SUPREME COURT NO. 93188-7
COURT OF APPEALS NO. 73225-1-I

IN THE SUPREME COURT OF THE STATE OF WASHINGTON

ANNA CHESTER,

Petitioner,

vs.

DEEP ROOTS ALDERWOOD, LLC, a Washington company; and BONNIE GILSON,

Respondents.

ON APPEAL FROM THE SUPERIOR COURT
OF THE STATE OF WASHINGTON FOR SNOHOMISH COUNTY

DEEP ROOTS ALDERWOOD, LLC'S ANSWER TO ANNA CHESTER'S PETITION FOR REVIEW

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I. IDENTITY OF RESPONDENT

Deep Roots Alderwood, LLC ("Deep Roots"), a defendant and Respondent below, submits this Answer in response to the Petition for Review filed by plaintiff and Appellant Anna Chester ("Chester").

II. INTRODUCTION

Co-Respondent tattoo artist Bonnie Gillson ("Gillson") tattooed Chester at Deep Roots' tattoo parlor on September 13, 2011 with tattoo ink that Gillson purchased from a reputable seller. Chester asserts that the ink was contaminated with microscopic bacteria during the ink manufacturing process. It is undisputed that neither Gillson nor Deep Roots were the source of contamination.

Chester's sole claim for liability against Gillson and Deep Roots is that Gillson should have used sterile ink in the tattoo. In the Court of Appeals' 3-0 decision affirming the trial court's order granting summary judgment to Deep Roots and Gillson, Division One thoroughly interpreted and analyzed Washington State's numerous and, at times, excruciatingly detailed tattoo-related statutes and regulations, holding that they do not require the use of sterile tattoo ink. *Chester v. Deep Roots Alderwood, LLC et al.*, __ Wn. App. __, __ P.3d__, 2016 WL 1305200 (No. 73225-1-I April 4, 2016) at *2 - *3. Because Chester similarly failed to establish a common law duty to use sterile ink, by way of an industry standard or

otherwise, the Court of Appeals also concluded that Chester could not sustain a common law negligence claim. *Chester* at *4-*5.

The Court should not accept review of this case. First, there is no conflict between the lower court's discussion of the negligence per se doctrine and any other Washington decision. The Court of Appeals properly applied RCW 5.40.050(3) to the statutes and rules related to the sterilization of needles and instruments used in the Washington tattoo industry. *See, e.g., Chester* at *2 ("the breach of tattooing regulations related to the use of sterile needles is negligence per se"), *3 ("[t]he negligence per se statute thus applies to the breach of any tattooing regulation having to do with precautions against the spread of disease").

The Court of Appeals also properly noted that there is no negligence per se for a purported violation of the federal Food, Drug, and Cosmetic Act ("FDCA"), "Prohibited acts", 21 U.S.C. § 331(c), given that the FDCA does not create a private cause of action. *Chester* at *4 (citing 21 U.S.C. § 337). Contrary to Chester's discussion of pre-Tort Reform Act law, "[a] breach of a duty imposed by statute [] **shall not** be considered negligence per se." RCW 5.40.050 (emphasis added). The only exceptions to Washington's prohibition of negligence per se are the legislatively-created private causes of action contained within RCW 5.40.050(1)-(4), and which do not include 21 U.S.C. § 331(c).

Likewise, there is no conflict between the underlying opinion and Washington law regarding the admissibility of expert opinions. There is no plain-language statutory or regulatory requirement for the use of sterile ink.[1] However, Chester's physician, Warren Dinges, M.D., Ph.D., opines that the regulations contain an unstated sterile ink requirement, which Respondents violated. The Court of Appeals correctly concluded that Dr. Dinges – who is not an expert in tattooing procedures or standards – improperly offered testimony on statutory interpretation, a question-of-law function that is in the exclusive province of the court.

Finally, the Court should not accept review for the requested purpose of judicially creating a duty of care for Washington tattoo artists to use sterile tattoo ink. While public health is a matter of public concern generally, the specific issues in this case are not matters of substantial public interest that should be decided by the Court. Not only has Chester failed to provide the evidence necessary for this Court to decide to create a sterile ink requirement, but sterility requirements in the tattoo industry have already been legislated in Washington, with the Department of

[1] For comparison, the regulations explicitly require sterile needles, instruments, and jewelry; the disinfection of work spaces; the sanitation of marking instruments; and the antiseptic treatment of customers' skin. WAC 246-145-050(2), (12), (19), (20), (21); WAC 246-145-060.

Health assuming responsibility for adopting proper regulations for tattooists and shops. RCW 70.54.340.[2]

III. COUNTERSTATEMENT OF THE CASE

A. Procedural History

On January 9, 2015, the Superior Court of Snohomish County granted Deep Roots' and Gillson's Motions for Summary Judgment, holding that Chester could not show the essential elements of negligence because there is no legislative, administrative, or common law duty to use sterile ink, Gillson complied with all statutory and regulatory requirements for tattooists, and there is no evidence that Gillson knew or should have known that the ink was contaminated. CP 5-9. The trial court also struck one portion of Dr. Dinges's Second Declaration as an improper legal conclusion, and only considered another portion as being germane to the medical field, not the tattooing field. CP 15-21.

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[2] In her issues presented for review, Chester asks whether a tattoo shop has a non-delegable duty to comply with the tattooing regulations, but does not discuss the issue further. Pet. for Rev. p. 2 (Issue 2). This issue is not ripe for appeal and the Court should disregard it. Deep Roots did not move for summary judgment on whether it had a non-delegable duty to Chester, or the lack of its right to control Gillson's work. CP 135, 420, 477. Accordingly, neither the trial court nor the appellate court decided the issue. "Issues not raised in the hearing for summary judgment cannot be considered for the first time on appeal." *Ashcraft v. Wallingford*, 17 Wn. App. 853, 860, 565 P.2d 1224 (1977) (citations omitted).

