

ORIGINAL

NO. 80264-5

**IN THE SUPREME COURT
OF THE STATE OF WASHINGTON**

UNIVERSITY OF WASHINGTON MEDICAL CENTER,

Respondent,

v.

WASHINGTON STATE DEPARTMENT OF HEALTH

and

SWEDISH MEDICAL CENTER,

Appellants.

**UNIVERSITY OF WASHINGTON MEDICAL CENTER'S
RESPONSE BRIEF**

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I. INTRODUCTION

This case involves a certificate of need (“CON”) for a liver transplant program that the Department of Health (“Department”) issued to Swedish Health Services (“Swedish”). By enacting the CON law, the legislature has provided for careful review of the need for new health care programs. An essential element of this review is the analysis of sufficient patient volumes necessary to optimize quality of service and improve outcomes of care. The legislature has further provided that in administering the CON program, the Department must assess the impact of new programs on existing health professional school and training programs. Sufficient patient volume is particularly important for a liver transplant program in an academic medical center where liver transplant physicians, surgeons and fellows in training must perform a certain number of procedures to maintain or achieve the needed skill levels, and where research and clinical trials are conducted. Careful review of liver transplant programs also necessarily takes into account the limited availability of donor livers.

This legislatively mandated careful review stands in stark contrast to the Department’s inadequate consideration of the impacts of the proposed Swedish transplant program on the existing liver transplant program of the University of Washington Medical Center (“UWMC”). In determining the “need” for a second transplant program, the Department’s designated decisionmaker, a Health Law Judge (“HLJ”), accepted flawed statistical analyses and outdated numerical comparisons with out-of-state

programs to theorize both that there may be Washington residents in need of transplant services who are not being identified, and that a greater volume of donor livers would be available to match with these potential recipients. She discounted, ignored, or disallowed relevant factual evidence that countered these theories. UWMC, concerned about the adverse impacts on medical, training, and research programs, as well as the overall impact on the public of the proposed new program, participated in the CON process. However, its participation was unlawfully hindered when the HLJ, on the motions of Swedish and the Department, adopted strict limits on the scope of evidence that would be allowed in the adjudicative proceeding and rejected UWMC's attempts to introduce evidence showing the statistical analyses by Swedish were flawed and that the impacts on its training programs could not be evaluated by looking only at the minimum accreditation requirements.

This case involves issues concerning the adequacy of the substantive and procedural bases of the agency order. First, there was inadequate evidence in the record, even without the countervailing proof that was offered, to support the agency's findings. Indeed, the failure of the applicant and the Department to assess the impacts of an additional program on the UWMC fellowship program by itself is sufficient reason to set aside the agency order. Second, the evidentiary restrictions imposed by HLJ are contrary to the Washington Administrative Procedure Act ("WAPA"), the Department's procedural rules, and due process rights these provisions are designed to safeguard. Finally, the particular

circumstances of this case are best addressed, and the public interest is best served, by setting aside the agency order rather than remanding the matter a second time and conducting a third hearing.

II. ASSIGNMENTS OF ERROR

Pursuant to RAP 10.3(h), UWMC sets forth the following errors it contends were made by the agency issuing the order:

1. The Department, through the Health Law Judge (“HLJ”), erred in entering its “Final Order on Remand Affirming Findings of Fact, Conclusions of Law, and Final Order Dated August 23, 2005” dated August 15, 2006, AR Remand 1906-1914, Appendix, Ex. B, including entry of Post Hearing Order No. 1 referenced in paragraph 1.10. AR Remand 286-289, Appendix. Ex. B.
2. The HLJ erred in entering her Findings of Fact, Conclusions of Law, and Final Order dated August 23, 2005. AR 994-1019. Appendix, Ex. C.
3. The HLJ erred in entering Finding of Fact 1.4. AR 997.
4. The HLJ erred in entering Finding of Fact 1.8. AR 999.
5. The HLJ erred in entering Finding of Fact 1.13. AR 1001.
6. The HLJ erred in entering Finding of Fact 1.14. AR 1001.
7. The HLJ erred in entering Finding of Fact 1.16. AR 1002.
8. The HLJ erred in entering Finding of Fact 1.17. AR 1002.
9. The HLJ erred in entering Finding of Fact 1.18. AR 1003.
10. The HLJ erred in entering Finding of Fact 1.19. AR 1003.

11. The HLJ erred in entering Finding of Fact 1.20. AR 1004.
12. The HLJ erred in entering Finding of Fact 1.21. AR 1004.
13. The HLJ erred in entering Finding of Fact 1.22. AR 1005.
14. The HLJ erred in entering Finding of Fact 1.23. AR 1005.
15. The HLJ erred in entering Finding of Fact 1.24. AR 1006.
16. The HLJ erred in entering Finding of Fact 1.25. AR 1006.
17. The HLJ erred in entering Finding of Fact 1.27. AR 1007.
18. The HLJ erred in entering Finding of Fact 1.28. AR 1008.
19. The HLJ erred in entering Finding of Fact 1.29. AR 1008.
20. The HLJ erred in entering Finding of Fact 1.30. AR 1008.
21. The HLJ erred in entering Finding of Fact 1.31. AR 1009.
22. The HLJ erred in entering Finding of Fact 1.32. AR 1009.
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33. The HLJ erred in entering Conclusion of Law 2.13. AR 1016.
34. The HLJ erred in entering Conclusion of Law 2.14. AR 1016.

35. The HLJ erred in entering Conclusion of Law 2.15. AR 1016.
36. The HLJ erred in entering Conclusion of Law 2.16. AR 1017.
37. The HLJ erred in entering Conclusion of Law 2.17. AR 1017.
38. The HLJ erred in entering Conclusion of Law 2.18. AR 1017.
39. The HLJ erred in entering Conclusion of Law 2.19. AR 1017.

III. ISSUES PERTAINING TO ASSIGNMENTS OF ERROR

UWMC restates the issues as follows:

1. Whether the Department's order is supported by substantial evidence when it deduces from national statistics that there should be more Washington patients receiving liver transplants and that significantly more donor livers will be available, without factual evidence to support these deductions.
2. Whether the mandatory requirement for assessment of the impact of a CON application on existing and proposed medical training programs is met by – and cannot go beyond – determining if existing programs can meet minimum accreditation standards.
3. Whether the HLJ erroneously interpreted the WAPA and the Department's procedural rules and denied UWMC a fair hearing in excluding evidence at 2005 and 2006 adjudicative hearings if the information did not exist as of December 31, 2003, a date shortly after the CON program closed the public comment record?
4. Whether a reviewing court may set aside an agency decision rather than ordering a second remand when the parties seeking

the remand did not address mandatory criteria, invited the erroneous evidentiary rulings, and where the CON applicant may submit a new application?

IV. STATEMENT OF THE CASE

A. Counterstatement of Facts

1. History and Background of Liver Transplantation

In 1963, a surgical team led by Dr. Thomas E. Starzl performed the world's first human liver transplant. Medical researchers worked to improve surgical techniques and develop immunosuppressant drugs to lower the risk of organ rejection, and by 1984 deceased donor liver transplantation became an accepted treatment for end-stage liver disease in adults and children. CP 874; *see also* AR 3964. Whether a specific donor liver is appropriate for a particular patient will depend on a number of factors such as blood types and appropriate size for the recipient. Additionally, liver transplant programs weigh the quality of the donor organ and the severity of illness in the patient.¹ AR 3699-3700, 3719-3722, 4097. The risk of transplant failure must be assessed based on hardship on the recipient and the prospects for retransplantation. AR 3698-3700, 3707. If a liver fails, another liver has to be available emergently within days or the patient will die. AR 3609 – 3610.

¹ An example of the interplay of these factors—the condition of the organ and the health of the recipient—is illustrated by a recent article that discusses guidelines that recommend against transplanting organs from persons with high-risk activities like drug use with needle-sharing unless the recipients are so likely to die that potential infection with H.I.V. seems a lesser threat. Denise Grady, *Patients Contract 2 Viruses in Transplants*, N. Y. Times, Nov. 14, 2007, at A 15.

As explained by Dr. Jorge Reyes, Chief of the UWMC Division of Transplantation, “[a]ll patients are different and all donor organs are different. They’re not one-size-fits-all type organs. So a particular organ in a particular patient with a certain MELD [Model for End-Stage Liver Disease²] score, for example, will work differently versus if you put the same liver in somebody with a different MELD score.” AR 3699-3700.

A broader question is how to prioritize among potential recipients of a donor liver when the number of patients in need always exceeds the availability of organ resources. After considering issues about equitable and medically effective use of donor livers, a task force created by the National Organ Transplant Act³ recommended the creation of a National Organ Procurement and Transplantation Network (“OPTN”) to oversee an organ allocation system. The system is administered under federal contract by the United Network for Organ Sharing (“UNOS”). AR 1798. The organ allocation rules give priority to the most medically urgent patients who are appropriate candidates for transplantation. Priority is first to compatible “status 1” transplant candidates, who have acute liver failure, offered first in the donor’s local area, then to the larger UNOS allocation region,⁴ then nationwide. AR 3152-3153. Because the local

² The MELD numerical scale ranges from 6 (less ill) to 40 (gravely ill). AR 4009. This scale is discussed *infra* at pp. 8, 9. See also AR 4009-4014.

³ The National Organ Transplant Act of 1984 (Pub. L. 98-507), amended by Pub. L. 100-607 and Pub. L. 101-616.

⁴ UNOS Region 6 includes Alaska, Hawaii, Idaho, Montana, Oregon, and Washington. AR 3138-3139. This differs from the Washington, Wyoming, Alaska, Montana, and Idaho (“WWAMI”) region; WWAMI is a five state cooperative effort in which the

area has priority for “status 1” patients, there is less risk of death following transplant failure in more populous areas such as California and New York than in less populated areas, since donor livers become available for a retransplant on a more frequent basis. AR 3610.

Prior to 2002, donor organs were allocated to patients, after the status 1 patients, based on the length of time the patient had been on the “wait list.” In 2002 the next level of medical urgency changed from “waiting time” to a Model for End-Stage Liver Disease (“MELD”) numerical scale. AR 3532, 4009-4013. *See also* AR 29. The MELD scale is based on objective laboratory tests that measure the progression of liver disease.⁵ *Id.* A patient with a MELD score of 15 or higher is very ill. *Id.* If a liver is not accepted for any Status 1 candidate, the liver is then offered to compatible patients according to MELD scores.⁶ A transplant candidate’s MELD score will be assessed and adjusted over time depending on the status of his or her liver disease. AR 3695-3696, 4014. For example, a patient may be initially placed on the waitlist with a lower MELD score and then due to a wait for a transplant, becomes “more ill”

University of Washington School of Medicine serves as the regional medical school and a regional network where the staffs of the University of Washington Medical Center, Harborview Medical Center, and Children’s Hospital Medical Center provide consultations to health care professionals in those states. AR 3163. Residents are not limited to where they seek transplant services regardless of regional delineations for these purposes. AR 3170, 3546.

⁵ Candidates age 11 and younger are placed in categories according to the Pediatric End-stage Liver Disease (“PELD”) scoring system.

⁶ The UNOS policies on allocation of livers was amended during the pendency of this matter to require a local priority followed by regional sharing for patients with MELD scores of greater than 15. *See* AR 3693-3694.

and thus be assigned a higher MELD score. *Id.* The MELD scores are entered into a UNOS computer program with protocols for timeliness. AR 3532.

Until recently, when patients were placed on wait lists was not standardized or monitored. Lack of standardization of wait lists was addressed in recent rule amendments by the Centers for Medicare and Medicaid Service ("CMS"). *See* Rules and Regulations, 72 Fed. Reg., No. 61 at 15204 (March 30, 2007), Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Part 121 (requiring wait list management, including updating on a regular basis, removing patients from the center's wait list if a patient receives a transplant or dies or if there is any other reason they should not be listed). *See also* Proposed Rules, 70 Fed. Reg., No. 23 at 6161 (Feb. 4, 2005) (discussing need for effective wait list management).

UNOS does, however, specify certain persons who cannot be wait listed unless and until certain issues are addressed. These include patients with conditions such as severe heart disease, metastatic disease, tumors, psychological disorders, active substance abuse, untreated infection, or a history of non-compliance with treatment plans. AR 29, 3687-3689.

The field of liver transplantation is relatively new and continues to evolve. One recent development has been in the area of living donor liver transplantation in which a living person donates a portion of his or her liver to another person. AR 30, 96. The first adult-to-adult living donor transplant was in 1996. AR 96-97. Adults require a larger segment (as

much as one-half or more of the donor's liver), which results in a more complex operative procedure with potentially greater risks for the donor. These risks include death or long term health effects.⁷ AR 3597-3598. As limitations were encountered in living donor liver transplants, interest grew in split-liver or cut down liver transplantation where the deceased donor liver is divided into segments and transplanted into two recipients or where a larger liver is "cut-down" to fit a small adult or child. AR 997. Only certain high quality donor livers are appropriate for a split liver procedure and only certain smaller adults or children are appropriate recipients. AR 3721-3722. Both living liver transplants and split liver transplants require two surgical teams and two UNOS certified liver transplant surgeons. AR 997, 3986-3988. Another recent development is enhanced availability of donation after cardiac death ("DCD") where the organ is procured quickly after cardiac standstill. AR 3715-3719. UWMC has been involved in studies regarding increased use of DCD organs. AR 3715.

2. UWMC Liver Transplant Program

UWMC is an academic medical center that treats patients, conducts research, and teaches future physicians and other health care providers. Its liver transplant program was established in 1989. AR 1406. In November 2003, UWMC's program had six liver transplant surgeons,

⁷ In 2002, the death of a donor resulted in the temporary closing of the live donor liver transplant program at Mount Sinai Hospital in New York. AR 3882-3883. The chances of donor death are 1 in 500. AR 3597.

all trained and UNOS certified to perform kidney, pancreas and liver transplants. AR 3653. It was at this time Dr. Jorge Reyes joined the UWMC as Chief of the Division of Transplantation. AR 3635. Dr. Reyes had completed his fellowship in transplantation with Dr. Starzl, the pioneer of liver transplantation, at the University of Pittsburgh Medical Center and went on to become a professor and director of pediatric transplantation in its Starzl Program. AR 3637. UWMC also had three hepatologists on staff in November 2003, including Dr. Robert L. Carithers, medical director of the liver transplant program, who has experience with over 1200 transplant patients. AR 3651; AR 3502.

At UWMC, liver transplant patients are managed by a team consisting of a liver transplant surgeon, the transplant surgical fellow, clinical hepatologists, endocrinologist, gastrointestinal fellows, and also general surgery residents, physician assistants, as well as other specialists in transplant services. All members of the team attend weekly patient selection conferences for the respective transplant services. Teams of these specialists work with transplant candidates, and also work with patients who do not meet the protocols for placement on the wait list to address social or medical conditions that prevent them from being eligible transplant candidates. AR 4079. Multiple studies and research are conducted at UWMC in transplantation and related topics, where two research scientists work with UWMC surgeons to investigate a variety of matters. AR 97-99; *see also* RCW 28B.20.462. UWMC participates in several clinical trials which seek better immunosuppression regimens for

counteracting rejection of transplanted organs. AR 97. As a direct result of UWMC research, significant advancements have been achieved in the treatment and management of transplant patients. *Id.*

Additionally, UWMC has an approved transplant fellowship program accredited by the American Society of Transplant Surgeons (“ASTS”) and approved by UNOS. AR 99. As part of the minimum criteria for approval, the program must perform at least 50 transplants each year and have adequate clinical and laboratory research facilities and an adequate faculty with appropriate training. AR 99. During a two-year fellowship, a fellow must perform at least 45 liver transplants as the primary surgeon or first assistant and at least 20 liver procurements and must complete a research project. AR 101, 1978-1989. Currently, UWMC sponsors two liver transplant fellows, on staggered two year programs, following approval in 2004 of UWMC’s application for a second transplant fellow. Clerk’s Papers (“CP”) 883, AR 99. A certain volume of transplants above the minimums is necessary to allow the flexibility for fellows to commence their training on less complex surgeries and progress to more difficult ones. *Id.* Also, UNOS-qualified liver transplant surgeons must perform an adequate number of surgeries to maintain their level of skill. AR 34. In 2001, UWMC performed 75 liver transplants. AR 1048. UWMC uses split liver and cut-down liver transplants where medically appropriate, and has performed a living donor transplant where the appropriate circumstance was presented. AR Remand 53.

3. Swedish's CON Application.

On June 11, 2003, Swedish submitted an application for a liver transplant program at its Seattle First Hill Campus. AR 1023. Liver transplantation is among the "tertiary health services" that are subject to CON review. *See* RCW 70.38.105(4)(f); WAC 246-310-035; WAC 246-310-020(1)(d)(i)(D). By definition a "tertiary health service" requires "sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." RCW 70.38.025(14). The legislature outlined matters to be included in the review of CON applications. *See* RCW 70.38.115. These include the specific directive that the Department consider a CON 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." RCW 70.38.115(2)(d).

Swedish's stated justification of need for its proposed program was that an estimated 111 Washington residents should have received liver transplants in 2001. Swedish came to this number by calculating a nationwide average of liver transplants per 100,000 residents, and then applying that ratio to Washington's population. AR 1048. It then subtracted the number of transplants performed in Washington and claimed that its project was needed because a group of 39 residents must have "out-migrated" to other states for liver transplants, showing

UWMC's program was not accessible or available. AR 1043. Swedish initially claimed:

We have documented the extent to which Washington residents have out-migrated from the state for liver transplants—a figure of about 40% of all transplants provided to state residents. We think this situation is not acceptable for such a complex surgical procedure, and the necessary follow-up care required.

AR 1071. Swedish also alleged its program was needed because donor organs were being sent out of state to other transplant programs. Swedish's application did not include any analysis of the reasons these livers were being exported, such as UNOS network's sharing agreements and requirements, patient compatibility, or the marginal condition of the organ. Nor did Swedish provide any documentation to show that the number of exported organs was excessive. *See* AR 1565-1566; *see also* AR 1342-1346.

Swedish also theorized more organs could be available through procedures such as living donor and split-liver transplants, and therefore there would be sufficient volumes for a second program.⁸ AR 626-627, 629. The application did not take into account that UWMC uses these procedures where medically appropriate. AR Remand 53.

⁸ *See* Final Order on Remand, AR 997, n.3 (“a new program such as Swedish's would not only lack the experience but the staffing levels to conduct such a procedure”). A living donor liver transplant center must have at least two UNOS-qualified liver transplant surgeons with specific demonstrated experience with live donor procedures, AR 1998, and both living donor and split-liver transplants require two surgical teams. AR 3221-3222. Swedish's proposed staffing included a single liver transplant surgeon and single liver transplant hepatologist, with backup from surgeons who are specialists in other areas. AR 3215-3216.

Swedish's application did not mention or assess the impact of its proposed liver transplant program on UWMC's Academic Medical Center, School of Medicine, liver transplant fellowships and other training programs, or UWMC's research programs associated with liver disease. AR 1056; *see generally* AR 1023-1069. Indeed, the application does not even mention health professional schools and the criteria related to those schools except to indicate "not applicable" under a criterion related to the proposed project's relationship to such schools. *See* AR 1056.

Swedish projected its program would perform, conservatively, six liver transplant surgeries in its first year of the program, 18 in the second year, 32 in the third year, 42 in the fourth year, and 46 by the fifth year. AR 1048.

