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COA No. 30688-7-III

FILED

APR 01 2013

COURT OF APPEALS
DIVISION III
STATE OF WASHINGTON
By_____

IN THE COURT OF APPEALS, DIVISION III

OF THE STATE OF WASHINGTON

PHYLLIS PAETSCH,

Appellant,

v.

SPOKANE DERMATOLOGY CLINIC, P.S., as a Washington Corporation; and WILLIAM P. WERSCHLER, M.D., individually,

Respondents.

APPELLANT'S REPLY BRIEF

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I. REPLY SUMMARY.

At its core, this appeal is about informed consent—a physician's switch of the standard of care represented to his patient. It is about the right of a patient contracting for cosmetic services from a private physician's offices to know who is injecting substances into their body, and the right to expect that the injection of products into their body are done as represented in compliance with federal minimum safety standards. It is also a medical negligence case, whereby a physician's delegation to his assistant of all of his duties falls below the physician's standard of care to which a patient is entitled in a physician patient relationship.

Respondents W. Philip Werschler and the Spokane Dermatology Clinic alleges a variety of deficiencies in this appeal, but have little to offer on its critical points. There is no precedent in the state of Washington which addresses a similar scenario, and Phyllis Paetsch presented sufficient evidence to entitle her to have her jury determine her bait-and-switch issues. She evidenced that a physician offered her an invasive cosmetic treatment, contracted with her, gave her informed consent, assured her that only FDA-approved Restylane

procedures would be used, released himself from liability, and then turned over all of her treatment *in its entirety* to his assistant's lesser standard of care, who injected substances into her in non-FDA approved fashion. Her jury should have been allowed to determine whether her consent was violated in that process, and whether her physician acted below his own standard of care.

The trial court's determining these issues by directed verdict, and by jury instructions which authorized a physician's assistant standard of care for Ms. Paetsch deprived her of a fair trial on her claims.

A. Reply to counter statement of the case.

On review of Respondents' brief, these facts remain undisputed:

Dr. Werschler is identified in the Clinic's contracts with Ms. Paetsch. *Response Brief at p. 3, and see Pl. Ex. 22, 23, 26, and 27.* The Restylane form signed by Ms. Paetsch identifies Dr. Werschler as her doctor, identifies Dr. Werschler as the provider informing her of risks, and in it, she consents only to an FDA approved Restylane procedure.[1] Clinic staff referred to "the doctor" as being on his way to

[1] *Pl. Ex. 27* ("Dr. Werschler has provided me with this informed consent ..."), *p. 1*, and "I know that Restylane has been approved by the United States Food and Drug

Ms. Paetsch. *Response Brief, p. 4.* A person then appeared, introducing himself only as "Dan." He made no effort to identify himself as a PA-C other than by wearing "scrubs" with script on them. *Id. at 5.* He did *not* discuss his status as a PA-C, nor did he discuss his intended use of a non-FDA approved procedure. *Id. at 6.* The PA-C began injecting substance into Ms. Paetsch. His injections of Restylane into Ms. Paetsch's forehead were not an FDA approved use of Restylane, per her Restylane "informed consent" form. *Id. at 4-5, and Pl. Ex. 22, p. 2.* Ms. Paetsch was additionally not informed of the higher risk of necrosis with Restylane injections into her glabellar area, because the PA-C did not *know* of the higher risk of that procedure. *Response Brief, p. 6-7.*

The PA-C's technique, whatever it was, caused a vascular compromise and ensuing necrosis in Phyllis Paetsch's forehead. *Response Brief, p. 11.* A necrosis complication is extremely rare.[2] The Clinic's PA-C plowed ahead anyway, without any involvement by Dr. Werschler or any other physician. *Id., p. 5, 10.* The PA-C

Administration (FDA) ...," *p. 3*, and "I agree to being treated with the products as described above, ..."), *p. 3.*

[2] *Response Brief, p. 3, and see p. 49, "1/50,000+."*

misdiagnosed his own damage, and gave Ms. Paetsch only treatment for an infectious condition not even present, when remedies were available that could have mitigated the damage the PA-C he had caused.[3]

Ms. Paetsch was never provided a physician, much less Dr. Werschler—the named physician who gave her "informed consent." *Pl. Ex. 27.* Dr. Werschler, named in all of her contracts as her doctor, did not do a single thing for her.

