal, as the OPTN/UNOS Policy 3.6 specifies.

- For completeness, and as an example, we note that there were 7 Status 1 livers in 2002 out of the 30 livers that were exported. The remainder were placed outside the state as the UW chose not to use them. Most commonly, the UW turned these livers down based on its judgment that these livers were not transplantable.

- Dr. Perkins argues in his letter that one must be cautious about which livers one accepts. He goes on to describe the "marginal" liver, and states that: "...centers must be held accountable for questionable practices that incur enormous costs and bestow few benefits. Utilizing re-transplantation in a cavalier manner such as this (using extended criteria donors) is the type of clinical practice that contributes to the very problem third party payers abhor—low quality, cost-ineffective transplantation based on the 'rule of rescue.'" (Page 4, Perkins letter.) By this statement, Dr. Perkins implies that the livers the UW was being offered were marginal and therefore not transplantable in his or his team's, judgment.

- We do not know what Dr. Perkins' "rule" is, but we do know there were 126 exported livers between 1999 and 2002 and 124 of those livers (98.4%) worked on transplant. Minus the ~7 livers per year that were mandatory share leaves 98 that were considered transplantable by the OPO but passed over by UW. Over the same time period, 64 UW wait list patients died.

- The UW lauds itself by comparing the regional export rate, 27.8% in 2002, to the national average, of 27.2%—they are statistically the same. This is another misinterpretation of the facts. We assert that the comparison should be our OPO rates to peer OPO rates, not the national average, because the national average includes areas without active transplant centers, such as Mississippi, thus raising the export rate. It also includes centers that exist in very populated regions such as the Eastern Seaboard. In these regions there is a greater likelihood of having a Status 1 recipient in a neighboring region, thus mandating liver export.

- To compare expected export rates with the export rates of Washington and Oregon, OPOs must be evaluated with service areas that have similar characteristics. Our area has a dominant transplant center and is surrounded in its region with centers that service relatively small populations. Similar environments can be found in Northern and Southern California and in rural state environments, such as Nebraska and Colorado.

- In comparison to the export rates of Washington and Oregon, OPOs servicing similarly sized programs, in similar markets to the University of Washington, have export rates as follow:

    - Bay Area 6 County area (4 transplant centers, population 6.6 million) exported ~10%, 2002
    - Los Angeles County (population 9.3 million, 4 transplant centers) exported ~10%, 2002
    - Nebraska (1.7 million, 1 transplant center) exported 10% in 2001 and 0% in 2002
    - Colorado (4.4 million, 2 transplant centers) exported 15.6% in 2002

- In 2002, of the 30 livers exported from LifeCenter Northwest, 7 were mandatory exports and the remaining 23 were offered to the UW with the right of first refusal. Thus, our "mandatory" export rate is only 6 percent (7/114). We have a high export of liver organs not because of some mandatory rule of law. Our export rate is high because the UW chooses not to transplant organs that we know from LifeCenter Northwest data, are viable, and virtually all (98.4%) functioned on transplant.

- Further, based on conversations with Bruce Zalneraitis, Executive Director, Life Alaska Donor Services, this issue of high exports is even more significant. Mr. Zalneraitis is very supportive of Swedish's CN application for liver transplantation because he believes that some Alaskan livers could be used that are not. He indicated on average his organization has 20 organ donors per year available but believes there could be more than this if a Center would be willing to use less than ideal donor organs. Given that Alaska is 1,500 miles from Seattle, and much further from other potential recipient sites, Seattle is at the practical geographic limit for liver organ transport of Alaska residents' donor organs. Thus currently if the UW judges that a donor liver is not transplantable it will go unused because distance does not allow for placement outside of our local area.

- In essence, the Alaskan situation exacerbates an already difficult problem, too few State residents receiving liver transplants locally. A second program creating competition for donor organs would correct this situation.

- Further evidence that the UW does not understand UNOS allocation policy (the organ allocation policy as put forth in UNOS Policy 3.0 (organ distribution), subsections 3.5, 3.6, 3.8) is demonstrated by its attempt to use kidney and pancreas allocation policies to cloud the issue.

- The UW makes mention of the comparison between kidney and liver sharing rules. The UW asserts we misunderstand organ sharing. We are not wrong. Mandatory sharing rules for kidneys and kidney pancreata are based on tissue matching. The reasons for this are beyond the scope of this discussion, but are based in experience and applied immunology. Kidneys that match in 6 of 6 locations are

shared on a mandatory basis. This is true whether the recipient is local or national. However, with kidneys, unlike livers, there are also "payback requirements." These "payback requirements" call for OPOs receiving the mandatory shared kidney to offer a kidney from the next suitable donor of the same blood type to the OPO from which the kidney they used was taken. (Exhibit 5).). The mandatory export rule for livers is based on severity of illness, giving first priority to local and then regional Status 1 candidates. After this the liver reverts to the local list and is allocated based on the MELD score. (Exhibit 4).

In summary, the liver export rate for Washington is extremely high. The UW attempts to appear knowledgeable in Liver Transplant Allocation, however it has misrepresented the facts. The LCNW export rate is 26.3%, when it would only be 6.14% if we exported only mandatory-shared Status 1 livers. Comparing itself to the national export rate is a further distortion of the truth. Since not every state has a large volume or an aggressive or committed liver transplant center, OPOs are sometimes forced to export livers to other states, thus raising the national export rate. One such example is that of Mississippi. Additionally, some OPOs are in regions with large population bases. Thus, regional Status 1 recipients occur more frequently than in relatively rural regions such as region 6.

The UW is simply wrong in suggesting that the liver export rate in Washington is anything but a result of its judgment and lack of aggressiveness. For the past decade, its policies and protocols for determining transplantable livers have been inadequate and not in the best interests of Washington State residents

WAC 246-310-230 (C) Structure and Process (Quality) of Care: Issue # 4: Minimum Liver Transplant Volumes

- The UW claimed that opening a second liver center would threaten the ability of UW to meet minimum payer standards Conversations with major commercial payers indicate there are limited minimum volume standards in existence for liver transplantation

    1. Pacificare representatives confirm no minimum volume standards and, since Swedish is "already contracted for kidney transplants, it should not be that difficult to amend that contract to include liver transplants."
    2. Regence BlueShield does not "credential to the degree for which certain procedures are allowed" and that is up to the organization
    3. First Choice does not have separate criteria

- While Aetna does require evaluation only after a transplant program has been in operation for 2 years, they are an exception to the major commercial payers.

- Medicare does have minimum volume requirements. New programs must perform at least 12 liver transplants and been operational for a 12-month period before Medicare will begin reimbursement for the procedure.

- Medicaid will not reimburse programs if annual liver transplant volume is less than 12.

- Our CN application did recognize payer policies and did explicitly adjust reimbursement for these government payers' reimbursement policies.

- Leapfrog does not have any minimum volume requirements per Nickol Tod, their Manager of Operations.

- Number of cases to maintain accreditation for training:

    1. The only minimum number that must be met to assure adequate training is 50 livers per year to maintain a fellowship.

- Number of cases to maintain accreditation for teaching residents and students:

    1. No requirement

- Number of cases to maintain accreditation as a program:

    1. No requirement

- We contend that the UW will not lose any of its patient base due to the opening of the second program. However, even if did lose some patients, the UW would not lose half of its referral base.

- Number of cases suggested by the literature as a minimum to assure top quality:

    1. An article published in the New England Journal of Medicine (Edwards, et al, NEJM, 1999, 341(27):2049-2053) (Exhibit 7) advocates that 20 livers must be done per year to assure quality. The authors draw their conclusions from the national database.

    2. While we have no reason to disagree with the data, it should be noted the data is strongly contested by others such as the group from Loma Linda, CA. (Exhibit 8). Loma Linda has among the best 3-year survival numbers in the country, but only performed 17 liver transplants per year for their first several years of service. (Exhibit 9).

    3. In any event, we have no intention of performing less than 20 liver transplants per year, as is clearly outlined in our application.

In summary, there is no conclusive evidence that minimum volumes below 20 would be detrimental to a program or the population it serves. Even programs currently performing below 20 liver transplants per year have shown high quality outcomes. The Swedish program would not drop the UW program below the 50 liver transplants necessary to maintain their fellowship program, the only significant minimum volume requirement. However, it is worthwhile to note that, if the UW had patients with higher MELD scores on their waiting list compared to those on a Swedish wait list, they would still have right of first refusal to available donor livers.

WAC 246-310-220 Financial Feasibility and WAC 246-310-240 Cost Containment: Issue # 5: Competition and Choice (Alternative Protocols)

Competition

- The United States transplant community recently decided the sickest persons awaiting a liver transplant should receive priority. The MELD scoring system was developed for this purpose and replaced the old "status" system for determining which patients should receive priority for a liver transplant. An excerpt from the announcement for this system by the UNOS Board noted: "The OPTN/UNOS Board of Directors, at its semi-annual meeting here today, unanimously approved a significant refinement to the national policy for matching donated livers with patients awaiting transplants, which should better identify urgent patients and reduce deaths among patients awaiting liver transplants. For all but the most severe and acute cases of liver failure, patients' priority for a transplant would be based primarily on a formula that calculates their short-term risk of death without transplantation. "(November 15, 2001 Alexandria, VA) <www.thetransplantnetwork.com/liver_allocation_policy_refineme.htm>

- The higher a person's MELD score, the greater priority that person has to receive a liver. If persons have the same score, then time on the waiting list is used to determine who receives the organ.

- The MELD score measures risk of death without a transplant (severity of illness) and thus, can be used to measure of how sick a patient who receives a given transplant is. Different centers employ different protocols, procedures and policies to determine the characteristics of acceptable transplant candidates. They base these on their institutional understanding of the literature, personal experience and skill sets.

- Historically, prior to the introduction of the MELD system, the UW transplanted a lower number of the sickest persons (Status 1) than did its peer centers. We have provided UNOS data, above, that confirms the UW still transplants relatively healthy persons, compared to its peers.

- The literature suggests that when a single or dominant liver transplant center exists within a given service area, its MELD scores are significantly lower than if more than one center is present (Exhibit10). In other words, centers where there is no competition tend to transplant patients who are less ill.

- This finding persisted even when patients were removed who would be expected to have low MELD scores, such as persons with liver cancer or metabolic diseases. The explanation for this is simple.

    - With more than one center, there is competition for local organs, and, given a finite supply of donor organs, the center whose patients have higher MELD scores receives organs first, based on UNOS liver allocation policy. This simply means, with multiple centers, there is a natural incentive to include sicker patients in the transplant candidate pool.

    - With more than one center, there is competition for local organs, and given a finite supply of donor organs, the center whose patients have higher MELD scores receive organs first, based on UNOS liver allocation policy.

    - This outcome was the intent of HRSA as expressed by Secretary Shalala in a 1999 memo, when she mandated establishment of an allocation policy based on patient need, not geography.

    - In a March 26, 1998 HHS press release, Secretary of Health Shalala said, "Patients who need an organ transplant should not have to gamble that an organ will become available in their local area, nor should they have to travel to transplant centers far from home simply to improve their chances of getting an organ, Instead, patients everywhere in the country should have an equal chance to receive an organ, based on their medical condition and the judgment of their physicians." <http://www.hrsa.gov/News-PA/organreg.htm>

    - The UW currently faces no local competition, thus it is not forced to aggressively seek more complex cases, i.e., patients with higher MELD scores. As we have pointed out above, this is exactly what UNOS data on the UW transplant patients shows.

    - This situation would change with a second center in town. Otherwise, the center with patients that have consistently lower MELD scores would not get livers.

- Competition will also bring living donor liver transplantation to Washington. This procedure will help fill an unmet need. The UW has publicly stated it will not offer this procedure. However, living donor liver transplantation may be the only option

for persons with liver diseases such as liver tumors and metabolic diseases to receive a liver transplant.

- Under the rules of allocation discussed above, patients with high MELD scores are much more likely to receive cadaver livers than those with lower scores. Since patients with liver tumors are not ill (and therefore have low MELD scores) in the early stages of their disease when transplantation is possible (before the tumor spreads) a living donor liver may be their only hope for survival.

- Similarly, persons with metabolic diseases rarely get sick enough to earn high MELD scores. Therefore, they are also unlikely to receive a liver transplant without a living donor.

- Thus, a second program brings Washington State residents two benefits, 1. transplantation for higher MELD score patients (currently excluded from the list) and 2. living donor liver transplantation.

- The UW presents a number of spurious arguments regarding competition. We think they are doing so to "protect" their market as the only local and regional liver transplant program.

- Perhaps the best example of their critique of competition is from Dr Read, a gastroenterologist who wrote in support of the UW position. Dr. Read wrote: "...not only was the competition in that situation (she's referring to San Francisco transplant center competition) fostered unhealthy, it was also very counterproductive. Energy is misdirected, egos intervene into decisions, and these factors rather than purely medical considerations can determine acceptance of perhaps marginal livers for transplants. ..a glaring, egregious example of what can occur as a result of competition is that of Chicago, where Medicare fraud was committed in an effort to gain preeminence in the acquisition of livers..."(Read Letter, paragraph 8)

- Dr Read ignores the facts regarding the liver transplant programs in San Francisco, and in so doing, ignores the benefits from competition. First, we should note that the population of San Francisco is only slightly greater than Seattle. But according to the 2000 census, the Bay area population that actually depends on San Francisco for service is about 6.6 million. This is very similar to Washington State's 6 million residents (as of the July 2002 census update by the U.S. Census Bureau). The Bay Area is served by 3 major liver transplant centers, UCSF, California Pacific Medical Center (a private Stanford teaching hospital) and Stanford. These are 3 of the peer medical centers we have provided data for to compare UW performance to—MELD scores, and graft and patient survival statistics.

- UNOS data clearly indicates that each of these San Francisco centers outperform the UW. We do not understand what Dr. Read is referring to when she cites the

"unhealthy," "counterproductive" effects of competition. We think the UW, and certainly our area residents could benefit from better performance. We think competition helps attain improved performance—it's that simple.

- Regarding Dr. Read's allegation of the Medicare fraud in Chicago, this is another example of her apparent lack of understanding. The situation that occurred at the University of Illinois (the State run institution) was an embarrassment for all in the field of transplantation. It is a clear example of dishonesty and manipulation of the public trust—it was not the result of competition. The department of organ transplantation at Swedish stands in unequivocal opposition to any practices that violate the public trust.

Choice (Alternative Protocols)

- In addition to opposition to competition, the UW opposes patient (and referring physician) choice—apparently they feel they have all the answers. Reflective of this attitude, the UW's Associate Dean for the School of Medicine, Dr. Edward Walker, states, "...This is not an issue of consumerism and choice; it is about the rational distribution of increasingly scarce resources,..." (Walker letter, paragraph 4)

- We are confused about statements like this—what are they opposed to? Choice extends far beyond the trivial issue of offering the consumer alternative facilities for care. The essence of choice in quaternary medicine is "option for treatment." All patients should be offered choice, despite what the UW seems to advocate.

- Institutions develop their own methods for dealing with or exploring complex problems. The choices an institution makes regarding complex problems are based on a variety of input that includes interpretation of the literature, personal experience and available skills. Thus, it is not unusual to have two neighboring institutions that offer the same complex service and yet approach specific clinical management issues in two very different ways.

- Clinicians develop protocols and procedures from conclusions drawn from the collective knowledge and experience of the practitioners at that institution, and from the wider body of scientific knowledge. Rarely is there a single way or answer to the complex questions that quaternary medical practice raise. This is why choice is very important.

- For example, Swedish is a national leader in the field of steroid free immunosuppression for kidney transplantation (Exhibit 11). Swedish was first to develop this type of protocol in the Northwest. Today, the UW also offers this protocol for kidney recipients but on a more limited basis and using a different version of our protocol. As the data develop, people in our service area and their physicians will be able to make choices based on what they believe is best for them with regard to the very complex area of immunosuppression and kidney

transplantation. We know both steroid free protocols work to varying degrees. They also have markedly different side affects and complication profiles. Only through time and study will we discover which is best in the long term.

- A more direct example related to liver transplantation is the issue of criteria for accepting donor liver organs. Under Dr. Marks' acceptance criteria for donor livers, the vast majority of the cadaver livers that were exported would have been transplanted into the citizens of Washington State and the WWAMI region. Dr. Marks deemed those livers transplantable and urged the UW to alter their acceptance criteria for patients on their wait list. Had a second program been available at Swedish, those livers that were not mandatory exports would have been utilized locally.

- The population served by a single center is subject to the protocols based on the interpretations and prejudices of a single group. The concept and value of second opinions is well appreciated. It is hubris and self-delusional to consider one's choices, protocols, procedures and interpretation of the field as "the only valid" ones to be made available to the public we serve.

- Examples of alternative policies/protocols related to liver transplantation include:

  1. Acceptance criteria for donor organs
  2. Acceptance criteria for liver transplant candidates
  3. Adult to adult living donor transplantation
  4. Research protocols that minimize blood loss (abstract by Dr. Precht)
  5. Novel immunosuppressive protocols
  6. Split livers (two livers from one)
  7. Cut-down livers ("down-size" a liver to sustain a smaller-sized recipient)

- Based on OPTN data, it is clear that Washington residents are denied access to liver transplantation through the UW's unwillingness to use many donor organs each year. However, to also not offer living donor, split donor, and down-sized donor organ transplantation in appropriate candidates, as do the organizations whose standards the UW compares itself to, adds to the disservice to our community.

In summary, competition improves performance—we do not see deleterious impacts from competitive actions, but rather see only benefits. There is certainly nothing in the literature that points to the issues the UW alleges. In fact, looking at San Francisco, where there is competition among liver transplant programs, there is much better performance than at the UW.

Not surprisingly, the UW will resist competition, as evidenced in its testimony and letters. It is always true that monopolists prefer the status quo. Competition will drive providers to improve, increasing incentives to focus on performance, and

identify and correct any program shortcomings. This is what the market demonstrates, this is the benefit of competition.

Competition allows choice, which is very important. The essence of choice in quaternary medicine is "option for treatment." All patients should be offered choice, despite what the UW would argue. With only one liver transplant program, patients are unable to get a second opinion locally. Those that have the financial means out-migrate, and those that do not, die.

WAC 246-310-220 Financial Feasibility and WAC 246-310-240 Cost Containment: Issue #6: Swedish Medical Center Capabilities

- The UW makes numerous assertions that its liver program is uniquely structured and operated and that structure is part of what makes it a "center of excellence." We heard this repeatedly from UW physicians. Moreover, these same physicians state Swedish Medical Center could not provide necessary staff skills and expertise to offer anything but a mediocre liver transplant program.

- As with the other UW assertions, these are more based on fiction than fact. We will explain why these allegations are false and, moreover, why the UW transplant service is neither unique nor uniquely qualified to provide liver transplant services.

- Swedish is very committed to transplantation service. Since its inception in 1993, the program has been built on an infrastructure capable of providing outstanding, state of the art care for transplant recipients. It is heavily invested in service, training and research and intends to remain that way.

- With regard to the UW allegation that Swedish did not anticipate or appreciate the additional clinical obligations or costs associated with a liver program, the most significant recruitment tool used to attract Dr. Marks from Yale was the institution's commitment to establishing a 'department of transplantation.' This single cost center is responsible for the personnel that work within its area of focus, which is solely transplantation.

<u>Swedish Transplant Program</u>

- The commitment to the patients at Swedish is evident in its style of practice. Swedish transplant surgeons round as a team every day (physician, surgeon, resident in training, inpatient nurse coordinator, patient floor nurse, pharmacist and social worker). The transplant faculty discusses problems and data together, face-to-face. Swedish transplant patients hear one message and most importantly, one plan. This minimizes the chance for mistakes and assures excellent patient

communication and training. At the end of rounds, the physician, surgeon and coordinator review rounds, plans and orders, and the inpatient nurse then makes 'sweep rounds' to clarify issues with the patients and oversee patient teaching and floor nurse education. This has occurred on a daily basis for the last 10 years. And the Swedish transplant team is available 24/7—a point the UW repeatedly makes, as if they are the only clinicians providing that level of service.

- The Swedish surgical faculty consists of three full-time, general surgeons, all Board Certified, all with multi-organ transplant training at a variety of American institutions. The team also includes one urologist. Dr. Chapman, an outstanding technical surgeon, but one who will not perform liver transplantation. He is responsible for the living donor program, which includes the laparoscopic donor program, and for the evaluation and management of complex urologic conditions and problems related to transplant.

- The Swedish medical faculty consists of one full-time nephrologist and 6 other nephrologists who rotate monthly under the direction of the medical director, Dr. Diana Perkinson. All members of the department attend regularly scheduled patient evaluation and educational conferences and Dr. Perkinson sits on the Board of LifeCenter Northwest Organ Procurement Organization.

- Swedish has 6 nurse coordinators and it anticipates a new coordinator as the liver program develops. Social work and financial counseling are mandated by UNOS and are a part of Swedish's departmental service. The transplant program also employs a full time data manager and a research fellow. The transplant inpatient floor consists of a 24-bed unit. The transplant inpatient nursing staff are specially trained and designated to care for transplant recipients. In addition, the transplant team has designated transplant program pharmacists, transplant specialty pathologists and a designated transplant infectious disease group.

- The Swedish commitment to transplantation extends to staff education. The Swedish transplant department gives annual scholarships to nurses to attend national transplant training and update conferences. The department also mandates and supports attendance at national transplant conferences by each transplant coordinator and members of the transplant faculty.

- The Swedish transplant team is committed to the long-term health of the patients they serve. During the 10 years since the inception of the organ transplant program, Dr. Marks has not had a single member of the faculty or hired member of the transplant nurse coordinator staff, social work or data staff, leave Swedish's employ. Each one shares a vision of individualized and dedicated patient care.

- Swedish never loses track of its patients. The transplant team feels a strong sense of dedication to the patient and their family, as every medical team should. And the team also feels a strong sense of obligation to the individual donor or donor family. Thus, Swedish's transplant team is doubly compelled to assure the safety and well

being of its patients. The success of the Swedish model is demonstrated by the outcome data for our program (see Exhibit 12).

- Swedish will bring this same sense of awe and dedication to its liver transplant program. We contend that our application was misinterpreted or misrepresented by the UW. The infrastructure we have in place to support our kidney and pancreas programs requires only modest additions to accommodate a new and robust liver program. That is one of the reasons that the organ transplant program was structured as it was in the first place.

- The budget accommodates a new surgeon and a new physician dedicated to liver care because we intend to add senior level, state of the art leaders in the field to our faculty. We do believe that a true center of excellence is required to meet the needs of the area, and not another average liver transplant program.

The University of Washington Liver Transplant Program

- The UW states that its program is unique. That may be the case, but let us evaluate how unique: The transplant service resides as a section within the department of surgery and its providers are drawn from several departments (cost centers) to serve the transplant service line. For example, the hepatologists come from the department of Medicine, the surgeons from the department of Surgery, Nurse coordinators from Nursing, etc. This type of organization actually leads to a fragmented form of patient care and adds layers of expense to the process. Within the UW system each department is a cost center and each member of the faculty practice plan must support the University tax structure which includes the usual overhead plus administrative and departmental taxes.

- The UW surgical staff has an unusual makeup for a liver transplant team. Until last year, it was staffed by Dr. Perkins (a Board Certified general surgeon trained in transplantation), 3 urologists and a general surgeon trained by Dr. Perkins but not yet Board Certified.

- Dr. Perkins was unfortunately disabled and has not been able to operate. Dr. Marsh, who is a Board Certified urologist, became the principal liver transplant surgeon following Dr. Perkins injury. Dr. Marsh, who was trained to do liver transplants by Dr. Perkins, left last year for Southern California. Dr. Kuhr is also a Board Certified urologist, and was trained to do liver transplants by Drs. Perkins and Marsh. Dr. Levy, a general surgeon who is not yet Board Certified (Board eligible), was trained to do liver transplants by Drs. Perkins, Marsh and Kuhr. Additional staff includes Dr. Bakthavatsalam, who received his initial training in general surgery in England and then completed his training as a urologist in Ireland before training at the University of Washington in transplantation under doctors Marsh, Kuhr and Levy. The UW also has a Fellow in training. For two years, their team was joined by Drs. Wrenshall and Stevens. Both trained at the University of Minnesota and both left to join the faculty at the University of Nebraska within 2 years of joining the UW faculty.

- This summer, the surgical staff was joined by Dr. Holversen, who is a general surgeon, and just completed his fellowship in multi-organ transplantation at the University of California San Francisco, and a new Fellow in training, Dr. Eng, from Bakersfield Hospital in California.

- Dr. Healy is also on staff. He is a pediatric surgeon who does not participate as an active member of the adult liver transplant service.

- Thus, the active UW adult liver transplant surgical faculty does not now and has not recently consisted of 6 or even 5 surgeons, as stated by the UW. This group of 4 surgeons (Drs Levy, Kuhr, Bakthavatsalam and Hoversen) is responsible for all of the liver, kidney and pancreata transplanted at the UW as well as procurement for the organs other than kidneys that they transplant This surgical faculty, a Board Eligible (non-Board certified) general surgeon, two urologists trained in liver transplantation at the UW and a newly graduated junior faculty member, is what the UW defines as "depth and breadth".

- The UW's medical transplant support faculty consists of 4 hepatologists and an infectious disease doctor. All are assisted by fellows in training and others as needed. For instance, when the hepatologists leave town for a meeting, Dr. Alexandra Read states that she covers the service (see letter by Dr Read). Dr. Read is a private practice physician with an appointment to the clinical faculty at the UW that allows her to cover during times each year when their "24/7" attending faculty are all away from the institution.

- The transplant service line also includes nurse coordinators, social workers and financial counselors, as noted in the UW's comments and presentations. With regard to these support staff, we understand the remarkable dedication of these individuals. Throughout the world, they are the backbone of every successful transplant program. We are sure the UW is not unique in this regard.

- **In summary, Swedish has shown that it is more than ready and able to establish a successful liver transplant program. The existence of a second program will bring alternative protocols and policies to the potential recipients in our region. These will be based on differing expertise, approaches to problem solving, and interests in comparison to the UW.**

- **Swedish understands the value that is derived from dissenting opinions, competing ideas and different approaches to complex problems. In the field of liver transplantation, the residents of Washington State are under-served and the service that is available is average by all standard measures. By its presence, a second liver transplant program will rectify this and also help to elevate the practice of liver transplantation in Washington State to a level of true excellence.**

Appendix A
Detailed Responses to Public Hearing Letters
November 24, 2003

Introduction

There were 23 letters submitted at the public hearing. For purposes of our responses, we class them into 3 groups: (1) those written by UW employees, including physicians; (2) those written by physicians either trained by or currently closely affiliated with the UW; and (3) gastroenterologists in the state who have made referrals to the UW liver transplant program.

We were not surprised at the criticism we received from University of Washington Medical Center employees. The UW is doing what it feels it must to protect its market monopoly. However, we were surprised at the data the UW claimed was objective, more by what it did not state, rather than by what it did. There are many instances in which these employees' assertions and conclusions are simply wrong. We believe, in large part, that we have addressed these criticisms in our Rebuttal. However, as appropriate, we will take each letter, in turn, as listed below, and address additional issues/concerns these employees have raised.

We were also surprised at some of the letters submitted by the UW from physicians. Apparently, the UW has convinced these physicians that there is no unmet need for a second liver transplant program in Washington. However, in defense of these letters, primarily from Washington gastroenterologists, they believe what they have been educated to believe about liver transplantation and they expect the level of service that they have been educated to expect. Many of these physicians have been trained by or have otherwise been associated with the UW—certainly, since the UW is the only transplant provider, area physicians perceive their range of choices very narrowly.

In terms of the criticisms of our application, there are many common themes—"24/7 coverage, difficult staffing issues that Swedish cannot handle, unnecessary duplication of service, world renowned service at UW," etc, —almost as if these physicians had been "coached." We have no issue with this. However, we do take issue with the inaccuracies, misstatements, and general lack of understanding of our application, and, very importantly, of the UW's shortcomings when compared to its peers. These areas, too, in very large part, have been addressed in our Rebuttal.

Letters from University of Washington Employees

1. Kathleen Sellick
2. Helen Shawcroft
3. Mary Kammenga Kester
4. Edward Walker, MD
5. Robert Carithers, MD
6. James Perkins, MD
7. Adam Levy, MD
8. Patrick Healy, MD

Physicians Trained/Affiliated with UW

There are selected issues we will address that have been raised by physicians trained by or affiliated with the UW liver transplant program. These physician letters include:

9. Alexandra Read, MD
10. George Cox, MD
11. William Pearce, MD
12. J. Thomas Vivisaker, MD

Others

We will not provide detailed responses to this final group, principally physicians. They have common themes, ones we have addressed in our Rebuttal Testimony. They include the following:

13. Kelly Wallace
14. John Halsey, MD
15. Barry Levenson, MD
16. Timothy Brown, MD
17. Gerald Bassett, MD
18. James Reed, MD
19. Harpreet Brar, MD
20. Michael Lyons, MD
21. Pankaj Sharma, MD
22. Steven Alabaster, MD
23. David Maccini, MD

Letters from University of Washington Employees

1) Kathleen Sellick, Executive Director, University of Washington Medical Center

   a. "Swedish's estimated Washington State acute liver transplant case volumes are seriously overstated:..." (Sellick letter, page 1 and Issue #1 of "Comments and Concerns")

      Response:

      We have addressed this above. See pages 1-8.

   b. "Swedish attempts to portray the program at UWMC as conservative and under performing. To the contrary, a review of published UNOS data demonstrates that UWMC's program is one of the most efficient, best performing liver transplant programs in the nation." (Sellick letter, page 2, and Issue #2 in "Comments and Concerns")

      Response:

      We have addressed this above. See pages 8-17.

   c. "Swedish's contention that the fact that donor organs are routinely being exported to other states serves as evidence of the need for a second provider demonstrates its fundamental lack of knowledge of the intent and purpose of the 1984 National Organ Transplantation Act (PL 98-507):..." (Sellick letter, page 2, and Issue #3 in "Comments and Concerns").

      Response:

      It is Ms. Sellick who demonstrates a lack of knowledge regarding the extent of liver exports from LifeCenter Northwest and the reasons for these exports. Dr. Marks, as Medical Director of LifeCenter Northwest, and Medical Advisor-elect of the national Association of Organ Procurement Organizations, fully understands the policies of the transplant act and the mission of the OPO. We address this issue above. See pages 18-21.

      Suffice it to say that the overwhelming majority of liver exports are not "mandatory," but because the UW, which has right of first refusal, rejected them as poor quality organs; not transplantable. Virtually all exported organs functioned on transplant.

d. "Swedish has a documented history of overstating transplant volumes." (Sellick letter, page 2, and Issue #4 in "Comments and Concerns").

Response:

This is neither true, nor relevant. We stand by our application volume estimates, and the rebuttal testimony we have provided herein.

e. "Given the complexity and institutional-wide commitment required to operate a liver transplantation service, the medical staff and clinical staff models proposed by Swedish are insufficient to staff and cover a transplantation service 24/7." (Sellick letter, page 2, and Issue #5 in "Comments and Concerns").

Response:

We have addressed this above. See pages 28-32.

2) Helen Shawcroft, Associate Administrator, University of Washington Medical Center

a. "As we are all well aware, Washington residents use medical services at rates below national averages. The same is true for liver transplantation." (Shawcroft letter, her issue #1).

Response:

This is not correct. We address this on pages 1-8.

b. "Swedish's application states they assume the majority of Washington residents that are out-migrating are going to California." (Her issue #2)

Response:

We agree we did mention California as a site for out-migrating Washington residents. We ran the same reports the UW did from databases from other states, where they exist. We found the same answers. We agree UNOS data confirms that 17 persons left Washington in 2002 for liver transplantation. The issue however is both actual and underserved residents. Where do sick liver disease patients go? They are not on the UW wait list, based on the UNOS data for MELD scores, and apparently only some of them leave the state. We have discussed this issue on pages 8-17.

c. "Swedish alludes to the fact that it intends to serve adults—yet it calculated its use rate and based its need estimates on the entire population and of the state." (Her letter, issue #3).

Response:

These are non-material issues—pediatric (persons 0-17 years old) liver transplants are 3.9% of Washington liver transplants, and about 10% of US transplants (UNOS website, data includes transplants in 2003, through November 7, 2003). Further, as utilized, our methodology was appropriate for estimating total number of transplants, subtracting UW and Children's estimated volumes, based on current market share, then estimating the residual—estimated out-migration.

d. "Swedish made no adjustment for either the known migration of Southwest Washington residents to Portland..., or the existence of national organ transplant networks used by some insurance companies..." (Her letter, Issue #4).

Response:

We have addressed this above. See pages 1-8.

3) Mary Kammenga Kester, Nurse, University of Washington Medical Center

Response:

We did not observe any criticism of our application, thus, no response is needed.

4) Edward Walker, MD, Medical Director, University of Washington Medical Center

a. "We exist primarily to train the next generation of physicians,...As the only medical school for a 5-state region...(Walker letter, 2nd and 3rd paragraphs)

Response:

The mission of the University is education. The University of Washington is known and respected throughout the country as a major research institution and as a remarkable center for the training of family practice physicians.

Liver transplantation is not a required or significant element in the makeup of its medical educational package. A poll of the number of students that rotate as a required experience on the liver transplant service would reveal a very small number. That is not to say that it is not an interesting elective for some

students, but we think that number as a percentage of each graduating medical school class would also be very small.

As a rotation for the training of residents, the liver transplant service is a very attractive rotation. It is NOT a required rotation for surgical training. It is NOT a required rotation for medical training. It IS a required rotation for transplant hepatology fellowship training and it IS a required experience for liver transplant fellowship training.

With regard to the Medical Center's mission to the people of the 5-state region for which it feels responsible, the data demonstrate that this region is underserved by the transplant service at the University of Washington. Opening a second program in Washington State promises to bring more services to the residents of Washington State and the region, NOT less.

a. "...we are increasingly held to external standards, such as those put forth by the Leapfrog Group, ..." (Walker letter, 3rd paragraph)

Response:

There are no volume standards put forth by the Leapfrog Group. Further, there are virtually no volume standards or other requirements put forth by any payers—Medicare and Medicaid do have minimum operational times, however. This is reflected in our financial model. The required number of cases that a program must perform annually to meet the fellowship requirements is 50.

b. "...our liver transplant program is a unique regional resource that cannot be duplicated or shared without serious degradation to our state health care mission... This is not about consumerism or choice; ... (Walker letter, 4th paragraph)

Response:

We have been and continue to be sincerely disturbed by the level of liver transplant service that is available to the residents of the WWAMI region. We have detailed how the UW compares to its peers, and we think residents deserve more.

5) Robert Carithers, MD, University of Washington Medical Center

a. ""No physician has complained that patients have to leave the state to receive a transplant." (Carithers 1st page of slides)

Response:

Dr. Carithers asserts that no physician has complained that patients have to leave the state to receive a transplant. We know for a fact that patients do leave the state. Mr. Metcalf testified at the hearing, and we have included his rebuttal letter to inaccurate information provided by the UW (Exhibit 2). We also talked to other patients who had to leave the state for the same reasons—the UW would not transplant them. Unfortunately, they elected not to testify, but their issues were the same as Mr. Metcalf's.

Regarding physicians, Dr. Greene testified that he had and currently has patients who have had to leave the state for a liver transplant. Dr. Carithers is not correct—patients do leave the state. The physicians the UW asked to submit letters to support its position are gastroenterologists who refer to the UW. It is clear they were responding to the same UW request--many use the same phraseology (for instance "24/7"), refer to the same issues such as questioning Swedish's commitment or ability to staff a liver program, or express concern about how a second program will diminish the UW's ability to function.

These well- meaning physicians readily submitted opinions based on inaccurate information supplied by the UW. We dare say that none read our proposal or are aware of the raw data. In fact, we would go so far as to guess that none are aware of the 3 year patient survival data for the UW, the average MELD scores of patients transplanted by the UW, the actual incidence of death from liver disease in Washington as compared to the rest of the country, or the transplant or listing rate per million in Washington compared to recipients in other states. Nor are they aware of the results for transplantation at transplant centers to which the UW compares itself in public.

These physicians also rely on Dr. Carithers and those either trained by him or who work for him as to what defines an acceptable candidate for transplantation. Thus, they believe what they have been educated to believe about liver transplantation and they expect the level of service that they have been educated to expect. Of course they have no reason to complain.

b. "Dying while waiting" (Carithers, 2nd page of slides)

Response:

Patients listed locally have fair access to available livers. The turn around time on the list for the UW is quick because the UW has a short list. It does not transplant sicker patients in appreciable numbers as do its peers. Were these patients on the list they would be the first to receive transplants and as is mandated by the MELD system.

c. "Postoperative Survival and Life." (Carithers 2nd page of slides)

Response:

Dr. Carithers states that 90% of the UW's patients survive the first year after transplant but fails to note the fact that the 3-year survival rate for its patients is statistically less than expected for its population.

d. "Postoperative Survival and Life." (Carithers, 2nd page of slides)

Response:

Dr. Carithers states that postoperative survival and life depends on a liver transplant center providing optimum care. And this requires an experienced clinical staff, fully developed training programs and a commitment to ongoing research. Certainly patient survival requires an excellent and committed staff. It also benefits from, but does not require, a major commitment to training or research. As it happens, the Swedish Organ Transplant Program is actively involved in both training and research, and its staff publishes and presents papers regularly. Dr. Marks and Swedish received a 2-year Immuno Tolerance Network award this year. As co-investigators Swedish will act as the primary Western Center for the study. Dr. Marks and the Swedish Organ Transplant Program were awarded about $1.4 million for this 2 year project. This is one of several ongoing research grants awarded to the Transplant Department at Swedish.

e. "The Question." (Carithers, 3rd page of slides)

Response:

Dr. Carithers asks if we "want to have two average programs focused primarily on fighting for market share in an [sic] localized urban area?" Frankly, we do not understand this question. At no time should a transplant program focus on fighting for market share. A transplant program should focus on excellence. We do not plan to run an average program. We do not plan to be satisfied by meeting or beating the national average. We expect to

be held to the standards set by institutions of recognized excellence. We see no reason why the UW should not feel the same way.

6) James Perkins, MD, Vice Chairman, Department of Surgery, Director Division of Transplantation, University of Washington Medical Center

a. "...first pediatric liver in the northwest in 1990, and the first split liver on Coast in 1999." (Perkins letter, 2nd paragraph)

Response:

The UW is to be congratulated on these accomplishments. The pediatric transplant program is not the issue in question and will not be pursued further. Based on UNOS data through August, 31, 2003, the split procedure was performed once in 1999. The UW touts this one success on its public information web site and the potential benefits of the procedure. However, the residents of Washington State have not realized the actual benefits of the procedure since they do not practice the procedure with any regularity.

b. "How the transplant system works." (Perkins letter, page 1, point 1)

Response:

The Organ Procurement and Transplantation Network (OPTN) was established by the federal government for the purpose of overseeing the process of donor organ procurement and to assure the fair distribution of organs for transplantation. OPTN awarded this contract to UNOS (United Network for Organ Sharing). At that time, UNOS was also subcontracted to form the Scientific Registry. As was made evident at the public hearing by the representative from the Scientific Registry, their data is quite complete and to the best of our knowledge, accurate.

Regarding organ sharing, Dr. Perkins is correct: organs must be shared. However, he knows that different organs are shared under different sets of rules. How many and which organs are shared is governed in part by the type of organ as well as by the needs of the recipients and skills and interests of the local transplant centers.

For instance, one of the two most difficult organs to place is the pancreas, partly because less than half of these organs are appropriate for transplantation and mostly because many centers either do not offer the procedure or are admittedly very conservative as to which organs they utilize (given that, unlike livers, a pancreas is not an immediately life-saving operation). For this reason, schema for how to better utilize

pancreata for whole organ and islet transplantation are under intense development and study.

Kidneys, on the contrary, are in constant demand everywhere. Rules for sharing are very well established. If the tissue-matching characteristics of a donor kidney and a potential recipient are ideal (what is known as a "no antigen mismatch," then that kidney is offered to that person without regard to location. If there are two or more individuals that similarly match that kidney, then it is offered to the individual with the longest waiting time. (Of course, there are exceptions to every rule, but in general this allocation scheme is in effect the vast majority of the time.)

Kidneys are in such demand that there is also a mandatory "payback" agreement. That is, if a kidney is exported due to its matching characteristics, the receiving OPO must export a kidney back to the OPO from which it received the kidney. Because kidneys are in such high demand, this rule is in effect whether the kidney went out alone or as part of a kidney/pancreas pair.

A direct comparison of liver allocation to pancreas or kidney allocation is a true case of comparing apples to oranges.

Livers are shared according to location and urgency, not matching. The rules are clearly put forth in UNOS POLICY 3.0 (Organ Distribution) subsection 3.6 (Liver Allocation). A liver is first offered to local Status 1 patients in descending point order, then to regional status 1 patients in descending point order, then to local "all patients" in descending order of mortality risk scores, [MELD scores] (probability of candidate death without transplantation), then to all regional patients in descending order of mortality risk scores, then to national Status 1 patients in descending point order, and finally to national patients in descending order of mortality risk scores (MELD). (Status 1, are acutely ill persons not expected to survive 7 days without a liver transplant.)

Dr. Perkins states that "Swedish appears to assume that all locally procured donor livers should be transplanted into Washington residents. This is a faulty assumption."