4. Public Hearing and Rebuttal Submissions on Swedish's Application

After a CON application is filed, the Department's CON Program undertakes a public input process that lasts 45 days, unless extended. WAC 246-310-160(1)(a). If requested, a public hearing may be held. *Id.* The public hearing is conducted by a member of the CON Program staff, and any interested person may make short oral statements and submit written statements. The "Public Hearing Agenda" for the CON application by Swedish outlines the typical elements of the public hearing. AR 1331-1332. Individuals may provide oral comments, limited to three minutes, and may submit written comments. Individuals may ask specific questions of the applicant or others who commented, with a limit of one

question until everyone has had an opportunity to ask questions. No substantive questions may be asked of CON program staff. At the end, the applicant has up to ten minutes to summarize their comments. AR 1331–1332.

A public hearing was held on Swedish's application on November 6, 2003. *Id.* Several of those testifying at the public hearing used their limited time to highlight concerns about the impact a second program would have on UWMC's training of future providers of liver transplant services. AR 3048-3051; 3057-3061, Appendix, Ex. G. The CON program analyst asked follow-up questions regarding the testimony, but asked none regarding training programs. *See* AR 3114-3117.

At the hearing, UWMC provided the CON Program with UNOS and Comprehensive Hospital Abstract Reporting System ("CHARS") patient information⁹ to refute Swedish's claim that statistical analysis indicated 39 residents went out-of-state in 2001 for liver transplantation." AR 1411-1412. UWMC indisputably showed only nine patients out-migrated for liver transplants in 2001, and that out-migration likely occurred because southwest Washington residents are closer to Portland programs, insurance or the Veteran's Administration require treatment at

⁹ Swedish was mistaken when it stated: "Although the number of transplants that occurred in Washington is known, either through UNOS or CHARS data, the rate of transplantation for Washington residents is not known, since there is no figure that quantifies the number of state residents who out-migrate to other states for transplants." AR 1047. In fact, this information is tracked and the UWMC showed the actual number of the out-migrations in its testimony at the public hearing. AR 1412-1413.

specific facilities, or patients planned to rely on family or other support providers that lived out of state. (AR 1412-1413).

Following a public hearing, the applicant and any interested person have ten days to submit documents addressing any submission or testimony taken at the public hearing. WAC 246-310-160(1)(a). Swedish, UWMC, and Children's Hospital simultaneously submitted rebuttal documents. AR 1572-1689. In its submission, Swedish conceded the UNOS out-migration numbers were accurate. AR 1633-1634. Swedish then shifted its theory of "need," after the public comment period ended, to a claim that there were unidentified patients who the statistics indicated should have received transplants but did not.¹⁰ Swedish theorized that some patients were going unserved, again based on a simple mathematical formula of the nationwide average of liver transplants per 100,000 residents. As described by the HLJ, in its November 24, 2003 rebuttal submission, "Swedish raised a new theory within its rebuttal statement regarding patients falling through the cracks." AR Remand 1907. Since these allegations were contained in Swedish's rebuttal, UWMC did not have an opportunity to respond to this new theory. After rebuttal submissions the CON Program closes the public comment record and

¹⁰ In its rebuttal submission Swedish also shifted the year from 2001 to 2002: "We agree UNOS data indicates 17 Washington residents left the state in 2002 for liver transplants." AR 1633. This shift in years apparently was not recognized by the CON Program, which refers to 17 residents as the number who left the state in 2001 as opposed to the nine who left in 2001. AR 1802.

begins its review of the application, the submissions, and any material it independently obtains.

5. The Department's Analysis and Issuance of the CON

The Department issued its findings and analysis on June 17, 2004, granting Swedish's application for a CON for its proposed adult liver transplant program. AR 1796-1811. The Program justified its decision that there was a need for Swedish's program by finding it would increase the number of Washington residents added to wait lists for liver transplants. While it was unlikely there would be a significant increase in the number or suitability of deceased donor livers, the CON Program said increasing use of living and split-liver procedures, and an increased willingness to transplant livers previously deemed sub-optimal by existing programs, could result in an increased number of patients receiving transplant procedures. AR 1804.

Under a sub-heading entitled "The project will not have an adverse effect on health professional schools and training programs," as required by WAC 246-310-210(4), the CON program evaluation states only "this sub-criterion is discussed below in section C. 4." AR 1805. The referenced section merely observes:

UWMC contends that [Swedish'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. . . . 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.

AR 1810. The Program found Swedish's proposed liver transplant program met the CON criteria and sent Swedish CON No. 1288 on June 30, 2004. AR 1814-1816.

B. Procedural History of Adjudicative Proceedings and Superior Court Review

1. Initial Adjudicative Proceeding and Order

UWMC filed a request for an adjudicative proceeding. AR 1-6. During the course of the first adjudicative proceeding in January and February 2005, the HLJ refused to allow UWMC to present documents or testimony that could not be directly tied to a statement or a document in the Program's application review record. AR 285-291. UWMC filed motions with the HLJ for reconsideration of her restrictive evidentiary rulings and also made an offer of proof during the course of the adjudicative proceeding. AR 293-309; *see, e.g.*, AR 3557-3572; 509-542. In addition, UWMC filed a motion for summary judgment alleging that a denial of due process occurred when the Program allowed Swedish to change its need justification in its rebuttal submission without providing UWMC an opportunity to respond. AR 63-93. The HLJ denied the motion on the bases her review was limited to the public input record and UWMC's remedy was required to request reconsideration of the CON Program's decision if it wanted to augment the record to address rebuttal. AR 285-291. At the end of the adjudicative proceeding, the HLJ issued

Findings of Fact, Conclusions of Law, and Final Order, adopting nearly verbatim the assertions Swedish made in its rebuttal and followed by the CON Program in its Analysis. AR 994-1019. UWMC then filed an amended petition for judicial review to appeal the HLJ's findings, conclusions, and order on September 20, 2005.¹¹

2. Remand Ordered by the Superior Court for the Taking of Additional Evidence

The UWMC filed a request to accept additional evidence or remand for further proceedings, and the superior court (CP 1564-1582) remanded the matter for additional evidence. AR Remand 1-3.

3. Second Adjudicative Proceeding on Remand

On remand, Swedish asked that the hearing be "limited to evidence that existed as of December 8, 2003" which was ten days after it submitted its rebuttal statement. AR Remand 81. The Department said new evidence should be "limited to evidence that was *known and in existence at the time of the Swedish rebuttal in November 2003.*" (Emphasis in original.) AR Remand 146. The HLJ orally ruled that she was limiting the evidence to information that existed on or before December 31, 2003.¹² See AR Remand 228. The HLJ ordered documents already

¹¹ Since the CON Program had issued a certificate, the UWMC filed a petition for judicial review and sought a stay. At various points in these proceedings UWMC and Swedish filed motions relating to the imposition or lifting of stays. The actions regarding the stays are not at issue here. To the extent Swedish argues it was unfairly forced to pursue its program during the pendency of these proceedings, Swedish's Opening Brief at 2, it was Swedish who successfully moved to lift a previous stay. CP 1054.

¹² The HLJ allowed UWMC to move for reconsideration of her ruling restricting the evidence, and set a briefing schedule. AR Remand 228-237. Although the HLJ had not

admitted into evidence in the initial hearing that contained post-December 31, 2003, information to be redacted. AR 913.

At the remand hearing Swedish objected to each exhibit that UWMC offered and the HLJ granted each objection.¹³ AR 1925-1965. Some of the HLJ's rulings were based on the claim that UWMC had not identified the witness or exhibit by a designated date, but most were based on the December 31, 2003, limit the HLJ had imposed on the scope of the evidence. CP 783-784. For example, the exhibits that the HLJ excluded solely because they were not in existence on December 31, 2003, included Center Specific Reports for UWMC and for all of the liver transplant centers used as peer institutions by Swedish. These reports contained data needed to refute the claims of Swedish that compared UWMC with other institutions, to refute the claim by Swedish that liver patients in Washington are "falling through the cracks," and to show that many statistical predictions made by Swedish have not come to pass. CP 784-785. UWMC presented limited testimony at the remand hearing consistent with the HLJ's evidentiary limitations. AR Remand 1979-

ruled on UWMC's motion for reconsideration by May 5, 2006, she required the parties to submit their preliminary witness lists and proposed exhibits by that date. AR Remand 288-289. On May 15, 2006, the HLJ orally denied the reconsideration motion. *See* AR Remand 912. During the May 15 unrecorded status conference, the HLJ stated several times that it would be helpful to have guidance on the scope of the evidence allowed at the hearing because she was concerned the case would be remanded again. *See* AR Remand 504. However, she refused to continue the hearing. AR Remand 919. UWMC sought clarification, but the superior court declined to grant interlocutory review. AR Remand 922-926.

¹³ The HLJ further held during the course of the hearing that UWMC's witnesses were not allowed to even speak the name of a post-December 31, 2003 document, let alone to testify about it. *See* AR 2012-2015.

2083. After receiving post-hearing briefs, the HLJ issued the Remand Order on August 15, 2006, upholding the issuance of CON No. 1288. AR Remand 1906-1919. UWMC filed another petition for judicial review on a number of bases, including that the Department engaged in unlawful procedure and decision-making, erroneously interpreted and applied the law, failed to follow the Department's rules set forth in chapter 246-310 WAC, and that the Remand Order was not supported by substantial evidence. CP 272-284. The superior court set aside that agency order, and Swedish and the Department appealed.

V. SUMMARY OF ARGUMENT

The Department's orders are not supported by substantial evidence. Applying a simple nationwide average number of transplants per 100,000 residents to Washington's population does not support the finding that patients are "falling through the cracks," particularly when there is no supporting evidence. Nor can statistical comparisons to programs that face different circumstances be accepted as substantial evidence of what is occurring in Washington. In any event, failure to assess the impacts of the proposed project on UWMC's liver transplant fellowship program, an assessment mandated by the legislature, is grounds alone for setting aside the agency decision.

Relevant evidence would have further demonstrated the proposed program does not meet criteria for issuance of a CON, but that evidence was not accepted because of limits the HLJ placed on the scope of

evidence that were contrary to the WAPA and the Department's own rules. Setting the agency order aside rather than ordering a third hearing is appropriate where Swedish and the Department urged the erroneous evidentiary rulings at two previous hearings, where the public interest would not be served, and where Swedish is not precluded from submitting a new application. The superior court order should be affirmed.

VI. ARGUMENT

A. The Department's Orders Are Not Supported by Substantial Evidence

The Court may reverse the Department's order if it is "not supported by evidence that is substantial when viewed in light of the whole record before the court." RCW 34.05.570(3)(e). There must be "evidence in sufficient quantum to persuade a fair-minded person of the truth of the declared premises." *Heinmiller v. Dep't of Health*, 127 Wn.2d 595, 607, 903 P.2d 433 (1995), cert. denied, 518 U.S. 1006 (1996).

B. Simply Applying the Nationwide Average Number of Transplants Per 100,000 Residents to Washington's Population Does Not Support the Finding That Patients Are "Falling Through the Cracks"

The linchpin of the Department's finding of "need" is acceptance of Swedish's selected statistics to theorize there are potential transplant patients who are "falling through the cracks." This finding is not supported by substantial evidence, even without considering the countervailing evidence the HLJ discounted or disallowed. A simple mathematical formula that applied "a nationwide average of liver

transplants per 100,000 residents to Washington's population, and then estimates 111 Washington residents should have received liver transplants in 2001," AR 1043, 1047, 1090, will not support a finding that there were actual patients who were not receiving appropriate consideration. The HLJ erred in finding "[t]he population, liver disease and deaths statistics indicate that patients in Washington state and WWAMI region are 'falling through the cracks'" without evidence that would demonstrate the reality of this conclusion. See AR 1005. Instead, the HLJ discounted the undisputed factual evidence of physicians who refer their patients to UWMC for end-stage liver disease care and possible transplantation who said their patients receive good care and do not have to seek care elsewhere, because this testimony did not match the statistics. AR 1006, n.31. Standing alone and without meaningful analysis, this statistical evidence is not the "kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs." Courts have rejected such minimal mathematical "proof" in other areas of the law. See, e.g., *Int'l Brotherhood of Teamsters v. United States*, 431 U.S. 324, 340, 97 S. Ct. 1843, 1856, 52 L. Ed.2d 396 (1977) (statistics' "usefulness depends on all of the surrounding facts and circumstances"); *City of Richmond v. J.A. Croson Co.*, 488 U.S. 469, 109 S. Ct. 706, 102 L. Ed.2d 854 (1989) (congressional finding based on nationwide discrimination in the construction industry had extremely limited probative value, since the scope of the problem would vary from market area to market area). And courts have taken to heart the folk wisdom that statistics are manipulable

and unreliable. *See, e.g., Keely v. Westinghouse Electric Corp.*, 404 F. Supp. 573, 579 (E.D. Mo. 1975).¹⁴

Here, one would expect that if in actuality 40 patients per year were “falling through the cracks” there would be concern expressed by gastroenterologists, the physicians who primarily care for patients with stomach, pancreas, liver, and intestinal problems. *See* AR 1577. To the contrary, gastroenterologists from around the state told the Department that the UWMC had provided appropriate and excellent services. AR 1529-1564. Even physicians supporting a second program indicated they had not experienced any problems with accessibility to the UWMC transplant program. AR 1392, 1393.

These letters caused the HLJ to discount the views of the physicians rather than to question the inference from the statistics: “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 1006, n.31. Thus, the HLJ turned on its head the caution that statistics’ “usefulness depends on all of the surrounding facts

¹⁴ Swedish suggests the reviewing court should defer to the HLJ’s determinations under the broad rubric of “credibility.” *See* Swedish’s Opening Brief at 18. Deference to credibility determinations should be given only where the nature of the evidence makes the opportunity to observe the witnesses important. *See, e.g., RCW 34.05.464(4)* (“[i]n reviewing findings of fact by presiding officers, the reviewing officers shall give due regard to the presiding officer’s opportunity to observe the witnesses”). *See also Universal Camera Corp. v. National Labor Relations Board*, 340 U.S. 474, 71 S. Ct. 456, 95 L. Ed. 456 (1951) (noting “findings of the [hearing] examiner are to be considered along with the consistency and inherent probability of testimony” and that their significance “depends largely on the importance of credibility in the particular case.” 340 U.S. at 496, 71 S. Ct. at 496. Here, the HLJ stated that “[i]n light of these statistics” the Swedish witnesses were more credible. AR 1006. In this context, the statements regarding credibility do not add weight to the findings.

and circumstances,” *Int’l Brotherhood of Teamsters*, 431 U.S. at 340, 97 S. Ct. at 1856, and made the usefulness of facts dependent on whether they matched the statistics.

1. Comparisons of MELD Scores at the Time of Transplant and Wait Lists Do Not Support Findings That Unidentified Persons Should Be Wait Listed

There is no substantial evidence for the HLJ’s findings that “healthier patients with lower MELD scores and an insufficient number of patients have been placed on the University’s liver transplant wait list.” AR 1001. Again, she relied on inapt statistical comparisons and not on study of the actual facts.¹⁵ There is no basis for finding that UWMC is too conservative in adding persons to its wait list based on the fact that UWMC patients have lower than average MELD scores *at the time of transplantation* than some other transplant centers. A MELD score is required by UNOS to be updated on a short and regular interval, and only reflects the condition of the patient when transplanted, not when listed. *See* AR 4010-4014. These lower MELD scores at transplantation mean only that patients do not wait as long to receive transplants at UWMC. AR 3434. Dr. Carithers explained: “One of the reasons that it may appear that MELD scores at the time of transplantation are lower at the University of Washington, is that patients get transplanted more quickly; in fact,

¹⁵ Similarly, Dr. Marks testified he had not studied the UWMC wait list criteria: Q. “Have you ever seen the University of Washington’s criteria for being wait-listed on its liver transplant list? A. No. And if I could just add to that. I’ve not seen the criteria. My assumption is that their criteria are conservative, based on what I see in terms of the severity of illness scale that they list.” AR 3224.

patients who are listed at the University of Washington, are actually sicker than patients in any of these peer groups.” *Id.* Despite this distinction between MELD scores at time of listing and time of transplant, the HLJ illogically concluded that MELD scores at the time of transplant proved UWMC was conservative in its approach to accepting patients for the wait list, and was therefore under-serving sicker patients. AR 1001.

Comparison of the length of UWMC’s liver transplant wait list to the national average, AR 3167, does not provide substantial evidence for the proposition that UWMC is too conservative in placing individuals on its wait list. As Dr. Fung, Chairman of the Department of General Surgery and Director of the Transplant Center at the Cleveland Clinic, testified:

A waiting list is not an accurate representation of whether a community is served or underserved. You can list a patient anytime you want, but in reality, unless you reach a certain threshold in the MELD score, which is how you prioritize patients, the patients that are listed with a low MELD score are unlikely to get transplanted. And by putting them on the list, “A”, you inflate the list. But, more importantly, you require those patients to have certain testing done on a regular basis that may not otherwise be required.

AR 4047-4048. The record contains no basis for meaningful comparison with the length of wait lists at other liver transplant centers. There was no showing of similar protocols on updating the lists; whether there was duplication on some of the wait lists in areas with liver transplant centers in close proximity; and no examination or review of the UWMC's actual wait list criteria and practices.¹⁷ Findings based on comparisons of the size of wait lists and the MELD scores at the time of transplantation simply are not a basis for extrapolation on whether appropriate candidates for transplants are not being included on the wait list.

2. There Is No Substantial Evidence To Support The Finding That Too Many Donor Livers Are Being Exported That Should Have Been Used In Washington

The HLJ also found that “the statistics indicate . . . the number of exported livers should not be as large as it is.” AR 1005. In this instance, Swedish chose not to compare UWMC's percentage use of local donor livers with the national statistics, which show that nationally Washington keeps more organs than the rest of the country. AR 1416, 1651. Swedish and the HLJ concluded “that is not a reasonable figure for comparison

¹⁷ Swedish also cites the testimony of their witnesses from other parts of the country. Swedish Opening Brief at 18–19. These witnesses looked only at Swedish's rebuttal materials, AR 3776, 3869, and simply observed these materials showed MELD scores at the time of transplant at UWMC were lower than many programs, or stated they would expect to see a longer wait list. Their testimony shows they could not determine the reasons for the differences in wait list length. *See, e.g.*, testimony of Dr. Miller of the Cleveland Clinic Foundation, AR 3842, (“I can't tell exactly why that is”) AR 3857, and testimony of Dr. Dickson of the Mayo Clinic in Jacksonville, AR 3772 (the wait list is “suggesting” that and “I suspect that” there are patients who are not being served) AR 3789, 3792. Indeed, the wait lists at the institutions they served were shorter or about the same length as the UWMC list. AR 1425, 1431.

purposes.” AR 1004. *See also* AR 1651-1652. Rather, Swedish selected and the HLJ accepted the San Francisco Bay area, Los Angeles County, Nebraska and Colorado as organ procurement areas “with similarities such as populations served and similar programs served” to compare to the export rates of Washington and Oregon. AR 1004. The HLJ noted that these “comparable organ procurement organizations” have export rates of 10 percent to 15 percent. *Id.* The only support for this comparison is found in Swedish’s rebuttal testimony, AR 1651-1652, which showed the populations served by these chosen comparators varied from 1.7 million for Nebraska to 9.3 million for Los Angeles County. Further, an earlier section of the same rebuttal submission shows that California has a 1.6 percent incidence of liver disease and Colorado 1.4 percent compared to Washington’s lower incidence listed as 1.2 percent. AR 1635. There is no clear explanation¹⁸ for what characteristics pull Nebraska and Los Angeles County into the same class and makes them appropriate for export rate comparison purposes.

