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Products Liability - The Effect of Medtronic, Inc. v. Lohr on Third Circuit Products Liability Litigation: Medical Device Amendments Do Not Pre-Empt State Law Tort Claims

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A disturbing reality of products liability law before 1996 was that the United States Food and Drug Administration’s ("FDA") approval of a drug or device could preclude an injured plaintiff from collecting damages from the manufacturer under common law tort theories. This fact resulted from the statutory language and judicial interpretation of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938 ("MDA"). The amended statute expressly states Congress’ intent that no

1. See Suzanne Darrow Kleinhaus, Medtronic v. Lohr: For Want of a Word, the Patient was Almost Lost—Fixing the Mischief Caused in Cipollone by Dividing the Pre-emption Stream, 53 FOOD & DRUG L.J. 297, 314 (1998) (assessing impact of 1996 decision by Supreme Court in Medtronic, Inc. v. Lohr); Rachel Tumidolsky, How Medtronic v. Lohr has Redefined Medical Device Regulation and Litigation, 65 Def. Couns. J. 268, 268 (1998) (stating “[s]tate law tort claims will no longer be pre-empted by the Medical Devices Amendments, and manufacturers now are faced with state product liability,” and attributing change to Supreme Court’s 1996 ruling). After extensive analysis of the Supreme Court’s holding in Medtronic, one commentator assessed its impact, stating “[s]ince Medtronic, however, plaintiffs previously denied recovery under state tort law causes of action have claimed that the Supreme Court has effectively overturn[ed] all of the cases which made the . . . conclusion that common law claims were requirements different or in addition to federal regulations . . . .” Kleinhaus, supra, at 34.


Provisions of the MDA that are pertinent to this issue provide:
§ 360k. State and local requirements respecting devices
(a) General rule
Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2) which related to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
(b) Exempt requirements
state may establish requirements applicable to medical devices that are different from, or in addition to, any federal requirements.\textsuperscript{3} Although federal courts have varied in their readings of this statute, many courts have interpreted it to pre-empt state tort law remedies for plaintiffs if the FDA had approved the device at issue.\textsuperscript{4} Such tort law claims pre-empted under this assumption included negligence, strict liability, misrepresentation and so-called “fraud on the FDA” claims.\textsuperscript{5}

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if —

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement —

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k. For further discussion of the MDA, see infra notes 21-38 and accompanying text.


4. See Jean M. Eggen, Sense or Sensibility?: Toxic Product Liability Under State Law After Cipollone and Medtronic, 2 Widener L. Symp. J. 1, 22-26 (1997) (discussing various circuit courts’ holdings regarding interpretation of “requirement” as used in Medical Device Amendments); see, e.g., Martin v. Telectronics Pacing Sys., Inc., 70 F.3d 39, 41 (6th Cir. 1995) (“We now join the majority of circuits and hold that § 360k(a) of the MDA expressly preempts plaintiffs’ state law product liability claims.”), vacated and remanded, 518 U.S. 1030 (1996); Becker v. Optical Radiation Corp., 66 F.3d 18, 20 n.2 (2d Cir. 1995) (“It is now well established that a ‘requirement’ for purposes of the preemption provision of the MDA may be created by state common law as well as by statutory law.”); Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392, 397-98 (4th Cir. 1995) (concluding that state law claims may impose requirements within meaning of § 360k), vacated and remanded, 518 U.S. 1030 (1996); Michael v. Shiley, Inc., 46 F.3d 1316, 1323 (3d Cir. 1995) (“We have already determined that the term ‘requirements’ as used in § 360k encompasses state common law claims.”); Martello v. Ciba Vision Corp., 42 F.3d 1167, 1168 (8th Cir. 1994) (“Thus, the MDA’s preemptive effect extends to state tort actions.”); Stamps v. Collagen Corp., 984 F.2d 1416, 1420-21 (5th Cir. 1993) (“We likewise must reject Stamps’s argument that Congress did not intend to preempt state tort law remedies when it enacted the MDA.”); King v. Collagen Corp., 985 F.2d 1150, 1134 (1st Cir. 1993) (holding that state requirement “may emanate from any requirement established by a state including statutes, regulations, court decisions or ordinances”); Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333-34 (7th Cir. 1992) (holding “Investigational Device Exemption Regulations” for intraocular lenses preempted claims).

5. See, e.g., Becker, 66 F.3d at 18 (finding MDA pre-emption in products liability action for defective design, defective manufacture, failure to warn and failure to test); Duvall, 65 F.3d at 392, 395 (finding MDA pre-emption of state law claims for strict liability in defective design, defective manufacture, failure to warn and claims for negligence in marketing, testing, promotion and sale of product).
In *Medtronic v. Lohr*, the Supreme Court of the United States sought to answer this pre-emption question definitively—ruling that the state law claims at issue in that case were not pre-empted by the MDA. This pronouncement by the Court prompted lower courts throughout the country not only to treat the issue differently in the future, but also to reconsider cases decided contrary to *Medtronic*. In addition, the ruling has changed the litigation landscape for developers and manufacturers of drugs and medical devices.

The United States Court of Appeals for the Third Circuit has considered the pre-emption question as well. With its recent decision in *In re Orthopedic Bone Screw Products Liability Litigation*, a divided panel extended the *Medtronic* rule and allowed state law tort claims. Specifically, the court held that a fraud on the FDA claim, if properly pleaded, might not be pre-empted by the MDA. This pronouncement overruled the Third Circuit's 1995 decision in *Michael v. Shiley, Inc.* in which the court found that the MDA pre-empted any state law claims. The court's ruling

7. See id. at 503 ("Accordingly, the judgment of the Court of Appeals is reversed insofar as it held that any of the claims were pre-empted [by the MDA] and affirmed insofar as it rejected the pre-emption defense.").
9. See Tumidolsky, supra note 1, at 268 (attributing changes in medical device regulation and litigation to *Medtronic*); Urquhart & Durgin, supra note 8, at 51-55 (discussing effects of *Medtronic* on litigation involving 510(k) devices, premarket approval devices and investigational device exemption devices); Gelsinger, supra note 8, at 676-78 (assessing impact of *Medtronic* on medical devices industry).
10. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 825 (3d Cir. 1998) (finding that *Medtronic* counsels rejection of defendant's pre-emption arguments and holding that state law of fraudulent misrepresentation would not be pre-empted by MDA).
11. 159 F.3d 817 (3d Cir. 1998).
12. See id. at 825-26 (addressing defendant's pre-emption arguments by citing *Medtronic* as controlling authority and finding defendant's arguments unpersuasive).
13. See id. at 829. The court stated:
Rather, we hold that (1) the plaintiffs' "fraud on the FDA" theory of liability is not so at odds with traditional principles of tort law that Buckman is entitled to a dismissal of all claims against it at this stage; and (2) if the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on Buckman in the circumstances alleged, that law would not be pre-empted by the MDA.

