

COURT OF APPEALS, DIVISION III
STATE OF WASHINGTON

FILED

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COURT OF APPEALS
DIVISION III
STATE OF WASHINGTON
By _____

TYLER ARNOLD and JASON SWANSON,

Petitioners,

vs.

WASHINGTON STATE DEPARTMENT OF HEALTH,

Respondent.

PETITIONERS' OPENING BRIEF

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I. ASSIGNMENTS OF ERROR

1. The Health Law Judge's Finding that the Device Used by Appellants to Remove Tattoos Penetrates the Skin and Alters Human Tissue is Not Supported by Substantial Evidence.

ISSUE: Does the administrative record contain substantial evidence that the use of the Palomar Q Yag 5 to remove tattoos "penetrates skin and alters human tissue" when the uncontroverted testimony at the hearing established that the light emitted by the device interacts only with tattoo ink deposited within the layers of the skin and does not interact with or alter the surrounding tissue.

2. The Health Law Judge Erred by Concluding that Appellants' Use of a Laser Device to Remove Tattoos Constitutes the Practice of Medicine Under Washington Law.

ISSUE: Whether the removal of a tattoo by use of a laser device that emits a pulse of light energy to break up tattoo ink deposited within the layers of the skin constitutes the practice of medicine under Washington law when the device does not physically penetrate the skin and does not alter human tissue.

II. STATEMENT OF THE CASE

This action arises out of an administrative decision by the Washington State Department of Health ("Department") resulting in an order being entered against Appellants to cease and desist providing tattoo removal services using a device known as the Palomar Q Yag 5. The Department of Health issued the order after determining that the use of that device to remove tattoos constitutes the practice of medicine under

Washington Law. Appellants' Petition for Review of that order in the Superior Court was denied. CP 1, 13. Appellants now seek review of the review in this Court.

Appellants are owners of a business that operates a licensed tattoo parlor under the name of Bullet Proof Tattoo. In addition to creating tattoos, the business also provides tattoo removal services. Administrative Record (“AR”) 246-47, 260-61.

Appellants perform tattoo removal using a laser device known as the Palomar Q Yag 5. AR 247. All persons who perform tattoo removal at Appellants’ business have been trained and certified in the proper use and application of the Palomar Q Yag 5 for tattoo removal. AR 247-34, 261-63, 277. Bullet Proof Tattoo has been performing tattoo removal using the Palomar Q Yag 5 since the beginning of 2008. AR 262.

Although the Palomar Q Yag 5 can be used to treat a number of medical conditions, Bullet Proof Tattoo uses the device solely for the purpose of removing tattoos. AR 270-72.

A tattoo is created by depositing ink between the layers of the skin. AR 282-83, 296-97. Although the ink will naturally fade somewhat with time, most tattoos are permanent because the ink is deposited in amounts too large to be absorbed by the body AR 283, 297. The Palomar Q Yag 5 is a device that produces a short, intense pulse of laser energy. AR 294. When used for tattoo removal, the laser interacts only with the ink granules that lie between the layers of skin. AR 301. The laser energy reacts with the ink granules causing them to fracture, allowing the ink to be absorbed by the body. AR 294, 297. More than one treatment is usually required to completely remove the tattoo. Treatment with the Palomar Q Yag 5 causes “frosting” of the skin in the treated area, which is a temporary modification of the optics of the skin. AR 299.

The Palomar Q Yag 5 has applications other than the removal of tattoo ink, including the treatment of pigmented lesions and vascular lesions. AR 300. When used for those purposes, the Palomar Q Yag 5 interacts directly with human tissues. AR 300. When calibrated for tattoo removal, however, the Palomar Q Yag 5 will interact only with the tattoo ink and will have no effect whatsoever when applied to an area of skin where there is no tattoo present. AR 301. Bullet Proof tattoo has never used the Palomar Q Yag 5 for any purpose other than tattoo removal. AR 271 - 272.

In January 2009, the Investigations and Inspections Office, Spokane Unit, of the Department received an anonymous request to investigate Appellant's business. The identity of the complainant is not known. However, Appellants believe the complainant is most likely a local competitor and not a former customer. As the Health Law Judge found, there is no evidence that any person has been harmed by Appellants' tattoo removal service.

After receiving the complaint, an investigator for the Department, Dwight Correll, contacted and interviewed Mr. Arnold at Bullet Proof Tattoo's place of business. AR 239. Mr. Arnold allowed the investigator to inspect the Palomar Q Yag 5 and answered all the investigator's questions. AR 240-41. In February 2012, the investigator made another on-site visit and spoke to Mr. Swanson. AR 241-42. Mr. Swanson answered the investigator's questions and showed him the Palomar Q Yag 5 device. AR 242.