Dr. Perkins is well aware of the rules of allocation for liver and other organs, as are we. The aim of the first part of his testimony regarding organ placement appears to be cloud the overarching issue, which is that over 20 transplantable livers leave Washington State each year even after mandated shares are accounted for. These livers were passed over each year based on the judgment of the UW liver transplant service.

Dr. Perkins is correct in stating there are other reasons a liver might need to be exported other than the Status 1 requirement, but these account for a very small number of exported organs. Using the examples Dr. Perkins provided, we rarely (0-2 times per year), export a liver for blood type purposes (AB blood type). The issue of size should not be a significant issue especially for high MELD candidates on the list. The ability to do cut-down livers or perform split livers makes the issue of size almost inconsequential. That takes us back to the issue of judgment as to what constitutes a transplantable liver. There is no other explanation for the high number of exported livers than the UW's conservative protocols.

Fortunately, the exported livers were used to save lives of patients in need, albeit at centers outside of Washington. And these livers were placed only because Dr. Marks, acting as the medical director for LCNW, established policies that allowed these livers to be placed with alternative centers.

The fact that LCNW imported an average of 7 livers a year during the 3-year period, 2000-2002, for UW patients, is irrelevant. Once again, the UW deserves congratulations for the clinical service it provides. However, the ~21 imported livers did not offset the loss of ~60 livers denied to patients on the UW waiting list over a period when 23 of the UW's patients died awaiting livers.

Dr. Perkins points out that the export rate for livers is in keeping with rates for other organs such as kidneys and pancreata and that this is in line with what should be expected for our OPO service area. We disagree strongly. When compared to a number of other OPOs, the LCNW exported liver rate is remarkably greater. For instance, in 2002, Northern California exported about 10% of its livers, Southern California about 10% of its livers, Iowa 12% of its livers, Colorado about 15% of its livers and Nebraska 10% in 2001 and 0% in 2002.

If LCNW exports had been restricted to mandatory exports (6% of available organs) and we assume that 1-3 others could have gone elsewhere because of special circumstances, then the LCNW export rate would have been in keeping with the experience reported by others. Twenty-eight percent of livers being exported is unacceptable with more than 100 patients waiting on the list and no densely populated areas within our region to account for a large number of Status 1 candidates. No excuses explain away this fact.

c. "A lower retransplant rate..." (Perkins letter, page 3, point #2)

Response:

The second point Dr. Perkins addresses in his testimony relates to quality and aggressiveness of practice. Dr. Perkins categorically states that Swedish's statement that the University of Washington is "very conservative and therefore not transplanting higher risk patients or utilizing extended criteria donors," is fallacious.

Dr. Perkins contends his program has "approximately the same percentage of Status 1 patients as the rest of the country, (and) patients with similarly high MELD scores as the rest of the country." In comparison to the UW's peer group, the data clearly demonstrate that the UW is generally not transplanting sick patients (see Figures 1 and 2 and Table 2). This is true if we examine the MELD scores (risk of mortality on the list scores) or Status 1 scores (risk for imminent death from acute liver failure within 7 days).

Dr. Perkins points to the UW's record for transplanting a higher number of patients on its waiting list than the "rest of the country," and it transplants its patients "more quickly than the rest of the country." The data demonstrate that the UW does not list sicker patients for transplantation and consequently has a short list.

When Dr. Marks became the medical director for LCNW, he worked together with the LCNW administration and clinical staff to aggressively increase the number of donors realized in the LCNW service area. The success of LCNW has made available a larger number or organs during the past 6 years than were available to the UW at any time in its past. Regardless, the number of patients who receive liver transplants at the UW has increased only slightly year to year. Likewise, the UW's waiting list has grown very slowly. Thus, the "stellar" turnaround of patients on the UW's list is a result of the relatively small size of its waiting list.

Dr. Perkins also states "re-transplant" rates should be considered an indicator of the quality of a transplant program rather than an indicator of the level of complexity of patients served by a program.

This is only partially true. More complex cases will necessarily be attended by greater complications. This is a truism in medicine and surgery. Of course it should go without saying that complications are not to be admired. After all, one of the main goals of surgeons is to avoid complications. But the fact that the UW's peer group suffers greater complications and the need for re-transplantation than does the UW can only mean one of a few things: either UW surgeons are so skilled that no

other transplant center on the West Coast can emulate their technique, or the UW is performing its transplant using only better quality livers and transplanting less sick patients.

As stated above, MELD scores clearly demonstrate that the UW is transplanting patients who are not as ill as those in its peer group.

Dr. Perkins touts the UW 1-month graft survival rate, and points out that it is considerably better than that of UCLA. That is correct, but it is only part of the story. In fact, the UW's patient survival rate is statistically below expected at 3 years. UCLA patient survival rate is as expected for both 1 and 3 year intervals despite the fact that its patients are sicker, as a group, than the patients at the UW. Further, the UW only uses livers of outstanding quality.

Finally, Dr. Perkins returns to the issue of extended or marginal donors. He argues that one must be cautious about which livers one accepts. He goes on to lecture us the "marginal" liver, and states that: "...centers must be held accountable for questionable practices that incur enormous costs and bestow few benefits. Utilizing re-transplantation in a cavalier manner such as this (using extended criteria donors) is the type of clinical practice that contributes to the very problem third party payers abhor—low quality, cost-ineffective transplantation based on the "rule of rescue." (Page 4, Perkins letter) By this statement, Dr. Perkins implies that the livers the UW was being offered were marginal and therefore not transplantable in his judgment.

As stated in the body of our main rebuttal statement, we do not know what Dr. Perkins' "rule" is but we do know there were 126 exported livers between 1999 and 2002 and 124 of those livers (98.4%) worked on transplant. Over the same time period, 64 UW wait list patients died.

d. "In summary, a transplant program needs..." (Perkins letter, page 4)

<u>Response:</u>

Dr. Perkins outlines the 5 characteristics he sees as necessary to be a "high-quality" program. While we do not necessarily agree that these are the 5 hallmarks of a high quality program, they are Dr. Perkins' choices, therefore we will address these 5 "characteristics" in the order he presented them with regard to the UW program.

1. The appropriate use of local donors: The UW does not use local donors to the full degree that it should. The exported livers far exceed any reasonable expectation for a program that enjoys our demographics and has over 100 persons on the waiting list.

2. The import and export of donor organs: The same issue as number 1. A high-quality program should use every reasonable import offered and export as few organs as its skills and experience allow it to utilize. In the case of the UW, its experience judging suitable organs is marginal, given the number of livers it passed up that were proven to work elsewhere despite the added cold time of storage during transportation. The UW also lacks the necessary experience and technical expertise to offer recipients cut down and split livers as part of its practice.

3. A low re-transplant rate: This is the ideal goal, but only in the face of transplanting a cohort of patients who are equally sick to those patients being treated at other high quality centers (or in this case, peer centers of excellence).

4. The transplantation of critically ill patients as needed: The transplantation of critically ill patients is a major part of what 'it' is all about. It is what the MELD system dictates. Of course, judgment is important. If a potential recipient's condition deteriorates to a point that they have a very high likelihood of dying despite a transplant, then that person should come off the list. Otherwise, the MELD system dictates that the sickest transplantable persons should receive a liver first. As the data show, the UW does not transplant a significant proportion of sicker patients compared to other high-quality peer centers.

5. Sufficient staffing: Dr. Perkins' description of staffing needs is understood as part and parcel of an active transplant program. Swedish and Dr. Marks designed the Swedish organ transplant programs to satisfy the requirements for a multi-organ abdominal transplant program from its inception in 1993. We do not expect that the UW transplant program should ever 'shut down' just as we would not expect any transplant program to ever "shut down" because we are performing similar transplants.

   The contract of a transplant center with its patients is to be available to them all day, every day. It is the responsibility of a transplant center to guarantee that it will be available to serve its patients. In so doing, we also honor our donors and their families by applying our skills to transplant their precious gifts. We can think of no other way to approach the transplantation of organs, regardless of type. This basic ethic should not be considered a characteristic of a 'high quality" program, rather it should be taken as part of the foundation on which any transplant program is constructed.

7) Adam Levy, MD, Assistant Professor of Surgery, University of Washington Medical Center

a. "...our team carries the heavy responsibility of deciding who among the many who will be the best candidate to shepherd this precious societal gift." (Levy letter, 3rd paragraph)

Response:

We appreciate Dr. Levy's outline of the process that must be negotiated by potential candidates for liver transplantation. However, we are somewhat concerned by his statement that "our team carries the heavy responsibility of deciding who among many will be the best candidate to shepherd this precious societal gift." That is just not how the system is designed to work.

Candidates are judged to be acceptable for transplantation based on their medical conditions, psychological state, social support systems and habits. In querying other programs of excellence, we are told that today, less than 20% of patients who are referred to most centers are considered non-candidates. The departmental or service-centered decision as to "who among the many will be the best candidate to shepherd this precious societal gift" was relegated to the past by the MELD system. If a person is judged acceptable as a candidate, then he or she needs to be placed on the list and let the system work in their behalf. Anything less is a disservice to the community of liver failure patients.

b. "Liver transplantation requires much more than a single hepatologist and liver transplant surgeon attached to an existing kidney program." (Levy letter,7th paragraph)

Response:

We do not know where in the package of materials that the UW circulated to its staff and referring community physicians that the idea came up that the Swedish program would work with a single Hepatologist and Surgeon. As we outlined previously on pages 21-25, Swedish has the complete infrastructure in place to support all the needs of a liver transplant program.

Dr. Levy's statement questioning the commitment of "a liver transplant surgeon attached to an existing kidney transplant program" is disingenuous. The UW has and continues to service its kidney, pancreas and liver transplant programs with a mixed group of 4 surgeons. Currently 2 of these (Drs. Bakthavatsalam and Kuhr) are urologists .

c. "Families can rest safely in the knowledge that the 1-month and 1-year patient and graft survival matches or exceeds those of liver transplant programs found thru [sic] out the country." (Levy letter, 7th paragraph)

Response:

Dr. Levy does not state that somewhere between one and 3 years the patient survival falls to a statistically significant level that is less than expected. This is significant and below peer performance.

d. "...we may unintentionally generate 2 centers of mediocrity,..." (Levy letter, 7th paragraph)

Response:

A second center in Washington State will not "generate 2 centers of mediocrity," as Dr. Levy suggests. A second center in Washington State will help elevate the current practice of liver transplantation to expected levels of excellence.

8) Patrick Healy, MD, Department of Pediatric Surgery, Children's Hospital and Regional Medical Center

a. "After complete evaluation, still roughly 50% of patients may be deemed unsuitable for liver transplantation." (Healy letter, 2nd paragraph)

Response:

We disagree that patient survival is roughly 50% reduced with retransplantation. UCLA, which has one of the highest retransplant rates in the country (attributed to their aggressive use of marginal donor livers as bridges to healthier livers for their sickest patients) has outcomes that are as expected at 1 and three years for patient survival. UCSF has a higher retransplant rate than UW and puts livers into sicker patients but has better than expected 1 and 3 year patient survivals. The UW has one of the lowest retransplant rates in the country because it transplants some of the healthiest patients in the country, and has 1 year survival that is as expected and 3 year patient survival that is significantly below the expected outcome.

b. "The goal of a transplant program is to provide the best care for their patients, achieve the highest possible patient and graft survival, and have the lowest morbidity and retransplant rates..." (Healy letter, 6th paragraph)

Response:

We agree. To achieve optimal long term success is THE laudable aim for transplantation. Excellent survival for donated organs is also important. However, these issues are not necessarily connected. If a person on the list has achieved a high MELD score or Status 1 classification, then it is imperative to find that person a liver. Even if it only functions poorly, it may function as a bridge until a better organ can be found. At least such a patient has a chance for survival.

c. "...and a local liver supply in this region that has typically provided approximately 110-115 donor liver grafts per year,...the liver transplant needs of Washington State,...are well met by the University of Washington,..." (Healy letter, 6th paragraph)

Response:

As Dr. Healy notes, 110-115 livers are made available each year for transplantation. We know that 6-7 leave for sharing criteria, and one or two others may be exported for miscellaneous reasons such as rare blood type. It may be that the liver transplant needs of the UW are well met. It is not true that the liver transplant needs of Washington residents are well met. Protocols and policies different from those in current practice by the UW are necessary if we are to use all transplantable liver locally.

As demonstrated by Dr. Marks' sending over 120 livers out of state for transplantation elsewhere, Swedish would establish a different set of criteria for transplantable livers than those employed by the UW. Swedish will also employ creative techniques such as split livers and cut-downs that would allow more persons to receive livers locally.

As long as persons are dying on the list for want of a liver and until the entire population that could benefit from liver transplantation is recognized and brought into the system, we strongly disagree with Dr. Healy's conclusion. See pages 15-18, where we detail the "export" issue

Physicians Trained/affiliated with UW

9) Alexandra Read, MD, Seattle Gastroenterology Associates

a. "During this time, the University has developed an excellent program, which serves its patients well....their statistics, which show a shorter waiting time (compared to national statistics) decreased mortality rate, lower liver export rate, and lower retransplantation rate,..." (Read letter, paragraph 4)

Response:

We have addressed this above. See pages 8-17 for the discussion of of UW liver transplant program quality as compared to peers, including waiting time, mortality rates, and retransplant rate. In summary, The UW under-performs compared to its peer institutions. UNOS data confirm that.

b. "...to consistently deliver quality care, a liver transplant program must be staffed 'wide' and 'deep.'...The need for a highly structured, adequately staffed program cannot be overemphasized. At Mt. Sinai Hospital in New York City, a living-related donor died postoperatively, in part due to insufficient and inadequately trained personnel. " Read letter, paragraph 5).

Response:

We have addressed staffing issues. See pages 21-25. For years, 2 of the 3 UW surgeons on the liver transplant service were Urologists, now two are and their liver transplanter (Dr. Levy) was trained in great part by urologists as a transplant fellow at the UW. The UW's entire hepatology team apparently leaves town at the same time each year in order to go to meetings. During this time, according to Dr. Read, they leave responsibility for expert hepatology coverage to her, a part-time community hepatologist.

We understand the need for team coverage. We invented it in the northwest. We have a multidisciplinary department of transplantation. The reason we do not need massive additional resources is that the program was set up 10 years ago as a multidisciplinary, multi-organ abdominal transplant program. Entire components of our medical or surgical or support teams have not been absent from hospital service for any reason in the 10-year life of our department.

Dr. Marks is intimately familiar with the situation at New York's Sinai Hospital. He has had numerous first hand discussions with those in charge and most responsible. The situation does not relate directly to the current argument but Dr. Read is correct in part that one issue of many was a failure to recognize and correct a dangerous lack of commitment by the surgery department and hospital leadership.

We don't know where Dr. Read gets her rounding information, at Swedish, the transplant team rounds as a group daily and consist of the entire team, which always includes the attending physician and surgeon. Rounds occur differently at the UW. Attending, fellows and/or residents round as individuals or in individual groups of physicians and surgeons. They communicate through notes, residents, fellows and students.

c. "...criticism of the UW transplant program...significant waiting time to access the system, coupled with poor communication and lack of timely response to referring physicians...This issue has now been addressed." (Read letter, paragraph 6).

Response:

We appreciate this problem and applaud the successes of the UW transplant program in this regard. Its future plans to help expedite access to liver transplant services and liver services in general are also laudable. A dedicated focus of liver care should in fact be a part of any liver transplant center. It should have been so for years past. Dr. Gold, currently the director of hepatic oncology at Swedish, attempted to establish the first such center at the UW several years ago. He informs us it was a failure due to lack of cooperation by many of the participants. We hope the new center will prove to function better on behalf of persons in need.

Such a center has been part of the core planning structure for Swedish's liver team since its inception. Dr. Marks organized the SLiPP (Swedish Liver Program Planning group) over one year ago. Besides himself, members include Dr. Martin Greene, Director, Gastroenterology, Dr. Michael Hart, hepatobiliary surgery and director for surgical training, Brian Kuske, Vice-president responsible for the department of transplantation, Pat Anderson, R.N., Vice-president, responsible for Nursing, Kate Rogers, R.N., Director, responsible for operating rooms, Chip Beagosian, MD, Director, Anesthesia, David Corwin, MD, Laboratory Services and Doug Brown, MD, Interventional radiology. Key individuals who will be substituted as the center develops include the full time hepatologist and full time senior liver transplant surgeon who will join us once the CN is issued.

d. "...Swedish Medical Center believes that a significant number of patients are being 'forced' to undergo transplantation out of state." (Read letter, paragraph 7)

Response:

We have addressed this above. See pages 1-6. This is the argument regarding "expected" vs. "known" that leave the state. Unmet need is actually

the unrecognized or ignored population. For example, to allow a person to die as the result of chronic liver disease is certainly more cost effective than to intervene with transplantation. But transplantation is more cost effective than the medical care for chronic liver disease. We submit that the ethics of this choice are not debatable.

Dr. Marks is intimately familiar with the arguments at play regarding self-inflicted ills. He was one of the authors of the UNOS Ethics Committee white paper on organ allocation, which was edited and overseen by the bioethisist, Dr. Robert Veach. Dr. Marks authored the section on "self inflicted" illnesses.

We know that transplant centers and community physicians routinely deny transplantation to persons in need for reasons that are not fully supported by data or universal opinion. This prejudice is not restricted to liver transplantation or the University of Washington and is a major reason that more than one transplant center must be available to any service area.

For example, Swedish is a leading advocate for kidney transplantation for morbidly obese persons with renal failure. The data clearly show that kidney transplantation extends the life of these individuals over dialysis yet they are denied transplantation by 52% of transplant centers in the U.S. These centers include OHSU (the University of Oregon) and selectively the University of Washington. Our data on patient and graft survival clearly demonstrate that these persons deserve to be transplanted (see abstracts and paper).

Other areas are also considered differently based on Center experience and skills. We clearly have a different set of parameters for judging meaningful histories for noncompliance than the University of Washington as we have successfully transplanted several persons who were turned down for transplantation by the UW due to a history of noncompliance. We should also state that we agreed with the UW regarding several persons referred to us for second opinions due to noncompliance.

e. Dr Read presents many statements regarding San Francisco liver transplant centers. "...not only was the competition that situation fostered unhealthy, it was also very counterproductive. Energy is misdirected, egos intervene into decisions, and these factors rather than purely medical considerations can determine acceptance of perhaps marginal livers for transplants. ..a glaring, egregious example of what can occur as a result of competition is that of Chicago, where Medicare fraud was committed in an effort to gain preeminence in the acquisition of livers..."(Read Letter, paragraph 8)

Response:

The population of San Francisco as of July 2002 is 776,773 persons, not much greater than Seattle. According to the 2002 census, the Bay area population that actually depends on San Francisco for service is about 6.78 million. This is very similar to 6.07 million population of Washington State, according to the July 2002 census update by the U.S. census bureau. In fact, the Bay Area is served by 3 major liver transplant centers, UCSF, California Pacific Medical Center (a private Stanford teaching hospital) and Stanford.

As Dr. Read surfaced this point, we should review some of the history for these institutions with regard to liver transplantation. Dr. Read mentioned in her letter that UCSF has a stellar history as a transplant institution under the direction of Dr. Nancy Ascher who they recruited from the University of Minnesota in the late 1980s. CPMC established a liver transplant program in 1992 when they recruited the equally eminent liver transplant surgeon, Dr. Carlos Esquivel from Pittsburgh. Outstanding hepatologists complimented both programs, Jack Lake at UCSF and Emmett Keeffe at CPMC. Both programs flourished. However, CPMC withdrew some of its commitment to the liver program during the early 90s and Drs Esquivel and Keeffe were recruited to Stanford. However, CPMC quickly recognized the need for continuing its commitment to liver transplantation. At that point Drs Ascher and Roberts stepped in to help reestablish their program. They recognized the volume of patients in their area could readily tolerate these programs. Dr. Ascher and Roberts practice was eventually restricted by the rules of UCSF and so they voluntarily withdrew as CPMC recruited in its own full time staff in replacement.

All three programs, UCSF, CPMC and Stanford continue to flourish, as their numbers and success clearly demonstrate. And all three should be considered benchmark institutions for the University of Washington Medical Center. We have provided UNOS data on performance for these centers above.—they treat sicker patients than the UW, and they outperform the UW based in almost every category including 3-year patient survival rates.

The situation that occurred at the University of Illinois (the State run institution) was an embarrassment for all of us in the field of transplantation. It is a clear example of dishonesty and manipulation of the public trust—it was not the result of competition. It was the result of well-intended but selfish and shortsighted leadership. The Department of Organ Transplantation at Swedish stands in unequivocal opposition to any practices that violate the public trust.

We will point out that in a service area that is just slightly less than twice that of Washington State and somewhat larger than the WWAMI region, Chicago

boasts 4 additional liver transplant centers (Northwestern, Loyola, University of Chicago, and Rush-Presbyterian-St. Lukes) that are vigorous, vibrant, and highly successful.

f. "Given the relatively finite number of donors, to divide the recipient population between two institutions...would increase overall costs,...and would potentially have a negative impact on quality of services,..."(Read letter, paragraph 9)

Response:

The number of Washington State and WAMI region potential recipients is underestimated and under serviced. It does not matter how or where these persons receive their livers. It only matters that these persons receive livers. A second program willing to use all transplantable livers would have been able to place over 20 additional livers into Washington State or WAMI region patients each year for the past 5 years. These livers would have stayed in our local service area.

In addition, an alternative center would have already put alternative procedures in place that would expand rather than contract the number of persons receiving service: Living donor procedures for tumors, living donor procedures for metabolic disease, cut downs and the use of marginal livers when necessary (not to be confused with the majority of livers that were exported from our region during the past half decade.)

There are few added costs for setting up a Swedish program. Dr. Marks anticipated this need when he was recruited to establish organ transplantation as a formal department at Swedish. The transplant center at Swedish has been structured since day one as a multi-organ department. Thus the necessary resources to support this expansion in to liver transplantation are minimal.

Geographic separation is not the issue. In fact the proximity of two programs to the spectacular resources of the Puget Sound Blood Center enhance the cost effectiveness of our proposal. It is likely that as the Swedish program develops that we will be able to work together with LCNW, the Puget Sound Blood Center and the University of Washington to bring about 'best practices' for many of the routine and/or mundane tasks that affect service.

Finally, we agree with Dr. Read that the implications of this decision for the future of transplantation in our area are enormous. However, we would point out that Dr. Read myopically identifies our service area as 'Puget Sound.' The constant need, the obligation, for all transplant programs in our region is to bring 'state of the art' transplant services to all residents of Washington State and the WAMI region.

10) George Cox, MD, The Everett Clinic

a. "...would not like to see any change in services...which would potentially jeopardize their excellent program."(Cox letter, paragraph one.)

Response:

Swedish has no desire or intent to jeopardize the UW Program. The excellence of the UW program is addressed in other parts of our rebuttal. They are average in performance, MELD scores are below the distribution of their peers and 3-year patient survival is significantly less than expected. Parenthetically, it should be noted that Dr. Cox was trained and educated as to the appropriateness, availability and performance expectations for liver transplant by the UW. He holds an appointment on their staff. Why should his opinions differ from those put forth by the UW?

b. Expeditious care, 24/7 coverage, and correlation of high volume and success/expertise (Cox letter, paragraph 1-3)

Response:

Regarding expeditious care, apparently he and Dr. Read see things differently in terms of access and past performance. Perhaps they have different expectations for communication and patient follow-up?

Regarding 24/7 coverage and comparison to other large centers, this has been addressed above. Benchmarked against "other large transplant centers throughout the nation," the UW receives average grades.

High volumes do not necessarily correlate with patient outcomes. 3-year patient survival and low MELD scores. There are no UNOS or Medicare operating requirements. (see Exhibit 8).

We are gratified that his patients are satisfied with the services rendered by the UW. Again we are not contending that what they do is passable for those that receive service. We contend that passable is not enough and that what they do not do is more important. Many Washington residents do not receive service.

11)William Pearce, MD, Valley Internal Medicine

a. Has depended on UW for 10 years and does not agree with the conclusions drawn by Swedish. Has never had a patient leave the state for a transplant and asserts that UW care is better than the national average.

Response:

The field of liver transplantation has changed radically during the past 10 years and continues to evolve. During the last few years alone, we have seen the introduction of UNOS/HRSA directives that dictate the principles of allocation through the MELD system, routine transplantation for HBV, HBC, and HCC, routine living donor transplantation, down-sizing of livers, experimental transplantation for HIV+ recipients, improved outcomes with marginal donors, and aggressive transplantation for high MELD recipients, to name some of the more obvious.

The listing criteria for the UW appear to have remained relatively unchanged. As judged by the tone of Dr. Perkins letter, the MELD scores of their transplanted patients, and the UW practice of only using excellent quality livers, they embrace a conservative approach to liver transplantation.

Dr. Pearce is a clinical associate professor of medicine on the UW faculty who has had a long and friendly relationship with the UW hepatology and liver transplant services. His opinions and expectations are formed by that relationship. His opinions and statements offered in response to the UW request for a letter of support, are understandable. However, it seems unlikely that Dr. Pearce is aware of how the UW performs in relation to its peer institutions in such categories as per capita listing rate, severity of illness, creative surgical techniques and 3-year patient survival.

b. Concern about the ability for Swedish to establish a program and its effect on the UW's ability to train physicians.

Response:

We have addressed this above. See 21-23 for minimum volumes and pages 28-32 for the discussion of program structure at Swedish.

12) J. Thomas Vlvisaker, MD, Group Health Cooperative

a. "...testify to the excellent care..."(letter, 1st paragraph)

Response:

Dr. Vlvisaker states that Group Health Cooperative is contracted to the UW for liver transplant services. He also states at the UW and has a close working relationship with the hepatology and gastroenterology staff. His opinions and those of his staff regarding liver transplantation are formed by his relationship with the UW transplant service.

It is impossible for us to criticize Dr. Vlvisaker's experience with the UW but we can ask the question,"How many people does Group Health care for aged 31-60 years who die each year with chronic liver disease or liver tumors and who are not candidates for liver transplantation by UW criteria?" The data strongly indicate that there must be a number of these persons. But, if for Group Health, the answer is "none," or "some for who were also turned down by an alternative liver transplant center," then Dr. Vlvisaker is correct. Although the 3-year patient survival rate is still less than expected

Others

As a group, the following letters express concerns about:

- The negative effect that a second program will have on the UW transplant program
- The inability of Swedish to devote the types of resources necessary to support a successful program
- The effect a new program will have on the cost of liver transplantation
- Their belief that they and their patients receive outstanding service from the UW

13) Kelly Wallace, Chief Financial Officer, Childrens Hospital

14) John Halsey, MD, Skagit Valley Medical Center

15) Barry Levinson, MD, Northwest Gastroenterology, PLLC

16) Timothy Brown, MD, Yakima Gastroenterology Associates

17) Gerald Bassett, MD, Wenatchee Valley Medical Center

18) James Reed, MD, Digestive Health Specialists

19) Harpreet Brar, MD, Gastroenterology Associates

20) Michael Lyons, MD, Tacoma Digestive Disease Center

21) Punkaj Sharma, MD

22) Steven Alabaster, MD, Digestive Health Specialists

23) David Maccini, MD, Spokane Digestive Disease Center

Response:

- We believe that our main document and responses to the above letters address the major concerns expressed by these physicians. It is safe to state that the data overwhelmingly demonstrate that Washington State residents with chronic liver disease are not adequately served by the UW liver transplant service.

- The fact that these well-intentioned physicians are unaware of the shortcomings of the UW transplant service is concerning but not surprising. Just as the common themes expressed in their letters demonstrate that they were coached to their positions by the UW, so does their acceptance that the UW liver transplant services, protocols, practices and policies function on a par with the best centers in the nation. These physicians simply do not understand that the chronic liver disease population of Washington and the other WAMI states is underserved because they have been schooled to their understanding of liver transplantation by a single source, the UW transplant service. Once again, these physicians expect what they have been taught to expect by the UW. When it comes to liver transplantation, their experience is quite narrow.

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Exhibit 1

Reviews in Gastroenterological Disorders - Chronic Hepatitis B and Hepatitis C in Asian Americans

Chronic Hepatitis B and Hepatitis C in Asian Americans

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Both chronic hepatitis B and hepatitis C are prevalent among the 12 million Asians and Pacific Islanders living in the United States. Significant epidemiological and clinical differences exist between Asian Americans and the general U.S. population, most notably the higher rate of primary liver cancer and the differential response to various antiviral therapies. Perinatal and childhood transmission is common for hepatitis B virus. Transmission of hepatitis C virus probably also occurs early in life and results from nosocomial transmission and person-to-person spread. Asian patients with chronic hepatitis B commonly have hepatitis B e antigen-negative hepatitis B with either the precore or core-promoter mutant hepatitis B virus, which may require long-term antiviral viral therapy because of high rates of relapse following therapy. Asian patients with chronic hepatitis C may have a substantially higher risk of liver cancer but a better response to interferon-based therapy, both in terms of sustained virological response and reduced future incidence of liver cancer. Understanding these differences will lead to improved care for Asian Americans with viral hepatitis and better disease control for hepatitis B and hepatitis C for the entire U.S. population. This review briefly summarizes the major issues in the clinical care of patients with chronic viral hepatitis and focuses on pertinent epidemiological and clinical differences between Asian-American and Caucasian patients.

[Rev Gastroenterol Disord. *2003;3(3):125–134*]

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Key words: Asian Americans • Chronic hepatitis B • Chronic hepatitis C • Hepatocellular carcinoma • Cirrhosis • Hepatitis B e antigen • Sustained virological response

Infection with the hepatitis B virus (HBV) and hepatitis C virus (HCV) is a major cause of morbidity and mortality in Asian patients worldwide. Common sequelae for both chronic hepatitis B and chronic hepatitis C include cirrhosis and hepatocellular carcinoma (HCC).[1,2] Chronic hepatitis B has long been recognized as a major cause of morbidity and mortality in Asians. In contrast,

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chronic hepatitis C in Asians is often underappreciated even though the prevalence of the disease in Asians is up to 3 times the overall U.S. prevalence.

According to the year 2000 census, there are approximately 11.9 million Asians and Pacific Islanders living in the United States.[3] From 1990 to 2000 the Asian population grew at a faster rate than the total U.S. population did (48% vs 13%). Although Asians account for only 4.2% of the total population, over one half (51%) of the Asian population resides in only three states: California, New York, and Hawaii. The majority of the remaining Asian population resides in just seven other states (Texas, New Jersey, Illinois, Washington, Florida, Virginia, and Massachusetts). Thus, Asians may represent a significant proportion of the patient population in the above-mentioned states.

Several aspects of the epidemiology, natural history, and responses to antiviral treatment of viral hepatitis in Asian American patients may differ substantially from those of non-Asian patients in the United States. Rather than give an exhaustive review of HBV or HCV infection in general, this article focuses on known and potential epidemiological and clinical differences between viral hepatitis in Asian Americans and the general U.S. population. Understanding these differences and their clinical implications may assist practitioners to care for Asian Americans with chronic viral hepatitis.

Epidemiology

According to the World Health Organization, in most of Asia the prevalence of chronic HBV infection is 8.0%–10.0% and of HCV infection is approximately 2.0%.[4,5] The prevalence of HCV infection is especially high in Southeast Asia (5.6% in Thailand and 6.1% in Vietnam).[6]

In the United States, based on data derived from the second National Health and Nutrition Examination Survey (NHANES II), conducted between 1976 and 1980, the prevalences of past and/or present HBV infection is 3.2% for Caucasians and 13.7% for African Americans[2,7]; the estimated total number of chronic HBV carriers is 1.25 million. The overall prevalence rate of HCV infection, derived from NHANES III, conducted between 1988 and 1994, is 1.8%[8]; the estimated total number of individuals with active HCV infections is 2.7 million. African Americans aged 30–49 years have the highest prevalence of HCV infection (6.1%), followed by Hispanics (3.4%), and Caucasians (2.9%), in the same age group.

It is estimated that 1.2 million, or 1 in 10, Asian Americans are chronically infected with hepatitis B virus.

The prevalences of chronic HBV and HCV infection in Asian Americans were not available from the above studies but can be expected to be significantly higher than those of Caucasians and closely resemble prevalence in their countries of origin.[9] It is estimated that 1.2 million, or 1 in 10, Asian Americans are chronically infected with HBV. The highest prevalence (14.0%) was found in Vietnamese Americans and Laotian Americans. Of note, the rate of positive hepatitis B serological tests in families of patients with chronic hepatitis B is similar in Asians born in Asia and Asians born in the United States (44.0% vs 38.0%). The importance of familial transmission of hepatitis B can also be illustrated by the high rate of infection in families who have adopted Asian children.[9]

The epidemiology of viral hepatitis in Asians differs significantly from that in the general U.S. population, not only in higher disease prevalences, but also in the mode and timing of acquisition of infection. Whereas many nonimmigrant U.S. patients acquire hepatitis B and C via use of injection drugs and high-risk sexual practices, most patients in Asia acquire hepatitis B either perinatally from infected mothers or from person-to-person contact during childhood. Similarly, they may acquire hepatitis C infection early in life from unsanitary medical practices or blood transfusions.[9,10] Thus, Asians with hepatitis B and C usually acquire their infection at a young age; they are subsequently at much higher risk for long-term complications of these infections by the fourth or fifth decade of life—approximately 20 years earlier than other North American patients, who usually do not acquire their infections until the second or third decade of life.[4,5]

Screening and Primary Prevention of Hepatitis B and C

The most effective and most important intervention to prevent HBV- or HCV-related end-stage liver disease and HCC is to prevent primary HBV and HCV infections. This includes the identification of infected patients and prevention of the spread of the disease. In Taiwan, universal vaccination against hepatitis B has proved successful in reducing the incidence of HCC, one of the most common causes of death among HBV-infected patients.[11,12]

All high-risk patients should be encouraged to undergo serologic testing (Table 1),[2,13,14] and infected patients should be offered appropriate therapy, follow-up, and counseling

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Table 1
Screening for Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) in High-Risk Patients

HBV	HCV
Persons born in hyperendemic areas	Anyone concerned with his/her HCV status
Men who have sex with men	Intravenous drug users
Injecting drug users	Persons receiving plasma-derived blood products prior to 1987
Dialysis patients	Persons receiving blood transfusion or solid organ transplantation prior to 1992
HIV-infected patients	Persons who have received chronic hemodialysis
Pregnant women	Persons with persistently elevated alanine aminotransferase
Family members of HBV-infected patients	
Household members of HBV-infected patients	
Sexual contacts with HBV-infected patients	

regarding lifestyle modifications and prevention of viral transmission. As blood transfusion and nosocomial spread are the major causes of HCV infection in Asia, Asian Americans born in HCV-endemic areas (eg, Southeast Asians) should probably also be offered testing for HCV infection.[10,15]

In addition to safe medical and sexual practices, active immunization is available for HBV and should be recommended to all high-risk individuals (Table 2).[16] Hepatitis B vaccines (Recombivax HB, Merck & Co., Inc., Whitehouse Station, NJ; or Engerix-B, GlaxoSmithKline Biologicals, Research Triangle Park, NC) can generally be given in three doses at 0, 1, and 6 months (doses vary depending on a patient's age and comorbidities, with higher doses in older, dialysis, and immunosuppressed patients).[17] A combination HBV and hepatitis A virus (HAV) vaccine (Twinrix, GlaxoSmithKline Biologicals, Research Triangle Park, NC) is also available. Protective titers (≥ 10 mIU/mL HBV surface antibody or anti-HBs) can be achieved in over 90% of healthy patients. Persons with continued exposure to HBV risk should, however, be tested for a response to vaccination.[2]

Passive immunization with hepatitis B immunoglobulin (HBIG), a polyclonal hyperimmune antibody preparation, is indicated for infants born to hepatitis B surface antigen (HBsAg)-positive mothers (0.13 mL/kg within 12 hours of birth).[13] A protection rate of 85%–95% is expected when given with an HBV vaccine.[17] HBIG is also indicated after sexual, percutaneous, or mucous membrane exposure to HBV (0.05–0.07mL/kg within 48 hours, or no longer than 7 days from exposures). Preventive vaccines against hepatitis C are not yet available.

The risks for HBV and HCV infection should be recognized, appropriate patients tested, and high-risk patients vaccinated against HBV. Current estimates of the hepatitis B vaccination rate among Asian-American children vary from 82% to less than 30%, according to reports from various geographic locations.[18,19] More efforts should be made both by health care

Table 2
Recommendations for Vaccination for the Primary Prevention of Hepatitis B Virus (HBV) Infection

High-risk individuals who should receive vaccination against HBV infection
Household members of HBV-infected persons
Sexual partners of HBV-infected persons
Infants born to HBsAg-positive mothers
All newborns
Previously unvaccinated children and adolescents
Health care workers
Dialysis patients
Recipients of clotting factor concentrates
Persons institutionalized in correctional facilities or facilities for the developmentally disabled
Travelers to endemic areas who stay for 6 months or longer

HBsAg, hepatitis B surface antigen.
Data from CDC.[16]

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Table 3
Recommendations for the Treatment of Chronic Hepatitis B

ALT/Liver disease	HBeAg	HBV DNA	Treatment strategy
Normal ALT			No treatment required
Normal ALT	+		Observe and consider treatment when ALT is elevated
Elevated ALT	+		Treatment with IFN-α or LAM or ADV
Elevated ALT	−	+	Treatment with IFN-α or LAM or ADV
Cirrhosis	+	+	LAM or ADV; low-dose IFN may be used in case of compensated cirrhosis only, but this requires close monitoring for decompensation

*Especially if greater than two times the upper normal limit.
ALT, alanine aminotransferase; HBeAg, hepatitis B e antigen; HBV, hepatitis B virus; IFN, interferon; LAM, lamivudine; ADV, adefovir dipivoxil.
Data from Nguyen MH, Wright TL,[8] Marcellin et al,[9] and Goodman et al.[10]

providers and public health workers to improve prevention of viral hepatitis in high-risk populations such as Asian Americans.

Treatment of Chronic Hepatitis B and C

For chronically infected patients, the goal of antiviral therapy is to prevent progression to cirrhosis, liver failure, and HCC. Because complications may take many years to develop, most trials of treatment of patients with chronic HBV or HCV infection have used intermediate end points, such as inhibition of viral replication and improvement in liver histology, to evaluate efficacy. The treatment end points for chronic HBV infection are normalization of alanine aminotransferase (ALT) levels, loss of HBV DNA, loss of hepatitis B e antigen (HBeAg), with or without anti-HBe seroconversion, and improvement of liver histology.[2,20] The treatment end points for chronic HCV are normalization of ALT levels; sustained virological response (SVR), defined as loss of HCV RNA in serum using an assay with a sensitivity of at least 100 copies (50 IU) per mL at the end of treatment and 6 months afterwards; and improvement of liver histology.[20,21]

Treatment options and expected therapeutic responses for the treatment of chronic HBV and HCV infection have been reviewed elsewhere.[2,13,17,20-29] The discussion below focuses on the salient aspects of therapy that require additional attention for Asian Americans.

Current estimates of the hepatitis B vaccination rate among Asian-American children vary from 82% to less than 30%, according to reports from various geographic locations.

Chronic Hepatitis B

Target treatment groups and available therapies for chronic HBV are summarized in Table 3 and Table 4.[20,30-34] In one study, long-term treatment up to 60 weeks with adefovir dipivoxil was not associated with resistance.[35] Adefovir was also effective in suppressing precore mutant HBV (HBeAg negative, HBV DNA > 10^5 copies/mL) and was particularly useful in the treatment of lamivudine-resistant YMDD mutant HBV infection.[36-39] Some studies suggest that peginterferon or interferon/lamivudine combination therapy may have added benefits, especially for patient subgroups with more difficult-to-treat disease,[32,40,41] but more studies are needed in this area.

Compared to Western patients, Asian patients with elevated ALT levels and HBeAg-positive chronic hepatitis B show no significant differences in response to interferon-α (IFN-α) and lamivudine.[2] However, most Asian patients acquire their infection in the perinatal period, and these patients typically have low or normal ALT levels, which predict a lower response to IFN-α.[13] High pretreatment HBV DNA levels (> 200 pg/mL) and long duration of infection are other factors commonly seen in Asian patients that are also predictors for poorer treatment response. These patients, therefore, are often not candidates for IFN therapy.

Furthermore, unlike the majority of Northern European and U.S. patients, many Asian and Southern European patients have HBeAg-negative chronic hepatitis B.[13] Whereas both IFN-α and lamivudine are effective in suppressing HBV DNA levels in this precore mutant HBV infection, relapse rates are very high when treatment is discontinued (approximately 50% for IFN-α and 90% for lamivudine).[2] Therefore, long-term therapy with either lamivu-

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Table 4
Rates of Response in Clinical Trials in the Treatment of Hepatitis B e Antigen (HBeAg)-positive Chronic Hepatitis B

Response	IFN-α 12–24 weeks % (placebo)	LAM 1 year % (placebo)	LAM 2 years % (placebo)	LAM 3 years % (placebo)	LAM 4 years % (placebo)	ADV 48 weeks % (placebo)	ADV 72 weeks % (placebo)
HBV DNA loss	37[a] (17)[b]	17–32[a] (6–11)[b]	50[a]	66 20[c]		21 (0)[c]	21[c]
HBeAg seroconversion	33 (12)[b]	16–18 (4–6)[b]	27	27	47	12 (6)[b]	17
HBsAg loss	7.8 (1.8)[b]	<1 (0)[b]					
YMDD mutation	NA	14–32 (0)[b]	38	57	67	0	
Biochemical improvement	28	72 (24)[b]	50	49	64	48 (16)[b]	21[b]
Histological improvement		49–66 (23–25)[b]		69		53 (25)[b]	

[a]HBV DNA measured by hybridization assay (lower limit = 1.6 pg/mL).
[b]HBV DNA measured by PCR assay (lower limit = 1000 copies/mL).
[c]Indicates response among nonresponders at 48 weeks.
[d]Corresponding values in placebo controls.
NA, not applicable; IFN-α, interferon-α; LAM, lamivudine; ADV, adefovir dipivoxil; HBsAG, hepatitis B surface antigen; PCR, Polymerase chain reaction.

dine or adefovir is usually required for the majority of these patients.