*Id.*
14. 46 F.3d 1316 (3d Cir. 1995).
15. See *Bone Screw Litigation*, 159 F.3d 817 at 825 (finding *Medtronic* controlling and noting "[i]n short, Lohr overruled everything in Michael that would prevent a
in *Shiley* was consistent with Third Circuit precedent.\(^{16}\) With *Bone Screw Litigation*, the Third Circuit has clearly stated its current rule on MDA pre-emption.\(^{17}\)

This Casebrief discusses the development of law in the Third Circuit concerning liability under state tort law of drug and medical device manufacturers for products that were approved by the FDA, considered in light of the Medical Device Amendments of 1976. Part II summarizes federal regulation of drugs and medical devices, the Supreme Court's ruling in *Medtronic* and the effect of this ruling on cases in other circuit courts of appeals.\(^{18}\) Part III traces the evolution of the Third Circuit's approach to state law tort claims vis-a-vis the Medical Device Amendments of 1976.\(^{19}\) Ultimately, this Casebrief focuses upon the Third Circuit's recent pronouncement in *Bone Screw Litigation*, which held that the Medical Device Amendments would not pre-empt any viable state law claim and that fraudulent misrepresentation to the FDA could be the proximate cause of injuries allegedly sustained by patients.\(^{20}\)

II. BACKGROUND

A. FDA Regulation of Medical Devices

A preliminary discussion of FDA regulatory procedure is necessary to provide the context for the specific pre-emption question recently addressed by the Third Circuit. With the passage of the MDA in 1976, Congress granted the FDA regulatory authority over medical devices prior to their introduction to the market.\(^{21}\) The statute comprehensively defines "medical device."\(^{22}\) As a result, medical devices may include any article plaintiff from pursuing a cause of action . . . based on common law principles"); Michael v. Shiley, 46 F.3d 1316, 1324 (3d Cir. 1995) (finding that regulations under common law, even if they do "not rise to the level of specificity present in the case of some other devices regulated by the FDA," they do present "specific requirements applicable to a particular device under the act").

16. See *Shiley*, 46 F.3d at 1323 (finding discussion of whether state common law imposes "requirements" in § 360k unnecessary because of Third Circuit's earlier ruling in *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 541-42 (3d Cir. 1994)).

17. See *Bone Screw Litigation*, 159 F.3d at 825, 829 (stating "[i]n short, *Lohr* overrules everything in *Michael* that would prevent a plaintiff from pursuing a cause of action . . . based on common law principles" and holding fraud claim not pre-empted if applicable).

18. For further discussion of federal regulation of drugs and devices, the Supreme Court's holding in *Medtronic* and its effect in other circuit courts, see infra notes 21-76 and accompanying text.

19. For further discussion of the Third Circuit's treatment of state law tort claims vis-a-vis the MDA, see infra notes 77-80 and accompanying text.

20. For further discussion of the Third Circuit's recent pronouncement in *Bone Screw Litigation*, see infra notes 82-124 and accompanying text.


22. See 21 U.S.C. § 321(h) (1994) (defining "medical device"). Provisions of the MDA that are pertinent to this issue provide:

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an
that is officially recognized in a national register, is meant to be used for a medical purpose and does not rely on chemical action to achieve its intended effect.\(^{23}\) Prompted by increased technological complexity of devices and mounting disclosures of shortcomings involving pacemakers, intrauterine devices and intraocular lenses, Congress responded by enacting the MDA to "provide for the safety and effectiveness of medical devices intended for human use."\(^{24}\) Recognized purposes of the MDA were to: "(1) assure public protection against unsafe and ineffective devices, (2) ensure that health practitioners could be confident about the medical equipment they prescribed for their patients, and (3) provide market protection for pioneers of new technologies."\(^{25}\)

Concurrently, Congress created a three-class system in order to achieve effective regulation of the various materials within the statute.\(^{26}\) Class I devices are the least restricted of the three and are subject to regulation regarding issues such as misbranding, banning, premarket notification, restrictions on sale or distribution and reporting of adverse experiences.\(^{27}\) Class II devices are those that require a greater degree of regulation than Class I devices and about which there is sufficient information available for the FDA to formulate a mandatory standard for the de-


\(^{23}\) See id. (listing what constitutes "medical device").

\(^{24}\) Medtronic v. Lohr, 518 U.S. 470, 476 (1996) (describing policy motivation for enactment of MDA); In re Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 819 (3d Cir. 1998) ("Congress enacted the MDA to address concerns regarding the safety and effectiveness of the wide variety of medical devices introduced into the market.").

\(^{25}\) James S. Benson et al., The FDA's Regulation of Medical Devices: A Decade of Change, 43 FOOD DRUG COSM. L.J. 495, 497 (1988) (summarizing legislative intent in enacting MDA).

\(^{26}\) See Bone Screw Litigation, 159 F.3d at 819 ("The MDA requires classification of medical devices into three categories based upon the risk that they pose to the public."). For the full text of classification of medical devices intended for human use, see 21 U.S.C. § 360c (1994).

\(^{27}\) See S. Rep. No. 94-33, at 55 (1976) (explaining conference committee substitute regarding Class I devices); Tumidolsky, supra note 1, at 269 (detailing "general controls" regulation of Class I devices).
vice. Oxygen masks are an example of Class II devices. Class III devices require premarket approval by the FDA—a long and comprehensive process—because the standards for both Class I and Class II are inadequate. Class III devices include breast implants, pacemakers and other prosthetic and implantable devices.

There are two situations in which a Class III device may be marketed without being subjected to the extensive premarket approval process. First, under the "investigational device exemption," the FDA will approve an experiment involving an unapproved device, thereby allowing the device to be used in human beings to collect data. The second possibility is to claim that the device is "substantially equivalent" to a pre-existing device on the market and thus avoid the premarket approval process by applying for FDA approval under the so-called "510(k) mechanism." Obtaining approval of a device by this method—claiming that the device is substantially equivalent to a device pre-dating the MDA—is the most efficient way to market a medical device. If a manufacturer seeks approval of a device using the 510(k) process, the company should first notify the FDA of this intention. After receiving this notice, the FDA has ninety days to object.