II. REPLY ARGUMENT.

A. The trial court's summary judgment order did not limit Paetsch's physician/patient claim.

Respondents argue that Ms. Paetsch's singular claim against Dr. Werschler was his failure to involve himself in her care "after learning from Mr. Rhoads of her post-injection presentation." *See Response Brief at p. 23.* That is incorrect. Ms. Paetsch's Amended Complaint charges Dr. Werschler with "bait and switch" processes, which, from the outset, violated her consent and were negligent. *CP 18-27, paras. 2.1, 2.3, 2.5, 2.9, 2.23, 2.24, 2.25, 2.30, 3.3, 3.4, 3.12.*

Respondents argue that Ms. Paetsch did not defend against

[3] *Id. at pp. 9-10; and see Opening Brief at pp. 17-18.*

summary judgment by alleging a contractual relationship with Dr. Werschler. *Response Brief, p. 12.* She did not have to. Respondents' summary judgment motion requested dismissal of claims relating only to Dr. Werschler's supervisory liability—not his direct liability. *CP 90, Relief Requested.*

Respondents argue that Ms. Paetsch was required to appeal the trial court's summary judgment order denying Respondent's motion to argue Dr. Werschler's personal liability. *See p. 23.* This is incorrect. The motion for summary judgment was denied. *CP 176.* There was nothing to appeal. In fact, the orders "clarified" that it was not Dr. Werschler's failure to supervise or train this PA-C that was at issue—the issue was Dr. Werschler's direct liability to his patient. "[T]he only cause of action against Dr. Werschler is one of direct medical negligence consistent with the above findings." The "above findings" confirmed that the genuine issues of fact which existed were those as to whether a physician/patient relationship arose between Dr. Werschler and Phyllis Paetsch *which established a duty* (for Dr. Werschler to provide follow up care of Ms. Paetsch)." *CP 176.* The order's limiting the claim only to "follow-up" care only would not make sense, and is

not how the order was thereafter applied.

First, if any physician/patient relationship arose at all, it did not arise through *direct* care, because there was none; it thus necessarily arose *from the outset* during the contractual process, when representations were also being made by the Clinic staff. *Pl. Ex. 27, 22; and, e.g., Opening Brief at pp. 7-10.* And if a physician/patient relationship arose from the outset, then Dr. Werschler's never having met with Ms. Paetsch at all would be probative of both medical negligence *and* lack of informed consent from the outset.

Moreover, the order was not applied as Respondents argue. The creation of the physician/patient relationship from the outset of treatment was tried to the jury. *RP 1579-80; RP 1584: 3 – RP 1585.* Even an entirely new cause of action, if tried without objection, can be a basis for recovery. *Harding v. Will*, 81 Wn.2d 132, 136, 500 P.2d 91, 95-96 (1972), citing to CR 15(b). Here, the contracts and forms were admitted, and Plaintiff's expert Dr. Wilensky testified that the standard of care was violated from the outset—start to finish—because Ms. Paetsch was never seen by a physician at all. *RP 300; and see Opening Brief, pp. 16-17.* Instead, he testified, the Clinic's PA-C was practicing

as a physician. *RP 300.* Ms. Paetsch's claim of negligence and of the failure of informed consent based on her physician's failure to tend to her from the outset was presented at trial, and the trial court dismissed her claims of direct liability notwithstanding the contracts in evidence. *RP 1587: 21-24.*

Respondent's claim that this issue was not preserved for appeal is without merit.

B. A finding that a physician's assistant is not negligent is not a finding that the physician was not negligent. It only confirms that the assistant isn't held to the same standard of care as the physician.