Additionally, the HLJ notes the only evidence on the condition of the 26 exported donor livers in 2001 is whether they were “successful upon transplantation” since statistics regarding transplant success for longer periods is not available.¹⁹ AR 1003. In peculiar circular reasoning,

¹⁸ The brief explanation provided is: “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.” AR 1651.

¹⁹ In compliance with sharing agreements, these exported organs were offered next to the Oregon liver transplant facilities. Dr. Ham noted: “Of the 26 organs that were exported

she concludes that one factor that shows the University has a conservative approach that keeps it from using these exported livers is that it has a lower retransplantation rate than other programs. AR 1004, n.22. She apparently concludes that UWMC should have transplanted the exported organs even if some organs failed, leading to the need for retransplantation or, if no other liver was available, death.

There is no substantial evidence to support the findings that too many donor livers are being exported that should have been used in Washington.

C. Failure to Assess the Impacts of the Proposed Project on UWMC's Liver Transplant Fellowship Program Is Grounds Alone For Setting Aside the Agency Decision

The HLJ converted minimum accreditation requirements for a liver transplant fellowship program into the maximum she could consider under the law. This application of the law to the facts is an error of law which the court considers de novo. *Mader v. Health Care Authority*, 149 Wn.2d 458, 469-470, 70 P.3d 931 (2003).

from the Seattle area [organ procurement organization] last year, and therefore made available to us in Oregon, we deemed only two as being of the quality necessary to be transplantable with acceptable outcomes. The remaining had sub-optimal characteristics for transplantation such as illicit drug use or infections with Hepatitis B in the donor." AR 1606. *See also* AR 1581.

1. The Legislature Mandated Assessment of the Adverse Impacts a Project Would Have on Existing and Proposed Health Professional Schools and Training Programs

The legislature recognized that it would be short-sighted to approve a new project that would undercut future availability and quality of trained health professionals. RCW 70.38.115(2)(d) specifically directs “[t]he department shall 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 . . .” Similarly, WAC 246-310-210(4) includes the following criterion for a determination of need for a project: “The project will not have an adverse effect on health professional schools and training programs . . .”

2. Swedish and the CON Program Did Not Assess the Potential Impacts on UWMC’s Training Program as Required by Statute and Rule

Despite the legislature’s emphasis on health professional schools and training programs, minimal or nonexistent consideration was given to these programs. Swedish’s application does not assess or discuss the impact of its proposed liver transplant program on UWMC’s transplant fellowships and other training programs, or its research programs associated with liver disease. *See generally* AR 1025-1073. In all applications for Department licenses, the burden is on the applicant to establish that the application meets all applicable criteria. WAC 246-10-606. Swedish lists citations to the record to support its claim that it

subsequently “addressed this issue at length,” Swedish’s Opening Brief at 26, but each of these references repeats the basic contention that its project would not cause UWMC’s transplant numbers to fall below the minimum number to maintain accreditation for a one-fellow program.²⁰

The CON Program did not separately address this criterion in its written evaluation following the public hearing process. Under the heading listing this sub-criterion, the CON Program states only that it “is discussed below in section C.4.” AR 1805. That “discussion” is very limited:

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. Under the projections contained in this application, SHS expects UWMC to be able to maintain that volume.

AR 1810. This constitutes the full extent of the Department’s inadequate evaluation and does not meet the legislative mandate.

²⁰ Swedish’s Opening Brief at 26 cites AR 1653 – 55, 1668-69, and 1687. The discussion at these pages simply repeats the minimum accreditation volumes like a mantra: “The only minimum number that must be met to assure adequate training is 50 livers per year to maintain a fellowship.” AR 1654. “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.” AR 1655. “We have addressed [training programs] above. See 21-23 [AR1653-55] for minimum volumes. . . .” AR 1687. “The required number of cases that a program must perform annually to meet the fellowship requirements is 50.” AR 1669.

3. The HLJ Erred As a Matter of Law in Limiting Consideration of the Adverse Impacts on UWMC's Training Programs to Minimum Accreditation Requirements

The HLJ refused to consider what was necessary to maintain a quality fellowship training program beyond the minimum 50 transplants per year needed for program accreditation, stating: "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" and concluding as a matter of law that minimum standards would be considered. AR 1007, 1012-1013.

This limited consideration is contrary to the legislative intent as expressed in the unambiguous language under RCW 70.38.115(2)(d). In order train its two fellows there must also be a sufficient volume of liver transplants to meet their individual standards, which require each liver transplant fellow to be the primary surgeon or first assistant on 45 liver transplants over a two-year period. AR 3645-3646; CP 882-883. The volumes must be sufficient to allow the fellows to begin with less difficult surgeries and then progress to more difficult surgeries. CP 883. Additionally, UWMC liver transplant surgeons must also perform an adequate number of transplants to maintain their level of skill. Performance of 120 liver transplants annually would afford two fellows the volumes and flexibility necessary to meet training requirements. AR Remand 26.

The number of donor organs available is therefore central to the effectiveness of the training, research and patient care at an academic

health center. Failure to conduct any meaningful assessment of the adverse effects a second program would have on health professional schools and training programs is contrary to the clear mandates of the law. The agency decision should be set aside based on this error alone.

D. The Department Excluded Relevant Evidence That Would Have Further Demonstrated the Proposed Program Does Not Meet Criteria for Issuance of a CON

Swedish and the Department repeatedly urged the evidentiary restrictions that the HLJ imposed in both the original hearing and the remand hearing, and which severely restricted UWMC's ability to respond to Swedish's claim and the Department's findings. These evidentiary restrictions erroneously interpreted the WAPA and the Department's procedural rules, and resulted in unlawful procedure and unfairness in the decision-making process. These rulings limiting the evidence according to the timeframe and content of the public input record were errors of law subject to de novo review. *Port of Seattle v. Pollution Control Hearings Bd.*, 151 Wn.2d 568, 593, 90 P.3d 659 (2004). This error of law standard applies to interpretations of law relating to the scope of evidence. *Id.* at 599, n.9

1. The Department's Attempt to Create a New Type of Hearing That Is Not Provided for in Statute or Rule Is Contrary to the Basic Principles of the WAPA

The HLJ's rulings that UWMC could not present any evidence that was not in existence on December 31, 2003, and requiring any evidence at the first and second adjudicative hearing to be tied to some reference in

the CON Program's public record, were errors of law. These rulings were premised on the arguments of Swedish and the Department that evidence presented in a CON adjudicative proceeding is limited to evidence in the "record" compiled by the CON Program during the application review process.

At the heart of the WAPA provisions for adjudicative proceedings is the right to a de novo hearing. Yet, the Department seeks agency variations that are contrary to explicit provisions of the WAPA, contrary to its own duly adopted rules, and without the principal components of an adjudicative procedure as established by the WAPA. The Court should reject this attempt to create a new type of proceeding that is not grounded in any statutory or rule language, and not even described in an interpretive ruling. Instead, the rules should be applied as written.

The WAPA reflects the Legislature's intent to bring consistency and standardization to the principal components of agency procedures. See William R. Andersen, *The 1988 Washington Administrative Procedure Act -- An Introduction*, 64 Wash. L. Rev. 781, 784 (1989). However, as Professor Andersen observed, "there is a natural desire of many agencies to be separated out from the general lot, and to be treated specially." If indeed there are settings that require a different approach, "the goal of clarity is protected by a requirement that agency variations be made by rule." *Id.* at 792.

2. The Washington Supreme Court Has Previously Rejected Limits on the Evidence Following an Agency Permit Decision As Inconsistent With a De Novo Proceeding

The “scope of evidence” issue in this case is analogous to the issue addressed in *Port of Seattle*, 151 Wn.2d at 597-598. The Pollution Control Hearings Board (“PCHB”) had to determine whether it should review a federal Clean Water Act § 401 certification based only upon the record available at the time Department of Ecology issued the certification or whether it could consider all information available at the time of the hearing, including post-certification plans, reports, and studies. The Court found the PCHB could consider plans, reports, and studies that were not available to Ecology, noting “[t]he scope of PCHB review is *truly de novo*, subject to established discovery deadlines.” (Emphasis added.)²¹ The Court explicitly rejected the project opponents’ theory that “Ecology’s certification must be based on reasonable assurance that there was compliance with water quality laws at the time of Ecology’s certification, and the PCHB should be strictly limited to review of the record available to Ecology at the time the certification was issued.” *Id.* at 597. The Court noted that under applicable rules PCHB adjudicative proceedings are trial-like in nature. The Court concluded: “Nothing suggests that review should be limited to the record below . . . the PCHB did not erroneously

²¹ The Court noted the meaning of “scope of review” as follows: “In this case we use the term ‘scope of review,’ as the PCHB uses it, to refer only to the scope of evidence that the PCHB can consider when reviewing an Ecology § 401 certification.” *Id.* at 596, n.7.

interpret or apply the law or act contrary to agency rule when it considered reports and studies that were not available to Ecology.” *Id.* at 597-598.

3. Excluding Relevant Evidence in the Adjudicative Hearing Is Contrary to the Explicit Language of the Governing Statutes and Rules

Both the WAPA and the Department’s rules state the parties should be afforded an opportunity to present all relevant evidence at adjudicative proceedings. Indeed, the Department’s rules on adjudicative proceedings specifically state: “The adjudicative proceeding shall be conducted as provided in RCW 34.05.449 through 34.05.455.” WAC 246-10-602(1). These provisions specify the broad scope of evidence to be considered by a presiding officer. For example, RCW 34.05.449(2) provides:

To the extent necessary for full disclosure of all relevant facts and issues, the presiding officer shall afford to all parties the opportunity to respond, present evidence and argument, conduct cross-examination, and submit rebuttal evidence, except as restricted by a limited grant of intervention or by the prehearing order.

The Department’s own rules are even more emphatic about the *de novo* nature of the hearing and the role of the HLJ as the agency’s fact finder. Among the actions the presiding officer may take are the following: conduct the hearing *de novo*; receive relevant evidence; interrogate witnesses called by the parties to develop any facts necessary to fairly and adequately decide the matter; and call additional witnesses and request additional exhibits deemed necessary to complete the record and receive

such evidence subject to full opportunity for cross-examination and rebuttal by all parties. WAC 246-10-602(2)(a),(f),(g), and (h).

In contrast, nothing in the applicable statutes or rules supports the view that “[t]he 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.” AR 1911. For this remarkable proposition, the HLJ cites one previous prehearing order in a CON adjudicative proceeding where the CON Program asserted it could change the entire bases for its decision on the eve of hearing because the adjudicative hearing was de novo. AR 1911, n.9; CP 200. Neither this citation to a prior administrative decision nor the unsupported claim that this represents a longstanding agency interpretation provides reason to defer to the HLJ’s view of her role. *See Cowiche Canyon Conservancy v. Bosley*, 118 Wn.2d 801, 815, 828 P.2d 549 (1992).

4. Excluding Relevant Evidence in the Adjudicative Hearing Is Contrary to Caselaw Holding a CON Adjudicative Hearing Is De Novo

The recent case of *DaVita, Inc. v. Dep’t of Health*, 137 Wn. App. 174, 887 P.2d 891 (2007), reviewed the role of the HLJ in determining whether a CON was properly issued. The Court found the HLJ appeared to have mistakenly considered her role as the “reviewing officer.” This view was in error, the Court noted, as the Department of Health had pointed out in its arguments in that case:

Instead, the HLJ was, as the Department of Health points out in its brief, the “[p]residing [o]fficer.” Br. of Resp’t at 2. WAPA provides that a presiding officer may be an administrative law judge designated by the agency to make the final decision and enter the final order. RCW 34.05.425(1)(b). And the presiding officer is defined in the Department of Health administrative code as “the person who is assigned to conduct an adjudicative hearing” who “may be an employee of the department who is authorized to issue a final decision as designee of the secretary.” WAC 246-10-102.

The HLJ presiding over a CON adjudicative proceeding is not a reviewing officer but a presiding officer that conducts the hearing de novo:

Furthermore, rather than reviewing the record, the presiding officer actually takes the evidence, listens to oral argument, and issues her own findings and conclusions. RCW 34.05.449(2) and .461(4). *The applicable WACs indicate that the presiding officer conducts the hearing de novo.* WAC 246-10-602(2)(a). Thus, the HLJ possesses all the decision making power; she does not need to rely on RCW 34.05.464. In other words, *she does not need to substitute her judgment for that of the fact finder; she is the agency's fact finder.*

Id. at 182. (Emphasis added.) The analysis of this decision is sound, grounded in statute and rules, and should apply equally to the case at hand.

An argument that the administrative law judge (“ALJ”) could not consider evidence not presented in the staff review record in a CON proceeding was rejected in *Marlboro Park Hosp. v. South Carolina Dep’t of Health and Environmental Control*, 595 S.E.2d 851, 853-854 (S.C. App. 2004). Under a statute similar in many respects to Washington’s, a “staff review hearing” was held where hospitals argued a proposed outpatient surgery center would adversely impact their operations, and that

the need for the center was insufficient. Staff recommended approval of the CON, and at a subsequent contested case hearing evidence was admitted that was not contained in the staff review record. The applicant appealed the ALJ's decision that the application did not meet the CON criteria to a review Board, which concluded that "parties are not allowed to submit new or additional facts for consideration at the contested case hearing which were not part of the administrative record at the time of the [staff review hearing]." *Id.* at 578. The court reversed, finding such limits on the evidence "inconsistent with applicable case law providing a de novo review for ALJ hearings conducted in a posture similar to that in the case at bar . . . A trial de novo is one in which the whole case is tried as if no trial whatsoever had been had in the first instance." *Marlboro Park Hosp.* at 579 (internal quotation marks and citations omitted).²² An analysis under Washington's statutory scheme yields a similar result. Limiting the evidence to the CON Program staff review record is inconsistent with a de novo hearing.

5. Cases Cited By Appellants to Support Limiting the Evidence Are Inapposite

Rather than citing any statute or rule to support their proposition that the record should be "closed" according to dates that precede the adjudicative hearing, the appellants rely on cases from inapposite contexts. *US West Communications, Inc. v. Wash. Utils. & Transp. Comm'n*, 134

²² The legislature has recognized that decisions of courts interpreting similar APA provisions may be instructive. *See* RCW 34.05.001.

Wn.2d 48, 949 P.2d 1321 (1997), involves evidence that post-dated the hearing before the final agency decisionmaker. UWMC agrees the agency record must close so the final agency decisionmaker may render a decision, but *US West* provides no support that this date should be before the final agency decisionmaker even conducts a *de novo* hearing. The rate case *Old Dominion Elec. Coop. v. Virginia Elec. & Power Co.*, 377 S.E.2d 422 (Va. 1989) does not bolster appellants' position. The court found the utility did not satisfy the criteria to re-open a record developed after a hearing where the utility had the benefit of its competitor's calculations before the hearing, did not pursue discovery on the issues, and at the hearing did not cross-examine witnesses or offer countervailing evidence as it could have done. *Id.* at 390. Neither the procedural rules nor the facts of *Old Dominion* bear any semblance to the case at hand.

Nor it is appropriate to import into CON law the concept of "vesting" of land use laws as described in *Friends of the Law v. King County*, 123 Wn.2d 518, 869 P.2d 1056 (1994). See Appellant Department of Health Brief at 37. The doctrine of "vesting" is limited to certain contexts, and *Port of Seattle*, 151 Wn.2d at 626, demonstrates that neither the facts nor the law are frozen upon the submission of an application.

6. Flawed Policy Arguments Do Not Provide A Basis to Substitute a Per Se Rule Excluding Evidence For the Introduction and Weighing of Evidence Allowed by the WAPA

Swedish and the Department advance several policy arguments in support of restricting the evidence according to the timeframe and submissions in the public input stage. The short answer to these arguments is that this position is contrary to the clear language of the WAPA and the Department's rules. Policy arguments are properly directed to the Legislature or the Secretary in her rulemaking capacity, not the court. However, even when one examines the policy reasons for the urged evidentiary restrictions, they are not persuasive.

One suggestion is that if an adjudicative proceeding is de novo, a party would "sandbag" the process by holding back evidence in the initial CON review process and public hearing. AR Remand 1911. This rationalization is purely hypothetical and not based on the record. "[I]t is not clear that this is a problem in practice." *See Port of Seattle*, 151 Wn.2d at 599 (responding to a PCHB argument that a de novo hearing would create a "moving target"). There would be little incentive for an applicant or affected party to withhold evidence that would support its position at the program level and risk an adverse CON program evaluation, particularly if the opposing party had the ability to respond in full in the adjudicative proceeding. The more likely scenario is that the evidentiary restrictions advanced by Swedish and the Department would create incentives for "sand bagging." Without the opportunity for full cross examination and submission of evidence in the adjudicative

proceeding, the process and is more susceptible to “gamesmanship” at the public input stage such as a party submitting new theories in a simultaneous rebuttal submission.

A second proffered policy concern is that allowing new evidence to be presented at the adjudicative hearing will allow a competing provider to improve its services in the interim. In the medical field there are rapid advances in science and medical technology that cause changes in the delivery of health care services. To automatically attribute such changes to a motive to keep a competitor out of the area by adopting a per se rule that limits evidence to a particular time period would not serve the public interest. Applying such a blanket rule would also exclude information directly relevant to the central CON determinations: whether there was sufficient need for the proposed facility or service and any adverse impacts the proposed facility or service would have on the provision of quality care by existing providers. Indeed, it may be that the need for a proposed project may increase before a final agency decision due to new developments such as the spread of disease. The public interest is not well served by limiting consideration of the relevant evidence in a manner that thwarts accurate determination of material facts. A “trial-type” evidentiary proceeding where all parties are permitted to fully address the factual issues will provide the fullest development of the record. When a central issue is the validity of projection of future need, the most recent information will be the most accurate information. Past projections may have already proven to be inaccurate, yet those past projections will be set

in stone well before there is any practical need to close the agency record.²³

Every proceeding must have an end point, decisions must be made and actions taken. But closing the evidentiary record well before that point in a CON proceeding by establishing an artificial cut-off is contrary to common sense and disserves the public interest. The CON law serves the public interest by ensuring unfettered marketplace competition does not result in underutilization of existing services and affect the ability to maintain quality, cost effective programs. *See St. Joseph Hosp. and Health Care Center v. Department of Health*, 125 Wn.2d 733, 742, 887 P.2d 891 (1995). It does not serve the public interest to make that determination on incomplete or outdated information that has not been subject to a full evidentiary hearing. The time-honored methods to test the accuracy of evidence include the introduction of evidence that is then subject to cross-examination or analysis through expert testimony, and the perspective of countervailing evidence.

E. The Superior Court Decision to Set Aside the Agency Action Rather Than Again Remanding the Matter Was Correct

When a court reviewing an administrative decision under RCW 34.05.570(3) determines there are grounds for relief, the WAPA provides the court with a number of options. RCW 34.05.574(1) provides in part:

²³ For example, in August 2004, Dr. Marks projected that if the increased number of transplants performed in that year by UWMC were annualized, "UWMC is on track to perform 168 liver transplants in 2004. CP 421. In fact, 126 were performed that year. AR 1008.

In a review under RCW 34.05.570, the court may (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.

Here the superior court determined, based on the unique history and background in this case, that “the matter will not be remanded again, instead the Court is setting aside the agency order.” CP 962. A number of factors support the relief ordered by the superior court.