28. See S. Rep. No. 94-33, at 55 (explaining conference committee substitute regarding Class II devices); Tumidolsky, supra note 1, at 269 (distinguishing Class II devices from Class I devices).

29. See Gelsinger, supra note 8, at 654 n.59.

30. See S. Rep. No. 94-33, at 55-56 (defining Class III devices as those that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health or which present a potential unreasonable risk of illness or injury"); Tumidolsky, supra note 1, at 269 (explaining deficiencies of Class I and Class II standards for Class III devices).

31. See Gelsinger, supra note 8, at 654 n.60 ("Class III devices include pacemakers (at issue in Medtronic), breast implants, and intrauterine contraceptive devices.").

32. See In re Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 819-20 (3d Cir. 1998) (discussing exceptions to full premarket approval process).

33. See Tumidolsky, supra note 1, at 269-70 ("Some devices are marketed under an investigational device exemption (IDE), which is an FDA-approved experiment that allows an unapproved device to be used in human beings in order to collect data.").

34. See 21 U.S.C. § 360e(b)(1)(B) (1994) (allowing for devices that are "substantially equivalent" to pre-existing devices in order to avoid the premarket approval process); see also Bone Screw Litigation, 159 F.3d at 819-20 (explaining exception known as "510(k) process"); Benson et al., supra note 25, at 513 (explaining "substantially equivalent" exception).

35. See Medtronic v. Lohr, 518 U.S. 470, 478-79 (1996) (comparing number of hours necessary to complete full premarket approval process with 510(k) process); Tumidolsky, supra note 1, at 270 (noting that 510(k) mechanism enables marketing at great speed and efficiency).

36. See Bone Screw Litigation, 159 F.3d at 819-20 (noting "[f]or a device to be approved under the § 510(k) process, the FDA must determine that the new device has the same intended use as the predicate device . . . ."); Tumidolsky, supra note 1, at 270 (explaining 510(k) process in full).
if no objection is made, the company may market the device. In addition, the actual time required for FDA review of a 510(k) application is a mere fraction of the time necessary for review of a full premarket approval application.


After the MDA was enacted in 1976, there remained some degree of uncertainty regarding its pre-emptive effect. The language of the statute appears comprehensive—stating simply that no state shall establish any requirement that is different from, or in addition to, the requirements imposed by the FDA. The question among the judiciary became focused on the meaning of the word “requirement.”

The doctrine of federal pre-emption permits federal law to pre-empt state law in three ways: by express provision, by precluding state regulation in the field or by conflicting with state law. In the first instance, the express words of the statute or accompanying legislative history articulate congressional intent to pre-empt state law and the degree to which this pre-emption occurs. In the second instance, congressional intent to pre-

37. See Tumidolsky, supra note 1, at 270 (charting time frame for 510(k) approval).
38. See Medtronic, 518 U.S. at 478-79 (comparing number of hours necessary to complete full premarket approval process with 510(k) process).
40. See 21 U.S.C. § 360k(a) (1994) (prescribing specific pre-emptive effect of regulations stated in Food, Drug, and Cosmetic Act pertaining to medical devices); see also Plant, supra note 2, at 87-88 (introducing discussion of possible federal pre-emption of tort claims with close inspection of statute’s language).
41. See Plant, supra note 2, at 88 (focusing discussion of pre-emption on specific issue of interpreting word “requirement”); see also Eggen, supra note 4, at 1 (noting that all but one of federal appeals courts have determined that “requirement” can apply to state law tort claims in addition to statutory and regulatory actions).
43. See Gade, 505 U.S. at 98 (stating recognized propositions of Court’s pre-emption jurisprudence); Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm’n, 461 U.S. 190, 203-04 (1983) (articulating instances in which federal law would pre-empt state law). The Court explained:
It is well-established that within Constitutional limits Congress may pre-empt state authority by so stating in express terms. Absent explicit pre-emptive language, Congress’ intent to supercede state law altogether may be found from a “scheme of federal regulation . . . so pervasive as to make
empt state law may be implied in the statute because of the particularly federal nature of the policy matter.\textsuperscript{44} In the third instance, the federal statute may directly conflict with a state statute, in whole or in part, thus making compliance with both statutes an impossibility.\textsuperscript{45} The federal government’s pre-emptive power is not limited to statutes and their legislative history; in addition, the United States Constitution, treaties and federal administrative regulations might have a pre-emptive effect.\textsuperscript{46} Accordingly, federal authority may pre-empt any of several types of state authority, such as a state’s common law, which serves as controlling authority in product liability and related tort claims.\textsuperscript{47}

If the federal authority at issue in a case does not expressly indicate its pre-emptive effect, the court must make an independent determination of any such effect.\textsuperscript{48} Courts typically consider several factors when ruling in pre-emption cases: (1) the legislative purpose and intent of Congress as indicated by the language of the statute, accompanying reports and other available legislative history; (2) the pervasive nature of the federal regulatory scheme as evidenced by the statute and ensuing administrative interpretation; (3) the nature of the regulated field and the extent to which uniform and exclusively federal regulation is vital to the national interest; and (4) whether—in the particular case under consideration—a state law hinders the complete execution of the full purposes and objectives of Congress.

reasonable the inference that Congress left no room for the states to supplement it,” “because the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject,” or because “the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose.” Even where Congress has not entirely displaced state regulation in a specific area, state law is pre-empted to the extent that it actually conflicts with federal law. Such a conflict arises when “compliance with both federal and state regulations is a physical impossibility,” or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”

\textit{Id.} at 203-04 (citations omitted).

\textsuperscript{44} See \textit{Pacific Gas}, 461 U.S. at 203-04 (articulating instances in which federal law would pre-empt state law). For the full text of the Supreme Court’s explanation of the types of pre-emption, see supra note 43 and accompanying text.

\textsuperscript{45} See id.

\textsuperscript{46} See Donato \& Neraas, supra note 2, at 313 (supporting analysis of First Circuit’s decision in \textit{King} with general discussion of federal pre-emption doctrine and citing \textit{Capital Cities Cable, Inc. v. Crisp}, 467 U.S. 691, 694 (1984)).