On April 4, 2016, Division One affirmed the trial court's order granting summary judgment, as well as the evidentiary rulings regarding Dr. Dinges's testimony, holding that "neither the regulations governing the tattoo industry nor the common law impose a duty to use sterile ink." *Chester* at *1. The Court of Appeals noted that "[t]he regulatory scheme as a whole indicates that the secretary [of health] carefully considered sterilization as it applies to the tattoo industry," and refused to judicially create a standard of care requiring the use of sterile tattoo ink. *Chester* at *3.

B. Gillson Did Not Know, and Had No Reason to Know, That the Ink Was Contaminated with Microscopic Bacteria.

Gillson used "One" brand black tattoo ink for parts of Chester's tattoo. CP 449. **It is undisputed that the One ink did not become contaminated, impure, or defective during the tattooing procedure.** Rather, Chester asserts that the One ink used in her tattoo was contaminated with microscopic bacteria during its manufacture before it was ever even opened by Gillson.[3] Pet. for Rev. p. 3; CP 502-04.

Gillson had selected and purchased the highly recommended One tattoo ink from supplier and co-defendant Kingpin Tattoo Supply

[3] Deep Roots sharply disputes Chester's claimed damages.

("Kingpin").[4] CP 233, 452. Kingpin is a large distributor from which Gillson purchased various tattoo supplies. CP 215, 260-351. Gillson had obtained the Material Data Safety Sheet for the ink, and knew Kingpin to be a reputable seller. CP 214, 217, 233.

It is undisputed that Gillson was unaware of any complaints, dangers, or hazards of One brand tattoo ink prior to performing Chester's tattoo. CP 460. Gillson had been tattooing customers with One brand tattoo ink for about a year and a half prior to Chester's tattoo without problem or concern. CP 450-51. Kingpin did not inform Gillson or Deep Roots of any customer reactions to One ink, nor did Kingpin publicize any such information. CP 463. There is no evidence that the FDA had banned or restricted One tattoo ink prior to Chester's tattoo.

Additionally, there is no evidence that Gillson knew or should have known that the bottle of ink at issue was different from any other bottles she had used – i.e., there was no difference in the liquid's consistency, smell, or color. The bacteria were invisible to the naked eye.

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[4] Chester's claims against co-defendants Kingpin and Papillon Studio Supply & Manufacturing, Inc., the manufacturer(s)/distributor(s) of the One ink and/or its pigment, are still pending in the trial court.

C. Dr. Dinges Opined That WAC 246-145-050(1) Includes an Unstated Sterile Ink Requirement.

In opposition to Respondents' Motions for Summary Judgment, Chester relied upon Dr. Dinges's opinion that WAC 246-145-050(1) implicitly requires the use of sterile tattoo ink. CP 370. Dr. Dinges did not demonstrate any specialized experience, education, knowledge, or training regarding tattooing standards, policies, or procedures. Rather, Dr. Dinges interpreted WAC 246-145-050(1) based on sterility concepts in the medical field.[5] CP 366-70.

D. There Is No Evidence That Tattoo Artists Can Verify Sterility or Sterilize Ink.

The use of sterile ink is clearly not the tattoo industry standard, and Chester does not argue that it is. Pet. for Rev. p. 16. She identified one brand of tattoo ink – "Intenze" – that had manufacturer claims of sterility and was available in the United States at the time of Chester's tattoo. At all material times, Intenze represented itself as the "world's **first and only** ink company taking the necessary measures to guarantee our consumers a safe and positive outcome." CP 359 (emphasis added). Yet, Intenze True

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[5] Dr. Dinges analogizes tattoo ink to medication in sealed vials. CP 369-70. Dr. Dinges did not provide any evidence that any tattoo inks are manufactured, marketed, or sold like sterile medications, or that tattoo needles and instruments would effectively work with such a set-up. Nor did Dr. Dinges show that he was familiar with the use, prevalence, development, or effectiveness of gamma irradiation in the tattoo industry.

Black ink still tested positive for bacteria, according to a European Academy of Dermatology and Venereology article.[6] CP 378, 382.

Moreover, there is no evidence as to how Respondents could have tested for sterile ink, or sterilized or decontaminated the ink.[7] To that end, Gillson could not know if the ink was sterile, or if it was contaminated. CP 213. In May 2016, the FDA confirmed in a Consumer Update that:

> [t]here's no sure-fire way to tell if the [tattoo] ink is safe. Just looking at it or smelling it won't tell you if it's contaminated. An ink can be contaminated even if the container is sealed or wrapped, or the label asserts the product is sterile. In fact, ink could become contaminated at any point in the production process.

Resp. App. p. 8. Chester submits no evidence that a tattoo artist can verify that ink is "in fact" sterile – the very requirement that she is asking this Court to adopt.

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[6] Indeed, of all the inks tested in the subject article, Intenze True Black had more bacterial colonies than any other ink tested, and, in June 2014, the European Union recalled three Intenze brand inks because of an unsafe chemical compound and/or trace metal contamination. CP 166-67, 378-80. The authors of the Academy of Dermatology and Venereology study "found that none of the [manufacturers'] claims [of sterility] could be verified and some were demonstrably false." *Chester* at *4.

[7] It is undisputed that, unlike jewelry and tattoo instruments, liquids cannot be sterilized through an autoclave sterilizer. CP 227.