Respondents argue that since no negligence was found on the part of the PA-C, then Dr. Werschler cannot be negligent as a physician. Respondents also argue that there is no evidence that the outcome of their PA-C's damage would have been different with a physician. Both arguments beg the question under appeal. Can a physician delegate his duty to his assistant's lesser standard of care and then argue that his assistant isn't negligent because the assistant's standard of care is far less? The answer is "no." Because the standards of care are so different, the law holds the physician's duties to be non-delegable. *Deaton v. Lawson*, 40 Wn. 486, 490, 82 P. 879 (1905);

Carson v. Fine, 123 Wn.2d 206, 218, 867 P.2d 610 (1994); *Smith v. Orthopedics, Int'l Ltd, P.S.*, 170 Wn.2d 659, 667, 244 P.3d 939 (2010).

And as Plaintiff's expert Dr. Wilensky testified, this physician's standard of care was violated from start to finish, because Ms. Paetsch was never seen by this physician. Again, the Clinic's PA-C was practicing as a physician. *RP 300; and see Opening Brief, pp. 16-17.*

In sum, Ms. Paetsch was damaged by a PA-C and subjected to a non-FDA approved procedure, when she had contracted with, and expected, a physician's care. The PA-C's actions may not have been below the standard of care for a PA-C ignorant of the product he was injecting or its status, but if the physician's standard of care was applied, and Ms. Paetsch properly determined to have *needed* Restylane in her forehead, then Dr. Werschler would have known both of the higher risk, and that his use of Restylane in Ms. Paetsch's forehead was off-label and not in keeping with his patient's consent. *Pl. Ex. 27.*

This is the damage arising from such switches of the standards of care without knowledge and approval of a patient. The patient is expecting, and is entitled to, a physician's skill and knowledge. The "consent" is given presuming that a physician is carrying out the

procedure, and thereby applying his level of skill and knowledge. *RP 767: 21 – RP 768: 1; RP 785: 6-97; RP 796: 4-25* (examples of where Ms. Paetsch testifies that she allowed the procedure to continue because she believed the PA-C was a physician delegated by Dr. Werschler).

Plaintiff's expert Dr. Jon Wilensky also testified that the medical outcome would have been different with a physician's *intervention*, even after the damage was done by the PA-C. *RP 405-07, 458-59.* All physicians present testified that they knew of effective remedies then available to break down the Restylane and prevent any necrosis that resulted from a procedure. *Record cites at Appellant's Brief, pp. 16-18.*

In sum, expert evidence was presented that Dr. Werschler was acting below the standard of care and negligent for *failing to act as a physician to his patient.* The "cause" of the resultant damage arose from Dr. Werschler's abdication of his role. This question was not allowed to be resolved by a jury; Dr. Werschler was dismissed from liability. The jury necessarily exculpated the PA-C under the PA-C's lesser standard of care. That is the error.

C. All contractual formation theories are properly at issue.

Respondents argue that "quasi contract/contract implied in law" arguments were not made below, and are not preserved for review. RAP 2.5 allows an appellate court to refuse to review a claim of error which was not raised in the trial court. *Lunsford v. Saberhagen Holdings, Inc.,* 139 Wn.App. 334, 338, 160 P.3d 1089, 1091 (2007) *aff'd.*, 166 Wn.2d 264, 208 P.3d 1092 (2009). The argument is incorrect; but again, even if an issue raised for the first time on appeal is "arguably related" to issues raised in the trial court, a court may exercise its discretion to consider newly-articulated theories for the first time on appeal. *Id.* Ms. Paetsch's responsibility was to raise the contractual formation "claim of error." She did so.

Ms. Paetsch argued that her physician could not be dismissed given his contractual duty. *RP 1579-81.* She presented direct writings as exhibits, evidence of staff conduct and staff statements and actions, and bait-and-switch omissions as essential to the contract formation. Contract formation law applies to her evidence, and all contract formation theories are "arguably related" to contract formation. Contract formation was the entire case against Dr. Werschler. This is

not a new issue, nor claim of error.

D. Dr. Werschler directly contracted with his patient. *Lam v Global* applies to create a physician/patient relationship.