\textsuperscript{47} See id. at 313 (describing various state sources of authority that might be found to be pre-empted by federal authorities and citing \textit{San Diego Bldg. Trades Council v. Garmon}, 359 U.S. 236, 247 (1959)). In \textit{Garmon}, the Court concluded that state action “to redress private wrongs or grant compensation for past harm” can be pre-empted by conflicting with federal law. See \textit{Garmon}, 359 U.S. at 247.

\textsuperscript{48} See, e.g., \textit{Gade}, 505 U.S. at 98-99 (stating “[o]ur ultimate task in any pre-emption case is to determine whether state regulation is consistent with the structure and purpose of the statute as a whole” and considering objective and policy of federal Occupational Safety and Health Act of 1970).
gress.\textsuperscript{49} Courts may apply one or all of these factors to discern the pre-emptive effect of a statute.\textsuperscript{50}

Prior to the Supreme Court’s ruling in \textit{Medtronic}, nearly every court to consider the pre-emptive effect of the MDA found that it pre-empted common law tort claims.\textsuperscript{51} Accordingly, nine of the federal courts of appeals held that the MDA may pre-empt common law tort claims.\textsuperscript{52} In addition, the majority of federal trial courts also held that the MDA has this pre-emptive effect.\textsuperscript{53} Incidentally, most state courts to consider the issue

\textsuperscript{49} See Jacklin, \textit{supra} note 42, at \S 2 (describing four factors employed by federal courts in determining pre-emptive effect of legislation); see generally Abbot v. American Cyanamid Co., 844 F.2d 1108, 1113-14 (4th Cir. 1988) (applying pre-emption analysis and considering various factors to discern congressional intent and purpose).

\textsuperscript{50} See Jacklin, \textit{supra} note 42, at \S 2 (explaining that courts may apply one or more of standard factors in ruling on pre-emption).

\textsuperscript{51} See Mark Herrman & Geoffrey J. Ritts, \textit{Preemption and Medical Devices: A Response to Adler and Mann}, 51 Food & Drug L.J. 1, 1 (1996) (assessing judicial interpretation of MDA’s pre-emptive effect). For a discussion of pre-\textit{Medtronic} jurisprudence, see \textit{supra} notes 4 & 5 and accompanying text.

\textsuperscript{52} See Herrman & Ritts, \textit{supra} note 51, at 1-2 n.4 (considering circuit court treatment of MDA pre-emption and listing decisions in which courts found state law remedies pre-empted); see, e.g., Martin v. Teletronics Pacing Sys., Inc., 70 F.3d 39, 41 (6th Cir. 1995) (finding MDA pre-empted certain common law claims); Mitchell v. Collagen Corp., 67 F.3d 1268, 1272 (7th Cir. 1995) (same); English v. Mentor Corp., 67 F.3d 477, 483 (3d Cir. 1995) (same); Becker v. Optical Radiation Corp., 66 F.3d 18, 19 (2d Cir. 1995) (same); Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392, 395 (4th Cir. 1995) (same); Talbott v. C.R. Bard, Inc., 63 F.3d 25, 26 (1st Cir. 1995) (same); Feldt v. Mentor Corp. 61 F.3d 431, 433 n.2, 436-38 (5th Cir. 1995) (same); Michael v. Shiley, Inc., 46 F.3d 1316, 1319 (3d Cir. 1995) (same); Reeves v. AcroMed Corp., 44 F.3d 300, 302 (5th Cir. 1995) (same); Martello v. CIBA Vision Corp., 42 F.3d 1167, 1169 (8th Cir. 1994) (same); National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 999 (8th Cir. 1994) (Loken, J., concurring) (same); Gile v. Optical Radiation Corp., 22 F.3d 540, 541 (3d Cir. 1994) (same); Mendes v. Medtronic, Inc., 18 F.3d 13, 14 (1st Cir. 1994) (same); Duncan v. Iolab Corp., 12 F.3d 194, 195 (11th Cir. 1994) (same); Stamps v. Collagen Corp., 984 F.2d 1416, 1418 (5th Cir. 1993) (same); King v. Collagen Corp., 983 F.2d 1130, 1131 (1st Cir. 1993) (same); Slater v. Optical Radiation Corp., 961 F.2d 1530, 1533-34 (7th Cir. 1992) (same).

agreed with the federal decisions that pre-empted state common law. Thus the MDA was generally recognized to pre-empt some common law decisions.
claims, and the debate focused on the scope of this pre-emption.\textsuperscript{55} As a result, some courts held that the FDA process used for approval of the device determines the effect of pre-emption.\textsuperscript{56} Others held that the extent of pre-emption varied depending on the classification of the device.\textsuperscript{57} Still others held that the existence of specific state and/or federal regulations were controlling.\textsuperscript{58}

\textsuperscript{55} See Herrman & Ritts, supra note 51, at 2-3 ("For the most part, the battles in the courts have been over the scope of preemption, not whether preemption exists at all.").

\textsuperscript{56} See id. at 3 n.7 (providing examples of courts allowing state law claims when device was cleared under premarket notification process and citing \textit{Larsen v. Pacesetter Sys., Inc.}, 887 P.2d 1273, 1281-82 (Haw. 1992) and \textit{Fogal v. Steinfeld}, 620 N.Y.S.2d 875, 882-83 (Sup. Ct. 1994)); see also Donato & Neraas, supra note 2, at 314-15 (suggesting that premarket approval is prerequisite for pre-emption).


\textsuperscript{58} See Hermann & Ritts, supra note 51, at 3-4, 4 n.9 (citing examples of decisions holding that plaintiffs may recover under state tort law if defendants do not meet federal requirements); see, e.g., National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 993 (8th Cir. 1994) (finding "when a statute only preempts state requirements that are different from or in addition to those imposed by federal law, plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements"); \textit{Parenteau}, 856 F. Supp. at 64-65 (D.N.H. 1994) ("Where specific FDA regulations regarding the design of a particular medical device have not been found, state-law claims of defective design are not preempted under section 360k(a) of the MDA."); Lance v. American Edwards Labs., 452 S.E.2d 185, 187 (Ga. App. 1994) (denying defendants' argument that plaintiff's duty to warn claim was pre-empted by MDA after finding no federal provision imposing duty to warn).
C. The Supreme Court Speaks on MDA Pre-emption: Medtronic, Inc. v. Lohr

Four years before the Supreme Court’s ruling regarding the pre-emptive effect of the MDA in Medtronic, the Court considered pre-emption in the context of another federal statute, the Public Health Cigarette Smoking Act of 1969. In Cipollone v. Liggett Group, Inc., the Court held that "requirement" as used in an express pre-emption statute—such as the MDA—might include other state authority besides statutes and regulations—this statutory language “easily encompass[es] obligations that take the form of common law rules.” Thus, state law tort claims were held to be pre-empted by that federal statute.