Chronic Hepatitis C

Combination therapy with peginterferon and ribavirin is currently the standard of care for eligible patients with chronic hepatitis C. The strongest predictors for treatment response are viral genotype other than genotype 1, viral load < 2 million copies/mL, and absence of advanced fibrosis. The expected SVR is approximately 42% for genotype 1 and 75% for genotypes 2 and 3.[22,23] The SVR is also associated with improved histology and a lower incidence of HCC on follow-up.

Race has been shown to influence both the histological progression and the response to interferon in patients with chronic hepatitis C.[42–45] African Americans with chronic hepatitis C have a significantly slower histological progression rate compared to the rates for Caucasians and Hispanics. At the same time, the response to IFN-based therapy is significantly poorer in African Americans than it is in Caucasians, based on the results of randomized controlled trials.[45,46]

Only one of these trials, however, included Asian Americans, and in this trial only 10 patients out of a total of 472 study patients were Asian Americans.[45] Studies from Asia, especially those from Japan, generally report a higher response to IFN (up to 50%). In many of these studies, high doses of IFN were used (eg, 1 group was given 10 million international units 6 times a week for 2 weeks then 3 times a week for 12 additional weeks).[47,48] Only a few small, randomized, controlled trials of IFN/ribavirin combination therapy have been carried out in Asia. Thus, data on treatment responses from large, randomized, controlled trials using IFN/ribavirin combination therapy is lacking in Asian patients with chronic hepatitis C.

A recent nonrandomized study done in Australia of Southeast Asian patients with chronic hepatitis C reported a higher response to combination IFN/ribavirin therapy than the response of Caucasian patients.[49] In this study, all patients received 1000–1200 mg ribavirin, and all underwent an induction period of 4–8 weeks with daily high-dose IFN (5 million units subcutaneously). Among patients with genotype 1b, the SVR was 59% in Southeast Asians compared to 34% in Caucasians. In addition, many Southeast-Asian patients with genotype 7, 8, or 9 were initially mistyped as genotype 1b by a commonly used line probe assay (INNO-LiPA HCV II; Innogenetics, Ghent, Belgium).

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Sequence analysis using the ABI PRISM® Dye Terminator Cycle Sequencing Ready Reaction Kit (Applied Biosystems, Foster City, CA) subsequently led to the identification of the correct genotype. Asian patients with genotype 7, 8, or 9 had a much higher response (79%) to the above combination therapy compared to those with genotype 1b (59%). According to the results of this study, Asians probably respond better to IFN-based therapy than Caucasians do, and accurate genotyping is essential in this patient group because of the high prevalence of novel genotypes and differential response rates in those with these unique genotypes.

Regarding the profile of treatment side effects, ribavirin-induced hemolytic anemia may be more common in Asians than it is in Western patients.[50] In a meta-analysis of 17 studies (N = 3520), the risk of ribavirin-induced hemolytic anemia was higher in the two Asian studies (n = 87; ribavirin 800–1200 mg daily) compared to the pooled risk for the non-Asian studies. A potential explanation for this observation may be the lower body-mass index in Asians. The number of Asian patients in this meta-analysis was, however, few and limits its conclusions.

Another notable difference in Asians compared to Western patients is the long-term effect of IFN therapy on the development of HCC. A 21.6% reduction in the risk of the incidence of HCC was seen in Asian patients treated with IFN-based therapy for chronic HCV compared to an only 10.0% reduction in non-Asian patients (approximate follow-up time was 4–5 years).[51] A greater reduction in risk may partly result from the higher HCC incidence and higher prevalences of the more responsive genotypes (ie, genotypes 2 and 3) in Asians.

IFN given after hepatic resection or local tumor ablation with ethanol or acetic acid may also significantly decrease the risk of recurrence, according to three randomized, controlled trials from Japan.[52-54] The benefit was observed even in patients who had only biochemical improvement. It is not clear whether non-Asian patients would demonstrate a similar response, but IFN in this setting appears to be beneficial for Asian patients with HCV-related HCC.

Although the risk for hepatocellular carcinoma (HCC) in HCV-infected patients without cirrhosis is minimal, the annual incidence of HCC in patients with cirrhosis is up to 8.0% in Asians (vs 3.0% in non-Asians).

Treatment of End-Stage Liver Disease

The late results of chronic viral hepatitis are end-stage liver disease and HCC. Although a comprehensive review of the various complications of end-stage liver disease is beyond the scope of this article, the following issues warrant a separate discussion: measures of preventive care, chemoprophylaxis for latent tuberculosis, and outcomes of liver transplantation in Asian Americans.

Preventive Care with Screening for Hepatocellular Carcinoma

Aside from preventive care appropriate for age, additional preventive therapy for various known complications should be considered in patients with chronic liver disease, as outlined in Table 5.[55-59] Among these, screening for HCC is probably one of the most important interventions. The annual, age-adjusted rate of the incidence of liver cancer reported to the California Cancer Registry for 1988–1992 was 49.5 per 100,000 among Vietnamese Americans compared to the overall California rate for 1988–1992 of 4.8 per 100,000, and the U.S. rate for 1985–1989 of 3.9 per 100,000.[60] This high incidence of liver cancer is probably the result of the high prevalence of hepatitis B as well as hepatitis C among Vietnamese Americans. HBV-infected patients, with or without cirrhosis, have a high risk for HCC. Compared to the relative risk for HCC among HBsAg-negative Asian patients, the relative risk among HBsAg-positive/HBeAg-negative patients is 9.6 and among HBsAg-positive/HBeAg-positive Asian patients is 60.2.[61] Although the risk for HCC in HCV-infected patients without cirrhosis is minimal, the annual incidence of HCC in patients with cirrhosis is up to 8.0% in Asians (vs 3.0% in non-Asians).

The higher HCC prevalence rates in Asians may also result from other causes, such as environmental factors (aflatoxin in HBV cases),[62] occult co-infection with hepatitis B (in HCV cases), long duration of infection, and potential race-related, genetic factors. The estimated risk for HCC was approximately tripled in Asian Americans compared to Caucasians with chronic hepatitis C and cirrhosis in a sample of over 400 patients in the San Francisco Bay area.[63] HBsAg-positive patients were excluded from this case-controlled study, and HCC risk estimates were adjusted for age, gender, and severity of liver disease.

Because they have such a high risk for HCC, Asian Americans with chronic viral hepatitis should undergo especially close surveillance for HCC. Although there are no randomized, controlled trials comparing HCC screening versus no screening in patients with chronic liver disease, several observational studies suggest

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Table 5
Preventive Care in Patients with Liver Disease*

Prevention of	Indications	Specific prophylactic therapy
Hepatitis A superinfection	Chronic liver disease without evidence of hepatitis A immunity	Hepatitis A vaccine
Bleeding esophageal varices/gastric varices (EV/GV)	Large EV without a history of bleeding	Propranolol or nadolol
Bleeding EV/GV	History of bleeding varices	Esophageal band ligation + varices propanolol or nadolol TIPS for GV or refractory cases of bleeding from EV
Spontaneous bacterial peritonitis (SBP)	History of SBP Significant ascites with ascitic total protein < 1 g/L or active/recent gastrointestinal bleeding (GIB)	Ciprofloxacin 750 mg weekly or norfloxacin 400 mg bid for 7 days in case of GIB
Hepatocellular carcinoma	Cirrhosis of any cause Hepatitis B virus carriers or chronic hepatitis B patients aged 35 or older	Serum alpha-fetoprotein plus liver ultrasound every 6 months

*In addition to other preventive care appropriate for age.
TIPS, transfugular intrahepatic portosystemic shunt.
Data from Centers for Disease Control,[illegible] D'Amico et al.,[illegible] de Franchis and Primignani,[illegible] Rimola et al.,[illegible] and Nguyen and Keeffe.[illegible]

that preclinical HCC cases detected via screening are more likely to be eligible for therapy and/or be associated with improved survival.[59,64-68] Long-term survival can be expected if patients are eligible for curative treatments such as hepatic resection or liver transplantation.[69] Palliative treatments, such as transcatheter chemoembolization, have also been shown to improve survival at 2 and 3 years.[70-73]

Long-term survival can be expected if patients are eligible for curative treatments such as hepatic resection or liver transplantation.

Isoniazid Treatment in Patients with Hepatitis B Infection

The high prevalence of latent tuberculosis among Southeast Asian immigrants, including those with HBV infection (53%), merits attention.[74,75] In a large cohort case study of Vietnamese immigrants in the Midwest, the rate of significant hepatotoxic side effects requiring discontinuation of isoniazid (INH) chemoprevention was 62% among HBeAg-positive patients compared to only 19% of those without HBeAg. No significant differences were seen between HBsAg-positive and HBsAg-negative patients.[74] Thus, Southeast Asians with latent tuberculosis should be tested for HBV status, including HBeAg. Those with HBeAg positivity should be monitored closely for evidence of significant INH-induced hepatotoxicity.

Liver Transplantation in Asian Americans

The rate of posttransplant HBV infection is 20%–35% with HBIG and less than 10% with HBIG and lamivudine.[13,76] Anti-HBs may also develop spontaneously in patients receiving lamivudine prophylaxis (without HBIG) following liver transplantation for chronic HBV infection.[77] Asian race is not an independent predictor for poorer 2-year and 5-year survival in two single-center and one multicenter outcome studies of liver transplantation for chronic hepatitis B.[78-80] However, 1-year mortality resulting from the recurrence of HBV may be higher in Asian-American patients.[78] Late referral and more advanced chronic liver disease at the time of transplantation may account for the higher early mortality in Asian Americans.

The recurrence of HCV posttransplantation is universal.[13] Nonrandomized studies of IFN plus ribavirin or peginterferon plus or minus ribavirin suggest that SVR could be achieved in approximately 20% of treated patients.[81] In addition, patients who

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achieved viral eradication had no significant progression of fibrosis during therapy.[82] A range of approximately 50%–72% of treated patients, however, required dose adjustments because of leukopenia and cytopenia.[81,82] There are no known differential survival or HCV recurrence rates among Asians and non-Asians following liver transplantation for HCV.

One of the most recent and largest cohort studies of all liver transplantations performed in the United States between 1988 and 1996 (total, N = 14,282; Asian Americans, n = 416, or 2.9%) reported significantly lower overall 2-year and 5-year survival rates in African Americans (74% and 48%) and Asian Americans (69% and 37%), compared to Caucasians (83% and 58%).[83] These results are intriguing and conflict with results of other studies of liver transplantation for HBV in Asian Americans. The etiologies of liver disease leading to end-stage liver disease and transplantation were not looked at in this study. These observations warrant further examination. ■

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Main Points

- Chronic hepatitis B has long been recognized as a major cause of morbidity and mortality in Asians. Chronic hepatitis C in Asians, however, is often underappreciated, although the prevalence rate of the disease in Asians is up to 4 times the overall U.S. prevalence rate.
- Asians with hepatitis B and C usually acquire their infection at a young age through perinatal and childhood transmission for hepatitis B and nosocomial or person-to-person spread for hepatitis C. Asians are subsequently at much higher risk for long-term complications.
- Asian Americans have a higher rate of primary liver cancer and a differential response to various antiviral therapies than the general U.S. population.
- Asian patients with chronic hepatitis B commonly have hepatitis B e-antigen negative, with either the precore or core promoter mutant hepatitis B virus; this may require long-term antiviral viral therapy because of high rates of relapse following therapy.
- Asian patients with chronic hepatitis C may have a substantially higher risk of liver cancer but a better sustained virological response to interferon-based therapy, and subsequently a reduced future incidence of liver cancer.

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Exhibit 2
Metcalf Rebuttal Letter

18101 NE 200th Court
Woodinville WA 98077
November 9, 2003

Randy Huyck
Certificate of Need Program
Washington State Dept. of Health
310 Israel Road
Tumwater WA 98501

Dear Mr. Huyck:

I am writing to rebut some things that I heard during the testimony on November 6, 2003 at the open hearing. I heard several statements that were entered as facts that I think are untrue and others that I have a difference of opinion on. Please forgive me if I can't quote on some matters, as I do not have a copy of the verbal transcript or the written testimony.

The first are some statements that Dr. Carithers presented. He suggested that there are three items that a transplant patient is interested in. They are: fairness, will they die waiting and lastly will they survive the operation? In the case of our 15-year-old daughter, she would have wanted to be fair, she was definitively concerned about dying waiting for a transplant, but when it comes to survival she just wanted a CHANCE. The UW did not give her that chance or choice. She was rejected out of hand. Secondly, Dr. Carithers stated that no doctors have ever mentioned they have referred a patient outside the area for a transplant. I wish to state that Dr. Thomas Pendergrass, an oncologist at Children's hospital, did just that. We had a terrible experience with Dr. Perkins, who entered the examination room, stated his name, told us that he had reviewed the films, stated that there was nothing that he could do for Erin and left the room stating that he would send in the oncologist. As you can imagine Erin was devastated! I will never forget the look on her face and the words she spoke. She said, "The wind is out of my sails".. Her spirit was broken. Dr. Pendergrass did all he could to put the wind back in her sails during the period he treated her. Dr. Pendergrass told us to again go to the UW and see if we could get on the Liver Transplant list. We asked to meet with Dr. Perkins who at the last minute could not make it so we met with Dr. Patrick Healey. Patrick was very compassionate, but was not able to help us because of protocol. I asked him point blank what he would do if he were in my shoes and he replied something to the effect that he would search everywhere to get a transplant, and we subsequently talked about other centers. Here are two doctors in the same basic facility that referred a patient outside of the Seattle area for a liver transplant; one of them a doctor on the UW staff, the other a doctor that is part of their consortium.

There was testimony by a nurse that stated how important it is to have a well-rounded medial approach to a transplant. I couldn't agree more, but that is only part of the story. What about a patient having to leave the area (read leaving family and friends) to secure a chance for life? I would suggest that it is even more important to have close support from one's loved ones. I don't think a phone call once or twice a day does it! In our case, my wife was with Erin for the three months of her recovery. That was the only close family contact she had except for the weekend trips the rest of the family took to

be with her. If one estimates a cheap plane ticket to Los Angeles at $350 per person (Erin has two sisters and myself as close family) that comes to $1,050 per trip. How many families have the financial resources to be close and supportive during the very critical first few months after a transplant? So my refute is that while the overall support by the medical community at the UW is great for those who have been selected for transplant, for those that have to go outside Seattle, there is little support for the ones that really matter, the family! Again choice and a chance are important here.

My third rebuttal is an indirect disagreement with the numbers Dr. Perkins read into testimony. I do not have those numbers to quote, but what I remember are very high percentages of success in the first month and the first year. It seems to me to be easier to have very high successful numbers if you handpick who can and who cannot get on the liver transplant list. It also seems to me that one can increase a success rate if one only accepts the very best cadaver livers to transplant. My supposition is that UW is being far too conservative so that their numbers look good. As I understand it, the UW lost accreditation for organ harvest in the past and perhaps this is why they are being so cautious now. We heard testimony that 126 livers had left the region and that they were transplanted successfully. That means that people waiting or even worse people that were refused to be listed did not have a chance at life! Again, choice and chance.

As you may have seen, Dr. Carithers spent a great deal of time with me after the meeting and offered that my wife and I visit the Liver Program Clinic and see all the changes. We have accepted, because our mission is to honor our daughter's request that we help children like her. We will do whatever we can in the community to do that. I am in full support of all the UW is doing to save lives. What I am in more support of is choice and chance. I do believe that with the conservative nature of the UW selection process, the people of Washington are best served by having a second liver transplant center. Again, I want to express my support for the Swedish transplant center as it will give patients in the Washington area a choice and hopefully increase their chances of receiving the vital transplant they so desperately need.

Sincerely,

Jerry W. Metcalf

Exhibit 3

Center for Health Statistics - Washington State Department of Health

Mortality Table C3: Leading Causes by Age Group and Sex for Residents, 2002

Mortality Table C3. Leading Causes by Age Group and Sex for Residents, 2002

Age Group with Causes and ICD-10 Codes	Total No.	Total Rate[1]	Total Pct[2]	Male No.	Male Rate[1]	Male Pct[2]	Female No.	Female Rate[1]	Female Pct[2]
All Ages									
All Causes	15,244	418.2	100.0	7,507	450.1	100.0	7,737	387.7	100.0
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	11,117	184.0	24.6	5,793	192.5	25.7	5,324	175.5	23.5
Malignant Neoplasms (C00-C97)	10,846	179.5	24.0	5,575	185.3	24.7	5,270	173.8	23.2
Cerebrovascular Diseases (I60-I69)	3,757	62.2	8.3	1,459	48.5	6.5	2,298	75.8	10.1
Chronic Lower Respiratory Diseases (J40-J47)	2,720	45.0	6.0	1,291	42.9	5.7	1,429	47.1	6.3
Alzheimer's Disease (G30)	2,238	37.0	4.9	677	22.5	3.0	1,561	51.5	6.9
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	2,182	36.1	4.8	1,445	48.0	6.4	737	24.3	3.3
Diabetes Mellitus (E10-E14)	1,501	24.8	3.3	741	24.6	3.3	760	25.1	3.4
Influenza and Pneumonia (J10-J18)	907	15.0	2.0	393	13.1	1.7	514	16.9	2.3
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	811	13.4	1.8	642	21.3	2.8	169	5.6	0.7
Chronic Liver Disease & Cirrhosis (K70,K73-K74)	527	8.7	1.2	331	11.0	1.5	196	6.5	0.9
All Other Causes	8,638	143.0	19.1	4,220	140.3	18.7	4,418	145.7	19.5
Under 1									
All Causes	462	532.1	100.0	263	655.0	100.0	187	405.1	100.0
Congenital Malformations (Q00-Q99)	105	132.9	23.2	59	145.8	22.3	46	119.3	24.6
Sudden Infant Death Syndrome (R95)	70	88.6	15.5	45	111.2	17.0	25	64.9	13.4
Short Gestation & Low Birth Weight (P07)	68	86.1	15.0	40	98.9	15.1	28	72.6	15.0
Maternal Complications of Pregnancy (P01)	24	30.4	5.3	11	27.2	4.2	13	33.7	7.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	18	22.8	4.0	9	22.2	3.4	9	23.3	4.8
All Other Causes	167	211.4	36.9	101	249.7	38.1	66	171.2	35.3
1-4									
All Causes	81	25.3	100.0	42	25.6	100.0	39	25.0	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	42	13.1	51.9	21	12.8	50.0	21	13.4	53.8
Congenital Anomalies (Q00-Q99)	7	2.2	8.6	4	.	9.5	3	.	7.7
Malignant Neoplasms (C00-C97)	7	2.2	8.6	3	.	7.1	4	.	10.3
Assault (Homicide) (X85-Y09,Y87.1)	6	1.9	7.4	3	.	7.1	3	.	7.7
Conditions Originating in Perinatal Period (P00-P96)	1	.	1.2	.	.	.	1	.	2.6
All Other Causes	18	5.6	22.2	.	.	.	7	4.5	17.9
5-14									
All Causes	137	16.9	100.0	99	22.4	100.0	38	9.1	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	44	5.1	32.1	36	8.2	36.4	8	1.9	21.1
Malignant Neoplasms (C00-C97)	32	3.7	23.4	23	5.2	23.2	9	2.1	23.7
Assault (Homicide) (X85-Y09,Y87.1)	10	1.2	7.3	8	1.8	8.1	2	.	5.3
Congenital Anomalies (Q00-Q99)	10	1.2	7.3	7	1.6	7.1	3	.	7.9
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	8	0.9	5.8	6	1.4	6.1	2	.	5.3
All Other Causes	33	3.8	24.1	19	4.3	19.2	14	3.3	36.8
15-19									
All Causes	255	82.7	100.0	185	82.2	100.0	70	32.9	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	129	29.5	50.6	95	42.2	51.4	34	16.0	48.6
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	38	8.7	14.9	30	13.3	16.2	8	3.8	11.4
Assault (Homicide) (X85-Y09,Y87.1)	20	4.6	7.8	18	8.0	9.7	2	.	2.9
Malignant Neoplasms (C00-C97)	20	4.6	7.8	12	5.3	6.5	8	3.8	11.4
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	7	1.6	2.7	7	3.1	3.8	.	.	.
All Other Causes	41	9.4	16.1	23	10.2	12.4	.	.	.
20-24									
All Causes	288	69.1	100.0	232	108.4	100.0	56	27.6	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	131	31.4	45.5	117	54.6	50.4	14	6.9	25.0
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	56	13.4	19.4	48	22.4	20.7	8	3.9	14.3
Assault (Homicide) (X85-Y09,Y87.1)	33	7.9	11.5	25	11.7	10.8	8	3.9	14.3
Malignant Neoplasms (C00-C97)	18	4.3	6.3	10	4.7	4.3	8	3.9	14.3
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	7	1.7	2.4	4	.	1.7	3	.	5.4
All Other Causes	43	10.3	14.9	28	13.1	12.1	15	7.4	26.8
25-34									
All Causes	718	85.6	100.0	515	119.8	100.0	203	49.7	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	250	29.8	34.8	201	46.8	39.0	49	12.0	24.1
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	112	13.4	15.6	97	22.6	18.8	15	3.7	7.4
Malignant Neoplasms (C00-C97)	91	10.9	12.7	36	8.4	7.0	55	13.5	27.1
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	47	5.6	6.5	29	6.7	5.6	18	4.4	8.9

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Mortality Table C3. Leading Causes by Age Group and Sex for Residents, 2002

Age Group with Causes and ICD-10 Codes	Total No.	Total Rate[1]	Total Pct[2]	Male No.	Male Rate[1]	Male Pct[2]	Female No.	Female Rate[1]	Female Pct[2]
15-34									
All Causes	[illegible]	[illegible]	100.0	[illegible]	[illegible]	100.0	[illegible]	[illegible]	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	383	39.9	24.5	260	53.8	26.9	123	25.8	20.6
Malignant Neoplasms (C00-C97)	276	28.8	17.7	114	23.6	11.8	162	34.0	27.1
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	198	20.6	12.7	131	27.1	13.6	67	14.1	11.2
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	177	18.4	11.3	139	28.8	14.4	38	8.0	6.4
HIV (B20-B24)	57	5.9	3.6	51	10.5	5.3	6	1.3	1.0
All Other Causes	472	49.2	30.2	270	55.8	28.0	202	42.4	33.8
35-54									
All Causes	[illegible]	[illegible]	100.0	1,959	[illegible]	100.0	1,765	[illegible]	100.0
Malignant Neoplasms (C00-C97)	1,013	113.0	31.4	503	112.9	25.7	510	113.1	40.3
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	582	64.9	18.0	437	98.1	22.3	145	32.1	11.5
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	313	34.9	9.7	227	51.0	11.6	86	19.1	6.8
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	182	20.3	5.6	129	29.0	6.6	53	11.8	4.2
Chronic Liver Disease & Cirrhosis (K70,K73-K74)	131	14.6	4.1	88	19.8	4.5	43	9.5	3.4
All Other Causes	1,004	112.0	31.1	575	129.1	29.4	429	95.1	33.9
55-74									
All Causes	[illegible]	[illegible]	100.0	2,724	988.9	100.0	1,891	676.2	100.0
Malignant Neoplasms (C00-C97)	1,777	320.0	38.5	950	344.9	34.9	827	295.4	43.7
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	1,045	188.2	22.6	727	263.9	26.7	318	113.6	16.8
Chronic Lower Respiratory Diseases (J40-J47)	265	47.7	5.7	126	45.7	4.6	139	49.7	7.3
Diabetes Mellitus (E10-E14)	219	39.4	4.7	128	46.5	4.7	91	32.5	4.8
Unintentional Injury (Accident) (V01-X59,Y85-Y86)	183	33.0	4.0	124	45.0	4.6	59	21.1	3.1
All Other Causes	1,128	203.1	24.4	669	242.9	24.6	459	164.0	24.2
75-84									
All Causes	[illegible]	[illegible]	100.0	4,169	2,602.8	100.0	[illegible]	[illegible]	100.0
Malignant Neoplasms (C00-C97)	2,701	792.4	36.5	1,441	899.6	34.6	1,260	697.3	39.0
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	1,693	496.7	22.9	1,103	688.6	26.5	590	326.5	18.3
Chronic Lower Respiratory Diseases (J40-J47)	619	181.6	8.4	333	207.9	8.0	286	158.3	8.
Cerebrovascular Diseases (I60-I69)	419	122.9	5.7	202	126.1	4.8	217	120.1	6.7
Diabetes Mellitus (E10-E14)	344	100.9	4.7	175	109.3	4.2	169	93.5	5.2
All Other Causes	1,620	475.3	21.9	915	571.3	21.9	705	390.2	21.8
85 and Over									
All Causes	15,020	13,330.0	100.0	6,508	16,390.7	100.0	[illegible]	[illegible]	100.0
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	3,358	1,369.4	25.7	1,806	1,801.2	27.8	1,552	1,070.7	23.7
Malignant Neoplasms (C00-C97)	3,264	1,331.1	25.0	1,719	1,714.4	26.4	1,545	1,065.9	23.5
Cerebrovascular Diseases (I60-I69)	1,251	510.2	9.6	548	546.5	8.4	703	485.0	10.7
Chronic Lower Respiratory Diseases (J40-J47)	1,058	431.5	8.1	479	477.7	7.4	579	399.4	8.8
Alzheimer's Disease (G30)	717	292.4	5.5	280	279.3	4.3	437	301.5	6.7
All Other Causes	3,422	1,395.5	26.2	1,676	1,671.5	25.8	1,746	1,204.6	26.6
85 and Over									
All Causes	13,140	13,310.0	100.0	4,902	16,908.0	100.0	8,237	13,715.0	100.0
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	4,172	4,572.6	31.0	1,546	5,332.3	31.5	2,626	4,218.7	30.8
Cerebrovascular Diseases (I60-I69)	1,782	1,953.1	13.3	557	1,921.2	11.4	1,225	1,968.0	14.3
Malignant Neoplasms (C00-C97)	1,645	1,803.0	12.2	762	2,628.2	15.5	882	1,417.0	10.3
Alzheimer's Disease (G30)	1,393	1,526.8	10.4	345	1,189.9	7.0	1,048	1,683.6	12.3
Chronic Lower Respiratory Diseases (J40-J47)	663	726.7	4.9	301	1,038.2	6.1	362	581.6	4.2
All Other Causes	3,785	4,148.4	28.2	1,391	4,797.7	28.4	2,394	3,846.0	28.0

[1] Rate per 100,000 population in each age-sex group.

[2] Percent of total deaths in each age-sex group. Percents may not add to 100% due to rounding.

* Rate not calculated because number of deaths was less than 5.

Total includes 1 death for which sex is unknown.

Source: Center for Health Statistics, Washington State Department of Health, 10/2003.

Mortality Table C8. Influenza & Pneumonia, Chronic Lower Respiratory Disease, and Chronic Liver Disease & Cirrhosis by County of Residence, 2002

	Pneumonia and Influenza (J10-J18)			Chronic Lower Resp. Dis. (J40-J47)			Chronic Liver Disease & Cirrhosis (K70,K73-K74)		
County	Number	Crude Rate[1]	Age-Adj Rate[2]	Number	Crude Rate[1]	Age-Adj Rate[2]	Number	Crude Rate[1]	Age-Adj Rate[2]
State Total	907	15.0	15.8	2,720	45.0	48.5	527	8.7	8.9
Adams	4	*	*	5	30.1	37.0	3	*	*
Asotin	6	29.0	20.2	11	53.1	42.9	1	*	*
Benton	15	10.2	12.8	72	48.8	59.9	10	6.8	7.2
Chelan	19	28.1	22.6	41	60.6	54.4	5	7.4	7.2
Clallam	18	27.7	17.3	50	77.0	46.9	5	7.7	5.2
Clark	33	9.1	11.5	166	45.7	57.9	20	5.5	5.8
Columbia	1	*	*	7	170.8	111.6	0	*	*
Cowlitz	21	22.2	19.9	71	75.2	69.5	14	14.8	14.0
Douglas	4	*	*	18	54.4	54.6	3	*	*
Ferry	0	*	*	4	*	*	0	*	*
Franklin	9	17.5	28.6	21	40.9	60.0	4	*	*
Garfield	2	*	*	1	*	*	0	*	*
Grant	23	30.1	35.2	40	52.4	58.4	7	9.2	10.1
Grays Harbor	14	20.5	16.9	55	80.4	66.2	10	14.6	12.4
Island	7	9.6	9.3	26	35.6	32.4	3	*	*
Jefferson	3	*	*	14	52.6	33.6	3	*	*
King	247	13.9	15.0	629	35.5	39.6	138	7.8	8.0
Kitsap	29	12.4	13.6	94	40.1	45.9	26	11.1	11.3
Kittitas	9	25.9	25.8	17	48.8	49.0	4	*	*
Klickitat	3	*	*	11	57.0	50.4	2	*	*
Lewis	14	19.9	15.4	48	68.4	54.5	11	15.7	13.5
Lincoln	0	*	*	6	58.8	37.2	1	*	*
Mason	10	20.1	17.6	29	58.2	47.1	7	14.1	11.2
Okanogan	13	32.7	29.4	25	62.8	57.8	10	25.1	24.2
Pacific	9	42.9	25.9	19	90.5	53.4	6	28.6	15.9
Pend Oreille	4	*	*	10	84.7	84.4	2	*	*
Pierce	79	10.9	13.0	332	45.8	54.6	47	6.5	6.8
San Juan	2	*	*	8	54.8	37.7	1	*	*
Skagit	15	14.3	11.8	52	49.5	41.1	8	7.6	7.2
Skamania	0	*	*	4	*	*	0	*	*
Snohomish	78	12.4	15.8	237	37.7	49.4	51	8.1	9.2
Spokane	88	20.7	18.8	249	58.5	56.6	51	12.0	12.0
Stevens	11	27.2	26.4	33	81.7	79.4	6	14.9	13.0
Thurston	20	9.4	9.7	98	46.2	48.4	17	8.0	8.3
Wahkiakum	0	*	*	4	*	*	2	*	*
Walla Walla	21	37.9	25.6	23	41.5	36.5	6	10.8	10.5
Whatcom	29	16.8	16.6	73	42.4	44.3	14	8.1	8.5
Whitman	6	14.8	18.4	6	14.8	19.4	3	*	*
Yakima	41	18.2	18.5	111	49.3	53.4	26	11.6	12.9

[1] Rate per 100,000 population.

[2] Rate per 100,000 age-adjusted to U.S. 2000 population. Does not include deaths where age is unknown.

* Rate not calculated because number of deaths was less than 5.

Note: Codes for International Classification of Diseases, Tenth Revision (ICD-10) are in parentheses after each group heading.

Rates based on fewer than 20 deaths are likely to be unstable and imprecise.

Mortality Table D2. Cancer by Primary Site by Sex for Residents, 2002

Cause with ICD-10 Codes	Total			Male			Female		
	No.	Crude Rate[1]	Age-Adj. Rate[2]	No.	Crude Rate[1]	Age-Adj. Rate[2]	No.	Crude Rate[1]	Age-Adj. Rate[2]
All Sites Combined (C00-C97)	10,846	179.5	190.6	5,575	185.3	229.0	5,270	173.8	165.2
Bladder (C67)	228	3.8	4.0	161	5.4	6.9	67	2.2	2.0
Brain, Meninges, & CNS (C70-C72)[3]	324	5.4	5.6	179	5.9	6.5	145	4.8	4.6
Brain (C71)	318	5.3	5.5	175	5.8	6.4	143	4.7	4.6
Breast (C50)	766	12.7	13.2	6	0.2	0.2	760	25.1	23.8
Cervix (C53)	n/a	n/a	n/a	n/a	n/a	n/a	45	1.5	1.4
Colorectal (C18-C21)[3]	963	15.9	16.9	475	15.8	19.5	488	16.1	14.9
Colorectal (C18-C20,C26.0)	963	15.9	16.9	475	15.8	19.5	488	16.1	14.9
Endometrium & Uterus (C54-C55)[3]	n/a	n/a	n/a	n/a	n/a	n/a	127	4.2	3.9
Endometrium (C54)	n/a	n/a	n/a	n/a	n/a	n/a	66	2.2	2.0
Esophagus (C15)	274	4.5	4.8	209	6.9	8.4	65	2.1	2.0
Hodgkin's Disease (C81)	17	0.3	0.3	9	0.3	0.3	8	0.3	0.3
Kidney & Renal Pelvis (C64-C65)	258	4.3	4.5	162	5.4	6.2	96	3.2	3.0
Larynx (C32)	67	1.1	1.2	51	1.7	1.9	16	0.5	0.5
Leukemia (C91-C95)[3]	455	7.5	8.1	270	9.0	11.2	185	6.1	5.8
Leukemia (C90.1,C91-C95)	457	7.6	8.1	272	9.0	11.2	185	6.1	5.8
Liver (C22)[3]	318	5.3	5.5	194	6.4	7.4	124	4.1	3.9
Liver (C22.0,C22.2-C22.4,C22.7,C22.9)	222	3.7	3.8	153	5.1	5.7	69	2.3	2.2
Lung, Bronchus & Trachea (C33-C34)[3]	3,093	51.2	54.8	1,671	55.5	67.7	1,421	46.9	45.5
Lung & Bronchus (C34)	3,093	51.2	54.8	1,671	55.5	67.7	1,421	46.9	45
Melanoma of Skin (C43)	155	2.6	2.7	92	3.1	3.5	63	2.1	2.0
Multiple Myeloma & Immunoproliferative (C88,C90)[3]	266	4.4	4.7	142	4.7	6.0	124	4.1	3.9
Multiple Myeloma (C90.0,C90.2)	256	4.2	4.6	134	4.5	5.7	122	4.0	3.8
Non-Hodgkin's Lymphoma (C82-C85)	497	8.2	8.7	289	9.6	12.2	208	6.9	6.3
Oral Cavity & Pharynx (C00-C14)	176	2.9	3.1	113	3.8	4.3	63	2.1	2.0
Ovary (C56)	n/a	n/a	n/a	n/a	n/a	n/a	342	11.3	10.8
Pancreas (C25)	608	10.1	10.7	297	9.9	12.0	311	10.3	9.8
Prostate (C61)	n/a	n/a	n/a	619	20.6	28.7	n/a	n/a	n/a
Stomach (C16)	214	3.5	3.8	133	4.4	5.5	81	2.7	2.5
Testis (C62)	n/a	n/a	n/a	5	0.2	0.2	n/a	n/a	n/a
Thyroid & Endocrine Glands (C73-C75)[3]	39	0.6	0.7	15	0.5	0.6	24	0.8	0.8
Thyroid (C73)	25	0.4	0.4	7	0.2	0.3	18	0.6	0.6
Site Unspecified (C80)	410	6.8	7.2	178	5.9	7.4	232	7.6	7.1
All Other Sites[4]	566	9.4	9.9	298	9.9	12.2	268	8.8	8.2

[1] Rate per 100,000 population.

[2] Rate per 100,000 age-adjusted to U.S. 2000 population. Does not include deaths where age is unknown.

[3] The ICD-10 codes selected for these groups differ slightly from Cancer Registry groups. See http://www3.doh.wa.gov/WSCR/ to obtain reports of the Washington State Cancer Registry or to obtain information about other cancer sites.

[4] ICD-10 Codes:C17,C23-C24,C26.1-C31,C37-C42,C44-C49,C51-C52,C57-C60,C63,C66,C68-C69,C76-C79,C88,C96-C97.

Note: Rates based on fewer than 20 deaths are likely to be unstable and imprecise.

Source: Center for Health Statistics, Washington State Department of Health, 10/2003.