1. Swedish and the Department Should Not Be Able to Argue for A Third Hearing on Remand When They Invited the Erroneous Evidentiary Rulings at Two Previous Hearings

Swedish and the Department completely failed to assess the impacts Swedish’s proposed liver transplant program would have on UWMC’s liver transplant fellowship and other training programs, despite an explicit legislative requirement to do so. This factor alone supports setting aside the agency action. In most judicial contexts, failure to meet the burden of production or proof concludes a matter without a remand that allows the party that had the burden to try again. The usual consequence of the failure to meet the party's burden of production or burden of proof is the dismissal of the suit or the loss of the case. *See, e.g., Sing v. John L. Scott, Inc.*, 134 Wn.2d 24, 948 P.2d 816 (1997) (judgment as a matter of law is appropriate when the court can say there is no substantial evidence to sustain a verdict for the nonmoving party).

Nor is this a matter in which an applicant unfairly must bear the consequence of another's actions. Rather, Swedish and the Department vigorously objected when UWMC attempted to introduce evidence on this very question. Appendix of Record, Ex. F; AR 3504-3506 and 4063-4071. In these circumstances, "a sound analogy can be drawn from the doctrine of invited error." See *Graham v. Graham*, 41 Wn.2d 845, 252 P.2d 313 (1953). A party should not be entitled to a remand to meet an unmet evidentiary burden when that party not only failed to introduce such evidence at the first hearing and the second hearing on remand, but also actively objected to the opposing party's introduction of such evidence. Claiming that another remand must be ordered to allow the taking of evidence that was improperly excluded is akin to a party claiming error because admissible evidence was excluded at that same party's request. See *McLeod v. Keith*, 69 Wn.2d 201, 203, 417 P.2d 861 (1966) (appellant could not assign error to trial court's failure to admit evidence of the surrounding circumstances and conduct of the parties, claiming that this was essential to a construction of the contract, when appellant's attorney objected when respondent sought to introduce such evidence), citing *Barash v. Robinson*, 142 Wash. 118, 123, 252 P. 680 (1927) (defendant could not complain that plaintiff had failed to prove harm for purposes of injunction when, after plaintiff proposed to show loss sustained, defendant objected and the trial court sustained the objection). By "sound analogy," *Graham*, 41 Wn.2d at 851, the WAPA should not require a remand in all circumstances, giving a party the opportunity to make omissions in proof

and advocate erroneous evidentiary rulings with no consequences because it would have another chance at another hearing.

Swedish failed to meet its burden in assessing the impacts of its CON application on liver transplant training programs. Swedish repeatedly urged the evidentiary restrictions that were in error. If Swedish chooses, it may submit a new CON application. The WAPA does not require a remand in these circumstances, giving a party the opportunity to make omissions and advocate erroneous evidentiary rulings with no consequences, knowing it would always have another chance on remand. If a party could escape the consequences of its failure to meet the burden of proof through an endless round of remands, there would be no disincentive to arguing for the most limited admission of evidence by the party's opponent.

2. A Second Remand Would Not Be in the Public Interest, Particularly Where Swedish May Submit a New CON Application.

The factors that make reversal rather than remand an appropriate remedy in this case are similar in many respects to the factors present in *Weyerhaeuser v. Pierce County*, 124 Wn.2d 26, 873 P.2d 498 (1994), which found invalidation of a permit rather than remand was the appropriate remedy. The Court upheld a trial court decision invalidating a conditional use permit granted after a county council's approval of a hearing examiner's decision. The Supreme Court agreed with the trial court that the hearing examiner should have allowed cross examination of

the county staff, that the environmental impact statement was “inadequate as a matter of law,” and that the county’s solid waste management plan “contains mandatory criteria which must be met, but this record does not establish whether those criteria have been met.” *Id.* at 28-29. The permit applicant argued the remedy should be remand rather than reversal. The applicant was not foreclosed from submitting a new application, just as Swedish is not precluded from submitting a new CON application. The permit applicant argued “it would be manifestly unjust and inefficient to reverse the entire case and thereby force the parties to spend significant time and financial resources repeating what has already been done.” Reply Brief of Appellants Land Recovery, Inc. and Resource Investments, Inc. at 20, filed in *Weyerhaeuser v. Pierce County*, 1993 WL 13156758. The Supreme Court noted:

The parties dispute whether this conclusion requires that the decision be reversed, or whether remand for correction of errors is appropriate. However, this case involves more than just inadequate findings and conclusions. We have held that the opportunity for oral cross examination of the county staff must be provided, and, as explained below, additional errors of law require reversal of the decision.

Weyerhaeuser, 124 Wn.2d at 37. Thus, the Court reversed the conditional use permit. *Id.* at 47.

The central issues in the case at hand relate to the future: whether there will be “sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care,” *see* RCW 70.38.025(14), and the impact of a new program “on existing *and*

proposed institutional training programs.” RCW 70.38.115(2)(d) (emphasis added). Critical to these issues are transplant volumes and whether the reality will match the projections that are based on assumptions such as the availability of livers through expanded use of alternative procedures. This focus is quite different from the rulings that have characterized this proceeding, which have attempted to freeze the evidence at a point in the past. Given the purposes of the CON law and the opportunity Swedish has to submit a new CON application, the public interest is best served by setting aside the agency decision.

VII. CONCLUSION

The superior court correctly concluded there were grounds to grant relief from the agency order and the relief ordered is appropriate to address the unique facts of this case. The Court should affirm the superior court's order.

RESPECTFULLY SUBMITTED this 2nd day of January, 2008.

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ORIGINAL

NO. 80264-5

SUPREME COURT OF THE STATE OF WASHINGTON

UNIVERSITY OF WASHINGTON MEDICAL CENTER,

Respondent,

v.

WASHINGTON STATE DEPARTMENT OF HEALTH,

and

SWEDISH HEALTH SERVICES,

Appellants.

UNIVERSITY OF WASHINGTON MEDICAL CENTER'S

APPENDIX OF RECORD

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University of Washington Medical Center

v.

Washington State Department of Health

And

Swedish Medical Center

Washington Supreme Court

No. 80264-5

University of Washington Medical Center's Appendix of Record

Exhibit	Record	Document
A	AR (Remand) 001906-001914	Final Order on Remand Affirming Findings of Fact, Conclusions of Law and Final Order Dated August 23, 2005
B	AR (Remand) 000286-00289	Post-Hearing Order No. 1: Scheduling Order Pursuant to Superior Court Remand (Corrects March 30, 2006 Order)
C	AR 000994-001019	Findings of Fact Conclusions of Law and Final Order
D	AR 000095-000110	Declaration of Jorge D. Reyes, M.D. in Support of Motion for Stay
E	AR 000049-000058	Declaration of James D. Perkins in Support of Petitioner's Request to Accept Additional Evidence or, in the Alternative, Remand to the Department of Health CON Program to Take Additional Evidence
F	AR 000024-000036	Declaration of Jorge D. Reyes, M.D., in Support of Petitioner's Request to Accept Additional Evidence or, in the Alternative, Remand to the Department of Health CON Program to Take Additional Evidence
G	AR 003036-003037 AR 003048-003051 AR 003057-003061 AR 003504-003506 AR 004063-00471	Excerpts from Public Hearing, Swedish Health Services Liver Transplant Program

EXHIBIT A

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)

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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

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.

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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

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

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.

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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

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

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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.

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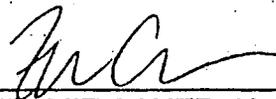
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001912

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,

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AUGUST 23, 2005

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).

FINAL ORDER ON REMAND
AFFIRMING FINDINGS OF FACT,
CONCLUSIONS OF LAW AND
FINAL ORDER DATED
AUGUST 23, 2005

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Docket No. 04-07-C-2005CN

001914

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,)	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.

CORRECTED POST-HEARING ORDER NO. 1:
SCHEDULING ORDER PURSUANT
TO SUPERIOR COURT REMAND

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000286

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

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CORRECTED POST-HEARING ORDER NO. 1:
SCHEDULING ORDER PURSUANT
TO SUPERIOR COURT REMAND

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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 13th day of April, 2006.


ZIMMIE CANER, Health Law Judge
Presiding Officer

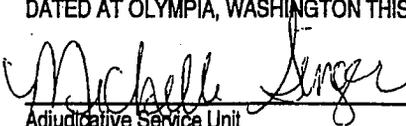
DECLARATION OF SERVICE BY MAIL

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.


Adjudicative Service Unit

cc: JANIS SIGMAN

CORRECTED POST-HEARING ORDER NO. 1:
SCHEDULING ORDER PURSUANT
TO SUPERIOR COURT REMAND

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Docket No. 04-07-C-2005CN

000289

EXHIBIT C

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) FINDINGS OF FACT,
) 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 meet the requisite CON criteria, and/or the Program's written analysis does not support the issuance of the Swedish CON.

FINDINGS OF FACT,
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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.

FINDINGS OF FACT,
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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.

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

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 organization¹² 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:

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 its 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 of 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 nation's 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

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 University²³ 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

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.

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patients with less conservative, more innovative wait list/treatment protocols, and through outreach/education of patients and health 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

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.

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

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.

⁴⁰ Swedish transplant program started 1993 and presently includes pancreas, kidney, and bone marrow. These programs have demonstrated innovations such as steroid free immunosuppression 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 surgeons⁴², 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

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.

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:

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 health 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

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
AND FINAL ORDER

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).

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
AND FINAL ORDER

Page 26 of 26

Docket No. 04-07-C-2005CN

001019

EXHIBIT D

RECEIVED
JUL 19 2004

EXPEDITE

Hearing is set
 Date: July 30, 2004
 Time: 9:00 a.m.
 Judge/Calendar: 04 JUL 23 P12:13

RECEIVED
CENTRAL OFFICE

FILED

JUL 23 2004

SUPERIOR COURT
 BETTY J. GOULD
 THURSTON COUNTY CLERK

ATTORNEY GENERAL'S OFFICE
AGRICULTURE & HEALTH DIVISION

ATTORNEY GENERAL
OF WASHINGTON

SUPERIOR COURT OF WASHINGTON FOR THURSTON COUNTY

UNIVERSITY OF WASHINGTON
MEDICAL CENTER,

Petitioner,

v.

WASHINGTON STATE DEPARTMENT
OF HEALTH,

Respondent.

04-2-01506-2
No. ~~02-2-01202-2~~

DECLARATION OF JORGE D. REYES,
M.D. IN SUPPORT OF MOTION FOR
STAY

RECEIVED

JUL 23 2004

DEPT. OF HEALTH
OFFICE OF THE SECRETARY

I, Jorge D. Reyes, M.D., hereby declare as follows:

1. I am a medical doctor and surgeon specializing in liver, kidney, pancreas, intestine and multi-organ transplantation as well as split liver and living donor operations. I am also the Chief of the Division of Transplant Surgery at the University of Washington Medical Center ("UWMC"), and Professor of Surgery at the University of Washington School of Medicine ("UW School of Medicine"). I have also served on numerous committees for the United Network for Organ Sharing ("UNOS") for over 15 years and have been closely involved with the development of organ allocation policies for adult and children, both on a regional and national basis. I am presently the Chairman of the UNOS Pediatric Committee. A true and correct copy of my curriculum vitae is attached

000095

DECLARATION OF JORGE D. REYES, M.D. IN
SUPPORT OF MOTION FOR STAY

1

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COPY

1 hereto as Exhibit A. I make this declaration of my own personal knowledge and am
2 competent to testify to its contents.

3 2. I was recently appointed as the Chief of the Division of Transplant
4 Surgery. Prior to my appointment, I was a Professor of Surgery at the University of
5 Pittsburgh Department of Surgery, a distinguished premier liver transplant program, and
6 have extensive experience in transplantation of all abdominal organs in adults and
7 children. I decided to apply for the UWMC Chief of the Division of Transplant Surgery
8 because the UWMC is a highly respected Academic Health Center which has an
9 impressive organ transplant program, a statistically high rate of survival, and a very high
10 rate of waitlisted patients who receive transplants. The UWMC's liver transplant
11 program is one of 44 training programs and 124 UNOS-Approved Liver Training
12 Transplant Centers in the United States.

13 *UWMC's Organ Transplant Program*

14 3. The UWMC commenced its adult liver transplant program in January
15 1968 when Dr. Tom Marchioro performed the state of Washington's first kidney
16 transplant. The UWMC performed the first liver transplant in the state of Washington
17 (and in the region) in January 1990. In May 1990, University of Washington surgeons
18 performed the region's first pediatric liver transplant at Children's. Although the
19 Department of Health's Analysis of Swedish Health Services' ("SHS's") liver transplant
20 certificate of need application suggests UWMC has not performed split liver or living
21 donor transplants, that is not the case. The UWMC performed its first split liver
22 transplant in July 1993, and in May 1998, it performed the region's first in-situ split liver
23 in a cadaveric donor yielding two successful liver transplants (one adult and one
24 pediatric). In July 1999, transplant teams from UWMC and Children's performed a
25 coordinated surgery on a two-and-a-half year old boy from Kingston, Washington, who
26 became the region's first recipient of a living related liver transplant. The boy's mother

1 was the donor. Currently, UWMC is an approved United Network for Organ Sharing
2 ("UNOS") facility for all its transplant services. UWMC transplant teams perform the
3 majority of extra-renal procurements in the Pacific Northwest, more specifically the
4 WWAMI Region (Washington, Wyoming, Alaska, Montana and Idaho). Almost all
5 UWMC's procurements are multi-organ procurements including liver, pancreas, and
6 kidneys.

7 4. The University of Washington Division of Transplantation performs its
8 work in the area of abdominal organ transplantation (liver, kidney, pancreas and islet).
9 The activities of the Division encompass patient care, research, and education, all with the
10 goal of helping people with end-stage organ failure regain organ function through
11 transplantation. The Division has seven transplant surgeons. In addition to myself, the
12 surgeons include: James Perkins, M.D. formerly served as Division Chief is now the
13 Vice-Chair, Department of Surgery and Professor of Surgery. Patrick Healey, M.D. leads
14 the pediatric transplantation program, based at Children's Hospital & Regional Medical
15 Center. Christian Kuhr, M.D. is Assistant Professor of Surgery with a joint appointment
16 in Urology. In addition to his clinical duties, Dr. Kuhr holds an NIH KO8 grant and
17 conducts research on the mechanisms of immune tolerance induction. Adam Levy, M.D. is
18 Assistant Professor of Surgery, and Ramasamy Bakthavatsalam, M.D. is Assistant
19 Professor of Surgery with a joint appointment in Urology. Jeffrey Halldorson, M.D.,
20 Acting Assistant Professor of Surgery, joined the Division in July 2003. The Division of
21 Transplantation joins with personnel from the UW School of Medicine and UWMC to
22 form Transplant Services. Transplant Services includes over fifty support staff of
23 transplant coordinators, patient care coordinators, research staff, pharmacists, dietitians,
24 administrative and clerical staff, and other professionals.

25 5. Our transplant program is distinguished by excellent statistical results. As
26 reported by the federal government, our one-month survival rate for liver transplantation is

1 significantly higher than expected. In comparison with nationwide data, our Liver Care
2 Program transplants a significantly higher percentage of liver patients on our waitlist with
3 a lower mortality rate, than transplant centers in the rest of the country. The mortality of
4 patients on our liver waitlist is significantly lower than expected. Our Kidney Care
5 Program provides a shorter time to transplant than the national average. Quality patient
6 care has resulted in excellent patient and graft survival. Additionally, special expertise is
7 provided by our Kidney Care Program in the care of pregnant transplant recipients. Our
8 Living Kidney Donor Program gives desensitization treatments to patients who have a
9 positive crossmatch against their designated living donor, so they can still receive the
10 kidney from this donor.

11 6. Additionally, UWMC has demonstrated outstanding statistical results through
12 the 2003 Benchmarking Project of the University HealthSystem Consortium, a group of
13 similar academic medical centers throughout the country. Our Liver Care Program and
14 Kidney Care Program are each rated more favorably than the top ten percent of
15 Consortium group members (based on our one-year patient survival rate). Our programs
16 are rated more favorably than the top 25 percent of group members in our hospital post-
17 transplant length-of-stay and the mortality rate on our waiting lists.

18 *UWMC's Research and Teaching Program*

19 7. A steady research agenda is pursued in the Division of Transplantation.
20 Two research scientists work with our surgeons to carry out our investigations: Wei Li,
21 M.D., Ph.D., and Carol Loretz, B.S. The Division's research focuses primarily on
22 tolerance, that state in which the body is conditioned to accept a transplanted organ without
23 need for immunosuppressive drug therapy. Current projects include utilizing the ingestion
24 of oral antigens in mice to study the role of the liver on peripheral tolerance, and an
25 examination of the *ex vivo* generation and sorting of dendritic and regulatory T cells for
26 application to a human tolerance protocol. Other projects have to do with cytomegalovirus

1 disease in liver transplant recipients, with calcineurin inhibitor toxicity, and with
2 developing a gene vector that can be used in transplant patients. In collaboration with our
3 medical colleagues who are part of our multi-disciplinary transplant team, the Division
4 participates in several clinical trials which seek better immunosuppression regimens for
5 counteracting rejection of transplanted organs. UWMC and the UW School of Medicine
6 regularly receive research grants from a variety of sources.

7 8. The Division of Transplantation implements a busy teaching schedule,
8 providing weekly attending lectures, weekly Transplant Grand rounds, and one-on-one
9 instruction in the operating room. Twenty-six residents are rotating through the Transplant
10 Service this year, as well as a number of visiting medical students.

11 9. The University of Washington is one of a handful of programs in the country
12 accredited by the American Society of Transplant Surgeons ("ASTS") to offer fellowship
13 training in multi-organ transplantation (liver, kidney and pancreas). ASTS requires
14 accreditation of Transplant Surgery Fellowship Programs. Currently, the two-year long liver
15 transplant fellowship program has one fellow. The fellowship is expected to expand to two
16 fellows within the year.

17 10. The formal training program for transplant surgeons also requires the
18 training program to be approved by the Membership and Professional Standards
19 Committee of UNOS. As part of the criteria for approval, the program must perform at
20 least 50 transplants each year to qualify for hepatic transplantation training. The training
21 program must also have adequate clinical and laboratory research facilities and an
22 adequate faculty with appropriate training to provide proper experience in research. Any
23 program that does not have any trainees during a period of five years between reviews
24 has to re-apply as a new program. The program director must be a board-certified
25 surgeon who meets the UNOS criteria as a transplant surgeon. The program must be
26

1 located at a medical center which transplants one or more organs and has a proven
2 commitment to graduate medical education.

3 11. The objective of a Transplant Surgery Fellowship Training Program is to
4 develop proficiency in the surgical and medical management of patients with end-stage organ
5 diseases amenable to transplantation. This objective should be achieved through a structured
6 supplemental program for the study and treatment of these diseases in an accredited and
7 properly supervised transplant surgery fellowship. Candidates for such training must have
8 satisfactorily completed a residency which satisfies the educational requirements for
9 certification by the American Board of Surgery or The American Board of Urology.

10 12. A Transplant Surgery Fellowship Training Program's objective can best be
11 achieved when it is based within an institution approved for graduate medical education in
12 General Surgery or Urology and also in those other disciplines particularly related, such as
13 Infectious Disease, Immunology, Radiology, Nephrology, Diabetology, Cardiology,
14 Pulmonary, and Gastroenterology. To provide for an effective training program, the
15 Transplant Surgery Section should be organized within the framework of a larger
16 administrative unit, such as a Department of Surgery, General Surgery, or Urology. It is
17 essential that the clinical component be centralized if a proper transplant surgery fellowship
18 program is to be conducted. This can be best achieved by establishment of a unit to which all
19 transplant cases are admitted. This should be under the direction of a qualified transplant
20 surgeon with continuous responsibility for teaching, quality of patient care, and research.
21 The director of the program should be certified by the American Board of Surgery or the
22 American Board of Urology. Other staff members should be experienced in transplant
23 surgery, dedicated to teaching, willing to devote the necessary time and effort to the
24 education program, and should be engaged in research activities as well.

