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IN THE COURT OF APPEALS FOR THE STATE OF WASHINGTON

ANNA CHESTER, Appellant, v. DEEP ROOTS ALDERWOOD, LLC, A WASHINGTON CORPORATION; AND BONNIE GILLSON Respondents.	)	No. 73225-1-I DIVISION ONE PUBLISHED OPINION FILED: April 4, 2016

SPEARMAN, C.J. — Anna Chester suffered an adverse reaction after being tattooed with ink that appears to have been contaminated with bacteria when the tattoo artist received it from the distributor. Chester brought negligence claims against the tattoo artist and the tattoo parlor, arguing that they had a duty to use sterile ink. The trial court dismissed her claims on summary judgment and Chester appeals. We affirm, because neither the regulations governing the tattoo industry nor the common law impose a duty to use sterile ink.

FACTS

Bonnie Gillson, a tattoo artist, applied a tattoo to Anna Chester at Deep Roots Alderwood, LLC, a shop specializing in tattoos and body piercing. For the black portion of the tattoo, Gillson used One brand tattoo ink. One was a popular

ink that Gillson had used for about a year and a half without problem. She ordered the ink from Kingpin, a distributor from whom she ordered many tattoo supplies.

A few weeks after applying Chester's tattoo, Gillson learned that several of her clients were experiencing adverse reactions to the black ink portions of their tattoos. An investigation by King County Public Health traced the reactions to a particular bottle of One brand black tattoo ink. The investigation indicated that the ink had likely been contaminated during manufacture. Gillson contacted every client she tattooed during the period of time she used the contaminated bottle of ink. Most clients suffered only a minor skin irritation that did not require medical treatment.

Chester, however, suffered a serious reaction to the contaminated ink. She consulted a doctor who diagnosed a bacterial infection at the tattoo site and prescribed a course of antibiotics. The infection did not respond to the prescribed treatment. Chester's kidney function declined rapidly. In the opinion of Chester's doctor, the bacterial infection aggravated an underlying chronic kidney disease. Chester was eventually referred to an infectious disease specialist, Dr. Warren L. Dinges. Dinges successfully treated the infection. But before the infection was brought under control Chester's kidneys had failed, requiring her to begin dialysis.

Chester brought product liability and negligence claims against Gillson and Deep Roots.[1] To support her negligence claims, Chester relied on two declarations from her medical expert, Dinges. Gillson and Deep Roots moved to strike Dinges's second declaration. The trial court granted the motion in part.

Gillson and Deep Roots moved for summary judgment. Chester conceded dismissal of her product liability claims, but opposed the motion as to her negligence claims. The trial court found as a matter of law that Chester's evidence failed to establish the essential elements of negligence and granted summary judgment for Gillson and Deep Roots. Chester appeals.

DISCUSSION

Chester argues that the trial court erred in finding that she did not show the elements of negligence. We review a decision on summary judgment de novo, engaging in the same inquiry as the trial court. Camicia v. Howard S. Wright Constr. Co., 179 Wn.2d 684, 693, 317 P.3d 987 (2014). To survive summary judgment on a negligence claim, Chester had the burden to produce evidence that the respondents owed her a duty of care and breached that duty. Hurley v. Port Blakely Tree Farms L.P., 182 Wn. App. 753, 773, 332 P.3d 469 (2014) review denied, 182 Wn.2d 2008 (2015), (citing Crowe v. Gaston, 134 Wn.2d 509, 514, 951 P.2d 1118 (1998)). She also had to show that the breach resulted in injury and was the proximate cause of that injury. Id.

[1] Chester also brought product liability claims against Kingpin and one of Kingpin's suppliers. These claims were not dismissed on summary judgment and are not before this court.

Chester first argues that the respondents were negligent per se because they violated a statutory duty of care. Chester relies on RCW 5.40.050(3), under which the breach of tattooing regulations related to the use of sterile needles is negligence per se. She asserts that WAC 246.145.050(1), which requires that tattoo artists use "sterile instruments and aseptic techniques at all times during a procedure," imposes a duty to use sterile ink.

We review questions of statutory interpretation de novo. Pham v. Corbett, 187 Wn. App. 816, 831, 351 P.3d 214 (2015) (citing State v. Wentz, 149 Wn.2d 342, 346, 68 P.3d 282 (2003). In interpreting statutes, our aim is to discern and implement the Legislature's intent. Id. (citing State v. J.P., 149 Wn.2d 444, 450, 69 P.3d 318 (2003)). We begin with the plain language of the statute. Id. Where the plain language is unambiguous and the legislative intent is apparent, we "'will not construe the statute otherwise.'" Id. (quoting J.P., 149 Wn.2d at 450). Legislative intent may be discerned from the statutory scheme as a whole. Id. (quoting Dep't of Ecology v. Campbell & Gwinn, LLC, 146 Wn.2d 1, 11, 43 P.3d 4 (2002)). The same principles apply to the interpretation of regulations as to the interpretation of statutes. Silverstreak, Inc., v. Washington State Dep't. of Labor and Industries, 159 Wn.2d 868, 898, 154 P.3d 891 (2007).