Exhibit 4

Center for Health Statistics - Washington State Department of Health

Mortality Table C3: Leading Causes by Age Group and Sex for Residents, 2001

Washington State Department of Health

Center for Health Statistics
Death Data

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Mortality Table C3. Leading Causes by Age Group and Sex for Residents, 2001

Age Group with Causes and ICD-10 Codes	Total No.	Total Rate[1]	Total Pct[2]	Male No.	Male Rate[1]	Male Pct[2]	Female No.	Female Rate[1]	Female Pct[2]
All Ages									
All Causes	44,563	745.8	100.0	21,987	739.0	100.0	22,575	752.6	100.0
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	11,229	187.9	25.2	5,773	194.0	26.3	5,456	181.9	24.2
Malignant Neoplasms (C00-C97)	10,780	180.4	24.2	5,563	187.0	25.3	5,217	173.9	23.1
Cerebrovascular Diseases (I60-I69)	3,760	62.9	8.4	1,455	48.9	6.6	2,305	76.8	10.2
Chronic Lower Respiratory Diseases (J40-J47)	2,636	44.1	5.9	1,227	41.2	5.6	1,409	47.0	6.2
Unintentional Injury (Accident) (V01-X59,Y85-Y86	2,064	34.5	4.6	1,318	44.3	6.0	746	24.9	3.3
Alzheimer's Disease (G30)	2,051	34.3	4.6	608	20.4	2.8	1,443	48.1	6.4
Diabetes Mellitus (E10-E14)	1,403	23.5	3.1	688	23.1	3.1	715	23.8	3.2
Influenza and Pneumonia (J10-J18)	960	16.1	2.2	442	14.9	2.0	518	17.3	2.3
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	710	11.9	1.6	566	19.0	2.6	144	4.8	0.6
Chronic Liver Disease & Cirrhosis (K70,K73-K74)	571	9.6	1.3	343	11.5	1.6	228	7.6	1.0
All Other Causes	8,399	140.6	18.8	4,004	134.6	18.2	4,394	146.5	19.5
Under 1									
All Causes	461	579.6	100.0	259	637.6	100.0	201	516.4	100.0
Congenital Malformations (Q00-Q99)	119	149.6	25.8	60	147.7	23.2	58	149.0	28.9
Sudden Infant Death Syndrome (R95)	60	75.4	13.0	34	83.7	13.1	26	66.8	12.9
Short Gestation & Low Birth Weight (P07)	49	61.6	10.6	27	66.5	10.4	22	56.5	10.9
Maternal Complications of Pregnancy (P01)	28	35.2	6.1	20	49.2	7.7	8	20.6	4.0
Unintentional Injury (Accident) (V01-X59,Y85-Y8	24	30.2	5.2	15	36.9	5.8	9	23.1	4.5
All Other Causes	181	227.6	39.3	103	253.6	39.8	78	200.4	38.8
1-4									
All Causes	85	26.7	100.0	44	27.0	100.0	41	26.5	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86	27	8.5	31.8	19	11.7	43.2	8	5.2	19.5
Malignant Neoplasms (C00-C97)	13	4.1	15.3	6	3.7	13.6	7	4.5	17.1
Congenital Anomalies (Q00-Q99)	10	3.1	11.8	4	*	9.1	6	3.9	14.6
Assault (Homicide) (X85-Y09,Y87.1)	5	1.6	5.9	3	*	6.8	2	*	4.9
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	4	*	4.7	2	*	4.5	2	*	4.9
All Other Causes	26	8.2	30.6	10	6.1	22.7	16	10.3	39.0
5-14									
All Causes	126	14.6	100.0	75	17.0	100.0	51	12.2	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86	46	5.3	36.5	27	6.1	36.0	19	4.5	37.3
Malignant Neoplasms (C00-C97)	22	2.6	17.5	12	2.7	16.0	10	2.4	19.6
Congenital Anomalies (Q00-Q99)	12	1.4	9.5	6	1.4	8.0	6	1.4	11.8
Assault (Homicide) (X85-Y09,Y87.1)	7	0.8	5.6	3	*	4.0	4	*	7.8
Chronic Lower Respiratory Diseases (J40-J47)	5	0.6	4.0	5	1.1	6.7	*	*	*
All Other Causes	34	3.9	27.0	22	5.0	29.3	*	*	*
15 - 19									
All Causes	243	55.9	100.0	162	72.3	100.0	81	38.4	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86	130	29.9	53.5	82	36.6	50.6	48	22.8	59.3
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	35	8.0	14.4	29	12.9	17.9	6	2.8	7.4
Assault (Homicide) (X85-Y09,Y87.1)	22	5.1	9.1	15	6.7	9.3	7	3.3	8.6

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Malignant Neoplasms (C00-C97)	18	4.1	7.4	10	4.5	6.2	8	3.8	9.9
Congenital Anomalies (Q00-Q99)	5	1.1	2.1	4	*	2.5	1	*	1.2
All Other Causes	33	7.6	13.6	22	9.8	13.6	11	5.2	13.6
20 - 24									
All Causes	333	82.3	100.0	250	120.3	100.0	83	42.2	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86	156	38.6	46.8	126	60.6	50.4	30	15.2	36.1
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	50	12.4	15.0	42	20.2	16.8	8	4.1	9.6
Assault (Homicide) (X85-Y09,Y87.1)	30	7.4	9.0	24	11.6	9.6	6	3.0	7.2
Malignant Neoplasms (C00-C97)	19	4.7	5.7	11	5.3	4.4	8	4.1	9.6
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	16	4.0	4.8	10	4.8	4.0	6	3.0	7.2
All Other Causes	62	15.3	18.6	37	17.8	14.8	25	12.7	30.1
25 - 34									
All Causes	655	78.0	100.0	439	102.1	100.0	216	52.7	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86	215	25.6	32.8	161	37.5	36.7	54	13.2	25.0
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	120	14.3	18.3	92	21.4	21.0	28	6.8	13.0
Malignant Neoplasms (C00-C97)	75	8.9	11.5	34	7.9	7.7	41	10.0	19.0
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	46	5.5	7.0	30	7.0	6.8	16	3.9	7.4
Assault (Homicide) (X85-Y09,Y87.1)	36	4.3	5.5	28	6.5	6.4	8	2.0	3.7
All Other Causes	163	19.4	24.9	94	21.9	21.4	69	16.8	31.9
35 - 44									
All Causes	1,470	151.5	100.0	947	193.9	100.0	523	108.6	100.0
Unintentional Injury (Accident) (V01-X59,Y85-Y86	332	34.2	22.6	240	49.1	25.3	92	19.1	17.6
Malignant Neoplasms (C00-C97)	276	28.4	18.8	128	26.2	13.5	148	30.7	28.3
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	211	21.7	14.4	143	29.3	15.1	68	14.1	13.0
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	138	14.2	9.4	115	23.5	12.1	23	4.8	4.4
Chronic Liver Disease & Cirrhosis (K70,K73-K74)	68	7.0	4.6	42	8.6	4.4	26	5.4	5.0
All Other Causes	445	45.9	30.3	279	57.1	29.5	166	34.5	31.7
45 - 54									
All Causes	3,006	341.4	100.0	1,876	428.7	100.0	1,130	255.1	100.0
Malignant Neoplasms (C00-C97)	937	106.4	31.2	473	108.1	25.2	464	104.8	41.1
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	553	62.8	18.4	418	95.5	22.3	135	30.5	11.9
Unintentional Injury (Accident) (V01-X59,Y85-Y86	275	31.2	9.1	209	47.8	11.1	66	14.9	5.8
Chronic Liver Disease & Cirrhosis (K70,K73-K74)	163	18.5	5.4	108	24.7	5.8	55	12.4	4.9
Intentional Self-Harm (Suicide)(X60-X84,Y87.0)	159	18.1	5.3	122	27.9	6.5	37	8.4	3.3
All Other Causes	919	104.4	30.6	546	124.8	29.1	373	84.2	33.0
55 - 64									
All Causes	4,331	837.5	100.0	2,583	1,006.9	100.0	1,748	670.8	100.0
Malignant Neoplasms (C00-C97)	1,703	329.3	39.3	936	364.9	36.2	767	294.3	43.9
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	975	188.5	22.5	701	273.3	27.1	274	105.1	15.7
Chronic Lower Respiratory Diseases (J40-J47)	237	45.8	5.5	121	47.2	4.7	116	44.5	6.6
Diabetes Mellitus (E10-E14)	191	36.9	4.4	107	41.7	4.1	84	32.2	4.8
Cerebrovascular Diseases (I60-I69)	179	34.6	4.1	104	40.5	4.0	75	28.8	4.3
All Other Causes	1,046	202.3	24.2	614	239.3	23.8	432	165.8	24.7
65 - 74									
All Causes	7,652	2,261.8	100.0	4,276	2,703.6	100.0	3,376	1,874.0	100.0
Malignant Neoplasms (C00-C97)	2,778	821.1	36.3	1,502	949.7	35.1	1,276	708.3	37.8
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	1,820	538.0	23.8	1,171	740.4	27.4	649	360.2	19.2
Chronic Lower Respiratory Diseases (J40-J47)	624	184.4	8.2	296	187.2	6.9	328	182.1	9.7
Cerebrovascular Diseases (I60-I69)	444	131.2	5.8	226	142.9	5.3	218	121.0	6.5
Diabetes Mellitus (E10-E14)	334	98.7	4.4	187	118.2	4.4	147	81.6	4.4
All Other Causes	1,652	488.3	21.6	894	565.2	20.9	758	420.8	22.5
75-84									
All Causes	13,381	5,500.4	100.0	6,547	6,577.1	100.0	6,834	4,754.7	100.0
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	3,588	1,474.9	26.8	1,848	1,856.5	28.2	1,740	1,210.6	25.5
Malignant Neoplasms (C00-C97)	3,288	1,351.6	24.6	1,707	1,714.8	26.1	1,581	1,100.0	23.1
Cerebrovascular Diseases (I60-I69)	1,318	541.8	9.8	554	556.5	8.5	764	531.5	11.2
Chronic Lower Respiratory Diseases (J40-J47)	1,071	440.2	8.0	500	502.3	7.6	571	397.3	8.4

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Alzheimer's Disease (G30)	692	284.5	5.2	254	255.2	3.9	438	304.7	6.4
All Other Causes	3,424	1,407.5	25.6	1,684	1,691.7	25.7	1,740	1,210.6	25.5
85 and Over									
All Causes	12,820	14,662.0	100.0	4,529	16,395.0	100.0	8,291	13,862.0	100.0
Diseases of the Heart (I00-I09,I11,I13,I20-I51)	4,003	4,578.3	31.2	1,446	5,234.6	31.9	2,557	4,275.2	30.8
Cerebrovascular Diseases (I60-I69)	1,667	1,906.6	13.0	491	1,777.4	10.8	1,176	1,966.2	14.2
Malignant Neoplasms (C00-C97)	1,650	1,887.1	12.9	743	2,689.7	16.4	907	1,516.5	10.9
Alzheimer's Disease (G30)	1,240	1,418.2	9.7	300	1,086.0	6.6	940	1,571.6	11.3
Chronic Lower Respiratory Diseases (J40-J47)	609	696.5	4.8	260	941.2	5.7	349	583.5	4.2
All Other Causes	3,651	4,175.7	28.5	1,289	4,666.2	28.5	2,362	3,949.2	28.5

[1]Rate per 100,000 population in each age-sex group.

[2]Percent of total deaths in each age-sex group. Percents may not add to 100% due to rounding.

*Rate not calculated because number of deaths was less than 5.

Note: Rates based on fewer than 20 deaths are likely to be unstable and imprecise.

Total includes 1 death for which sex is unknown.

Source: Center for Health Statistics, Washington State Department of Health, 07/2002.

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Washington State Department of Health

Center for Health Statistics
Death Data

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Mortality Table C8. Influenza & Pneumonia, Chronic Lower Respiratory Disease, and Chronic Liver Disease & Cirrhosis by County of Residence, 2001

	Pneumonia and Influenza (J10-J18)			Chronic Lower Resp. Dis. (J40-J47)			Chronic Liver Disease & Cirrhosis (K70,K73-K74)		
County	Number	Crude Rate[1]	Age-Adj Rate[2]	Number	Crude Rate[1]	Age-Adj Rate[2]	Number	Crude Rate[1]	Age-Adj Rate[2]
State Total	**960**	**16.1**	**17.2**	**2,636**	**44.1**	**48.2**	**571**	**9.6**	**9.8**
Adams	1	*	*	7	42.2	50.9	3	*	*
Asotin	2	*	*	10	48.3	38.4	1	*	*
Benton	18	12.4	15.9	71	49.0	60.2	10	6.9	8.2
Chelan	11	16.4	14.0	36	53.7	47.3	9	13.4	13.2
Clallam	21	32.4	19.3	47	72.5	43.0	7	10.8	7.3
Clark	36	10.2	13.0	149	42.3	54.1	28	7.9	8.2
Columbia	2	*	*	7	170.6	117.7	0	*	*
Cowlitz	19	20.2	17.7	61	65.0	61.2	14	14.9	14.5
Douglas	7	21.3	21.9	23	70.1	70.7	1	*	*
Ferry	0	*	*	1	*	*	2	*	*
Franklin	3	*	*	14	27.8	40.8	4	*	*
Garfield	2	*	*	3	*	*	1	*	*
Grant	13	17.1	20.3	24	31.6	35.5	4	*	*
Grays Harbor	31	45.3	38.5	70	102.2	84.9	8	11.7	10.0
Island	15	20.7	20.1	22	30.4	27.3	3	*	*
Jefferson	6	23.0	15.0	14	53.6	32.6	3	*	*
King	273	15.5	17.0	567	32.2	36.7	145	8.2	8.6
Kitsap	31	13.3	15.3	97	41.6	48.1	26	11.1	11.7
Kittitas	15	44.1	41.7	20	58.8	61.3	2	*	*
Klickitat	2	*	*	12	62.2	57.1	0	*	*
Lewis	10	14.4	11.6	41	59.0	47.4	8	11.5	10.2
Lincoln	1	*	*	9	88.2	56.6	0	*	*
Mason	16	32.3	28.5	25	50.4	43.1	6	12.1	10.3
Okanogan	12	30.2	27.8	34	85.6	80.4	6	15.1	12.8
Pacific	9	42.9	25.8	26	123.8	74.3	12	57.1	39.3
Pend Oreille	1	*	*	3	*	*	1	*	*
Pierce	77	10.8	13.3	359	50.3	61.0	82	11.5	12.8
San Juan	2	*	*	7	48.6	33.3	2	*	*
Skagit	26	25.0	20.5	49	47.1	40.0	9	8.6	8.0
Skamania	1	*	*	3	*	*	0	*	*
Snohomish	93	15.0	19.6	232	37.5	50.4	69	11.2	12.8
Spokane	67	15.9	14.6	249	58.9	57.8	42	9.9	10.0
Stevens	7	17.4	16.3	26	64.5	60.9	3	*	*
Thurston	34	16.2	17.0	118	56.1	60.3	20	9.5	9.3
Wahkiakum	4	*	*	2	*	*	0	*	*
Walla Walla	16	29.0	22.9	29	52.5	43.8	4	*	*
Whatcom	24	14.1	14.1	68	39.9	42.0	13	7.6	8.0
Whitman	11	27.3	31.5	10	24.8	32.8	1	*	*

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Exhibit 5

National Organ Transplant Act, 1984, UNOS and OPTN
Liver Allocation Algorithm

3.0 ORGAN DISTRIBUTION

The following policies apply to the allocation of organs for transplantation.

3.6 ALLOCATION OF LIVERS. Unless otherwise approved according to Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances), Policy 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) and Policy 3.11.4 (Combined Intestine-Liver Organ Candidates), and Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates), the allocation of livers according to the following system is mandatory. For the purpose of enabling physicians to apply their consensus medical judgement for the benefit of liver transplant candidates as a group, each patient will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Mortality risk scores shall be determined by the prognostic factors specified in Tables 1 and 2 and calculated in accordance with the Model for End-Stage Liver Disease (MELD) Scoring System and Pediatric End Stage Liver Disease (PELD) Scoring System described in Policy 3.6.4.1 and 3.6.4.2, respectively. Patients will be stratified within MELD or PELD score by blood type similarity as described in Policy 3.6.2. No individual or property rights are conferred by this system of liver allocation.

NOTE: The amendments to Policy 3.6 (Allocation of Livers) shall be implemented following programming on the UNOS system.

Livers will be offered to patients with an assigned Status of 1 in descending point sequence with the patient having the highest number of points receiving the highest priority before being offered for patients listed in other categories within distribution areas as noted below. Following Status 1, livers will be offered to patients based upon their probability of candidate death derived from assigned MELD or PELD scores, as applicable, in descending point sequence with the patient having the highest probability ranking receiving the highest priority before being offered to patients having lower probability rankings.

At each level of distribution, adult livers (i.e., greater than or equal to 18 years old) will be allocated in the following sequence (adult donor liver allocation algorithm):

Adult Donor Liver Allocation Algorithm

Local
1. Status 1 patients in descending point order

Regional
2. Status 1 patients in descending point order

Local
3. All other patients in descending order of mortality risk scores (probability of candidate death)

Regional

4. All other patients in descending order of mortality risk scores (probability of candidate death)

National

5. Status 1 patients in descending point order
6. All other patients in descending order of mortality risk scores (probability of candidate death)

Within liver Status 1 and the organ distribution system defined in this policy for adult donor livers, a liver recovered from a pediatric organ donor shall be allocated to a pediatric liver candidate before the liver is allocated to an adult candidate (according to the pediatric donor liver allocation algorithm set forth below); provided, however, that the recipient transplant program cannot use only part of the liver in a single patient without offering the remaining portion(s) for transplantation:

(i) in sequence, as determined by the adult donor liver allocation algorithm set forth above and defining "local" based upon the Host OPO's local area, to the highest-ranking patient on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the donor organ procurement procedure has started, or

(ii) into patients listed with the recipient program or any medically appropriate candidate on the UNOS Patient Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure has started.

In the event that the transplant program receiving the liver offer declines to transplant the whole organ into the designated candidate or to transplant a part of the organ into the designated candidate, offering the remaining portion(s) for transplantation as described earlier in this paragraph, then the donor liver shall be allocated to the next candidate on the waiting list, in the sequence outlined below (i.e., the pediatric donor liver allocation algorithm). For purpose of Policy 3.6, pediatric patients and organ donors are defined as less than 18 years of age.

Pediatric Donor Liver Allocation Algorithm

Local

1. Pediatric Status 1 patients in descending point order
2. Adult Status 1 patients in descending point order

Regional

3. Pediatric Status 1 patients in descending point order
4. Adult Status 1 patients in descending point order

Local

5. All other pediatric patients with a PELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
6. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
7. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
8. All remaining adult patients in descending order of mortality risk scores (probability of candidate death)

Regional

9. All other pediatric patients with a PELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
10. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
11. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
12. All remaining adult patients in descending order of mortality risk scores (probability of candidate death)

National

13. Pediatric Status 1 patients in descending point order
14. Adult Status 1 patients in descending point order
15. All other pediatric patients with a PELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
16. All other adult patients with a MELD score at or above a 50% risk of 3-month candidate mortality in descending order of mortality risk scores (probability of candidate death)
17. All remaining pediatric patients in descending order of mortality risk scores (probability of candidate death)
18. All remaining adult patients in descending order of mortality risk scores (probability of candidate

death)

The liver must be transplanted into the original designee or be released back to the Host OPO or to the UNOS Organ Center for distribution. If a liver is offered to a patient who is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the liver is being distributed, then the liver shall be released back to the Host OPO or to the UNOS Organ Center for allocation to other liver transplant candidates in accordance with UNOS Policy 3.6. The final decision whether to use the liver will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that patient. This will allow physicians and surgeons to exercise judgement about the suitability of the liver being offered for their specific patient; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If a liver is declined for a patient, a notation of the reason for the decision not to accept the liver for that patient must be made on the appropriate UNOS form and promptly submitted to UNOS.

Allocation Sequence for Patients with PELD or MELD Scores Less Than or Equal to 6 (All Donor Livers).

Adult patients with a MELD score of 6 will be considered together with all pediatric patients with a PELD score less than or equal to 6. These patients will be initially ranked based upon waiting time. Those waiting list positions assigned to pediatric candidates based on this initial ranking (e.g., if the 3rd and 5th on the ranked list are held by pediatric patients) will then be re-distributed amongst the pediatric group based on PELD score, with the patient with the highest PELD score receiving the highest available pediatric ranking position. The next available pediatric ranking position will be assigned to the pediatric candidate with the next highest PELD score. Re-distribution of pediatric candidates continues until the pediatric candidate with the lowest PELD score is assigned the last pediatric ranking position.

3.6.1 **Preliminary Stratification.** For every potential liver recipient, the acceptable donor size must be determined by the responsible surgeon. The UNOS Match System will consider only potential liver recipients who are an acceptable size for that particular donor liver.

3.6.2 **Blood Type Similarity Stratification/Points.** For Status 1 transplant candidates, patients with the same ABO type as the liver donor shall receive 10 points. Candidates with compatible but not identical ABO types shall receive 5 points, and candidates with incompatible types shall receive 0 points. Blood type O candidates who will accept a liver from an A_2 blood type donor shall receive 5 points for ABO incompatible matching. Within each MELD/PELD score, donor livers shall be offered to transplant candidates who are ABO-identical with the donor first, then to candidates who are ABO-compatible, followed by candidates who are ABO-incompatible with the donor.

3.6.2.1 **Allocation of Blood Type O Donors.** With the Exception of Status 1 patients, blood type O donors may only be allocated to blood type O patients, or B patients with a MELD or PELD score greater than or equal to 20.

3.6.2.2 **Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type.** For Status 1 candidates, or candidates with a MELD or PELD score of 25 and greater, centers may specify on the waiting list those patients who will accept a liver from a donor of any blood type.

3.6.3 **Time Waiting.** Transplant candidates on the UNOS patient waiting list shall accrue waiting time within Status 1 or any assigned MELD or PELD score; however, waiting time accrued while listed at a lower MELD/PELD score will not be counted toward liver allocation if the patient is upgraded to a higher MELD/PELD score. Stratification of patients within a particular MELD/PELD score shall be based on total waiting time currently and previously accrued at that score on the same waiting list registration added to waiting time accrued at any higher MELD/PELD score. For example, if there are 2 persons with a MELD score of 30 who were both of identical blood type with the donor, the patient with the longest accrued

waiting time in MELD score 30 or higher would receive the first offer. Waiting time will not be accrued by patients awaiting a liver transplant while they are registered on the UNOS Patient Waiting List as inactive.

Patients in Status 1 will receive waiting time points based on their waiting time in Status

1. Ten points will be accrued by the patient waiting for the longest period for a liver transplant and proportionately fewer points will be accrued by those patients with shorter tenure. For example, if there were 75 persons of O blood type waiting who were of a size compatible with a blood group O donor, the person waiting the longest would accrue 10 points (75/75 x 10). A person whose rank order was 60 would accrue 2 points. ((75-60)/75 x 10 = 2).

3.6.4 Degree of Medical Urgency. Each patient is assigned a status code or mortality risk score (probability of candidate death) which corresponds to how medically urgent it is that the patient receive a transplant.

3.6.4.1 Adult Patient Status. Medical urgency is assigned to an adult liver transplant patient (greater than or equal to 18 years of age) based on either the criteria defined below for Status 1, or the patient's mortality risk score as determined by the prognostic factors specified in Table 1 and calculated in accordance with the MELD Scoring System. A patient who does not meet the criteria for Status 1, or have a MELD score that, in the judgment of the patient's transplant physician, appropriately reflects the patient's medical urgency, may nevertheless be assigned to Status 1 or a higher MELD score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, by consensus medical judgment, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients listed as Status 1 or having the higher MELD score. The justification must include a rationale for incorporating the exceptional case as part of the Status 1 criteria or the MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the Status 1 and MELD criteria. During the initial implementation of the MELD/PELD scoring system, the minimum listing criteria in effect prior to implementation of the MELD/PELD system (a CTP score of 7) shall remain in effect,

Status	Definition
7	A patient listed as Status 7 is temporarily inactive. Patients who are considered to be temporarily unsuitable transplant patients are listed as Status 7, temporarily inactive.
1	A patient greater than or equal to 18 years of age listed as Status 1 has fulminant liver failure with a life expectancy without a liver transplant of less than 7 days. For the purpose of Policy 3.6, fulminant liver failure shall be defined as:

(i) fulminant hepatic failure defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. While no single clinical observation or laboratory test defines fulminant hepatic failure, the diagnosis is based on the finding of stage II encephalopathy (i.e., drowsiness, inappropriate behavior, incontinence with asterixis) in a patient with severe liver dysfunction. Evidence of severe liver dysfunction may be manifest by some or all of the following symptoms and signs: asterixis (flapping tremor), hyperbilirubinemia (i.e.,

bilirubin>15mg%), marked prolongation of the INR (i.e., >2.5), or hypoglycemia.; or

(ii) primary non-function of a transplanted liver within 7 days of implantation; or

(ii) hepatic artery thrombosis in a transplanted liver within 7 days of implantation; or

(iii) acute decompensated Wilson's disease.

Patients who are listed as a Status 1 automatically revert back to their most recent MELD Score after 7 days unless these patients are relisted as Status 1 by an attending physician. Patients must be listed with MELD laboratory values in accordance with Policy 3.6.4.1.1 (Adult Patient Recertification and Reassessment Schedule) at the time listing. A patient listed as Status 1 shall be reviewed by the applicable UNOS Regional Review Board. In those Regions that have agreed to allow UNOS RRB staff to review standard Status 1 cases, the RRB will only review Status 1 exceptional cases. A completed Liver Status 1 Justification Form must be received by UNOS on UNet℠ for a patient's original listing as a Status 1 and each relisting as a Status 1. If a completed Liver Status 1 Justification Form is not entered into UNET℠ when a candidate is registered as a Status 1, the candidate shall be reassigned to their most recent MELD score. A relisting request to continue a Status 1 listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in a review of all local Status 1 liver patient listings.

All other adult liver transplant candidates on the UNOS Patient Waiting List shall be assigned a mortality risk score calculated in accordance with the MELD scoring system. For each liver candidate registration, the listing transplant center shall enter data on the UNOS computer system for the prognostic factors specified in Table 1. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Table 1
Model for End-Stage Liver Disease (MELD) Scoring System

Prognostic Factor	Regression Coefficient	Std. Error	*P*
Serum creatinine (Log_e value)	0.957	0.142	<0.01
Serum bilirubin (Log_e value)	0.378	0.117	<0.01
INR (Log_e value)	1.120	0.331	<0.01

* The maximum serum creatinine considered within the MELD score equation will be 4.0mg/dl (i.e., for patients with a serum creatinine of greater than 4.0 mg/dl, the serum creatinine level will be set to 4.0 mg/dl). For patients on dialysis, defined as having 2 or more dialysis treatments within the prior week, the serum creatinine level will automatically be set to 4.0 mg/dl.

Using these prognostic factors and regression coefficients, the UNOS computer system shall assign a MELD score for each patient based on the following calculation:

$$\text{MELD Score} = 0.957 \times Log_e(\text{creatinine mg/dL}) + 0.378 \times Log_e(\text{bilirubin mg/dL}) + 1.120 \times Log_e(\text{INR}) + 0.643$$

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the MELD score calculation.

As an example, for a hypothetical patient with cirrhosis caused by hepatitis C virus who has a serum creatinine concentration of 1.9 mg/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:

MELD Score= $(0.957 \times \text{Log}_e 1.9) + (0.378 \times \text{Log}_e 4.2) + (1.120 \times \text{Log}_e 1.2) + 0.643 = 2.039$

The MELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical patient in the example described above, therefore, would be assigned a risk score of 20. The MELD score will be limited to a total of 40 points maximum.

3.6.4.1.1 **Adult Patient Reassessment and Recertification Schedule.** The appropriateness of the MELD score assigned to each patient listing shall be re-assessed and recertified by the listing transplant center to UNOS in accordance with the following schedule:

Adult Patient Reassessment and Recertification Schedule

Status 1	Status recertification every 7 days.	**Laboratory values must be no older than 48 hours.**
MELD Score 25 or greater	Status recertification every 7 days.	**Laboratory values must be no older than 48 hours.**
Score <= 24but > 18	Status recertification every 1 month.	**Laboratory values must be no older than 7 days.**
Score <= 18 but >=11	Status recertification every 3 months.	**Laboratory values must be no older than 14 days.**
Score <= 10 but > 0	Status recertification every 12 months.	**Laboratory values must be no older than 30 days.**

This reassessment and recertification must be based on the most recent clinical information (e.g., laboratory test results and diagnosis), including the dates of the laboratory tests. In order to re-certify, laboratory values must not be older than the "age of laboratory values" specified in the chart above. In order to change a MELD score voluntarily, all laboratory values must obtained on the same day. UNOS shall notify the listing transplant center of the need to reassess and recertify a patient's MELD score within 48 hours of the applicable deadline indicated in the recertification schedule. If a patient is not recertified in accordance with the schedule, the patient shall be re-assigned to their previous lower MELD score. If a patient has no previous lower MELD score, and is not recertified in accordance with the schedule, the patient shall be reassigned to a MELD score of 6.

3.6.4.2 **Pediatric Patient Status.** Medical urgency is assigned to a pediatric liver transplant patient (less than 18 years of age) based on either the criteria defined below for Status 1, or the patient's mortality risk score as determined by the prognostic factors specified in Table 2 and calculated in accordance with the Pediatric End-Stage Liver Disease Scoring System (PELD) A patient who does not meet the criteria for Status 1, does not have a risk of candidate mortality expressed by the PELD score that, in the judgement of the patient's transplant physician, appropriately reflects the patient's medical urgency or was listed at less than 18 years of age and remains on or has been returned to the Waiting List upon or after reaching age 18 may nevertheless be assigned to Status 1 or a higher PELD score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, by consensus medical judgement, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients listed as Status 1 or having the higher PELD score. The justification must include a rationale for incorporating the exceptional case as part of the Status 1criteria or the PELD calculation. A report of the decision of the Regional Review Board and the basis for it

shall be forwarded to UNOS for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the Status 1 and PELD criteria. Data required to compute the MELD score (creatinine, INR, bilirubin) must be entered for all candidates 12 years and older.

Status	Definition
7	A pediatric patient listed as Status 7 is temporarily inactive. Patients who are considered to be temporarily unsuitable transplant patients are listed as Status 7, temporarily inactive.
1	A pediatric patient listed as Status 1 is located in the hospital's Intensive Care Unit (ICU) due to acute or chronic liver failure, has a life expectancy without a liver transplant of less than 7 days and meets at least 1 of the following criteria:

(i) Fulminant hepatic failure defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. While no single clinical observation or laboratory test defines fulminant hepatic failure, the diagnosis is based on the finding of stage II encephalopathy (i.e., drowsiness, inappropriate behavior, incontinence with asterixis) in a patient with severe liver dysfunction. Evidence of severe liver dysfunction may be manifest by some or all of the following symptoms and signs: asterixis (flapping tremor), hyperbilirubinemia (i.e., bilirubin>15mg%), marked prolongation of the INR (i.e., >2.5), or hypoglycemia.

(ii) Primary non-function of a transplanted liver within 7 days of implantation.

(iii) Hepatic artery thrombosis in a transplanted liver within 7 days of implantation.

(iv) Acute decompensated Wilson's disease.

(v) On mechanical ventilator.

(vi) Upper gastro-intestinal bleeding requiring at least 10 cc/kg of red blood cell replacement which continues or recurs despite treatment.

(vii) Hepatorenal syndrome: The presence of progressive deterioration of renal function in a patient with advanced liver disease requiring hospitalization for management, with no other known etiology of renal insufficiency, and a rising serum creatinine 3 times baseline. In addition to these major criteria, the patient should meet at least one of the following: a) urine volume < 10 ml/kg/d; b) urine sodium < 10 mEq/l; or c) urine osmolality > plasma osmolality (U/P ratio > 1.0).

(viii) Stage III or IV encephalopathy unresponsive to medical therapy.

(ix) Refractory Ascites/Hepato-Hydrothorax: Severe persistent ascites or hepatohydrothorax, defined as any one of the following: unresponsive to diuretic and salt restriction therapy leading to respiratory distress, or requiring supplemental tube feeding, or requiring parenteral nutrition, or requiring supplemental oxygen, or requiring paracentesis.

(x) Biliary sepsis requiring pressor support of 5 mcg/kg/min of dopamine or greater.

With the exception of hospitalized pediatric liver transplant candidates with Ornithinine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I,

patients who are listed as a Status 1 automatically revert back to their most recent PELD score after 7 days unless these patients are relisted as Status 1 by an attending physician. Patients must be listed with PELD laboratory values in accordance with Policy 3.6.4.2.1 (Pediatric Patient Recertification and Reassessment Schedule) at the time of listing. A patient listed as Status 1 shall be reviewed by the applicable UNOS Regional Review Board. A completed Liver Status 1 Justification Form must be received by UNOS on UNet^{sm} for a patient's original listing as a Status 1 and each relisting as a Status 1. If a completed Liver Status 1 Justification Form is not entered into UNet^{sm} when a candidate is registered as a Status 1, the candidate shall be reassigned to their most recent PELD score. A relisting request to continue a Status 1 listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in a review of all local Status 1 liver patient listings.

All other pediatric liver transplant candidates on the UNOS Patient Waiting List shall be assigned a mortality risk score calculated in accordance with the PELD scoring system.. For each liver candidate registration, the listing transplant center shall enter data on the UNOS computer system for the prognostic factors specified in Table 2. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Table 2
Pediatric End-Stage Liver Disease (PELD) Scoring System

Prognostic Factor	Regression Coefficient	*P Value*
Albumin (Log_e value)	-0.687	0.0111
Total Bilirubin (Log_e value)	0.480	0.0004
INR (Log_e value)	1.857	<0.0001
Growth Failure (<- 2SD)	0.667	0.009
Age (<1 Yr.)*	0.436	0.11

* Scores for patients listed for liver transplantation before the patient's first birthday continue to include the value assigned for age (<1 Year) until the patient reaches the age of 24 months.

Using these prognostic factors and regression coefficients, the UNOS computer system shall assign a PELD score for each patient based on the following calculation:

PELD Score= 0.436 (Age (<1 YR.)) – 0.687 x Log_e(albumin g/dL) + 0. 480 x Log_e(total bilirubin mg/dL) + 1.857 x Log_e (INR) +0.667 (Growth failure (<- 2 Std. Deviations present))

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the PELD score calculation. Growth failure will be calculated based on age and gender using the current CDC growth chart.

As an example, for a hypothetical patient 6 months of age with growth failure (<-2 standard deviations) who has a serum albumin concentration of 1.9 g/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:

$$\text{PELD Score} = 0.436 - (0.687 \times \text{Log}_e 1.9) + (0.480 \times \text{Log}_e 4.2) + (1.857 \times \text{Log}_e 1.2) + 0.667 = 1.689$$

The PELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical patient in the example described above, therefore, would be assigned a risk score of 17.

3.6.4.2.1 **Pediatric Patient Reassessment and Recertification Schedule.** The appropriateness of the PELD score assigned to each patient listing shall be re-assessed and recertified by the listing transplant center to UNOS in accordance with the following schedule:

Pediatric Patient Reassessment and Recertification Schedule

Status 1	**Status recertification every 7 days.**	**Laboratory values must be no older than 48 hours.**
PELD Score 25 or greater	**Status recertification every ~~7~~ 14 days.**	**Laboratory values must be no older than ~~48~~ 72 hours.**
Score <=24 but > 18	**Status recertification every 1 month.**	**Laboratory values must be no older than 7 days.**
Score <= 18 but >=11	**Status recertification every 3 months.**	**Laboratory values must be no older than 14 days.**
Score <= 10	**Status recertification every 12 months.**	**Laboratory values must be no older than 30 days.**

This reassessment and recertification must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) including the dates of the laboratory tests. In order to recertify, laboratory values must not be older than the "age of laboratory values" specified in the chart above. In order to change a PELD score voluntarily, all laboratory values must be obtained on the same day. UNOS shall notify the listing transplant center of the need to reassess and recertify a patient's PELD score within 48 hours of the applicable deadline indicated in the recertification schedule. If a patient is not recertified in accordance with the schedule, the patient shall be re-assigned to their previous lower PELD score. If a patient has no previous lower PELD score, and is not recertified in accordance with the schedule, the patient shall be reassigned to a PELD score of 6.

NOTE #1: ***The amendments to Policy 3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule) shall be implemented following programming on the UNOS system.***

NOTE #2: ***Only modifications for PELD $\geq$25 were approved.***

NOTE #3: ***The boxes for Status 1 were <u>not</u> amended in the table as originally proposed.***

3.6.4.3 **Pediatric Liver Transplant Candidates with Metabolic Diseases (e.g., OTC or Crigler-Najjar Disease Type I).** A pediatric liver transplant candidate with a metabolic disease such as Ornithine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I shall be assigned the medical urgency ranking, either Status 1 or the PELD score, that, in the judgment of the patient's transplant physician, appropriately reflects the patient's medical urgency upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board. The patient, if not already a Status 1, may be upgraded to a Status 1 if the patient is hospitalized for an acute exacerbation of their disease. The patient shall remain a Status 1 as long as he or she remains hospitalized. Decisions by the Regional Review Boards in these cases shall be guided by standards

developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. Status 1 cases must receive retrospective review by the applicable RRB. Those cases where a higher PELD score is requested must receive prospective approval by the applicable RRB within twenty-one days after application; if approval is not given within twenty-one days, the patient's transplant physician may list the patient at the higher PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

3.6.4.4 **Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).** Patients with Stage I or Stage II HCC in accordance with the modified Tumor-Node-Metastasis (TNM) Staging Classification set forth in Table 3 that meet all of the medical criteria specified in (i) and (ii) may receive extra priority on the waiting list as specified below. A patient with an HCC tumor that is less than 2 cm in size (Stage T1 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to an 8% probability of candidate death within 3 months. A patient with an HCC tumor that is greater than or equal to 2 cm in size or multiple lesions, the largest being less than 3 cm in size (Stage T2 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months. Patients will receive additional MELD/PELD points equivalent to a 10% increase in candidate mortality to be assigned every 3 months until these patients receive a transplant or are determined to be unsuitable for transplantation based on progression of their HCC if the patient meets the criteria specified in (iii). Patients with downsized tumors (i.e., having undergone ablative therapy) whose original/presenting tumor was greater than Stage T2 tumor will be referred to the applicable UNOS liver Regional Review Board (RRB) for prospective review. To receive the additional points at 3-month intervals, the transplant program must re-submit an HCC MELD/PELD score exception application with an updated narrative every three months. Patients with downsized tumors (i.e., having undergone ablative therapy) whose original/presenting tumor was greater than a Stage T2 tumor will be referred to the applicable UNOS liver Regional Review Board (RRB) for prospective review. Patients meeting Stage 1 criteria based on an alpha-fetoprotein level of >= 500 nanograms, as specified in (i) must continue to demonstrate an alpha-fetoprotein level of >=500 nanograms in order to extend the application.

NOTE: The amendments to the Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellur Carcinoma (HCC) shall be implemented following programming on the UNOS system.

(i) The patient has undergone a thorough assessment to evaluate the number and size of tumors and to rule out any extrahepatic spread and/or macrovascular involvement (i.e., portal or hepatic veins). A pre-listing biopsy is not mandatory but the lesion must meet established imaging criteria. The assessment of the patient should include ultrasound of the patient's liver, a computerized tomography (CT) or magnetic resonance imaging (MRI) scan of the abdomen and chest, and a bone scan. In addition, the patient must have one of the following: a tumor > 1 cm in size with a blush corresponding to the area of suspicion seen on the above imaging studies, an alpha-fetoprotein level of >200 ng/ml, an arteriogram confirming a tumor, a biopsy confirming HCC, chemoembolization of lesion, radio frequency, cryo, or chemical ablation of the lesion. The alpha-fetoprotein level is required for all HCC exception applications. Patients with chronic liver disease who alpha-fetoprotein level is >/= 500 nanograms on at lease one occasion may be listed as a Stage I HCC without RRB review even though there is no evidence of a tumor based on imaging studies.

(ii) The patient is not a resection candidate.

(iii) Continued documentation of the tumor via repeat CT or MRI is required every three months for the patient to receive the additional 10% mortality points while waiting. Invasive studies such as biopsies or ablative procedures and repeated bone scans and chest CTs are not required after the initial upgrade request is approved to maintain the patient's HCC priority scores.

If the number of tumors that can be documented at the time of extension is less than upon initial application or prior extension, the type of ablative therapy must be specified on the extension application. For patients whose tumors have been resected since the initial HCC application or prior extension, the extension application must receive prospective review by the applicable RRB.

A patient not meeting the above criteria may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the patient must be listed at the calculated MELD/PELD score with no additional priority given because of the HCC diagnosis. patients meeting all of the criteria in (i) and (ii) will receive a MELD/PELD score based on the tumor stage as described above without RRB review. Patients not meeting these criteria must be prospectively reviewed by the applicable RRB If the initial request is denied by the RRB, the center may appeal but the patient will not receive the additional MELD/PELD priority until the case is approved by the RRB. Cases where the appropriate RRB has found the listing center to be out of compliance with Policy 3.6.4.4 will be referred to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee for review and possible action. Cases not resolved within 21 days will be referred to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

The recipient pathology report must be sent to the UNOS Policy compliance Department for those patients who receive a liver transplant while receiving additional priority under the HCC criteria. Pathology reports that do not specify an HCC tumor will be sent to the Liver and Intestinal Organ Transplantation Committee for review.

Policy 3.6.4.4 will be reevaluated six months after implementation, to assess the appropriateness of the level of MELD/PELD points awarded to these patients.

Table 3
American Liver Tumor Study Group Modified Tumor-Node-Metastasis (TNM) Staging Classification (1)

Classification	Definition
TX, NX, MX	Not assessed
TO, NO, MO	Not found
T1	1 nodule <=1.9 cm
T2	One nodule 2.0-5.0 cm; two or three nodules, all <3.0 cm
T3	One nodule >5.0 cm; two or three nodules, at least one >3.0 cm
T4a	Four or more nodules, any size
T4b	T2, T3, or T4a plus gross intrahepatic portal or hepatic vein involvement as indicated by CT, MRI, or ultrasound
N1	Regional (portal hepatis) nodes, involved
	M1 Metastatic disease, including extrahepatic portal or hepatic vein involvement

Stage I	T1
Stage II	T2
Stage III	T3
Stage IVA1	T4a
Stage IVA2	T4b
Stage IVB	Any N1, any M1

Reference

1. American Liver Tumor Study Group – A Randomized Prospective Multi-Institutional Trial of Orthotopic Liver Transplantation or Partial Hepatic Resection with or without Adjuvant Chemotherapy for Hepatocellular Carcinoma. Investigators Booklet and Protocol. 1998.

3.6.4.4.1 **Pediatric Liver Transplant Candidates with Hepatoblastoma.** A pediatric patient with non-metastatic hepatoblastoma who is otherwise a suitable candidate for liver transplantation may be assigned the medical urgency ranking, either Status 1 or the PELD score, that, in the judgment of the patient's transplant physician, appropriately reflects the patient's medical urgency upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board. Decisions by the Regional Review Boards in these cases shall be guided by standards developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. Status 1 cases must receive retrospective review by the applicable RRB. Those cases where a higher PELD score is requested must receive prospective approval by the applicable RRB, within twenty-one days after application; if approval is not given within twenty-one days, the patient's transplant physician may list the patient at the higher PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

3.6.4.5 **Liver Candidates with Exceptional Cases.** Special cases require prospective review by the Regional Review Board. The center will request a specific MELD/PELD score and shall submit a supporting narrative. The Regional Review Board will accept or reject the center's requested MELD/PELD score based on guidelines developed by each RRB. Each RRB must set an acceptable time for Reviews to be completed, within twenty-one days after application; if approval is not given within twenty-one days, the patient's transplant physician may list the patient at the higher MELD or PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees. Exceptions to MELD/PELD score must be reapplied every three months; otherwise the patient's score will revert back to the patient's current calculated MELD/PELD score. If the RRB does not recertify the MELD/PELD score exception, then the patient will be assigned a MELD/PELD score based on current laboratory values.

3.6.4.5.1 **Liver Candidates with Hepatopulmonary Syndrome (HPS).** Patients with a clinical evidence of portal hypertension, evidence of a shunt, and a $PaO_2 < 60$ on room air may be referred to the RRB for consideration of a MELD score that would provide them a reasonable probability of being transplanted within 3 months. Patients should have no significant clinical evidence of underlying primary pulmonary disease.

3.6.4.5.2 **Liver Candidates with Familial Amyloidosis or Primary Oxaluria.** Patients with familial amyloidosis or primary oxaluria may be referred to the RRB for consideration of a MELD score that would allow them to be transplanted within 3 months.

3.6.4.6 On-Site Review of Status 1 Patient Listings. If a transplant center's listing of patients as Status 1 has been disapproved on 3 occasions at the final review of the applicable regional review board, and the patients receive a transplant while listed at the disapproved status, then UNOS shall conduct an on-site review of that center's Status 1 patient listings. The listing center shall reimburse all necessary and reasonable expenses incurred by UNOS in performing this on-site review. If there are no policy violations and the disapproved listings are found to be appropriate, the center will not be responsible for the necessary and reasonable expenses incurred by UNOS while performing the on-site review.

3.6.4.7 Combined Liver-Intestine Candidates. Patients awaiting a combined liver-intestine transplant who are registered on both waiting lists will automatically receive an increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality. The center must verify that an intestinal transplant is required and took place.

NOTE: New Policy 3.6.4.7 (Combined Liver-Intestine Candidates) shall be implemented following programming on the UNOS system.

3.6.5 Center Contact and Acceptance. Livers shall be offered in descending computer print-out order but the offering calls may be made concurrently (e.g., 5 liver teams may be called and given donor information provided that each team is told its priority number for the liver offer). Policy 3.4.1 (Time Limit for Acceptance) assures that each team will know within one hour whether or not another center with a patient who has higher points has accepted or rejected the offer.

3.6.5.1 Execution of the UNOS Liver Match System. The UNOS match system for liver allocation shall be executed within 8 hours prior to the initial liver offer. This match system printout of the liver transplant patient waiting list shall be utilized by the Host OPO for placement of the donor liver. The liver match system may be re-executed if a previously accepted liver is subsequently turned down because there is a change in specific medical information related to the liver donor. Any re-execution of the liver match system for the same donor for other reasons must be retrospectively reviewed by the Regional Review Board. This policy shall not apply to a donor liver that has been recovered and has not been placed within 2 hours of organ recovery.