The Supreme Court sought to resolve the pre-emption question regarding the MDA in Medtronic, a case involving a manufacturer of a pacemaker that had been cleared by the FDA as a Class II device under § 510(k). The plaintiff sought damages for defendant's alleged common law negligence and strict liability, pertaining to the design of the device; the plaintiff raised additional common law claims on theories of defective manufacturing and mislabeling of the device. Defendant ar-

61. Id. at 505; see Hermann & Ritts, supra note 51, at 6-7 (citing Cipollone as example of statutory interpretation based on ordinary meaning of Congress' language and stating “[a]pplying the ‘ordinary meaning’ of the language of statutes such as [the Medical Device Amendments], courts regularly find preemption of common law tort claims”—prior to Supreme Court’s ruling in Medtronic).
62. See Cipollone, 505 U.S. at 530-31 (summarizing holding). The Court concluded with the following recapitulation of their holdings:

The 1965 Act did not pre-empt state law damages actions; the 1969 Act pre-empts petitioner’s claims based on a failure to warn and the neutralization of federally mandated warnings to the extent that those claims rely on omissions or inclusions in respondents’ advertising or promotions; the 1969 Act does not pre-empt petitioner’s claims based on express warranty, intentional fraud and misrepresentation, or conspiracy.

Id.

63. See Medtronic v. Lohr, 518 U.S. 470, 480 (1996) (“As have so many other medical device manufacturers, petitioner Medtronic took advantage of § 510(k)’s expedited process in October of 1982, when it notified FDA that it intended to market its Model 4011 pacemaker lead as a device that was ‘substantially equivalent’ to devices already on the market.”).
64. See id. at 481 (cataloguing claims made in plaintiffs’ complaint). The court so recounted the complaint:

Their complaint contained both a negligence count and a strict liability count. The negligence count alleged a breach of Medtronic’s “duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker” in several respects, including the use of defective materials in the lead and a failure to warn or properly instruct the plaintiff or her physicians of the tendency of the pacemaker to fail, despite knowledge of other earlier failures. The strict liability count alleged that the device was in a defective condition and unreasonably dangerous to
gued that the MDA pre-empted any state law claims; the Supreme Court, however, disagreed.65 The Court interpreted the MDA pre-emption provisions narrowly by emphasizing several factors that must be present in order to find pre-emption: (1) the state requirement must be "with respect to" the device and relate "to the safety or effectiveness of the device;" (2) the specific federal requirement must be "applicable to the device" in question; (3) the state requirement must be "different from, or in addition to" federal requirements; and (4) the federal requirements must be "specific counterpart regulations" or "specific" to a "particular device."66 The Court held that nothing in the pre-emption provision of the MDA denies states the right to provide traditional damages remedies for violations of common law or state tort law duties.67

D. Circuit Court Reaction to Medtronic

The circuit courts considering the pre-emptive effect of the MDA apply the rule announced in Medtronic unevenly, and several of the courts have yet to rule.68 Some courts apply Medtronic's principle by analogy to other federal statutes, including those that regulate insecticides, animal inspections and flammable fabrics.69 The decisions regarding federal statutes other than the MDA, however, are too inconsistent to conclude that

foreseeable users at the time of its sale. (A third count alleging breach of warranty was dismissed for failure to state a claim under Florida law.)

Id. (citations omitted).

65. See id. at 486-87 (rejecting arguments made by Medtronic). In response to Medtronic's argument that the negligent design claim should have been pre-empted by the MDA, the Court stated that "Medtronic's argument is not only unpersuasive, it is implausible." Id. at 487.

66. See id. at 500 (explaining MDA's "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest").

67. See id. at 491 ("There is, to the best of our knowledge, nothing in the hearings, the committee reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices.").

68. Compare Martin v. American Med. Sys., Inc., 116 F.3d 102, 104 (4th Cir. 1997) (holding that plaintiff may state claim under tort theories in light of Medtronic), with Martin v. Telelectronics Pacing Sys., Inc., 105 F.3d 1090, 1099 (6th Cir. 1997) (analyzing case in light of Medtronic and concluding that manufacturing and design defect claims were pre-empted).

69. See Symens v. SmithKline Beecham Corp., 152 F.3d 1050, 1054 (8th Cir. 1998) (holding that state law claims were pre-empted by Animal and Plant Health Inspection Service Regulations); Kuiper v. American Cyanamid Co., 131 F.3d 656, 660-61 (7th Cir. 1997) (holding that manufacturer might raise claim that Federal Insecticide, Fungicide and Rodenticide Act pre-empted claims); Grenier v. Vermont Log Bldgs., Inc., 96 F.3d 559, 564-65 (1st Cir. 1996) (holding that Federal Insecticide, Fungicide and Rodenticide Act pre-empted builder's failure to warn claims); Wilson v. Bradlee's, Inc., 96 F.3d 552, 553 (1st Cir. 1996) (holding that Flammable Fabrics Act did not pre-empt common-law products liability claims).
the Medtronic principle will control future rulings on the pre-emptive effect of any such regulatory statute.\textsuperscript{70}

The Courts of Appeals for the Sixth, Seventh and Ninth Circuits hold that the MDA may have a pre-emptive effect when a plaintiff brings an action under a state law tort claim.\textsuperscript{71} Courts distinguish Medtronic by various means, such as emphasizing the differences between federal regulation of pacemakers (the product in Medtronic) and the product at issue in a particular case.\textsuperscript{72} In addition, the Courts of Appeals for the First, Seventh and Eighth Circuits hold that other federal statutes may have a pre-emptive effect on certain state law claims.\textsuperscript{73}

The Courts of Appeals for the Fourth, Fifth, Seventh, Eighth, Ninth and Tenth Circuits hold that state tort law claims might lie pursuant to the Supreme Court’s Medtronic ruling.\textsuperscript{74} Most courts state simply that Medtronic controls the decision, leaving no alternative but to allow common law claims.\textsuperscript{75} Further, the Court of Appeals for the First Circuit holds that another federal statute, the Flammable Fabrics Act, does not pre-empt certain state law tort claims.\textsuperscript{76}

\textsuperscript{70} For a comparison of two cases reaching opposite conclusions after considering plaintiffs’ tort claims in light of Medtronic, see supra note 68 and accompanying text.

\textsuperscript{71} See Teletronics, 105 F.3d at 1099 (analyzing case in light of Medtronic and concluding manufacturing and design defect claims pre-empted); see also Mitchell v. Collagen Corp., 126 F.3d 902, 913-14 (7th Cir. 1997) (holding that FDA’s premarket approval can have pre-emptive effect); Papke v. Tambrands, 107 F.3d 737, 738 (9th Cir. 1997) (finding plaintiff’s various negligence claims pre-empted by MDA).

\textsuperscript{72} See Papke, 107 F.3d at 742 (distinguishing Medtronic accordingly, “[i]t’s result is entirely consistent with Medtronic, which did not involve device-specific federal requirements”).

\textsuperscript{73} For a catalogue of cases involving pre-emption and other federal statutes, see supra note 69.

\textsuperscript{74} See Norgaard v. Depuy Orthopedics, Inc., 121 F.3d 1074, 1075, 1078 (7th Cir. 1997) (affirming lower court’s decision because plaintiff failed to make timely appeal based on Medtronic); Martin v. American Med. Sys., Inc., 116 F.3d 102, 103 (4th Cir. 1997) (holding that MDA does not pre-empt common law tort and implied warranty claims); Oja v. Howmedica, Inc., 111 F.3d 782, 785 (10th Cir. 1997) (holding that negligent failure to warn claim was not pre-empted by MDA); Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 (7th Cir. 1997) (holding MDA did not pre-empt Indiana law negligent manufacture claim); Reeves v. Acromed Corp., 105 F.3d 442, 444 (5th Cir. 1997) (holding “unreasonably dangerous” claim regarding device was not pre-empted by MDA); Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 924, 326-27 (4th Cir. 1996) (holding that state law failure to warn, breach of implied warranty, negligence and strict liability claims were not pre-empted by MDA); Sanders v. Optical Radiation Corp., No. 95-1967, 1996 WL 423124, at *2 (4th Cir. July 30, 1996) (affirming in part and vacating and remanding based on Medtronic’s holding on pre-emption).

\textsuperscript{75} See, e.g., Duvall, 103 F.3d 324 at 326 (“In light of the recent decision of the Supreme Court in Medtronic, Inc. v. Lohr, we hold that § 360k(a) does not preempt Duvall’s claims.”).

\textsuperscript{76} See Wilson v. Bradlees, Inc., 96 F.3d 552, 553 (1st Cir. 1996) (holding that Flammable Fabrics Act did not pre-empt common-law products liability claims).
III. Analysis

A. Pre-Medtronic Cases in the Third Circuit

Because the Third Circuit's recent ruling in Bone Screw Litigation reverses Third Circuit precedent, practitioners should not rely on earlier cases. The court has considered the issue of MDA pre-emption three times since the MDA was enacted in 1976. In each case, the court found plaintiffs' state law claims pre-empted by the express pre-emption provision of the MDA. In the earliest post-1976 case, however, the court allowed common law tort claims to lie without explicitly deciding the pre-emption issue. Decisions of district courts within the Third Circuit did not send the clear message the Third Circuit panels had articulated.

B. Third Circuit Adopts Rule Announced in Medtronic: In re Orthopedic Bone Screw Products Liability Litigation

The Third Circuit's recent ruling in response to Medtronic is narrow but forceful. In Bone Screw Litigation, the court initially held that the plaintiffs' fraud on the FDA theory of liability is not so unworkable that the defendant was entitled to dismissal of all claims brought against it without

77. See In re Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 825 (3d Cir. 1998) (finding Medtronic controlling and noting it overrules Third Circuit precedent "that would prevent a plaintiff from pursuing a cause of action for fraudulent misrepresentation").

78. See English v. Mentor Corp., 67 F.3d 477, 478 (3d Cir. 1995) (considering two issues on appeal: "(1) whether the Medical Device Amendments of 1976 pre-empt their state law tort and contract claims against the manufacturer . . . and (2) whether the Amendments also pre-empt these claims for a medical device cleared for marketing under the 'substantial equivalence' exception . . . "); Michael v. Shiley, Inc., 46 F.3d 1316, 1319 (3d Cir. 1995) ("we must decide whether 21 U.S.C. § 360k pre-empt Nina Michael's state law causes of action for negligent manufacture and design, strict product liability, breach of the implied warranty of merchantability, breach of an express warranty, and common law fraud against Shiley Inc."); Gile v. Optical Radiation Corp., 22 F.3d 540, 542-43 (3d Cir. 1994) (responding to plaintiff's arguments that neither tort claims generally nor her specific claims are pre-empted under § 360k(a)).

79. See English, 67 F.3d at 483-84 (holding that breach of express warranty claim not pre-empted because duties created by parties themselves, but FDA regulations pre-empted state law claims of plaintiffs); Shiley, 46 F.3d at 1319 (holding that MDA pre-empted tort claims for negligence, strict liability, breach of implied warranty and fraud on FDA, even though MDA did not pre-empt state law contract claims); Gile, 22 F.3d at 542-45 (finding patient's state law tort claims were pre-empted under MDA).

80. See Stanton v. Astra Pharm. Prod., Inc., 718 F.2d 553, 581 (3d Cir. 1983) (allowing negligence and products liability claims and suggesting implicit finding that MDA does not pre-empt state law claims).


82. See Bone Screw Litigation, 159 F.3d at 829 (beginning summary of conclusion with statement "[o]ur holding is a narrow one").
further demonstration of causation or lack thereof.\textsuperscript{83} In addition, the court held that a fraudulent misrepresentation claim, such as the fraud on the FDA claim brought against the defendant, would not be pre-empted by the MDA.\textsuperscript{84} In this way, the court ruled that at least the state law tort of fraudulent misrepresentation would not be pre-empted by this federal statute.

\textit{Bone Screw Litigation} involved over 2,000 individual plaintiffs who claim to have suffered injuries directly related to orthopedic bone screws that were implanted in the pedicles of their spines.\textsuperscript{85} The plaintiffs brought products liability claims and claims based on civil conspiracy and concert of action theories against several different defendants, including the manufacturer, physicians, hospitals, professional associations and a consulting firm.\textsuperscript{86} The actions were consolidated for pre-trial proceedings pursuant to the multi-district litigation statute.\textsuperscript{87} At the time of the Third Circuit’s ruling on MDA pre-emption, the plaintiffs had dismissed most of their claims against the physicians, hospitals and professional societies, and the plaintiffs had reached a settlement agreement with AcroMed, the manufacturer.\textsuperscript{88}

The defendant in \textit{Bone Screw Litigation}, Buckman, is a consulting company that had advised AcroMed during the FDA approval process for this device.\textsuperscript{89} Plaintiffs claimed that Buckman’s efforts on behalf of AcroMed constituted misrepresentations to the FDA, which played a substantial role

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\textsuperscript{83} See id. ("[T]he plaintiffs’ ‘fraud on the FDA’ theory of liability is not so at odds with traditional principles of tort law that Buckman is entitled to a dismissal of all claims against it at this stage."); see also Joseph Slobodian, ‘Off-Label’ Case Setback: Court Reinstates Part of Fraud Claim Over FDA Misrepresentations, NAT’l L.J., Nov. 30, 1998, at B4 (focusing on fraud on FDA claim in recounting Third Circuit’s recent ruling).

\textsuperscript{84} See Bone Screw Litigation, 159 F.3d at 829 ("If the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on Buckman in the circumstances alleged, that law would not be preempted by the MDA."); see also Pedicle Screws: Divided 3rd Circuit Panel Reverses Fraud-on-FDA Claims in Pedicle Case, 3 No. 23 MEALEY’S LITIG. REP.: DRUGS & MED. DEVICES 7 (Dec. 4, 1998) (summarizing Third Circuit’s findings regarding pre-emption).

\textsuperscript{85} See Bone Screw Litigation, 159 F.3d at 818 (providing history of multidistrict litigation at issue in present case); Linda Mullenix, Federal Practice: Complex Litigation, NAT’l L.J., Nov. 16, 1998, at B10-11 (providing comprehensive background and history on multidistrict litigation at issue in present case).

\textsuperscript{86} See Mullenix, supra note 85, at B10-11 (providing comprehensive background and history on multidistrict litigation at issue in present case).

\textsuperscript{87} See id. (same).

\textsuperscript{88} See id. at B11 (detailing terms of plaintiffs’ settlement with AcroMed).

\textsuperscript{89} See Bone Screw Litigation, 159 F.3d at 820 (explaining Buckman’s relationship to AcroMed and consequent involvement in present litigation). Buckman Company Incorporated’s world wide web page describes the company accordingly, “Buckman Company, Inc. (BCI) provides regulatory and clinical consulting services to the medical device & biotechnology industries. Our skills and strengths are recognized by FDA personnel and other members of the regulatory community.” Buckman Company, Incorporated (visited Jan. 31, 1999) <http://www.fda-help.com/index.html>.
in the events resulting in their injuries; the specific claim was "fraud on the FDA."90 The district court dismissed this claim as applied to Buckman, relying on Michael v. Shiley.91 After the Supreme Court's ruling in Medtronic, the district court reaffirmed the dismissal on a defendant's motion.92 The court distinguished the negligence claim in Medtronic from the fraud on the FDA claim in this case, explaining that the object of this fraud was the FDA rather than the plaintiffs themselves.93 Although the court acknowledged that pre-emption would not be an appropriate ground upon which the court could dismiss the plaintiffs' fraud claim, the court found that the pre-emption issue did not arise in this case.94 Instead, the court held that the claim should be dismissed because the MDA does not provide a private right of action.95

The Third Circuit reversed the district court.96 Initially, the court found that there was no express pre-emption at issue, because the common law claim did not "conflict" with any federal law at issue.97 Next, the court disagreed with the district court's finding that the MDA does not provide a private cause of action.98 After demonstrating the error in the lower court's reasoning, the Third Circuit proceeded to address the two issues raised by Buckman in defense—the pre-emption and causation is-

90. See Bone Screw Litigation, 159 F.3d at 818 (describing plaintiffs' specific allegations against Buckman).


92. See id. (reaffirming granted motion requesting dismissal of plaintiffs' fraud on FDA claim).

93. See id. at *3 (analyzing pre-emption issue in light of Medtronic, stating that finding FDA as object of fraud rather than plaintiffs themselves "transforms an otherwise simple fraud claim that would not be preempted by the MDA according to the reasoning of Lohr into one that is precluded by virtue of the fact that the MDA does not provide for a private right of action").

94. See id. ("Hence, Lohr established that the doctrine of preemption would be an inappropriate ground upon which the court should dismiss plaintiffs' fraud-on-the-FDA claim, but it did not otherwise alter the court's ruling in Pretrial Order No. 12.").

95. See id. (explaining affirmation of Pretrial Order No. 12).

96. See In re Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 819 (3d Cir. 1998) ("We will reverse.").

97. See id. at 823 (finding, based on Medtronic ruling, that "there is no federal 'requirement' applicable to the device at issue here; nor is there a state 'requirement' with respect to that device" (quoting Medtronic v. Lohr, 518 U.S. 470, 500 (1996))).

98. See id. at 825 (relying on Supreme Court's ruling in Medtronic to disagree with district court regarding existence of private right of action). The court stated, "[r]efusing to entertain Buckman's fraudulent misrepresentation claim solely because the statutory scheme does not contain a private cause of action would be the equivalent of finding preemption of state law claims contrary to the clear holding of Lohr." Id. The court concluded, "[i]n short, Lohr overrules everything in Michael [v. Shiley] that would prevent a plaintiff from pursuing a cause of action for fraudulent misrepresentation based on common law principles." Id.
sues. More specifically, the court considered whether the MDA preempts the fraud claim and whether the complaints sufficiently showed causation of injury as a result of defendant's alleged misrepresentations.

Buckman raised several arguments to support that the MDA preempts any state law claims; in reaction, the Third Circuit held that the Supreme Court's rulings in Medtronic defeated each of them. First, the court considered the defendant's efforts to distinguish this case from Medtronic. Buckman argued that because the fraud on the FDA claim pertained to FDA approval procedures, rather than a claim regarding the product itself, Medtronic should not be controlling. Further, Buckman distinguished Medtronic because the FDA itself—the very agency responsible for enforcing the MDA—has been the object of the fraud. In responding to these arguments the court relied on the MDA. The court disagreed with Buckman's arguments and found them "simply unpersuasive."