Respondents argue that *Lam v. Global Med. Systs., Inc., P.S.*, 127 Wn.App. 657, 111 P.3d 1258 (2005) cannot be read to impose a physician/patient relationship on Dr. Werschler, because even though the *Lam* physicians involved had not met the patients, they personally gave patient care instructions over the telephone. *See Response Brief at 27*, citing *Lam*, 127 Wn.App. at 665. But Dr. Werschler had far greater interaction that the physicians in *Lam*. Dr. Werschler actively gave Ms. Paetsch her informed consent. *Pl. Ex. 27 ("Dr. Werschler has provided me with this informed consent.")*. He told Ms. Paetsch in writing that he was her doctor. *Pl. Ex. 22*. He told her in writing that she was his patient. *Id.* He required her in writing to directly release him personally from liability for the procedure he allegedly would perform on her. *Pl. Ex. 27, p. 2.*

Lam controls. Dr. Werschler had more interaction than a random phone call into the clinic—he contracted directly with a patient, and then simply abdicated from treating his patient.

E. Jury instructions: The necessary exception was taken by Ms. Paetsch to the trial court's failure to give her physician/patient duty instructions.

Respondents argue that Ms. Paetsch didn't take proper exception in strict compliance with CR 51(f) to the trial court's failure to give her proposed instructions on the physician/patient duty. She did. *RP 1620 – RP 1621.*

Ms. Paetsch's physician's duty of care instructions are at CP 370, CP 371, CP 372, CP 375, and CP 377. They are not numbered, but referenced by their page number among the sixteen-page proposal of instructions. *RP 1620, referencing 370 ("page 8"), 371 ("page 9"); 372 ("Instruction 10 of 16"); 375 ("the abandonment instruction") – i.e., pp. 13, 14 and 15).* These instructions were all rejected as a package, and as a concept. *Id.* at 1620-21. As the trial court explained, it dismissed Dr. Werschler from liability on the grounds that he had no physician/patient relationship with Ms. Paetsch, and the court would not thereby instruct on a physician's duty of care. *CP 1621: 22-24.* Respondents' claim of failure to take exception contradicts the record.

Respondents claim that Ms. Paetsch's failure to attach her instructions in an appendix is grounds for an Appellate Court to refuse

to review an assigned error. That is contrary to RAP 10.4(c). The latter recommends that any instruction which must be "studied" should be copied into the appendix.[4] The instructions here do not need the referenced "study." Here, what is excluded in the instructions is the entire *concept* of the physician/patient duty, not just specific language within a specific instruction. The trial court's exclusion of the duty in its entirety is the claimed error. Sufficient exception was taken, and review proper.

F. Jury Instructions: An "either/or" standard of care allowed only a PA-C standard of care. Dr. Werschler was not present, and thus had no duty to the patient per the trial court's very instructions.

Respondents argue that Court's "either/or" Instruction No. 9 at CP 607 allowed the jury to find the Clinic liable if Dr. Werschler was found negligent. *See Response Brief, pp. 25-26.* That is incorrect. That instruction directs that the jury use a PA-C standard of care for all claims.

Court's Instruction 9 calls both a PA-C or a physician a

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[4] RAP 10.4 states in relevant part as follows: " **(c) Text of Statute, Rule, Jury Instruction, or the Like.** If a party presents an issue which requires study of a statute, rule, regulation, jury instruction, finding of fact, exhibit, or the like, the party should type the material portions of the text out verbatim or include them by copy in the text or in an appendix to the brief."

"dermatology specialist." It directs the jury to use a physician *or* a PA-C standard of care based on the qualification of the actual provider. It states, "a health care professional such as a physician or (PA-C) owes to the patient a duty to comply with the standard of care for one of the profession or class to which he or she belongs." *CP 607.* The PA-C was the actual provider, and his standard of care must therefore be used.

Respondents argue that Ms. Paetsch could still have argued that Dr. Werschler was negligent for delegating his duty to the PA-C. She could not meaningfully do so. First, she would have invited a mistrial by arguing that a dismissed defendant was liable for violating his physician/patient duty. Second, she would have lacked all credibility. The jury instructions omit Dr. Werschler entirely as a defendant. The "nature of the claim" instruction mentions only Dan Rhoads, PA-C, not Dr. Werschler. *CP 600.* Dr. Werschler is not on the caption sheet. *CP 596.* The verdict form does not mention him. *623 (Verdict form).* Even before the instructions were given with the modified heading, one juror even filled in the case caption on their questionnaire for a witness with the singular defendant, "Spokane Derm." *CP 625.* Third, defense

counsel then *told* the jury in closing argument that the Clinic was the "only defendant *left* in this case..." *RP 1730: 24, emphasis added.* A reasonable jury would properly conclude that, as Dr. Werschler was not directly involved in the treatment and no longer "left," then his standard of care was not to be used. A reasonable jury looking at Instruction No. 9 would know that they were to apply the PA-C standard to the PA-C. Period. Any argument to the contrary would lack credibility.