IV. ARGUMENT

A. The Court of Appeals' Decision Does Not Conflict With Washington Law Regarding the Doctrine of Negligence Per Se.

Washington law prohibits negligence per se in nearly all circumstances. "A breach of a duty imposed by statute, ordinance, or administrative rule shall not be considered negligence per se." RCW 5.40.050. The only exceptions to this prohibition of the negligence per se doctrine are the private causes of action that the State Legislature carved out in RCW 5.40.050(1)-(4).

Relevant here, RCW 5.40.050(3) creates a negligence per se cause of action for the breach of any duty provided by statute or administrative rule relating to the "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." After thoroughly analyzing various regulations and statutes falling within RCW 5.40.050(3), the Court of Appeals properly concluded that Chester failed to show a regulatory or statutory duty to use sterile ink, and, consequently, her negligence per se claims pursuant to RCW 5.40.050(3) fail as a matter of law. *Chester* at *1-*4.

There is no conflict or confusion arising out of the Court of Appeals' negligence per se analysis. 21 U.S.C. § 331(c), relied upon by

Chester, is not subject to RCW 5.40.050(3) and does not provide for a private cause of action. Furthermore, the Court properly recognized that Gillson acted in good faith, a defense to a purported violation of 21 U.S.C. § 331(c).

1. Because 21 U.S.C. § 331(c) Is Not Related to Washington's Regulatory Scheme for the Tattoo Industry, RCW 5.40.050(3) Does Not Apply.

Chester erroneously argues that WAC 246-145-050(18), which states that tattoo "[i]nks or pigments must not be banned or restricted by the FDA," adopts 21 U.S.C. § 331(c). Section 331 is a federal criminal statute allowing the United States (and, under some circumstances, individual states) to prosecute certain "acts and the causing thereof," including "[t]he receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise."[8] 21 U.S.C. § 331(c). The statute defines and classifies certain actions as crimes; it does not ban or restrict products, nor does it contain any ink sterilization requirements. 21 U.S.C. § 331(c) is not a tattooing precaution required by RCW 70.54.350, and it is therefore not subject to the negligence per se doctrine under RCW 5.40.050(3).

[8] Neither Respondent was a product seller of the tattoo ink, and neither "delivered" it to Chester.

2. The Court Correctly Noted That 21 U.S.C. § 331(c) Does Not Create a Private Cause of Action.

As the Court of Appeals noted, § 331(c) does not provide for a private cause of action. *Chester* at *4. 21 U.S.C. § 337 explicitly and affirmatively states that there is no private cause of action for a violation of 21 U.S.C. § 331(c), expressly evidencing a legislative intent that individual remedies are not allowed. Resp. App. p. 7; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) (state law tort claims based solely on violations of the FDCA are preempted by federal law).

In *Mina v. Boise Cascade Corp.*, 104 Wn.2d 696, 703-04, 710 P.2d 184 (1985), upon which Chester relies, this Court confirmed that a private cause of action was not a precursor to the utilization of the doctrine of negligence per se. However, the next year, Washington's Tort Reform Act went into effect, and RCW 5.40.050 abrogated the "idea that a plaintiff could recover by showing either the applicability and breach of a statutory duty, or the existence and breach of the common law duty of reasonable care." *Templeton v. Daffern*, 98 Wn. App. 677, 684, 990 P.2d 968 (2000).

The Court of Appeals' opinion does not "effectively eliminate[] negligence per se." Pet. for Rev. p. 11. The Washington Legislature has

already done so. No longer may a court apply the negligence per se doctrine and substitute a statutory standard of conduct even though the legislative enactment does not explicitly apply to a private suit. *Templeton*, 98 Wn. App. at 687 ("[b]ecause of RCW 5.40.050 [] plaintiffs cannot prevail based on a statutory violation alone"). The Court of Appeals' opinion applied the negligence per se doctrine to tattooing statutes and regulations consistently with RCW 5.40.050.

3. The Court Correctly Noted the Good Faith Exception to 21 U.S.C. § 331(c).

The Court of Appeals properly noted the good faith exception to 21 U.S.C. § 331(c), which is consistent with the ordinary care defense to the negligence per se doctrine.[9] *See Chester* at *4; WPI 60.01.01.

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[9] Chester misreads 21 U.S.C. § 333(c). The good faith defense contained therein absolves a party who receives and delivers adulterated products from both criminal and civil penalties, but not the party who introduces the adulterated product into interstate commerce. 21 U.S.C. App. § 333(c). Resp. App. p. 2. This is because 21 U.S.C. § 333(c) was "designed to protect innocent dealers who receive goods shipped in interstate commerce," not those who adulterate products. *United States v. Parfait Powder Puff Co.*, 163 F.2d 1008, 1010 (7th Cir. 1947). The Senate passed 21 U.S.C. § 333(c) to safeguard and protect "the innocent dealer who distributes goods he has received from interstate sources [. . .] thus allowing the prosecution to lie solely against the guilty shipper." *Id.* (citing Senate Report No. 493, 73d Cong.2d Sess., accompanying S. 2800).

The cases relied upon by Chester are not controlling. In *United States v. Park*, 421 U.S. 658, 672-73 (1975), the defendant was prosecuted under 21 U.S.C. § 331(k), not § 331(c), and the good faith defense in 21 U.S.C. § 333(c) was not at issue. *See also United States v. Torigian Labs,*

Chester agrees that the ink was not adulterated by Gillson. She has failed to show any evidence that problems with bacteria contamination in tattoo ink was commonly known throughout the tattoo industry, that Kingpin had warned Respondents or other tattooists of customer complaints regarding the ink at issue, or that Gillson's receipt and use of the ink should have indicated that the ink was contaminated. Considering that Chester has failed to show a lack of ordinary care or good faith, Chester's argument regarding the application of 21 U.S.C. § 331(c) to Respondents is futile.