The Legislature authorized the secretary of health to regulate the tattoo industry and instructed the secretary to adopt rules "in accordance with nationally recognized professional standards." RCW 70.54.340. The legislature further directed the secretary to "consider the standard precautions for infection control, as recommended by the United States centers for disease control." RCW

70.54.340. In compliance with these directives, the secretary of health adopted chapter 246-145 WAC to regulate electrology, body art, body piercing, and tattooing.

WAC 246-145-050 details 24 "universal precautions" applicable to tattoo artists and body piercers. Three subsections include sterilization requirements. Artists must use "sterile instruments and aseptic techniques at all times during a procedure." WAC 246-145-050(1). They must use only presterilized single-use disposable tattoo needles. WAC 246-145-050(2). Artists must obtain jewelry used in body piercing presterilized or sterilize the jewelry on site prior to the procedure. WAC 246-145-050(20). The regulation includes two provisions concerning tattoo ink. Tattoo artists must use single-use ink containers for each client to prevent contaminating the unused portion of ink. WAC 246-145-050(15). Artists may not use inks that are banned or restricted by the FDA. WAC 246-145-050(18).[2]

The next regulation, WAC 246-145-060, details the requirements for "**[s]terile procedures in body art, body piercing and tattooing**." The regulation repeats the requirement to use only single-use, presterilized disposable needles. WAC 246-145-060(1)(a). It requires artists to only reuse instruments intended for multiple use that have been cleaned and sterilized between clients. WAC 246-145-060(1)(c). The regulation gives specific

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[2] The FDA does not require that tattoo inks be sterile. See Centers for Disease Control, Morbidity and Mortality Weekly Report (MMWR), Tattoo-Associated Nontuberculous Mycobacterial Skin Infections—Multiple States, 2011-2012 (August 24, 2012) Vol. 61, No. 33, 653-656 at http://www.cdc.gov/mmwr/pdf/wk/mm6133.pdf

requirements for sterilizing and storing reusable instruments. WAC 246-145-060(1)(c)-(g). The regulation includes no requirements for ink.

There is no regulation that, by its plain language, creates a duty to use sterile ink. The regulatory scheme as a whole indicates that the secretary carefully considered sterilization as it applies to the tattoo industry. The regulations require that some items be obtained presterilized and that others be sterilized on site, according to detailed procedures. The secretary also considered tattoo ink and issued rules concerning what ink may be used and how ink must be dispensed.

Considering the detail of the regulatory scheme, the specific requirements concerning sterilization, and the attention given to tattoo ink, it is not reasonable to conclude that the secretary intended to require the use of sterile ink but couched that duty within the requirement to use sterile instruments and aseptic technique. We conclude that the plain language of the regulation is not ambiguous and the legislative intent is clear. There is not a regulatory requirement to use sterile ink.

Chester next argues that the definition section of RCW 70.54.330 is an independent basis for finding the respondents negligent per se. RCW 70.54.330(4) defines "tattooing" as an indelible mark "introduced by insertion of nontoxic dyes or pigments into or under the subcutaneous portion of the skin." Chester contends that this section creates a duty to use only nontoxic ink and that the respondents breached this duty by using contaminated ink. The

respondents argue that the section does not apply to the negligence per se statute, RCW 5.40.050(3). We agree with the respondents.

RCW 5.40.050 establishes negligence per se for the breach of a duty created by statute or rule relating to "(3) sterilization of needles and instruments used by persons engaged in the practice of body art, body piercing, tattooing, or electrology, or other precaution against the spread of disease, as required under RCW 70.54.350." The referenced statute, RCW 70.54.350 states, "[a]ny person who practices electrology or tattooing shall comply with the rules adopted by the department of health under RCW 70.54.340." The negligence per se statute thus applies to the breach of any tattooing regulation having to do with precautions against the spread of disease. The definition of tattooing in RCW 70.54.330(4) is not such a regulation.