And if even the former indications that only a PA-C standard was to be used weren't fully convincing, then the trial court instructed the jury directly—in its Instruction No. 11, it directed the jury that the PA-C was authorized to select Ms. Paetsch's course of treatment from start through finish. *CP 609 ("Exercise of judgment" Instruction No. 11, and see infra at G).*

With Instruction 9 then instructing the jury to apply a PA-C standard of care to a PA-C's treatment, and Instruction No. 11 instructing the jury that the PA-C was entitled to select alternative courses of treatment for Ms. Paetsch, any argument about a physician's standard of care was precluded, just as intended, following the

dismissal of Dr. Werschler. Respondents' claim that the argument for physician negligence could have been made regardless is fanciful.

G. Jury Instructions: The trial court's "exercise of judgment" jury instruction determined the case. It validated the "bait and switch" in standards of care, directed a PA-C standard of care, and destroyed Paetsch's claim of lack of informed consent.

Respondents claim that Ms. Paetsch failed to take exception to the exercise of judgment instruction. They then cite her very exceptions in the same footnote. *Response Brief at 35, ftnte. 20, referencing 1600-01 (where counsel objects to Instruction No. 12 – which was at that time the exercise of judgment instruction. See RP 1600: 24 – RP 1601: 7); and 1619: 11-19 (excepting to the court's "two alternative forms of treatment" which, again, was then Instruction "12" because it instructed the jury that the PA-C had the option to determine the treatment).*

Respondents then claim that the exceptions and argument are incomprehensible and incoherent. *Response Brief at pp. 35-36 at ftnte. 20, 21 and p. 38.* The point seems obvious. An alternate course of treatment/exercise of judgment instruction instructs the jury that the

PA-C is properly treating Ms. Paetsch within his own standard of care.[5] It allows Dr. Werschler to delegate his role to the PA-C as an "alternative courses of treatment," and it then allows the PA-C to choose between "alternative courses of treatment." If a PA-C may select alternative forms of treatment, then the trial court has just validated the bait-and-switch of medical standards of care. Respondents reiterate the point. Respondents argue that the instruction is properly applied to the PA-C's decision to use Restylane in Paetsch's forehead. Paetsch agrees. This is the very issue. Court's instruction No. 11 authorizes every facet of this physician's delegation and of this PA-C's care.

The exercise of judgment instruction nullifies Ms. Paetsch's claim of lack of informed consent. The physician did not violate consent because he used his judgment to delegate, and the PA-C did not violate consent for selecting off label use of Restylane in Paetsch's

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[5] The instruction states as follows:

"A physician *or* certified physician's assistant is not liable for selecting one of the two or more alternative courses of treatment if, *in arriving at the judgment to follow the particular course of treatment, the physician or certified physician's assistant exercised reasonable care* and skill within the standard of care the physician or certified physician's assistant was obliged to follow."

RP 609, Court's Instruction No. 11, emphasis added.

forehead because he is only "selecting one of the two or more alternative courses of treatment." *RP 609, emphasis added.* The instruction literally validates an off label use of Restylane, because Respondents argued that "everyone does it," and it is thus a proper alternative treatment, which the PA-C may select. And as the PA-C testified, he just didn't know about FDA status or the higher risk of the procedure.

In sum, an alternative treatment/exercise of judgment instruction is not designed for a circumstances where 1) the very identity of the proper provider is at issue; 2) the giving of the instruction validates the treatment by a physician's assistant when a patient consented only to a physician's procedure; 3) the instruction validates a non-FDA approved injection procedure as an "alternative course of treatment" when the patient consented only to an FDA-approved procedure, and 4) the instruction authorizes continued treatment by a PA-C who has damaged the patient.

It was error to give this instruction.