3.6.6 Removal of Liver Transplant Candidates from Liver Waiting Lists When Transplanted or Deceased. If a liver transplant candidate on the UNOS Patient Waiting List has received a transplant from a deceased donor, or has died while awaiting a transplant, the listing center, or centers if the patient is multiple listed, shall immediately remove that patient from all liver waiting lists and shall notify UNOS within 24 hours of the event. If the deceased donor liver recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the patient is relisted. If a liver transplant candidate on the UNOS Patient Waiting List has received a transplant from a living donor, the listing center, or centers if the patient is multiple listed, shall immediately transfer that patient to inactive status until the patient requires a subsequent transplant or one year following the date of the patient's prior transplant, whichever is the first to occur. If the patient has not returned to active status during this one-year period, then the listing center, or centers if the patient is multiple listed, shall immediately remove that patient from all liver waiting lists and shall notify UNOS within 24 hours of the event. If the living donor recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the patient is relisted. Data necessary to calculate the patient's current MELD or PELD score is required upon removal from the waiting list.

3.6.7 UNOS Organ Center Assistance with Liver Allocation. It is recommended that the UNOS Organ Center be notified when a liver donor is identified and provided all clinical information that is necessary to offer the liver to potential recipients on the UNOS Patient Waiting List. Upon request by the OPO, the Organ Center shall attempt to locate a liver

recipient on the UNOS Patient Waiting List or identify backup recipients for the liver.

3.6.8 **Local Conflicts.** Regarding allocation of livers, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the UNOS Liver and Intestinal Organ Transplantation Committee and Board of Directors.

3.6.9 **Minimum Information for Liver Offers.**

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to ~~UNOS~~ OPTN Policy 3.4.1 (Time Limit for Acceptance); however, this requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

(i) Donor name and ~~UNOS~~ OPTN Donor I.D. number, age, sex, race, height and weight;
(ii) ABO type;
(iii) Cause of brain death/diagnosis;
(iv) History of treatment in hospital including current medications, vasopressors and hydration;
(v) Current history of hypotensive episodes, urine output and oliguria;
(vi) Indications of sepsis;
(vii) Social and drug activity histories;
(viii) Vital signs including blood pressure, heart rate and temperature;
(ix) Other laboratory tests within the past 12 hours including:
(1) Total Bilirubin
(2) ~~SGOT/~~ASTALT
(3) ~~PT~~ INR (PT if INR not available)
(4) ~~BUN~~ Alkaline phosphatase
(5) ~~Electrolytes~~ GGT
(6) WBC
(7) HH
(8) Creatinine;
(x) Arterial blood gas results;
(xi) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred). ~~for HIV, hepatitis, CMV, HTLV and VDRL/RPR.~~

NOTE: The amendments to Policy 3.6.9 (Minimum Information for Liver Offers) shall be implemented August 1, 2003.

3.6.9.2 **Listing Accuracy and Appropriateness.** Any instance in which an organ is allocated to a recipient center for a transplant candidate and the Host OPO or any UNOS Member questions the accuracy or appropriateness of the candidate's status may be reported retrospectively to the Host OPO's Regional Review Board with reasons for the concern. Upon receipt of two such reports regarding cases from the same institution within a one-year period, the Review Board shall refer the matter to the UNOS Membership and Professional Standards Committee with a request for an on-site audit of the institution.

3.6.10 **Allocation of Livers for Other Methods of Hepatic Support.** A liver shall not be utilized for other methods of hepatic support prior to being offered first for transplantation. Prior to being utilized for other methods of hepatic support, the liver shall be offered by the UNOS Organ Center in descending point order to all Status 1 candidates, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) in the Host OPO's region followed by Status 1 candidates, and then by all candidates in order of the MELD PELD scores (probability of candidate death) in all other regions. If the liver is not accepted

for transplantation within 6 hours of attempted placement by the Organ Center, the Organ Center shall offer the liver to Status 1, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) for whom the liver will be considered for other methods of hepatic support. Livers allocated for other methods of hepatic support shall be offered first locally, then regionally, and then nationally in descending point order to transplant candidates designated for other methods of hepatic support.

3.6.11 Allocation of Livers for Segmental Transplantation. A transplant center that accepts a liver for segmental transplantation shall offer the remaining segment:

(i) in sequence, as determined by the deceased donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers) and defining "local" based upon the Host OPO's local area, to the highest-ranking patient on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the donor organ procurement procedure has started, or

(ii) into patients listed with the recipient program or any medically appropriate candidate on the UNOS Patient Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure has started.

3.6.12 Transition of Currently Listed Patients. Patients listed as Status 2A at the time the MELD system is implemented will be grandfathered into the new system for a period of 30 days following the implementation date. Patients who are still listed as Status 2A at the end of 30 days would be converted to a MELD score based on the MELD criteria. These patients shall be listed on the UNOS match-run printout ahead of patients who are listed by MELD scores and stratified based on the liver allocation criteria specified in UNOS Policy 3.6 in effect prior to implementation of the MELD and PELD scoring systems. At the end of the 30 days, patients still in Status 2A will receive 30 days of waiting time towards their current MELD score. Those patients who no longer meet the Status 2A criteria during the first 30 days will receive time accrued in Status 2A since the implementation.

Patients listed as Status 2B or 3 at the time the MELD and PELD systems are implemented will be converted to a MELD or PELD score based on the MELD or PELD criteria. All waiting time accrued by these patients under the prior status system would apply toward their eligibility for a liver offer under the MELD and PELD system for a period of 1 year while the patients are listed at their initial or lower mortality risk scores under the new system criteria. After 1 year, this previously accrued waiting time will not be counted and only the waiting time accrued under the MELD/PELD system from the date of its implementation would apply toward liver allocation thereafter. If the data required to calculate the MELD or PELD score (as applicable) have not been entered into the UNet℠ system at the time of implementation, the patient will automatically be assigned a MELD or PELD score of 6.

3.6.12.1 **Transition for Currently Listed Status 2B HCC Patients.** Patients listed as Status 2B under the previous HCC criteria at the time the MELD and PELD systems are implemented will receive a MELD score equivalent to a 15% probability of candidate death within 3 months. No additional testing will be required for these patients unless a center wishes to apply for the T2 MELD score as described in policy 3.6.4.4. In these cases, the center must submit documentation that the patient meets the criteria specified in 3.6.4.4(i). Previously accrued waiting time will be applied to the patient's initial or lower MELD score, for a period of one year. These patient's must be reevaluated at 3-months, at which time the new criteria will be applied.

Exhibit 6

National Organ Transplant Act, 1984, UNOS and OPTN Kidney Allocation Policy

3.0 ORGAN DISTRIBUTION

The following policies apply to the allocation of organs for transplantation.

3.5 ALLOCATION OF DECEASED KIDNEYS. Deceased kidneys must be allocated according to the following policies. The final decision to accept a particular organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of the patient. This allows physicians and surgeons to exercise their medical judgment regarding the suitability of the organ being offered for a specific patient; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia time and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If an organ is declined for a patient, a notation of the reason for that decision must be made on the appropriate form and submitted promptly to UNOS.

3.5.1 **Definition of Expanded Criteria Donor and Standard Donor.** For purposes of Policy 3.5 (Allocation of Deceased Kidneys), expanded criteria donors are defined by an "X" in the decision matrix shown below indicating relative risk of graft failure for donors older than 10 years of age > 1.7, based upon the following factors: age, creatinine, CVA, and hypertension. Standard donors are all other donors. Unless specified as an expanded criteria donor or standard donor, the term donor(s) means all donors, expanded and standard. For purposes of distinguishing expanded criteria donors from standard donors, the most recent creatinine at the time of kidney placement shall be used.

Patients who agree to receive expanded criteria donor kidneys shall be eligible also to receive standard donor kidneys according to the policies described below for allocating standard donor kidneys. The program shall obtain consent from patients prior to their being listed for expanded criteria donor kidney transplantation.

Donor Condition	Donor Age Categories				
	< 10	10 – 39	40 – 49	50 – 59	≥ 60
CVA + HTN + Creat > 1.5				X	X
CVA + HTN				X	X
CVA + Creat > 1.5				X	X
HTN + Creat > 1.5				X	X
CVA					X
HTN					X
Creatinine > 1.5					X
None of the above					X

X=Expanded Criteria Donor
CVA=CVA was cause of death
HTN=history of hypertension at any time
Creat > 1.5 = creatinine > 1.5 mg/dl

3.5.2 **ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients.** Blood type O kidneys must be transplanted only into blood type O patients except in the case of zero antigen mismatched patients (as defined in Policy 3.5.3.1) who have a blood type other than O. Additionally, blood type B kidneys must be transplanted only into blood type B patients except in the case of zero antigen mismatched patients (as

defined in Policy 3.5.3.1) who have a blood type other than B. Therefore, kidneys from a blood type O donor are to be allocated only to blood type O patients and kidneys from a blood type B donor are to be allocated only to blood type B patients, with the exception for zero antigen mismatched patients noted above. This policy, however, does not nullify the physician's responsibility to use appropriate medical judgment in an extreme circumstance.

3.5.3 Mandatory Sharing of Zero Antigen Mismatched Kidneys. The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is a patient on the UNOS Patient Waiting List with a zero antigen mismatch:

3.5.3.1 Definition. A zero antigen mismatch is defined as occurring when a patient on the UNOS Waiting List has an ABO blood type that is compatible with that of the donor and the patient and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus. Phenotypic identity means that the donor and patient each has the same antigens identified at each pair of A, B, and DR HLA loci. Patients with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or patient typed as A2, A- (blank) would be considered A2, A2. A zero antigen mismatch would also include cases where both antigens are identified at a locus in the patient but the donor is typed as being homozygous for one of the patient's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14. DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into the UNOS computer system prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any patient on the UNOS Patient Waiting List. Pre-procurement tissue typing is expected consistent with Policy 2.7 (Expedited Organ Procurement and Placement) in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to patient waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to UNOS.

3.5.3.3 Mandatory Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, if there is any patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate UNOS member for the patient with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, if there is any patient on the UNOS Patient Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate UNOS member for the patient with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a patient with a zero antigen mismatch does not have the implicit right to choose between the two kidneys. The final decision as to which of the two kidneys is to be shared rests with

the Host OPO. In lieu of the four additional points for a patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all patients for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

3.5.3.3.1 First to identical blood type zero antigen mismatched patients in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as follows:

i local patients; then to
ii 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
iii 80% or higher PRA patients on the regional waiting list; then to
iv 80% or higher PRA patients on the national waiting list; then to
v less than 80% PRA patients who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
vi less than 80% PRA patients who are less than 18 years old on the regional waiting list; then to
vii less than 80% PRA patients who are less than 18 years old on the national waiting list; then to
viii 21%-79% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
~~vi~~x 21%-79% PRA patients on the regional waiting list; then to
~~vii~~x 21%-79% PRA patients on the national waiting list; then to
~~viii~~xi less than or equal to 20% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
~~ix~~xii less than or equal to 20% PRA patients on the regional waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
xiii less than or equal to 20% PRA patients on the national waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

3.5.3.3.2 Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched patients, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i) – (viii) below, and, then, to blood type A and AB zero antigen mismatched patients, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i) – (viii) below, and (2) in the case of blood type A, B, and AB donor kidneys, to all compatible blood type zero antigen mismatched patients in descending point sequence in the case

of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)– (viii) below:

i local patients; then to

ii 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

iii 80% or higher PRA patients on the regional waiting list; then to

iv 80% or higher PRA patients on the national waiting list; then to

v less than 80% PRA patients who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

vi less than 80% PRA patients who are less than 18 years old on the regional waiting list; then to

vii less than 80% PRA patients who are less than 18 years old on the national waiting list; then to

viii 21%-79% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

~~v~~ix 21%-79% PRA patients on the regional waiting list; then to

~~vii~~x 21%-79% PRA patients on the national waiting list; then to

~~viii~~xi less than or equal to 20% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

~~ix~~ii less than or equal to 20% PRA patients on the regional waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

xiii less than or equal to 20% PRA patients on the national waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

xiv less than or equal to 20% PRA patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt), ranked by OPO in inverse order of the highest number of payback obligations owed by the OPO if more than one OPO is in this category.

NOTE: The amendments to Policy 3.5.3.3 & Policy 3.5.3.4 (Mandatory Sharing) shall be implemented following programming on the UNOS system.

3.5.3.4 Kidney/Non-Renal Exception. When kidneys are procured for the purpose of simultaneous kidney and non-renal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch. In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched patients. This exception does not apply to kidney-islet combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized patients as defined in Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

3.5.3.5 Time Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through the UNOS Organ Center within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta). The UNOS Organ Center will attempt to place standard donor organ(s) for zero antigen mismatched patients according to the national lists of patients waiting for combined kidney/pancreas or isolated kidney transplantation, as applicable, for a period of four hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1 (first locally, then regionally, and then nationally). The period of time allowed for acceptance of zero antigen mismatched standard kidney offers made within the four hours permitted for placing these organs, but with less than an hour before the four hours will expire, shall equal the time remaining within the four-hour period for placement of standard zero mismatched donor kidneys. In the event the Host OPO declines the opportunity to allocate standard donor organ(s) locally, then the UNOS Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of waiting patients. Acceptance of organs declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) even if accepted for a zero antigen mismatched patient. The UNOS Organ Center will attempt to place expanded criteria donor organ(s) for zero antigen mismatched patients according to the national lists of patients waiting for expanded criteria donor kidney transplantation for a period of two hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 (first locally, then regionally, and then nationally) for patients designated as eligible to receive expanded criteria donor kidneys. The period of time allowed for acceptance of zero antigen mismatched expanded criteria donor kidney offers made within the two hours permitted for placing these organs, but with less than an hour before the two hours will expire, shall equal the time remaining within the two-hour period for placement of expanded criteria zero mismatched donor kidneys. Time available for organ acceptance, if shorter than one hour, shall be communicated with the organ offer. The UNOS Organ Center will document each offer and each response.

3.5.4 **Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates.** An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with the donor, who is also a candidate for a combined kidney-pancreas transplant, must be accompanied by an offer of the pancreas from the donor. For purposes of this policy, "highly sensitized" is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.

3.5.4.1 Mandatory Sharing. When kidneys are procured with the option of simultaneous kidney and pancreas transplantation, if there is any highly sensitized patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney and pancreas from that donor shall be offered to the appropriate UNOS member for the patient with the zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting.

3.5.5 **Payback Requirements.** Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen

mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable donor, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated four or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than four.

3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated four or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for kidneys allocated for a kidney-pancreas transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than four.

3.5.5.2 **Exception for Prior Living Organ Donors.** Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed

in Policy 3.5.3.3 (Mandatory Sharing).

3.5.6 Geographic Sequence of Deceased Kidney Allocation. In general, kidneys are to be allocated locally first, then regionally, and then nationally.

3.5.6.1 Local Allocation. With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5 or 3) are allocated according to a voluntary organ sharing arrangement as provided in Policy 3.4.6, all kidneys will be allocated first to local patients as defined in Policy 3.1.7 the locale where the kidneys are procured.

3.5.6.2 Regional Allocation. If a standard donor kidney is not accepted by any of the local transplant centers for local patients, the kidney is to be allocated next via the regional list consisting of all patients listed on the Waiting Lists of other UNOS Members within the same UNOS region as the UNOS member which procured the kidney. When a standard donor kidney is allocated regionally, it is to be offered to UNOS Members for specific patients in the region according to the point system described in Policy 3.5.11 in descending point order beginning with the patient in the region who has been assigned the highest number of points. With all regionally-shared standard donor kidneys, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points to seek alternate patients within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the patient. Selection of alternate patients must be according to the UNOS point system for standard kidney allocation. If a local potential recipient(s) who has agreed to receive expanded criteria donor kidneys is not identified (*i.e.*, a match run and process for notifying the appropriate transplant program(s) initiated) within six hours post cross clamping of the donor aorta, the kidney is to be allocated next via the regional list consisting of all patients who have agreed to receive expanded criteria donor kidneys listed on the Waiting Lists of other UNOS Members within the same UNOS region as the UNOS member which procured the kidney. When an expanded criteria donor kidney is allocated regionally, it is to be offered to UNOS Members for specific patients in the region according to the point system described in Policy 3.5.12 in descending point order beginning with the patient who has agreed to receive expanded criteria donor kidneys in the region who has been assigned the highest number of points. With all regionally-shared expanded criteria donor kidneys, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points to seek alternate patients who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the patient. Selection of alternate patients must be according to the UNOS point system for expanded criteria kidney allocation.

3.5.6.3 National Allocation. If a standard donor kidney is not accepted by any transplant center in the UNOS region in which the UNOS member which procured the kidney is located, the kidney is to be allocated to UNOS Members for specific patients in the other UNOS regions nationally according to the point system described in Policy 3.5.11 in descending point order beginning with the patient who has the highest number of points. With all nationally shared standard donor kidneys, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points to seek alternate patients within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that patient. Selection of alternate patients must be according to the UNOS point system for standard donor kidney allocation. If an expanded criteria donor kidney is not accepted by any transplant center in the UNOS region in which the UNOS member which procured the kidney is located, the kidney is to be allocated to UNOS Members for specific patients who have agreed to receive expanded criteria donor kidneys in the other UNOS regions nationally according to

the point system described in Policy 3.5. 12 in descending point order beginning with the patient who has the highest number of points. With all nationally shared expanded criteria donor kidneys, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points to seek alternate patients who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that patient. Selection of alternate patients must be according to the UNOS point system for expanded criteria donor kidney allocation.

3.5.6.4 UNOS Regions. UNOS Members belong to the UNOS region in which they are located. The UNOS regions are as follows:

Region 1 -	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Region 2 -	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
Region 3 -	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 4 -	Oklahoma, Texas
Region 5 -	Arizona, California, Nevada, New Mexico, Utah
Region 6 -	Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 7 -	Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 8 -	Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
Region 9 -	New York
Region 10 -	Indiana, Michigan, Ohio
Region 11 -	Kentucky, North Carolina, South Carolina, Tennessee, Virginia

3.5.7 **Double Kidney Allocation.** Kidneys from adult donors must be offered singly unless the donor meets at least two of the following conditions and the OPO would not otherwise use the kidneys singly:

(i) Donor age greater than 60 years;
(ii) Estimated donor creatinine clearance less than 65 ml/min based upon serum creatinine upon admission;
(iii) Rising serum creatinine (greater than 2.5 mg/dl) at time of retrieval;
(iv) History of medical disease in donor (defined as either longstanding hypertension or diabetes mellitus);
(v) Adverse donor kidney histology (defined as moderate to severe glomerulosclerosis (greater than 15% and less than 50%)).

Kidneys offered for double kidney allocation will be allocated, first locally, then regionally, and then nationally, according to the sequence and point system described in Policies 3.5.6 and 3.5.11.

3.5.8 **Expanded Criteria Donor Kidney Allocation.** Kidneys from expanded criteria donors must be offered for patients who have agreed to receive these organs in accordance with the geographic sequence of deceased kidney allocation set forth in Policy 3.5.6 and pursuant to the point system described in Policy 3.5.12.

3.5.9 **Minimum Information/Tissue for Kidney Offer.** The Host OPO must provide the following information to the potential recipient center with each kidney offer:

(i) Donor name and ~~UNOS~~ OPTN Ddonor I.D. number, age, sex, and race;
(ii) Date of admission for the current hospitalization;
(iii) Diagnosis;
(iv) Blood type;

(v) HLA typing;
(vi) Current history of abdominal injuries and operations;
(vii) Pertinent past medical or social history;
(viii) Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
(ix) Final urinalysis;
(x) Final BUN and creatinine;
(xi) Indications of sepsis;
(xii) Assurance that final blood and urine ~~or ureter tips~~ cultures are pending;
(xiii) ~~Pre-transfusion serology including:~~ Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
~~(1) Hepatitis B surface antigen~~
~~(2) Anti-HIV 1 and 2~~
~~(3) Anti-HTLV 1~~
~~(4) RPR/VDRL~~
(xiv) Current medication and transfusion history;
(xv) Recovery blood pressure and urine output information;
(xvi) Recovery medications;
(xvii) Type of recovery procedure (e.g., en bloc); flush solution and method (e.g., in situ); and flush storage solution;
(xviii) Description of typing material available, including, as a minimum for each kidney:
- ~~Two~~ One 7 to 10ml. clot (red topped) tubes, plus
- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm wedge of spleen in culture medium, if available
- ~~Either:~~

~~5 lymph nodes and one 2 X 4 cm. wedge of spleen in culture medium (and, if possible 40 ml. of peripheral blood in ACD (yellow-topped) tubes;~~

~~Or (if the spleen cannot be recovered) 8 lymph nodes and 40 ml. of peripheral blood in ACD (yellow-topped) tubes;~~

~~Or (if the spleen cannot be recovered and there is no additional peripheral blood) 12 lymph nodes;~~

~~Or (if nodes and additional peripheral blood are not available) three 2 X 4 cm. wedges of spleen in culture medium;~~

~~Or for pediatric donors, the amount of blood to be drawn or tissue to be collected will be at the discretion of the physician responsible for donor management.~~

(xix) Warm ischemia time and organ flush characteristics; and
(xx) Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood vessels, ureter(s) or kidney.

***NOTE:** The amendments to Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) shall be effective August 1, 2003.*

3.5.10 Preservation Mode of Shared Kidneys. Unless agreed upon in advance by the Host OPO and recipient center, a recipient center shall not change the preservation mode until the final crossmatch is complete and it is certain that the recipient center will use the kidney.

3.5.11 The Point System for Kidney Allocation. When information about a standard donor is entered into the UNOS Match System, all patients who have an ABO blood type that is compatible with that of the donor and who are listed as active on the UNOS Patient Waiting List will be assigned points and priority as follows:

3.5.11.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active patient listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on the UNOS Computer; provided, however, that "time of waiting" under this policy shall not precede the date of the patient's listing. Programs must be able to verify with appropriate supporting documentation, supplementing the Waiting Time Qualification Form referred to below, that the patient met the criteria as of the date submitted; this documentation will be subject to audit by UNOS either through on site audits or otherwise upon request for submission to UNOS. A completed kidney-kidney/pancreas Waiting Time Qualification Form documenting satisfaction of the criteria must be received by UNOS within 24 hours of entry of the information on the Computer ~~(See Policy 3.2.5 regarding accrual of waiting time while a patient is listed as inactive)~~:

- measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of dialysis.

"Time of waiting" for candidates listed for an isolated kidney or combined kidney/pancreas transplant who are less than 18 years old begins when the patient is placed on the UNOS Patient Waiting List. Candidates, regardless of age, shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

NOTE #1: *The amendments to Policy 3.5.11.1 (The Point System for Standard Donor Kidney Allocation – Time of Waiting) shall be implemented following programming on the UNOS system.*

NOTE #2 *Modifications apply to ALU's as well as the national system.*

3.5.11.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the patient waiting for the longest period with fractions of points being assigned proportionately to all other patients, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point (75/75 x 1 = 1). The next person in order would receive a fraction of one point defined by the following equation: 74/75 x 1 = X. For each full year of waiting time a patient accrues, an additional 1 point will be assigned to that patient. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only patients on the local Patient Waiting List. The regional points calculation includes only patients on the regional list, without the local patients. The national points calculation includes all patients on the national list excluding all patients listed on the Host OPO's local and regional lists.

3.5.11.2 Quality of Antigen Mismatch. Points will be assigned to a patient based on the

number of mismatches between the patient's antigens and the donor's antigens at the DR locus. An antigen mismatch occurs when a donor antigen would be recognized by the recipient as being different from the recipient's own antigens. Quality of match points are assigned as follows:

- 2 points if there are no DR mismatches, as defined in the table below or;
- 1points if there is 1 DR mismatch as defined in the table below.

UNOS HLA Mismatch Definitions*

Mismatch Category	# HLA Locus Mismatches		
	A	B	DR
0 ABDR MM	0	0	0
0 DR MM	0	1	0
	0	2	0
	1	0	0
	1	1	0
	1	2	0
	2	0	0
	2	1	0
	2	2	0
1 DR MM	0	0	1
	0	1	1
	0	2	1
	1	0	1
	1	1	1
	1	2	1
	2	0	1
	2	1	1
	2	2	1

- Antigens that UNOS considers to be equivalent for matching purposes are currently shown in Appendix C of the UNOS Computer User's Manual.

There is a pair of antigens at each HLA locus. Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus (i.e., When only one of the antigens in the pair at an HLA locus is identified, the other antigen is presumed to be identical). For example, a donor typed as A2, A-(blank) would be considered A2, A2. In the following example, the recipient would receive 2points for having a zero, DR mismatch (no mismatches at DR locus) because the recipient would not recognize any DR donor antigens as foreign.

Donor Phenotype	Recipient Phenotype
A23, A- (blank)	A1, A9
B7, B8	B7, B8
DR, DR4	DR1, DR4

3.5..11.3 Panel Reactive Antibody. A patient will be assigned 4 points if he or she has panel reactive antibody (PRA) level of 80% or greater based upon historical or current serum samples, as used for crossmatch to determine suitability for transplant, and there is a negative preliminary crossmatch between the donor and that patient. For geographic allocation units with UNOS approved renal allocation variances that assign points for PRA level, PRA points will also be assigned based on the historic or current serum sample as used for crossmatch to determine crossmatch suitability.

3.5.11.4 Medical Urgency. No points will be assigned to patients based upon medical urgency for regional or national allocation of kidneys. Locally, the patient's physician has the authority to use medical judgment in assignment of medical urgency points if there is only one renal transplant center. When there is more than one local renal transplant center, a cooperative medical decision is

required prior to assignment of medical urgency points.

3.5.11.5 Pediatric Kidney Transplant Candidates. Kidney transplant candidates who are less than 11 years old shall be assigned four additional points for kidney allocation. Candidates who are 11 years old or older but less than 18 years old will be assigned three additional points for kidney allocation. These points shall be assigned when the candidate is registered on the UNOS Patient Waiting List and retained until the candidate reaches 18 years of age.

3.5.11.5.1 Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals. Kidneys that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing and who have not received a kidney transplant within the time periods set forth in Policy 3.5.11.5.2 irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed patients based upon total points assigned under UNOS policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these patients in descending point sequence with the patient having the highest number of points receiving the highest priority. The priority assigned for pediatric patients under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates) or in satisfaction of payback debts pursuant to Policy 3.5.5 (Payback Requirements).

3.5.11.5.2 Pediatric Goals for Transplanting Kidney Transplant Candidates. The goals for transplanting pediatric kidney transplant candidates are as follows:

(a) Candidates 0-5 years old at time of listing- within 6 months of listing.
(b) Candidates 6-10 years old at time of listing- within 12 months of listing.
(c) Candidates 11-17 years old at time of listing- within 18 months of listing.

3.5.11.6 Donation Status. A patient will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the patient's physician must provide UNOS with the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other patient information required to be submitted under UNOS policy. Additionally, at the local level of organ distribution only, patients assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these patients according to length of time waiting.

3.5.12 **The Point System for Expanded Criteria Donor Kidney Allocation.** When information about an expanded criteria donor is entered into the UNOS Match System, all patients who have agreed to receive expanded criteria donor kidneys, have an ABO blood type that is compatible with that of the donor, and who are listed as active on the UNOS Patient Waiting List will be assigned points and priority as follows:

3.5.12.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active patient listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on the UNOS Computer; provided, however, that "time of waiting" under this policy shall not precede the date of the patient's listing. Programs must be able to verify with appropriate supporting documentation, supplementing the Waiting Time Qualification Form referred to below, that the patient met the criteria as of the date submitted; this documentation will be subject to audit by UNOS either through on site audits or otherwise upon request for submission to UNOS. A completed kidney-kidney/pancreas Waiting Time Qualification Form documenting satisfaction of the criteria must be received by UNOS within 24 hours of entry of the information on the Computer ~~(See Policy 3.2.5 regarding accrual of waiting time while a patient is listed as inactive)~~:

- measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of dialysis.

"Time of waiting" for candidates listed for an isolated kidney or combined kidney/pancreas transplant who are less than 18 years old begins when the patient is placed on the UNOS Patient Waiting List. Candidates, regardless of age, shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

NOTE #1: ***The amendments to Policy 3.5.12.1 (The Point System for Expanded Criteria Donor Kidney Allocation – Time Waiting) shall be implemented following programming on the UNOS system.***

NOTE #2 ***Modifications apply to ALU's as well as the national system.***

3.5.12.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the patient waiting for the longest period with fractions of points being assigned proportionately to all other patients, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point (75/75 x 1 = 1). The next person in order would receive a fraction of one point defined by the following equation: 74/75 x 1 = X. For each full year of waiting time a patient accrues, an additional 1 point will be assigned to that patient. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only patients on the local Patient Waiting List. The regional points calculation includes only patients on the regional list, without the local patients. The national points calculation includes all patients on the national list excluding all patients listed on the Host OPO's local and regional lists.

3.5.13 **Choice of Right Versus Left Donor Kidney.** Except in the case of donor kidney(s) offered for zero antigen mismatched patients under Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) or for kidney and non-renal organ transplantation, the recipient center offered a kidney for a patient based upon priority on the waiting list may selects which of the

two kidneys it will receive, if both kidneys from the donor are transplantable.

3.5.14 **Broad and Split Antigen Specificities**. HLA ~~M~~matching of A, ~~and~~ B, and DR locus antigens is based on the antigens which are listed in Appendix 3A. Appendix 3A will be updated annually by the UNOS Histocompatibility Committee. For matching purposes, split antigens not on this list will be indicated on the UNOS Patient Waiting List as the parent antigens and will match only with the corresponding parent antigens. Laboratories are encouraged to assign all splits.

NOTE: The amendments to Policy3.5.14 (Broad and Split Antigen Specificities) shall be implemented following programming on the UNOS system.

3.5.15 **Local Conflicts**. Regarding allocation of kidneys, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the UNOS Kidney and Pancreas Transplantation Committee and Board of Directors.

3.5.16 **Allocation of Deceased Kidneys with Discrepant HLA Typings**. Allocation of deceased kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the donor, the kidney may be allocated in accordance with the original HLA typing, or the recipient center may reallocate the kidney locally, according to UNOS Policy 3.5.

Exhibit 7

New England Journal of Medicine
The Effects of the Volume of Procedures at Transplantation Centers on Mortality After Liver Transplantation

THE EFFECT OF THE VOLUME OF PROCEDURES AT TRANSPLANTATION CENTERS ON MORTALITY AFTER LIVER TRANSPLANTATION

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ABSTRACT

Background For many complex surgical procedures there is an association between a low volume of procedures and an increased risk of death for the patients who undergo the procedures.

Methods We examined the effect of the volume of procedures at transplantation centers on the risk of death after liver transplantation. We analyzed all liver transplantations performed in the United States between October 1, 1987, and April 30, 1994. Because the results for 1987 to 1991 were largely similar to those from 1992 to 1994, we focused on the more recent period.

Results Between January 1, 1992, and April 30, 1994, 47 centers performed 20 or fewer liver transplantations each per year (total, 837 transplantations) and were designated low-volume centers, and 52 centers performed more than 20 transplantations each per year (total, 6526) and were designated high-volume centers. The one-year mortality rate for the low-volume centers was 25.9 percent, as compared with 20.0 percent for the high-volume centers. Thirteen centers, all of which had low volumes, had one-year mortality rates of more than 40 percent. Low-volume centers that were affiliated with high-volume centers, such as pediatric transplantation programs, had results similar to those of the high-volume centers. The one-year mortality rate at unaffiliated low-volume centers was 28.3 percent, as compared with a rate of 20.1 percent for the group of all high-volume centers plus affiliated low-volume centers ($P<0.001$).

Conclusions As a group, liver-transplantation centers in the United States that perform 20 or fewer transplantations per year have mortality rates that are significantly higher than those at centers that perform more than 20 transplantations per year. Information regarding the outcome of liver transplantation at transplantation centers should be made widely available to the public. (N Engl J Med 1999;341:2049-53.)
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CURRENTLY, organ transplantation is limited by the availability of donor organs. In the United States, there have been small increases in the number of donor organs available. Nonetheless, since 1994, a rapid rise in the number of patients awaiting transplantation has led to longer waiting times and a greater number of deaths each year among patients on waiting lists for transplants. The death of a patient soon after transplantation also represents the loss of an organ that might have saved another patient's life.

In 1994, Hosenpud et al.[1] analyzed the effect of the volume of procedures at transplantation centers on survival after cardiac transplantation. They found that the risk of death was 33.1 percent higher 12 months after transplantation in centers that performed fewer than nine transplantations per year than in those that performed nine or more procedures. A multivariate analysis demonstrated that the risk of death was independent of differences in the characteristics of the patients from center to center. We used the same methods to examine the effect of the volume of procedures on the risk of death after liver transplantation.

METHODS

We analyzed all liver transplantations performed in the United States between October 1, 1987, and April 30, 1994. We excluded recipients of partial liver transplants from living donors and patients who underwent multiorgan transplantations, in which the liver and other organs from a single donor are transplanted into one recipient. The data were verified by the individual transplantation centers and organ-procurement organizations in conjunction with the *1997 Report of Center-Specific Graft and Patient Survival Rates*,[2] a study of the outcome of all solid-organ transplantations conducted under the auspices of the Health Resources and Services Administration of the Department of Health and Human Services.

To estimate the effect of the volume of procedures at a center on the risk of death after transplantation while controlling for differences among centers in the donors' and recipients' characteristics, we used a generalized additive model, an extension of standard logistic regression.[3] This model is a useful exploratory tool for obtaining simultaneous estimates of the effects of covariates that may be nonlinear. Many of the donor and recipient covariates included in the model were used in the analysis of liver-transplantation outcomes in the *1997 Report of Center-Specific Graft and Patient Survival Rates*.[2] The list of covariates included characteristics of the recipients (the number of previous transplantations, age, race, diagnosis, medical condition at the time of transplantation, the serum creatinine concentration at transplantation, and the year of transplantation) and factors related to the donor (age, race, and the duration of cold ischemia).

The outcome measure was the mortality rate one year after transplantation. To determine the relation between the volume of procedures and the risk of death, we determined the average number of transplantations performed per year at each center. The log-transformed value was included as an additional covariate in the generalized additive model; log transformation corrected for the fact that there were only a few centers with very large volumes. An estimate of the effect of the number of procedures performed per year was calculated on the basis of data obtained during two periods: October 1, 1987, to December 31, 1991, and January 1, 1992, to April 30, 1994. Rather than choose arbitrary volume catego-

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TABLE 1. CHARACTERISTICS OF THE LIVER-TRANSPLANTATION CENTERS, ACCORDING TO THE AVERAGE NUMBER OF PROCEDURES PERFORMED PER YEAR, 1987–1994.

VARIABLE	≤20 PROCEDURES/YR	>20 PROCEDURES/YR	TOTAL
October 1, 1987, to December 31, 1991			
No. of centers	61	27	88
No. of transplantations	1946	7677	9623
No. of patients	1738	6622	8360
1-Year mortality (%)	29.9	25.1	26.1
Patients with complete follow-up data at 1 year (%)	99.5	99.6	99.6
January 1, 1992, to April 30, 1994			
No. of centers	47	52	99
No. of transplantations	837	6526	7363
No. of patients	770	5929	6699
1-Year mortality (%)	25.9	20.0	20.7
Patients with complete follow-up data at 1 year (%)	95.9	94.8	95.0

ries, we grouped the centers into two categories on the basis of these analyses.

Many low-volume centers were identified as being closely affiliated with adjacent centers that had high volume; many of these affiliated centers were pediatric programs in separate but affiliated pediatric hospitals. In a preliminary analysis, we found that the outcome was markedly poorer at low-volume centers that were not affiliated with high-volume centers than at all other centers as a group. Therefore, for some analyses, the centers were subcategorized as affiliated or unaffiliated.

To determine the final estimate of the effect of the number of procedures performed per year on the one-year mortality rate, we entered the data for 1992 to 1994 into a multivariate logistic-regression model in which the response variable was the death of the patient within one year after transplantation. In this model, rather than excluding patients with insufficient follow-up, we weighted the data on patients who were not followed up for one year.[3] An indicator variable was created for the category of the center as determined from the generalized additive model, and this variable was included in the logistic-regression model along with the donor and recipient covariates. The modal category or mean values were used for covariates with missing data; for example, data on the duration of cold ischemia were missing for 6.7 percent of transplantations, whereas data on other covariates were missing for less than 1 percent.

Because follow-up was not complete, particularly in the case of transplantations performed in 1992 or later, unadjusted mortality rates were calculated according to the Kaplan–Meier method.[4] All statistical calculations were performed with S-Plus for Windows (version 3.3, StatSci, Seattle) or SAS (version 6.09, SAS Institute, Cary, N.C.) statistical software. In the analysis of the patients' characteristics, the chi-square test was used for categorical variables[5] and the t-test was used for continuous variables.[6] Differences in survival curves were compared with the use of the log-rank test.[7] All reported P values are two-sided.

RESULTS

Table 1 shows the number of transplantation centers and the number of transplantations performed from October 1, 1987, to December 31, 1991, and from January 1, 1992, to April 30, 1994. Between January 1, 1992, and April 30, 1994, 47 centers performed 20 or fewer liver transplantations each per year and 52 performed more than 20 per year. The centers in the low-volume group (20 or fewer transplantations per year) performed 11 percent of all transplantations during this period, whereas high-volume centers (more than 20 procedures per year) performed 89 percent.

The relation between the number of procedures performed per year and the mortality rate one year after liver transplantation from 1992 to 1994, as determined by the generalized additive model, is shown in Figure 1 and closely resembles the findings for the period from 1987 to 1991 (data not shown). During both periods, mortality rates stabilized at centers that performed more than 20 transplantations per

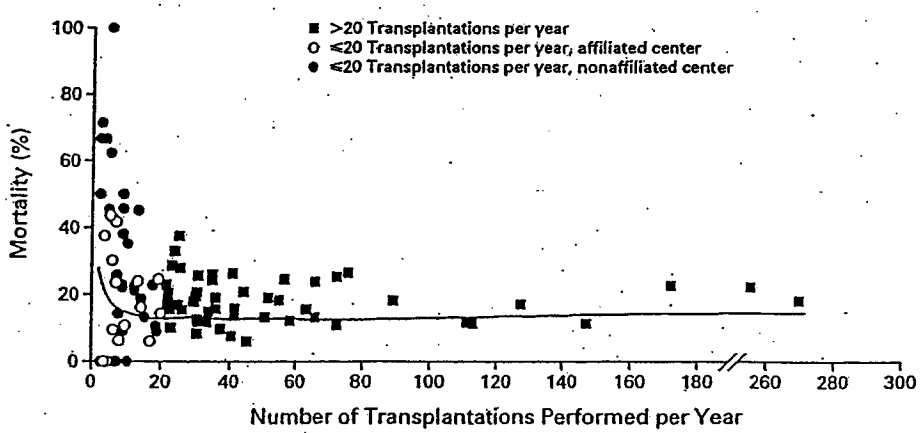

Figure 1. Relation between the Number of Procedures Performed per Year and the Mortality Rate One Year after Liver Transplantation at 99 Centers from January 1, 1992, to April 30, 1994.

An affiliated center was one that was closely affiliated with an adjacent high-volume center.

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TABLE 2. RELATION BETWEEN THE NUMBER OF PROCEDURES PERFORMED PER YEAR AND AFFILIATION STATUS AND THE RISK OF DEATH ONE YEAR AFTER LIVER TRANSPLANTATION, 1992–1994.

GROUP	NO. OF TRANSPLANTATIONS	NO. OF CENTERS	1-YEAR MORTALITY	ADJUSTED ODDS RATIO (95% CI)*
			%	
Affiliated centers performing ≤20 transplantations per year	309	15	21.8	1.06 (0.74–1.50)
Unaffiliated centers performing ≤20 transplantations per year	528	32	28.3	2.08 (1.65–2.61)
Affiliated centers performing >20 transplantations per year	995	11	18.2	1.11 (0.91–1.35)
Unaffiliated centers performing >20 transplantations per year	5531	41	20.4	1.00†
Unaffiliated centers performing ≤20 transplantations per year	528	32	28.3	2.04 (1.63–2.55)
Affiliated centers performing ≤20 transplantations per year plus all centers performing >20 transplantations per year	6835	67	20.1	1.00†

*Odds ratios were adjusted for the donor's age and race and for the recipient's age, race, diagnosis, number of previous liver transplantations, serum creatinine concentration at transplantation, medical condition at transplantation, and year of transplantation. CI denotes confidence interval.

†This group served as the reference group.

year and increased inversely with transplantation volumes of less than 20 per year. Thirteen centers, all of which had low volumes, had mortality rates of 40 percent or more. Accordingly, using the data for 1992 to 1994, we grouped centers into those that performed 20 or fewer transplantations per year and those that performed more than 20 per year.