25 13. In addition, the program must provide instruction in the clinical and basic
26 sciences, encompassing anatomy, physiology, pathology, and immunology including

1 histocompatibility testing, as they relate to the diagnosis and treatment of end-stage organ
2 diseases. Case material in sufficient volume must be available for the development of skill in
3 the management of patients requiring transplantation. Adequate facilities must also be
4 available for instructing the trainee in the performance and interpretation of special diagnostic
5 techniques and instrumentations necessary for the management of transplant patients. Most
6 importantly, the candidate must be provided with an adequate volume of operative
7 experience.

8 14. The activity of the training program must be sufficient to insure adequate
9 exposure to the surgical procedures applied to transplantation. To qualify for accreditation by
10 the ASTS, a transplant surgery fellowship program must have 75 patients available for each
11 transplant fellow to serve as the principal surgeon over the course of their training. In
12 addition, for accreditation as a kidney transplant training program, each transplant fellow
13 must perform at least 30 kidney transplants over the course of their fellowship. For
14 accreditation as a liver transplant training program, each fellow must perform at least 45 liver
15 transplants over the course of their fellowship. In addition, sufficient activity in multi-organ
16 procurement is required such that the transplant center exists within organ procurement
17 organization boundaries that can account for at least 25 multi-organ procurements annually.
18 The program must also be of sufficient duration to allow the trainee to acquire skill in the
19 pre-and postoperative management of transplant patients. The length of the fellowship
20 period should be no less than 24 months. Programs offering training in both renal and
21 extrarenal transplantation including multi-organ procurement should offer at least 18 months
22 of clinical training, with the balance of the two-year fellowship spent in additional clinical
23 work or laboratory experience.

24 15. Typically, a fellow in the UWMC's program works with the team for three
25 to six months before becoming proficient in cadaveric organ procurement. Once the
26 fellow is qualified, the fellow then rotates on the organ procurement team with the

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7

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1 surgeons. The transplant fellow is involved in the evaluation of all procurement donor
2 organs and manages fluids and medications after termination or brain death, along with
3 the organ procurement coordinators. The transplant fellow alternates with the surgical
4 residents, assists on all living donor nephrectomies with the transplant attending. The
5 fellow is responsible for seeing the potential donors in the transplant clinic, evaluating the
6 entire workup, and discussing the procedures with the potential donors.

7 16. As stated, the transplant service at UWMC is a combined medical/surgical
8 service under which the Department of Surgery contributes members from the Division
9 of Transplantation, including surgical attending physicians, a transplant fellow,
10 physicians' assistants and others. The Department of Medicine contributes personnel
11 from the Division of Nephrology, Hepatology, Pulmonology, and Infectious Disease.
12 The liver team consists of a surgery attending physician, hepatology attending physician,
13 endocrinologist, transplant fellow, gastrointestinal fellow, physician's assistant, third-
14 year surgery resident, second-year surgery resident and third-year medicine resident. The
15 UWMC transplant team performs the majority of extra-renal procurements in the Pacific
16 Northwest, more specifically the WWAMI Region.

17 17. Each week the extended transplant service conducts a morbidity and
18 mortality conference, where all cases of the prior week are discussed. Following this
19 discussion, there are transplant grand rounds each week. Additionally, other weekly
20 conferences are held, including biopsy conferences where all specimens from the prior
21 week are reviewed, and a radiology conference, where all pertinent x-rays of the prior
22 week are reviewed. All members of the team attend weekly patient selection conferences
23 for the respective transplant services. On a monthly basis, there is a separate transplant
24 surgery research conference. In this conference, multiple studies are conducted in
25 transplantation and related topics are coordinated. Weekly immunology conferences are
26 also sponsored by the Department of Immunology, and attended by the transplant team.

DECLARATION OF JORGE D. REYES, M.D. IN 8
SUPPORT OF MOTION FOR STAY

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1 Through these conferences, the fellow meets with scientists and research ideas and
2 projects are discussed.

3 18. UWMC also provides training for transplant physicians. Each liver
4 transplant program must have on site a qualified transplant physician and must have one
5 year of specialized training in transplantation under the direct supervision of a qualified
6 liver transplant physician and in conjunction with the liver transplant surgeon at a
7 UNOS-approved liver transplant center. The transplant physician also must have been
8 involved in the primary care of 30 or more liver transplant recipients and will have
9 followed 30 patients for a minimum of three months from the time of their transplant.

10 *UWMC's Status as an Academic Health Center*

11 19. The UWMC is an Academic Health Center providing services to the
12 residents of Washington State, WWAMI and neighboring states. As an Academic Health
13 Center, UWMC provides a number of important benefits to both the local communities
14 and the nation. On the national level, Academic Health Centers:

- 15 • Care for almost one-third of uninsured patients in their hospitals (The
16 Commonwealth Fund Task Force on Academic Health Centers,
17 1997a).
- 18 • Account for a significant share of the nation's specialized services,
19 such as burn units, transplant programs, and neonatal units.
- 20 • Account for almost one-third of national health-related research and
21 development funds (The Commonwealth Fund Task Force on
22 Academic Health Centers, 1997a).
- 23 • Produce approximately 16,000 medical school graduates and are the
24 dominant providers of graduate medical education (GME), sponsoring
25 58 percent of all GME programs (The Commonwealth Fund Task
26 Force on Academic Health Centers, 1997a).

- Graduate about 15,000 nursing school graduates (American Association of Colleges of Nursing, 2002). Each year, almost 40 percent of these graduates are prepared at the master's and doctoral levels, representing an important supply of faculty for all nursing schools (American Association of Colleges of Nursing, 2002).
- Graduate about 6,000 public health professionals annually (Association of Schools of Public Health, 2001).

20. Locally, UWMC not only contributes to providing charity care for disadvantaged persons, it also contributes to the local economy. UWMC has a significant economic impact in the region each year through the direct and indirect generation of jobs and spending in the local area.

21. Like UWMC, just over half of the Academic Health Centers in this country are publicly sponsored organizations. These other public organizations are at the forefront of medical teaching and research. Centers, like UWMC, are valuable centers of learning and it is imperative that their well-being be taken into account when considering adding additional programs to competing hospitals. It is important that any new programs do not adversely impact programs in Academic Health Centers designed to further treatment and research.

22. UWMC Transplant Services has a vital responsibility in providing academic and clinical training of the pediatric transplant surgeon at Children's. By sharing UWMC expertise and resources, both clinical and research outcomes at Children's are enhanced. The existing partnership between UWMC and Children's is essential in maintaining our collaborative living donor and split-liver programs. Established clinical protocols support the care of mutual donor and recipient patients.

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1 transplant program in Seattle, or Washington would likely result in the redistribution of a
2 finite number of transplant procedures between two hospitals, further endangering the
3 viability of the UWMC's teaching and research programs.

4 26. In addition, I reviewed Swedish's estimate that 39 Washington State
5 residents out-migrated for liver transplant services in 2001 and found this number is
6 incorrect. I understand Swedish conceded this number is in error in its rebuttal
7 submission. Exact data for the United Network for Organ Sharing ("UNOS") shows that
8 in 2001, only nine Washington residents underwent liver transplants in other states.
9 Although the Department's Analysis states 17 Washington residents left the state for liver
10 transplants in 2001, that number is inconsistent with UNOS' data. The reason that some
11 of these individuals left the state for liver transplants is explained in part by the fact that
12 they were Veterans Administration patients who are required to go to Portland, Oregon of
13 liver transplant services or were residents of the Vancouver, Washington area who
14 obtained liver transplants in Portland. In addition, others were treated by "transplant
15 centers of excellence networks," commonly used by third-party payors to assure quality
16 and minimize costs, or insurance carrier agreements required the surgery to be performed
17 at a specific facility. This information was given to the Department during the review
18 process.

19 27. In addition, there are no facts to support Swedish's contention that too
20 many donor livers are transported out of Washington State. Donor organs come in
21 different sizes, shapes and quality. All organs assessed as usable, given the medical
22 severity of our patient population, were in fact used and account for the minimal
23 mortality that our patients present while waiting for organs. While being very critical of
24 the need to export locally procured livers, Swedish does not acknowledge that liver
25 *imports* also occur. In fact, Washington received eight in 2000, nine in 2001, and four in
26 2002. Organ procurement organization ("OPO") data are available from multiple

1 sources, including UNOS, the Scientific Registry of Transplant Recipients ("SRTR"),
2 and the Association of Organ Procurement Organizations ("AOPO").

3 28. At no point in its application does Swedish acknowledge local, regional,
4 and national organ sharing. Swedish appears to assume that all locally procured donor
5 livers should be transplanted into Washington residents. This is a faulty assumption.
6 Organ sharing is a requirement for participation in the national Organ Procurement and
7 Transplantation Network ("OPTN"), which is administered for the Health Resources and
8 Services Administration ("HRSA") by contract through UNOS. Not all locally procured
9 donor organs will be transplanted at local centers. The distribution system is far more
10 complex. While donor livers are exported from Washington State, this is to be expected,
11 given the requirements of the national Organ Procurement and Transplantation Network.
12 All available donor livers will rarely, if ever, be fully utilized locally, but the sharing rate
13 in the Seattle-area is more favorable than it is nationally. Nonetheless, despite organ
14 sharing, patients who are waitlisted at the University of Washington have a much higher
15 transplant rate than do patients waitlisted elsewhere in the U.S.

16 29. In addition, sometimes UWMC does not even know an organ from a
17 Washington donor is available for transplant. For example, very recently I learned from a
18 former colleague at the University of Pittsburgh that an organ from a Washington donor
19 had left the State unbeknownst to UWMC. The organ was allowed to leave the state in
20 contravention of UNOS rules when a staff person at a local donor facility, Life Center
21 Northwest, made an error and offered the organ to a facility in Pittsburgh without
22 offering it to a UWMC patient. Similar mistakes explain how some of these organs are
23 "allowed" to leave the state. In response to this incident, I contacted Life Center
24 Northwest and am implementing a program to ensure that this does not happen again. A
25 copy of a letter from Life Center Northwest dated July 19, 2004, explaining this error is
26 attached as Exhibit B.

1 30. Indeed, no real or empirical evidence or data is provided by Swedish
2 suggesting that persons with serious liver disease who might benefit from liver
3 transplantation are not currently being referred to the Hepatology Program at the
4 University of Washington. A patient-based analysis is required to demonstrate there are
5 patients who do not have an opportunity to be waitlisted so as to support Swedish's
6 allegation there is an unmet need for liver-related surgeries and procedures. Swedish,
7 however, has submitted no compelling evidence to this effect. Although Swedish
8 maintains that its liver transplant program will effectively identify through its protocols
9 and treat what has heretofore been an unmet need for liver-related surgeries and
10 procedures, it has not identified the specific protocols it will use to do so. I am
11 exceedingly skeptical and concerned with Swedish's suggestion that it will perform more
12 transplants, and save more lives, by performing very high-risk split liver and living donor
13 surgeries. This is an especially disconcerting claim considering Swedish's proposed
14 program will have new, relatively inexperienced staff performing these procedures.
15 Notably, Swedish has not shown the Department or UWMC its protocols for
16 transplantation. In reality, Swedish will unlikely be able to duplicate existing services.
17 Its program will have deleterious consequences for UWMC and the UW School of
18 Medicine, as well as the community, the state, and the region.

19 31. Equally troubling, the liver transplant program staffing plan Swedish
20 proposes is inadequate. A single liver transplant surgeon is insufficient to meet the
21 demands associated with the provision of liver transplant services. The employment of a
22 single hepatologist is equally questionable given a program that demands coverage 24
23 hours per day, 7 days a week, and 365 days per year. At a minimum, the program should
24 employ two UNOS qualified liver transplant surgeons and, preferably, two qualified
25 hepatologists.

1 32. Swedish has hired a surgeon from Minnesota to oversee its proposed
2 program. This individual has not performed a liver transplant in at least two years and
3 therefore has no current working knowledge of transplant techniques. Liver transplants
4 are one of the most difficult and complex organ transplant procedures. By way of
5 illustration, a kidney transplant operation generally takes about three hours, a
6 kidney/pancreas transplant about seven hours, and a liver transplant about eight hours.
7 See Exhibit C attached hereto, a true and correct copy of the University of Washington
8 Department of Surgery Division of Transplantation Resident Orientation Manual, p. 17

9 33. The staffing plan at Swedish should be contrasted with that of UWMC.
10 UWMC has six (6) liver transplant surgeons and four (4) hepatologists associated with its
11 liver transplant program. Besides myself, they including the following individuals:

- 12 • Ramasamy Bakthavatsalam, M.D. (kidney, pancreas, and liver
13 transplantation)
- 14 • Patrick J. Healey, M.D. (liver transplantation)
- 15 • Christian S. Kuhr, M.D. (kidney, pancreas, and liver transplantation)
- 16 • Adam E. Levy, M.D. (liver transplantation)
- 17 • James D. Perkins, M.D. (kidney, pancreas, and liver transplantation)
- 18 • Robert L. Carithers, Jr., M.D. (hepatology)
- 19 • Kris Kowdley, M.D. (hepatology)
- 20 • Anne Larson, M.D. (hepatology)
- 21 • Bruce Tung, M.D. (hepatology)

22 34. Without question, UWMC's liver transplant program is adequately staffed
23 to meet the complexities of patient evaluation, the uncertainties associated with the
24 timing of liver transplantation, as well as the rigors of postoperative medical and surgical
25 patient care, is able to provide all state-of-the-art surgical transplant options including
26 split liver and living donor procedures and is on the cutting edge of transplant innovation.

DECLARATION OF JORGE D. REYES, M.D. IN 15
SUPPORT OF MOTION FOR STAY

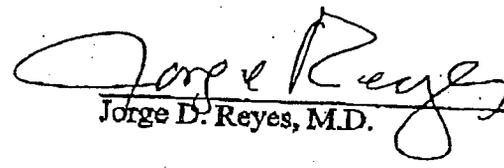
LANE POWELL SPEARS LUBERSKY LLP
111 Market Street NE, Suite 360
Olympia, Washington 98501
Telephone: (360) 754-6001
Facsimile: (360) 754-1605

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35. Attached hereto as Exhibit D is a true and correct copy of the Application for Renewal of ASTS Accreditation.

I declare under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct.

Signed this 23 day of July, 2004, at 01:05 PM Chicago, IL.


Jorge D. Reyes, M.D.

DECLARATION OF JORGE D. REYES, M.D. IN SUPPORT OF MOTION FOR STAY

16

LANE POWELL SPEARS LUBERSKY LLP
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EXHIBIT E

COPY

RECEIVED
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<input checked="" type="checkbox"/>	EXPEDITE
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	Date: <u>December 23, 2005</u>
	Time: <u>9:00 a.m.</u>
	Judge/Calendar: <u>Tabor</u>

ATTORNEY GENERAL'S OFFICE
AGRICULTURE & HEALTH DIVISION '05 DEC 16 AM 10:46

DEC 16 2005

SUPERIOR COURT OF WASHINGTON FOR THURSTON COUNTY

UNIVERSITY OF WASHINGTON
MEDICAL CENTER,

No. 04-2-01506-2

Petitioner,

DECLARATION OF JAMES D. PERKINS
IN SUPPORT OF PETITIONER'S
REQUEST TO ACCEPT ADDITIONAL
EVIDENCE OR, IN THE
ALTERNATIVE, REMAND TO THE
DEPARTMENT OF HEALTH CON
PROGRAM TO TAKE ADDITIONAL
EVIDENCE

v.

WASHINGTON STATE DEPARTMENT
OF HEALTH.

Respondent.

I, James D. Perkins, M.D., hereby declare as follows:

1. I am a medical doctor and surgeon specializing in liver transplantation, which includes donor organ transplants as well as split liver, cut-down liver, and living donor surgeries. I was the Director of Transplant Surgery at the University of Washington Medical Center ("UWMC") from 1989 to 2004 and am now the Vice Chairman for the department of surgery at the UWMC and a Professor of Surgery at the University of Washington School of Medicine ("UW School of Medicine"). I was also the Program Director for UWMC's liver transplant fellowship program from the mid 1990's to July 2004. I am a UNOS qualified liver transplant surgeon and have been performing liver transplants since 1985. I have performed over 900 liver transplants.

DECL OF DR. PERKINS IN SUPPORT OF
REQUEST TO ADMIT ADD'L EVIDENCE

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000049

1 including 14 split-liver transplants, one living donor, and several cut down liver
2 transplants, all at the UWMC. I have also served on numerous committees associated
3 with liver transplantation for the United Network for Organ Sharing ("UNOS").

4 2. I have reviewed the rebuttal submission ("Rebuttal") from Swedish
5 Medical Center ("Swedish") and can refute much of the information contained in it.
6 However, during the adjudicative proceeding on this matter, I was not allowed to testify
7 about some erroneous, overstated, and disparaging statements that were made in the
8 Rebuttal because of rulings made by the Department of Health's Law Judge. If allowed,
9 I would testify as follows regarding these statements in the Rebuttal.

11 a. Swedish states in its Rebuttal that the reason the number of Washington
12 patients who "out-migrated" for liver transplants in 2002 was less than the 39 patients
13 Swedish included in its Application was because there is a group of people "falling
14 through the cracks" that are not reflected in data. In support of this statement, Swedish
15 says there must be people "falling through the cracks" because (1) Washington has a
16 higher rate of incidence of liver disease compared to the national rate; and (2) part of the
17 appropriate recipient population was never identified because these people, "were never
18 given the opportunity to receive a transplant within Washington and did not have the
19 knowledge and/or resources to seek alternative opinions."¹ RR 604. Swedish then
20 concludes that these stated reasons are correct and proceeds to set forth a series of
21
22

23 ¹ Notably, Swedish changed the year it used for comparison of out-migration statistics from its Application
24 to its Rebuttal. In its Application, Swedish cites statistics from 2001, but when forced to concede that 39
25 people did not leave the state for transplants in 2001, it cited the out-migration statistics from 2002 because
26 that year 17 persons left the state for transplants, which was closer to the 39 patients Swedish calculated in
its Application. Actually, only nine patients left the state for transplants in 2001. Moreover, Swedish did
not dispute that those nine patients out-migrated for transplants for reasons other than a lack of access to
UWMC's program or inability to receive a transplant at UWMC.

1 inaccurate and wholly fabricated allegations to bolster its claims that there is a large
2 unmet need in Washington for liver transplants and that its program will provide
3 transplant to these patients "falling through the cracks."

4 Current accurate statistics show that rate of incidence of liver disease in the
5 Pacific Northwest, and the WAMI region, is less than the rest of the country. I attempted
6 to provide the attached charts showing the national death rates from liver disease. These
7 charts, obtained from CDC/NCHS, a nationally recognized source, clearly show
8 Washington's population is significantly lower than the national average for liver disease.
9 Dr. Mark's included the northwest in his definition of the "western states" and asserted
10 that since the "western states" have a higher incidence of liver disease, so must the
11 Northwest. As is clear from the charts, the incidence of liver disease in California,
12 Arizona and part of Nevada is significantly higher than the national average, which skews
13 the results if one looks at the "western states". However, the rate of liver disease in the
14 northwest is remarkably different from that in the southwest. This reputable nationally
15 recognized data refutes one of the bases of Swedish's claim that people are "falling
16 through the cracks".