As part of his investigation, Mr. Correll went to the website for the Federal Food and Drug Administration and determined that the Palomar Q Yag 5 was developed and used in surgical use in General and Plastic Surgery and was categorized as a prescriptive

device by the FDA. AR 241. However, Mr. Correll did not investigate the use of the Palomar Q Yag 5 or any other similar device for tattoo removal. Nor did Mr. Correll visit any other tattoo parlors engaged in tattoo removal to determine whether any of those businesses were using the same or similar device to remove tattoos. AR 243. In addition, Mr. Correll has no knowledge of how the Palomar Q Yag 5 actually works when used for tattoo removal. AR 243.

In April 2012, almost three years after Mr. Correll conducted his first on-site visit to Bullet Proof Tattoo, the Department served Mr. Swanson and Mr. Arnold with a separate "Notice of Intent to Issue Cease and Desist Order." AR 1-21; 22-44. Answers were filed by Mr. Swanson and Mr. Arnold on May 7, 2012. AR 44-47; 48-50. On May 29, 2012, the two matters were consolidated for administrative review. AR 85-86.

On November 13, 2012, a hearing was held before Health Law Judge Jerry Mitchell. At the hearing, Mr. Correll testified on behalf of the Department. Mr. Swanson and Mr. Arnold both testified on their own behalf and explained the use of the Palomar Q Yag 5 for tattoo removal. Appellants also presented testimony from Patrick J. Clark, CEO of Medical Laser Dynamics.

Mr. Clark testified that the Palomar Q Yag 5 does not physically penetrate the skin, but uses a laser light pulse to break up tattoo ink so that the ink can be naturally absorbed by the body. AR 294. Mr. Clark also testified that, when used in tattoo mode, the light emitted by the Palomar Q Yag 5 reacts only with the tattoo ink and does not have any effect on the surrounding tissue. AR 295; 304. Mr. Clark testified that, when used properly in tattoo mode, the Palomar Q Yag 5 can have temporary side effects, such as irritation or swelling, but would not change the tissue. AR 295. When used correctly

in tattoo mode, the device does not cause blistering and does not cause any permanent change in the surrounding tissue. AR 297 - 298.

Mr. Swanson testified that tattoo removal using the Palomar Q Yag 5 can have certain side effects, such as swelling and scabbing. AR 268, 273-274. However, Mr. Swanson also testified that the act of creating the tattoo has the same side effects. AR 280 - 281. Mr. Swanson testified that, although the screening process for tattooing is less rigorous, the process of applying a tattoo is actually more invasive than the laser because it requires repeated physical penetration of the outer layers of the skin with a needle. AR 282 - 283. The Department did not offer any evidence to rebut Mr. Clark's testimony or the testimony of Mr. Swanson concerning the use of the Palomar Q Yag 5 and its mode of operation when used for tattoo removal.

Following the hearing, the Health Law Judge entered Findings of Fact and Conclusions of Law upholding the Department's Cease and Desist Orders. AR 198-209; 214-226. The Health Law Judge found that tattoo ink lies beneath the skin and that, because the use of lasers penetrates the skin and alters tissues, the laser is considered a prescriptive device. AR 218. The Health Law Judge further found that the use of a laser device to remove tattoos can result in complications such as visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation. AR 218. The Health Law Judge then concluded that Appellants had engaged in the unlicensed practice of medicine as defined under RCW 18.71.011 and WAC 246-919-605. AR 219-220.

III. STANDARD OF REVIEW

When determining whether an error of law has occurred as the result of an agency interpretation, the appellate court applies de novo review. *Hospice of Spokane v. Washington State Dept. of Health*, 178 Wn.App. 442, 448, 315 P.3d 556 (2013). The Court of Appeals "sits in the same position as the superior court" and applies the standards of review directly to the record before the agency." *Tapper v. Employment Sec. Dep't*, 122 Wn.2d 397, 402, 858 P.2d 494 (1993).

The burden of demonstrating the invalidity of agency action is on the party asserting invalidity. RCW 34.05.570(1)(b). The court shall grant relief from an agency order if it determines that the order is outside the statutory authority or jurisdiction of the agency, the agency erroneously interpreted or applied the law, or the order is not supported by substantial evidence. RCW 34.05.570(3).

IV. ARGUMENT:

1. As Used by Appellants to Remove Tattoos, the Palomar Q Yag 5 Device Does Not Result in Penetration of the Skin or Alteration of Human Tissue.