H. Informed consent: Paetsch is entitled to a new trial.

Respondents argue that in order to obtain reversal of the trial

court's denial of her motion for a new trial, Ms. Paetsch was required to demonstrate her *lack* of informed consent. She did so.

Many requests for a new trial involve conflicting evidence. *See, e.g., Davenport v. Taylor*, 50 Wn. 2d 370, 377, 311 P.2d 990, 994-95 (1957). This one does not. Here, it is undisputed that Ms Paetsch produced contracts under which she accepted 1) *Dr. Werschler's* informed consent for, 2) his FDA-approved Restylane procedure on her. *Pl. Ex. 27, 22.* She received neither. She received 1) a PA-C, 2) performing an FDA unapproved procedure. This undisputed evidence cannot support a finding that Ms. Paetsch knowingly consented to a PA-C injecting Restylane in FDA unapproved fashion.

Respondents thus argue that the foregoing facts are not "material" facts of her medical treatment. They are wrong as a matter of law.

1) <u>The standard of care of the provider about to perform an invasive medical procedure is a material fact of medical treatment.</u>

Respondents essentially argue that a bait-and-switch of medical provider standards of care is not a material fact of a medical treatment. *RCW 7.70.050.* Coming from a physician's clinic and a physician, the

argument is frightening. Substituting a PA-C for a physician is already established as a "treatment related" fact, because physician/patient duties are nondelegable as a matter of law. This is because of the differences in standards of care. *Deaton v Lawson,* 40 Wn. at 490; *Carson v. Fine*, 123 Wn.2d at 218; *Smith v. Orthopedics, Int'l Ltd, P.S.*, 170 Wn.2d at 667. Respondents' precedent does not support their bait-and-switch proposition either. In each of Respondent's precedent—*Housel v. James*, 141 Wn.App. 748, 756, 172 P.3d 712, 716 (2007), *Whiteside v. Lukson*, 89 Wn.App. 109, 112, 947 P.2d 1263, 1265 (1997), and *Thomas v. Wilfac, Inc.*, 65 Wn.App. 255, 261, 828 P.2d 597, 601 (1992)—the issue was whether a *physician*'s qualifications are necessarily disclosed as a material fact of his own treatment. But whatever a physician's qualifications, he is a physician, and held to a physician's standard of care. This is far different from the situation here, where a physician assigns a PA-C and a PA-C's lesser standard of care entirely after his patient has consented to a physician performing the procedure.

Respondents argue that the jury could have found that the identity of the provider was not material. First, not true. The jury was

not allowed to *determine* that question. The court dismissed Dr. Werschler from consideration, and also instructed the jury that the PA-C had the right to exercise his judgment. This removed the provider identity aspect of Ms. Paetsch's informed consent claim from the jury. *CR 59 (a)(8), and see e.g. State v. Carter,* 31 Wn.App. 572, 577, 643 P.2d 916, 920 (1982)(holding that a defendant was entitled to a new trial where the court applied the incorrect burden of proof).

Second, if the jury did indeed find that the level of a provider is not a material fact of invasive medical treatment, then substantial justice was not done. *CR 59(a)(9)*. This state's law does not allow for bait-and-switch elective medical care after a patient's consent to a physician is obtained. These are nondelegable duties. *See supra.* And where substantial justice has not been done in a given case, it is the right and duty of the court to set the verdict aside. *Potts v. Laos*, 31 Wn.2d 889, 897, 200 P.2d 505, 509 (1948).

2) <u>FDA approval status of an injected substance is a material fact of treatment.</u>

Respondents also argue that a physician's representing an FDA approved use of a product, followed by his Clinic PA-C engaging in unapproved use, is not material to informed consent, because

physicians often use such products off-label. *See Response Brief, pp. 46-47.* First, the point here is that this PA-C is not a physician. Second, off-label use would have been improper by the physician himself as a violation of informed consent in this situation. Both the Clinic's Botox and its Restylane consent forms guarantee Ms. Paetsch FDA approval of the use of each substance to entice her into accepting the procedures identified, and to assure her of safety. *Pl. Ex. 25 ("Botox is approved by the U.S. Food and Drug Administration (FDA) for the treatment of a glabellar (forehead) wrinkles") and Pl. Ex. 27 ("I know that Restylane has been approved by the United States Food and Drug Administration (PDA)...").* These are specific promises of safety made to Ms. Paetsch. And it is not disputed that the off label use of Restylane in the forehead in fact does carry a greater risk of necrosis. *RP 1035:20-22.* Ms. Paetsch's consent to these procedures was thus indisputably violated when Restylane was injected into her forehead, whether by a physician or not.