We used logistic-regression analysis to estimate the odds of death at one year for transplantations performed during the period from 1992 to 1994 at centers categorized according to the number of procedures per year and affiliation status, after adjustment for the following covariates: donor's age and race and recipient's age, race, diagnosis, number of previous liver transplantations, serum creatinine concentration at the time of transplantation, medical condition at the time of transplantation, and year of transplantation. The performance of affiliated low-volume centers and affiliated high-volume centers was similar, as was the performance of affiliated and unaffiliated high-volume centers (Table 2). In a separate comparison of low-volume centers, the odds of death within one year after liver transplantation at all unaffiliated centers was nearly twice that at all affiliated centers (adjusted odds ratio, 1.97; 95 percent confidence interval, 1.32 to 2.94). Therefore, in the remainder of the analyses, the centers were divided into two groups: unaffiliated low-volume centers and high-volume centers plus affiliated low-volume centers. As compared with the odds of death for the entire group of high-volume centers and affiliated low-volume centers, the odds ratio for death at low-volume unaffiliated centers was 2.04 (95 percent confidence interval, 1.63 to 2.55).

The characteristics of the donors and the liver-transplant recipients are shown in Table 3. Donors and recipients at unaffiliated low-volume centers were younger than those at high-volume centers and affiliated low-volume centers. The percentage of recipients who were less than 18 years of age was similar in the two groups. Recipients at unaffiliated low-volume centers were more likely to be black and less likely to have received a previous liver transplantation. Figure 2 shows Kaplan–Meier estimates of survival at one year. The survival rates were significantly higher ($P<0.001$) in the group of high-volume centers and affiliated low-volume centers than in the unaffiliated low-volume centers. The difference in mortality rates between the two groups was 6.8 percentage points at 90 days and 8.2 percentage points at 1 year (Table 3).

It has been suggested that the sickest liver recipients may have a higher risk of death if they undergo transplantation at low-volume centers. Using the logistic-regression model, we tested this hypothesis for recipients of a second transplant and for those who were receiving life support at the time of transplantation. Patients who were receiving life support at the time of transplantation had a higher risk of death if they underwent the procedure at an unaffiliated low-volume center rather than at a high-volume center or an affiliated low-volume center (mortality rate, 51.4 percent vs. 39.3 percent; adjusted odds ratio, 2.2; 95 percent confidence interval, 1.25 to 3.74). For recipients of a second or subsequent transplant, the mortality rate was 64.4 percent at unaffiliated low-volume centers, as compared with 41.3 percent at the other centers (adjusted odds ratio, 3.1; 95 percent confidence interval, 0.99 to 9.88). The wide confidence intervals reflect the small number of recipients of a second or subsequent transplant at low-volume centers (31 recipients).

DISCUSSION

We found that, as a group, liver-transplantation centers in the United States that perform 20 or fewer transplantations per year had mortality rates that were significantly higher than those at centers that perform more than 20 transplantations per year. The effect on mortality of the number of procedures performed per year was even greater when low-volume centers that were affiliated with a high-volume center were compared with low-volume centers that were not so affiliated. In the initial analysis, we found that

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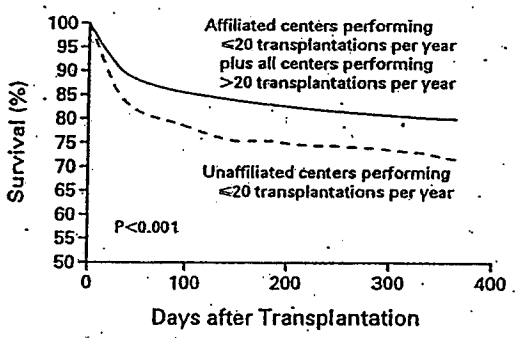
TABLE 3. CHARACTERISTICS OF LIVER-TRANSPLANT DONORS AND RECIPIENTS, 1992–1994.*

CHARACTERISTIC	AFFILIATED CENTERS PERFORMING ≤20 TRANSPLANTATIONS PER YEAR PLUS ALL CENTERS PERFORMING >20 TRANSPLANTATIONS PER YEAR (N=6835)	UNAFFILIATED CENTERS PERFORMING ≤20 TRANSPLANTATIONS PER YEAR (N=528)	P VALUE
Donors			
Age — yr	30.7±0.2	28.6±0.7	<0.001
Race — no. (%)			
White	5352 (78.3)	384 (72.7)	0.003
Black	782 (11.4)	66 (12.5)	
Other	701 (10.3)	78 (14.8)	
Recipients			
Age — yr	42.0±0.2	39.8±0.8	0.004
Age <18 yr — %	14.5	14.4	
Race — no. (%)			
White	5232 (76.6)	380 (72.0)	<0.001
Black	502 (7.3)	67 (12.7)	<0.001
Other	1101 (16.1)	81 (15.3)	
Previous liver transplantation — no. (%)	812 (11.9)	31 (5.9)	0.003
Diagnosis — no. (%)			
Cholestatic liver disease or cirrhosis	1153 (16.9)	85 (16.1)	
Other type of cirrhosis	3854 (56.4)	319 (60.4)	
Cancer	234 (3.4)	13 (2.5)	
Other	1594 (23.3)	111 (21.0)	
Medical condition at transplantation — no. (%)			
Hospitalized in intensive care unit			
Not receiving life support	1554 (22.7)	108 (20.5)	
Receiving life support	986 (14.4)	71 (13.4)	
Hospitalized but not in intensive care unit	1346 (19.7)	114 (21.6)	
Other	2949 (43.1)	235 (44.5)	
Mortality rate — %			
At 90 days	14.1	20.9	<0.001
At 1 yr	20.1	28.3	<0.001

*Plus–minus values are means ±SE.



NO. AT RISK					
Affiliated centers performing ≤20 transplantations per year plus all centers performing >20 transplantations per year	6835	5787	5473	5299	4577
Unaffiliated centers performing ≤20 transplantations per year	528	405	381	371	344

Figure 2. Kaplan–Meier Estimates of Survival at One Year, According to the Number of Transplantations Performed per Year.

An affiliated center was one that was closely affiliated with an adjacent high-volume center.

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a significant number of children underwent transplantation at affiliated low-volume centers and that the results were similar to those at high-volume centers.

The increased risk of death in the unaffiliated low-volume centers did not appear to be an effect of the patients selected. Patients who are in the intensive care unit and those who are receiving life support at the time of liver transplantation have a higher risk of death than do healthier liver-transplant recipients.[2] The percentages of transplantations that were performed in patients who were receiving life support or were in the intensive care unit at the time of the procedure were similar in unaffiliated low-volume centers and the entire group of affiliated low-volume centers plus all high-volume centers. The outcome of transplantation for these sicker patients was poorer at the unaffiliated low-volume centers. A higher percentage of black patients underwent transplantation at low-volume unaffiliated centers. Black patients have a higher mortality rate after liver transplantation than white patients.[8] Our analysis adjusted for the potential effect of the recipient's race on the risk of death.

We found that some centers that perform 20 or fewer liver transplantations per year had a low mortality rate. In part, this may reflect statistical variation. It may also reflect other factors that we were unable to measure.

The association between a low volume of procedures and an increased risk of death among patients undergoing complex surgical procedures is well established.[9,10] It is therefore not surprising that we found an association between the number of procedures performed per year and the outcome of liver transplantation. The responsible factors might include the experience of the center and the experience and skill of the surgeons. In the case of heart transplantation,[1] Hosenpud et al. found no difference in the risk of death among the first 10 patients who underwent transplantation at a center as compared with the next 10 patients, suggesting that the accumulated experience of the center was not an important factor in determining survival. We have also found that cumulative experience at a liver-transplantation center was not a factor in determining mortality (data not shown).

Is there adequate information to enable physicians to steer their patients away from transplantation centers with high mortality rates? Thirteen centers had mortality rates that exceeded 40 percent, and the rate at one of these centers was 100 percent (Fig. 1). It would be reasonable to assume that, given this information, patients would decide to undergo transplantation at a center with low mortality rates.

Our findings suggest that the information available to patients and referring physicians is inadequate or that regional health care systems may be forcing patients to go to centers with poor results. Information regarding the outcomes of liver transplantation at transplantation centers should be made widely available to the public in a timely manner.

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Exhibit 8

New England Journal of Medicine
Correspondence: Volume Procedures at Transplantation Centers and Mortality after Liver Transplantation

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

◄ Previous Volume 342:1527-1528 May 18, 2000 Number 20 Next ►

Volume of Procedures at Transplantation Centers and Mortality after Liver Transplantation

To the Editor: Edwards et al.[1] (Dec. 30 issue) compared the one-year survival at centers performing 20 or fewer liver transplantations per year with survival at centers performing more than 20 transplantations per year and found excess mortality in the former group.

The authors seek to determine a turning point for experience. Unfortunately, they did not choose a priori categories. They justified their choice of the number 20 by appealing to their Figure 1. They state that "mortality rates stabilized at centers that performed more than 20 transplantations per year and increased inversely with transplantation volumes of less than 20 per year." However, this choice appears to have been arbitrary. To our eyes, in fact, the graph may very well "stabilize" beyond 20, perhaps at 30, transplantations per year, with the result that those sites with mortality rates above 30 percent would be included. The authors offer no statistical definition of "stability."

Moreover, Figure 1 simply reflects the greater statistical variability of small samples than of large ones; the choice of cutoff point should not be based on it at all. For example, all the excess mortality may be attributable to centers performing 1 to 10 (or 1 to 15) liver transplantations, with those performing 11 to 20 (or 16 to 20) at no disadvantage. A statistical analysis that carefully compared proper subgroups, which Edwards et al. do not report, would be required for the accurate identification of a turning point for experience.

Hunsicker, one of the authors of the study by Edwards et al., was reported in the *New York Times* to have said that medical research shows that patients fare best in centers that perform at least 20 liver transplantations per year.[2] Hunsicker has used the number 20 to argue that there should be one liver transplantation program in Iowa, not two, because the number of usable donated organs is about 40 per year. Hunsicker was quoted as saying, "So if we had two programs and we split evenly, then we would both be at the very lowest end of the numbers necessary to maintain competence."[2] Thus, we are concerned that the number 20 may have been chosen for political, not scientific, reasons.

Mitchell P. Laks, M.D., Ph.D.

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To the Editor: The use of survival data from transplantations performed more than five years ago is misleading, since one-year survival among patients improved steadily throughout the 1990s. The one-year mortality rates quoted by Edwards et al. are unacceptable by today's standards. The 20 percent mortality rate for "high-volume" centers is well above the national average reported more recently by the United Network for Organ Sharing (UNOS).[1] According to recent UNOS data, one-year survival rates do not differ significantly between centers with different volumes of transplantation procedures. One-year survival at "low-volume" centers (with "low volume" arbitrarily defined as 23 or fewer liver transplantations per year) is an excellent 85.8 percent.[1] This does not differ from the overall one-year survival of 86.9 percent and surpasses the 74.1 percent reported by Edwards et al.

It is unclear why Edwards et al. chose the arbitrary cutoff point of 20 transplantations per year for low-volume centers, since the mortality rates (shown in Figure 1 of their article) appear to be relatively stable at centers performing approximately 15 transplantations per year. Changing the definition of low volume from 20 to 15 would probably lead to the same conclusions yet have a substantially different effect on how many liver-transplantation centers would be viewed as low volume and less competent. In addition, the unacceptably high one-year mortality rates at centers performing fewer than 10 transplantations per year may have skewed the data, resulting in the apparent finding of lower survival at low-volume centers.

We take exception to the inference that at low-volume centers the lower mortality rates "may reflect statistical variation." We have performed approximately 19 liver transplantations per year during the past five years. Our one-year survival rate of 94 percent (exceeding the expected survival rate of 82 percent) is included in recently reported UNOS data.[1] We agree that this information must be made readily available to the public. However, we disagree with the classification of liver-transplantation centers as low-volume or high-volume and the implication that low-volume centers offer inferior transplantation services to their patients.

Donald J. Hillebrand, M.D.
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1. United Network for Organ Sharing (UNOS) Web site. (See: http://www.unos.org/frame_Default.asp?

To the Editor: Can Edwards et al. explain more accurately the criteria used in their initial analysis to set the cutoff at 20 patients per year? In addition, the performance of the multivariate models used was not specified; that is, what proportion of the variation in the outcome was explained by the independent variables? Moreover, the use of better clinical covariates — for instance, the severity of disease and coexisting illnesses — could have improved the case-mix adjustment.

Edwards et al. also acknowledge that some unmeasured factors may have influenced the relation between volume and outcome. The total number of solid-organ transplantations — not just liver transplantations — done at the hospitals may be an important covariate. Similarly, the volume of liver surgery other than transplantations, the amount and quality of intensive care resources, and the availability of outstanding services for the treatment of infectious diseases and outstanding hematology and interventional radiology services may also be important determinants of the rates of death and complications.

Vincent Bettschart, M.D.
Bernard Burnand, M.D.
François Mosimann, M.D.
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The authors reply:

To the Editor: In an analysis in which a covariate (such as sample size) is related to an outcome (such as patient survival) in a nonlinear way, there is always an element of judgment about which model to use. The least subjective approach is to use a nonparametric method to graph the relation and to divide the centers into two groups according to the apparent inflection point. Those centers with volumes closest to the cutoff point will be less divergent from the reference group.

Laks et al. suggest that the less favorable outcomes in the smaller centers might be the result of greater variability in the outcome because of smaller numbers. This would be true for the outcome at a single center. But the outcomes at the smaller centers, as a class, are less favorable than those in the reference group. The total number of patients at the smaller centers was sufficient for this conclusion to be very robust, as confirmed by the statistical tests of significance that we used. Laks et al. also ask whether political issues in Iowa affected the choice of cutoff point. The initial analyses for this study were done before the issue in Iowa arose, and it therefore had no influence on these analyses.

Hillebrand and Concepcion note that UNOS data on more recent liver transplantations did not show a significant effect of volume. However, that analysis lacks risk adjustment and does not account for center affiliation. Our analysis of data from 1987 through 1991 and 1992 through 1994 demonstrates that the effect of volume has been present during different eras and is unlikely to disappear suddenly.

In response to Bettschart et al.: our multivariate model, which included only donor and recipient factors, accounted for

about 40 percent of the variability in center-specific mortality rates. Effects related to the transplantation center, of which the volume is a component, may account for a significant portion of the remaining 60 percent. However, Cox and Wermuth cautioned that the interpretation of R^2 is misleading in linear regressions with binary responses because "low values are inevitable even if an important relation is present."[1]

Clearly, many transplantation-center factors that might contribute to variability in outcomes were not included in this model because the data were unavailable in the scientific registry. We agree that having more clinical detail permits better discrimination, but the message is clear: a lower volume of procedures at transplantation centers is associated with higher mortality after liver transplantation.

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Exhibit 9

Loma Linda University Medical Center
Scientific Registry of Transplant Recipients

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Table 7
Deceased Donor Transplant Recipient Characteristics
Patients transplanted between 01/01/2002 and 12/31/2002
Center: Loma Linda University Medical Center
Organ: LI: Liver

Characteristic		Percentage in each category Center (N=26)	Region (N=753)	U.S. (N=4,968)
Race (%)				
	White	88.5	79.0	83.4
	African-American	0.0	4.9	9.6
	Asian	3.8	12.4	4.3
	Other	7.7	3.6	2.7
	Unknown	0.0	0.1	0.0
Ethnicity (%)				
	Hispanic	53.8	27.0	13.3
	Non-Hispanic	46.2	72.0	86.5
	Unknown	0.0	1.1	0.2
Age (%)				
	<2	0.0	7.2	4.3
	2-10	0.0	2.8	2.8
	11-17	0.0	2.8	2.6
	18-34	3.8	5.3	5.6
	35-49	30.8	27.2	31.5
	50-64	61.5	46.9	46.2
	65+	3.8	7.8	7.0
	Unknown	0.0	0.0	0.0
Gender (%)				
	Male	65.4	62.9	66.0
	Female	34.6	37.1	34.0
Blood Type (%)				
	O	57.7	42.9	42.0
	A	23.1	37.1	39.3
	B	15.4	14.5	13.1
	AB	3.8	5.6	5.6
Previous Transplant (%)				
	Yes	3.8	10.1	10.0
	No	96.2	89.9	90.0
Body Mass Index (%)				
	0-20	3.8	17.8	13.6
	21-25	19.2	26.4	27.2
	26-30	30.8	20.1	25.9

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31+	15.4	18.5	19.4
Unknown	30.8	17.3	13.8
Primary Disease (%)			
Acute Hepatic Necrosis	3.8	8.8	7.7
Non-Cholestatic Cirrhosis	84.6	58.6	60.2
Cholestatic Liver Disease/Cirrhosis	0.0	7.3	9.8
Biliary Atresia	0.0	4.2	3.3
Metabolic Diseases	7.7	3.9	3.1
Malignant Neoplasms	0.0	9.3	7.2
Other	3.8	6.6	8.5
Missing	0.0	1.3	0.2
Medical Urgency Status/MELD/PELD at Transplant (%) *			
Status 1	15.4	15.8	9.7
Status 2A	11.5	7.7	3.8
Status 2B	0.0	2.7	7.7
Status 3	0.0	1.5	1.5
MELD 6-10	3.8	11.7	10.8
MELD 11-20	11.5	28.7	34.8
MELD 21-30	11.5	11.0	16.3
MELD 31-40	46.2	16.3	9.9
PELD less than or equal 10	0.0	1.6	2.8
PELD 11-20	0.0	2.1	1.6
PELD 21-30	0.0	0.4	0.7
PELD 31 or greater	0.0	0.3	0.2
Temporarily Inactive	0.0	0.3	0.1
Recipient Medical Condition at Transplant (%)			
Not Hospitalized	23.1	48.9	67.7
Hospitalized	38.5	17.3	14.7
ICU	38.5	24.4	14.7
Unknown	0.0	9.4	2.9

Note: Percentages add to 100% for each characteristic. N=Number.

* MELD/PELD score based on laboratory measures at the time of transplant is shown rather than status where available beginning 2/27/2002 unless recipient is Status 1 or Temporarily Inactive. MELD/PELD scores based on exception rules are not used.

Based on data available as of 04/30/2003. Release at www.ustransplant.org on 07/09/2003.

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Table 10
Graft Survival by Donor Type by Age at Transplant and by Time since Transplant
For Patients Transplanted between 01/01/2000 and 06/30/2002 for the 1 Month and 1 Year Cohorts; between 01/01/1998 the 3 Year Cohort
Center: Loma Linda University Medical Center
Organ: LI: Liver (Single-Organ Transplants Only)
Note: Deaths and retransplants are counted as graft failures

	Graft Survival by Time since Transplant				
	This Center			United S	
	1 Month	1 Year	3 Years	1 Month	1 Ye
Deceased Donor					
Adult (Age 18+)					
Transplants (n=number) [1]	63	63	35	10,060	10,0
Graft Survival (%) [2]	93.65	84.49	88.57	91.29	81.2
Expected Graft Survival (%) [3]	91.71	79.62	73.23	NA	NA
Ratio of Observed to Expected Failures	0.77	0.70	0.40	NA	NA
95% Confidence Interval: Lower Bound [4]	0.21	0.32	0.11	NA	NA
Upper Bound [4]	1.96	1.33	1.02	NA	NA
P-value (2-sided) [5]	0.804	0.355	0.059	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA
Follow-up days reported by center (%) [6]	100.0	96.4	98.4	99.3	95.
Maximum Days of Follow-up (n)	30	365	1,095	30	36
Pediatric (Age < 18)					
Transplants (n) [1]	1	1	-	1,071	1,07
Graft Survival (%) [2]	0.00	0.00	-	87.83	80.9
Expected Graft Survival (%) [3]	63.60	50.23	-	NA	NA
Ratio of Observed to Expected Failures	2.85	3.20	-	NA	NA
95% Confidence Interval: Lower Bound [4]	0.04	0.04	-	NA	NA
Upper Bound [4]	15.83	17.81	-	NA	NA
P-value (2-sided) [5]	0.593	0.536	-	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	-	NA	NA
Follow-up days reported by center (%) [6]	100.0	100.0	-	99.5	96.
Maximum Days of Follow-up (n)	15	15	-	30	36
Living Donor					
Adult (Age 18+)					
Transplants (n) [1]	-	-	-	849	84
Graft Survival (%) [2]	-	-	-	90.31	80.4
Expected Graft Survival (%) [3]	-	-	-	NA	NA

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Ratio of Observed to Expected Failures	-	-	-	NA	NA
95% Confidence Interval: Lower Bound [4]	-	-	-	NA	NA
Upper Bound [4]	-	-	-	NA	NA
P-value (2-sided) [5]	-	-	-	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA
Follow-up days reported by center (%) [6]	-	-	-	98.1	95.
Maximum Days of Follow-up (n)	-	-	-	30	36
Pediatric (Age < 18)					
Transplants (n) [1]	1	1	-	257	25
Graft Survival (%) [2]	0.00	0.00	-	87.50	78.6
Expected Graft Survival (%) [3]	77.95	57.69	-	NA	NA
Ratio of Observed to Expected Failures	9.55	8.08	-	NA	NA
95% Confidence Interval: Lower Bound [4]	0.12	0.11	-	NA	NA
Upper Bound [4]	53.12	44.98	-	NA	NA
P-value (2-sided) [5]	0.199	0.233	-	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	-	NA	NA
Follow-up days reported by center (%) [6]	100.0	100.0	-	99.6	97.
Maximum Days of Follow-up (n)	7	7	-	30	36
Transplant Time Period	**01/01/2000-06/30/2002**	**01/01/2000-06/30/2002**	**01/01/1998-12/31/1999**	**01/01/2000-06/30/2002**	**01/01/ 06/30/**

NA=Not Applicable.

[1] Transplants during the time period indicated in the last row of the table.

[2] Because different cohorts are followed for each time period, it is possible for reported 3-year survival to exceed 1-year survival.

[3] Based on U.S. graft failure rates adjusted for recipient and donor characteristics as indicated in the Analytical Methods.

[4] The 95% confidence interval gives a range of values for the true ratio of deaths at the facility to those expected based on the national experie between this lower and upper bound 95% of the time.

[5] A p-value less than or equal to 0.05 indicates that the difference between the actual and expected graft survival is probably real and is not du a p-value greater than 0.05 indicates that the difference could possibly be due to random chance.

(a) This difference could plausibly be just a chance occurrence.

[6] Of days expected to be included in the follow-up period, the percentage of days covered by follow-up reporting by this center for these tranpl indicate a non-representative sample from this facility for followup. This measures the possibility that events such as failure have occurred wit is not a measure of compliance.

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Table 11
Patient Survival by Donor Type by Age at First Transplant and by Time since Transplant
For Patients Receiving their First Transplant of this type between 01/01/2000 and 06/30/2002 for the 1 Month and 1 Yea 01/01/1998 and 12/31/1999 for the 3 Year Cohort
Center: Loma Linda University Medical Center
Organ: LI: Liver (Single-Organ Transplants Only)

	Patient Survival by Time since First Transplant				
	This Center			United S	
	1 Month	1 Year	3 Years	1 Month	1 Yea
Deceased Donor					
Adult (Age 18+)					
Transplants (n=number) [1]	60	60	32	9,171	9,171
Patient Survival (%) [2]	93.33	85.69	96.88	95.03	86.40
Expected Patient Survival (%) [3]	94.50	83.26	78.98	NA	NA
Ratio of Observed to Expected Deaths	1.26	0.81	0.13	NA	NA
95% Confidence Interval: Lower Bound [4]	0.34	0.35	0.00	NA	NA
Upper Bound [4]	3.23	1.60	0.74	NA	NA
P-value (2-sided) [5]	0.782	0.706	0.010	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Statistically Higher (b)	NA	NA
Follow-up days reported by center (%) [6]	100.0	94.7	92.4	97.4	92.9
Maximum Days of Follow-up (n)	30	365	1,095	30	365
Pediatric (Age < 18)					
Transplants (n) [1]	-	-	-	897	897
Patient Survival (%) [2]	-	-	-	94.20	90.18
Expected Patient Survival (%) [3]	-	-	-	NA	NA
Ratio of Observed to Expected Deaths	-	-	-	NA	NA
95% Confidence Interval: Lower Bound [4]	-	-	-	NA	NA
Upper Bound [4]	-	-	-	NA	NA
P-value (2-sided) [5]	-	-	-	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA
Follow-up days reported by center (%) [6]	-	-	-	96.8	92.6
Maximum Days of Follow-up (n)	-	-	-	30	365
Living Donor					
Adult (Age 18+)					
Transplants (n) [1]	-	-	-	838	838
Patient Survival (%) [2]	-	-	-	97.02	88.22
Expected Patient Survival (%) [3]	-	-	-	NA	NA
Ratio of Observed to Expected Deaths	-	-	-	NA	NA
95% Confidence Interval: Lower Bound [4]	-	-	-	NA	NA

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Upper Bound [4]	-	-	-	NA	NA
P-value (2-sided) [5]	-	-	-	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA
Follow-up days reported by center (%) [6]	-	-	-	94.4	88.6
Maximum Days of Follow-up (n)	-	-	-	30	365
Pediatric (Age < 18)					
Transplants (n) [1]	1	1	-	247	247
Patient Survival (%) [2]	0.00	0.00	-	93.52	83.66
Expected Patient Survival (%) [3]	71.27	53.82	-	NA	NA
Ratio of Observed to Expected Deaths	3.51	5.29	-	NA	NA
95% Confidence Interval: Lower Bound [4]	0.05	0.07	-	NA	NA
Upper Bound [4]	19.54	29.46	-	NA	NA
P-value (2-sided) [5]	0.496	0.344	-	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	-	NA	NA
Follow-up days reported by center (%) [6]	42.3	42.3	-	95.6	92.1
Maximum Days of Follow-up (n)	26	26	-	30	365
Transplant Time Period	**01/01/2000-06/30/2002**	**01/01/2000-06/30/2002**	**01/01/1998-12/31/1999**	**01/01/2000-06/30/2002**	**01/01/20 06/30/2(**

NA=Not Applicable.

[1] Transplants during the time period indicated in the last row of the table.

[2] Because different cohorts are followed for each time period, it is possible for reported 3-year survival to exceed 1-year survival.

[3] Based on U.S. patient mortality rates adjusted for recipient and donor characteristics as indicated in the Analytical Methods.

[4] The 95% confidence interval gives a range of values for the true ratio of deaths at the facility to those expected based on the national experie be between this lower and upper bound 95% of the time.

[5] A p-value less than or equal to 0.05 indicates that the difference between the actual and expected patient survival is probably real and is not while a p-value greater than 0.05 indicates that the difference could possibly be due to random chance.

(a) This difference could plausibly be just a chance occurrence.
(b) This difference is unlikely due to random chance and probably represents a real difference from the expected survival.

[6] Of days expected to be included in the follow-up period, the percentage of days covered by follow-up reporting by this center for these tranpl indicate a non-representative sample from this facility for followup. This measures the possibility that events such as failure have occurred witl it is not a measure of compliance.

Based on data available as of 04/30/2003. Release at www.ustransplant.org on 07/09/2003.

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Exhibit 10

Liver Transplantation – The Sickest First?. Disparities With Model for End-Stage Liver Disease – Based Organ Allocation" One Region's Experience

The Sickest First? Disparities With Model for End-Stage Liver Disease–Based Organ Allocation: One Region's Experience

Randolph L. Schaffer III, Sanjay Kulkarni,* Ann Harper,† J. Michael Millis,* and David C. Cronin II**

February 27, 2002, allocation of cadaver livers for transplantation changed from a waiting-time–based system to an evidence-based system referred to as the Model for End-Stage Liver Disease (MELD). We reviewed data from 1 of the 11 United Network for Organ Sharing regions to determine the impact of the MELD on the allocation of cadaver livers for transplantation in that region. The region of interest (study region) consists of three distinct geographic areas (referred to as Transplant Service Areas [TSAs]). Based on information obtained from the Organ Procurement and Transplantation Network for the United States and for the study region, the following observations were made: (1) study region patients who received a cadaver liver had higher mean and median MELD scores than cadaver liver recipients in the United States (study region mean score, 25.1; median, 26.0; US mean score, 23.9; median, 24.0); (2) within the study region, TSAs with competing liver transplant programs performed transplantation on patients at a significantly higher mean MELD score than TSAs dominated by a single center (TSA-1 mean score, 27.3; TSA-2 mean score, 26.6; TSA-3 mean score, 21.3); this disparity persisted when transplantations for hepatocellular carcinoma (HCC) were excluded; and (3) study region patients removed from the waiting list because of death or being too sick for transplantation have higher MELD scores than the national average (study region mean score, 25.4; US mean score, 23.8). Overall, implementation of the MELD resulted in a substantial increase in the number of transplantations performed for HCC, and MELD exceptions for all reasons were more common in TSAs that have multiple centers. Despite the MELD, there remains disparity in organ allocation within the study region. The MELD may accurately predict pretransplantation mortality, but it does not ensure equitable organ distribution. We propose that intraregional sharing of cadaver livers based on the MELD may help limit disparities in organ allocation. (*Liver Transpl 2003;9:1211-1215.*)

In 1999, the Institute of Medicine recommended that allocation of cadaveric livers for transplantation could be improved by instituting a mechanism that favored disease severity and de-emphasized patient waiting time.[1] Consequently, the Department of Health and Human Services adopted the Final Rule, which established that allocation of cadaveric livers for transplantation in the United States be based primarily on medical urgency.[2] After careful evaluation, the Model for End-Stage Liver Disease (MELD) was identified as potentially meeting these requirements. Previous studies had confirmed the accuracy of the MELD in predicting mortality in patients undergoing transjugular intrahepatic portosystemic shunt procedures,[3] and this risk model subsequently was validated in other groups of adult patients with end-stage liver disease.[4-7] However, it was noted that in several conditions, urgency for transplantation is not driven by hepatic failure, but rather by the progression of disease to the point that the patient may no longer benefit from transplantation. MELD exceptions were established to advantage patients not well served by the MELD equation.

On February 27, 2002, the MELD was officially adopted as an evidence-based means of organ allocation and replaced waiting-time–based allocation for patients receiving a liver transplant in the United States. However, during its preimplementation evaluation, preliminary data suggested there was a small, but significant, amount of regional variation in MELD scores at the time of transplantation or removal from the list for death.[8] After 6 months under the new allocation system, we asked the following question: Did the MELD system achieve the stated goal of prioritizing liver allocation to the "sickest patients"?[9]

Materials and Methods

The United States is divided into 11 distinct regions, determined by the United Network for Organ Sharing (UNOS). One UNOS region was selected for study based on its three distinct geographic areas, heretofore referred to as Transplant Service Areas (TSAs). Within the study region, TSA-1 has

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1527-6465/03/0911-0012$30.00/0
doi:10.1053/jlts.2003.50192

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one organ procurement organization (OPO) and five centers that perform adult liver transplants. TSA-2 has one OPO that serves two adult liver transplant centers. TSA-3 has two OPOs. One of the OPOs has two centers that perform adult liver transplantations, and the other OPO has one center.

To evaluate local and regional characteristics within the study region, we queried the Organ Procurement and Transplantation Network (OPTN) for data during the first 8 months after implementation of the MELD. End points were collected for the entire study region and each TSA in the study region. The two OPOs in TSA-3 were combined by the OPTN to avoid the release of center-specific data. Data for the United States also were collected to serve as a benchmark in each category. Data for all requested MELD scores, provided by the OPTN, included mean, minimum, maximum, median, 25th percentile, and 75th percentile scores and SDs. Specifically requested MELD scores included score at listing, score at transplantation (living, cadaveric, and all combined), and score at the time of removal for death or being too sick for transplantation. Scores reported by the OPTN represented the MELD score for each patient according to the UNOS list, whether calculated (laboratory score) or based on an approved exception. The maximum possible MELD score for any patient was 40 points.

We also examined the number of MELD exceptions requested and scores granted for all reasons, as well as the number of patients with hepatocellular carcinoma (HCC) who underwent transplantation in the 6 months before the MELD and since the MELD. During the study period, patients with HCC received MELD exception scores of 24 points for stage I disease and 29 points for stage II disease. In that time, there was a growing national consensus that these scores were overly advantaging patients with HCC. We were concerned that the number of transplantations performed for patients with HCC might artificially increase average MELD scores, resulting in an inaccurate representation of the illness severity of liver transplant recipients in each of the TSAs. Therefore, we also requested MELD scores for all transplantations (cadaveric) from the OPTN, excluding those for HCC. No other MELD exceptions were excluded from this analysis.

The study focused on adult patients receiving cadaver livers for transplantation to assess the impact of the new allocation system. Pediatric transplantations and Pediatric End-Stage Liver Disease scores were not included in this study. MELD score data provided by the OPTN represented the period from February 27, 2002, through November 15, 2002, as reported November 22, 2002, and updated March 10, 2003. Mann-Whitney *U* test was used to perform statistical comparisons.

Results

The study region accounts for approximately 9% to 10% of the nation's annual cadaveric liver transplantations (10.1% in 2000, 8.9% in 2001, and 9.2% in 2002). During the period reviewed, the region accounted for 9.2% of all liver waiting list additions in the United States (523 additions in the study region, 5,661 additions in the United States) and 9.7% of all cadaver liver transplantations nationwide (289 transplantations in the study region, 2,967 transplantations in the United States). During the same period, the study region was responsible for 11.2% of all removals from the national list because death or patients who were too sick to undergo transplantation (109 of 970 removals).

Mean MELD score at the time of listing in the study region was 16.1 compared with the national average of 15.8 ($P < .5$). Mean scores at the time of cadaveric liver transplantation or removal from the list for death or being too sick to undergo transplantation across the United States were 23.9 and 23.8, respectively. Mean MELD scores in these two groups of patients in the study region were slightly higher, averaging 25.1 for patients receiving a cadaveric liver ($P < .001$; confidence interval [CI] = 95%) and 25.4 for those removed because of death or being too sick to undergo transplantation ($P < .001$; CI = 95%).

TSA-1

The TSA-1 OPO added 230 patients to the liver waiting list during the 8-month period. This number represented 44% of waiting list additions for the study region. One hundred fifteen cadaver liver transplantations (40% of the region total) were performed in the OPO, with a mean MELD score of 27.3. MELD score for these recipients ranged from a minimum score of 8.0 to a maximum score of 40. Twenty-fifth percentile, median, and 75th-percentile MELD scores were 24.0, 29.0, and 30.0, respectively.

TSA-2

Within the TSA-2 OPO, 157 patients (30% of the study region additions) were added to the wait list during the time of the study. Seventy-six cadaveric transplantations (26% of the study region) were performed in patients with an average MELD score of 26.6. The range of scores was broad (10.0 to 40.0), but more evenly distributed. The 25th-percentile MELD score was 24.0, whereas median score was 26.5 and 75th-percentile score was 29.5.

TSA-3

Mean MELD score for patients receiving a cadaver liver in TSA-3 was 21.3 (range, 8.0 to 40.0), with a 25th-percentile score of 16.0, median score of 21.0, and

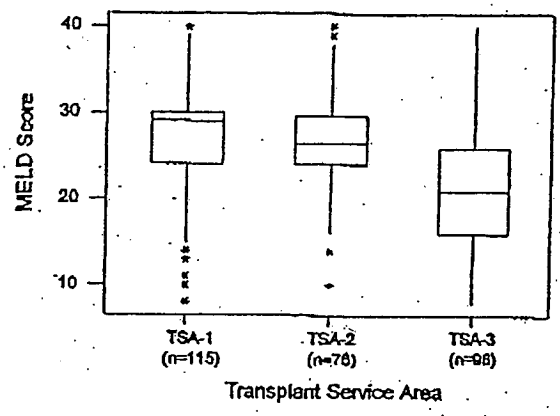

Figure 1. Distribution of MELD scores for all patients undergoing cadaveric liver transplantation in the study region. TSA-1 versus TSA-2 ($P = .18$), TSA-1 versus TSA-3 ($P < .0001$), TSA-2 versus TSA-3 ($P < .0001$).

75th-percentile MELD score of 26.0. Ninety-eight cadaver liver transplantations (34% of the study region) were performed in these OPOs during the study period, whereas 136 patients were listed (26% of the region total).

Mean MELD score at transplantation in TSA-3 was significantly lower than in TSA-2 (21.3 *v* 26.6; $P < 0.001$; CI = 95%) and TSA-1 (21.3 *v* 27.3; $P < 0.001$; CI = 95%). There was no significant difference between scores in TSA-1 and TSA-2 ($P < 0.5$; Fig. 1).

HCC

Immediately after implementation of MELD-based allocation, we noted an increase in the number of reported cadaver liver transplantations performed for HCC. Review of OPTN data showed this was a nationwide trend. The number of patients with HCC who underwent transplantation in the 6 months before MELD and the 6 months after MELD were 230 versus 513 nationally and 38 versus 66 in the study region. This increase may, in part, result from underreporting of HCC before implementation of the MELD.

Eighty-nine of 289 cadaver transplantations performed in the study region between February 27, 2002, and November 15, 2002, were for HCC. Ten of these patients (11.2%) required an extension of their MELD exception beyond the first 90 days before undergoing transplantation. There were 54 cadaver transplantations for HCC performed in TSA-1, 22 transplantations in TSA-2, and 13 transplantations in TSA-3. This resulted in approximately 11 transplantations for HCC per transplant center within TSA-1 and TSA-2 (10.8 and 11 transplantations, respectively) and an average of 4.3 cadaver liver transplantations per center in TSA-3. Because of the higher number of transplantations performed for patients with HCC in TSA-1 and TSA-2, we were concerned that these cases might artificially increase average MELD scores for the two areas. This would result in an inaccurate representation of the illness severity of liver transplant recipients in these areas. For this reason, patients with HCC were excluded from data analysis and MELD scores of transplantations for all non-HCC diagnoses were examined in each OPO. TSA-1's mean MELD score for patients without HCC was 26.4; TSA-2, 25.6; and TSA-3, 20.4 ($P < .001$; CI = 95%; Fig. 2).

Within the United States, there were 1,957 exceptional case requests for patients believed to not be adequately served by the MELD scoring system during the study dates. These included patients with HCC (1,192 of 1,278 requests granted), familial amyloidosis (14 of 16 requests granted), hepatopulmonary syndrome (78 of 89 requests granted), metabolic diseases (10 of 10 requests granted), nonmetastatic hepatoblastoma (6 of 6 requests granted), primary oxaluria (7 of 7 requests approved), portopulmonary hypertension (5 of 10 requests approved), and other specified indications (366 of 541 requests granted). As designed by the current MELD allocation system, regional review boards (RRBs) evaluated all exceptional case requests. Patients received their MELD exception scores by either approval of the representative RRB or failure of the RRB to answer the request within 21 days of submission.

From February 27, 2002, through November 15,

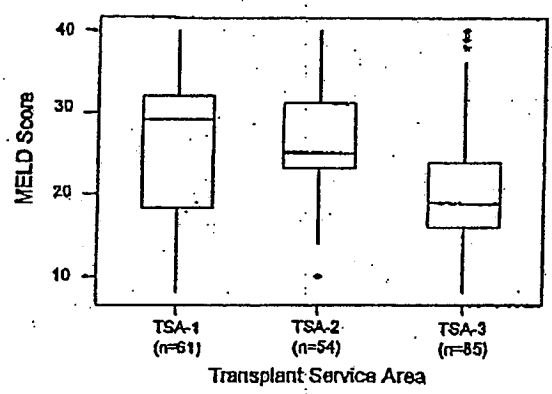

Figure 2. Distribution of MELD scores for patients undergoing cadaveric liver transplantation for non-HCC diagnoses in the study region. TSA-1 versus TSA-2 ($P = .5$), TSA-1 versus TSA-3 ($P < .0001$), TSA-2 versus TSA-3 ($P < .0001$).

2002, the study region requested 207 MELD exceptions (10.6% of total US cases). Within the region, indications for MELD exception requests included HCC (122 of 131 requests granted), familial amyloidosis (4 of 4 requests approved), hepatopulmonary syndrome (5 of 6 requests granted), primary oxaluria (2 of 2 requests granted), and others (43 of 64 requests granted). TSA-1's transplant centers requested a total of 123 case exceptions, or 24.6 exceptions/center. The study region's RRB granted 108 of the MELD exception requests (21.6 exceptions/center). TSA-2 submitted 58 case exceptions (29 exceptions/center), of which 48 were granted (24 exceptions/center). Programs in TSA-3 requested 26 exceptional case reviews (8.7 exceptions/center), of which 20 were approved (6.7 exceptions/center).

Nontransplant Removal

Of 970 patients nationwide removed from the liver waiting list for reasons of death or being too sick to undergo transplantation, 109 patients (11.2%) came from the study region. However, within the region, the number of removals varied among TSAs. TSA-1 accounted for 78 such removals (71.6%), with a mean MELD score of 25.0 (median score, 27.5). TSA-2 removed 23 patients (21.1%) with MELD scores averaging 26.8 (median, 30.0) at the time of removal, and TSA-3 removed 8 patients from the list, with a mean MELD score for these patients of 24.8 (median score, 23.0). The number of patients removed in TSA-3 was too small to allow for meaningful statistical comparison.

Discussion

February 27, 2002, UNOS adopted the MELD as an evidence-based system for the allocation of cadaver livers for transplantation. The MELD satisfied the recommendations of the Institute of Medicine and the Department of Health and Human Services for a system that emphasized disease severity over waiting time. Early assessment of national and regional data suggested that equitable allocation of livers for transplantation was occurring. However, analysis of data within the study region argues otherwise. Although the region as a whole appears to be representative of the nation's liver transplant population, uniformity does not occur within its distinct geographic areas.