This reading is in harmony with other statutory and regulatory provisions defining tattooing. RCW 18.300.010, which became effective at the same time as the tattoo regulations, explicitly states that its definitions apply to RCW 5.40.050, the negligence per se statute. The statute defines "tattooing" as "to pierce or puncture the human skin with a needle or other instrument for the purpose of implanting an indelible mark." RCW 18.300.010(8). The regulations also use this definition. WAC 246-145-101(25). Neither the statutory nor the regulatory definition encompassed by the negligence per se statute includes the word "nontoxic."

At oral argument and in a statement of additional authorities, Chester also asserted that the respondents were negligent per se because they violated the

Federal Food, Drug, and Cosmetic Act (FDCA). Chester argued that the respondents violated 21 U.S.C. § 331, which prohibits introducing or receiving in interstate commerce any adulterated cosmetic. This argument is without merit because the FDCA does not create a private right of action. 21 U.S.C. § 337. Furthermore, the Act does not impose penalties on retailers who deliver adulterated cosmetics in good faith. 21 U.S.C. § 333(c).

We conclude that Chester has not shown the existence of a statutory duty to use sterile ink and we reject her claim of negligence per se.

Chester argues in the alternative that she established the elements of common law negligence. Chester asserts that even if the respondents owed only a duty of reasonable care, they breached that duty by not using sterile ink or confirming that the ink was not contaminated.

Chester does not assert that sterile ink is the industry standard. But she argues that even if sterile ink is not routinely used, the risks associated with using contaminated ink far outweigh the burden of using sterile ink. She argues that the respondents thus breached a duty of reasonable care by failing to ensure the ink they used was sterile.

Chester relies on Helling v. Carey, 83 Wn.2d 514, 519 P.2d 981 (1974), in which the Supreme Court quoted Judge Learned Hand and followed his cost-benefit analysis. Id. at 519. In Helling, a 32-year-old patient became partially blind due to undetected glaucoma. Id. at 516. The defendant ophthalmologists presented evidence that glaucoma is uncommon in young patients and the industry standard was to administer routine glaucoma tests after the age of 40.

Id. But the court held that, given the severity of glaucoma and the availability of a simple and harmless test to detect the disease, the doctors breached a duty by failing to administer the test. Id. at 519.

Chester's argument falls short because she glosses over the burden of using sterile ink. In Helling, it was undisputed that the ophthalmologists could easily administer a simple glaucoma test. Helling, 83 Wn.2d at 519. Chester asserts that using sterile ink is similarly easy as "Gillson can simply order sterile rather than non-sterile ink . . . ." Br. of Appellant at 23. She further argues that the respondents had not only a duty to purchase ink advertised as sterile, but also a duty to ensure that ink was in fact sterile. However, Chester has not shown that sterile ink was widely available at the time in question, that claims of sterility were reliable, or that tattoo artists had the means to test ink for contamination and sterilize it on site.

Chester presented evidence that Intenze brand tattoo ink was advertised as sterile about the time that Gillson purchased the One brand ink. She also produced the article Microbial status and product labelling of 58 original tattoo inks (2011) as evidence of the association between tattoo ink and bacterial infection. The article reports on a study of 58 inks for sale in the European market. Concerning those inks claiming to be sterile, the authors found that none of the claims could be verified and some were demonstrably false. The authors found that Intenze black ink, advertised as sterile, contained a high level of bacterial contamination.

The record includes a further example of an unreliable claim of sterility. At some point prior to March 2012, the One brand website claimed that its ink was sterile. An inspection determined that, although the manufacturer was having the ink treated with gamma radiation, the dosage of radiation was not sufficient to support the claim of sterility.

Chester has not shown that sterile ink was readily available or that claims of sterility were reliable. She offered no evidence that tattoo artists have the means to test ink for contamination or sterilize ink received from distributors. We conclude that Helling is distinguishable. Chester has not established that the respondents' duty of reasonable care required them to use sterile ink.

Chester also argues that the trial court erred in striking one paragraph of Dinges's second declaration and in considering another paragraph only as medical opinion. She argues that the court should have considered the declaration in its entirety and that the declaration is evidence that the respondents had a duty to use sterile ink.

The de novo standard applies to evidentiary rulings on admissibility. Keck v. Collins, 184 Wn.2d 358, 368, 357 P.3d 1080 (2015) (citing Folsom v. Burger King, 135 Wn.2d 658, 663, 958 P.2d 301 (1998)). Affidavits in support of a summary judgment motion must contain facts that would be admissible in evidence. CR 56(e). Statements in an affidavit are not inadmissible because they "embrace[] an ultimate issue to be decided by the trier of fact." ER 704. However, a witness may not draw "conclusion[s] of law." Everett v. Diamonds, 30 Wn. App. 787, 791, 638 P.2d 605 (1981). Statutory interpretation is the province of the

court, and is not a proper subject of testimony. Id. at 792 (citing Ball v. Smith, 87 Wn.2d 717, 722-723, 556 P.2d 936 (1976)).