FDA approval is material to informed consent because it is a representation of safety. While FDA guidelines do not provide for a civil cause of action, they do govern labels and warnings about drugs,

and set minimum requirements for the drug. *Washington State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 328, 858 P.2d 1054, 1061 (1993), citing 6 *American Law of Products Liability* § 89:9, at 17 (3d ed. 1987). FDA regulations ensure safety of the product for the intended use by, e.g., classification of products as to use, rigorous approval process designed to assure safe use, adverse event reporting, and exceptions for the use of non approved drugs only in, e.g., public health emergencies. 21 U.S.C.A. § 355, 355-1.[6]

In *United States v. Bader*, 678 F.3d 858, 875 (10th Cir. 2012) *cert. denied*, 133 S. Ct. 355, 184 L. Ed. 2d 159 (U.S. 2012), cited by Respondents, the court discusses FDA approval as being connected with safety concerns. In *Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 496 (6th Cir. 2012), also cited by Respondents, the court holds that FDA approval may be relevant depending on the claim. The use of a product in an FDA-approved manner is a promise

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[6] The Washington Administrative Code also uses FDA approval to classify drugs, e.g., WAC 182-530-1050, identifying the "drug evaluation matrix" as a "criteria-based scoring sheet used to objectively and consistently evaluate the food and drug administration (FDA) approved drugs to determine drug coverage status"; or, e.g., defining a "single source drug" as a drug produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA)).

to a patient. That promise is material to let the patient know that this is a standard and safe use of a drug. Ms. Paetsch's consent to such safe procedures was violated, as FDA status was a material fact of her consent and her treatment, and any verdict which concludes that informed consent to this off-label treatment existed is not supported by *any* evidence in this record.

Respondents argue that the jury was not "obligated" to find that a patient would *not* have consented to being injected with Restylane if informed of its FDA approval status. That would be an entirely speculative verdict, because Ms. Paetsch was never so informed.

There is *no* evidence in this record supporting a finding that Ms. Paetsch consented to a non-FDA approved injection of Restylane. She should be allowed a new trial.

III. CONCLUSION.

Ms. Paetsch pursued an elective cosmetic procedure from a private physician on the open "cosmetic services" market, protected only by her contract and consent with her physician, and the law. She was turned over to a PA-C, injected with Restylane in a non-FDA approved procedure, damaged, and never given a physician's care. She

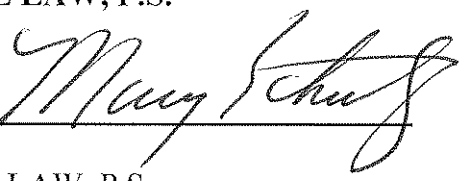
asks for reversal and retrial before a properly instructed jury allowed to determine whether her physician was liable for the damage caused her by his failure to attend to her—both as negligence and as a violation of her consent. She is entitled to a new trial on the issue of informed consent.

This matter should be reversed for retrial.

DATED this 1 day of April, 2013.

Respectfully submitted,

MARY SCHULTZ LAW, P.S.



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CERTIFICATE OF SERVICE

The undersigned hereby certifies under penalty of perjury under the laws of the State of Washington that she is a person of such age and discretion as to be competent to serve papers; and that on the 1st day of April, **2013**, she served a copy of **Appellant's Reply Brief** to the following individuals in the manner indicated below:

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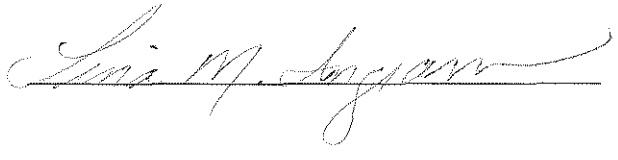
Dated this 1st day of April, 2013.