17
18
19 b. Swedish also claims that there must be people falling through the cracks
20 because Washington has a high Asian and Asian-Pacific Islander American population
21 that is more prone to liver disease. Inexplicably, Swedish concludes that the Asian and
22 Asian-Pacific Islander American population was not counted in arriving at the rate of
23 liver disease in Washington as set forth in the attached charts. There is no reason to think
24 that is true: all population groups were included in this analysis. Swedish then
25 compounds this error by stating that since Washington has more liver disease than the
26

1 national average, there must be Asian and Asian-Pacific Islander Americans in need of
2 transplants who are "falling through the cracks." The clear inference is that UWMC's
3 program does not transplant a proportional number of Asian and Asian-Pacific Islander
4 Americans and that this population is therefore underserved. RR 605 - 606. Swedish
5 obviously did not review the transplant statistics for Asian and Asian-Pacific Islander
6 Americans who received transplants at UWMC. Had Dr. Marks reviewed this data, he
7 would have found that 7.6 percent of the transplants performed at UWMC were on Asian
8 and Asian-Pacific Islander American patients compared to the national average of 4.3
9 percent (RR 461). Swedish's own Rebuttal statistics state that Asian and Asian-Pacific
10 Islanders represent 5.9 percent of the population while this same group represents 3.7
11 percent of the United State's population. Swedish's Rebuttal, however, just omits the
12 fact that UWMC transplants a higher percentage of Asian and Asian-Pacific Islander
13 Americans than the percentage of these populations in the state, and far more than
14 nationally. Swedish's Rebuttal arguments on this issue are absolutely false.

15
16
17 c. Swedish's Rebuttal attempts to "quote" me as stating that UWMC will not
18 perform living donor, split liver, or cut down liver procedures. The Department in its
19 decision adopts this quote without ever asking me, or giving me any opportunity to refute
20 this "quote." I did not make this statement. UWMC can and does perform living donor,
21 split liver, and cut down liver transplants. There are no program restrictions on these
22 procedures at the UWMC. I stated at the meeting referenced in Swedish's Rebuttal that
23 the UWMC does not perform these cutting edge procedures unless absolutely necessary.
24 We are fortunate in this region to have a greater supply of donor organs than other
25 regions and are therefore able to wait for an excellent donor organ and patient match.
26

1 However, when a patient is too sick to wait and the appropriate circumstance is
2 presented, UWMC does perform these procedures. Swedish infers that these cutting edge
3 procedures should be performed routinely, which would not meet the standard of care for
4 this community. These are extremely difficult and risky procedures and UWMC is
5 unwilling to expose a patient to the additional risk if a suitable donor organ is available.

6
7 Swedish's statement is also disingenuous because it knows that UWMC
8 performed the first living donor, in conjunction with Children's Hospital in 1999. As
9 stated, I have also personally performed 14 split-liver transplants, one living donor, and
10 several cut down liver transplants, all at the UWMC.

11 d. I have reviewed the proposed staffing for Swedish's proposed liver
12 transplant program and, based on my experience and expertise, it is absolutely my
13 opinion that Swedish's program will not be able to perform these high risk cutting edge
14 procedures with their limited staff. In fact, the staffing levels of one UNOS qualified
15 liver transplant surgeon and one UNOS qualified liver transplant hepatologist is
16 inadequate for any liver transplant program, especially a start-up program like Swedish is
17 proposing. Any program staffed by only one transplant surgeon and one hepatologist
18 cannot cover the needs of a 24 hour - 7 day a week liver transplant program. A liver
19 transplant program must have this 24/7 coverage because of the need to transplant
20 immediately when an organ becomes available; the extensive pre-and post-operative care
21 necessary for these very sick patients; the selection procedures and office visits required;
22 administration responsibilities; and responsibilities associated with procuring and
23 determining compatibility of the donor organs that are offered. A program with such
24 limited staffing will only be able to perform selected limited transplants, which will
25
26

1 impact the development of physician and team expertise and run the risk for poor
2 outcomes, or few transplant opportunities for patients seeking care at that program.

3 e. Swedish tries to create the impression that there is a large underserved
4 group of patients that are denied access to UWMC's wait list because UWMC's wait list
5 protocols are too restrictive which results in their waitlist being "too short". This is
6 absolutely false. The wait list criteria used by UWMC is universal; it is wholly consistent
7 with other UNOS transplant programs across the nation. If Swedish were allowed to
8 implement its program, its wait list would contain the same criteria.
9

10 However, the number of patients on the UWMC waitlist is smaller compared to
11 similar regions. This is not the result of overly strict criteria as stated above but rather a
12 result of a combination of other factors. One of those factors is that UWMC transplants
13 patients at a significantly higher rate than the rest of the country. I would have
14 introduced current UNOS data confirming those statistics. The result of that higher
15 transplant rate is that patients move off the list at a higher rate and the waitlist is shorter.
16 A collateral result of this high transplant rate is the corresponding reduction in the
17 demand for more risky transplants such as living liver and cut down liver transplants.
18 With a shorter waitlist, the UWMC can better match patients to the pool of donor organs
19 that are available and the need to perform more radical (and risky) procedures is
20 diminished.
21

22 More importantly, the length of a wait list has more to do with timing than
23 access. Some programs wait list patients early, even though they have very low MELD
24 scores and are not ready for a transplant. It is only when a MELD score reaches 15 that a
25 patient will receive greater benefit from a transplant than not having the transplant. This
26

1 MELD 15 benchmark is recognized by liver transplant programs throughout the United
2 States. The addition of a second program will have no impact on the length of a wait list
3 at UWMC or Swedish. A review of the extremely variable lengths of transplant
4 programs' wait lists illustrates this well. In the public hearing, UWMC submitted an
5 exhibit that showed programs' wait list lengths ranged from under 100 patients to well
6 over 400 patients. What is important is the time to transplant, survival rates, and quality
7 and experience of the physicians and transplant teams.

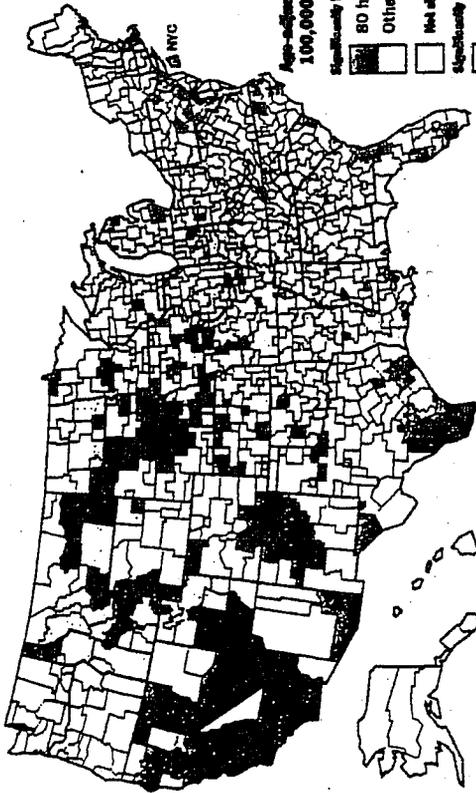
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9 f. Swedish extensively criticizes UWMC's performance as a liver transplant
10 program and bases this criticism on a claim that UWMC's three-year survival rate is
11 lower than that at peer institutions. This criticism is completely unfounded. The
12 statistics used by Swedish are cherry-picked and do not make a complete or fair
13 comparison. Actual data of all academic health center programs, and in fact, all
14 programs, shows UWMC's survival rates are at or above the national average.
15 Additionally, looking at a single year's survival rate can be misleading since liver
16 transplant programs may have some difficult cases in a given year that distort that year's
17 three-year survival rates. Programs that are performing the more risky procedures will
18 also have lower survival rates. UWMC's survival rates are excellent, especially when all
19 these contributing factors are considered.

20
21 The other factor to be considered when assessing a patient's survival while in a
22 liver transplant program is the survival rate while waiting on the waitlist. Again, since
23 the UWMC transplants patients significantly faster than the rest of the country, the
24 waitlist survival rate at UWMC is significantly better than the rest of the country.
25
26

ATTACHMENT TO
DECLARATION OF
JAMES D.
PERKINS, M.D.

DEATH RATES OF EACH HSA
COMPARED WITH U.S. RATE

LIVER DISEASE
WHITE MALE



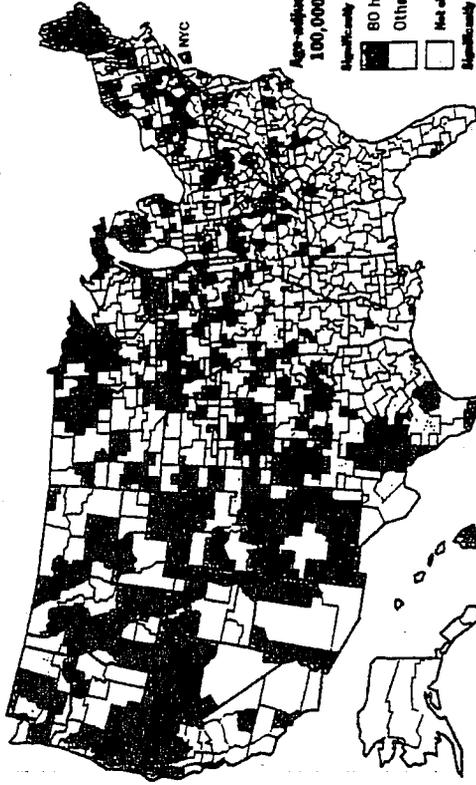
U.S. rate = 11.7

SOURCE: CDC/NCHS

* See text

DEATH RATES OF EACH HSA
COMPARED WITH U.S. RATE

LIVER DISEASE
BLACK MALE



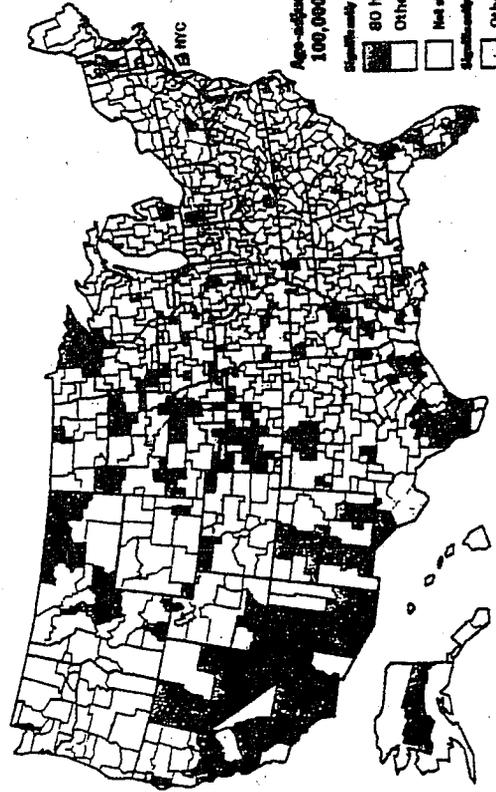
U.S. rate = 19.5

SOURCE: CDC/NCHS

* See text

DEATH RATES OF EACH HSA
COMPARED WITH U.S. RATE

LIVER DISEASE
WHITE FEMALE



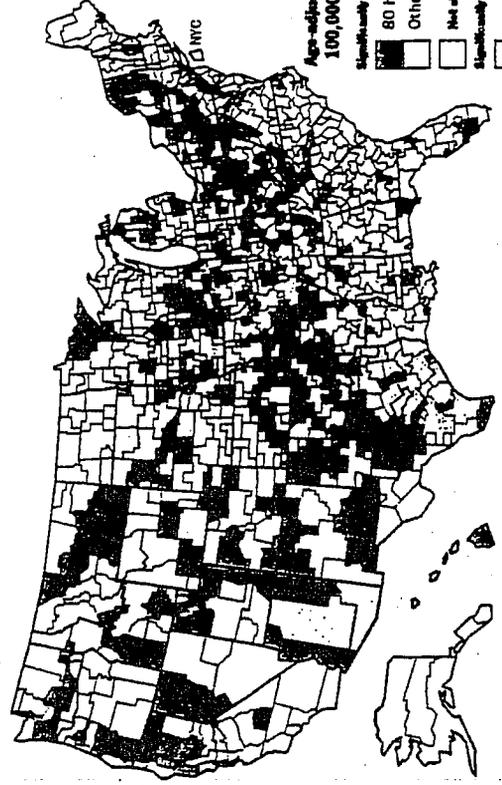
U.S. rate = 4.9

SOURCE: CDC/NCHS

* See text

DEATH RATES OF EACH HSA
COMPARED WITH U.S. RATE

LIVER DISEASE
BLACK FEMALE



U.S. rate = 8.4

SOURCE: CDC/NCHS

* See text

EXHIBIT F

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<input checked="" type="checkbox"/> EXPEDITE
<input checked="" type="checkbox"/> Hearing is set
Date: <u>December 23, 2005</u>
Time: <u>9:00 a.m.</u>
Judge/Calendar: <u>Tabor</u>

SUPERIOR COURT OF WASHINGTON FOR THURSTON COUNTY

UNIVERSITY OF WASHINGTON
MEDICAL CENTER.

Petitioner.

v.

WASHINGTON STATE DEPARTMENT
OF HEALTH.

Respondent.

SWEDISH MEDICAL CENTER.

Intervenor.

No. 04-2-01506-2

DECLARATION OF JORGE D. REYES,
M.D., IN SUPPORT OF PETITIONER'S
REQUEST TO ACCEPT ADDITIONAL
EVIDENCE OR, IN THE
ALTERNATIVE, REMAND TO THE
DEPARTMENT OF HEALTH CON
PROGRAM TO TAKE ADDITIONAL
EVIDENCE

I, Jorge D. Reyes, M.D., hereby declare as follows:

1. I am the Chief of the Division of Transplant Surgery at the University of Washington Medical Center ("UWMC"), Director of Transplant Services for Children's Hospital and Regional Medical Center ("Children's"), and Professor of Surgery at the University of Washington School of Medicine ("UW School of Medicine"). I oversee all solid organ transplants performed at UWMC, which include liver, kidney, and pancreas transplants. I also oversee and supervise the transplants that are performed at Children's, which includes both liver and kidney transplants.

DECL OF DR. REYES IN SUPPORT OF REQUEST
TO ADMIT ADD'L EVIDENCE

BENEDICT GARRATT PLLC
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1 2. In my previous declarations, I set forth my educational medical training
2 and experience. Briefly, I attended medical school in Brazil, received Pathology training
3 at Harvard Medical School and general surgery training at New York Medical College in
4 New York City. I did my fellowship in transplantation at the University of Pittsburgh
5 Medical Center with Dr. Thomas Starzl. Dr. Starzl is considered the pioneer of
6 transplantation and the Pittsburgh Transplantation Program is considered one of the best
7 transplant programs in the United States. In 1989, I became part of the faculty at the
8 University of Pittsburgh where I did mostly adult liver transplantation and some adult
9 kidney transplants. In 1991, I began performing pediatric liver transplants and for about
10 five or six years thereafter, combined adult and pediatric liver transplantation. In 1994, I
11 and others at the University of Pittsburgh began working to develop intestinal and multi-
12 organ transplants. I also worked with developing living donor programs in Pittsburgh,
13 initially for children and then for adults, and the split-liver transplantation program. I
14 was promoted to a professor of surgery and became the Director of Pediatric
15 Transplantation at Children's Hospital in Pittsburgh from 1995 until July 2004. I began
16 my current directorship at UWMC on July 5, 2004. I continue to perform both adult and
17 pediatric liver transplants and am implementing an intestinal transplant program that was
18 recently granted a certificate of need by the Department of Health ("Department").

19 3. I testified at the adjudicative proceeding, appealing the Department's
20 issuance of the certificate of need to Swedish Medical Center ("Swedish") but because of
21 rulings by the Health Law Judge ("HLJ") was unable to testify to certain crucial matters
22 raised by Swedish in its rebuttal submission ("Rebuttal"). For example, I was asked to
23 explain the American Society of Transplant Surgeons ("ASTS") standards for liver
24 transplant fellowship programs. I know these standards well since both UWMC and the
25 University of Pittsburgh Medical Center are academic health centers subject to the
26 standards. Additionally, UWMC was approved by ASTS for two liver transplant fellows

1 in the fall of 2004, which required compliance with both the ASTS and UNOS standards
2 for liver transplant fellowship programs.

3 I began to testify that I am uniquely aware of ASTS and UNOS patient volume
4 standards because UWMC has to maintain those numbers or the fellowship will be
5 canceled. Transcript of Hearing (1/27/05), pg. 153. I also began to explain that a liver
6 transplant fellow must follow 75 transplants patients. I was not allowed to complete this
7 testimony because the judge ruled that the ASTS standards were not part of the record,
8 even though the UNOS criteria referenced the ASTS standards. Had I been allowed to
9 fully testify. I would have explained that ASTS requires a transplant fellow to be the
10 primary surgeon or the first assistant on 75 transplants - 45 liver transplants and 30
11 kidney transplants over a two-year period. As set forth at length in UWMC's Application
12 for Renewal of ASTS Accreditation as an Approved Multi-Organ Transplant Fellowship
13 Program (attached hereto as Exhibit A), each of these fellows must also perform at least
14 20 liver procurements as primary surgeon or first assistant over the two-year period.
15 Additionally, each liver transplant fellow must have a current working knowledge of liver
16 transplantation, including the management of patients with end-stage liver disease,
17 patient selection, donor selection, histocompatibility and tissue typing, pre- and post-
18 operative care, use of immunosuppressive therapy, and interpretation of allografts,
19 biopsies, and ancillary tests for liver dysfunction.

20 In my opinion, a liver transplant fellowship program must have at least 120
21 surgeries to afford the program the volumes and flexibility necessary to allow two
22 fellows to meet the UNOS, ASTS and UWMC program requirements. This is because it
23 is not appropriate for fellows to commence their training by performing surgeries on
24 more difficult patients. Since fellows have all the responsibilities described above,
25 timing of appropriate surgeries can become difficult. A fellow must also comply with the
26 ASTS and UNOS organ procurement requirements and research requirements.

1 In reality, however, a fellowship program requires far more than just patient
2 volumes. As experience and qualifications dictate, fellows may perform a liver transplant
3 as the primary surgeon, but this is always jointly with a UNOS-qualified and ASTS-
4 certified transplant surgeon. Typically, a fellow becomes proficient in kidney and
5 pancreas transplantation within the first year of the fellowship and in the second year
6 gains proficiency in liver transplantation. The liver transplant fellow has some
7 responsibility for all transplant cases for the two years of the liver transplant fellowship
8 program. In addition, a fellow is responsible for consultations, organizing the operating
9 room for all vascular access cases, and is either the primary surgeon or first assistant for
10 all vascular access cases, jointly with the attending transplant surgeon. The fellow must
11 also attend core lectures which include transplant immunology, histocompatibility, and
12 immunogenetics. In addition, the transplant fellow must attend grand rounds where
13 lectures on immunogenetics and histocompatibility are given and each fellow is
14 encouraged to spend time at the tissue typing lab and work on specific projects.

15 A fellow must also undertake a research program and write two papers. Typical
16 fellowship research has included histology of biopsies, diagnosis of rejection, tissue
17 matching, and transplantation and studies to increase the quality of organs. The fellow
18 usually presents this research at regional and national meetings and is encouraged to
19 submit the papers for publication. Thus, a two-year liver transplant fellowship program
20 has numerous components that have their own time demands. The program must have
21 sufficient surgical volumes to give the program the flexibility necessary to complete all
22 the requirements.