A agency order is invalid if it is based on findings not supported by substantial evidence. An order is supported by substantial evidence if there is "a sufficient quantity of evidence to persuade a fair-minded person of the truth or correctness of the order." *Hardee v. Dep't of soc. & Health Servs.*, 172 Wn.2d 1, 6, 256 P.3d 339 (2011).

Here, the Health Law Judge made several findings that are directly contrary to the evidence presented at the hearing. First, the Health Law Judge found that tattoo ink "lies beneath the skin." AR 220. However, the uncontroverted testimony at the hearing

establishes that a tattoo is created by depositing ink between the layers of the skin, not beneath the skin. AR 282 - 283; 296 - 297. The ink is deposited below the top layer of the skin in particles that are too large to be removed by the body naturally, so that the tattoo becomes permanent. AR 283. Thus, the finding that tattoo ink lies "beneath the skin" is contrary to the evidence presented at the hearing.

The Health Law Judge also found that "the use of lasers penetrates the skin and alters tissues." AR 220. The testimony at the hearing, however, was that the light emitted by the Palomar Q Yag 5 when used in tattoo mode "looks through healthy tissue" to seek out tattoo ink and does not interact with or have any direct effect on the surrounding tissue. AR 295. To the extent that the light emitted by the Palomar Q Yag 5 can be said to "penetrate" the skin, it is no different from sunlight. AR 295; 302. Furthermore, the light emitted by the Palomar Q Yag 5 has no effect whatsoever on the skin in areas where there is no tattoo ink present, since it is targeted specifically to interact only with the tattoo ink. AR 295. That testimony was likewise uncontroverted by any evidence presented by the Department. Thus, the evidence establishes beyond question that the light emitted by the Palomar Q Yag 5 penetrates only the outer layer of the skin and does not directly alter human tissue.

In light of the uncontroverted testimony at the hearing, it is clear that the findings of the Health Law Judge are not supported by any substantial evidence and that there was no evidence sufficient to persuade a fair-minded person of the truth or correctness of those findings. The Health Law Judge therefore erred by finding that tattoo ink lies beneath the skin and that use of the Palomar Q Yag 5 to remove tattoos results in penetration of the skin and alteration of human tissue.

2. Appellants' Use of the Palomar Q Yag 5 Device Solely for the Purpose of Removing Tattoos Does Not Constitute the Practice of Medicine as Defined Under Washington Law.

The Health Law Judge concluded that Appellants had engaged in the practice of medicine under RCW 18.71.011 and WAC 246-919-605. AR 222 - 223. RCW

18.71.011 provides:

A person is practicing medicine if he or she does one or more of the following:

(1) Offers or undertakes to diagnose, cure, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;

(2) Administers or prescribes drugs or medicinal preparations to be used by any other person;

(3) Severs or penetrates the tissues of human beings;

(4) Uses on cards, books, papers, signs, or other written or printed means of giving information to the public, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human disease or conditions the designation "doctor of medicine," "physician," "surgeon," "m.d.," or any combination thereof unless such designation additionally contains the description of another branch of the healing arts for which a person has a license: PROVIDED HOWEVER, That a person licensed under this chapter shall not engage in the practice of chiropractic as defined in RCW 18.25.005.

The Health Law Judge did not specify which subsection was the basis for his conclusion. Only subsection (3) appears to be applicable here, since no finding were made relevant to subsections (1), (2) or (4).

Appellants have been unable to find any published authority interpreting the phrase "severs or penetrates" as used in RCW 18.71.011(3). A common sense reading of the statute, however, leads to the conclusion that tattoo removal using a laser device such as the Palomar Q Yag 5 does not involve severing or penetrating tissues of human beings in any manner that would constitute the practice of medicine. First, the use of the term

"severs" in conjunction with "penetrates" indicates the legislature meant to include only complete physical penetration of tissue by some object, such as a knife or needle, not partial penetration of the skin by light or other similar form of energy.

Interpreting RCW 18.71.011(3) to include partial penetration of the skin by light would lead to absurd results. Since subsection (3) does not require that any particular purpose or result be intended or accomplished by the severing or penetrating of tissue, the simple act of shining a light on a person's skin would qualify as the practice of medicine. Thus, almost all human activity that does not take place in complete darkness would require licensing as a physician or other medical practitioner. A person operating a tanning salon would be practicing medicine and would need to be licensed, as would innumerable other common, everyday activities.

The fact that the Palomar Q Yag 5 uses a concentrated form of light does not render the procedure for tattoo removal different in any significant way. As the testimony at the hearing clearly establishes, the effect of the light emitted by the Palomar Q Yag 5 on the skin is no different than that of sunlight. AR 296 - 299.