OPTN data showed that transplant centers within TSA-3 performed cadaver liver transplantations at a lower average disease severity than centers in TSA-1 and TSA-2. This disparity held even when transplantations for HCC were excluded from analysis.

Among the five adult liver transplant centers served by the OPO in TSA-1, distribution of MELD scores was weighted more heavily toward sicker patients than for programs in either of the other TSAs in the region. Within TSA-1, more than two thirds (68%) of all cadaver transplantations were performed in patients with MELD scores of 29 or greater. The OPO in TSA-2, which has two active adult transplant centers, also performed transplantation on patients with significantly higher average MELD scores (45% with MELD > 29) compared with TSA-3 programs (20% with MELD > 29). Both TSA-2 and TSA-3 had more even distributions of MELD scores than TSA-1.

MELD score disparity also existed between TSAs for patients removed from the liver waiting list for reasons of death or being too sick to undergo transplantation. The largest number of patients removed came from the TSA-1 OPO, followed by TSA-2. TSA-3, which also happened to list the fewest patients during the study period, removed the fewest patients because of death or being too sick to undergo transplantation. Average MELD score for TSA-3 patients removed from the list was lower than that at the time of removal and lower than the score at the time of transplantation for patients in TSA-1 and TSA-2.

Proponents of the MELD have stated that in an allocation system based on a continuous disease severity scale, patients should receive organs earlier in the course of their disease because they are never superceded by less ill patients with more waiting time.[7] Although this concept appears to be reflected in the allocation of organs within an individual OPO, it does not hold true for allocation within the study region. As OPTN data clearly show, less ill patients in one OPO can supercede sicker patients in another OPO within the same region.

The UNOS Liver Disease Severity Score Committee recognized at the inception of the MELD that the scoring system could potentially provide too much advantage to sicker patients with diminished survival probability. For this reason, the maximum MELD score of 40 was created. Patients with a MELD score greater than 40 could undergo transplantation, but would only receive a MELD score equal to 40. Selection criteria for listing and, similarly, reasons for turning down a patient for liver transplantation have always been left to the discretion of the individual transplant program.

Data suggest that competition among centers in an OPO (or the lack of competition) also might factor into the decision of whether to list and perform transplantation on a patient. Centers with competition perform

transplantation on patients at higher MELD scores than centers without competition. Patients often recognize this, and as a result, those considered too sick to undergo transplantation by one center may go to another center willing to perform transplantation on patients with high MELD scores to be listed. Similarly, patients with lower MELD scores listed in a competitive OPO also may get listed in another OPO known to perform transplantation on patients at lower MELD scores with shorter waiting times.

One limitation of this study is that it is based on MELD scores for listed patients. There still remains an unknown denominator that includes patients in each TSA with undiagnosed liver disease, patients diagnosed but never referred to a transplant center, and patients evaluated by a transplant center but not listed for transplantation. Unfortunately, these are numbers that cannot be known precisely. Regardless of practice patterns within individual TSAs, there clearly is disparity in organ allocation among areas in the study region.

Currently, a system is in place for regional sharing among status 1 patients that prioritizes the sickest patients on a regional level and ensures fair organ distribution. Using this as a model, we propose regional sharing for patients based on MELD scores. In the spirit of the Institute of Medicine's original recommendations, regional sharing would shorten the waiting time for sicker patients in the region, potentially allowing each patient to undergo transplantation at a lower MELD score. Regional sharing would not only obviate the need for patients to be listed with multiple centers, but likely would equalize the listing criteria of each center in the region. Based on data from the study region, regional sharing could potentially allow for transplantation of many of those patients otherwise removed because of death or being too sick. Ultimately, regional sharing in the study region's population would more equitably distribute organs among the sickest patients in the region.

When the MELD was evaluated for use as the new national allocation system for cadaver livers for transplantation, the system was touted as being responsive to the continuous assessment of patient risk. This flexibility would allow the system to be adjusted for a maximization of outcomes.[10] The MELD also allows for reproducible comparison of patients awaiting transplantation, as well as comparison of transplant recipients across geographic areas. From these data, it has become clear that there is disparity among transplant centers when it comes to the selection of patients for transplantation. It also is apparent that there is a subsequent disparity in organ allocation. Modification of the evidence-based MELD allocation system to include regional sharing of organs would result in a transparent equitable system in which all patients are offered equal access to liver transplantation, based solely on illness severity.

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Exhibit 11

American Transplant Congress – Steroid Free Immunosuppression with Delayed Introduction of a Calcineurin (CI) Inhibitor and Mycophenolate Mofetil (MMF) in Cadaver and Living Donor Kidney Transplants

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American Transplant Congress

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Category: Kidney
Topic: Immunosuppression - Clinical trials
Award: No, do not consider me for this award.
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Presentation format: Oral.
Presenting Author: William H. Marks, MD, PhD **Presenting Author Department/Institution:** Organ Transplantation, Swedish Medical Center
Disclosure: 1. Yes 2. No 3. No 4. No

Keyword 1: Kidney transplantation **Keyword 2:** Immunosuppression **Keyword 3:** Induction therapy **Keyword 4:** Cadaveric organs

Title: STEROID FREE IMMUNOSUPPRESSION WITH DELAYED INTRODUCTION OF A CALCINEURIN (CI) INHIBITOR AND MYCOPHENOLATE MOFETIL (MMF) IN CADAVER AND LIVING DONOR KIDNEY TRANSPLANTS

William H. Marks, MD, PhD [1]*, Lisa S. Florence, MD, Phillip H. Chapman, MD, Diana T. Perkinson, MD and Donald R. Howard, MD, PhD. [1]Organ Transplant Program, Swedish Medical Center.

Abstract:
The purpose of this study was to evaluate a steroid-free immunosuppressive (SFI) strategy in CD and LD kidney recipients that avoids the early nephrotoxicity of CI and the marrow suppressive effect of MMF co-administered with Thymoglobulin (TMG). **Methods:** Study population: 19 sequentially transplanted first time kidney recipients, (CD n=9 and LD n=10). Immunosuppression: TMG 1.5 mg/kg POD 0, 1, 3, 5, 7 (7.5 mg/kg total dose). One anti-inflammatory dose of methylprednisolone (1-2 mg/kg) in the OR. MMF and full dose CI were started on POD6 and both continued as maintenance therapy. Exclusion criteria: PRA 60% and/or African American CD recipient.
Demographic and risk factors:
[table 1]
Characteristics of the donor organs and recipient diagnoses:
[table 2]
Results:
[table 3]
No major complications occurred. One rejection episode occurred in each group. The CD recipient was haploidentical, had ESRD due to CGN and received no steroids prior to transplantation. Rejection was reversed with steroids. The LD recipient received a 6 AgMM sibling kidney. Five years pretransplant he received prednisone for kidney disease. This

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rejection required OKT3. Both recipients remain on steroids. **Conclusions:** This SFI strategy was effective for CD and LD kidney transplantation. Donor organ type, matching, diabetes, CMV status, and DGF were not associated with adverse events. Significant prior exposure to steroids may be a risk factor for acute rejection with SFI even when exposure occurred years prior to transplantation.

Tx type total=19	Age(yr) *p=.04*	SEX, M/F	Months post-txplt *ns*	Mismatch (#≥5MM)	CMV pos donor to CMV neg recip	EBNA neg recipients	CI CsA/FK
CD n=9	53.5±9.9	6/3	8.1±3.2	3.4±1.5 (3)	3	1	9/0
LD n=10	43.6±10	7/3	8.9±2.9	2.7±2.7 (4)	3	1	9/1

Donor organ type	Cold time	ESRD Diagnoses					
		HTN	CGN	DM	IgA	PCKD	pylo
CD: Heart Beating 7, non-Heart Beating 2	14h ± 3.1	3	1	3	1	1	
LD: Open donor 3, Laparoscopic donor 7	n/a	3	1	1	2	2	1

Tx type	Graft & Patient Survivals	Delayed Graft Function	Rejection #, Class, (POD)	Mean ± SD sCr at 3 mos	Complications cmv	↓wbc	other
CD	100%	5/9 pts.	1, Banff 1a, (12)	1.4±0.2	1	0	1
LD	100%	0	1, Banff 1b, (14)	1.6±0.4	0	1	0

Disclsoure:
Thymoglobulin, Cyclosporin, FK506, Mycophenolate Mofetil.
None of the authors have a commercial relationship with any of the manufacturers. The study was partially supported by an unrestricted grant from Sangstat.

Signature of Contact Author:

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Clinical Science Topic: 1121. Immunosuppression - Clinical Trials

Award: No, do not consider me for this award.
Member type: No member type listed.

Disclosure: 1. Yes 2. Yes 3. No 4. No
Keyword 1: Immunosuppression **Keyword 2:** Kidney transplantation **Keyword 3:** Induction therapy **Keyword 4:** Antilymphocyte antibodies

COMPARISON OF TWO PREDNISONE-FREE IMMUNOSUPPRESSIVE REGIMENS FOLLOWING ANTITHYMOCYTE INDUCTION FOR KIDNEY TRANSPLANTS: CYCLOSPORIN/MYCOPHENOLATE (CSA/MMF) VERSUS TACROLIMUS/SIROLIMUS (TAC/SRL).

William H Marks, MD, PhD [1], Julie R Zivin, MD [1], Lisa S Florence, MD [1], Judith A Malmgren, PhD [1], Ron Wang, BSE [1] and Diana T Perkinson, MD [1]. [1]Organ Transplant Program, Swedish Medical Center, Seattle, WA.

Body: Purpose: To compare two different prednisone-free immunosuppressive regimens for kidney transplants (tx).

Methods: A single center open label 52 cohort study of consecutive kidney recipients (28 living donors (LDT) and 24 cadaver donors (CAD)) transplanted between 2000-2002 (4-24 months) and who qualified for inclusion (<20% PRA, first tx, no history of prolonged steroid use and no pre-existing disease requiring steroid therapy) was evaluated. All patients received Rabbit Antithymocyte Globulin (SangStat) induction (6-7 mg/kg) and either CSA (target trough 180 ng/ml) and MMF (2g/d) (19 LDT, 16 CAD) or TAC (trough 5-8 ng/ml) and SRL (level 5-8 ng/ml) (9 LDT, 8 CAD). Endpoints were graft and patient survivals; incidence, time to and severity of rejection; infection rates; post-tx diabetes; hyperlipidemia; and leukocytopenia.

Results: There were no differences between the two treatment groups by age, race, sex, body mass index, HLA mismatch, or pre-existing conditions. Major risk factors included CMV neg recipient of CMV pos organ 10/52 (19.2%), diabetes 12/40 (23.1%), and coronary artery disease 5/40 (9.6%). LDTs had a significantly higher rate of leukocytopenia (46%) compared to CADs (18%) [Pearson chi square (p=.029)] and a higher rate of HLA mismatches (LDTs (3.2 MM) and CADs (2.75MM) [(p=.008)]). No differences between

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treatment groups were observed for patient survival, allograft survival or acute rejection (table). Overall, there were 21.1% bacterial infections (including UTIs) and 11.5% viral infections (including CMV neg to CMV pos conversions). The single mortality was a cardiac death. Post-tx diabetes occurred in one recipient, (TAC/SRL).

Conclusions: These short-term results show that CSA/MMF and TAC/SRL, when combined with TMG induction, are highly effective and equivalent regimens for prednisone-free immunosuppression for kidney tx. Continued study is necessary to determine long-term outcomes and if significant differences develop between the two groups.

	CSA/MMF (N=35)	TAC/SRL (N=16)
Patient Survival	97.2% (n=1)	100%
Allograft Survival	97.2% (n=1)	100%
Acute Rejection (n)	11.4% (4)	6.4% (1)
Days to onset	14, 17, 19, 425	300
Banff grade	1A (n=2), 1B (n=2)	1B

Disclosure: Product: Thymoglobulin, Commercial Supporter: SangStat Medical Corporation, Relationship: Grant

Signature of Presenting Author:

William H Marks

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Exhibit 12

Swedish Medical Center Kidney Single-Organ Transplant
University of Washington Medical Center Kidney Single-Organ Transplant
Scientific Registry of Transplant Recipients

KIDNEY Comparison

ustransplant.org
Scientific Registry of Transplant Recipients

Jump to:
◂ Previous Table | Table 10: Graft Survival Rates by Age at Transplant and Time since Transplant

Table 10

Graft Survival by Age at Transplant and by Time since Transplant

For Patients Transplanted between 01/01/2000 and 06/30/2002 for the 1 Month and 1 Year Cohorts; between 01/01/1998 the 3 Year Cohort

Center: Swedish Medical Center

Organ: KI: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

	Graft Survival by Time since Transplant				
	This Center			United S	
	1 Month	1 Year	3 Years	1 Month	1 Ye
Adult (Age 18+)					
Transplants (n=number) [1]	152	152	126	32,777	32,7
Graft Survival (%) [2]	94.29	89.50	91.81	96.53	90.9
Expected Graft Survival (%) [3]	97.05	92.50	85.35	NA	NA
Ratio of Observed to Expected Failures	1.52	1.37	0.72	NA	NA
95% Confidence Interval: Lower Bound [4]	0.49	0.55	0.31	NA	NA
Upper Bound [4]	3.54	2.81	1.43	NA	NA
P-value (2-sided) [5]	0.473	0.513	0.457	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA
Follow-up days reported by center (%) [6]	55.5	30.0	45.9	97.6	92.
Maximum Days of Follow-up (n)	30	365	1,095	30	36
Pediatric (Age < 18)					
Transplants (n) [1]	1	1	-	1,699	1,69
Graft Survival (%) [2]	100.00	100.00	-	96.55	93.9
Expected Graft Survival (%) [3]	97.66	92.64	-	NA	NA
Ratio of Observed to Expected Failures	0.00	0.00	-	NA	NA
95% Confidence Interval: Lower Bound [4]	-	-	-	NA	NA
Upper Bound [4]	-	-	-	NA	NA
P-value (2-sided) [5]	0.999	0.999	-	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	-	NA	NA
Follow-up days reported by center (%) [6]	33.3	2.7	-	97.5	92.
Maximum Days of Follow-up (n)	10	10	-	30	36
Transplant Time Period	01/01/2000-06/30/2002	01/01/2000-06/30/2002	01/01/1998-12/31/1999	01/01/2000-06/30/2002	01/01/2 06/30/

NA=Not Applicable.

[1] Transplants during the time period indicated in the last row of the table.

[2] Because different cohorts are followed for each time period, it is possible for reported 3-year survival to exceed 1-year survival.

[3] Based on U.S. graft failure rates adjusted for recipient and donor characteristics as indicated in the Analytical Methods.

Jump to:
◂ Previous Table | Table 11: Patient Survival Rates by Age at Transplant and Time since Transplant

Table 11
Patient Survival by Age at First Transplant and by Time since Transplant
For Patients Receiving their First Transplant of this type between 01/01/2000 and 06/30/2002 for the 1 Month and 1 Yea 01/01/1998 and 12/31/1999 for the 3 Year Cohort
Center: Swedish Medical Center
Organ: KI: Kidney (Single-Organ Transplants Only)

	Patient Survival by Time since First Transplant				
	This Center			United S	
	1 Month	1 Year	3 Years	1 Month	1 Yea
Adult (Age 18+)					
Transplants (n=number) [1]	139	139	108	28,665	28,66
Patient Survival (%) [2]	97.84	95.44	93.52	99.08	95.47
Expected Patient Survival (%) [3]	99.14	95.66	91.72	NA	NA
Ratio of Observed to Expected Deaths	2.53	1.12	0.76	NA	NA
95% Confidence Interval: Lower Bound [4]	0.51	0.41	0.31	NA	NA
Upper Bound [4]	7.39	2.44	1.57	NA	NA
P-value (2-sided) [5]	0.235	0.895	0.611	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA
Follow-up days reported by center (%) [6]	56.0	30.3	44.9	97.3	92.0
Maximum Days of Follow-up (n)	30	365	1,095	30	365
Pediatric (Age < 18)					
Transplants (n) [1]	1	1	-	1,526	1,526
Patient Survival (%) [2]	100.00	100.00	-	99.67	99.10
Expected Patient Survival (%) [3]	-	-	-	NA	NA
Ratio of Observed to Expected Deaths	-	-	-	NA	NA
95% Confidence Interval: Lower Bound [4]	-	-	-	NA	NA
Upper Bound [4]	-	-	-	NA	NA
P-value (2-sided) [5]	-	-	-	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA
Follow-up days reported by center (%) [6]	33.3	2.7	-	97.1	91.6
Maximum Days of Follow-up (n)	30	365	-	30	365
Transplant Time Period	01/01/2000-06/30/2002	01/01/2000-06/30/2002	01/01/1998-12/31/1999	01/01/2000-06/30/2002	01/01/20 06/30/2(

NA=Not Applicable.
[1] Transplants during the time period indicated in the last row of the table.
[2] Because different cohorts are followed for each time period, it is possible for reported 3-year survival to exceed 1-year survival.
[3] Based on U.S. patient mortality rates adjusted for recipient and donor characteristics as indicated in the Analytical Methods.
[4] The 95% confidence interval gives a range of values for the true ratio of deaths at the facility to those expected based on the national experie

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Table 11
Patient Survival by Age at First Transplant and by Time since Transplant
For Patients Receiving their First Transplant of this type between 01/01/2000 and 06/30/2002 for the 1 Month and 1 Yea 01/01/1998 and 12/31/1999 for the 3 Year Cohort
Center: University of Washington Medical Center
Organ: KI: Kidney (Single-Organ Transplants Only)

	Patient Survival by Time since First Transplant				
	This Center			United S	
	1 Month	1 Year	3 Years	1 Month	1 Yea
Adult (Age 18+)					
Transplants (n=number) [1]	184	184	112	28,665	28,66
Patient Survival (%) [2]	99.46	98.37	91.96	99.08	95.47
Expected Patient Survival (%) [3]	99.05	95.07	90.28	NA	NA
Ratio of Observed to Expected Deaths	0.57	0.35	0.82	NA	NA
95% Confidence Interval: Lower Bound [4]	0.01	0.07	0.37	NA	NA
Upper Bound [4]	3.18	1.01	1.55	NA	NA
P-value (2-sided) [5]	0.957	0.053	0.680	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA
Follow-up days reported by center (%) [6]	99.7	94.6	93.3	97.3	92.0
Maximum Days of Follow-up (n)	30	365	1,095	30	365
Pediatric (Age < 18)					
Transplants (n) [1]	-	-	-	1,526	1,526
Patient Survival (%) [2]	-	-	-	99.67	99.10
Expected Patient Survival (%) [3]	-	-	-	NA	NA
Ratio of Observed to Expected Deaths	-	-	-	NA	NA
95% Confidence Interval: Lower Bound [4]	-	-	-	NA	NA
Upper Bound [4]	-	-	-	NA	NA
P-value (2-sided) [5]	-	-	-	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA
Follow-up days reported by center (%) [6]	-	-	-	97.1	91.6
Maximum Days of Follow-up (n)	-	-	-	30	365
Transplant Time Period	01/01/2000-06/30/2002	01/01/2000-06/30/2002	01/01/1998-12/31/1999	01/01/2000-06/30/2002	01/01/20 06/30/2(

NA=Not Applicable.
[1] Transplants during the time period indicated in the last row of the table.
[2] Because different cohorts are followed for each time period, it is possible for reported 3-year survival to exceed 1-year survival.
[3] Based on U.S. patient mortality rates adjusted for recipient and donor characteristics as indicated in the Analytical Methods.
[4] The 95% confidence interval gives a range of values for the true ratio of deaths at the facility to those expected based on the national experie

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Table 10

Graft Survival by Age at Transplant and by Time since Transplant

For Patients Transplanted between 01/01/2000 and 06/30/2002 for the 1 Month and 1 Year Cohorts; between 01/01/1998 the 3 Year Cohort

Center: University of Washington Medical Center

Organ: KI: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

	Graft Survival by Time since Transplant				
	This Center			United S	
	1 Month	1 Year	3 Years	1 Month	1 Ye
Adult (Age 18+)					
Transplants (n=number) [1]	199	199	136	32,777	32,7
Graft Survival (%) [2]	95.98	92.86	86.51	96.53	90.9
Expected Graft Survival (%) [3]	96.45	90.90	82.78	NA	NA
Ratio of Observed to Expected Failures	1.16	0.83	0.77	NA	NA
95% Confidence Interval: Lower Bound [4]	0.50	0.46	0.45	NA	NA
Upper Bound [4]	2.28	1.40	1.21	NA	NA
P-value (2-sided) [5]	0.777	0.594	0.304	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA
Follow-up days reported by center (%) [6]	100.0	97.1	95.9	97.6	92.
Maximum Days of Follow-up (n)	30	365	1,095	30	36!
Pediatric (Age < 18)					
Transplants (n) [1]	-	-	-	1,699	1,69
Graft Survival (%) [2]	-	-	-	96.55	93.9
Expected Graft Survival (%) [3]	-	-	-	NA	NA
Ratio of Observed to Expected Failures	-	-	-	NA	NA
95% Confidence Interval: Lower Bound [4]	-	-	-	NA	NA
Upper Bound [4]	-	-	-	NA	NA
P-value (2-sided) [5]	-	-	-	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA
Follow-up days reported by center (%) [6]	-	-	-	97.5	92.
Maximum Days of Follow-up (n)	-	-	-	30	36!
Transplant Time Period	01/01/2000-06/30/2002	01/01/2000-06/30/2002	01/01/1998-12/31/1999	01/01/2000-06/30/2002	01/01/2 06/30/

NA=Not Applicable.

[1] Transplants during the time period indicated in the last row of the table.

[2] Because different cohorts are followed for each time period, it is possible for reported 3-year survival to exceed 1-year survival.

[3] Based on U.S. graft failure rates adjusted for recipient and donor characteristics as indicated in the Analytical Methods.

CURRICULUM VITAE

William Henry Marks, M.D, Ph.D.

DATE OF BIRTH:	August 16, 1948
MARITAL STATUS:	Married
SPOUSE:	Christine
CHILDREN:	Annika Jennifer Daniel William Susan Alexandra Julia Christine

EDUCATION:

Undergraduate:	Loyola University, Chicago, IL, Bachelor of Science, 1970
Graduate:	University of Illinois Medical Center, Chicago, IL, Masters, 1973
	University of Lund, Sweden, Doctorate, 1984
Professional:	Loyola University Medical Center, Chicago, IL M.D., *cum laude*, 1977

POST DOCTORAL CLINICAL TRAINING:

Internship:	University of Michigan, Department of Surgery, 1977
Assistant Resident:	University of Michigan, Department of Surgery, 1978
Resident:	University of Michigan, Department of Surgery, 1981,1982
Chief Resident:	University of Michigan, Department of Surgery, 1983-1984
Fellow in Transplantation:	University of Michigan, Department of Surgery, 1984-1985

ACADEMIC APPOINTMENTS and CURRENT POSITION:

Teaching Assistant:	University of Illinois at the Medical Center, Department of Pharmacognosy and Pharmacology 1971-1973
Instructor:	University of Michigan, Department of Surgery, 1984-1985
Assistant Professor of Surgery and Biochemistry; Chief, Section of Surgical Endoscopy	Loyola University Medical Center - Stritch School of Medicine, Department of Surgery, 1985-1987
Assistant Professor of Surgery; Associate Director of Organ Transplantation	Yale University School of Medicine and Yale-New Haven Hospital, New Haven, CT, 1987-1988
Associate Professor of Surgery; Associate Director of Organ Transplantation; Director, Pancreas Transplantation; Director, Surgical Endoscopy	Yale University School of Medicine and Yale-New Haven Hospital, New Haven, CT, 1988-1993 1987-1991
Chief, Surgery Clinics	1991-1993
Adjunct Assistant Professor of Natural Products Chemistry	University of Illinois at the Medical Center, Department of Pharmacognosy, College of Pharmacy, Chicago, IL, 1986-1991
Adjunct Associate Professor of Natural Products Chemistry	1992-2003
Adjunct Professor	2003-Present
Robert B. McMillen Chair for Organ Transplantation	Organ Transplant Programs and Laboratory for Transplantation Biology, Swedish Medical Center/Seattle 1993-Present
Medical Director	Life Center Northwest - Organ Procurement Organization 1998 - Present

RESEARCH INTERESTS:

1. Pancreas transplantation, whole organ and islet
2. Organ specific proteins as diagnostic indications of injury
3. Clinical renal transplantation

GRANTS & AWARDS:

"Proteases and Inhibitors in Pancreas Transplantation" 1984-1986, Loyola University, Department of Surgery
Islet Isolation Using Ultrasound-Equipment grant - Cooper LaserSonics, 1984-1988
"Diagnosis of Mesenteric Ischemia", Smith, Kline & French ACS Fellowship, 1985-1986, 1986-1987
"Diagnosis of Pancreas Allograft Rejection", V.A. Central Office Grant, 1987-1988
"Diagnosis of Pancreas Allograft Rejection", American Diabetes Association, Illinois, Young Investigator Award, 1986-1987
"Diagnosis of Pancreas Allograft Rejection", Diabetes Research and Education Foundation, 1987-1988
"Isolation of Islet Growth Factor", Molecular Therapeutics - Miles Laboratories, 1989-1991
"Protease Inhibitors in Allograft Rejection", NIH Digestive Diseases Research Core Center Grant, 1991-1992
ATG Induction Therapy for Renal Transplantation, UpJohn 1994-1996
A sialoglycoprotein receptor / FK506 interaction, Syntex Corporation 1995-1996
Boeing Health Sciences Research Grant: IFABP as an Early Marker for Necrotizing Enterocolitis 1996-1998
Mycophenolate Mofetil affect on renal allograft histology, Roche 1997-1998
Atgam Out Patient Infusion, UpJohn Pharmacia, 1998-2001
"Simultaneous Kidney Islet Transplantation for Type 1 Diabetes", Clinical Project Co-PI HITS (Human Islet Transplant Consortium-Seattle), Juvenile Diabetes ResearchFoundation 2002- present
"Steroid Free Immunosuppression for Kidney Transplants", Sangstat 2000-2003
Co-Investigator: Immuno Tolerance Network, Long-Term Kidney Allograft Tolerance, 2002

CONSULTING POSITIONS:

Cooper LaserSonics, Inc., Santa Clara, CA, 1984-1989
Synergen Corporation, Boulder, CO, 1988
SmithKline Beecham Corporation, Surgical Advisory Board, 1990-1995
Sangstat, California, 2000- present

REVIEWER/EDITOR:

Journal of Histochemistry and Cytochemistry, 1985-
Journal of Surgical Research, 1986-
Transplantation, 1989-
Gastroenterology, 1991-
Contemporary Surgery for Residents (ed board), 1992-1998
Journal of Phytomedicine (ed board), 1992-
Canadian Medical Research Council, 1993, 1996, 1997
Northwest Kidney Center Research Council, 1999-2002

CERTIFICATION AND LICENSURE:

Medical Licensure:	Washington, Idaho, Montana, Alaska
Board Certification:	National Board of Medical Examiners
	American Board of Surgery (re-certified 1996)

HONORS AND AWARDS:

Beta Beta Beta, National Biological Honorary
Sigma Xi, National Research Honorary
Rho Chi, National Honorary for Pharmaceutical Sciences
Lange Award, Outstanding Achievement as a Medical Student, 1977
M.D., *cum laude*
University of Michigan, Department of Surgery Scholar, Clinical Tour, 1983
Smith, Kline & French ACS Fellowship, 1985-1986, 1986-1987
American Diabetes Association, Illinois, Young Investigator Award, 1986-1987
Diabetes Research and Education Foundation Award, 1987-1988
Resident Teaching Award-Surgery, Swedish Medical Center, 1997

MEMBERSHIPS AND OFFICES IN PROFESSIONAL and SCHOLARLY SOCIETIES:

Active= (A)

American Association for the Advancement of Science
(A) American College of Surgeons-Fellow
American Pancreatic Association (APA)
American Society for Gastrointestinal Endoscopy (ASGE)
(A) American Society of Transplantation (AST)
(A) American Society of Transplant Surgeons (ASTS)
Association for Academic Surgery
(A) Association of Organ Procurement Organizations
(A) Frederick Coller Surgical Society
International Association of Pancreatology
(A) North Pacific Surgical Association
(A) Pacific Coast Surgical Association
(A) Seattle Surgical Society
Society of American Gastrointestinal Endoscopic Surgeons (SAGES)
(A) Society for Surgery of the Alimentary Tract
Society for Surgical Investigation
Society of University Surgeons
(A) Surgical Biology Club III
The Pancreas Club
(A) The Transplantation Society

COMMITTEE AND ADMINISTRATIVE SERVICES:

ASTS Standards for Organ Procurement Committee
Utilization Review - University of Michigan, 1984
Educational Resources - Loyola University, 1985

Pilot Projects - Hines/Loyola, 1985-1987
Animal Studies - Hines/Loyola, 1985-1987
Library Studies - Loyola, 1986-1987
Program Committee, Association for Academic Surgery, 1988, 1989
Yale University, Animal Care and Use Committee, 1988-1990
Yale-New Haven Hospital, Endoscopy Committee, 1987-1991
Yale-New Haven Hospital, Tissue Committee, 1987
Yale University/Yale-New Haven Hospital, Surgical Residency Coordinating Committee, 1988, 1989
Trustee, New England Organ Bank, 1987-89
Medical Affairs Committee, New England Organ Bank, 1989-1993
Chairman, Pancreas sub-Committee on Allocation and Issues, 1991-1993
Ethics Committee, United Network for Organ Sharing, At Large-1989-1990
Ethics Committee, United Network for Organ Sharing, Region 1 rep., 1990-1992
Subcommittee on General Principles of Organ Allocation, Ethics Committee, United Network for Organ Sharing, 1991
Region 1 Nominating Committee, United Network for Organ Sharing, 1991
Vice President, Conn. Division, American Diabetes Association, 1990-1992.
Board of Directors, Conn. Division, American Diabetes Association, 1990-1993
Executive Committee, Conn. Division, American Diabetes Association, 1990-1992
Development Council, Conn. Division, American Diabetes Association, 1991-1992
Bylaws Committee, American Society of Transplant Surgeons, 1990-1993
Human Investigation Committee, Surgical Representative, Yale University and Yale New Haven Hospital, 1990-1993
OSHE Grants Committee, Yale University, Department of Surgery, 1990-1993
Medical Data Review Committee, American Society of Transplant Surgeons, 1991-1997
Chairman, Medical Advisory Committee, General Clinical Research Center, Yale University School of Medicine, 1991-1993
Safety Council, Department of Surgery, Yale University School of Medicine, 1991
Director, Surgical Clinics, Department of Surgery, Yale University School of Medicine 1991-1993
Schell Center Program on Human Rights and Organ Transplantation, Yale University School of Medicine and Yale University School of Law, 1992
Medical Staff Practice Plan Task Force, Office of the President, Yale New Haven Hospital, 1992-1993
United States Medical Licensing Examination Step 2 Test Material Development and National Board of Medical Examiners Committee, 1993-1995
Ethics Committee, Swedish Medical Center, 1993-1996
Board of Trustees, Northwest Kidney Centers, 1993-2000
Long-Range Planning Committee, Northwest Kidney Centers, 1993-1996
Medical Advisory Board, Northwest Kidney Centers, 1995
Regional Representative to the UNOS Communications Committee, 1995-1996
Scientific Advisory Committee, UNOS (Region #6 Representative) 1995-1998
Chairman, Abdominal sub-Committee, 1997-1998
Chairman, ASTS Informatics and Data Committee, 1995-1998
Medical Information Systems Team, Swedish Medical Center, 1995-present
Secretary, Board of Directors, CenterSpan Transplant Informatics Project, 1996-1998
Founding Secretary, Board of Directors, LifeCenter Northwest (OPO) 1996

Board of Directors, Northwest Kidney Center, Seattle, Washington, 1997-2001
Member of the Board of Directors, LifeCenter Northwest, 1997-present
Member, Executive, Finance and Medical Advisory Committees, LCNW, 1997-present
Medical Director, LifeCenter Northwest, 1998-present
Ethics Committee, United Network for Organ Sharing, 2001- present
Chairman Medical Advisory Board, University of Illinois, UIC/NIH Center for Botanical, Dietary Supplements Research, 2000- present
Program Chairman, Seattle Surgical Society, 2000-2002
Medical Advisor (elect) – Association Organ Procurement Organization (AOPO) – 2003

THESES:

1. Cytotoxic Principles of Parguentina Nigrescens. Masters thesis, University of Illinois at the Medical Center, Marks WH, 1973.
2. Pancreatic Secretory Trypsin Inhibitor: Experimental and Clinical Studies in the Rat and Man. Doctoral dissertation, University of Lund, Sweden, Marks WH, 1983.

Trainees/Research Fellows: Ken Newell, M.D., Ph.D. (Faculty, Tulane University); Kent Brusett, M.D. (Cardiothoracic Surgery, UNC); Gerald Gollin, M.D. (Ped Surg Faculty, Loma Linda); Paul Morrisey, M.D. (Faculty, Deaconess, Rhode Island Hospital); Josh Lieberman, M.D. (Transplant lab fellow, Swedish); David Lim, M.D (Resident, U C, San Diego).

Thesis Advisor: Surgically Induced Nesidioblastosis in Rats. David Lim, (Yale) 1993.
Thesis co-Advisor: Cyclofillin and Cyclosporin Interaction. Monica MacDonald, (Yale) 1992.

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4. **Marks WH** and Ohlsson K: A radioimmunoassay for rat pancreatic secretory trypsin inhibitor. Scand J Gastroenterol 18:401-405, 1983.
5. **Marks WH** and Ohlsson K: Elimination of pancreatic secretory trypsin inhibitor from the circulation. A study in man. Scand J Gastroenterol 18:955-959, 1983.
6. Strodel WE, Dent TL, Nostrant TT, Eckhauser FE, Campbell DA and **Marks WH**: Treatment alternatives in renal failure and renal transplantation patients with non-obstructive colonic dilatation (NCD). Transplantation 36:37-40, 1983.
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9. **Marks WH**, Genell S, Hjelmqvist B and Ohlsson K: Pancreatic secretory proteins in sera from rats before and after induction of experimental pancreatitis. Scand J Gastroenterol 19:552-560, 1984.
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11. **Marks WH**, Wehlin L, Ohlsson K and Russick C: Quantitation of some pancreatic juice exocrine proteins in the presence of radiocontrast medium used in endoscopic retrograde pancreatography (ERP). Endoscopy 16:211-213, 1984.
12. **Marks WH**, Ohlsson K, Wehlin L and Russick C: Pancreatic secretory trypsin inhibitor, cathodal trypsin, and pancreatic elastase in pancreatic juice collected at endoscopic retrograde cholangiopancreatography. Current Surgery 42(1):26-28, 1985.
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15. Dafoe DC, Campbell Jr. DA, **Marks WH**, Wilson GN and Turcotte JG: Karyotypic chimerism and rejection in a pancreaticoduodenosplenic transplant. Transplantation, 1985.
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18. Borgström A, **Marks WH**, Dafoe DC, Campbell DA and Turcotte JG: Immunoreactive anionic and cationic trypsins in serum after experimental porcine pancreatic transplantation. Surgery 100:841-848, 1986.
19. Borgström A, Wider M, **Marks WH**, Lloyd R, Herman G and Vinik AI: Immunohistochemical localization of a specific ileal peptide in the pig. Histochem 86:101-105, 1986.
20. Dafoe DC, Campbell DA, **Marks WH**, Borgström A, Lichter AS and Turcotte JG: The effect of irradiation of the donor spleen on rejection of porcine pancreaticoduodenosplenic allografts. Transplantation 42:686-687, 1986.
21. **Marks WH** and Strodel WE: Emergency Endoscopy in Emergency Medicine Clinics of North America, August, 1986.
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23. Borgström A, **Marks WH**, Dafoe DC, Campbell DA Jr and Turcotte JG: Parallel rejection of exocrine and endocrine tissue after porcine pancreatic whole organ transplantation. Transplantation Proceedings 19:1026-1028, 1987.
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29. **Marks WH**, Salvino C, Newell K, Wider M and Marks C: Circulating concentrations of porcine ileal peptide but not hexosaminidase are elevated following 1 hr of mesenteric ischemia. J Surg Res 45:134-139, 1988.
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PAPERS in Progress:

Marks WH, Florence L, Chapman, P, Perkinson D, Howard D. Steroid-Free Immunosuppression With Delayed Introduction of A Calcineurin Inhibitor and Mycophenolate Mofetil In Cadaver And Living Donor Kidney Transplants. In manuscript 2002.

Marks WH, Florence L, Chapman P, Howard D, Perkinson D. Should True Morbidly Obese Patients Be Denied Kidney Transplantation? In manuscript 2002.

INVITED LECTURES, PRESENTATIONS:

1. Cyclosporin in Transplantation: The Impact and Future Role of Natural Products on Transplantation, University of Illinois at the Medical Center in Chicago, Department of Collaborative Research in the Pharmaceutical Sciences, 1986.
2. Short Gut Syndrome: Immediate and Long Term Management, Surgical Update, Cook County Graduate School of Medicine, Chicago, 1987.
3. American Surgical Perspective on Severe Acute Pancreatitis, University of Lund/Bayer Symposium on Severe Acute Pancreatitis, Malmo, Sweden, 1987.
4. Pathogenesis of Clinical Pancreatitis, Synergen Corporation, Boulder, Colorado, September 1987.
5. Pancreas Transplantation: State of the Art, Lawrence & Memorial Hospital, New London, Connecticut, October 1987.
6. Current State of Transplantation, The Westerly Hospital, Westerly, Rhode Island, October 1987.

7. Current State of Pancreas Transplantation, Annual Address to Connecticut Chapter of the American Diabetes Association, Waterbury, Connecticut, November 1987.
8. Post-Endoscopic Pancreatitis, ERCP Pancreatic Study Group, Boulder, Colorado, 1988.
9. Non-Immune Organ Specific Markers for Rejection of Pancreas and Small Bowel Allografts, GI Research Group, Yale University, March 1988.
10. Do you think it's his gut?, Grand Rounds, Yale-New Haven Hospital, 1988.
11. Small Bowel Ischemia, Surgical Grand Rounds, St. Luke's Hospital, New York City, 1988.
12. Pancreas Transplantation, Grand Rounds, Yale-New Haven Hospital, 1989.
13. Current Research in Pancreas Transplantation, Alumni Day Speaker, Department of Surgery, Yale University School of Medicine, 1989.
14. Transplantation - Then, Now and Then What?, Scientific Session Address, Connecticut State Medical Society, 1989.
15. Pancreatic Transplantation, Grand Rounds, St. Joseph Hospital, Chicago, IL, 1989.
16. Diagnosis of Pancreas Transplant Rejection, University of Chicago, Grand Rounds, Chicago, IL, 1989.
17. Pancreas Transplantation - Today and Tomorrow, American Diabetes Association, Connecticut Division, Annual Meeting, 1989.
18. Transplantation - Modern Therapies, Ancient Dilemmas, Annual Sackler Lecture, Greenwich Hospital, Greenwich, CT, 1989.
19. Cyclophillin, The Natural Receptor for Cyclosporine, Norman R. Farnsworth Symposium on Natural Products Research, Chicago, IL, 1990.
20. Pancreas Transplantation Update, Grand Rounds, Waterbury Hospital, Waterbury, CT, 1990.
21. Pancreas Without Kidney Transplantation, ESRD Network of New England, Annual Meeting, Sturbridge, MA, 1990.
22. Pancreas Transplantation in the 1990's, Annual Meeting of the Board of Directors, ADA, Connecticut Division, 1990.
23. Pancreas Transplantation, Surgical Grand Rounds, Hospital of Saint Raphael, 1990.
24. The Surgical Therapy of Diabetes, Surgical Grand Rounds, St. Mary's Hospital, 1991.
25. The Role of Anodal Trypsinogen and Clinical Pancreas Transplantation, Research Rounds, Department of Surgery, Division of Transplantation, University of Iowa, 1991.
26. Kidney-Pancreas Transplantation in 1991 and in the Future, Connecticut Association of Diabetes Educators, 1991.
27. Pancreas Alone Transplantation, Alumni Grand Rounds, Yale University School of Medicine, 1991.
28. Exocrine Proteins as Biochemical Markers for Pancreatic Allograft Rejection, JDF Student Research Lecture Series, Yale University School of Medicine, 1991.
29. Transplantation Today and Into the Future: Grand Rounds, St. Joseph's Hospital, Chicago, Il, 1991
30. The Process of Science in Medicine - Transplantation Today: ISIS Science Teachers Program, Southern Connecticut State University, 1991.
31. The Immunocompromised Host, Basic Science Lecture, St. Mary's Hospital, Waterbury, CT, 1991.
32. Fatty Acid Binding Proteins during Intestinal Ischemia, Abbott Laboratories Diagnostic Division, Abbot Park, IL, February 1992.