23 4. I also was not allowed to testify to other information contained in
24 Swedish's Rebuttal because the HLJ restricted my testimony to November 23, 2004,
25 because, as I understand it, that was the date the judge decided my testimony became
26 relevant, since that's when I interviewed for my position with UWMC. Had I been

1 allowed to testify without this restriction. I would have offered testimony to refute the
2 following portions of Swedish's Rebuttal.

3 a) I attended the hearing and heard Dr. Marks testify that he had
4 prepared Swedish's Rebuttal. Dr. Marks is not a liver transplant expert or a UNOS-
5 qualified liver transplant surgeon; he has not been responsible for a liver transplant
6 program, a liver transplant fellowship program, or any other fellowship program in an
7 academic health center. Additionally, Dr. Marks does not have expertise in determining
8 whether a donor liver is acceptable or compatible with patients on UWMC's wait list.
9 Dr. Marks testified that he had never even reviewed UWMC's patient wait list criteria
10 and has not reviewed UWMC's transplant patient protocols. However, the Rebuttal
11 makes statements that criticize UWMC's program, wait list, and protocols at length. In
12 my opinion, Dr. Marks, a kidney transplant surgeon, is not qualified in the area of liver
13 transplantation. Liver transplant surgeries are far more complex at all levels of care, pre-
14 transplant, transplant, and post-transplant. Because of Dr. Marks' lack of expertise, there
15 are gross inaccuracies in the data that was included in Swedish's Rebuttal.

16 b) Dr. Marks asserts that UWMC's transplant wait list is too short, in
17 comparison to other transplant centers, and that this is an indication that there are patients
18 who are "falling through the cracks" and not receiving transplants. (RR 599). This again
19 illustrates Dr. Marks' lack of understanding regarding the wait listing process for liver
20 transplant patients. Liver transplant patients are listed under a recently instituted MELD
21 scoring system. MELD scores are not given to kidney transplant patients and therefore
22 Dr. Marks has not had any personal working experience with assigning patients MELD
23 scores or how sick those patients are at each MELD score level.

24 Dr. Marks states that he has never seen the UWMC's wait list or the wait
25 list criteria and, at best, his opinions are therefore based on literature and his training prior
26 to coming to Swedish more than 13 years ago. Dr. Marks also states that UWMC is

1 unwilling to place high risk patients on its wait list. This is also simply untrue. Dr. Marks
2 does not have a working knowledge of liver transplantation procedures to make these
3 unsupported sweeping statements. I would therefore put no weight on his opinion
4 regarding UWMC's program and how it compares with its peers.

5 c) UWMC's wait list criteria is the same or similar to other liver
6 transplant programs in the United States. Dr. Marks apparently also does not understand
7 that liver transplant wait list criteria are based on exclusion criteria that are very specific
8 because they are stipulated by UNOS. In fact, UWMC, like the other transplant
9 programs, does not wait list patients who are high risk for tolerating the procedure; who
10 may have irreversible neurologic problems; a previous history of malignancies; severe
11 ischemic heart or disease; or uncontrolled pulmonary hypertension. The criteria also
12 exclude patients with untreated infections, active substance abuse, history of non-
13 compliance, and other factors that would negatively impact the post-transplant outcome.
14 Since there are never enough donor organs to provide transplants for all patients who
15 need new livers, the UWMC must carefully select patients and appropriate donor organs
16 for those patients to obtain the best results. The unfortunate truth is that for every patient
17 who receives a liver transplant, another patient does not and may die.

18 d) In my opinion, Swedish's Rebuttal is advocating that UWMC
19 become a center that takes high risk patients and places marginal livers in those patients
20 because this would give more patients a chance for survival. What Swedish does not
21 disclose is that this type of practice has been the source of great controversy and concern
22 and has recently led to a congressional probe into organ transplant centers. See Exhibit
23 B. UNOS likewise has been concerned because certain centers have taken high risk
24 patients and knowingly transplanted them with marginal organs, and then the graft fails.
25 Once the graft fails, the patient is placed in a life-threatening situation, which gives them
26 a Status 1 MELD score and thereby makes them a candidate for the next available liver.

1 UWMC does not and will not operate its transplant program in this manner. Moreover, if
2 Swedish is proposing to operate a liver transplant program that takes high risk patients
3 (Dr. Marks refers to them as sicker patients), then I would have serious patient care and
4 ethical concerns regarding Swedish's program, especially as a new startup program.

5 e) Dr. Marks suggests that UWMC is not transplanting high risk
6 (sicker patients) because UWMC's MELD scores show that most of its patients are
7 transplanted with MELD scores between 11 - 20 and 21 - 30. What Dr. Marks fails to
8 understand is that patients with these MELD scores of 15 or above are very sick patients.
9 A MELD score of 15 means that for a particular liver graft, there is a mandatory local and
10 regional requirement so those patients receive an opportunity for a donor liver before that
11 liver can be shared with any other region. A patient with a high MELD score, 31 - 40 or
12 Status 1, means the patient is very sick; transplantation in this score range is done
13 routinely at the UWMC.

14 Dr. Marks relies heavily on Table II in the Rebuttal in an attempt to show
15 the UWMC's MELD scores are significantly lower than its peer institutions. I was able
16 to testify that this table reflects patients MELD scores at the time of listing and does not
17 reflect the patients' MELD scores at the time of transplant. If you look at the MELD
18 scores of UWMC patients at the time of transplant, the MELD scores are significantly
19 higher, and comparable to most university transplant centers. This again illustrates Dr.
20 Marks' lack of expertise in dealing with MELD scores. UWMC compares very favorably
21 and, in fact, transplants as sick or sicker patients than the national average, and does so
22 more quickly and with better survival.

23 f) Dr. Marks also states that UWMC does not perform living donor
24 liver transplants on Washington residents. This is untrue. UWMC not only has
25 performed living donor transplants, it also performs split liver and cut-down or reduced
26 liver transplants. These more cutting edge surgeries, however, should only be undertaken

1 when donor organs are not available and a patient needs to be transplanted relatively
2 quickly and must be done by surgeons with expertise in this area. In my opinion, given
3 Swedish's CON proposal, it would be dangerous for Swedish's startup program to
4 perform split liver, living donor, or cut down liver transplants. Swedish does not have an
5 experienced liver transplant team to undertake these complex procedures. In fact,
6 Swedish's program would not even qualify under the UNOS criteria to perform living
7 donor transplants because the UNOS criteria requires two UNOS-qualified liver
8 transplant surgeons who have undertaken a minimum of 20 major hepatic resectional
9 surgeries (to include living donor operations, splits, reductions, resections, etc.), seven of
10 which must have been live donor procedures over a minimum of three years and a
11 maximum of five years. (RR 962). Swedish has told the Department that its program
12 will only be staffed by a single UNOS-qualified liver transplant surgeon and a single liver
13 transplant hepatologist for at least the first three - five years of its program. Therefore,
14 Dr. Marks' assertions that Swedish's liver transplant program will provide transplants to
15 people falling through the cracks because UWMC's program does not perform split liver,
16 cut down, or living donor transplants is false and again reflects his lack of understanding
17 regarding liver transplantation. If Swedish's program is going to undertake these types of
18 transplants as a startup program, I would have serious reservations regarding the safety of
19 patients and question whether UNOS would even certify the program.

20 g) Dr. Marks also states that data regarding donor organs indicates
21 UWMC is turning away too many usable organs. As stated, Dr. Marks is not qualified to
22 make statements regarding whether any particular organ should have been transplanted in
23 any patient on UWMC's wait list. Nevertheless, Dr. Marks states that he collected data
24 through his Life Center Medical Directorship which showed that all but one of UWMC's
25 exported organs "worked" and these organs could therefore have been transplanted in
26 Washington patients. Having heard this testimony, I have since followed up with Life

1 Center Northwest and have asked staff, Suzanne Ball, what data Dr. Marks was
2 referencing. My concern was that if this data did exist, as the head of UWMC's
3 transplant program, I would want to review it. I was told that Life Center does not collect
4 data regarding the survival rate of grafts from exported organs that have been
5 transplanted. The data that is collected is ad hoc. The only "data" collected is actually a
6 single telephone call from Life Center staff to the hospital where the organ was sent to
7 ask whether the liver functioned at the time it was placed into the patient. There is no
8 documentation as to who made the call, what was asked, or who from the recipient
9 hospital stated that the organ functioned. Thus, the data to which Dr. Marks testified is
10 nothing but anecdotal information, which in no way reflects the "function" of the organ:
11 it is not hard data and is clearly not scientifically significant because it does not include
12 the collection of lab work, blood tests, or the following of liver function after transplant.
13 At the present time UNOS is trying to develop means by which such information can be
14 collected, however, it does not exist today.

15 Additionally, in listening to Dr. Marks' testimony, it is apparent that he
16 does not understand that referring to whether a liver "worked" is not a valid reference in
17 liver transplantation. No data is collected on liver function following a transplant
18 anywhere in the United States. At best, the data collected is based on patient survival
19 rates, which does not tell you anything about how the graft functioned once the patient
20 was transferred to the ICU, or for any given time after the transplant. A patient's survival
21 is dependent on a variety of factors. According to Dr. Marks, an organ "works" if there is
22 liver function following transplant if when the clamps are removed, the liver became pink
23 - therefore immediate function. In other words, the patient did not die when the liver was
24 transplanted but left the OR and was placed in the ICU. Beyond the ICU, no further data
25 is collected.

26

1 Further. UWMC's organ export rate is at the national average as Life
2 Center staff stated in their letter to the Department of Health, which is in the record. If
3 the Court has any concerns with regard to my assessment of the testimony by Dr. Marks
4 and the above statements in Swedish's Rebuttal, I would ask the Court to obtain an
5 independent liver transplant program director and surgeon to review the data to verify
6 UWMC's use of donor organs is not inappropriate.

7 h) Dr. Marks makes numerous statements regarding UWMC's
8 performance in comparison to some of its peer academic health centers. It is difficult to
9 address each of Dr. Marks' statements because he uses different academic health centers
10 and hospitals as comparisons in different charts, depending on which centers or hospitals
11 will make his point. I have spent my entire career in academic health centers and despite
12 the Health Law Judge's ruling, I believe I am qualified to testify regarding academic
13 health centers and their liver transplant programs. Had I been allowed to testify
14 regarding my knowledge of academic health centers, and UWMC's reputation among
15 these centers, I would have been able to explain in detail why UWMC has an excellent
16 program. Its program has been well staffed and funded and has been fortunate to be
17 located in a region where more people donate organs than in other areas of the United
18 States. Thus, UWMC is able to transplant its patients much faster than its peer academic
19 health centers and hospital transplant programs. UWMC's survival rates are at, or above,
20 the national average.

21 5. In addition to refuting Dr. Marks' statements in Swedish's Rebuttal, I
22 would have also testified in further detail regarding the staffing levels of Swedish's
23 proposed program. Based on my experience in liver transplant programs, Swedish's
24 program will not be adequately staffed with a single UNOS-qualified liver transplant
25 surgeon (to be hired) and Dr. Marks and/or Swedish's other kidney transplant surgeons,
26 Dr. Florence and Dr. Precht. Dr. Marks does not have the expertise to perform liver

1 transplant surgeries, nor does Dr. Florence. Both are kidney transplant surgeons, which
2 was pointed out at the hearing. However, Dr. Marks apparently believes that he can
3 become proficient as a liver transplant surgeon by acting as the first assistant to the liver
4 transplant surgeon to be hired. Such limited expertise is not what the people in this
5 community, state, and region need.

6 Dr. Precht is also not a UNOS-qualified liver transplant surgeon because.
7 contrary to Dr. Marks' testimony, he did not complete a liver transplant fellowship. Dr.
8 Precht attended the University of California, San Diego Medical Center and participated
9 in their pediatric abdominal organ transplant surgery fellowship program. He did not
10 participate in a liver transplant fellowship program because San Diego Medical Center
11 did not have a UNOS qualified liver transplant fellowship program at that time.

12 The Health Law Judge also did not allow me to testify regarding the
13 number of fellows in UWMC's program. UWMC's liver transplant fellowship program
14 is very highly respected nationally. There are only a handful of liver transplant
15 fellowship programs in the United States, and very few have been authorized by ASTS
16 and UNOS for two fellows. Ironically, the CON Program's analyst assumed (without
17 ever asking) that UWMC only had a single fellow. UWMC was in the process of
18 becoming approved for the second fellow while Swedish's application was under review.
19 Further, at the time Swedish submitted its application, UWMC was performing
20 approximately 80 liver transplants per year. Although UWMC's volumes are increasing,
21 the increase is necessary to adequately support UWMC's two fellows.

22 In addition, the Department and Swedish have never considered the
23 impact on UWMC's clinical program. UWMC's liver transplant program also must
24 ensure that its UNOS qualified surgeons can maintain their skill levels by having an
25 appropriate volume of transplants. If I had been allowed, I would have testified that our
26

1 clinical program's seven transplant surgeons should annually perform approximately 20
2 liver transplants in order to maintain skill levels.

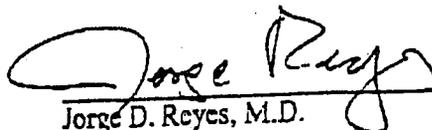
3 6. In contrast to UWMC's program, Swedish's program will be severely
4 understaffed because it plans to have a single liver transplant surgeon. Patients who
5 receive transplants at a program with a single liver transplant surgeon and a single liver
6 transplant hepatologist, in my opinion, will receive inferior care. A liver transplant
7 program must be a 24-hour, seven-day-a-week program, 365 days per year, and with one
8 qualified surgeon and only one qualified hepatologist available, there is not sufficient
9 coverage. These types of problems have caused programs to turn away organs and
10 patients and in some cases, programs have even been terminated. As an example, the
11 University of California Irvine Liver Transplant Program was unable to hire a full-time
12 liver transplant surgeon for over a year and was forced to close its program. In the
13 interim, patients who had been wait listed died while the program turned down scores of
14 organs that might have been appropriate for transplant. The situation at the University of
15 California Irvine was the catalyst for the congressional probe into organ transplant
16 centers. Adding another liver transplant program six miles away from UWMC is
17 therefore more than just disconcerting. The substance, planning, and lack of depth in
18 Swedish's proposed liver transplant program will likely result in mediocre care of
19 patients.

20 Swedish's plainly inadequate coverage and the impact on UWMC's clinical,
21 fellowship, and research programs should have been a great cause of concern for the
22 Department of Health but was never addressed. Patient safety and the maintenance of a
23 state-funded medical program should have been a paramount concern for the Department
24 of Health. UWMC has spent enormous resources to build its reputation and programs,
25 and in my opinion, Swedish's new program will have an extremely adverse impact if
26 allowed to operate.

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I declare under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct.

Signed this 16 day of December, 2005, at Seattle, Washington.



Jorge D. Reyes, M.D.

DECL OF DR. REYES IN SUPPORT OF REQUEST 13
TO ADMIT ADD'L EVIDENCE

BENEDICT GARRATT PLLC
1235 Fourth Avenue East, Suite 200
Olympia, Washington 98506
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000036

EXHIBIT G

RECEIVED

MAR 10 2005

CERTIFICATE OF NEED PROGRAM
DEPARTMENT OF HEALTH

PUBLIC HEARING

SWEDISH HEALTH SERVICES
LIVER TRANSPLANT PROGRAM -

FILED

MAR 16 2005

Adjudicative Clerk Office

November 6, 2003
1:00 p.m.
Seattle, Washington

EXHIBIT NO. 11
Admitted: X
Not Admitted:
Date:
Case: Swedish
0407C 2005

003036

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1 MR. HUYCK: Thank you, Doctor.

2 As we go down the list and accept the comment
3 from those of you who have attended today, you can probably
4 go ahead and speak from where you're sitting. These
5 microphones pick up fairly well. If you're more
6 comfortable coming up to the front, it doesn't matter to me
7 one way or the other where you choose to speak from.

8 Also, if you have written copies of your comments
9 that you'd like to turn in for us to have a hard copy of
10 that, I'll go ahead and take that after you have finished
11 speaking.

12 First person on the list today is Dr. Edward
13 Waller, or is that Walker?

14 DR. WALKER: Walker. I submit on behalf of
15 the institution, our oral response to the proposal.

16 MR. HUYCK: Thank you.

17 DR. WALKER: I'm here today representing on
18 two roles within UW Medicine; first as medical director of
19 our medical center, and secondly as associate dean for our
20 school of medicine. My message this afternoon is simple
21 and straightforward: approval of the certificate of need
22 would seriously interfere with our ability to carry out our
23 state-mandated mission.

24 As medical director, I lead one of the most
25 remarkable medical staff organizations in the world. We

1 are a quaternary academic medical staff, that is, our
2 mission is to care for the most complicated patients in the
3 region. Since 1989, our liver transplant service has done
4 over 800 transplants; we have the 18th largest program in
5 the nation.

6 Such care is extraordinarily expensive, time-
7 consuming, and resource intensive. We've invested heavily
8 over long periods of time to have the appropriate
9 infrastructure, to safely care for these and other
10 remarkably complicated patients. We are a 24/7, full-core
11 press operation with the necessary professionals,
12 resources, and commitment to earn the U.S. News rank 10th
13 best hospital in the nation.

14 As associate dean for the school of medicine, I
15 also maintain our focus on educational and research
16 missions. We exist primarily to train the next generation
17 of physicians and we are very clear about our training
18 needs.

19 There is a well-established correlation between
20 volume of cases and higher quality outcomes, and we are
21 increasingly held to external standards such as those put
22 forth by the Leapfrog group, to achieve these volume
23 benchmarks. We cannot allow the dilution of our training
24 volumes to weaken the programs that foster clinical
25 excellence.

1 Furthermore, our trainees and those that teach
2 them are additionally subject to nationally benchmarked
3 educational requirements that specify how many cases are
4 needed to certify their competence. As the only medical
5 school for a five-state region encompassing the quota of
6 the land mass of the United States, we have no choice but
7 to vigorously defend the volumes you require for training.
8 We do not agree there are enough patients for two programs
9 without seriously impairing our educational mission.

10 In summary, our Liver Transplant Program is a
11 unique regional resource that cannot be duplicated or
12 shared without serious degradation to our state health care
13 mission. As a quaternary academic medical center we live
14 in the most expensive sector of the health care industry;
15 an issue that should be not duplicated unnecessarily.

16 This is not an issue of consumerism and choice,
17 it is about the rational distribution of increasingly
18 scarce resources and the preservation of rapidly
19 diminishing health care dollars at a time when we, as a
20 state, tell too many of our citizens that they cannot
21 obtain basic health care.

22 As a public institution, we vigorously embrace
23 both our duty to teach the next generation of physicians as
24 well as our obligation to maintain the safety net and
25 provide the highest quality of care in the region. Please

1 help us maintain the integrity of this important public
2 service by supporting our state-mandated mission of
3 teaching through the provision of quaternary medical care.
4 Thank you.

5 MR. HUYCK: Thank you, Doctor.

6 Next is Robert Carithers.

7 MR. CARITHERS: I'm Robert Carithers, the
8 medical director of (inaudible) over at the University of
9 Washington. I've been working in liver transplantation
10 since 1984. Some people think I'm crazy because I started
11 two (inaudible) transplantations, one in Virginia and one
12 at University of Washington Medical (inaudible).

13 I've also been asked, because of this duration of
14 experience with transplantation (inaudible) transplantation
15 (inaudible) United States.