B. The Court of Appeals' Decision Does Not Conflict With Washington Law Regarding the Rules of Statutory Interpretation and Expert Witness Testimony.

The Court of Appeals' exclusion of portions of Dr. Dinges's opinion is consistent with well-settled law that statutory interpretation is a question of law for the courts. *See Jewels v. City of Bellingham*, 183 Wn.2d 388, 394, 353 P.3d 204 (2015). The meaning of the terms within a statute may certainly come from the statute, a dictionary, legislative history, or, in the case of technical terms, testimony. *Gorre v. City of Tacoma*, 184 Wn.2d 30, 37, 357 P.3d 625 (2015). However, regardless of the source, the court, not a witness, determines the meaning and effect of the rule or statute to carry out legislative intent. *Gorre*, 184 Wn.2d at 41.

Inc., 577 F. Supp. 1514, 1526 (E.D.N.Y. 1984) (violations of 21 U.S.C. § 331(a), (k); 21 U.S.C. § 333(c) not at issue).

WAC 246-145-050(1) requires that a tattoo artist "[u]se sterile instruments and aseptic techniques at all times during a procedure."[10] Dr. Dinges attempts to discern the Department's intent in the following sections of his opinion:

> 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.
>
> . . .
>
> To ensure sterile instruments and aseptic technique throughout the procedure, **the procedure has to start with sterile tattoo ink.**

CP 370 (emphases added).

As the Court of Appeals recognized, Dr. "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

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[10] "Aseptic technique" is defined in WAC 246-145-010(2). "Sterile" is not defined, although both "sterilization" and "sterilizer" are. WAC 245-145-010(23)-(24).

prohibits the use of non-sterile ink." *Chester* at *6. Dr. Dinges "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."[11] *Id.* at 7.

The Court of Appeals' holding does not conflict with the cases cited in Chester's Petition for Review. The witnesses in *State v. Nw. Magnesite Co.*, 28 Wn.2d 1, 34-36, 182 P.2d 643 (1947) opined whether the activity at the mine was "treatment" (facts), but the Court determined whether the statute allowed a deduction for the activity (law). Likewise, the expert witness in *Gorre* opined whether valley fever is a respiratory disease (facts), but the Court determined whether the statute allowed for workers' compensation benefits for valley fever. *Gorre*, 184 Wn.2d at 36 n.2, 40. It is for a court, not Dr. Dinges, to determine whether the tattooing regulations require the use of sterile ink.[12]

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[11] In properly exercising its authority to construct statutes, the Court of Appeals disagreed with Dr. Dinges's interpretation of WAC 246-145-050(1) because "it is not reasonable to conclude that the secretary intended the use of sterile ink but couched that duty within the requirement to use sterile instruments and aseptic technique." *Chester* at *3.

[12] Although Chester argues that Dr. Dinges is qualified to testify as to the use of sterile ink because the Washington Legislature instructed the Department to "consider" guidelines from the CDC, the Legislature

C. The Court Should Decline Chester's Request for the Judicial Adoption of a Sterile Ink Requirement.

Given that there is no statutory, industry standard, or other common law duty to use sterile ink, Chester asks this Court to depart from its typical judicial role in order to create a standard of care where there previously was none. The imposition of a sterile ink requirement should be directed by the State Legislature or the Secretary of Health, which already regulate the Washington tattoo industry, or the federal government, which already regulates the manufacture and sale of tattoo ink.[13]

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actually ordered that the Department's rules "shall" be "in accordance with nationally recognized professional standards . . . employed by [. . .] tattoo artists." RCW 70.54.340. "This [CDC] 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." *Chester* at *7. Dr. Dinges is not an expert in tattooing. *Id.*

[13] Chester's request is similar to the request in *Burkhart v. Harrod*, 110 Wn.2d 381, 385-86, 755 P.2d 759 (1988), wherein the plaintiff advocated for the adoption of social host liquor liability. This Court refused to do so because such a decision "requires a balancing of the costs and benefits for society as a whole, not just the parties of any one case. Yet because judicial decisionmaking is limited to resolving only the issues before the court in any given case, judges are limited in their abilities to obtain the input necessary to make informed decisions" on issues of "broad public policy questions." *Id.* at 385.

Chester, the party advocating for the adoption of a judicially-created standard of care, has not provided this Court with the information necessary to conclude that the risks of non-sterile tattoo ink outweigh the burden of sterile ink. Glaringly missing is any evidence that the health risks from ink that is not marketed as sterile are greater than the health risks from ink that is marketed as sterile, or that the risk of harm from tattoo ink is greater than the risk of harm from other product defects.[14] Conversely, Chester has not provided evidence to counter the known burdens and challenges to the effective use of sterile ink.[15]

Finally, Chester ignores longstanding Washington law that places legal responsibility for product safety on manufacturers precisely because manufacturers are in the best position to investigate the design, manufacturing, and testing of the products that they place into the stream

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[14] Chester has not shown the probability of bacterial contamination in ink marketed as sterile versus non-sterile, the percentage of tattoo customers at risk, the likelihood of injury from bacteria versus other causes (i.e. bloodborne pathogens or unsafe chemicals), or that the severity of injury from bacteria is greater than other causes. The FDA states that there has been a "previous lack of evidence of safety problems specifically associated with these [ink] pigments," and the CDC call harmful mycobacterial outbreaks "rare." Pet. App. pp. A-41, A-60.

[15] Chester has not shown that sterile ink was widely available at the time of Chester's tattoo, that manufacturer claims of sterility were reliable, or that tattoo artists had the means to test for and/or sterilize ink. *See Chester* at *5.

of commerce. Chester is not left without legal redress here; she has strict liability claims against the ink manufacturer.

V. CONCLUSION

The Court of Appeals properly concluded that "Chester has not established that the respondents' duty of reasonable care required them to use sterile ink." *Chester* at *5. This Court should decline review of the Court of Appeals' decision; or, if accepted, should affirm the trial court's dismissal of Chester's claims against Respondents.

Respectfully submitted this 2nd day of June 2016.

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APPENDIX

DEEP ROOTS ALDERWOOD, LLC'S ANSWER TO ANNA CHESTER'S PETITION FOR REVIEW

*** Current through PL 114-156, approved 5/16/16 ***

TITLE 21. FOOD AND DRUGS
CHAPTER 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT
PROHIBITED ACTS AND PENALTIES

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21 USCS § 333

§ 333. Penalties

(a) Violation of *21 USCS § 331*; second violation; intent to defraud or mislead.

(1) Any person who violates a provision of section 301 [*21 USCS § 331*] shall be imprisoned for not more than one year or fined not more than $ 1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) [of this section], if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $ 10,000 or both.

(b) Prescription drug market violations.

(1) Notwithstanding subsection (a), any person who violates section 301(t) [*21 USCS § 331(t)*] by--

(A) knowingly importing a drug in violation of section 801(d)(1) [*21 USCS § 381(d)(1)*],

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 503(c)(1) [*21 USCS § 353(c)(1)*],

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 503(c)(2) [*21 USCS § 353(c)(2)*], or

(D) knowingly distributing drugs in violation of section 503(e)(1) [*21 USCS § 353(e)(1)*],

shall be imprisoned for not more than 10 years or fined not more than $ 250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 301(t) [*21 USCS § 331(t)*] because of a violation of section 503(c)(1) [*21 USCS § 353(c)(1)*] or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 503(b) [*21 USCS § 353(b)*] or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $ 50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $ 1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 301(t) [*21 USCS § 331(t)*] because of a failure to make a report required by section 503(d)(3)(E) [*21 USCS § 353(d)(3)(E)*] shall be subject to a civil penalty of not more than $ 100,000.

(4) (A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 301(t) [*21 USCS § 331(t)*] because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 503(c)(1) [*21 USCS § 353(c)(1)*] or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence--

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 301(t) [*21 USCS § 331(t)*] because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 503(c)(1) [*21 USCS § 353(c)(1)*], such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $ 125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 804(b) [*21 USCS § 384(b)*] and knowingly fails to comply with a requirement of section 804(e) [*21 USCS § 384(e)*] that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than $ 250,000, or both.

(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 [*21 USCS § 351*] and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $ 1,000,000, or both.

(c) Exceptions in certain cases of good faith, etc. No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301(a) or (d) [*21 USCS § 331(a)*, (d)], if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a) [*21 USCS § 331(a)*], that such article is not adulterated or misbranded, within the meaning of this Act [*21 USCS §§ 301* et seq.], designating this Act, or to the effect, in case of an alleged violation of section 301(d) [*21 USCS § 331(d)*], that such article is not an article which may not, under the provisions of section 404 or 505 [*21 USCS § 344* or *355*], be introduced into interstate commerce; or (3) for having violated section 301(a) [*21 USCS § 331(a)*], where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary, under this Act [*21 USCS §§ 301* et seq.], if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act [*21 USCS §§ 301* et seq.]; or (4) for having violated section 301(b), (c) or (k) [*21 USCS § 331(b)*, (c) or (k)] by failure to comply with section 502(f) [*21 USCS § 352(f)*] in respect to an article received in interstate commerce to which neither section 503(a) [*21 USCS § 353(a)*] nor section 503(b)(1) [*21 USCS § 353(b)(1)*] is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 301(i)(2) [*21 USCS § 331(i)(2)*] if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) [*21 USCS § 331(i)(3)*] if the

person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food. No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 301 [*21 USCS § 331*] involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) [*21 USCS § 343(a)(2)*] because of its advertising.

(e) Prohibited distribution of human growth hormone.

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 505 [*21 USCS § 355*] and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, United States Code, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, United States Code, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under section 413 of such Act [*21 USCS § 853*].

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f) Violations related to devices.

(1) (A) Except as provided in subparagraph (B), any person who violates a requirement of this Act [*21 USCS §§ 301* et seq.] which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $ 15,000 for each such violation, and not to exceed $ 1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 704(g) [*21 USCS § 374(g)*] who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this Act [*21 USCS §§ 301* et seq.] that relates to devices.

(B) Subparagraph (A) shall not apply--

(i) to any person who violates the requirements of section 519(a) or 520(f) [*21 USCS § 360i(a)* or *360j(f)*] unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 519(e) or 519(g) [*21 USCS § 360i(e)* or (g)] (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 501(a)(2)(A) [*21 USCS § 351(a)(2)(A)*] which involve one or more devices which are not defective.

(2) (A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) [*21 USCS § 342(a)(2)(B)*] or any person who does not comply with a recall order under section 423 [*21 USCS § 350l*] shall be subject to a civil money penalty of not more than $ 50,000 in the case of an individual and $ 250,000 in the case of any other person for such introduction or delivery, not to exceed $ 500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 [*21 USCS § 334*] or the injunction authorities of section 302 [*21 USCS § 332*] with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B) [*21 USCS § 346a(g)(2)(B)*]. The third sentence of paragraph (5)(A) shall not apply to any investigation under this paragraph.

(3) (A) Any person who violates section 301(jj) [*21 USCS § 331(jj)*] shall be subject to a civil monetary penalty of not more than $ 10,000 for all violations adjudicated in a single proceeding.

(B) If a violation of section 301(jj) [*21 USCS § 331(jj)*] is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii) [of the Public Health Service Act] [*42 USCS § 282(j)(5)(C)(ii)*], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $ 10,000 for each day of the violation after such period until the violation is corrected.

(4) (A) Any responsible person (as such term is used in section 505-1 [*21 USCS § 355-1*]) that violates a requirement of section 505(o), 505(p), or 505-1 [*21 USCS § 355(o), 355(p), or 355-1*] shall be subject to a civil monetary penalty of--

(i) not more than $ 250,000 per violation, and not to exceed $ 1,000,000 for all such violations adjudicated in a single proceeding; or

(ii) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of $ 250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $ 1,000,000 for any 30-day period, and not to exceed $ 10,000,000 for all such violations adjudicated in a single proceeding.

(B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 505(o), 505(p), or 505-1 [*21 USCS § 355(o), 355(p), or 355-1*] for which the responsible person is subject to such civil penalty.

(5) (A) A civil penalty under paragraph (1), (2), (3), (4), or (9) shall be assessed, or a no-tobacco-sale order may be imposed, by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and *section 554 of title 5, United States Code*. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty, or upon whom a no-tobacco-sale order is to be imposed, under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, or the period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2), (3), (4), or (9). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.

(6) Any person who requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty or the imposition of a no-tobacco-sale order and who is aggrieved by an order assessing a civil penalty or the imposition of a no-tobacco-sale order may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued, or on which the no-tobacco-sale order was imposed, as the case may be.

(7) If any person fails to pay an assessment of a civil penalty--

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) [*21 USCS § 387f(d)*] at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone, or at the nearest regional or field office of the

Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

(9) Civil monetary penalties for violation of tobacco product requirements.

(A) In general. Subject to subparagraph (B), any person who violates a requirement of this Act [*21 USCS §§ 301* et seq.] which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $ 15,000 for each such violation, and not to exceed $ 1,000,000 for all such violations adjudicated in a single proceeding.

(B) Enhanced penalties.

(i) Any person who intentionally violates a requirement of section 902(5), 902(6), 904, 908(c), or 911(a) [*21 USCS § 387b(5), 387b(6), 387d, 387h(c),* or *387k(a)*], shall be subject to a civil monetary penalty of--

(I) not to exceed $ 250,000 per violation, and not to exceed $ 1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, $ 250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $ 1,000,000 for any 30-day period, and not to exceed $ 10,000,000 for all such violations adjudicated in a single proceeding.

(ii) Any person who violates a requirement of section 911(g)(2)(C)(ii) or 911(i)(1) [*21 USCS § 387k(g)(2)(C)(ii)* or *387k(i)(1)*], shall be subject to a civil monetary penalty of--

(I) not to exceed $ 250,000 per violation, and not to exceed $ 1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, $ 250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $ 1,000,000 for any 30-day period, and not to exceed $ 10,000,000 for all such violations adjudicated in a single proceeding.

(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.

(g) Violations relating to direct-to-consumer advertising

(1) With respect to a person who is a holder of an approved application under section 505 [*21 USCS § 355*] for a drug subject to section 503(b) [*21 USCS § 353(b)*] or under section 351 of the Public Health Service Act [*42 USCS § 262*], any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $ 250,000 for the first such violation in any 3-year period, and not to exceed $ 500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(4) [subsec. (f)(4) of this section]) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and *section 554 of title 5, United States Code*. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

(A) Whether the person submitted the advertisement or a similar advertisement for review under section 736A [*21 USCS § 379h-1*].

(B) Whether the person submitted the advertisement for review if required under section 503B [*21 USCS § 353b*].

(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period.

(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

(G) Whether the violations were material.

(H) Whether the person who created the advertisement or caused the advertisement to be created acted in good faith.

(I) Whether the person who created the advertisement or caused the advertisement to be created has been assessed a civil penalty under this provision within the previous 1-year period.

(J) The scope and extent of any voluntary, subsequent remedial action by the person.

(K) Such other matters, as justice may require.

(4) (A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused another party to disseminate such advertisement after incorporating each comment received from the Secretary.

(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owed by the United States to the person charged.

(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)--

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

HISTORY:

(June 25, 1938, ch 675, Ch. III, § 303, 52 Stat. 1043; Oct. 26, 1951, ch 578, § 2, 65 Stat. 649; July 12, 1960, P.L. 86-618, Title I, § 105(b), 74 Stat. 403; July 15, 1965, P.L. 89-74, §§ 7, 9(d), 79 Stat. 233, 235; Oct. 24, 1968, P.L. 90-639, § 3, 82 Stat. 1361; Oct. 27, 1970, P.L. 91-513, Title II, Part G, § 701(b), 84 Stat. 1281; April 22, 1976, P.L. 94-278, Title V, § 502(a)(2)(B), 90 Stat. 411; April 22, 1988, P.L. 100-293, § 7(b), 102 Stat. 99; Nov. 18, 1988, P.L. 100-690, Title II, Subtitle E, § 2403, 102 Stat. 4230; Nov. 28, 1990, P.L. 101-629, § 17(a), 104 Stat. 4526; Nov. 29, 1990, P.L. 101-647, Title XIX, § 1904, 104 Stat. 4853; Aug. 26, 1992, P.L. 102-353, § 3, 106 Stat. 941; Aug. 13, 1993, P.L. 103-80, § 3(e), 107 Stat. 775; Sept. 13, 1994, P.L. 103-322, Title XXXIII, § 330015, 108 Stat. 2146; Aug. 3, 1996, P.L. 104-170, Title IV, § 407, 110 Stat. 1535; Oct. 28, 2000, P.L. 106-387, § 1(a), 114 Stat. 1549; Oct. 26, 2002, P.L. 107-250, Title II, § 201(c), 116 Stat. 1609; Dec. 8, 2003, P.L. 108-173, Title XI, Subtitle C, § 1121(b)(2), 117 Stat. 2469; Sept. 27, 2007, P.L. 110-85, Title II, Subtitle B, § 226(b), Title VIII, § 801(b)(2), Title IX, Subtitle A, §§ 901(d)(4), 902(b), 121 Stat. 854, 920, 940, 943; June 22, 2009, P.L. 111-31, Div A, Title I, § 103(c), 123 Stat. 1835; Jan. 4, 2011, P.L. 111-353, Title II, § 206(c), 124 Stat. 3943.)

(As amended July 9, 2012, P.L. 112-144, Title VII, § 716, 126 Stat. 1075; Nov. 27, 2013, P.L. 113-54, Title II, § 207(a), 127 Stat. 640.)

*** Current through PL 114-156, approved 5/16/16 ***

TITLE 21. FOOD AND DRUGS
CHAPTER 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT
PROHIBITED ACTS AND PENALTIES

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21 USCS § 337

§ 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act [*21 USCS §§ 301* et seq.] shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b) (1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) [*21 USCS § 341*, *343(b)*, (c), (d), (e), (f), (g), (h), (i), (k), (q), or (r)] if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)--

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

HISTORY:

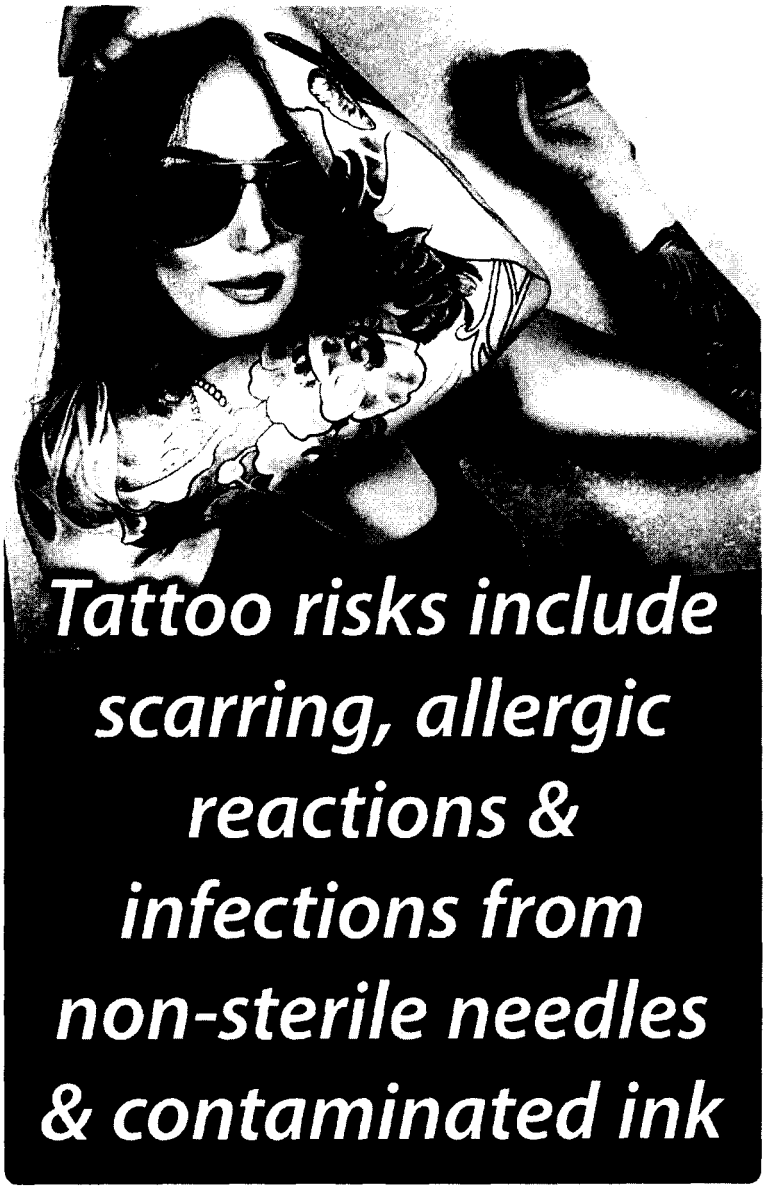
(June 25, 1938, ch 675, Ch. III, § 310 [307], 52 Stat. 1046; Sept. 3, 1954, ch 1263, § 37, 68 Stat. 1239; Nov. 8, 1990, P.L. 101-535, § 4, 104 Stat. 2362; May 13, 1992, P.L. 102-282, § 2, 106 Stat. 150.)

A Tattoo for You? Seven Key Questions to Consider

There are many tattooed Americans. Surveys estimate that about one in five Americans now has at least one.

And with the rising popularity of tattoos, the Food and Drug Administration (FDA) is also seeing an increase in reports of people developing infections from contaminated tattoo inks, as well as having bad reactions to the inks themselves, according to Linda Katz, M.D., M.P.H., director of FDA's Office of Cosmetics and Colors.