33. Visiting Lecturer, University of Washington at Seattle, Diagnosis of Rejection in Whole Organ Pancreas Allografts, April 1992.
34. Visiting Lecturer, Seattle Transplant Society, Small Bowel Transplantation: State of the Art, April 1992.
35. Visiting Lecturer, University of Nebraska at Omaha, Department of Surgery, Transplantation Research Rounds: Diagnosis of Rejection Occurring in Small Bowel Allografts and Diagnosis of Rejection Occurring in Pancreatic Allografts using the Anodal Trypsinogen Assay, May 1993.
36. Isolated Pancreas Transplantation: Current Status. Department of Medicine, Nephrology Rounds, Yale University, May 1993.
37. Transplantation Today. Grand Rounds, Swedish Hospital, April 1994.
38. Pancreas Transplantation Today and the Future. Nephrology Day, University of Washington, April 1994.
39. "Alternative?. . .Semantics!" Overlake Hospital Grand Rounds, 1995.
40. Percutaneous Endoscopic Gastrostomy for Gastric Decompression in Metastatic Gynecologic Malignancies, Albert Einstein Medical Center, NY, 1995.
41. IFABP for the Early Diagnosis of Intestinal Ischemia. Centocore Inc., PA, 1995.
42. Anodal Trypsinogen for the Diagnosis of Pancreatic Rejection. University of Cincinnati, OH, 1995.
43. "Alternative?. . . Semantics!" Swedish Medical Center Grand Rounds, 1996.
44. Visiting Professor, 'The potential beneficial impact of kidney transplantation in the developing countries'; University of Zimbabwe, Harare, 1997.
45. Visiting Professor, 'Basic surgical skills for living donor transplantation,' 'Antithymocyte preparations for the treatment of acute allograft rejection,' University of Khabarovsk and the Dalmed Medical Center, Regional Hospital #1, Khabarovsk, Russia, 1997.
46. Visiting Researcher; IFABP as a marker for acute injury to the intestinal mucosa, University of Miami, February 1998.
47. Organ procurement and the medical community, institute of medicine, Tacoma General Hospital, Tacoma, WA, 1998.
48. Transplantation: What to do with yourself when you are through with yourself and why, Seattle Rotary, Seattle, WA, 1998.
49. Current strategies for short and long term immunosuppression after renal transplantation: The Transplant Society of Costa Rica, San Jose, CR, January 1999.
50. Pancreas Transplantation: an update of current practice: The Transplantation Society of Costa Rica, San Jose, Costa Rica. January 1999.
51. Immunologic mechanisms of polyclonal induction therapy. The Danish Transplant Society. Copenhagen, Denmark, April 1999.
52. Intestinal Fatty Acid Binding Protein: Background, Rationale and Clinical Correlations. Dept. of Gastrointestinal Surgery. University Hospital, Malmo, Sweden, 1999.
53. Transplantation: Modern Dilemmas, Alderwood Rotary, 1999.
54. American College of Chest Physicians, 11th Annual General Thoracic & Cardiac Surgery Update, St. Thomas, USVI, Dec. 3, 1999.
55. Organ Donation - The Living Organ Donor Issue, Microsoft, Redmond, WA, 2000
56. Pancreas and Islet Transplantation, Washington Chapter, American Nephrology Nurses Association, June 2001.
57. "Kidney Transplantation Without Steroids", Montana State Nephrology and Nephrology Nurses 2002.
58. Human Islet Transplantation of Seattle (HITS)-Clinical update, International Islet Update, Annenberg Center, Palm Springs, 2002.

59. "The Economics of Specialty Surgical Practice", Timpangos Surgical Society, Sundance, UT, 2002.
60. Surgical Resident Training – The American History; Timpangos Surgical Society, Sundance, UT, 2003.
61. "Steroid Free Immunosuppression for Kidney Transplant", UCSF Transplant Grand Rounds, San Francisco, CA, 2003.
62. "Steroid Free Immunosuppression for Kidney Transplant", Standford Transplant Grand Rounds, Palo Alto, CA, 2003.
63. "TMG Induction for Kidney Transplant", Sangstat Scientific Program, San Diego, CA, 2003.
64. "Morbid Obesity is Not a Contraindication to Kidney Transplantation", North Pacific Surgical Association, Portland, OR, 2003.

Abstracts and Posters:

1. On the mechanism of taurocholate (TC) induced pancreatitis. Resident Program, Michigan Chapter, American College of Surgeons, 1982.
2. Localization of exocrine pancreas proteins in human pancreas tissues. World Congress of Gastroenterology, Stockholm, Sweden, 1982.
3. Exocrine pancreatic secretion in normal and diseased glands. World Congress of Gastroenterology, Stockholm, Sweden, 1982.
4. The effect of radiocontrast media on the immunochemical analysis of some proteins in human pancreas juice collected at ERCP. World Congress of Gastroenterology, Stockholm, Sweden, 1982.
5. Immunocytochemical localization of trypsinogen and pancreatic secretory trypsin inhibitor in the human pancreas - Results in normal and tumor tussies - 1982. Resident Section, Mayo Lecture Series, University of Michigan, 1982.
6. Pulsatile mass and jaundice in a 4 year old following Kawasaki's Syndrome. Michigan Pediatric Surgery Club, Detroit, 1983.
7. Pancreatic secretory trypsin inhibitor. Doctoral defense, Malmo, Sweden, 1983.
8. Immunoreactive trypsinogen, pancreatic elastase and pancreatic secretory trypsin inhibitor in pancreas juice collected at ERCP. Frederick A. Coller Surgical Society, Scientific Section, Florida, 1983.
9. Serine proteases and their inhibitors in pancreatic inflammation and carcinoma. Resident Section, Mayo Lecture Series, University of Michigan, 1983.
10. Pancreatic secretory trypsin inhibitor, trypsin, pancreatic elastase and amylase in the pancreatic juice of patients with normal and diseased glands. Society of University Surgeons, Resident Section, Chicago, 1984.
11. Porcine pancreaticoduodenal allotransplantation. Frederick A. Coller Surgical Society, Scientific Section, California, 1984.
12. Hepatic adenomas: Failure of regression after discontinuance of oral contraceptives. Frederick A. Coller Surgical Society, Scientific Section, New Zealand, 1985.
13. Porcine ileal peptide: A potential marker for rejection of small intestine allografts. First International Symposium on Small Bowel Transplantation, Kiel, BDR, 1985.
14. Potential recipients for small bowel transplantation in the United States and United Kingdom. First International Symposium on Small Bowel Transplantation, Kiel, BDR, 1985.
15. Duodenal histology during rejection of whole organ pancreaticoduodenal allografts in the pig. First International Symposium on Small Bowel Transplantation, Kiel, BDR, 1985.

16. Parallel rejection of exocrine and endocrine tissue after porcine pancreatic whole organ transplantation. The Transplantation Society, Helsinki, Finland, 1986.
17. Ileal specific peptide: Behavior during prenecrotic ischemia in the pig. Medical Student Research Forum, Galveston, 1987.
18. "Does ischemia cause pancreatitis?" Pancreas Club, Chicago, 1987.
19. *In situ* ultrasonic disruption of the pancreas: A new method for isolating large yields of highly purified islets of langerhans in a large animal model. American Society of Transplant Surgeons, Chicago, 1987.
20. Circulating concentrations of ileal specific peptide but not hexosaminidase are elevated following one hour of mesenteric ischemia. Association for Academic Surgery, Orlando, Florida, 1987.
21. Serum immunoreactive anionic trypsin is diagnostic for rejection of vascularized pancreas allograft. The Transplantation Society, Sydney, Australia, 1988.
22. The tissue distribution of cyclophilin - The primary receptor for cyclosporine. American Society of Transplant Physicians, Chicago, 1989.
23. Serum anodal trypsinogen is a predictive biochemical marker of pancreas allograft rejection. International Congress on Pancreatic and Islet Transplantation, 1989.
24. Effect of SMS 201-995 on bile induced acute canine pancreatitis. American Pancreatic Association, 1989.
25. Serum markers for pancreas rejection: Long term behavior following clinical pancreatico-duodenal transplantation. The Transplantation Society, San Francisco, 1990.
26. Cyclophilin binding: A more accurate measure of cyclosporine immunosuppressive activity after renal transplantation. Poster, The Transplantation Society, San Francisco, 1990.
27. Decreased tissue inhibitor on metalloproteinases (TIMP) in abdominal, aortic aneurysm tissue. Twenty-fourth Annual Meeting, Association for Academic Surgery, 1990.
28. High dose CCK induces intracellular activation of trypsin in a new cellular model of acute pancreatitis. Pancreas Club, Chicago, 1990.
29. Effect of the cholecystokinin receptor antagonist L-364, 718 on bile induced acute canine pancreatitis. Pancreas Club, Chicago, 1990.
30. Are calcium channel blockers protective against first dose reactions to OKT3? 10th Annual Meeting, American Society of Transplant Physicians, Chicago, 1991.
31. The effect of cyclosporine therapy on the cellular distribution and content of cyclophilin. 17th Annual Scientific Meeting, American Society of Transplant Surgeons, 1991.
32. A three year clinical experience using serum anodal trypsinogen, a biochemical marker for rejection in pancreatic allografts: False positives, tissue biopsy, comparison to other markers, and diagnostic strategies. Plenary Session,17th Annual Scientific Meeting, American Society of Transplant Surgeons, Chicago, 1991.
33. Early detection of small intestinal ischemia by elevated circulating intestinal fatty acid binding protein (I-FABP). Surgical Forum, American College of Surgeons, Chicago, 1991.
34. N-tosyl-L-lysyl-chloromethylketone (TLCK) or N-p-tosyl-phenylalanineketone (TPCK) inhibition of T-cell activation. Society of University Surgeons, Residents' Section, Cincinnati, 1991.
35. Serum levels of intestinal fatty acid binding protein in a luminal model of necrotizing enterocolitis (NEC). American Pediatric Surgical Association, Colorado Springs, 1992.
36. Hepatic re-transplantation: A regional experience. 18th Annual Scientific Meeting, American Society of Transplant Surgeons, 1992.
37. Pancreatic exocrine protein concentrations in amniotic fluid are elevated in duodenal but not distal, small bowel atresia. American College of Surgeons, Surgical Forum, 1992.

38. Biochemical detection of small intestinal allograft rejection by elevated circulating levels of serum intestinal fatty acid-binding protein (I-FABP). Society of University Surgeons, Seattle, 1993.
39. Small bowel allograft rejection detected by serum intestinal fatty acid-binding protein (I-FABP) is reversible. American Society of Transplant Surgeons, Houston, 1993.
40. Calcium channel blockers do not exhibit in vivo immunosuppression. American Society of Transplant Physicians, Houston, 1993.
41. TLCK, a serine protease inhibitor, prolongs heterotopic cardiac allograft survival in the rat. American Society of Transplant Physicians, Houston, 1993.
42. Biochemical detection of rejection occurring in cardiac allografts by serum heart fatty acid binding protein (H-FABP). American College of Surgeons, San Francisco, 1993.
43. Serum and urine levels of intestinal fatty acid-binding protein are associated with acute intestinal ischemia. Society of University Surgeons, Residents' Program , Denver, 1995.
44. Systemic inflammatory response syndrome after human syngeneic intestinal transplantation with evidence for disruption of enterocyte barrier function. In collaboration with the Division of Transplantation at Stanford University Medical Center, 1995.
45. Intestinal fatty acid binding protein (I-FABP) is present in surgical patients with systemic inflammatory response syndrome (SIRS). In collaboration with the Division of Trauma, Yale University.
46. Elevated plasma intestinal fatty acid binding protein levels identifies grad 3 nec within 8 hours of onset. The Society for Pediatric Research, 1996.
47. Co-monitoring serum anodal trypsinogen, serum amylase, and serum creatinine accurately differentiates rejection from other causes of allograft dysfunction after simultaneous pancreas kidney transplantation. American Society of Transplant Surgeons, Dallas, TX, 1996.
48. Asialogalactoproteins-asialogalactoprotein receptor (AGP-AGPr) interaction is an important mechanism for the uptake of FK506 by hepatocytes. American Society of Transplant Surgeons, Dallas, TX, 1996.
49. Atgam induction with sequential mycophenolate mofetil (MMF) decreases the incidence of early allograft rejection in cadaveric renal transplants. American Society of Transplant Surgeons, Dallas, TX, 1996.
50. Atgam induction with sequential mycophenolate mofetil (MMF) as immunosuppression for renal transplantation: a 2 year follow-up. American Society of Transplant Surgeons, Chicago, IL, 1997.
51. Correlation of Systemic Inflammatory Release Syndrome and the Concentration of Urinary Intestinal Fatty Acid Binding Protein (I-FABP), Eastern Trauma Society, Miami, Fl, 1998.
52. Quantification of Intestinal Fatty Acid Binding Protein (I-FABP): Evaluation in critically ill patients of an immunologically distinct cytoplasmic protein, which is site specific for the mature small intestinal epithelium. Bethesda, MD, 1999.
53. Kidney Donation from older living donor is safe and an important source of transplantable kidneys, American Society of Transplant Surgeons, Chicago, 1999.
54. Steroid-Free Immunosuppression With Delayed Introduction of A Calcineurin Inhibitor and Mycophenolate Mofetil In Cadaver And Living Donor Kidney Transplants, American Society of Transplant Surgeons, Washington, D.C., April 2002
55. Should True Morbidly Obese Patients Be Denied Kidney Transplantation?, American Society of Transplant Surgeons, Washington, D.C., April 2002
56. A Comparison of Two Steroid Free Regimens for Kidney Transplantation, American Society of Transplantation, Washington, D.C., May 2003.

FILMS:

Application of the CAVITRON Ultrasonic Surgical Aspirator to Resection of the Pancreas (with Dr. W. Strodel), 1985.

(Revised November 24, 2003)

EXHIBIT G

ORIGINAL

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

IN RE: Certificate of Need Application of Swedish Medical Center.	) Docket No. 04-07-C-2005CN

FILED
APR 18 2005
Adjudicative Clerk Office

TRANSCRIPT OF PROCEEDINGS
Day 4, 9:30 A.M. - 10:45 A.M.

A P P E A R A N C E S

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1 objection on foundation. It's already been covered by
2 Dr. Marks.
3 JUDGE CANER: Overruled. Goes to weight.
4 And I've ruled earlier on the standing objection.
5 A I think this data showing that the WWAMI region is
6 grossly underrepresented in persons on the wait list per
7 million residents, falling only below Georgia, which, by
8 the way, has recognized a need for another program and
9 is starting a second liver transplant program.
10 MS. BENEDICT: Objection, Your Honor.
11 JUDGE CANER: Mr. Pentz, your response?
12 MR. PENTZ: Your Honor, again, I think
13 he's established his expertise and knowledge in this
14 area. He's rendering an expert opinion.
15 Again, Dr. Reyes was asked as an expert his opinion
16 upon general issues relating to liver transplantation
17 and was allowed, that testimony was admitted.
18 MS. BENEDICT: Your Honor, it was not
19 admitted. It was sustained.
20 JUDGE CANER: I'm going to sustain this
21 objection because I know I did not allow in more updated
22 information regarding the amount of transplants in the
23 programs that are beyond this record. So I'm going to
24 sustain the objection.
25 MR. PENTZ: Just to clarify, Your Honor,

1 because it was a long response. The objection only is
2 sustained as to Dr. Dickson's reference to a second
3 program in the state of Georgia; is that correct?
4 JUDGE CANER: Correct.
5 Q (By Mr. Pentz) Dr. Dickson, you were interrupted there.
6 I don't know if it affected your train of thought. But
7 the question was, in your opinion, do you have an
8 opinion as to whether, in light of this data, Washington
9 residents are being adequately served by the University
10 of Washington liver transplant program. And your answer
11 was yes, and you were giving a response.
12 A My response was that I was concerned that they were not
13 being served as the number of patients on the wait list
14 was disproportionately low, that it should be higher.
15 Q And what is the basis for that opinion?
16 A Well, I think that, in order to get access to liver
17 transplants, you need to be evaluated and placed on a
18 waiting list. And if your waiting list per million
19 residents is very low, with a national average of 60,
20 it's suggesting that there are many more patients that
21 should be on the list awaiting a liver transplant.
22 Q Now, Dr. Dickson, during the course of this proceeding,
23 the University of Washington has raised a concern that
24 the addition of a second liver transplant program at
25 Swedish will, in their view, result in the area having

1 two, quote-unquote, average or two, quote-unquote,
2 mediocre programs.
3 Do you have an opinion about the validity of the
4 concern raised by the University of Washington?
5 MS. BENEDICT: Objection, no foundation
6 whatsoever. There's a variety of factors that go into
7 whether there will be an impact to which Dr. Reyes
8 testified at lengths, and he's established no
9 foundation.
10 JUDGE CANER: Mr. Pentz?
11 MR. PENTZ: Your Honor, I have in my
12 notes that Dr. Reyes was asked a direct question as to
13 whether the addition, what impact the addition of a
14 second program would have. Dr. Ham was also asked that
15 question, and he was allowed to testify.
16 Again, I myself object to the representation that
17 Swedish has presented its case-in-chief, the burden of
18 proof in this proceeding is on the University of
19 Washington to establish that the department did not
20 reach a correct decision. We are allowed to rebut
21 testimony made by Dr. Reyes and Dr. Ham regarding the
22 effect of having a second program enter the market.
23 MS. BENEDICT: Your Honor, in both of
24 those cases, a foundation was well established, all the
25 factors were addressed, and then the opinion question

1 was asked.

2 And as far as the burden of proof, it is clear from
3 the department's own rules that the burden of proof is
4 on the applicant, primarily, to establish they met the
5 criteria when they filled out their application. And
6 the burden, then, is on the department to show that
7 their analysis meets the criteria.

8 And this is an order that was issued under APA, and
9 the department has the obligation to uphold that order
10 and show that they can make a prima facia case. And
11 that's basic administrative law.

12 JUDGE CANER: We don't need to get into
13 the burden of proof issue now. The UW is appealing the
14 case. It's a preponderance of evidence to prove that
15 the department was wrong. But we don't need to get into
16 that argument here. This is a foundation issue, and I
17 want to keep it to that. Let's try not to sidetrack in
18 our arguments.

19 Mr. McCartan, do you have any response to the
20 foundation objection as to opinion and the impact on the
21 University of Washington?

22 MR. McCARTAN: I think would go more to
23 weight than admissibility.

24 JUDGE CANER: I'm going to overrule. And
25 I agree, I think it goes as to weight, rather than to

1 admissibility.

2 Dr. Dickson, you may answer the question.

3 THE WITNESS: Could you repeat that, one

4 more time?

5 JUDGE CANER: I'll ask counsel to.

6 Q (By Mr. Pentz) Doctor, during the course of this

7 proceeding, the University of Washington has raised a

8 concern that, in its opinion, the addition of a second

9 liver transplant program at Swedish will result in the

10 area having two, quote-unquote, average or two,

11 quote-unquote, mediocre programs.

12 Do you have an opinion about the validity of the

13 concern raised by the University of Washington?

14 A I can say I have a very strong opinion about that, based

15 on my personal experience, which I gather from the

16 previous objection I'm not allowed to discuss. But it's

17 my feeling that a second program actually will improve

18 the quality of the other program, that competition and

19 actually having another program in the state forces the

20 program to be more innovative, to take better care of

21 the referring physicians, to take better care of their

22 patients, to many of the patients. And I suspect that,

23 given the numbers, that a large number of patients are

24 falling through the cracks, that the population would be

25 better served by having a second program. It's my

1 experience that a second program, unless the existing
2 program is entirely inadequate, which my opinion, at the
3 University of Washington, is that it's not, that it's a
4 very reasonable program. But in the absence of the
5 program being entirely inadequate, that it will
6 actually, in some ways, make it a better program. My
7 guess is that transplants in the entire state and region
8 will increase, quality will increase, and it will be
9 better service, both to the provider sending the patient
10 and to the patient and their family.
11 Q And just two final questions, Doctor. The University of
12 Washington has also, in the course of this proceeding,
13 suggested that, based upon the type of argument you've
14 just made, that that's all well and good, but there's a
15 limited universe of livers available for transplant --
16 MS. BENEDICT: Objection, Your Honor.
17 JUDGE CANER: Let him finish his
18 question.
19 Q (By Mr. Pentz) Again, Dr. Dickson, the University of
20 Washington has argued during the course of this
21 proceeding that the types of things you are saying may
22 be well and good, but after all, there's a, reportedly,
23 a limited universe of livers available for transplants,
24 so these benefits may never materialize.
25 Do you have an opinion as to that?

ORIGINAL

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE CLERKS OFFICE

In Re:	)	
	)	
CERTIFICATE OF NEED	)	
APPLICATION OF	)	No. 04-07-C-2005CN
SWEDISH MEDICAL CENTER,	)	
	)	
Applicant.	)	

TRANSCRIPT OF PROCEEDINGS
DAY 4, A.M. & P.M.
FEBRUARY 3, 2005

APPEARANCES:

Presiding Officer:	ZIMMIE CANER Health Law Judge
For the CON Program:	RICHARD A. McCARTAN Assistant Attorney General P.O. Box 40109 Olympia, Washington 98504-0109
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Kent, Washington
February 3, 2005

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1 A Well, I just had one here about three months ago, and
2 by the time they got here they were too ill and actually
3 died before they could complete their evaluation, who was
4 we had felt was a good candidate.
5 Q And based on that one anecdote, it's your opinion that
6 there are patients falling through the cracks in the State
7 of Washington?
8 A No, the anecdote supports my feeling about that.
9 Q Have you reviewed--
10 A I think that with the low waiting list numbers that I
11 suspect that there are patients that are not, either not
12 getting access to the system or are being, either just
13 because of education of community of who is a good
14 transplant patient, or are being denied being placed on the
15 list.
16 Q Have you reviewed the University of Washington's wait
17 list criteria?
18 A I have not.
19 Q Have you participated in any conferences regarding
20 selection of patients for transplant?
21 A I've certainly been involved in criteria of selection
22 both at the three institutions I have been involved with.
23 Q The question was regarding the University of
24 Washington.
25 A And at the Mayo Foundation level.

EXHIBIT H

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FILED
APR 28 2005
Adjudicative Clerk Office

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE CLERKS OFFICE

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FEBRUARY 3, 2005

APPEARANCES:

Presiding Officer:	ZIMMIE CANER Health Law Judge
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1 you ask him for an opinion--

2 MR. PENTZ: I did ask him for an opinion.

3 JUDGE CANER: Yes, but not to rehash what

4 the numbers say.

5 MR. PENTZ: I asked him for an opinion.

6 JUDGE CANER: Okay, that's fine.

7 Q (By Mr. Pentz) Dr. Miller, do you recall the

8 question? We're done objecting.

9 A I think you better repeat it so I do this--

10 Q I'm referring to Table 2, which has the MELD scores?

11 A Yes.

12 Q In your opinion what does Table 2 tell us about the

13 MELD scores of patients at the University of Washington

14 Liver Transplant Program at the time of transplant?

15 A Well, specifically at the University of Washington

16 tells you what level of MELD scores are being transplanted.

17 And what the table does is compares it to other major

18 transplant centers in the west.

19 And when you look at it that way, it appears that

20 a higher proportion of patients are being transplanted at

21 the lower MELD scores and less Status 1 patients than at

22 the majority of the other transplant centers, major

23 transplant centers in the west.

24 Q Thank you, Doctor. Doctor, if you could please turn

25 to page 16 of the rebuttal statement, which is page 618 of

1 the administrative record. Are you there?
2 A Yes, I'm here, I'm here. I'm just sitting on the side
3 of the road.
4 Q Have you previously reviewed Table 5 on page 16 of the
5 rebuttal statement?
6 A Yes.
7 Q Are you still there, Dr. Miller?
8 A I'm here.
9 Q Based upon your review of the rebuttal statement, your
10 review of the specific portions of the record I've referred
11 to you, and your review of Table 5, what would you conclude
12 about the waiting list in the WAMI or WWAMI region based
13 upon this data?
14 MR. PRICE: Your Honor, I'm going to object
15 based on foundation and the question is vague.
16 A Can I answer?
17 JUDGE CANER: I'm sorry, Dr. Miller, we're
18 doing legal wrangling again. This is Judge Caner. I'll
19 tell you when and if you can answer. Okay, don't worry.
20 MR. PRICE: Two bases, one is the question's
21 vague and it's not clear to me what he has reviewed, it's
22 not clear from the question what he has reviewed. And
23 certainly the preface of the question is based upon his
24 review of a certain list of documents.
25 Secondly, it's cumulative along the lines of my

1 previous objection.

2 JUDGE CANER: I'm going to overrule, that

3 can go to weight. And since he's a different specialist,

4 he may testify to this. Go ahead.

5 Q (By Mr. Pentz) Dr. Miller, you can answer the

6 question now.

7 A Oh, okay. This is a simple table of patients on liver

8 waiting lists, in states or areas, the population of those

9 and then a rate of number of persons per million residents

10 in an area. And you can see California has 106 people per

11 million on their list; Georgia is at the other end of the

12 spectrum is 17 patients per million on a transplant list;

13 and then Washington or WAMI, whatever that is, is really

14 below, even below Georgia with 14.

15 So a very small number of patients per million

16 population have access to the liver transplant patient

17 waiting list at any one point in time.

18 Q And you're referring with respect to the WAMI region;

19 is that correct?

20 A Yeah, and it's 14 patients per million population. So

21 that's the lowest number here on that list and that's what

22 the table says, compared to the United States which is the

23 broad brush of 60 patients per million population; it's

24 quite a, you know, 25 percent of that.

25 Q Now, Doctor, based upon the data you've reviewed, do

1 you have an opinion as to whether residents of the State of
2 Washington are being adequately served by the existing
3 adult liver transplant program?
4 MR. PRICE: Your Honor, I'd object on the
5 basis of foundation. He hasn't testified as to--
6 A Can I answer?
7 JUDGE CANER: Not yet.
8 MR. PENTZ: Not yet, sorry.
9 MR. PRICE: -- as to anything he's reviewed
10 with respect to-- actually I withdraw the objection.
11 JUDGE CANER: Dr. Miller, you can answer the
12 question. Do you remember it?
13 A Whether the patients are-- actually why don't you
14 repeat it.
15 Q (By Mr. Pentz) Based upon the data you've reviewed,
16 do you have an opinion as to whether residents of the State
17 of Washington are being adequately served by the University
18 of Washington Liver Transplant Program?
19 A Well, I think the patients that get there and get
20 listed and are transplanted may be well-served, certainly
21 in a way that it's equal to any kind of average in the
22 United States from looking at the UNOS data.
23 What is somewhat troubling is this rate of
24 numbers getting on to the list as well as the transplant
25 rate which actually if you look at it has got .89 per

1 100,000, or 8.9 per million in WAMI and it's about double
2 that in the United States. So there's a very low
3 transplant patient rate and I'm not, I can't tell exactly
4 why that is.
5 Patients do come in all varieties and so it's a
6 little unusual to see MELD scores that low. And so I think
7 my, the other issue is that in my experience centers with
8 regional or local monopolies actually can never serve the
9 community as well as centers or regions with non-
10 monopolies.
11 I can tell you I did the first liver transplant
12 in New York State and I actually had the only program in
13 New York State for a while, but the plan was always to--
14 Q Doctor, Doctor, Doctor?
15 A (No response)
16 JUDGE CANER: Do you want to try calling him
17 again?
18 (Pause in proceedings)
19 JUDGE CANER: This is Judge Caner. Just to
20 remind you where you were, Dr. Miller, you were in the
21 answer talking about, quote, monopolies versus having more
22 than one facility in the area.
23 A (Continuing) Yes. So, you know, obviously we had
24 built a sizable program in New York that, I don't know,
25 they were doing 80 a year or something and the other

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1 programs were certainly scheduled to come on and, you know,
2 we tried to work together using a single list to bring them
3 up.
4 And, in fact, what happened in New York State was
5 that more centers came on in an orderly fashion after, you
6 know, we'd met thresholds of about 50, I think, the volume
7 and the quality of service in New York just improved. So
8 it's the most, it's one of the states with the largest
9 number of liver transplants done per capita and many ways
10 has some of the most innovative results.
11 Hello?
12 Q (By Mr. Pentz) Yes; we just weren't sure if you were
13 finished.
14 A And so I think that you-- there's another issue, you
15 know, even as the program in Cleveland has grown and as it
16 gets larger, cadaveric organs come in a queue that has to
17 do with the plus or random variables, which means it's
18 like, you know, you're standing on a road and cars are
19 coming by but they don't come by in a linear fashion every
20 ten seconds, they come five at one time and then there's no
21 cars for a little bit, and then, you know, three.
22 And so what happens is a single center can't
23 really staff to the level it needs to, to take advantage of
24 these swings of rates of donors coming through. And so by
25 having a second center you can more fully utilize your

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1 organs in a better and more effective way.

2 Competition, by the way, is good for this; it

3 builds innovation and reduces complacency.

4 Q One final question, Dr. Miller, and you touched upon

5 this a bit in your answer, so I don't want you to repeat

6 yourself. But one of the arguments that the University of

7 Washington has made during this proceeding is that they are

8 concerned that the addition of a program at Swedish will

9 result in the area having two, quote/unquote, average or

10 two, quote/unquote, mediocre programs.

11 Do you have an opinion about the validity of the

12 University's concern?

13 A Knowing the principles, actually, of both institutions

14 I don't believe that at all. First of all, I know that Dr.

15 Marks will have an outstanding program and I believe that

16 the University of Washington will continue to have an

17 excellent program.

18 I don't think competition drives to mediocrity,

19 it will drive to excellence. This is collegial

20 competition, okay, I'm talking about; it's not cutthroat

21 competition.

22 Q Now-- go ahead, go ahead, I didn't mean to interrupt

23 you.

24 A And I'm confident that that's what would happen there

25 because that's what's happened all over the country.

EXHIBIT I

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

ORIGINAL

IN RE: Certificate of Need Application of Swedish Medical Center.	) Docket No. 04-07-C-2005CN)

TRANSCRIPT OF PROCEEDINGS
Day 1

A P P E A R A N C E S

FILED
APR 18 2005
Adjudicative Clerk Office

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Tumwater, Washington
January 25, 2005

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1 Pacific Northwest, particularly to our service
2 population. Basically, they were an underserved
3 population.
4 Q As part of that evaluation, did you arrive at the
5 conclusion that the liver transplant program at the
6 University of Washington Medical Center was restrictive
7 in its policies?
8 A We felt that they were somewhat restrictive and very
9 conservative in their approach to the patient population
10 and that as a result of whatever their policies were,
11 that there were a population of patients that were not
12 being transplanted. At least, not being transplanted
13 within Washington, that should have been candidates.
14 Q And in this connection, I'd like to ask you a few
15 questions about the liver transplant waiting list at the
16 University of Washington Medical Center. If we could
17 turn to page 604 of the administrative record, please.
18 First of all, was Swedish's conclusions about
19 UWMC's liver transplant program based in part on the
20 characteristics of its waiting list for liver
21 transplants?
22 A Yes, it was.
23 Q Could you explain how the characteristics of the UW
24 waiting list influenced Swedish's evaluation of whether
25 to proceed with this project?

1 A Well, there are two areas that we were concerned about.
2 The first is the size of the waiting list, relative to
3 the disease in our, what we expected the disease to be,
4 incidence of disease. And the second was the severity
5 of illness that we were seeing represented on their
6 waiting list by the MELD scores that they were, that
7 they had for candidate characteristics, transplant
8 characteristics. And then finally, we were concerned
9 that, given the small list and given the relatively --
10 Well, given the characteristics of their MELD scores
11 represented by their patient population, that there was
12 the potential that a number of patients were not being
13 recognized and not having the opportunity to receive
14 transplants.
15 Q I'd like to talk a little bit about this issue of the
16 incidence of liver disease in the state of Washington.
17 Is it true that at the public hearing in this
18 matter, a representative of the University of Washington
19 took the position that --
20 MS. BENEDICT: Objection, leading.
21 JUDGE CANER: Please let him finish his
22 question.
23 MR. PENTZ: I'll re-ask the question.
24 I'm just trying to save time.
25 Q (By Mr. Pentz) Did any representative of the University

1 of Washington make any representations about the
2 incidence of liver disease in Washington at the public
3 hearing?
4 A Yes.
5 Q What sort of representations were they? And I'm
6 referring to page 604 of the record, which is part of
7 the Swedish rebuttal statement.
8 A The statement that's on 604 refers to Ms. Shawcroft's
9 statement that the incidence of liver disease is less
10 and utilization of facilities on the basis of liver
11 disease is less in the state of Washington than it is in
12 the rest of the country. This was a direct response to
13 that statement.
14 Q So the purpose of this portion of the rebuttal testimony
15 was to test the validity of Ms. Shotcroft's statements
16 at the public hearing; is that correct?
17 A That's correct.
18 Q And if you could turn to page 605 of the administrative
19 record, which is page three of the Swedish rebuttal
20 testimony. Could you please explain what Table 1 on
21 that page shows us?
22 A This is a table that's made of the statistics derived
23 from the CDC, the Center for Disease Control. It
24 relates for the United States or states in the WWAMI
25 region, that's representative states throughout the

1 country, what the total number of deaths are in that
2 state on an annual basis and the incidence of liver
3 disease in those states accounting for those deaths,
4 chronic liver disease.
5 Q You used another acronym there. There's a lot of
6 acronyms flying around, but you said WWAMI, which is
7 W-W-A-M-I. Could you tell us what that is, please?
8 A Yes. It's Washington, Wyoming, Alaska, Montana and
9 Idaho as the states that are dependent medically on
10 University of Washington as a site for training.
11 Q Sorry to interrupt.
12 A So this table -- If I may, also, the table has these
13 states, it shows the total number of deaths in those
14 states, and then shows the total number of deaths of
15 chronic liver disease in those states and the percentage
16 and the incidence that that percentage represents.
17 In the United States, for instance, assuming a
18 population, when this was done, of 2.4 million people,
19 roughly, we had 26,000 deaths, which is about
20 1.1 percent of those deaths due to chronic, chronic
21 liver disease.
22 If you take a look at other states, they are
23 variable. California peaks with a 1.6 percent
24 incidence. Hawaii, where chronic liver disease is quite
25 minimal, they actually don't even have a statistic

1 because it doesn't fit into their top ten. But in
2 general, 1.1 percent across the country. And some
3 similar states, such as Oregon, it's 1 percent; and New
4 York, 1 percent; Missouri is .8; and Colorado,
5 1.4 percent.
6 Take a look at Washington. We aren't at or below
7 the national incidence, we're actually above the
8 national incidence for chronic liver disease at
9 1.2 percent. And the states who are within our WWAMI
10 region show that that range goes from .9 percent in
11 Idaho to 1.7 percent in Alaska, and averages out to
12 1.2 percent for the whole region as well. So .1 percent
13 higher than the national statistic incidence for chronic
14 liver disease.
15 Q So what does this information lead you to conclude about
16 the statement made by the University of Washington
17 representative at the public hearing regarding the
18 health of Washington residents with respect to liver
19 disease?
20 A That Washington residents and those in the area that we
21 serve have an incidence of chronic liver disease that's
22 at or higher than the rest of the United States.
23 Q And if you could, please turn to page 617 of the
24 administrative record, which is page 15 of the Swedish
25 rebuttal testimony.

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FILED
APR 28 2005
Adjudicative Clerk Office

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE CLERKS OFFICE

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Kent, Washington
February 3, 2005

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1 MR. PENTZ: We'll just cut to the chase.

2 Q (By Mr. Pentz) As the medical director of LifeCenter

3 Northwest, the local OPO, it's part of your duties to know

4 what happens to livers that are transplanted, that are

5 exported from this area; is that correct?

6 A That's correct.

7 Q And based upon your duties as the medical director of

8 LifeCenter Northwest, do you in fact know what has happened

9 to the organs, the livers that have been exported from this

10 area?

11 A Yes, I do.

12 Q And do you recall Dr. Ham testifying that in his

13 opinion the livers rejected by the University of Washington

14 were not usable except for perhaps two?

15 A Yes, I do.

16 Q And do you agree with that testimony?

17 A No.

18 Q And why is that?

19 A Because we know that the livers worked, we know that

20 Dr. Ham never examined those livers directly himself. We

21 know that he did ask, or his people have asked repeatedly

22 each time a liver is turned down from LifeCenter Northwest

23 personnel whether they feel why the liver was turned down

24 here.

25 He was given the turn down code and/or the reason

1 that is offered, which is always from the University of
2 Washington because the University of Washington is the only
3 local center and he acts on that information. And we know
4 that of the, at least in this record the 127, I think it
5 was, or 28 livers that were exported, average about 28
6 livers per year, that only two have primary non-function at
7 the time this record was put together and that the others
8 worked.
9 We know that during that same period at least 68
10 people died on the University of Washington waiting list
11 and we know that, we are certain that there was a mortality
12 associated with organs list.
13 MS. BENEDICT: Your Honor, I'm going to move
14 to strike again. Everything that he testified to was
15 simply a laundry list of all the points he made in his
16 direct testimony.
17 I don't think it's appropriate for rebuttal for a
18 witness to simply reiterate in a laundry-list style what
19 you hope to refresh the judge's memory about and what his
20 positions are. But all those were testified at length by
21 Dr. Marks in his testimony on direct, every single piece of
22 that testimony, and I move that it be stricken.
23 And I also, again, ask Dr. Marks to identify who
24 we is. Is it him or is it UNOS or some other staff person
25 at UNOS.

1 JUDGE CANER: I'll have that clarifying
2 question first. What are you talking about, which hat?
3 DR. MARKS: This is the AOPO hat, this is
4 the LifeCenter Northwest hat that I was just speaking to.
5 JUDGE CANER: And that's who you meant as
6 we?
7 DR. MARKS: As we.
8 JUDGE CANER: Then in terms of the motion,
9 denied. I think it's reasonable rebuttal. It may be a
10 restatement of what was said on direct, but it is couched
11 in response to testimony made by Dr. Ham that contradicts
12 his testimony and I find it helpful.
13 Q (By Mr. Pentz) Dr. Marks, if you could please turn to
14 page 389 of the administrative record.
15 A (Witness complying)
16 Q Do you recall Ms. Carona testifying at this hearing
17 that she had prepared this document on behalf of the
18 University of Washington?
19 A Yes, I do.
20 Q And do you recall her testifying at this hearing
21 regarding this particular concern, quote/unquote, relating
22 to Swedish's estimate of pancreas transplants and its
23 Certificate of Need application?
24 A I do.
25 Q And in asking these questions I know full well that at

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EXHIBIT J

ORIGINAL

FILED
APR 28 2005
Adjudicative Clerk Office

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE CLERKS OFFICE

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FEBRUARY 3, 2005

APPEARANCES:

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Kent, Washington
February 3, 2005

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1 respect to research. Do you have an opinion as to whether
2 a certain volume of liver transplants is needed in order to
3 maintain a research program?
4 A Yes.
5 Q And what is your opinion?
6 A My opinion is that a volume between 45 and 50 liver
7 transplants is appropriate to meet the research objective.
8 Q And do you have an opinion as to whether a certain
9 volume of liver transplants is necessary in order to
10 maintain a training program in liver transplant surgery?
11 A Yes, and again the volume is between 45 and 50 liver
12 transplants to give adequate exposure.
13 Q And do you have an opinion as to whether a certain
14 volume of liver transplants is necessary in order to
15 maintain a training program for hepatologists?
16 A And for hepatologists it's essentially the same
17 volume, between 45 and 50 liver transplants.
18 Q And finally, Dr. Hart, do you have an opinion as to
19 whether a certain volume of liver transplants is necessary
20 at an institution in order to maintain other educational
21 programs such as other residency programs and medical
22 student training?
23 A Well, the medical students' training and residency
24 training are not as closely linked to the volume of
25 transplants and is more closely linked to educating the

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1 students and residents about the principles of
2 transplantation. So, again, the volume is not as
3 important, but a program that does anywhere close to 45 to
4 50 certainly would meet the academic needs for the medical
5 students and residents.
6 MR. PENTZ: Dr. Hart, I have no further
7 questions for you, but Ms. Benedict and Mr. McCartan may
8 ask you cross-examination questions.
9 JUDGE CANER: Dr. Hart, this is Judge Caner;
10 I'm going to ask Mr. McCartan first if he has any questions
11 for you.
12 MR. McCARTAN: No.
13 JUDGE CANER: And he does not, so I'm
14 turning to Ms. Benedict now. Ms. Benedict, do you have any
15 cross-examination questions for Dr. Hart?
16 MS. BENEDICT: Yes.
17 JUDGE CANER: You may proceed.
18 MS. BENEDICT: Could we have just one
19 minute?
20 JUDGE CANER: Yes. Dr. Hart, we're just
21 going to give Ms. Benedict a minute to collect her thoughts
22 and decide what she's going to ask you.
23 THE WITNESS: Okay.
24 JUDGE CANER: We can go off the record.
25 (Discussion off the record)

1 programs.

2 Q In a case where there is, is there usually a primary

3 physician and a first assistant?

4 A Yes. There are cases in which there is a primary

5 surgeon which would be the attending and the first

6 assistant oftentimes is a fellow or a senior-level

7 resident. If on the other hand there is concern that the

8 case is complex, then the first assistant would be another

9 attending surgeon.

10 Q So if the first assistant is an ASTS liver transplant

11 fellow, does that case count as one of the 45 liver

12 transplant cases for fellowship purposes?

13 A Yes, as long as the fellow or the first assistant

14 participates materially in the case.

15 MR. PENTZ: I have no further questions,

16 Your Honor.

17 JUDGE CANER: Dr. Hart, I'm going to ask Ms.

18 Benedict if she has any further cross-examination.

19 MS. BENEDICT: I just have maybe four

20 questions.

21 JUDGE CANER: Dr. Hart, Ms. Benedict is

22 going to ask you a few questions.

23 **EXAMINATION**

24 BY MS. BENEDICT:

25 Q Dr. Hart, why is it that UCSD does not have a liver