16 I would like to address three, the major
17 questions that patients ask us continually regarding liver
18 transplantation. The three major questions are: will I
19 have a fair and equitable opportunity to receive a
20 transplant; will I die waiting for a transplant; if I have
21 a transplant, what are my chances of surviving the
22 operation and returning to a full and rich life?

23 At the University of Washington we make great
24 efforts to make certain that our selection process is
25 equitable and fair for all citizens (inaudible) Washington.

1 He's the chief executive officer of California
2 Pacific in San Francisco; they were in the same process of
3 deciding whether or not to have a Liver Transplant Program,
4 which we've seen discussed today. They have a very good
5 program there, and as of two days ago I talked with
6 (inaudible) who's a, a president elect of the American
7 Gastroenterological Association; he's at Stanford and he
8 tells me that the three programs in San Francisco, in the
9 Bay Area, are transplanting over 220 patients a year in
10 that area, they're all doing fine, the patients are doing
11 well, and no program has folded because another one has
12 started up.

13 Finally, I just want to say one other thing. I
14 know I'm clinical faculty at the University, (inaudible)
15 teaching there and contributing my time and my money to the
16 University for more than 30 years. I hope to continue to
17 do that; I don't find that there's any conflict of interest
18 whatsoever in me getting up here and advocating for the
19 patients in the state of Washington and are (inaudible) to
20 have a second high-quality Liver Transplant Program. Thank
21 you very much.

22 MR. HUYCK: Thank you, Doctor.

23 John Ham?

24 DR. HAM: Thank you for allowing me the
25 opportunity to come to speak today. I'm the director of

1 liver transplant at Oregon Health and Sciences University;
2 I'm one of the transplant surgeons there. I began my
3 training in 1988; and went to the Medical College at
4 Virginia before that; I was the director of (inaudible)
5 transplants.

6 I wanted to speak to the issues of having another
7 program in the, in the area. I feel a little bit out of
8 place (inaudible) strongly about the (inaudible) relations
9 programs and the dilution of resources in transplantation.

10 And one of the things that, that I've been
11 learning on the jobs was the, that we're in a very low-
12 volume, high-cost business, and I don't know what the
13 (inaudible) laws of it not necessarily follow (inaudible).
14 We don't, we don't have the opportunity to have them high
15 volumes, low cost to reduce our expenses. And I'm, I'm
16 concerned that the, that that's really not a reality.

17 I can speak to the fact that the, the
18 institutional needs are about (inaudible) program, also for
19 maintaining the program over the long-term, and it does
20 cross multiple disciplinary boundaries and the cost
21 eventually is to keep those programs to maintain a high
22 (inaudible).

23 Our program is an interesting program in that we,
24 we serve patients not just in our, in Oregon, but we do
25 serve patients in Idaho and also in Southwestern

1 Washington. In addition to that, we serve patients
2 nationwide, mainly on the western half of the United States
3 for the Veterans Administration. And, so, because of this,
4 we do draw patients out of Washington State, especially in
5 the Southwest Washington area, because patients live there
6 and it's convenient for them to (inaudible).

7 Of course, because we have the VA contract, we
8 get all of the VA patients in the region, and of all the VA
9 patients about 25 percent of our patients come from the
10 Northwest, (inaudible). Of those, about a quarter of those
11 are from (inaudible); about 50 percent of those are from
12 Washington State. So we do draw patients from Washington
13 for (inaudible) basically contract business with, with the
14 Veterans Administration.

15 We do have a few patients that we do because of
16 commercial contracts as well, and as a, quite frankly, one
17 of Dr. Perkins' competitors.

18 I guess one of the issues that, that I wanted to
19 specifically address regarding the patients that come to us
20 and why patients leave (inaudible) to, to transplant
21 another, to get a transplant at another location, has to do
22 with issues of support, like family support, comfort, some
23 of them, they don't have a very (inaudible) structure to be
24 required to have that before we can have a transplant. And
25 sometimes it's more of a need to move to an area where

1 there is (inaudible) transplant (inaudible).

2 And, finally, what I'm most concerned about
3 (inaudible) is, I think, I think if you dilute a program
4 out to the point where you have a mediocre program, which
5 is what I think you will get at the University of
6 Washington if you dilute the number of transplants out,
7 you're going to really impact on your ability to train
8 surgeons in the future who do transplantation, train people
9 in fellowship.

10 I think it also impacts significantly on a number
11 of patients that you can enter into your own research
12 protocols as well as research protocols that other
13 institutions (inaudible) looked at as not having very many
14 patients in your system.

15 And so, for the, for those reasons I think, I
16 think that my program for our patients eventually will
17 suffer if, if the programs are, are diluted. From, from
18 the, from the point of view of the competition, (inaudible)
19 actually let a program start would be easier to compete
20 against a program is the point (inaudible). And
21 (inaudible) maybe somewhat of a first wave looking at
22 things, but it certainly is something that I would think
23 would be the case.

24 And, finally, as a transplant program that's in
25 the region, I, the way we share our livers is that,

1 University of Washington doesn't want (inaudible). I'm in
2 the same region as they are, and for the most part I could
3 offer those livers. And in the last 12 months, we had 26
4 offers for livers, two of which we felt we could
5 transplant, six of which we felt because of size or age
6 wouldn't fit in the transplant, and the remainder of which
7 we didn't think we were programmed for transplantation, so
8 they were sent out.

9 I think it's important in our business to
10 maintain a situation where institutions can put in the
11 resources that they need to put into the programs to
12 maintain high-quality programs for our patients. I don't
13 think that the usual economics of life, transplantations
14 (inaudible). And those are the things that I (inaudible)
15 support the, I started the new program.

16 MR. HUYCK: Thank you, Doctor.

17 James Perkins?

18 DR. PERKINS: Thank you.

19 My name is James Perkins and I'm the director of
20 the division of transplantation at the University of
21 Washington. And I'd like to focus on two main points
22 today.

23 First, how the transplant system works. The
24 National Organ Transplant Act passed in 1984 mandated some
25 clear objectives. Foremost of those objectives were that

1 in a critically ill patient is to determine if there
2 is any alternative therapy which could potentially be
3 successful, and avoid the necessity for a transplant.
4 That expertise takes a tremendous amount of training
5 and experience strictly in hepatology, and knowing
6 the relative benefits and risks of other forms of
7 therapy compared to transplantation. That's very
8 highly specialized training that is not provided to
9 the average gastroenterologist; for example at the
10 university we established one of the first training
11 programs for gastroenterologists, in which we take
12 graduates of our gastroenterology program and give
13 them additional training in transplant --

14 MR. PENTZ: Objection, beyond the scope
15 of the record.

16 MR. PRICE: Your Honor, clearly the
17 University has made its position clear that it's
18 important that transplant hepatologists have
19 specialized training. That's represented on page
20 548. This is explaining that testimony directly.

21 MR. PENTZ: Your Honor, I believe what
22 is happening is supplementing testimony, and I think
23 we all know that this is a crucial issue in this
24 case. I was okay for him to describe what a
25 hepatologist does, I don't have any problem with

1 that. Doctor Marks gave that testimony, but now he's
2 starting to talk about some specific training and
3 education programs which the University of Washington
4 failed to identify during the chance they had an
5 opportunity to do so, and all of the references that
6 we discovered and UW discovered are general
7 references to training and fellowships.

8 They failed to submit that information, and
9 it's beyond the scope of the record at this point. I
10 mean they can't boot-strap their way into
11 supplementing the record.

12 JUDGE CANER: Mr. McCartan?

13 MR. MCCARTAN: I would join in that --

14 JUDGE CANER: Mr. Price? Oh, I'm sorry,
15 Mr. McCartan, do you have, you're joining in his
16 arguments?

17 MR. MCCARTAN: Yes.

18 MR. PRICE: Your Honor, clearly the
19 argument made here of specialized training is
20 necessary. Now it's also clear that witnesses in
21 these types of hearings are allowed to explain what's
22 in the record. We're not adding anything to the
23 record, we're explaining the record.

24 JUDGE CANER: I'm going to sustain the
25 objection because I think it's going beyond

1 explaining. I think it's giving the history of the
2 training program at the University of Washington
3 regarding training hepatologists, and that was not
4 included, and so I'm going to sustain that objection.

5 Q. (By Mr. Price) Well, Doctor, you already
6 explained why it's important to have a transplant
7 hepatologist. Let me ask you this question: do you
8 have an understanding of the University's position
9 with respect to the requisite number of transplant
10 hepatologists related to a transplant program?

11 MR. PENTZ: Objection, vague.

12 JUDGE CANER: Overruled.

13 A. In bargaining with the University we have
14 taken the position, using national standards, that
15 there needs to be at least a full-time hepatologist
16 for every 30 patients who undergo transplantation.

17 MR. PENTZ: Objection, not in the
18 record. There's nothing in the record about minimum
19 standards for transplant hepatologists, nothing at
20 all, and I object.

21 MR. PRICE: Your Honor, I would refer
22 you not only to page 548, but also to the bottom of
23 547.

24 JUDGE CANER: Yes. Let me take a moment
25 to read that paragraph.

1 were the first to perform that on the West Coast and that
2 was all at the University of Washington; and transplanting
3 the smaller part at Children's Hospital.

4 Q What's your experience with liver transplant teaching
5 and fellowship programs?

6 A My main experience has been at the University of
7 Washington where I've been the Program director since
8 arriving. We applied for a fellowship and got it. I think
9 our first fellow was the middle of '90 and I've been the
10 Program director of the transplant fellowship until this
11 last July 1st.

12 Q And that includes, I suspect, liver transplant
13 fellows?

14 A Yes; liver, kidney, and pancreas. We've been fully
15 for all three organs.

16 Q How many liver transplant fellows does the University
17 currently have?

18 A We have one fellow currently.

19 Q At the time of the application you had one fellow; is
20 that correct?

21 A Yes. There is a period where we might have had two at
22 one time, but right then I think it was one.

23 MR. PENTZ: Objection, move that it be
24 stricken. I realize she's qualifying him as an expert, but
25 it is important as to how many fellowships the University

1 had and there's nothing in the record regarding the number
2 of fellowships, so I would move to strike.

3 MS. BENEDICT: May I respond?

4 JUDGE CANER: Yes. I thought I read
5 something in the record--

6 MS. BENEDICT: There's plenty of references
7 to the fellowship training program. And, you know, whether
8 we put it in exact number at that particular time or
9 whether that number shifted down the road is perfectly
10 reasonable testimony for the person who has been uniquely
11 involved in the fellowship program.

12 JUDGE CANER: I'm going to overrule the
13 objection. You can go ahead.

14 Q (By Ms. Benedict) So does the number of fellows in
15 the liver transplant program, does that number vary from
16 time to time?

17 MR. McCARTAN: Your Honor, perhaps counsel
18 could identify where in the record they talk about--

19 MS. BENEDICT: Let me withdraw the question.

20 MR. McCARTAN: As far as I know it has never
21 been brought out. So unless I'm missing something there is
22 nothing in the record about a fellowship program.

23 JUDGE CANER: And I may be mixing up my
24 recollection from the record what was in the briefs. So,
25 Ms. Benedict, if you could show where in the record--

1 MS. BENEDICT: Well, I gave that long list,
2 but I remember, I've got it memorized now, 411 is Dr.
3 Walker's--

4 JUDGE CANER: I realize there's reference to
5 the fellowship program, training program, but are there
6 references to the numbers of fellows?

7 MS. BENEDICT: No, but at the same, you
8 know, there are things in this record that aren't
9 specifically identified as numbers; for example, how many
10 kidney transplant physicians are there.

11 JUDGE CANER: You know what, I'm going to
12 allow testimony regarding the number of fellows in the
13 Program within a reasonable time period, let's say two
14 years before the application and two years since then, to
15 get a general idea of what the range has been in four years
16 surrounding the application date.

17 MR. PENTZ: Your Honor, if I could, I would
18 like to renew my objection, starting with the Superior
19 Court case that led to the stay and following the
20 submission of Dr. Reyes' declaration in support of the
21 motion for summary judgment, which we moved to strike, the
22 University of Washington has tried twice now to identify
23 them having two fellowships, two fellows.

24 And I think it's very important because there's
25 been a lot of testimony about the number of liver

1 transplants that a fellow needs to participate in and I
2 think we can anticipate there's going to be an argument
3 that there's not enough volume to support a fellowship
4 program and it's very important that they did not make any
5 attempt to introduce the number of fellows and they've been
6 trying to get it in and it hasn't happened and I object to
7 this coming in.

8 MR. McCARTAN: It seems like this would be
9 part of the offer of proof.

10 JUDGE CANER: Yes; go ahead, Ms. Benedict.

11 MS. BENEDICT: If I may respond; Your Honor,
12 that's the point is Dr. Perkins has already testified at
13 some, and I'll nail it down to the time frame in which
14 you've referenced, but sometimes there's one, sometimes
15 there's two; so it depends and that's what he's going to
16 explain.

17 MR. McCARTAN: We were never given that
18 information.

19 JUDGE CANER: Yes, that's my concern.

20 MS. BENEDICT: Your Honor, if I may respond.
21 We were never given all the information in the rebuttal
22 submission and our response was to make the
23 reconsideration.

24 JUDGE CANER: Yes, and we've been through
25 that. Since the University failed to give this information

1 in their rebuttal and didn't move for reconsideration to
2 have it in and it isn't in the record that it would be
3 appropriate to put it in in your offer of proof and not in
4 at this time.

5 MS. BENEDICT: If I may respond. My point
6 is that the University identified its fellowship program
7 numerous times as a fellowship program; Dr. Ham put in
8 information about a fellowship program; the
9 gastroenterologist mentioned a fellowship program; we
10 mentioned we have fellowship programs, it's on their
11 website.

12 The fact that they don't know the exact number
13 is, in my argument or assertion is something if they wanted
14 to know the exact number they could have asked or they
15 could have called it a pivotal unresolved issue or
16 otherwise address that. We're held to the burden of we
17 should have gone through reconsideration because we
18 didn't--

19 JUDGE CANER: Let's not rehash that.

20 MS. BENEDICT: But you know, it's a two-way
21 street here; but the information is a plethora of
22 information about this training program and I think it's
23 reasonable for the University to explain what its liver
24 transplant fellowship program is and it is a program that's
25 certified for two. And if people come and go and they're

1 staggered in and I think that's an appropriate ground for
2 testimony, to explain that.

3 JUDGE CANER: I understand what you're
4 saying. It would have made sense for this to have come in
5 at the hearing stage and now I have to rule that my
6 understanding of the law is that it is not in the record
7 and wasn't placed in the record. You may make an offer of
8 proof and put it as an offer of proof in this record in
9 this adjudicative proceeding, but I'm not going to allow
10 it.

11 MS. BENEDICT: So if I understand where
12 we're left then is that we can identify that we have a
13 fellowship program, we can explain everything about it, but
14 we can't say the exact number of fellows at any given time?

15 JUDGE CANER: Whatever is not in the record
16 in terms of the--

17 MS. BENEDICT: See, the problem because
18 they've explained at length on a plethora of information
19 and we're talking about one little number and there's a lot
20 of numbers been floating around, but when we at least talk
21 about how we stagger fellows--

22 JUDGE CANER: Let me ask a question. I
23 can't remember in the testimony presented by Swedish, did
24 you present any testimony in your rebuttal regarding the
25 fellowship programs?

1 MR. PENTZ: No, we didn't; I know that I
2 didn't ask Dr. Marks about that.

3 MR. McCARTAN: To my knowledge there are a
4 few vague references to training programs, I don't think
5 the word fellowship is anywhere in here. We were not asked
6 to evaluate the impact of Swedish's program on the
7 fellowship program, we had no information about that at any
8 point in the process.

9 JUDGE CANER: Ms. Benedict, did you have a
10 comment on the scope of rebuttal is what I'm concerned
11 about now.

12 MS. BENEDICT: Yes, because fellowship
13 programs came up with regard to the testimony of Dr. Roland
14 Dickson and he described the impact in his opinion of
15 another program coming into an area on a teaching program
16 and described some other testimony regarding that type of
17 an impact.

18 And it's my recollection, please correct me if
19 I'm wrong, I'm sure they will, that also Dr. Hart from UCSD
20 testified regarding what a fellowship needed, how many you
21 had to follow, and those sorts of things, and I recall
22 specifically asking him certain questions.

23 But the point is, if I can address a different
24 point, nothing was put in by Swedish in its application,
25 they put not applicable. Nothing was put in at the public

1 hearing and they didn't in the rebuttal address that, yet
2 the burden under the CON need criteria is they have to
3 establish--

4 JUDGE CANER: Yes, I understand it's the
5 applicant's responsibility, burden, and then the Department
6 has to write an analysis and then we're here at this point,
7 so at each stage there's a burden basically put on the
8 applicant, and the Program needs to fulfill its
9 responsibility at the adjudicative level; the appealing
10 party has the preponderance of the evidence.

11 My concern is the scope of the record and the
12 record's closed and also I realized I had a second concern
13 too, which was the scope of rebuttal and my recollection is
14 somewhere I think there was discussion of training programs
15 and fellowships in general.

16 And my concern is protecting the integrity of the
17 system at the administrative level that encourages
18 interested parties and the applicant to get the information
19 at the agency level so things can be done as efficiently as
20 possible and not allow additional information at the
21 hearing level that should have been brought to the
22 attention of the Department earlier, and that is my
23 concern.

24 So I am going to keep with my ruling on that and
25 you may put that information in through an offer of proof.

1 MS. BENEDICT: And I guess I'd just like as
2 part of that offer of proof to have the record reflect it's
3 not that the information regarding the fellowship wasn't
4 put into the record, it's the number of fellows in the
5 Program that wasn't put in the record; is that your ruling?

6 JUDGE CANER: Yes.

7 MS. BENEDICT: Thank you.

8 Q (By Ms. Benedict) Can you describe your liver
9 transplant fellowship program at the University?

10 A It's for surgeons that have their training that want
11 extra experience in doing liver transplants and they're
12 involved in all aspects of care from doing the transplant
13 to patient selection to donor management, meeting all the
14 UNOS requirements that they have to meet before they can go
15 out and be a transplant surgeon.

16 Q And for each fellow you'd have in the Program it would
17 have to be qualified by, would it have to be qualified by
18 any oversight organization?

19 A As far as the residents that are qualified when they
20 come in?

21 Q For actual positions, for a fellowship position. In
22 other words, would your program have to be--

23 A They have to have either boards in general surgery or
24 urology or osteopathic surgery or are able to get those
25 boards when they enter the fellowship program.

ORIGINAL

NO. 80264-5

SUPREME COURT OF THE STATE OF WASHINGTON

UNIVERSITY OF WASHINGTON MEDICAL CENTER,

Respondent,

v.

WASHINGTON STATE DEPARTMENT OF HEALTH,

and

SWEDISH HEALTH SERVICES,

Appellants.

ON APPEAL FROM THURSTON COUNTY SUPERIOR COURT

(Hon. Richard D. Hicks)

DECLARATION OF SERVICE

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The undersigned declares under penalty of perjury under the laws of the State of Washington that I am now and at all times herein mentioned a citizen of the United States, a resident of the State of Washington, over the age of eighteen years, not a party to or interested in the above-entitled action, and competent to be a witness herein.

On the 2nd of January, 2008, I caused to be served University of Washington Medical Center's Response Brief on the following individuals in the manner indicated:

Peter S. Ehrlichman	<input checked="" type="checkbox"/>	U. S. Mail
Brian W. Grimm	<input type="checkbox"/>	Hand Delivery
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Signed this 2nd day of January, 2008, at Olympia, Washington.



Lorraine A. Kimmel