In his second declaration, Dinges comments on the use of "sterile instruments and aseptic techniques at all times during a procedure" as required by WAC 246-145-050(1). Dinges states:

> Regardless of the credentials of the person performing the injection, the requirement to "use sterile instruments ...at all times during a procedure" seems unambiguous to me. The only meaning that I can attach to that rule is that, if a tattoo artist inserts into a customer, by way of an instrument, understood to be a needle used to penetrate the surface of the skin, ink that is contaminated with bacteria, then clearly "sterile instruments" were not used at all times during the procedure because the instrument, meaning the instrument used to penetrate the customer's skin, was contaminated with bacteria.

Clerk's Papers (CP) at 369.

Chester asserts that the trial court erred in striking this passage as legal opinion. She argues that the statement that the tattoo needle was not "sterile" is a statement of fact, not a legal opinion. Chester further argues that this paragraph contains only explanations of the regulatory terms.

In the stricken paragraph, Dinges does not merely explain the term "sterile" or state that a tattoo needle is no longer sterile after it has come into contact with contaminated ink. Dinges states that it "seems unambiguous" that by requiring "'sterile instruments'" the regulation prohibits the use of any non-sterile ink. (Quoting CP at 369). Dinges then draws the conclusion that, in the circumstances of the present case, "clearly 'sterile instruments' were not used." The paragraph both construes the regulation and reaches the legal conclusion

that the respondents violated the regulation. Conclusions of law and statutory interpretation are not proper subjects for testimony. Everett, 30 Wn. App. at 791.

Chester next argues that the statement is admissible as Dinges's understanding of the standard of care and a breach of that standard. Chester quotes White v. Kent Med. Ctr., Inc., P.S., 61 Wn. App. 163, 171, 810 P.2d 4 (1991), for the proposition that the standard of care and a breach of that standard "'ordinarily must be shown by expert medical testimony.'" White, however, is inapposite because it involved a claim of medical negligence. Id. Expert knowledge of the profession at issue is necessary to testify to the standard of care within that profession. Young v. Key Pharmaceutical, Inc., 112 Wn. 2d a 216, 227-230, 770 P,2d 182 (1989) (pharmacist not qualified to testify that physicians breached their standard of care). Dinges does not claim to be a tattoo artist or an expert in tattooing. His testimony is therefore not admissible to establish the standard of care for tattoo artists. The trial court did not err in striking the paragraph as legal opinion.

Chester also argues that the trial court erred in considering the following paragraph of Dinges's declaration only as medical opinion:

> In my opinion the absolute minimum that is required for a tattoo artist (or any person intending to inject a substance into a person) to be able to claim the use of sterile instruments and aseptic technique at all times during the procedure is that the artist only use ink that is in fact sterile. In this case, the artist did not use ink that was in fact sterile because the black ink in Ms. Chester's tattoo was contaminated with bacteria.
>
> To ensure sterile instruments and aseptic technique throughout the procedure, the procedure has to start with sterile tattoo ink.

CP at 370.

Chester argues that the legislature directed the secretary of health to "consider the standard precautions for infection control, as recommended by the United States centers for disease control" (CDC). RCW 70.54.340. She asserts that this directive indicates that medical doctors and the secretary of health share the same understanding of sterility, and Dinges is qualified to testify to that shared understanding. She argues that the trial court erred in not considering the challenged paragraph to establish the elements of negligence.

Chester's argument fails because, while Dinges is qualified to testify to the meaning of the term "sterile," his statement goes beyond explaining the term. The challenged statement includes Dinges's opinion that the regulation requiring the use of sterile instruments and aseptic technique includes an unstated requirement to use sterile ink. To the extent Dinges interprets the statute, his statement is inadmissible because statutory interpretation is the province of the court. To the extent Dinges testifies to the standard of care, his testimony is inadmissible because he is not an expert in tattooing.

Chester's argument concerning the CDC does not change this result. The legislature instructed the secretary to adopt rules "in accordance with nationally recognized professional [tattoo] standards" and to "consider the standard precautions for infection control, as recommended by the United States centers for disease control." RCW 70.54.340. This instruction to the secretary does not impose CDC or other medical standards on tattoo artists. The secretary of health and medical professionals may share an understanding of sterility, as Chester

asserts, but the secretary did not promulgate regulations imposing medical standards on tattoo artists. Dinges is a medical expert. We conclude that the trial court did not err in considering his statement as medical opinion, but not as evidence of duty and breach within the tattoo industry.

Affirmed.

Spearman, C.J.

WE CONCUR: