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I. INTRODUCTION

The notion of addressing the vagaries of negligence per se theories in the context of pharmaceutical and medical device litigation seems to promise little more than a monograph anesthetized by a body of obscure pharmaceutical and medical device provisions viewed through the lenses of various states' negligence law. Maybe little more than that can be assured. However, the issue of how courts should address negligence per se theories in this context implicates a variety of "larger" (or, possibly, more interesting) legal issues in general and pharmaceutical and medical device litigation in particular. Perhaps foremost among these issues is the interaction of legislative intent and judicial deference to that intent. Possibly no less important (and, likely, more common) an issue is the application of a regulatory body's judgment and how that judgment should be treated—whether it should be given the status of law on par with that of the legislature's judgment and, if so, whether a judge or jury should second-guess those judgments.

The statutory and regulatory requirements for drug approval in the United States present many potential traps for the wary and unwary alike. The potential pitfalls vary in number and type. The Federal Food, Drug, and Cosmetic Act (FDCA), the Medical Device Amendments (MDA), and supporting Federal Food and Drug Administration (FDA) regulations present not only the opportunity to incur fines and criminal penalties,[1] but also (unsurprisingly), the possibility of civil liability for injuries caused by any violations. The word "possibility" is important. The FDCA expressly states that all proceedings for violations of its provisions "shall be by and in the name of the United States."[2] That is, there is no private right of action for violations of the FDCA. State and federal courts, however, have permitted private actions for violations of the FDCA, the MDA, and FDA regulations to proceed under the guise of a variety of theories,[3] including negligence per se. The Supreme Court addressed this issue tangentially when it determined that a negligence per se theory based on alleged violations of the FDCA does not enjoy federal question subject matter jurisdiction.[4] The Court, however,

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1. *See generally* Erica L. Niezgoda & Maureen M. Richardson, *Federal Food and Drug Act Violations*, 35 AM. CRIM. L. REV. 767 (1998) (describing criminal violations of the FDCA and FDA's enforcement efforts against individuals and corporations).

2. 21 U.S.C. § 337(a) (2000).

3. *See generally* Richard M. Cooper, *Regulation Through Private Litigation*, 47 FOOD DRUG L.J. 437 (1992) (observing the ways in which "violations of food and drug law requirements can be costly to a party in private litigation," through products liability claims, Lanham Act/false advertising claims, and trademark infringement).

4. *See* Merrell Dow Pharms., Inc. v. Thompson, 478 U.S. 804, 805-06, 809-10 (1986).

did not decide (and, in all likelihood, should not have decided) whether such an allegation was viable *ab initio*. In fact, the Court only conceded that "Congress did not intend a *private* federal remedy for violations of the [FDCA]."[5] The result is that, from state to state,[6] and even between state courts within the same state[7] and federal[8] courts within the same state, there is disagreement on the propriety of these provisions defining the standard of care for a negligence per se cause of action. Although courts start from common doctrinal foundations, each state has its own gloss on the elements of a negligence per se cause of action; each gloss differs in terms of its constitutive elements and the emphasis courts place on them. With respect to the FDCA, the MDA, and FDA regulations, further, courts would apply these elements differently depending on what provision is alleged to support the negligence per se theory asserted. Fundamentally, however, permitting a negligence per se theory to proceed in this context, in effect, creates a private right of action based on the FDCA and related provisions by grafting those provisions onto a common law negligence theory.

This Article addresses the propriety of basing a negligence per se cause of action on violations of the FDCA, the MDA, and FDA regulations. Part II describes the purpose, elements, and features of negligence per se in general, with a secondary emphasis on how these principles interact with pharmaceutical and medical device product liability claims. Part III addresses apparently conflicting legislative intent between the purpose of the FDCA and intent to foreclose a private right of action based on the FDCA. The courts that permit a negligence per se claim to proceed in this context do so, largely, on the basis that it furthers the purpose of the FDCA and MDA, which is to protect those who use drugs and medical devices. Those courts, however, overlook express legislative intent by neglecting the fact that when Congress explicitly prohibited a private right of action for violations of the FDCA, Congress intended exactly what it said. Claimants should not be permitted to end-run congressional intent through a negligence per se cause of action.

Part IV analyzes the issue of the nature of the requirements in the FDCA, the MDA, and FDA regulations and how the nature of the provision at issue impacts

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5. *Id.* at 811 (emphasis added).

6. *See* O'Donnell v. Elgin, J. & E. Co., 338 U.S. 384, 389-90 (1949) (noting "the diversity of judicial opinion concerning the consequences attributed in negligence actions to the violation of a statute").

7. *Compare* Armstrong v. Optical Radiation Corp., 57 Cal. Rptr. 2d 763, 772 (Cal. Ct. App. 1996) (holding that the MDA does not preempt a negligence per se claim), *and* Evraets v. Intermedics Intraocular, Inc., 34 Cal. Rptr. 2d 852, 859 (Cal. Ct. App. 1994) (holding that to permit a negligence per se claim in the MDA context does not transgress the statutory ban on private rights of action and finding that the negligence per se claim is not preempted), *with* Scott v. CIBA Vision Corp., 44 Cal. Rptr. 2d 902, 911-12 (Cal. Ct. App. 1995) (upholding summary judgment that dismissed plaintiff's negligence per se claim and expressly disagreeing with *Evraets*), *and* Powers v. Optical Radiation Corp., 44 Cal. Rptr. 2d 485, 490-91 (Cal. Ct. App. 1995) (unpublished) (holding that, in this context, to permit a negligence per se claim to proceed would be tantamount to creating a private right of action for violations of the FDCA).

8. *Compare* Valente v. Sofamore, S.N.C., 48 F. Supp. 2d 862, 876 (E.D. Wis. 1999) (allowing a negligence per se claim based on alleged violations of the MDA), *and* Lukaszewicz v. Ortho Pharm. Corp., 510 F. Supp. 961, 964-65 (E.D. Wis. 1981) (allowing a claim of negligence per se based on a pharmaceutical company's failure to warn about a drug's side effects), *amended by*, 532 F. Supp. 211 (E.D. Wis. 1981), *with* Cali v. Danek Med., Inc., 24 F. Supp. 2d 941, 954 (W.D. Wis. 1998) (holding that the absence of any legislative intent that the FDCA be a basis for civil liability precludes a negligence per se theory based thereon).

whether it can appropriately define the standard of care. Courts that view these requirements as "safety" provisions (those meant to set standards) tend to be inclined to find a negligence per se theory based on them to be appropriate. Courts that view these provisions as administrative in nature (ministerial), however, are less inclined to permit a negligence per se theory to proceed. Courts that address this issue largely (and necessarily) do so depending on what specific statutory or regulatory provision is at issue, and whether that provision can be characterized as providing a safety standard or an administrative requirement. Part V addresses the issue of whether the FDCA, the MDA, and FDA regulations are sufficiently clear and specific to serve to define the applicable standard of care. Part V addresses the myriad of issues implicated by allowing FDA regulations to support a negligence per se theory. These issues include concern over the authority and accountability of an unelected body essentially serving a legislative function, whether FDA rules and regulations warrant deference from the judiciary due to the FDA's expertise (and, therefore, compensate for the perceived lack of authority to "make law" and absence of accountability), the propriety of the regulatory compliance defense, the FDA's independence, and the practical implications of making the FDA regulations and decisions fodder for civil liability.

This Article concludes that, if negligence per se is intended to represent judicial deference to legislative judgments and intent, then such theories are wholly inappropriate in pharmaceutical and medical device litigation. On the regulatory front, use of this theory to give lay judges and juries license to review and second-guess an FDA ruling or refusal to make a ruling risks superimposing potentially (or, perhaps, necessarily) inconsistent state tort regimes on the efforts to regulate the pharmaceutical and medical device industry. Short of a prohibition of these theories in this context, however, use of negligence per se theories should be severely restricted to situations in which (1) the court has determined that the specific provision is appropriate to support the imposition of civil liability, (2) the FDA has determined that a defendant violated a specific provision, and (3) the plaintiff proves that the violation caused his or her injury.

II. NEGLIGENCE PER SE

Negligence per se is a legal doctrine by which a court adopts a legislative enactment or administrative regulation to define the standard of care.[9] As Justice

9. *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 286 (1965); Myers v. United States, 17 F.3d 890, 899 (6th Cir. 1994) (observing that the doctrine of negligence per se does not operate "as a means of deciding when a duty of care arises, but rather as a means of defining the particular standard of conduct such a duty requires"). Not all states recognize the doctrine of negligence per se. "The doctrine of negligence per se has never been adopted in Louisiana and that is not a viable cause." Hayes v. State *ex. rel* Dep't of Pub. Safety, 798 So. 2d 148, 150 (La. Ct. App. 2001). In Vermont, courts do not regularly permit negligence per se claims to stand but, rather, treat statutory violations as a rebuttable presumption of negligence. *See, e.g.*, Wilkinson v. Russell, 182 F.3d 89, 99 (2d Cir. 1999) (citing Marzec-Gerroir v. D.C.P. Indus., Inc., 674 A.2d 1248 (Vt. 1995) (Dooley, J., concurring)). Other states do not recognize a negligence per se claim but will admit evidence of statutory violations as evidence of negligence. *See, e.g.*, Jackson v. United States, 156 F.3d 230, 234 (1st Cir. 1998) (applying West Virginia law) (citing Waugh v. Traxler, 412 S.E.2d 756, 759-60 (W. Va. 1991); Miller v. Warren, 390 S.E.2d 207, 208-09 (W. Va. 1990)); Elliott v. S.D. Warren Co., 134 F.3d 1, 5 (1st Cir. 1998) (applying Maine law) (citing French v. Willman, 599 A.2d 1151, 1152 (Me. 1991)). These holdings are similar to

Cardozo observed, violation of such a provision "is more than some evidence of negligence. It is negligence in itself."[10] According to Professors Prosser and Keeton, a court adopts a statute "out of deference and respect for the legislature."[11] Broadly speaking, applicability of negligence per se requires proof of the following: (1) violation of a statute or regulation; (2) the plaintiff is among the class of people for whose particular benefit the statute or regulation had been enacted; (3) recognition that a private right of action would promote the legislative purpose behind the statute or regulation; and (4) creation of the right would be consistent with the overall legislative scheme.[12] If the purpose of the statute or regulation is to protect a particular class of persons or set of interests, the claimant must fall within that class or have had those interests violated to state a viable negligence per se theory.[13] In many states, importantly, statutes or regulations intended for the protection of the community or the public at large create only an obligation to the state and, therefore, are not appropriate to define the applicable standard of

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those in which courts find that, if a claimant cannot prove a negligence per se cause of action, it can adduce evidence of the statutory or regulatory violation as evidence of negligence. *See, e.g.*, Campbell v. Keystone Aerial Surveys, Inc., 138 F.3d 996, 1002-03 (5th Cir. 1998) (applying Texas law).

10. Martin v. Herzog, 126 N.E. 814, 815 (N.Y. 1920) (emphasis omitted).

11. W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 36, at 222 (5th ed. 1984) (citing Rudes v. Gottschalk, 324 S.W.2d 201 (Tex. 1959)); *see also* Perez v. United States, 167 F.3d 913, 919 (5th Cir. 1999) ("[T]he negligence per se doctrine borrows statutory law in deference to the decisions of legislatures and administrative agencies . . . ."); David C. Sobelsohn, *Comparing Fault*, 60 IND. L.J. 413, 417 (1985). A real question exists as to whether, and to what extent, courts should afford this deference to regulatory bodies. *Cf.* RESTATEMENT (SECOND) OF TORTS § 285 cmt. b (stating that both statutes and regulations can be adopted to define the applicable standard of care, but observing that adoption of regulations is "comparatively infrequent"). *See* discussion *infra* Part V.A.1.

12. *See, e.g.*, Martin v. Shell Oil Co., 180 F. Supp. 2d 313, 324 (D. Conn. 2002); Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 448 (W.D.N.Y. 2001); Alexander v. Smith & Nephew, P.L.C., 98 F. Supp. 2d 1276, 1285 (N.D. Okla. 2000); Ward v. Presbyterian Healthcare Servs., 79 F. Supp. 2d 1276, 1278 (D.N.M. 1999); Jordan v. City of Philadelphia, 66 F. Supp. 2d 638, 644 (E.D. Pa. 1999); Short v. Ultramar Diamond Shamrock, 46 F. Supp. 2d 1199, 1200 (D. Kan. 1999); Ponthieux v. Danek Med., Inc., No. 96-3141, 95-2542, 1999 WL 33486689, at *9 (W.D. Tenn. May 28, 1999); Thomas v. McDonald, 667 So. 2d 594, 597 (Miss. 1995). This general description, of course, glosses over a host of subtle and not-so-subtle differences with respect to how states characterize and evaluate negligence per se causes of action. With respect to the first element, the *Restatement* identifies four purposes underlying the statute or regulation: (1) to protect a class of persons; (2) to protect a particular interest; (3) to protect a particular interest against a kind of harm; and (4) to protect a particular interest against a particular hazard. RESTATEMENT (SECOND) OF TORTS § 286 (1965). The Texas Supreme Court identified five factors to consider when determining whether tort liability attaches for the violation of a particular statute:

> (1) whether the statute is the sole source of any tort duty from the defendant to the plaintiff or merely supplies a standard of conduct for an existing common-law duty; (2) whether the statute puts the public on notice by clearly defining the required conduct; (3) whether the statute would impose liability without fault; (4) whether negligence per se would result in ruinous damages disproportionate to the seriousness of the statutory violation . . . ; and (5) whether the plaintiff's injury is a direct or indirect result of the violation of the statute.

Perry v. S.N., 973 S.W.2d 301, 309 (Tex. 1998). These factors are not exclusive and the issue is not resolved by a simple tally of how many factors fall in each direction. *Id.* at 306.

13. RESTATEMENT (SECOND) OF TORTS § 286 cmt. f (1965).

care.[14] Other courts, however, place considerable emphasis on the intent to protect the community or public at large and will defer to that intent to decide that a particular statute or regulation should define the standard of care.[15] In the products liability context, importantly, the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY provides that, in the context of marketing or design defect strict liability claims, failure to comply with an applicable statute or regulation renders that product defective per se.[16]

It is important to emphasize that, in two respects, violation of a statute or regulation does not relieve the claimant of having to prove the other elements of its negligence claim. First, "[n]egligence *per se* lessens the plaintiff's burden only on the issue of the 'actor's departure from the standard of conduct required of a reasonable man.'"[17] Acceptance of a statutory or regulatory violation for a negligence per se theory simply defines the standard of care or duty that a defendant owes the plaintiff. Therefore, the claimant must prove the breach of that standard and causation. That is, the claimant must show that the violation of the statute or regulation was a proximate cause of the claimed injury.[18] In the context of violations of the FDCA, the MDA, and FDA regulations, in fact, many courts have avoided the issue of whether those provisions are appropriate to define the standard of care and have instead ruled that no causation was present even if these provisions were appropriate fodder for such a theory.[19] Second, violation of a statute or regulation does not create absolute liability because such a violation can

14. *See, e.g.*, 325-343 E. 56th Street Corp. v. Mobil Oil Corp., 906 F. Supp. 669, 687 (D.D.C. 1995); Rollo v. City of Kansas City, Kansas, 857 F. Supp. 1441, 1448 (D. Kan. 1994); Federal Sav. & Loan Ins. Corp. v. Musacchio, 695 F. Supp. 1053, 1065 (N.D. Cal. 1988); Thomas Learning Ctr., Inc. v. McGuirk, 766 So. 2d 161, 171 (Ala. Civ. App. 1998) ("'When a statute impose[s] a duty for the public at large . . . [a]ny individual injured . . . would acquire no new right by virtue of the enactment of the statute[].'" (quoting Flint City Nursing Home, Inc. v. Depreast, 406 So. 2d 356, 360 (Ala. 1981))); Lingle v. Dion, 776 So. 2d 1073, 1077 (Fla. Dist. 2001) (stating that violation of such a statute "constitutes evidence of negligence and not negligence per se" (citation omitted)); Grube v. Daun, 563 N.W.2d 523, 528 (Wis. 1997); RESTATEMENT (SECOND) OF TORTS § 288 cmt. b (1965).

15. *See, e.g.*, Martel v. Mont. Power Co., 752 P.2d 140, 145 (Mont. 1988); Harden v. Danek Med., Inc., 985 S.W.2d 449, 452 (Tenn. Ct. App. 1998). *See* discussion *infra* Part III.A.

16. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(a) (1998).

17. Ahles v. Tabor, 34 P.3d 1076, 1078 (Idaho 2001) (quoting RESTATEMENT (SECOND) OF TORTS § 288B cmt. b (1965)).

18. *See, e.g.*, Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 448 (W.D.N.Y. 2001); Scott v. Matlack, Inc., 39 P.3d 1160, 1166 (Colo. 2002); Ahles v. Tabor, 34 P.3d at 1078 (stating that negligence per se "lessens the plaintiff's burden only on the issues of the actor's departure from the standard of conduct required of a reasonable man" (internal citations and quotations omitted)); Sikora v. Wenzel, 727 N.E.2d 1277, 1281 (Ohio 2000) ("Negligence *per se* . . . is not equivalent to a finding of liability *per se* because the plaintiff will also have to prove proximate cause . . . ." (internal quotations and citations omitted)). *But see* Insolia v. Philip Morris Inc., 216 F.3d 596, 604 (7th Cir. 2000) (applying Wisconsin law for the proposition that, unlike a negligence claim, a negligence per se claim does not require the claimant to prove foreseeability).

19. *See, e.g.*, Kipp v. United States, 88 F.3d 681, 685 (8th Cir. 1996) ("Because [plaintiff] failed to prove causation, we need not discuss the other issues pertaining to his negligence claims."); Monson v. Acromed Corp., No. 96-C-1336, 1999 WL 1133273, at *21 (E.D. Wis. May 12, 1999) ("There is a conflict among the Wisconsin district courts as to whether there is a cause of action under the MDA, but the court need not address the issue since the causation issue is dispositive of the plaintiff's negligence *per se* claim."); Parks v. Danek Med., Inc., No. 2:95

be excusable.[20] That is, a party's violation may be justifiable and therefore excusable based on, *inter alia*, lack of knowledge of the failure to comply,[21] the fact that the party did everything reasonably possible to comply with the law,[22] or the fact that the party was compelled to action or inaction due to an emergency.[23] The RESTATEMENT (SECOND) OF TORTS provides a non-exclusive list of these and other excuses that apply to negligence per se claims generally.[24] Although these excuses have been considered in the products liability context,[25] they may be short-lived under the RESTATEMENT (THIRD) (to the extent it anticipates and does not simply "restate" the law).[26] The RESTATEMENT (THIRD) does not recognize any excuse

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CV 206, 1999 WL 1129706, at *11 (N.D. Ind. June 17, 1999) ("Assuming that Indiana would recognize a negligence *per se* action based upon violations of the FDCA, and also assuming that such a violation has occurred, it is clear that [the plaintiff] cannot establish the element of proximate causation."); Arinder v. Danek Med., Inc., No. 1:95-CV-326-B-D, 1999 WL 1129647, at *4 (N.D. Miss. June 21, 1999); Jones v. Danek Med., Inc., No. Civ.A. 4:96-3323-12, 1999 WL 1133272, at *6 (D.S.C. Oct. 12, 1999); Harden v. Danek Med., Inc., 985 S.W.2d 449, 453 (Tenn. Ct. App. 1998) ("Assuming *arguendo* that FDCA violations could be the basis for a negligence per se action .... [and a]ssuming defendant did breach § 360, such breach was not the proximate cause of plaintiff's injuries."). In *Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999), although the Fourth Circuit held that the FDCA and FDA regulations at issue cannot define the standard of care for a negligence per se violation, it also held that the alleged violation had no causal relationship to the alleged injury. *Id.* at 159-60. *See also* Uribe v. Sofamor, S.N.C., No. 8:95CV464, 1999 WL 1129703, at *16 (D. Neb. Aug. 16, 1999) (agreeing with *Talley* that the FDCA provisions and FDA regulations at issue cannot define the standard of care, and also holding that plaintiff failed to demonstrate causation, "an essential element of a negligence per se claim"); Menges v. Depuy Motech, Inc., 61 F. Supp. 2d 817, 829 (N.D. Ind. 1999) (applying Wisconsin law for the proposition that alleged violations of the FDCA can support a claim for negligence per se, but stating that the claim fails because the plaintiff failed to prove proximate cause); Valente v. Sofamor, S.N.C., 48 F. Supp. 2d 862, 876-77 (E.D. Wis. 1999) (permitting plaintiff's negligence per se claim based on alleged violations of certain MDA provisions, but dismissing this claim due to the plaintiff's failure to raise an issue of fact with respect to causation); Moses v. Danek Med., Inc., No. CV-S-95-512 PMP RLH, 1998 WL 1041279, at *6 (D. Nev. Dec. 11, 1998) (failing to consider whether alleged violations of the MDA could support a negligence per se claim, assuming a violation for the sake of argument, but finding no evidence of causation); Huntman v. Danek Med., Inc., No. 97-2155-IEG RBB, 1998 WL 663362, at *7 (S.D. Cal. July 24, 1998) (casting causation as "reliance" on the alleged statutory violation and finding it absent).

20. *See, e.g.*, Chen v. United States, 854 F.2d 622, 627 (2d Cir. 1988) (applying New York law); Stanton v. Astra Pharm. Prods., 718 F.2d 553, 564-65 (3d Cir. 1983) (applying Pennsylvania law); Abarca v. Chevron USA, Inc., 75 F. Supp. 2d 566, 571 (E.D. Tex. 1999); Chadbourne v. Kappaz, 779 A.2d 293, 295 (D.C. 2001); Weiss v. Bal, 501 N.W.2d 478, 481 (Iowa 1993); Sikora v. Wenzel, 727 N.E.2d at 1281; Carter v. William Sommerville & Son, Inc., 584 S.W.2d 274, 278 (Tex. 1979).

21. *See, e.g.*, Stanton v. Astra Pharm. Prods., 718 F.2d at 564-65; Sikora v. Wentzel, 727 N.E.2d at 1279.

22. Chadbourne v. Kappaz, 779 A.2d at 295-96; Impson v. Structural Metals, Inc., 487 S.W.2d 694, 696 (Tex. 1972) (citing RESTATEMENT (SECOND) OF TORTS § 288A (1965)).

23. *See, e.g.*, Totsky v. Riteway Bus Serv., Inc., 607 N.W.2d 637, 645 (Wis. 2000) (referring to this excuse as "the emergency doctrine"); Weiss v. Bal, 501 N.W.2d at 479-80 (observing that legal excuse is not the same as sudden emergency, as "[s]udden emergency may be an element of legal excuse with respect to statutory violations, but it also has independent significance in common-law claims").

24. RESTATEMENT (SECOND) OF TORTS § 288A (1965).

25. *See, e.g.*, Stanton v. Astra Pharm. Prods., Inc., 718 F.2d at 564-65 (recognizing the validity of these defenses but upholding the jury's refusal to find that they absolved the defendant of liability).

26. *See* James A. Henderson, Jr. & Aaron D. Twerski, *The Products Liability Restatement in the Courts: An Initial Assessment*, 27 WM. MITCHELL L. REV. 7, 31 (2000).

or justification defense because a manufacturer "has the option of deferring sale until statutory or regulatory compliance is achieved."[27]

Another important feature of a negligence per se theory in this context is that it is not the equivalent of strict liability. The RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, on the contrary, provides that violation of a statute or regulation renders a product defective per se (perhaps best described as "strict liability per se").[28] There is a significant difference between the foundations of negligence per se and strict liability per se theories. A traditional negligence per se theory focuses on the defendant's conduct; whereas the RESTATEMENT (THIRD)'s strict liability per se theory ostensibly ignores conduct and focuses on the product vis-à-vis the legal requirements.[29] The distinction is not academic, especially depending upon the jurisdiction, as some jurisdictions apply comparative fault principles to strict products liability claims based upon this analogy,[30] while others reject any comparison to support the application of comparative fault principles to strict liability claims.[31]

III. SUPPORTING THE PURPOSE OF THE FDCA THROUGH PRIVATE ENFORCEMENT V. LEGISLATIVE INTENT TO FORECLOSE PRIVATE ENFORCEMENT

The elements and permutations of a cause of action for negligence per se aside, the threshold question is and should be whether a particular statute or regulation should serve as the basis for the imposition of civil liability. With respect to a statute that expressly provides a private right of action, the answer to this question is relatively clear. For statutes that do not create a private right of action, such as the FDCA, the answer to this question is not as clear. The FDCA expressly provides that all enforcement proceedings for violations "shall be by and in the name of the United States."[32] Many courts have observed that duties set forth in laws and regulations "'do not . . . automatically create duties cognizable under *local tort law*.'"[33] As a result, courts are largely free to determine whether to allow a par-

27. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. d (1998).

28. *Id.* § 4(a). *See also* Duncan v. Cessna Aircraft Co., 665 S.W.2d 414, 426 (Tex. 1984) (stating that "strict liability is closely analogous to negligence per se"); Dippel v. Sciano, 155 N.W.2d 55, 64-65 (Wis. 1967) (applying comparative negligence statute to strict products liability claim on the grounds that a strict products liability claim is analogous, if not identical, to a negligence per se claim).

29. *See* Sobelsohn, *supra* note 11, at 427-28. The excuses identified in the RESTATEMENT (SECOND) OF TORTS (and expressly rejected in the strict liability discussion in the RESTATEMENT (THIRD)), with their focus on necessity or efforts to avoid violating a statute or regulation, further reinforce the distinction between negligence per se and strict liability per se.

30. *See, e.g.*, Fiske v. MacGregor, 464 A.2d 719, 727 (R.I. 1983); Star Furniture Co. v. Pulaski Furniture Co., 297 S.E.2d 854, 861-62 (W. Va. 1982).

31. *See, e.g.*, Murray v. Fairbanks Morse, 610 F.2d 149, 157-58 (3d Cir. 1979) (applying Virgin Islands law); Kimco Dev. Corp. v. Michael D's Carpet Outlets, 637 A.2d 603, 605-06 (Pa. 1993); Fuchsgruber v. Custom Accessories, Inc., 628 N.W.2d 833, 836 (Wis. 2001).

32. 21 U.S.C. § 337(a) (2000).

33. Johnson v. Sawyer, 47 F.3d 716, 729 (5th Cir. 1995) (en banc) (quoting Art Metal-U.S.A., Inc. v. United States, 753 F.2d 1151, 1158 (D.C. Cir. 1985)). *See also* Talley v. Danek Med., Inc., 179 F.3d 154, 158 (4th Cir. 1999) (stating that negligence per se "is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute"); *In re* Silicone Gel Breast Implant Prods. Liability Litig., 318 F. Supp. 2d 879, 902 (C.D. Cal. 2004) ("What the FDA requires a medical device manufacturer to do is not the *per se* standard for determining what that manufacturer's duty is in a state law negligence case."); Short v. Ultramar Diamond Shamrock, 46 F. Supp. 2d 1199, 1200 (D. Kan. 1999).

ticular statute or regulation to be the basis for a negligence per se cause of action.[34]

A. Permitting a Negligence Per Se Claim Does Not Create a Private Right of Action but Supports the Underlying Purpose of the FDCA

The RESTATEMENT (SECOND) OF TORTS clearly contemplates that a statute may not provide for civil liability but still be appropriate to define the standard of care.[35] Similarly, the Sixth Circuit recognized that "a mere congressional intent to preclude a private right of action at the federal level for violations of the FDCA would not necessarily indicate that Congress intended to preclude a state remedy under a theory of negligence per se."[36] A paradox exists, in fact, in which providing for a private right of action could simply make a negligence per se cause of action redundant (except, in the case of federal statutes, for the party seeking to prevent removal based on federal question subject-matter jurisdiction).

Many courts decline to recognize that permitting a negligence per se claim to proceed in this context creates a private right of action. As a California appellate court observed, simply, "[w]e perceive a difference between suing directly on the FDCA statutes and regulations and suing on a state law theory which incorporates the federal law as a standard of conduct."[37] The Alabama Supreme Court has also held that to permit a negligence per se claim based on alleged violations of the FDCA does not create a cause of action under the FDCA but, rather, merely establishes a standard of care.[38] As such, permitting a negligence per se theory does not transgress section 337(a)'s prohibition on private enforcement of the FDCA.[39] The U.S. District Court for the Northern District of Illinois has held similarly, suggesting that such a theory does not even implicate section 337(a): "[plaintiff] relies on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet. Nothing prohibits [plaintiff] from using the FDCA or its accompanying regulation in that fashion."[40] An Oregon appellate court

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34. RESTATEMENT (SECOND) OF TORTS § 286 cmt. d (1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e (1998).

35. *See* RESTATEMENT (SECOND) OF TORTS § 286 cmt. d (1965); *see also* Coastline Terminals, Inc. v. USX Corp., 156 F. Supp. 2d 203, 210 (D. Conn. 2001) ("The statutory basis for a negligence *per se* claim need not provide for a private right of action."); Sharp v. Artifex, Ltd., 110 F. Supp. 2d 388, 392 (W.D. Pa. 1999).

36. *In re* Benedictin Litig., 857 F.2d 290, 314 (6th Cir. 1988). Perhaps trying to equivocate, however, the court did note that "the congressional decision not to provide a private cause of action under the FDCA becomes quite important in considering the propriety of a state negligence per se action for violation of the FDCA." *Id.* The Sixth Circuit did not decide this issue. *Id.* at 313.

37. Evraets v. Intermedics Intraocular, Inc., 34 Cal. Rptr. 2d 852, 859 n.6 (Cal. Ct. App. 1994).

38. Allen v. Delchamps, Inc., 624 So. 2d 1065, 1067-68 (Ala. 1993) (conceding that the FDCA does not create a private right of action).

39. *Id.* at 1068.

40. Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 716 (N.D. Ill. 1989) (citing Orthopedic Equip. Co. v. Eutsler, 276 F.2d 445, 460 (4th Cir. 1960)); *see also* Loewy v. Stuart Drug & Surgical Supply, Inc., No. Civ. 91-7148 (LBS), 1999 WL 216656, at *2 (S.D.N.Y. April 14, 1999) ("Plaintiff seeks to recover for the common law tort of negligence and to use any MDA violations as proof that Stuart breached its duty of care. Importing the MDA standards in this way does not expand the universe of individuals to whom [defendant] owes an obligation, it simply helps to define the scope of the duty owed to the individuals already entitled to some degree of protection.") (citing Practico v. Portland Terminal Co., 783 F.2d 255, 265-67 (1st Cir. 1985)).

phrased the issue somewhat differently, stating that it found "nothing in the text of [federal] regulations to indicate that the federal government has chosen to prevent them from being used to establish a standard of care in a common-law negligence action."[41]

For many courts, this distinction appears to be critical: state law creates the cause of action; the FDCA, the MDA, and/or FDA regulations merely establish the standard for an element of that cause of action. This distinction appears to find support in how the Supreme Court framed the issue when it held that alleged violations of the FDCA to support a negligence theory do not create federal question jurisdiction. It described the issue as "the presence of a federal issue in a state-created cause of action."[42] The Supreme Court did not, however, directly rule on the propriety of relying on the FDCA to inform a negligence per se claim.

Almost all courts that allow the FDCA, the MDA, and FDA regulations to define the standard of care acknowledge that these provisions do not allow a private right of action. However, these courts allow negligence per se claims to proceed in this context based on furthering the policy that underlies these provisions. An example of permitting a negligence per se claim to proceed on this basis is the Third Circuit's decision in *Stanton v. Astra Pharmaceutical Products, Inc.*,[43] in which the plaintiff claimed to have been injured by the failure of Astra Pharmaceutical Products, Inc. (Astra) to provide annual reports regarding its local anesthetic, Xylocaine®, as FDA regulations require.[44]

The court would not entertain the possibility that the FDA enacted this regulation for any reason other than to protect individuals from adverse drug reactions.[45] The Third Circuit noted that the RESTATEMENT (SECOND) OF TORTS provides that a court "may" adopt a regulation to define the standard of care.[46] The court, however, also observed that "Pennsylvania law views a statutory violation as *conclusive* evidence of negligence, in the absence of an excuse for that violation."[47] The court found this rule to be all the more compelling due to the fact that the public interest requires the law to "'hold[] . . . companies which make and sell drugs and medicine for use in the human body to a high degree of responsibility under both the criminal and civil law for any failure to exercise *vigilance* commensurate with the harm which would be likely to result from relaxing it.'"[48] The court, however, emphasized that, although violation of a statute or regulation is "conclusive" evidence of negligence, the plaintiff must still prove that the violation was a proxi-

41. Axen v. Am. Home Prods. Corp., 974 P.2d 224, 240 (Or. Ct. App. 1999) (citing English v. Gen. Elec. Co., 496 U.S. 72, 89 (1990)), *modified*, 981 P.2d 340 (Or. Ct. App. 1999).

42. Merrell Dow Pharms., Inc. v. Thompson, 478 U.S. 804, 809-10 (1986) (citing Textile Workers v. Lincoln Mills, 353 U.S. 448, 470 (1957) (Frankfurter, J., dissenting)). *But see* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352-53 (2001) (expressing doubt that a state-law theory based "solely" on "the violation of FDCA requirements" is viable and rejecting "the proposition that any violation of the FDCA will support a state-law claim").

43. 718 F.2d 553, 565 (3d Cir. 1983).

44. *Id.* at 556-57.

45. *Id.* at 564 ("Astra cannot seriously dispute that section 130.35 was promulgated to protect individuals such as [the plaintiff] from precisely the type of harm that here occurred—an unexpected adverse reaction to Xylocaine.").

46. *Id.* at 563 n.22.

47. *Id.* at 563-64 n.22.

48. *Id.* (quoting Incollingo v. Ewing, 282 A.2d 206, 219 (Pa. 1971)).

mate cause of his or her injury.[49] Ultimately, the Third Circuit questioned the jury's conclusion that this violation of an FDA regulation proximately caused plaintiff's injuries,[50] but felt that any infirmities were insufficient to overrule the district court's denial of the defendant's motion for judgment notwithstanding the verdict.[51]

In reaching this decision, the court also rejected Astra's defense that the statutory violation was excused. Specifically, Astra argued that its conduct was excused because: (1) it neither knew nor should have known of the need to comply with the regulations at issue; (2) Astra's counsel advised it that it did not need to comply with the regulations; and (3) it had prepared reports available to the FDA.[52] The Third Circuit acknowledged that these defenses are viable under Pennsylvania law, but found that the record supported the jury's rejection of Astra's attempt to invoke these defenses.[53]

The viability of these defenses notwithstanding, by permitting the negligence per se claim in this context, the Third Circuit's rationale in *Stanton* is at odds with its decision in *Ries v. National Railroad Passenger Corp.*[54] In *Ries*, the Third Circuit, applying Pennsylvania law, would not permit a negligence per se theory based on alleged violations of OSHA regulations. The court would not permit such claims because to do so would "upset the congressional scheme for enforcing workplace safety."[55] In *Stanton*, however, the Third Circuit gave no such consideration to the congressional scheme for enforcing compliance with the FDCA—a scheme that figures largely in the Supreme Court's opinion later in *Buckman Co. v. Plaintiffs' Legal Committee.*[56] Perhaps equally important is the fact that the Third Circuit's decision is also inconsistent with one of its more recent decisions from the same legislative and regulatory milieu.

The more recent Third Circuit decision in *In re Orthopedic Bone Screw Products Liability Litigation*[57] was the appellate disposition of over two thousand lawsuits consolidated through multi-district litigation.[58] The plaintiffs alleged that the defendants conspired to violate the MDA.[59] The Third Circuit rejected this claim as a conspiracy theory for which no underlying "independent" tort existed.[60]

Plaintiffs sought to support their conspiracy theory by reference to a negligence per se cause of action based on violations of the MDA and FDA regulations.[61] The Third Circuit noted the host of courts that allow negligence per se claims to stand when based on alleged violations of the FDCA and FDA regulations.[62] The court, however, would not allow plaintiffs to bootstrap a negligence

49. *Id.*
50. *Id.* at 568 (stating that "plaintiff's evidence of causation is not very strong" and "the case thus is an extremely close one").
51. *Id.* at 569.
52. *Id.* at 564.
53. *Id.* at 564-65.
54. 960 F.2d 1156 (3d Cir. 1992).
55. *Id.* at 1164.
56. 531 U.S. 341 (2001). *See* discussion *infra* Part III.B.2.
57. 193 F.3d 781 (3d Cir. 1999).
58. *Id.* at 784.
59. *Id.* at 786-87.
60. *Id.* at 789-792
61. *Id.* at 790.
62. *Id.* (citing Stanton *ex rel.* Brooks v. Astra Pharm. Prods., Inc., 718 F.2d 553, 565 (3d Cir. 1983)); Orthopedic Equip. Co. v. Eutsler, 276 F.2d 455, 461 (4th Cir. 1960).

per se claim to a civil conspiracy allegation. A negligence per se claim "does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort."[63] A violation of the FDCA or FDA regulations, therefore, can only establish a breach of the duty of care, leaving plaintiffs to show causation and damages.[64]

To that end, the court held that the plaintiffs were not advancing a negligence theory but, rather, "contend[ing] the violations themselves form a cause of action."[65] Ironically (given the holding in *Stanton*), the court would not countenance this claim on the grounds that this "theory would undermine section 337(a) by establishing a private, state-law cause of action for violations of the FDCA, so long as those actions are brought against more than one defendant."[66] Although on the one hand, consistent with courts that view these provisions as supplying only an element of a cause of action, this rationale appears to undermine the Third Circuit's decision in *Stanton*. On the other, the threat of undermining section 337(a) is no less present in the context of a negligence per se claim than it is in a "private state-law cause of action" (assuming there is a difference between the two). Fundamentally, to characterize the holdings in cases such as *Stanton* as defining a standard of care and not creating a cause of action appears to create a distinction without a difference.[67]

Despite the apparent inconsistency in the Third Circuit's analyses in *Stanton*, *Ries*, and *In re Orthopedic Bone Screw Products Liability Litigation*, the analysis in *Stanton* implicitly or explicitly serves as the basis of other courts' decisions to permit the FDCA, the MDA, or FDA regulations to support a negligence per se theory. A Pennsylvania state court explicitly relied on *Stanton* to decide that a plaintiff's negligence per se claim based on a violation of the MDA was appropri-

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63. *Id.* (citing Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 716 (N.D. Ill. 1989)).

64. *Id.* (citing *In re* TMI, 67 F.3d 1103, 1118 (3d Cir. 1995)); Stanton *ex rel.* Brooks v. Astra Pharm. Prods., Inc., 718 F.2d at 564 n.22. Perhaps more fundamentally, negligence generally cannot serve as the tort underlying a conspiracy claim, which is intentional in nature. *See, e.g.*, Ernst & Young, L.L.P. v. Pac. Mut. Life Ins. Co., 51 S.W.3d 573, 583, n.7 (Tex. 2001); 16 AM. JUR. 2D *Conspiracy* § 51 (1998) ("Thus, civil conspiracy is an intentional tort requiring a specific intent to accomplish the contemplated wrong and, because negligence is, by definition, not an intentional wrong, the parties cannot engage in civil conspiracy to be negligent.").

65. *In re* Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d at 791.

66. *Id.*; *see also* Ries v. Nat'l R.R. Passenger Corp., 960 F.2d 1156, 1164 (3d Cir. 1992) (holding that to allow a negligence per se theory based on alleged OSHA violations to proceed would, in effect, create an implied right of action and upset the congressional scheme for enforcement).

67. *See* Scott v. Ciba Vision Corp., 44 Cal. Rptr. 2d 902, 911-12 (Cal. Ct. App. 1995) (holding that to permit a negligence per se claim based on alleged violations of the MDA "was 'tantamount to creating a private right of action to enforce FDA regulations concerning medical devices where no such right exists'" (quoting Powers v. Optical Radiation Corp., 44 Cal. Rptr. 2d 485, 490-91 (Cal. App. 1995))); Baker v. Smith & Nephew Richards, Inc., No. 99-58737, 1999 WL 811334, at *18 (Tex. Dist. Ct. June 7, 1999) ("[W]hen [plaintiff] styles his claim as one for negligence per se, he is effectively attempting to enforce the FDCA and MDA by means of a private suit."), *aff'd on other grounds sub nom.*, McMahon v. Smith & Nephew Richards, Inc., No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000); *cf.* Tidelands Marine Serv. v. Patterson, 719 F.2d 126, 128 n.3 (5th Cir. 1983) ("That which looks like a duck, walks like a duck, and quacks like a duck will be treated as a duck even though some would insist upon calling it a chicken.").

ate.[68] The court held that the negligence per se theory was viable, despite the prohibition in section 337(a), on the basis that at issue was a common-law tort action, not a statutory action.[69]

Similarly, in *Valente v. Sofamor, S.N.C.*, the court permitted negligence per se claims based on violations of the MDA.[70] The court so held based on a perverse gloss on legislative intent. That is, the court noted the MDA's preemption clause and also acknowledged that "the law is settled that Congress did not expressly intend for the FDCA to become a basis for civil liability under federal law."[71] The court, however, relying on Supreme Court precedent, found that "Congress's failure to provide such a federal remedy was persuasive evidence *not* to preempt common law liability for such conduct . . . ."[72] Further, the court inferred congressional intent to allow for a private cause of action "'from the language and the surroundings of the statute.'"[73] Similar to those courts that allow a negligence per se cause of action based on furthering the purpose of the FDCA, the court in *Valente* discerned a "clear intent that the statute's primary motivation is to protect the safety of those who use medical devices."[74]

Despite allowing a private right of action under the guise of negligence per se, the court in *Valente* went to great lengths to limit the scope of its holding. It expressly limited its opinion "to the specific FDCA violation alleged by the plaintiffs—that the defendants did not receive premarket approval to market and sell the . . . system for inserting screws into a person's pedicles, contrary to 21 U.S.C. § 351(f)."[75] As a result, the court cautioned against reading its opinion to support the proposition that *any* violation of the FDCA will support a negligence per se theory and emphasized that the provision at issue must be "concerned with the FDCA's overall purpose."[76] Although the court ultimately recognized that the plaintiffs' claims were permissible in theory, in practice the court dismissed the claims due to the plaintiffs' inability to raise a triable issue of fact with respect to causation.[77]

Similar to the rationale in *Valente*, other courts have allowed claimants to use the FDCA, the MDA, and FDA regulations to define the applicable standard of care on the basis that these provisions are intended to protect a specific class of persons. To allow these provisions to support a negligence per se cause of action

68. Cabiroy v. Scipione, 767 A.2d 1078, 1081-82 (Pa. Super. Ct. 2001) (reasoning that the statutory provision at issue was meant "to protect an individual such as [plaintiff] from being administered a non-labeled, non-sterile unapproved drug to avoid unexpected negative results").

69. *Id.* at 1081-82 & n.1.

70. 48 F. Supp. 2d 862, 867 (E.D. Wis. 1999).

71. *Id.* at 874, 876.

72. *Id.* at 875-76 (citing Medtronic v. Lohr, 518 U.S. 480, 487 (1996)). The reference to preemption in this context appears to be misplaced as the salient question with respect to legislative intent is whether Congress intended the provisions in the FDCA and MDA to support civil litigants' attempts to impose liability based on those provisions, no matter how such an action is denominated.

73. *Id.* at 876 (quoting Johnson v. Blackburn, 582 N.W.2d 488, 497 (Wis. Ct. App. 1998), *aff'd*, 595 N.W.2d 676 (Wis. 1999)).

74. *Id.* (explaining further that Congress passed the MDA "to protect a certain class of people—users of medical devices").

75. *Id.*

76. *Id.*

77. *Id.*

purportedly furthers this purpose. This rationale conforms with an approach suggested in the RESTATEMENT (SECOND) OF TORTS, which provides that, in the absence of legislative intent to create civil liability, a "court is under no compulsion to accept" a provision to define the standard of care.[78] In these circumstances, however, a court can adopt this standard "to further the general purpose which it finds in the legislation."[79]

The Second Circuit, for example, held that a negligence per se claim is viable on this exact basis in *Ezagui v. Dow Chemical Corp.*[80] In *Ezagui*, the Second Circuit held, simply, that failure to provide an adequate warning with a prescription drug violated both the FDCA and New York Education Law.[81] Because the plaintiff fell within the class of people for whom these statutes were passed, New York law supported his negligence per se claim.[82] The Second Circuit provided no other support for its decision on this claim and did not at all acknowledge Congress's clear intent to prohibit a private right of action under the FDCA.[83] Despite the summary treatment of this issue, at least two other New York courts have directly relied on this decision,[84] and courts outside New York have analyzed this issue similarly.

In *Sharp v. Artifex, Ltd.*,[85] for example, the U.S. District Court for the Western District of Pennsylvania held that a claimant can rely on the FDCA and MDA in a negligence per se cause of action.[86] The court held that the fact that the FDCA and MDA fail to provide a private right of action is not dispositive of this issue.[87] The court distinguished its holding from other cases such as *Cali v. Danek Medical, Inc.*,[88] based on the differences between Wisconsin's law of negligence per se and Pennsylvania's.[89] Wisconsin law requires "'some expression of legislative intent that the statute become a basis for civil liability.'"[90] Pennsylvania law, however, requires only that the purpose of the statute in question be designed to protect a particular group of persons and allowance of a negligence per se claim furthers the purpose of the statute.[91] Congress passed the MDA "'to provide for the safety and effectiveness of medical devices intended for human use'"[92] and "to protect the interests of those individuals who require the use or implantation of medical de-

78. RESTATEMENT (SECOND) OF TORTS § 286 cmt. d (1965).

79. *Id.*; *cf.* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. d (1997) (providing that courts take the purpose of a statute or regulation into account when determining whether a violation renders the product defective).

80. 598 F.2d 727, 736 (2d Cir. 1979).

81. *Id.* at 733.

82. *Id.* (stating that the plaintiff then need only show proximate cause).

83. *See id.*

84. Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 448 (W.D.N.Y. 2001); Lawrence v. Sofamor, S.N.C., No. 95-CV-1507, 1999 WL 592689, at *6 (N.D.N.Y. Aug. 2, 1999).

85. 110 F. Supp. 2d 388 (W.D. Pa. 1999).

86. *Id.* at 393.

87. *Id.* at 392.

88. 24 F. Supp. 2d 941 (W.D. Wis. 1998).

89. Sharp v. Artifex, Ltd., 110 F. Supp. 2d at 393-94.

90. *Id.* at 393 (quoting Cali v. Danek Med., Inc., 24 F. Supp. 2d at 954).

91. *Id.* at 393-94.

92. *Id.* at 394 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 474 (1996)).

vices."[93] Permitting a negligence per se theory in this context, then, would clearly support these purposes.

In many ways, these cases use the concept of furthering the policy of the statute as a proxy for legislative intent to create a private right of action. That is, the legislative intent to protect consumers or users of products governed by the FDCA, the MDA, or FDA regulations prevails over the clear legislative decision to prohibit a private right of action based on those provisions. The question stands, however, as to whether the FDCA, the MDA, and FDA regulations exist to protect a certain, specific class of individuals (as some courts claim) or the public at large. If this distinction is at all meaningful, the question is important. "All legislation promotes the public welfare to some degree."[94] Therefore, to allow the FDCA, the MDA, and/or FDA regulations to support a negligence per se claim on the grounds that these provisions are meant to protect consumers would eviscerate the requirement that a statute or regulation must be intended to protect a certain, specific class of individuals. As such, the claim to "further the purpose" of these statutory and regulatory provisions loses its persuasive force. The appeal of this claim fades even further in light of the clear congressional intent not to permit private litigants to enforce the FDCA.

B. Deference to Legislative Intent Requires Precluding Negligence Per Se Theories Based on Violations of the FDCA, the MDA, and FDA Regulations

1. Congress Intended to Foreclose a Private Right of Action Based on the FDCA

An important consideration with respect to whether a court should consider alleged violations of the FDCA, the MDA, or FDA regulations actionable under the guise of negligence per se is whether these provisions provide a private right of action.[95] As noted above, section 337(a), which governs both the FDCA and MDA, bars private enforcement of its provisions.[96] Courts have not only been resolute in enforcing section 337(a) with respect to naked attempts to enforce the FDCA, the MDA, and FDA regulations,[97] but also when litigants have attempted to end-run

93. *Id.* (citing Murray v. Synthes (U.S.A.), Inc., No. Civ. A. 95-7796, 1999 WL 672937, at *8 (E.D. Pa. Aug. 23, 1999); Taylor v. Danek Med., Inc., No. Civ. A. 95-7232, 1998 WL 962062, at *10 (E.D. Pa. Dec. 29, 1998)).

94. Cooper v. Eagle River Mem'l Hosp., Inc., 270 F.3d 456, 460 (7th Cir. 2001).

95. *See, e.g.*, E. 56th St. Corp. v. Mobil Oil Corp., 906 F. Supp. 669, 688 (D.D.C. 1995) (citing Frederick L. v. Thomas, 578 F.2d 513, 517 (3d Cir. 1978); Schwartzman, Inc. v. Atchison, Topeka & Santa Fe Ry. Co., 857 F. Supp. 838, 848 (D.N.M. 1994)).

96. 21 U.S.C. § 337(a) (1997) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States.").

97. *See, e.g.*, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions. . . ."); Ellis v. C. R. Bard, Inc., 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) ("[N]o private right of action exists for a violation of the FDCA."); Reeves v. AcroMed Corp., 44 F.3d 300, 307 (5th Cir. 1995); Valente v. Sofamor, S.N.C., 48 F. Supp. 2d 862, 876 (E.D. Wis. 1999) ("[T]he law is settled that Congress did not expressly intend for the FDCA to become a basis for civil liability under federal law."); Eon Labs. Mfg. Inc. v. Watson Pharms., Inc., 164 F. Supp. 2d 350, 361 n.14 (S.D.N.Y. 2001) ("[C]ase law is clear on the point that no private right of action exists under the FDC Act."); Am. Bioscience, Inc. v. Bristol Meyers Squibb Co., No. CV 00-08577-WMB AJWX, 2001 WL 1278348, at *1 ("There is no private right of action to remedy an alleged failure of BMY to

this provision by ostensibly relying on a different statute.[98] By its express terms, then, the FDCA and MDA suggest that their provisions cannot support a negligence per se cause of action. In many states, section 337(a) would be dispositive of this issue.[99]

The clear indication that Congress did not intend to create a private right of action for violations of the FDCA finds further support in the FDCA's legislative history. Congress expressly considered, and rejected, providing a private right of action for violations of the FDCA. In 1933, Congress considered approving an amendment to the FDCA to provide that "[a] right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act."[100] Although at least one person testifying appeared to have a positive opinion about this provision,[101] the majority of testimony and comments about its inclusion was hostile.[102] After two days of debate (on matters including, but not limited to, the private right of action), the Senate subcommittee reviewing the amendment eliminated any reference to a private right of action.[103] Courts have expressly considered this rejection of a private right of action in rejecting theories to enforce the FDCA.[104] Similarly, Congress's consideration and rejection of a private right of action bolsters the argument that Congress simply did not intend for the FDCA to be a source of civil liability.

Moreover, there is a palpable difference between failing to provide for a private right of action and *expressly prohibiting* a private right of action. That is, in section 337(a), Congress stated a clear intent to foreclose a private right of action

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comply with its obligations under the FDCA. An action to enforce the FDCA or to restrain violations thereof may only be brought by and in the name of the United States."); Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 260 (E.D.N.Y. 1999) (acknowledging that "there is no express or implied private cause of action provided for plaintiffs under these statutes"); Martin v. Ortho Pharm. Corp., 661 N.E.2d 352, 355 (Ill. 1996) ("Federal courts have uniformly refused to imply a private cause of action under the Food, Drug and Cosmetic Act (FDCA) . . . .").

98. *See, e.g.*, Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1329-30 (Fed. Cir. 2001) (characterizing a claim "to delist a patent from the Orange Book," as "an impermissible attempt by a private party to enforce the FDCA"); Cottrell, Ltd. v. Biotrol Int'l, Inc., 191 F.3d 1248, 1254-55 (10th Cir. 1999) ("It is also clear that, because no private right of action exists under the FDCA, a plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation."); Healthpoint, Ltd. v. Styratus Pharms., Inc., 273 F. Supp. 2d 769, 786 (W.D. Tex. 2001) (rejecting the plaintiff's attempt to enforce the FDCA through the Lanham Act).

99. *See, e.g.*, Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) (citing Murthy v. N. Sinha Corp., 644 So. 2d 983, 985-86 (Fla. 1994)); Short v. Ultramar Diamond Shamrock, 46 F. Supp. 2d 1199, 1201 (D. Kan. 1999); Isely v. Capuchin Province, 880 F.□Supp. 138, 1150 n.14 (E.D. Mich. 1995) (stating that, because no private right of action existed, the issue of negligence per se does not arise).

100. *A Bill to Prevent the Manufacture, Shipment, and Sale of Adulterated or Misbranded Food, Drugs, and Cosmetics, and to Regulate Traffic Therein; to Prevent the False Advertisement of Food, Drugs, and Cosmetics, and for Other Purposes: Hearings on S. 1944 Before a Subcommittee of the Senate Committee on Commerce*, 73d Cong. 10 (1934).

101. *Id.* at 277 (brief of Donald J. Burke, Vice President of Geo. H. Lee Co. (stating that the private right of action would give the FDCA "additional teeth")).

102. *See id.* at 161 (statement of John F. Anderson, Vice President, E. R. Squibb & Sons (referring to the private right of action as duplicative)), 169 (statement of Sen. Royal Copeland).

103. *Id.* at 494-98 (showing the revised bill, which did not contain a private right of action).

104. *See, e.g.*, Bailey v. Johnson, 48 F.3d 965, 967-68 (6th Cir. 1995); Nat'l Women's Health Network, Inc. v. A. H. Robins Co., 545 F. Supp. 1177, 1179-80 (D. Mass. 1982).

based on violations of the FDCA.[105] "Assertion of a negligence cause of action predicated on an alleged violation of a statute," then, could properly be construed as "[l]ittle more than an attempt to assert a private cause of action for damages by privately enforcing the statute in question."[106] Furthermore, if, as Professors Prosser and Keeton state, negligence per se is a form of judicial deference to the legislature,[107] legislative intent should control this issue by precluding negligence per se claims based on violations of the FDCA, the MDA, and FDA regulations. This conclusion would seem to hold with greater strength when there is a clear intent to prohibit a private cause of action.[108] By prohibiting a private right of action, as opposed to being silent on the matter, Congress made a clear statement that the provisions of the FDCA do not and should not expose the alleged violator to civil liability.

Some courts have found this fact persuasive and held that a negligence per se cause of action based on alleged violations of the FDCA, the MDA, or FDA regulations cannot stand. In *Blinn v. Smith & Nephew Richard, Inc.*,[109] the U.S. District Court for the Middle District of Florida held that Florida law requires a demonstration of legislative intent that a statute creates a private right of action before the statute can support a negligence per se cause of action.[110] Not only does the FDCA not allow for a private right of action, "the law expresses the opposite intention."[111] As such, the MDA and, by extrapolation, the FDCA, cannot support a negligence per se theory.[112] Other decisions are appropriately categorized with *Blinn*. Under Wisconsin law, for example, a plaintiff must show that "there is some expression of legislative intent that the statute become a basis for civil liabil-

105. Merrell Dow Pharms., Inc. v. Thompson, 478 U.S. 804, 811 (1986). The Court went on to state that "Congress did not intend a *private remedy* for violations of the FDCA." *Id.* (emphasis added).

106. Schwartzman, Inc. v. Atchison, Topeka & Santa Fe Ry. Co., 857 F. Supp. 838, 848 (D.N.M. 1994).

107. KEETON ET AL., *supra* note 11, § 36, at 222; *see also* Scovill v. City of Astoria, 921 P.2d 1312, 1316 (Or. 1996) ("Whether a statute creates a duty, or enacts a standard of care, is determined by discerning what the legislature intended.").

108. *See, e.g.*, Lutz v. Chromatex, Inc., 718 F. Supp. 413, 428 (M.D. Pa. 1989); *see also* Perez v. United States, 167 F.3d 913, 919 (5th Cir. 1999). *Lutz* concerned a negligence per se claim with respect to violations of Pennsylvania environmental laws. Lutz v. Chromatex, Inc., 718 F. Supp. at 426-28. In *Lutz*, the court stated that, "[f]ar from acting out of deference and respect to the legislature, . . . the court would be going against the expressed intentions of the legislature by permitting plaintiffs' negligence *per se* claim to proceed." *Id.* at 428 (citing KEETON ET AL., *supra* note 11, § 36). Note, however, that Pennsylvania courts recognize negligence per se claims based on alleged violations of the FDCA and FDA regulations. *See, e.g.*, Sharp v. Artifex, Ltd., 110 F. Supp. 2d 388, 395 (W.D. Pa. 1999).

109. 55 F. Supp. 2d 1353 (M.D. Fla. 1999).

110. *Id.* at 1361 (citing Murthy v. N. Sinha Corp., 644 So. 2d 983, 985-86 (Fla. 1994)).

111. Cali v. Danek Med., Inc., 24 F. Supp. 2d 941, 954 (W.D. Wis. 1998).

112. *See* Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d at 1361; Cali v. Danek Med., Inc., 24 F. Supp. 2d at 954; *see also* Stevens v. Danek Med., Inc., No. 95-14293-CIV-PAINE, 1999 WL 33217282, at *5-6 (S.D. Fla. Apr. 16, 1999); Baker v. Danek Med., Inc., 35 F. Supp. 2d 875, 878 (N.D. Fla. 1998).

ity."[113] Texas courts also defer to this rationale on the grounds that to allow plaintiffs to pursue a negligence per se cause of action would "ignore[] the Congressional prohibition of private rights of action."[114] The U.S. District Court for the Northern District of Ohio has reached the same conclusion based on identical grounds.[115] Illinois law also leads to this result.[116] Although not deciding this issue, other courts appear to be similarly inclined.[117]

2. *Permitting Civil Actions Through a Negligence Per Se Theory Would Frustrate the FDA's Regulation and Enforcement Efforts*

In determining whether a provision should support a negligence per se theory, the RESTATEMENT (SECOND) OF TORTS provides that it is appropriate to consider whether the creation of a right would be consistent with the overall legislative scheme of the provision to be enforced.[118] Similarly, the Supreme Court has stated that "[t]he presumption that a remedy was deliberately omitted from a statute is strongest when Congress has enacted a comprehensive legislative scheme includ-

113. Cali v. Danek Med., Inc., 24 F. Supp. 2d at 954 (quoting Tatur v. Solsrud, 498 N.W.2d 232, 235 (Wis. 1993)); *see also* Chapman *ex rel.* Chapman v. Mut. Serv. Cas. Ins. Co., 35 F. Supp. 2d 699, 705 (E.D. Wis. 1999) ("For an administrative rule to form an independent basis for civil liability, some expression of legislative intent to create such a private right of action must be present in the form and language of the rule."). *But see* Valente v. Sofamor, S.N.C., 48 F. Supp. 2d 862, 875-76 (E.D. Wis. 1999) (expressly disagreeing with *Cali* and holding that a negligence per se cause of action can be predicated on alleged violations of the FDCA).

114. Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at *18 (Tex. Dist. Ct. June 7, 1999), *aff'd on other grounds sub nom.* McMahon v. Smith & Nephew Richards, Inc., No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000); *see also* Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) (noting that the FDCA does not provide a private right of action and finding the rationale in *Baker* persuasive). The court in *Baker* provided an extensive and comprehensive analysis of negligence per se claims based on violations of the FDCA and MDA. The decision in *Baker* reflects Texas courts' hesitancy to allow a statute or regulation to define the standard of care if doing so would be inconsistent with legislative intent. *See* Smith v. Merritt, 940 S.W.2d 602, 607 (Tex. 1997); Wal-Mart Stores, Inc. v. Seale, 904 S.W.2d 718, 720 (Tex. App.—San Antonio 1995) (holding that the fact that OSHA does not provide for a private cause of action suggests that it cannot support a negligence per se cause of action), *appeal dism'd by* No. 04-94-00295-CV, 1995 WL 654562 (Tex. App.—San Antonio Nov. 8, 1995); Hand v. Tavera, 864 S.W.2d 678, 680 (Tex. App. 1993) (noting that a claim of violation of a federal statute to treat emergency patients cannot support a claim for negligence per se because the statue does not allow a private cause of action).

115. Estep v. Danek Med., Inc., No. 1:96CV2580, 1998 WL 1041330, at *2 (N.D. Ohio Dec. 8, 1998); *see also In re* Bendectin Litig., 857 F.2d 290, 314 (6th Cir. 1988) (observing that Congress's refusal to provide a private right of action is important in considering the viability of a negligence per se cause of action).

116. Martin v. Ortho Pharm. Corp., 661 N.E.2d 352, 355-56 (Ill. 1996). *But see* Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 716 (N.D. Ill. 1989) (permitting a plaintiff to rely on the FDCA or FDA regulations to establish the standard of care).

117. *See, e.g.*, Baraukas v. Danek Med., Inc., No. 6:97CV00613, 2000 WL 223508, at *4 n.2 (M.D.N.C. Jan. 13, 2000) (stating that a defendant's argument that the FDCA should not support a negligence per se cause of action because it prohibits private rights of action "appears to have merit").

118. RESTATEMENT (SECOND) OF TORTS § 874A (1979); *See also* Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 452 (W.D.N.Y. 2001); Williams-Garrett v. Murphy, 106 F. Supp. 2d 834, 842 (D.S.C. 2000).

ing an integrated system of procedures for enforcement."[119] With respect to the FDCA, courts generally (and appropriately) characterize Congress's grant of authority to the FDA as comprehensive.[120] Courts have similarly described the FDA's implementation of specific provisions of the FDCA, including the New Drug Application (NDA) and approval process,[121] pre-market approval of Class III medical devices,[122] classification of medical devices,[123] regulation of vaccines,[124] and warning requirements for drugs[125] as comprehensive. Although courts have been reluctant to accept this characterization as a basis for suggesting that the FDCA preempts state-law theories of recovery,[126] the question remains as to whether the FDCA's enforcement scheme should preclude a state-law theory intended solely to enforce its provisions.

In the context of the MDA's preemption clause,[127] similarly, the First Circuit observed that the "central enforcement role" Congress gave to the FDA "represents a permissible decision . . . that the public interest will best be served by relying exclusively on the FDA to strike the proper balance between reasonably assuring safety and promoting innovation with regard to new devices that have the potential both to enhance and injure human health."[128] Although the First Circuit's words are in the context of the MDA, which has its own preemption clause, the logic is equally applicable to the rest of the FDCA. The First Circuit was express-

119. Northwest Airlines, Inc. v. Transp. Workers Union of Am., AFL-CIO, 451 U.S. 77, 97 (1981). The Supreme Court further admonished that, although courts are to interpret ambiguous laws, they are not "to fashion a new rule or to provide a new remedy which Congress has decided not to adopt." *Id.*

120. *See, e.g.*, United States v. Sage Pharms., Inc., 210 F.3d 475, 479 (5th Cir. 2000) (noting "[t]he FDCA's comprehensive scheme of drug regulation"); Shea v. Oscor Med. Corp., 950 F. Supp. 246, 247 (N.D. Ill. 1996) ("The MDA has given the United States Food and Drug Administration (FDA) comprehensive regulatory authority over medical devices."); Kellogg Co. v. Mattox, 763 F. Supp. 1369, 1380 (N.D. Tex. 1991) (describing drug regulations as "comprehensive").

121. Syntex (U.S.A.), Inc. v. Interpharm, Inc., Civ. A. No. 1:92-CV-03HTW, 1993 WL 643372, at *1 (N.D. Ga. March 19, 1993).

122. Oja v. Howmedica, Inc., 111 F.3d 782, 786 (10th Cir. 1997).

123. Martin v. Teletronics Pacing Sys., Inc., 105 F.3d 1090, 1095 (10th Cir. 1997).

124. Mazur v. Merck & Co., Inc. 742 F. Supp. 239, 245-46 (E.D. Pa. 1990).

125. Walls *ex rel.* Estate of Christopher v. Armour Pharm. Co., 832 F. Supp. 1467, 1484-85 (M.D. Fla. 1993).

126. *See, e.g.*, Bansemer v. Smith Labs, Inc., Civ. A. No. 86-C-1313, 1990 WL 132579, at *3 (E.D. Wis. Sept. 12, 1988) ("The FDA regulations are therefore not comprehensive; they may be supplemented by the common law of the duty to warn."). The court in *Bansemer*, however, made this statement with respect to the defendant's claim that FDA labeling regulations were "so pervasive that [they] impl[y] a federal intent to occupy the field." *Id. But see* Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 349-51 (2001) (observing the comprehensive nature of the FDCA and FDA enforcement powers and suggesting that the FDCA preempts negligence per se claims).

127. 21 U.S.C. § 360k(a) (1997 & Supp. 2004).

128. Talbott v. C. R. Bard, Inc., 63 F.3d 25, 30 (1st Cir. 1995) (quoting and affirming Talbott v. C. R. Bard, Inc., 865 F. Supp. 37, 40 (D. Mass. 1994)).

ing concern for "the possibility of disuniform treatment" from discrete and disparate judges and juries essentially operating parallel to the FDA.[129]

More recently, the Supreme Court made this precise observation in *Buckman*, in which it observed that allowing private litigants to pursue fraud-on-the-FDA claims would only upset the enforcement scheme Congress created when it passed the FDCA.[130] Further, FDCA-based theories would pose the possibility of a perverse situation in which a manufacturer's disclosures to the FDA, "although deemed appropriate by the Administration, will later be judged insufficient in state court."[131] The likely result would be a situation in which manufacturers of medical devices would inundate the FDA with unneeded or unwanted information. The Court did not distinguish its concern for this result between the MDA (which contains a preemption clause) and the FDCA (which does not contain a preemption clause): "As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA."[132] The rationale in *Buckman* is not an aberration given that, outside the context of the FDCA, the Supreme Court has disapproved of state-law theories that would frustrate congressional intent to create a uniform system of regulation and enforcement.[133] To permit a state court to do what Congress empowered a regulatory agency to do, the Court reasoned, would vitiate the system of uniformity Congress contemplated when it enacted the law.[134]

The questionable status of a negligence per se claim in this context is apparent not only based on the absence of a private right of action and the presence of a comprehensive legislative and regulatory scheme, but also based on the absence of a remedy. Justice Brennan acknowledged this argument, noting that "[i]t may be that a decision by Congress not to create a private remedy is intended to preclude all private enforcement."[135] If so, any state cause of action predicated on a violation of the FDCA is preempted.[136] Justice Brennan's treatment of this issue was in the context of the propriety of federal subject-matter jurisdiction over a negligence

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129. *Id.* at 29. In *Talbott*, the First Circuit found that the case before it did not implicate these concerns. *Id.* at 30; *see also* Richard C. Ausness, *The Case for a "Strong" Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1219 (1996) (observing that the varying states' tort laws disrupt the uniformity of federal regulations "without providing any increased safety benefit"); R. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1442 (1994).

130. *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 348 (describing the MDA, at least, as "a somewhat delicate balance of statutory objectives").

131. *Id.* at 351; *cf.* Grundberg v. Upjohn Co., 813 P.2d 89, 97 (Utah 1991) ("Allowing individual courts and/or juries to continually reevaluate a drug's risks and benefits ignores the processes of this expert regulatory body . . . .").

132. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 350.

133. *See, e.g.*, Chicago & N. W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 325-26 (1981).

134. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 353; Chicago & N. W. Transp., 450 U.S. at 325-26 (noting further that this conclusion is bolstered if the regulatory agency approved the accused's conduct); *see also* Ausness, *supra* note 129, at 1219 (stating that an "advantage of federal regulations is that they apply uniformly throughout the country").

135. Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804, 831 (1986) (Brennan, J., dissenting).

136. *Id.* (Brennan, J., dissenting).

theory based on violations of the FDCA. His evaluation of this issue would appear to favor pharmaceutical manufacturers who are defendants in products liability cases in two respects. First, it would support an argument that section 337(a), by precluding a private enforcement of the FDCA, preempts negligence per se theories based on alleged violations of the FDCA.[137] Second, this analysis suggests that, to the extent the FDCA does not preempt a negligence per se claim, such a theory should support federal subject-matter jurisdiction.[138]

Justice Brennan's evaluation of this issue also anticipated the Court's analysis in *Buckman*, which facially suggests that all such claims—whether based on the FDCA or MDA—should be pre-empted. In *Buckman*, the Court's ruling, specifically, is that federal law preempts state-law fraud-on-the-FDA claims.[139] The Court made this ruling in the context of alleged misrepresentations to the FDA to obtain approval of orthopedic bone screws.[140] The language and rationale of this opinion, however, clearly suggest that the FDCA—independent of the MDA—preempts fraud-on-the-FDA and negligence per se claims.

As medical devices, orthopedic bone screws are governed by the MDA.[141] The MDA contains an express preemption clause that does not apply to the rest of the FDCA.[142] Importantly, however, the Court did not base its preemption ruling on this express preemption clause.[143] In fact, the Court expressly stated that its analysis rested on application of "ordinary preemption principles" and not application of the MDA's express preemption provision.[144] Similar to the dissent in *Merrell Dow*,[145] the Court in *Buckman* reasoned that the FDCA "amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives."[146] Importantly, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."[147] Allowing private litigants to pursue state-law fraud-on-the-FDA claims would only upset this balance.[148]

To permit such claims to proceed would place a host of burdens on manufacturers and the FDA alike. Tort liability would be a disincentive to those manufacturers seeking approval of new products with beneficial off-label use out of fear of being subjected to "unpredictable civil liability."[149] To avoid the appearance of

137. *Id.* at 831-32 (Brennan, J., dissenting).

138. *Id.* at 828 (Brennan, J., dissenting) ("[T]he possibility that the federal law will be incorrectly interpreted in the context of adjudicating the state-law claim implicates the concerns that led Congress to grant the district courts power to adjudicate cases involving federal questions in precisely the same way as if it was federal law that 'created' the cause of action.").

139. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 348.

140. *Id.* at 343.

141. *Id.* at 344-46.

142. 21 U.S.C. § 360k (2000).

143. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 348 n.2 ("[W]e express no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k.").

144. *Id.* at 352.

145. Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. at 830-31 (Brennan, J., dissenting) (observing that the FDCA conferred "[p]rimary responsibility for overseeing [its] implementation" on "a specialized administrative agency," the FDA, which has "a wide-ranging arsenal of weapons to combat violations.").

146. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 348.

147. *Id.* at 349 n.4; *see also id.* at 352.

148. *Id.* at 348.

149. *Id.* at 350.

having withheld any information from the FDA, moreover, manufacturers will "have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application."[150]

This rationale clearly appears to support the conclusion—contrary to years of precedent from lower courts[151]—that the FDCA, or at least its regulatory regime, impliedly preempts negligence per se theories. The Court made this preemption ruling based on the statutory and enforcement scheme of the FDCA in general. The acknowledgement that the FDA has the means of pursuing its own mandate and to allow private litigants to duplicate these efforts would only frustrate FDA's charge. Further, the Court did not rely on the MDA's preemption clause but, rather, expressly and repeatedly relied on section 337(a)'s express prohibition on a private right of action to enforce the FDCA.[152]

The Court tempered these otherwise clear suggestions of preemption, however, with hints that the FDCA's preemptive scope is limited. First, and perhaps most important, the Court did not overrule *Medtronic, Inc. v. Lohr*.[153] The Court gave its clearest indication that the FDCA may not preempt a negligence per se theory, for example, by stating that "*Medtronic* can be read to allow certain state-law causes of action that parallel federal safety requirements," but further stated that *Medtronic* "does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim."[154] Second, the Court made these statements in an effort to conform its opinion to its opinions in *Silkwood v. Kerr-McGee Corp.*[155] and *Medtronic*. The Court observed that its opinion did not conflict with *Silkwood* because the issues in *Buckman* did not concern "traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant."[156] Similarly, one could argue, a negligence per se claim based on violations of the FDCA *does* concern "traditional state tort law principles of the duty of care" owed by a manufacturer to a consumer. Given this ambiguous message, it is not surprising that a number of courts have rejected arguments that *Buckman* supports blanket preemption of state-law tort claims.[157] Although the rejection of *Buckman* as support for blanket preemption of state-law

150. *Id.* at 351.

151. *See, e.g.*, Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1380-81 (11th Cir. 1999); Hill v. Searle Labs., 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA approval is not a shield to liability. FDA regulations are generally minimal standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area." (citations omitted)); Motus v. Pfizer, Inc., 127 F. Supp. 2d 1085, 1092 (C.D. Cal. 2000); Mazur v. Merck & Co., Inc., 742 F. Supp. 239, 247 (E.D. Pa. 1990).

152. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 349 n.4, 352.

153. 518 U.S. 470 (1996).

154. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 353.

155. 464 U.S. 238 (1984).

156. Buckman v. Plaintiffs' Legal Comm., 531 U.S. at 352 (citing Silkwood v. Kerr-McGee Corp., 464 U.S. at 241).

157. *See, e.g.*, Eve v. Sandoz Pharm. Corp., No. IR 98-1429-C-Y/S, 2002 WL 181972, at *2 n.4 (S.D. Ind. Jan. 28, 2002) (stating that, if the case involved a medical device, then the MDA would preempt the plaintiff's inadequate warning and testing claims and noting further that "when read together, these three Supreme Court cases—*Buckman*, *Silkwood*, and *Medtronic*—make clear that the only theory preempted is that resting exclusively on the fact that the federal agency was itself the victim of the fraud").

tort claims is clearly defensible (and likely correct), it does not speak to whether negligence per se theories based on the FDCA and related provisions are preempted under *Buckman*. The language and rationale in *Buckman* clearly suggest that negligence per se claims are in fact preempted.

IV. NATURE AND SPECIFICITY OF THE PROVISIONS IN THE FDCA, THE MDA, AND FDA REGULATIONS

Two closely related considerations with respect to the propriety of negligence per se claims in this context are the nature of the provisions in the statute or regulation and the provision's clarity in defining the applicable standard of care. Neither of these considerations lends itself to the general treatment that is appropriate for the issue of legislative intent. A litigator or court must address questions of whether a provision identifies a standard of care or is sufficiently specific on a statute-by-statute or regulation-by-regulation basis.

A. Administrative Requirement or Standard of Care?

In determining the nature of a provision and whether it can support a negligence per se claim, the gravamen of the inquiry may be best reduced to whether the provision is "intended to make the actor responsible to the state, rather than to any individual."[158] The Fourth Circuit's decision in *Talley v. Danek Medical, Inc.*,[159] is an example of a court characterizing the FDCA, the MDA, and FDA regulations as administrative in nature or as licensing requirements. In *Talley*, the plaintiff alleged that use of an internal spinal fixation device for her spinal fusion operation injured her when the screws in that device became loose and her spine did not fuse properly.[160] Among her theories of recovery was the claim that violations of certain portions of the FDCA constituted negligence under Virginia law.[161] The district court granted the defendant's motion for summary judgment on all counts and the plaintiff appealed.[162]

The Fourth Circuit noted that an unexcused violation of a statute does not automatically expose the violator to tort liability.[163] Moreover, negligence per se does not create a new cause of action but recognizes a legislative standard when there is an underlying common-law duty.[164] A statute is particularly inappropriate to support a negligence per se claim when that statute "does not define a standard of care but merely imposes an administrative requirement . . . ."[165] "Even if the

158. RESTATEMENT (SECOND) OF TORTS § 288 cmt. d (1965).

159. 179 F.3d 154 (4th Cir. 1999).

160. *Id.* at 155-56.

161. *Id.* at 157.

162. *Id.*

163. *Id.* at 158 ("[Negligence per se] has long been recognized as a moderate rule which simply substitutes a general legislative judgment for a specific judicial judgment in instances where the legislature has set forth the standard of conduct that a 'reasonable man' must follow.").

164. *Id.* (quoting Williamson v. Old Brogue, Inc., 350 S.E.2d 621, 624 (Va. 1986)). In this respect, the Fourth Circuit's characterization of the FDCA as merely providing one element of a cause of action, and not the cause of action itself, could appropriately be categorized with those opinions in which courts find that permitting a negligence per se claim does not violate section 337(a)'s prohibition on private rights of action. *See supra* Part III.A.

165. Talley v. Danek Med., Inc., 179 F.3d at 159.

regulatory scheme as a whole is designed to protect the public or to promote safety, the licensing duty itself is not a standard of care, but an administrative requirement."[166] The Fourth Circuit found this distinction to be critical in deciding that the plaintiff's negligence per se theory was not viable.

The plaintiff's negligence per se theory in *Talley* rested on the claim that the defendant marketed a surgical device that the FDA had not approved and this failure to obtain approval prior to marketing constituted a violation of various provisions of the MDA.[167] The specific provisions the plaintiff claimed were violated are the requirements for approval of certain medical devices before marketing[168] and the prohibition on introducing adulterated or misbranded devices into interstate commerce.[169] The Fourth Circuit held that, even assuming that the defendant marketed these unapproved devices for use on the spine, it did not constitute a breach of a standard of care and did not cause the plaintiff's injury.[170]

Two features of the Fourth Circuit's decision are particularly noteworthy. The first that warrants emphasis is the interplay between causation and whether the statute defines a standard of care or is simply an administrative requirement. The court noted that the distinction between these two elements is often blurred and Virginia courts tend to resolve such issues by finding that the violation of the statute or provision was not a proximate cause of the injury.[171] With respect to this distinction and its impact on the plaintiff's claims, the court deferred to the reasoning of Professors Prosser and Keeton on the impact of driving without a license in an automobile accident: "'the act of driving certainly causes the collision; the absence of the license, or the existence of the statute, of course does not.'"[172]

The second important aspect of the Fourth Circuit's decision in *Talley* is the court's inclination to limit its holding. The plaintiff argued that the Fourth Circuit's decision in *Orthopedic Equipment Co. v. Eutsler*,[173] supported "her claim that any violation of the FDCA constitutes negligence *per se* in Virginia."[174] The court rejected this argument, but would not reject its holding in *Eutsler*. The court reconciled its holding in *Eutsler* with its decision in *Talley* by extending the automobile analogy. The provision violated in *Eutsler*, according to the Fourth Circuit, was a misbranding or mislabeling requirement.[175] The statute at issue in *Eutsler*

166. *Id.* (citing Ridge v. Cessna Aircraft Co., 117 F.3d 126, 131 (4th Cir. 1997)).

167. *Id.* at 160.

168. *E.g.*, 21 U.S.C. § 360e(a) (1997) (amended 2002).

169. *Id.* § 331(a).

170. Talley v. Danek Med., Inc., 179 F.3d at 160.

171. *Id.* at 159 (citing Laughlin v. Rose, 104 S.E.2d 782, 786 (Va. 1958); White v. Edwards Chevrolet Co., 43 S.E.2d 870, 871 (Va. 1947); Bentley v. Felts, 445 S.E.2d 131, 133 (Va. 1994)). *See supra* note 19 and accompanying text (identifying cases in which courts have avoided determining the propriety of a negligence per se claim based on the FDCA, MDA, and/or FDA regulations by finding that there was no causation).

172. Talley v. Danek Med., Inc., 179 F.3d at 159 (quoting KEETON ET AL., *supra* note 11, § 36).

173. 276 F.2d 455, 461-62 (4th Cir. 1960) (applying Virginia law to hold that the FDCA imposes a duty on manufacturers not to misbrand their products).

174. Talley v. Danek Med., Inc., 179 F.3d at 161.

175. *Id.* (citing Orthopedic Equip. Co. v. Eutsler, 276 F.2d 455, 461 (4th Cir. 1960)). In a thorough opinion, a Texas state court suggested that the opinion in *Eutsler* was unsound due to the fact that "it was decided before the judicial recognition that the FDCA does not provide for a private right of action." Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at *17 n.5 (Tex. Dist. Ct. June 7, 1999), *aff'd on other grounds sub nom.* McMahon v. Smith & Nephew Richards, Inc., No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000).

is analogous to a speed limit, which is a specific, substantive standard of care.[176] The failure to obtain approval before marketing, as alleged in *Talley*, is an administrative requirement akin to obtaining a driver's license.[177] Pre-marketing approval "is only a tool to facilitate administration of the underlying regulatory scheme."[178] The court specifically stated that although such pre-marketing approval is essential to the regulation of drugs and medical devices, it is only administrative in nature and insufficient to support a negligence per se theory.[179]

A number of courts have found the Fourth Circuit's reasoning persuasive. The U.S. District Court for the District of Nebraska relied extensively on the Fourth Circuit's holding that regulatory approval is an administrative, and not a substantive, standard.[180] Although the court also noted the plaintiff's failure to prove causation (both of the device alleged to be the source of injury and of the absence of FDA approval causing the alleged injury), each part of this holding relied on *Talley*'s characterization of FDA approval as administrative in nature and not a standard of care.[181] Relying on *Talley*, similarly, the U.S. District Court for the Northern District of Oklahoma held that a negligence per se claim "is inapplicable to labeling and marketing violations under the Food, Drug, and Cosmetic Act."[182] Regulations that apply to labeling and promotion of medical devices "are administrative and do not impose a standard of care, as could form the basis of a negligence per se claim."[183] Adoption of this view of pre-approval requirements is not a denial that these requirements are important, but is merely a recognition that these requirements lack sufficient substance to support a negligence per se theory.[184]

These cases and the rationale in each should not be considered to apply solely to medical device cases. As these cases make clear, negligence per se based on failure to secure FDA approval intersects frequently with allegations of off-label use.[185] Allegations that off-label use was impermissible and caused a plaintiff's injuries are frequently made the basis for a manufacturer's purported liability.[186]

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176. Talley v. Danek Med., Inc., 179 F.3d at 161.

177. *Id.*

178. *Id.*

179. *Id.*

180. Uribe v. Sofamor, S.N.C., No. 8:95CV464, 1999 WL 1129703, at *16 (D. Neb. Aug.□16, 1999).

181. *Id.*

182. Alexander v. Smith & Nephew, P.L.C., 98 F. Supp. 2d 1310, 1319 (N.D. Okla. 2000).

183. *Id.* at 1320. The court further stated that these provisions "lack any independent substantive content." *Id.* at 1321 (citing Johnson v. Smith & Nephew Richards, Inc., No. 97-CV-363-K, 1999 WL 1117105, at *2 (N.D. Okla. Sept. 30, 1999)). In rejecting the negligence per se theory, the court also relied on the facts that (1) the FDA does not regulate physicians' decisions to use medical devices "off label" and (2) the FDCA does not provide a private right of action. *Id.*

184. *See* King v. Danek Med., Inc., 37 S.W.3d 429, 460 (Tenn. Ct. App. 2000) (quoting *Talley* and concluding that the plaintiffs could prove no set of facts to support their negligence per se theory); *see also* Bish v. Smith & Nephew Richards, Inc., W1998-00373-COA-R9-CV, 2000 WL 1294324, at *2-5 (Tenn. Ct. App. Aug. 23, 2000) (relying on *King* and concluding that the trial court properly dismissed plaintiffs' negligence per se claims and properly excluded evidence of FDA regulatory activity with respect to fixation devices).

185. *See, e.g.*, Uribe v. Sofamor, S.N.C., 1999 WL 1129703, at *16.

186. *See, e.g.*, Hamm v. Rhone-Poulenc Rorer Pharms., Inc., 187 F.3d 941, 946 (8th Cir. 1999); Rubel v. Pfizer, Inc., 276 F. Supp. 2d 904, 905 (N.D. Ill. 2003); McCallister v. Purdue Pharma L.P., 164 F. Supp. 2d 783, 787 (S.D. W. Va. 2001); Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at *1 (Tex. Dist. Ct. June 7, 1999), *aff'd on other grounds sub nom.* McMahon v. Smith & Nephew Richards, Inc., No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000).

The possibilities for incurring liability multiply considering the chances of misstatements from sales representatives,[187] and the traps presented by the Mack-Frist provision in the Food and Drug Administration Modernization Act (FDAMA), which permits communication of information on unapproved uses of drugs, biologics, and medical devices.[188]

B. Clarity of the Statutes and Regulations

An important consideration with respect to adopting a particular statute or regulation to support a negligence per se claim is whether that statute or regulation is specific about what conduct is prohibited or required. This consideration is closely related to the statute's characterization as substantive or administrative. In FDCA cases outside the negligence per se context, courts have found that the FDCA "is sufficiently clear to pass constitutional muster," and that "Congress has provided in the FDCA clear proscriptions . . . that can be consistently followed by the FDA in enforcing them."[189] As true as these statements may be, if a statute or regulation does not clearly define what conduct is required—even if it is not constitutionally suspect—it will not support a negligence per se claim.[190] In providing that noncompliance with a relevant statute or regulation renders a product defective, the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY recognizes that a court may take into account, *inter alia*, the clarity of the provision.[191] This inquiry raises the question of whether the FDCA, the MDA, or FDA regulatory provision at issue defines the standard of care with a sufficient degree of precision to support the imposition of civil liability.

The requirement is that the provision at issue must establish a standard of care.[192] A Texas state district court has held, broadly, that "[t]he FDCA, MDA, and FDA guidelines are not clear about prohibited conduct."[193] With respect to certain purported marketing activities, for example, the difference between activities performed for promotional purposes and those performed for educational or scientific purposes is difficult to discern.[194] Similarly, other courts have observed that, in many respects, the FDCA and FDA regulations are insufficiently clear to

187. *See, e.g.*, Baldino v. Castagna, 478 A.2d 807, 812 (Pa. 1984).

188. 21 U.S.C. §§ 360aaa-360aaa-6 (1997); *see also* Dissemination of Information in Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 21 C.F.R. §§ 99.1-99.501 (2004).

189. United States v. Travia, 180 F. Supp. 2d 115, 123-24 (D.D.C. 2001).

190. *See, e.g.*, Perry v. S.N., 973 S.W.2d 301, 307-08 & n.7 (Tex. 1998) ("A statute's lack of clarity need not rise to a constitutionally suspect level in order to be a factor in our determination of whether imposing negligence *per se* is appropriate.").

191. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. d (1998).

192. King v. Danek Med., Inc., 37 S.W.3d 429, 460 (Tenn. Ct. App. 2000); *see also* Faragher v. City of Boca Raton, 524 U.S. 775, 811 n.1 (1998) (Thomas, J., dissenting) (describing an EEOC regulation as "wholly precatory and as such cannot establish negligence *per se*").

193. Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at *10 (Tex. Dist. Ct. June 7, 1999), *aff'd on other grounds sub nom.* McMahon v. Smith & Nephew Richards, Inc., No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000).

194. *Id.* (quoting Guidance for Industry: Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,095 (Dec. 3, 1997)).

impose substantive standards of care and, therefore, are more appropriately characterized as administrative in nature.[195]

V. FDA REGULATIONS AND THE FDA

The majority of opinions that address the propriety of a negligence per se claim do so in the context of alleged statutory violations. Many opinions that address regulations, however, treat them as co-equal with statutes. The existence of these two potential sources of negligence per se liability raises a variety of questions with respect to the propriety of FDA regulations supporting such a theory. These questions revolve around three themes: authority, expertise, and implementation.

The ALI has observed that adoption of regulations to define the standard of care is "comparatively infrequent."[196] This observation suggests the question of whether regulations, and particularly FDA regulations, should serve to define the standard of care. If, as Professors Prosser and Keeton observe, negligence per se reflects deference to the legislature,[197] the question stands as to whether the judiciary should afford the same deference to a regulatory body and, if so, in what context and to what extent. To question the propriety of a negligence per se theory based on violation of a regulation is not to question the FDA's competence but, rather, to question the source of the FDA's (or any other regulatory body's) authority. Although some may question the significance of the availability of federal regulations for negligence per se theories,[198] the role of regulations in this context is particularly important given their ubiquity and the fact that they implicate expertise that courts and juries do not possess.

A. Authority and Accountability of Regulatory Bodies

1. Should the Judiciary Recognize Delegation of Law-Making Authority to a Regulatory Body?

The institutional dimension of the propriety of regulations serving to define the standard of care concerns the nature of democratic government. Those states that regard statutory violations as negligence per se and regulatory violations as only evidence of negligence suggest the problem. The Sixth Circuit (applying Michigan law) and the highest courts in New York and Ohio have confronted this

195. Talley v. Danek Med., Inc., 179 F.3d 154, 159 (4th Cir. 1999); Baraukas v. Danek Med., Inc., No. 6:97CV00613, 2000 WL 223508, at *4 n.2 (M.D.N.C. Jan. 13, 2000) (stating that the defendant's claim that "the FDCA is too vague to act as a standard of care which could be used to establish negligence per se" appears to have some support under North Carolina law) (citing Goodman v. Wenco Foods, Inc., 423 S.E.2d 444 (N.C. 1992)); Alexander v. Smith & Nephew, P.L.C., 98 F. Supp. 2d 1276, 1286 (N.D. Okla. 2000); Uribe v. Sofamor, S.N.C., No. 8:95CV464, 1999 WL 1129703, at *16 (D. Neb. Aug. 16, 1999).

196. RESTATEMENT (SECOND) OF TORTS § 285 cmt. b (1965).

197. KEETON ET AL., *supra* note 11, § 36, at 222.

198. Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. REV. 1129, 1139-40 n.38 (1994) (stating that the reason to be skeptical of the role of negligence per se based on regulatory violations is due, in large part, to many courts' reluctance to treat regulations as being on par with statutes).

problem directly.[199] Although these courts' treatments of this issue may be specific to each state's constitution, the issues they raise are generic. The foundation of this analysis regards "[t]he legislative process and accountability" as "the cornerstones of the democratic process which justify the [legislature]'s role as lawmaker."[200] Regulations do not have this direct source of authority. Rather, regulations are tools to facilitate the policies underlying the statute(s) in question.[201] The source of a regulatory body's authority derives from that of the legislature.[202] Moreover, regulators are appointed, not elected, and the rules they create lack any collaboration from elected officials.[203] Although administrative agencies possess unique expertise in their respective fields, they do not enjoy the same degree of democratic legitimacy the legislature possesses and are not accountable to the legislature.[204]

To defer to administrative bodies "to propose and adopt rules which alter the proof requirements between litigants" would cede to those bodies authority that the legislature alone should possess.[205] Only the legislature has the authority and accountability sufficient to make law. To cede this role to regulatory bodies "would be tantamount to an unconstitutional delegation of legislative authority, since administrative agencies cannot dictate public policy."[206] In this context, therefore, state constitutions construe permitting regulatory agencies to dictate public policy akin to impermissibly delegating Congress's authority as embodied in the U.S. Constitution.[207] The effect of this view would appear to preclude use of FDA

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199. *See, e.g.*, Union Oil Co. v. Prof'l Realty Invs., Inc., No. 94-2021, 1995 WL 717021 (6th Cir. 1995) (applying Michigan law); Bauer v. Female Acad. of the Sacred Heart, 767 N.E.2d 1136, 1140 (N.Y. 2002); Elliott v. City of New York, 747 N.E.2d 760, 762 (N.Y. 2001); Chambers v. St. Mary's Sch., 697 N.E.2d 198, 201 (Ohio 1998).

200. Chambers v. St. Mary's Sch., 697 N.E.2d at 202; *see also* Bauer v. Female Acad. of the Sacred Heart, 767 N.E.2d at 1141.

201. Elliott v. City of New York, 747 N.E.2d at 762; Chambers v. St. Mary's Sch., 697 N.E.2d at 202; Bauer v. Female Acad. of the Sacred Heart, 767 N.E.2d at 1140.

202. *See* Chambers v. St. Mary's Sch., 697 N.E.2d at 202.

203. *Id.*; *see also* Long v. Forest-Fehlhaber, 433 N.E.2d 115, 117 (N.Y. 1982) (stating that administrative rules "lack[] the force and effect of a substantive legislative enactment").

204. Chambers v. St. Mary's Sch., 697 N.E.2d at 202.

205. *Id.*; *see also* Elliott v. City of New York, 747 N.E.2d at 762 (questioning the wisdom of granting regulatory bodies the authority to alter state common law when such authority is "more properly left to the Legislature and not to a 'subordinate rule-making body'" (internal citations omitted)). The New York Court of Appeals' refusal to permit a regulation to support a negligence per se claim calls into question the validity of the decision in Berish v. Richards Med. Co., 937 F. Supp. 181 (N.D.N.Y. 1996), in which the district court upheld the plaintiff's claim that the defendant failed to comply with an FDA regulation. *Id.* at 186. The court, however, only addressed the issue of whether the MDA preempted this claim and did not consider whether this theory stated a claim under New York law. *Id.*

206. Chambers v. St. Mary's Sch., 697 N.E.2d at 202.

207. *See generally* U.S. CONST. art. I, § 1; *see also* Mistretta v. United States, 488 U.S. 361, 371-72 (1988) ("[W]e long have insisted that 'the integrity and maintenance of the system of government ordained by the Constitution' mandate that Congress generally cannot delegate its legislative power to another Branch." (quoting Field v. Clark, 143 U.S. 649, 692 (1892)); Thomas W. Merrill, *Capture Theory and the Courts: 1967-1983*, 72 CHI.-KENT L. REV. 1039, 1104 (1997) (noting that, "if taken seriously," this policy "would call into question the constitutionality of any delegation of power to promulgate legislative rules or otherwise make policy having binding effect on the public"). The courts, however, have permitted delegation of broad policy-making functions to agencies so long as Congress provides an "intelligible principle" to guide the agency's discretion. Mistretta v. United States, 488 U.S. at 372 (citing J. W. Hampton, Jr. & Co. v. United States, 276 U.S. 394, 409 (1928)).

regulations and determinations to define the standard of care when use of the provisions in the FDCA may otherwise be appropriate.

Finally, there is a significant concern that deference to regulations to define the standard of care would, in effect, create a moving target for defendants subject to potential liability under a negligence per se theory. The concern is that, unlike statutes, administrative rules can change "according to the whim or caprice of any officer, board or individual."[208]

2. *Delegated Authority and the Public Review Process*

There is truth in the suggestion that regulations may be easier to change than legislation, but, with respect to FDA regulations at least, this claim may overstate the ease with which they can change and minimize the scrutiny they receive. Moreover, the ability to change FDA regulations without an extended deliberative process subject to the horse trading prevalent in the passage of bills may be a source of strength. Concerns regarding the legitimacy of the FDA's authority notwithstanding, the FDA does not derive its authority *ex nihilo* and does not create rules and regulations in a vacuum. Congress has expressly delegated "[t]he authority to promulgate regulations" to the FDA.[209] There is a case to be made that, with respect to the powers of many federal agencies and the FDA in particular, these bodies have authority to issue rules with the force of law (i.e., the authority of a statute).[210] As with regulations from other agencies, FDA regulations undergo a public hearing process.[211] The FDA has issued specific guidelines "[t]o encourage public participation in all agency activities."[212] Through a citizen's petition, any person can petition the FDA to issue, amend, or revoke certain rules and regulations or take or refrain from certain action.[213] One can also request reconsideration of an FDA decision,[214] although the FDA is not required to consider any matter.[215] Similarly, an "interested person" is entitled to request the

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208. Elliott v. City of N.Y., 747 N.E.2d at 762 (internal citations omitted); *see also* Taylor v. Gate Pharms., 639 N.W.2d 45, 53-54 (Mich. Ct. App. 2001) (stating that it is inappropriate for Michigan law to defer to FDA efficacy determinations as "it is known at the outset that the relevant feature will be in constant flux"), *rev'd sub nom.* Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127 (Mich. 2003).

209. 21 U.S.C. § 371(a) (2000).

210. *See, e.g.*, United States v. Mead Corp., 533 U.S. 218, 226-27 (2001); *see also* Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules With the Force of Law: The Original Convention*, 116 HARV. L. REV. 467, 476-77 (2002) (arguing that various agencies have the authority to issue "'legislative' rules"—rules with "the force and effect of law"). For a detailed discussion of FDA rulemaking in particular, see *id.* at 557-65.

211. 21 U.S.C. § 371(e)(1) (2000) (requiring, with respect to issuance, amendment, or repeal of certain regulations, the FDA to "publish such proposal and . . . afford all interested persons an opportunity to present their views thereon, orally or in writing"); *see also* Merrill & Watts, *supra* note 210, at 477-78 (noting how the Administrative Procedure Act's requirement of a notice-and-comment period for certain proposed rules and regulations suggests that those rules have the force and effect of law).

212. FDA Administrative Practices and Procedures, 21 C.F.R. § 10.10 (2004).

213. *Id.* § 10.30 (describing the format and substantive requirements of a citizen petition); *see also* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 349 (characterizing this regulation as permitting citizens to "report wrongdoing and petition the agency to take action").

214. 21 C.F.R. § 10.33(b) (2004).

215. *See id.* § 10.33(a) (providing that the Commissioner "*may* at any time reconsider a matter" (emphasis added)).

FDA to stay any administrative action,[216] but, once again, the FDA is not required to grant such a request.[217] FDA regulations, furthermore, provide for a public hearing if one is required by statute and the person requesting the hearing "has a right to an opportunity for a hearing."[218] The FDCA, however, "does not require a hearing in every case in which an adversely affected person files an objection."[219] Anyone adversely affected by an FDA rule, regulation, or order may seek judicial review of the order in the court of appeals in the circuit in which that person resides or has its principal place of business.[220] (Depending on the circumstances, of course, the FDA can take action without the notice and comment process.)

This process certainly does not answer the questions of democratic legitimacy the Ohio and New York Supreme Courts pose, but it suggests that the FDA's rulemaking process is neither as byzantine nor as insulated from the democratic or collaborative process as some would maintain.[221] Many courts, however, do not consider the public review process to be sufficient to grant the imprimatur of democratic legitimacy that statutes possess. The public review process simply "constrain[s]" rulemaking and "do[es] not elevate rulemaking to the status of lawmaking for purposes of applying negligence *per se* to violations of administrative rules."[222] Although these considerations do not lend themselves to resolution through a generalized analysis, they are important to address with respect to negligence per se claims based on violations of FDA regulations, as the applicable state law may be determinative of whether such claims are viable.

B. Deference to the FDA's Expertise

1. Expertise and Flexibility

Concerns regarding the legitimacy of the regulatory body may be overblown given the fact that, at the federal level at least, the legislature delegates the authority to these bodies, and to the FDA in particular.[223] This argument cuts both ways,

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216. *Id.* § 10.35(b).

217. *Id.* § 10.35(a), (d) (requiring an action to be stayed only if the Commissioner determines that a stay is in the public interest or a statute or court order requires a stay).

218. *Id.* § 10.50(a) ("The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing under part 12 whenever all of the following apply . . . .").

219. Pineapple Growers Ass'n v. FDA, 673 F.2d 1083, 1085 (9th Cir. 1982) (citing 21 U.S.C. § 371(e)(3) (2000)).

220. 21 U.S.C. § 371(f)(1); Judicial Review, 21 C.F.R. § 12.140 (2004) ("The Commissioner's final decision constitutes final agency action from which a participant may petition for judicial review under the statutes governing the matter involved.").

221. *See* United States v. Mead Corp., 533 U.S. 218, 226-27 (2001) (noting how the notice-and-comment process contributes to agency rules carrying the force of law); Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2147-52 (2000) (describing a "structured and public rulemaking process") [hereinafter Noah, *Rewarding Regulatory Compliance*].

222. Chambers v. St. Mary's Sch., 697 N.E.2d 198, 202 n.2 (Ohio 1998).

223. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 165 (2000) (Breyer, J., dissenting) (quoting J. O'REILLY, FOOD AND DRUG ADMINISTRATION § 6.01, 6-1 (2d ed. 1995)); Caraker v. Sandoz Pharms. Corp., 172 F. Supp. 2d 1018, 1035 (S.D. Ill. 2001) ("What Congress did intend to do is delegate broad authority to an administrative agency, the FDA, to regulate consumer product labeling"); Berlex Labs., Inc. v. FDA, 942 F. Supp. 19, 25 (D. D.C. 1996) (noting the "breadth of Congress' delegation of authority to FDA") (citing Lyng v. Payne, 476 U.S. 926, 939 (1968)).

however, as the congressional scheme for enforcement of the FDCA is also a basis for denying private litigants the ability to enforce those same provisions.[224] An additional basis for denying negligence per se claims in this context is the fact that the FDA possesses expertise that is beyond that of the average court and juror. The broad grant of authority to the FDA, in conjunction with its scientific expertise, has earned the FDA a substantial degree of deference from the courts.[225] The FDA's expertise and flexibility give it a degree of credibility and authority that is arguably lacking due to its status as an unelected body with (ostensibly) insufficient oversight.

The changing nature of regulations that the New York Court of Appeals criticizes[226] may more properly be regarded as its strength. The Supreme Court has characterized the FDA's flexibility as "a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives."[227] Furthermore, unlike the FDA, Congress does not normally track the impact of its work.[228] Some of these provisions, however clear they may be, represent legislative and regulatory judgments based on data and knowledge available at the time they were made and, therefore, violation of any of these provisions may not be unreasonable.[229] The question, then, is whether civil liability should be imposed on a drug or device manufacturer despite this uncertainty. As a result, as between Congress and the FDA, the FDA is more likely to keep regulations and enforcement decisions less dated, or even current with, scientific developments.[230] That is, the FDA is better equipped to be current with science, as that is precisely what its charge requires. Moreover, courts widely, and almost uniformly, recognize that "chemical and pharmacological" issues are "within the pe-

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224. *See supra* Part III.B.2.

225. *See, e.g.*, Merrell Dow Pharms., Inc. v. Thompson, 478 U.S. 804, 830 (1986) (Brennan, J., dissenting) (noting that Congress conferred authority to implement the FDCA on the FDA, "a specialized administrative agency"); Pharmanex v. Shalala, 221 F.3d 1151, 1154 (10th Cir. 2000) (noting the FDA's "special institutional competence"); Berlex Labs., Inc. v. FDA, 942 F. Supp. at 25; Abbott Labs. v. Zenith Labs., Inc., 934 F. Supp. 925, 934 (N.D. Ill. 1995).

226. *See, e.g.*, Elliott v. City of N.Y., 747 N.E.2d 760, 762 (N.Y. 2001) ("[C]ontrast[ing] the procedures for amending or repealing . . . rules with . . . statutes" and suggesting that rules can change based on the "whim or caprice" of the regulators) (internal citations omitted).

227. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001).

228. Noah, *Rewarding Regulatory Compliance*, *supra* note 221, at 2149-52 (contrasting the FDA regulatory regime against the judicial process and concluding that judges and juries possess less expertise and are less accountable than the FDA); Paul Sherman, *Use of Federal Statutes in Negligence Per Se Actions*, 13 WHITTIER L. REV. 831, 839 (1992) (noting that agencies have greater flexibility than Congress to amend regulations and make their intentions known) (citing Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 721 (1985)).

229. *See* Sheila G. Bush, *Can You Get There From Here?: Noncompliance with Environmental Regulations as Negligence Per Se in Tort Cases*, 25 IDAHO L. REV. 469, 478 (1988-89). This problem is particularly appropriate given the fact that, with respect to creating laws and regulations, Congress and the FDA cannot always keep up with science. *Cf.* Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996) ("Law lags science; it does not lead it."). However, it is likely that, as between Congress and the FDA, the FDA is more likely to keep regulations and enforcement decisions less dated, or even current with, scientific developments. *See* Noah, *Rewarding Regulatory Compliance*, *supra* note 221, at 2148-50 (describing the process through which the FDA creates regulations, weathers judicial review, clarifies regulations, and "revisit[s] regulations in light of changed circumstances").

230. *See* Noah, *Rewarding Regulatory Compliance*, *supra* note 221, at 2148-50.

culiar expertise of the FDA."[231] Courts and juries lack this expertise.[232] Under principles of administrative law as articulated under *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*,[233] this deference is particularly strong when considering the FDA's interpretation of its own rules and regulations.[234]

This expertise and flexibility clearly mitigates against permitting judges and juries to review or second guess the FDA's actions or refusals to act. This conclusion, however, may apply with equal force to both negligence per se theories and the regulatory compliance defense.

2. *Negligence Per Se and the Regulatory Compliance Defense*

A theme that is the inverse of, or parallel to, negligence per se is the regulatory compliance defense. The regulatory compliance defense concerns some of the exact same topics that concern the propriety of negligence per se theories based on the FDCA, MDA, and FDA regulations. These topics include: the specificity of regulations, interference with the FDA's enforcement powers, and concern for the source of the FDA's authority to make law. The symmetry between a negligence per se theory and the regulatory compliance defense could dictate that acceptance (or rejection) of the former requires acceptance (or rejection) of the latter. The widespread concerns about the propriety of the regulatory compliance defense, however, do not appear to have dissuaded courts from permitting negligence per se claims.[235] This fact is all the more paradoxical given that Congress has precluded

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231. Upjohn Co. v. Kessler, 938 F. Supp. 439, 444 (W.D. Mich. 1996) (citing Weinberger v. Bentex Pharms., Inc., 412 U.S. 645, 653-54 (1973)); *see also* Zeneca, Inc. v. Shalala, 213 F.3d 161, 170 (4th Cir. 2000); Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1320 (D.C. Cir. 1998) (noting that the area of the FDA's expertise warrants a "'high level of deference'" (internal citations omitted)); Schering Corp. v. FDA, 51 F.3d 390, 399 (3rd Cir. 1995); Premo Pharm. Labs., Inc. v. U.S., 629 F.2d 795, 802 (2d Cir. 1980) (stating that FDA is "the publicly recognized repository of expertise in . . . matters" related to evaluation and approval of drugs); Healthpoint, Ltd. v. Stratus Pharms., Inc., 273 F. Supp. 2d 769, 815-16 (W.D. Tex. 2001).

232. *See* Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1381 (11th Cir. 1999). In *Goodlin*, the court stated:

> It seems presumptuous, to say the least, to permit a jury composed of ordinary citizens, none of whom we can expect to have significant medical training, to second-guess a decision, already extensively and rigorously considered by some of the most qualified minds in the relevant medical and scientific fields, regarding the rather complicated question of the safety of a particular medical device.

Id.; *see also* Ausness, *supra* note 129, at 1220 (maintaining that "courts are institutionally incapable of resolving complicated product safety issues").

233. 467 U.S. 837, 843-44 (1984) (stating that "legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute").

234. *See* Sigma-Tau Pharms., Inc. v. Schwetz, 288 F.3d 141, 146 (4th Cir. 2002) (observing that such deference is even greater when "the regulation concerns 'a complex and highly technical regulatory program'" (quoting Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994)); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1071 n.13 (D.C. Cir. 1998) ("We owe substantial deference to an interpretation by the FDA of its own regulations, which has controlling weight unless it is plainly erroneous or inconsistent with the regulation." (internal quotations omitted)).

235. *See* Lars Noah, *Statutes and Regulations: If Noncompliance Establishes Negligence Per Se, Shouldn't Compliance Count for Something?*, 10 KAN. J.L. & PUB. POL'Y 162, 164 (2000) ("[F]ears about regulatory obsolescence and ambiguity have not deterred courts from using violations of these safety standards to assist plaintiffs' in making negligence *per se* claims.").

private rights of action based on the FDCA, but has not prohibited compliance with the FDCA, MDA, or FDA regulations as a defense.

In nearly every jurisdiction in the United States, the standard rule is that regulations (including FDA regulations) provide a minimum of what is required of a regulated party and do not immunize that party from tort liability.[236] The premise for this view is that statutory and regulatory standards are "presumptively suboptimal."[237] Advocates of the regulatory compliance defense posit that satisfac-

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236. *See, e.g.*, O'Gilvie v. Int'l Playtex, Inc., 821 F.2d 1438, 1442-43 (10th Cir. 1987) (stating that regulatory compliance is insufficient to immunize a manufacturer from liability from negligence if the plaintiff can show that a reasonable manufacturer would have done more); Ohler v. Perdue Pharma, L.P., No. CIV.A.01-3061, 2002 WL 88945, at *13 n.37 (E.D. La. Jan. 22, 2002) ("Agency regulations in the field of prescription drug labeling were not intended to displace State regulation, but instead to establish minimum standards."); Caraker v. Sandos Pharms. Corp., 172 F. Supp. 2d 1018, 1033 n.11 (S.D. Ill. 2001) (citing cases); Motus v. Pfizer, Inc., 127 F. Supp. 2d 1085, 1092 (C.D. Cal. 2000) ("[M]ost courts have found that FDA regulations as to design and warning standards are minimum standards which do not preempt state law defective design and failure to warn claims."); Ramirez v. Plough, Inc., 863 P.2d 167, 172-73 (Cal. 1993) (noting design and warning standards, but permitting a statutory compliance defense with respect to foreign language labeling of non-prescription drugs); Merrell Dow Pharms., Inc. v. Oxendine, 649 A.2d 825, 828 (D.C. 1994) ("FDA prescription drug regulations and safety determinations are intended to be minimum standards."); Toner v. Lederle Labs., 732 P.2d 297, 311 n.12 (Idaho 1987) (rejecting the argument "that FDA certification ought to constitute non-negligence *per se*"); Edwards v. Basel Pharms., 933 P.2d 298, 302 (Okla. 1997) ("It is the widely held view that the FDA sets minimum standards for drug manufacturers as to design and warnings."); Wash. State Physicians Ins. Exch. & Ass'n v. Fisons Corp., 858 P.2d 1054, 1069 (Wash. 1993) (" 'Evidence of compliance with FDA regulations does not necessarily relieve a drug manufacturer of liability for failure to furnish an adequate warning of possible side effects . . . .' " (quoting AMERICAN LAW OF PRODUCTS LIABILITY § 89:15, at 26 (3d ed. 1987))); James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 320 (1990). Henderson and Twerski note:

> [F]or reasons that we find difficult to understand, courts have not deferred to the determinations of product safety agencies such as the Food and Drug Administration or Consumer Product Safety Commission. The analysis usually begins and ends with the statement that agency standards are minimum, not maximum, standards and that courts are therefore free to disregard them.

Id.; *see also* Kahn, *supra* note 198, at 1132 ("In general, the safety precautions required of regulated parties to limit potential tort liability are often as great or greater than those required by the express regulatory mandates which they face."); Kahn, *supra* note 198, at 1157, 1161-62 (stating that compliance with FDA regulations does not provide protection against products liability claims despite "the unusually comprehensive nature of pharmaceutical regulation"); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2075 (2000) (observing this standard rule, but noting that "there is no warrant in the governing statute or the agency for doing so").

The court in *Caraker* suggested that one of the reasons a regulatory or statutory compliance defense should not exist is that state law was meant to supplement "FDA regulation[s] by creating a compensatory mechanism not available under federal law." Caraker v. Sandros Pharm. Corp., 172 F. Supp. 2d at 1033 (citing Mazur v. Merck & Co., 742 F. Supp. 239, 247 (E.D. Pa. 1990); Feldman v. Lederle Labs., 592 A.2d 1176, 1192 (N.J. 1991)). This rationale suggests that, in fact, there should be symmetry between negligence per se and the statutory/regulatory compliance defense—neither should be available or both should be available.

237. Noah, *Rewarding Regulatory Compliance*, *supra* note 221, at 2153 (noting further that "[a]t some level, the longstanding rejection of a compliance defense appears to reflect a populist faith in laypersons and an accompanying distrust of distant federal bureaucracies").

tion of relevant regulations should be dispositive of whether the defendant met the applicable standard of care or, in some cases, should establish that a product is not defective.[238] The regulatory compliance defense may be best characterized as a form of preemption under which "courts should be prohibited from co-regulating pharmaceuticals through the award of tort damages."[239] Both Michigan and Texas have codified the regulatory compliance defense in some contexts and to some degree.[240]

A Michigan appellate court's decision in *Taylor v. Gate Pharmaceuticals*,[241] although reversed on appeal, perhaps best addresses the intersection of multiple themes with respect to the scope and safe harbor of FDA regulations. These themes include the propriety of delegating law-making authority to a regulatory body. *Taylor* concerned the propriety of M.C.L. § 600.2946(5), which limited the liability of pharmaceutical manufacturers in products liability suits if the FDA approved the drug and the manufacturer labeled the drug in accordance with FDA standards.

A number of fen-phen plaintiffs challenged the constitutionality of M.C.L. § 600.2946(5) on the grounds that it violated the Michigan Constitution by delegating the legislature's law-making authority to the FDA.[242] Under Michigan law, the standard for delegating legislative authority requires there to be "sufficient standards and safeguards" to direct and check the exercise of the delegated power.[243] The court did not rule, as the New York Court of Appeals and Ohio Supreme Court likely would have,[244] that delegation to an administrative body was, ipso facto, unconstitutional.[245] Rather, the court held that delegation of *state* law-making to the FDA, a *federal* agency, "[ran] afoul of the constitutional prohibition against delegation of legislative power because the Michigan Legislature retains no oversight function and is unable to guide the exercise of its delegated power by the establishment of standards."[246] The FDA's expertise in this field was of no consequence as M.C.L. § 600.2946(5) placed this regulatory body, without oversight

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238. *See* Ausness, *supra* note 129, at 1212 (describing a "strong" regulatory compliance defense which provides that a product is not defective if the manufacturer has satisfied relevant regulatory standards); Rabin, *supra* note 236, at 2049-50 (describing a case in which the defendant argued that its satisfaction of all regulatory compliance conclusively proved that it exercised due care).

239. Viscusi et al., *supra* note 129, at 1478.

240. *See* MICH. COMP. LAWS ANN. § 600.2946(5) (2004). The Michigan statute provides:

> a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

Id.; see also TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (Vernon 2003) (providing that FDA approval of a drug or device warning supports a rebuttable presumption that the manufacturer provided an adequate warning).

241. 639 N.W.2d 45 (Mich. Ct. App. 2001), *rev'd sub nom.* Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127 (Mich. 2003).

242. *Id.* at 50 (observing that, although there is no constitutional provision for the non-delegation doctrine, Michigan courts have acknowledged and applied it).

243. *Id.*

244. *See* Elliott v. City of New York, 747 N.E.2d 760, 762 (N.Y. 2001); Chambers v. St. Mary's Sch., 697 N.E.2d 198, 202 (Ohio 1998).

245. Taylor v. Gate Pharm., 639 N.W.2d at 52.

246. *Id.*

from the Michigan legislature, "in the position of final arbiter with respect to whether a particular drug may form the basis of a products liability action in Michigan."[247] Similar to the New York Court of Appeals, moreover, the Michigan appellate court expressed concern for the legislature adopting a standard over which it has no control and may change in the future as further underscoring the infirmities of M.C.L. § 600.2946(5) with respect to Michigan's non-delegation doctrine.[248]

The Michigan Supreme Court, however, reversed the intermediate appellate court's holding. The Michigan Supreme Court based this reversal on the fact that M.C.L. § 600.2946(5) was not a delegation of authority to the FDA but, rather, was a determination that a "factual conclusion of independent significance, i.e., the FDA conclusion regarding the safety and efficacy of a drug" will require Michigan courts to find that a pharmaceutical manufacturer acted with due care.[249] That is, the FDA's determination of the safety and efficacy of a drug will be the "measure" of whether a manufacturer exercised reasonable care.[250] The Michigan Supreme Court relied heavily on the fact that, because the FDA's safety and efficacy determinations had significance outside and independent of the law that refers to them, "there is no delegation."[251] Despite the Michigan Supreme Court's acceptance of M.C.L. § 600.2946(5), the rationale underlying the intermediate appellate court's concern over ceding legislative and judicial powers to a regulatory body is seen in resistance to adoption of comment k to section 402A of the RESTATEMENT (SECOND) OF TORTS (and, presumably, section 6(c) of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY) as a matter of law.[252]

3. Necessary Adjunct to the FDA's Enforcement Efforts or Source of Interference?

A host of policy and practical considerations are at odds with the application of negligence per se to violations of FDA regulations and the regulatory compliance defense. These considerations revolve around the concern that permitting a jury of lay persons to consider compliance with the FDCA or FDA regulations would, effectively, constitute second-guessing the FDA's decisions to act or sit still. The salient issue, therefore, is how private causes of action should interact with the FDA discretion to enforce alleged violations of the FDCA or FDA regulations.

Some view a private right of action in the form of negligence per se to be a necessary adjunct to the FDA's enforcement efforts. As Justice Stevens's concurring opinion in *Buckman* noted, though in the context of a fraud-on-the-FDA claim,

247. *Id.* at 53.

248. *Compare id.* at 54 ("Where, however, as here with the FDA efficacy determinations, it is known at the outset that the relevant feature will be in constant flux, a fatal problem does present itself under the constitutional nondelegation doctrine as developed and applied in Michigan."), *with* Elliott v. City of N.Y., 747 N.E.2d at 762 (expressing concern that, unlike statutes, administrative rules can change "according to the whim or caprice of any officer, board or individual" (citations omitted)).

249. Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127, 134 (Mich. 2003).

250. *Id.*

251. *Id.* at 136 (describing this characterization as "central" to the court's ruling).

252. *See, e.g.*, Shanks v. Upjohn Co., 835 P.2d 1189, 1197 n.10 (Alaska 1992) ("While a deferential standard of review is appropriate when directly reviewing an agency decision . . . we feel that such deference in the face of allegations of serious injuries caused by FDA-approved drugs would amount to an abdication of judicial responsibility." (citations omitted)).

permitting civil causes of action to proceed "would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme."[253] Private enforcement of violations of federal standards will provide one more incentive to comply with those standards.[254] That is, the tort system is perceived to have a role in educating the public about the dangers of certain conduct.[255] The observation of the role of the tort system in educating the public is not nearly so unequivocal in terms of the benefits it is alleged to confer, however, and its greatest weaknesses are in the context of negligence per se theories and friction it creates with regulatory bodies.[256] As such, there are a host of arguments why FDA inaction should not undermine a negligence per se cause of action and should not create a regulatory compliance defense.

An economic argument is that the costs of tort liability are overstated as economists count them twice, the first time with respect to the costs of tort liability itself and the second with respect to the costs of regulatory compliance, which purportedly includes the costs of tort liability.[257] As a result, purportedly, the cost of tort liability is overstated. Furthermore, with respect to the information that exists concerning drugs and medical devices, the root of the problem is that the FDA (similar to any other agency), is a passive body. That is, the FDA is dependent upon pharmaceutical and medical device manufacturers for the information it receives and, therefore, the decisions it does or does not make.[258] The first, most common, argument that is part of this position is that pharmaceutical and medical device manufacturers do not always provide complete and accurate information to the FDA.[259] The FDA, further, ostensibly lacks "the resources to monitor and ensure universal compliance of a large, technologically complex, and informationally massive industry."[260] This purported inability is particularly acute with respect to postmarketing approval reports, which, arguably, pose a greater

253. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 354 (2001) (Stevens, J., concurring); *see also* Edward J. Parr Jr., *How to Buck Preemption in Drug Cases*, TRIAL, Nov. 2001, at 35, 40 (observing that the FDA "has neither the resources nor the will to enforce the FDCA in every circumstance").

254. Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996) ("The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."); *see also id.* at 513 (O'Connor, J., concurring in part and dissenting in part) (providing a remedy for violations of the MDA "will give manufacturers an additional cause to comply").

255. *See* Rabin, *supra* note 236, at 2068-70 (addressing "the educational role of tort law").

256. *See* Buckman v. Plaintiffs' Legal Comm., 531 U.S. at 350 ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives.").

257. Kahn, *supra* note 198, at 1134 (arguing that the marginal costs of regulation are negligible).

258. *See* Thomas O. McGarity, *Beyond* Buckman*: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 558-59 (2002); Rabin, *supra* note 236, at 2069 ("Even in the case of a comprehensive regulatory regime like FDA certification of new drugs, the agency process is noninvasive: the burden is on the company to produce evidence in support of its new drug application, and the agency does not conduct its own testing and experimentation.") (citation omitted).

259. McGarity, *supra* note 258, at 559-63.

260. Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 482 (1997).

potential for a failure to provide complete and accurate information to the FDA.[261] A host of influences, both tacit and explicit, present the possibility of undermining the quality of the information manufacturers provide to the FDA.

Another common argument is rooted in the concept of "agency capture." "Agency capture" describes the situation in which a regulated industry gains control over regulators to the extent that the regulators are serving the interests of the regulated industry.[262] Put simply, the core of the agency capture critique is the obvious problem of the fox guarding the hen house.[263] As the argument would apply in the context of the FDA, agency capture results from the biases of political appointees, a malleable FDA, a need for the FDA to work with pharmaceutical and medical device manufacturers, a "revolving door" between agencies and the industries they oversee, and a view that the drug approval process consists of horse-trading.[264] Even advocates of a regulatory compliance defense concede the industry's ability and willingness to marshal resources to influence the FDA's actions.[265] To permit negligence per se claims to proceed would, in effect, correct the effects of regulatory capture.[266] Under agency capture theory, therefore, one would *want* private parties and juries to correct the FDA's acts and omissions.

The agency capture critique is largely based on the assumption that an absence of FDA action with respect to an alleged violation does not indicate that there wasn't a violation but, rather, is the result of data withheld by the manufacturer, misleading data provided by the manufacturer, a complicit FDA, or an agency with insufficient resources to pursue violations of the FDCA or FDA regulations. In its most simplistic and crass form, there are no justifiable or even innocent examples of FDA inaction, only a multitude of examples in which pharmaceutical manufacturers manipulate a pliant and over-worked FDA. Any principled expression of capture theory, however, must "recognize that regulations are not always caused by capture" and assuming capture theory is persuasive, "regulations that are caused by capture are not always bad."[267] Regulatory agencies, to their credit, are required to and should take into account a diversity of interests and opinions in making decisions.[268] An embrace of agency capture theory, furthermore, must anticipate the consequences such as "a revival of the nondelegation doctrine" in

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261. Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2122-23 (2000).

262. John Shepard Wiley Jr., *A Capture Theory of Antitrust Federalism*, 99 HARV. L. REV. 713, 723-26 (1986) (describing a shift in the perception of antitrust policy in which "[r]egulation, formerly conceived of as a method of advancing public interest over private advantage, in many instances came to be conceived of as a method of subsidizing private interests at the expense of the public good").

263. McGarity, *supra* note 258, at 564; *see also* Vincent R. Johnson, *Liberating Progress and the Free Market from the Specter of Tort Liability*, 83 Nw. U. L. REV. 1026, 1051-52 (1989) (reviewing A REVIEW OF LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES (1998)).

264. *See* McGarity, *supra* note 258, at 564-67; Johnson, *supra* note 263, at 1051-53.

265. *See, e.g.*, Noah, *Rewarding Regulatory Compliance*, *supra* note 221, at 2154-55 ("[N]o one disputes the tremendous resources that industry can deploy to influence the legislative and regulatory processes. . . .").

266. *See* McGarity, *supra* note 258, at 564.

267. *See* Wiley, *supra* note 262, at 742-43.

268. Ausness, *supra* note 129, at 1219.

which Congress would (have to?) cede less responsibilities to agencies.[269] One possible result is "an improvement in the quality of public policy" in which "critical policy decisions were made by Congress, and agencies were reined in so as to make capture harder to achieve."[270] A more likely result would be an emasculated FDA, which would pose the real possibility (read: likelihood) of a regulatory regime ill-suited and ill-equipped to address the needs of a rapidly changing industry.

C. A Deluge of Information and Opening the Floodgates of Litigation

There are two possible results from permitting negligence per se actions premised on alleged violations of FDA regulations to proceed. These causes of action would, in effect, overburden both FDA and the judiciary. In order to avoid the specter of anything less than a full and complete provision of information to the FDA, pharmaceutical and medical device manufacturers are likely "to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application."[271] The Ohio Supreme Court also observed a practical problem with permitting administrative rules to define the standard of care. First, there are so many administrative rules, that to make violations of these rules actionable "could open the floodgates to litigation."[272] It may be virtually impossible for actors to strictly comply with these rules and regulations.[273]

Further, there is a fundamental difference in how a tort claimant proves its case and how an agency creates regulations and regulates an industry. The products liability claimant must present judicially admissible evidence to prove liability by a preponderance of the evidence.[274] An administrative agency, including the FDA, "considers legislative facts and exercises its judgment to adopt a regulation setting a numerical standard based on the scientific evidence presented, and incorporating a margin of safety."[275] The FDA also has substantial discretion with respect to whether and how it chooses to enforce alleged violations of FDA regulations. The result of this regulatory process is a more nuanced and comprehensive assessment of a drug's risks and benefits—a regime that tort liability should not undermine and can only frustrate.[276]

The discretion Congress has afforded to the FDA is the source of much of the friction in both the questions of negligence per se and the regulatory compliance defense. As observed above, Congress delegated substantial authority to the FDA, making it the sole arbiter of when a violation has occurred and when to prosecute an alleged violation. "Permitting enforcement of the FDCA through common law negligence *per se* claims," similarly, "places a plaintiff in a position to act as a

269. *See* Merrill, *supra* note 207, at 1104.
270. *Id.*
271. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 351 (2001).
272. Chambers v. St. Mary's Sch., 697 N.E.2d 198, 202-03 (Ohio 1998).
273. *Id.* at 203.
274. Bush, *supra* note 229, at 483-84.
275. *Id.* at 484.
276. *See* Viscusi et al., *supra* note 129, at 1475 (concluding that the tort system is "almost certainly" less accurate than the FDA).

prosecutor when the FDA has declined to accept that role."[277] In evaluating and enforcing such a claim, therefore, a court would "usurp [the FDA's] responsibility for interpreting and enforcing potentially ambiguous regulations."[278] That is, juries will inevitably step on the FDA's feet whether they are considering compliance with FDA regulations in the context of negligence per se or the regulatory compliance defense. The result is especially inappropriate given that courts and juries are ill-equipped to address the complex regulatory and scientific issues that will confront them.[279]

This rationale is similar to that which many courts have found to be persuasive in the application of comment k to section 402A of the RESTATEMENT (SECOND) OF TORTS. Under comment k, prescription drugs are not defective or unreasonably dangerous if "properly prepared [] and accompanied by proper directions and warning."[280] That is, comment k exempts prescription drugs from defective design strict liability. Allowing courts and juries to evaluate a prescription drug's risks and benefits with respect to a design defect claim would undermine the FDA's role and authority in such determinations.[281] Comment k, interestingly may be one of the areas in which the regulatory compliance may be especially compelling despite the infirmities of a negligence per se theory. The case for the regulatory compliance defense with respect to comment k may be so compelling precisely because it is an example of the FDA actively considering an issue of compliance and then making an express ruling on that issue.

VI. CONCLUSION

If the beginning and the end of assessing the propriety of a negligence per se claim is legislative intent, such a claim should not stand. Negligence per se is rooted in deference to the legislature and permitting such claims in this context would make this profession of deference insincere at best. It is inescapable that Congress expressly entrusted all power to enforce the FDCA and MDA to the FDA. Congress expressly foreclosed the FDCA as a source of civil liability but made no such foreclosure with respect to whether compliance can serve as a defense against liability. To the extent that determining the propriety of negligence per se claims requires analysis beyond legislative intent, however, this inquiry must begin with two specific issues: applicable state law and the specific statute or regulation that was allegedly violated.

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277. Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at *18 (Tex. Dist. Ct. June 7, 1999), *aff'd on other grounds sub nom.* McMahon v. Smith & Nephew Richards, Inc., No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000).

278. Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990) (noting further that regulation of marketing over-the-counter drugs "is vested jointly and exhaustively in the FDA and the FTC" and neither statute that established these bodies "creates an express or implied private right of action"); *see also* Viscusi et al., *supra* note 129, at 1475-78 (noting that litigation "can lessen the value or even countermand the judgments of the FDA" and maintaining that "courts should be prohibited from co-regulating pharmaceuticals through the award of tort damages").

279. *See* Ausness, *supra* note 129, at 1219; Green & Schultz, *supra* note 261, at 2122 (stating that it "seems correct" that the FDA sets standards that are "at least better than any other entity that exists").

280. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998).

281. *See, e.g.*, Grundberg v. Upjohn Co., 813 P.2d 89, 97-99 (Utah 1991).

Acceptance of a negligence per se theory based on the FDCA, the MDA, and FDA regulations need not be an either-or proposition. Perhaps the best solution is a limited and targeted acceptance of negligence per se theories—similar to what some advocate for the regulatory compliance defense.[282] First, the court would assess whether the specific provision is appropriate to support the imposition of civil liability. Second, the court would determine whether the FDA has determined that the defendant violated this provision. Third, the plaintiff must prove that the violation actually caused his or her injury. This compromise would avoid permitting a negligence per se theory to proceed when the theory would not serve the purpose of the FDCA or its enforcement scheme and, perhaps more importantly, would avoid the specter of lay judges and juries co-regulating drugs and medical devices. The assertion of a negligence per se claim or the regulatory compliance defense, then, would only be appropriate in the context of an express determination of breach or compliance. Such determinations are likely rare, but so should be the viability of this theory of recovery.

Prohibiting negligence per se claims predicated on violations of the FDCA, the MDA, and FDA regulations does not strip a claimant of the right to sue and does not even deprive a claimant of suing under a negligence theory.[283] Right or wrong, many states provide plaintiffs with a host of theories for recovery in the context of pharmaceutical and medical device products liability claims. Moreover, preclusion of a negligence per se cause of action in this context would not necessarily prevent a claimant from adducing evidence of alleged statutory and regulatory violations when such evidence comports with the applicable rules of evidence.[284] It does, however, comport with congressional intent underlying the FDCA to preclude private litigants from enforcing its provisions and would reflect the deference to the legislative branch that is supposed to inform the policy underlying negligence per se claims.

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282. *See* Rabin, *supra* note 236, at 2082-83 (citing Ramirez v. Plough, Inc., 863 P.2d 167 (Cal. 1993)).

283. Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at *9 (Tex. Dist. Ct. June 7, 1999) (observing that "[t]he alleged violations of the FDCA and MDA are surplusage if [plaintiff] can prove negligence or strict liability"), *aff'd on other grounds sub nom.* McMahon v. Smith & Nephew Richards, Inc., No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston [14th Dist.] July 20, 2000).

284. KEETON ET AL., *supra* note 11, § 36, at 231 ("There is, in other words, a statutory custom, which is entitled to admission as evidence.").