Similarly, interpreting RCW 18.71.011(3) to include any partial penetration of skin by any means would expand the definition of the practice of medicine to include many activities that are not now regulated by the Department and which the Legislature clearly did not intend to regulate as the practice of medicine. For example, tattooing itself involves the repeated, partial penetration of the skin with a needle or other instrument in order to deposit ink between the layers of the skin. Tattoo Artists are regulated by the Department of Licensing under RCW 18.300.010, not by the Department of Health, and the Department here does not suggest that the act of creating a tattoo

constitutes the practice of medicine. Yet, the act of creating a tattoo is clearly more invasive than the act of removing the same tattoo using a device like the Palomar Q Yag 5. In addition, the act of creating the tattoo has the same potential side-effects as does removal using the Palomar Q Yag 5. Thus, the Department's position that the former does not constitute the practice of medicine while the latter does is logically untenable.

WAC 246-919-605 states in part:

Use of laser, light, radiofrequency, and plasma devices as applied to the skin.

(1) For the purposes of this rule, laser, light, radiofrequency, and plasma devices (hereafter LLRP devices) are medical devices that:

(a) Use a laser, noncoherent light, intense pulsed light, radiofrequency, or plasma to topically penetrate skin and alter human tissue; and

(b) Are classified by the federal Food and Drug Administration as prescription devices.

(2) Because an LLRP device penetrates and alters human tissue, the use of an LLRP device is the practice of medicine under RCW 18.71.011. The use of an LLRP device can result in complications such as visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation.

(3) Use of medical devices using any form of energy to penetrate or alter human tissue for a purpose other than the purpose set forth in subsection (1) of this section constitutes surgery and is outside the scope of this section.

WAC 246-919-605 does not purport to define the practice of medicine generally, but only as to the use of laser, light, radiofrequency, and plasma (LLRP) devices, which are defined as "medical devices" because they use LLRP to "topically penetrate skin and alter human tissue" and are classified as prescription devices by the federal Food and Drug Administration. The uncontroverted testimony at the hearing was that the Palomar Q Yag 5 does not, when used for tattoo removal, penetrate and alter human tissue. When calibrated for use in removing tattoos, the light emitted by the Palomar Q Yag 5 interacts only with tattoo ink and has no direct effect on the surrounding tissue. Thus, the Health Law Judge clearly erred by concluding that Appellants' use of the Palomar Q Yag 5

constituted the use of a "medical device" as defined under WAC 246-919-605. While the Palomar Q Yag 5 can function as a medical device and be used for purposes that would constitute the practice of medicine, it does not function in that manner and is not used for that purpose by Appellants. Therefore, the device is not a "medical device" as defined by WAC 246-919-605 when used by Appellants.

It is anticipated that the Department will argue that tattoo removal using the Palomar Q Yag 5 can cause temporary side effects, such as irritation of the skin, swelling, scabbing, and "frosting" of the skin, the device alters human tissue. The record demonstrates, however, that any such side effects are not caused by the light emitted by the device and do not result from any permanent change in the tissue itself. Such side effects are the result of the tattoo ink being heated in the process of being broken into smaller pieces. AR 296 - 299. Those side effects are no different than what can happen to the skin when exposed to sunlight. AR 296, 298.

The fact that the use of the Palomar Q Yag 5 to remove tattoos can have certain side effects is not determinative as to whether such use constitutes the practice of medicine. Washington law does not define the practice of medicine based upon the potential side effects of a procedure. Instead, both RCW 18.71.011 and WAC 246-919-605 define the practice of medicine based on the effects of the procedure itself.

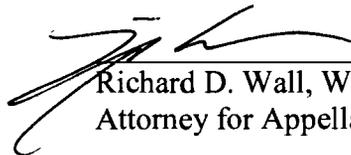
If the practice of medicine were to be defined by the potential side effects of a particular procedure, then many businesses that clearly do not involve the practice of medicine would require licensing as a physician. Such businesses would include tattooing, tanning, piercing, and many others. The Department does not take the position that those businesses involve conduct that constitutes the practice of medicine. Thus, it

appears that Appellants' tattoo removal business has been singled out for some unknown reason.

V. CONCLUSION

For the foregoing reasons, this Court should hold that the use of the Palomar Q Yag 5 device to remove tattoos does not constitute the practice of medicine as defined by Washington law. The Court should reverse the decision of the Health Law Judge and vacate the Final Orders of the Department.

Respectfully submitted this 31st day of April, 2014.


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Attorney for Appellant

CERTIFICATE OF SERVICE

The undersigned hereby certifies under penalty of perjury under the laws of the State of Washington that on this date the foregoing was caused to be served on the following person(s) in the manner indicated:

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Dated this 21st day of April, 2014.