Before you get a tattoo, consider these seven important questions (as answered by Dr. Katz):



1. Should I be concerned about non-sterile needles, or the ink itself?

Both. While it's true that you can get infections from unhygienic practices and equipment that isn't sterile, in the last several years there have been cases in which people got infections because the ink itself was contaminated with microorganisms, such as bacteria and mold introduced either at the time of manufacture or at the tattoo parlor. Using non-sterile water to dilute the pigments is a common culprit, although not the only one.

There's no sure-fire way to tell if the ink is safe. Just looking at it or smelling it won't tell you if it's contaminated. An ink can be contaminated even if the container is sealed or wrapped, or the label asserts the product is sterile. In fact, ink could become contaminated at any point in the production process.

State, county or local health departments oversee the operation of tattoo parlors. In situations in which firms recall tattoo inks, FDA is often involved in alerting firms to problems related to their inks and working with the firms to make sure

recalls are effective. FDA also alerts the public when it becomes aware of a public health concern.

2. What does FDA know about inks?

The information the agency has about inks is limited. But FDA is analyzing tattoo inks and pigments for contaminants, heavy metals, degradants, potentially toxic chemicals—including pH stabilizers, microbicides and coating agents—and other materials that are not intended to be placed into the body. There are reports in the published scientific literature of tattoo inks that contain everything from pigments used in printer toner to pigments used in car paint.

3. What about do-it-yourself tattoo inks and kits?

Inks and kits sold online to consumers have been associated with reports of infection or allergic reaction. The agency is also concerned that, unlike most licensed tattoo artists, consumers will not have sufficient knowledge or the means to control and avoid all possible sources of contamination and subsequent infections in the process of giving themselves a tattoo.

4. What kinds of reactions have been seen with tattoos?

You might notice a rash—redness or bumps—in the area of your tattoo, and you could develop a fever. Serious infections can require months of treatment with a variety of antibiotics. More virulent or aggressive infections may be associated with high fever, shaking, chills, and sweats. If these symptoms arise, you may need antibiotics, hospitalization and/or surgery. Your physician or other health care professional will make that determination.

If you have an allergic reaction, the exact cause may be hard to pinpoint. You could have an allergic reaction to a pigment (one of the ingredients that add color to the ink) or to a diluent (the liquid used to dilute the pigments). Or you could have a reaction to a contaminant that got into the ink during manufacturing.

And because the inks are permanent, the reaction may persist.

5. If I get a tattoo and develop an infection or other reaction, what should I do ?

Three things: First, contact your doctor or other health care professional.

Second, notify the tattoo artist. That way he or she can identify the ink that was used, and avoid using it again. Plus, you can ask the tattoo artist for detailed information on the brand, color, and any lot or batch information that may be useful in determining the source of the problem and how to treat it.

Third, report the problem to FDA. FDA urges consumers, tattoo artists, and even health care professionals to report tattoo-related problems to FDA. Here's how:

- You can report a problem by contacting FDA's Medwatch Program online or by calling 1-800-FDA-1088 (*https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home*)
- You can also contact the FDA district office consumer complaint coordinator for your geographic area (*http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/ucm2008077.htm*).

Provide as much detail as possible about the ink and your reaction and outcome. Reports from consumers are one of our most important sources of safety information.

6. What about later on? Could other problems occur?

Although research is ongoing at FDA and elsewhere, there are still a lot of questions the research hasn't answered yet. These include questions about the long-term effects of the pigments, other ingredients, and possible contaminants in tattoo ink.

Then there's the question of tattoo removal. We know that people have laser treatments to remove tattoos, but we don't know the short- or long-term consequences of how the pigments break down after laser treatment. However, we do know that there may be permanent scarring from some of the tattoo removal procedures.

7. What's the bottom line?

Think before you ink. Because of all the unknowns described above, this is not a decision to be made without careful consideration.

This is especially important because, despite advances in laser technology, removing a tattoo is a painstaking process and complete removal without scarring may be impossible.

If you do decide to get a tattoo, make sure the tattoo parlor and artist are in compliance with all state and local laws. The National Conference of State Legislatures has a Web page on state laws, statutes and regulations governing tattooing and body piercing. For information on local regulations, contact your county or city health department. FDA

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SUPREME COURT NO. _____
COURT OF APPEALS NO. 73225-1-I

IN THE SUPREME COURT OF THE STATE OF WASHINGTON

ANNA CHESTER,

Petitioner,

vs.

DEEP ROOTS ALDERWOOD, LLC, a Washington company; and BONNIE GILSON,

Respondents.

ON APPEAL FROM THE SUPERIOR COURT
OF THE STATE OF WASHINGTON FOR SNOHOMISH COUNTY

CERTIFICATE OF SERVICE

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The undersigned certifies that on the 2nd day of June 2016, she caused to be filed via legal messenger to the Court of Appeals, Division I, one original and one copy of the following documents:

- Deep Roots Alderwood, LLC's Answer to Anna Chester's Petition for Review
- Appendix
- Certificate of Service

and served, via legal messenger, two copies of the same on all parties of record, identified as follows:

Counsel for Anna Chester
George M. Ahrend
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and served, via U.S. Mail, postage prepaid, one courtesy copy on the following:

Papillon Studio Supply and MRG, Inc.
118 Pearl Street
Enfield, Connecticut 06082

I certify under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct this 2nd day of June 2016.

Laura K. Criss

Laura K. Criss, Paralegal

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Subject: RE: Chester v Deep Roots et al - Supreme Court Case Number 931887

Received 6/3/2016.

Supreme Court Clerk's Office

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Subject: Chester v Deep Roots et al - Supreme Court Case Number 931887

Hello Ms. Carlson:

We understand the Supreme Court assigned the case number (931887) to this matter today.
Per request, please see the attached courtesy copy of the documents filed with the Appeals Court, Division I yesterday. Thank you.

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