The court proceeded to address the pre-emption issue from a broader perspective, acknowledging that the MDA may certainly pre-empt state law claims when there are "clear and direct conflicts between the requirements of state law and those of the [Food, Drug, and Cosmetic Act]."

The court warned that this pre-emption provision in combination with

99. See id. at 825-26 (addressing defendant's pre-emption argument and alternative argument that complaints do not state claim for fraudulent misrepresentation).

100. See id. (considering each of defendant Buckman's pre-emption arguments and turning to causation issue). Because this Casebrief is focused on the issue of MDA pre-emption, I limit my analysis to the pertinent portion of the opinion.

101. See id. at 825 ("Buckman advances a number of preemption arguments in addition to the one adopted by the district court. In each instance, we conclude that [Medtronic] counsels rejection.").

102. See id. at 825-26 ("In the context of the text of that section as construed in [Medtronic], Buckman's suggested distinctions are simply unpersuasive.").

103. See id. at 825 (distinguishing Medtronic because claim pertains to FDA procedures rather than product itself).

104. See id. (arguing further that Medtronic is not controlling "because the target of the alleged fraud here is 'a creature of statute' which has the sole responsibility for enforcing the [Food, Drug, and Cosmetic Act] and the regulation promulgated thereunder").

105. See id. at 825-26 ("Once again, we look first to Congress' express message concerning preemption—§ 360k.").

106. See id. at 826 ("In the context of the text of that section as construed in Lohr, Buckman's suggested distinctions are simply unpersuasive."). The court acknowledged that a distinction can certainly be drawn between FDA procedures and substantive requirements when ruling on pre-emption, noting "[i]ndeed, given that there must be state and federal requirements with respect to a device, it is harder to argue preemption under § 360k based on FDA procedures than based on FDA substantive requirements for a regulated device." Id.

107. Id. at 826 (allowing for pre-emption under § 360k in circumstances of direct conflict with state law).
Medtronic's presumption against pre-emption in areas of traditional state concern suggests a reluctance to find implied pre-emption. Continuing, Buckman advanced the general theory that suits alleging common law fraud in the FDA approval process are simply inconsistent with the allocation of authority and procedures established by the Food, Drug, and Cosmetic Act. The court responded sharply, stating "[w]e see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA and preserving the right of people in the plaintiffs' position to bring common law fraudulent misrepresentation claims." Additionally, the court noted that judicial review would in no way duplicate, replace or second-guess the FDA's procedures.

Although the court, in conclusion, noted that its holding in Bone Screw Litigation is "a narrow one," this ruling on the pre-emptive effect of the MDA is quite clear. In its analysis of Medtronic, the Third Circuit em-

108. See id. ("The existence of § 360k, its relatively narrow scope, and [Medtronic v.] Lohr's presumption against preemption of areas traditionally occupied by state law, however, counsel caution in finding implied preemption where no express preemption exists.").

109. See id. ("Here, appellees' argument boils down to a contention that the litigation of suits of this kind is fundamentally inconsistent with the regulatory process established by the FDCA.").

110. Id.

111. See id. ("Moreover, we do not share appellees' apparent perception that litigation of such claims holds the potential for courts and juries second-guessing the FDA."). The court continued, "Indeed, there is ample precedent, in related contexts, to support a claim premised on misrepresentations made to a federal agency." Id.

112. In re Orthopedic Bone Screw Prods. Liab. Litig., Nos. 98-1762, 98-1829, 1999 WL 796833, at *8 (3d Cir. Oct. 7, 1999) (restating its adoption of Medtronic rule in 1998 bone screw litigation, "[I]n Bone Screw I, we interpreted Medtronic to mean that common law claims of fraudulent misrepresentation are not preempted by the MDA, even if the conduct underlying those claims violated the FDCA."). In this later, separate appeal as part of the bone screw MDL, plaintiffs appealed the district court's dismissal of the conspiracy and concert of action claims. See id. Plaintiffs argued that the holdings in Medtronic and Bone Screw I suggest that the district court erred in dismissing claims of conspiracy to violate the FDCA. See id. The Third Circuit disagreed with this argument, distinguishing its earlier holding: Medtronic and Bone Screw I are crucially different from this case, however. Both raised the issue whether state common law claims were preempted by the FDCA and Medical Device Amendments. After Medtronic, it is clear that such claims survive, and Bone Screw I so held. Consequently, state law claims such as negligence, breach of implied warranty, and fraudulent misrepresentation are viable, even to the extent they seek recovery for conduct that may also have violated the FDCA. But neither Medtronic nor Bone Screw I purports to allow private plaintiffs to sue directly for violations of a federal statute in the absence of a separate underlying cause of action. They merely hold that such causes of action as previously existed under state law were not preempted by the FDCA and Medical Device Amendments.

Id.; see Fraud-On-FDA: Divided 3rd Circuit Panel Reverses Fraud-on-FDA Claims in Pedicle Case, 2 No. 2 MEALEY'S LITIG. REP.: FEN-PHEN/REdux 25 (Dec. 11, 1998) [hereinafter Fraud-On-FDA] (reporting pedicle screw decision and noting its possible impact on diet drug litigation accordingly, "Editor’s Note: Although this is not a diet drug
phasized the limited effect of the MDA in the face of "the general obligations imposed by the state common law."113 Although the holding in Bone Screw Litigation addresses exclusively the plaintiffs' fraud on the FDA claim, the Third Circuit gave no indication that its holding might not be extended to allow any state law claims based on tort and contract theories, so long as such claims do not directly conflict with provisions of the Food, Drug, and Cosmetic Act.114 Indeed, the court read the MDA and understood the Supreme Court's ruling in Medtronic to require nearly express pre-emption.115 A defendant simply could no longer raise Buckman's arguments because the Third Circuit has followed the Supreme Court's ruling in Medtronic and overruled Third Circuit precedent to the contrary.116

C. Implications of Bone Screw Litigation

The Third Circuit's recent pronouncement could have significant effects on product liability litigation involving drugs and medical devices in the circuit.117 In addition, this ruling may have collateral effects on litigation regarding other federally regulated substances, such as pesticides, as has occurred in other circuits.118 There are two perspectives on the effect that Medtronic might have on consumers, and these potential effects can be applied by analogy to the Third Circuit.119

case, the issues involving fraud allegations are significant and coverage is provided as a service to our readers

113. Bone Screw Litigation, 159 F.3d at 823 (analyzing Supreme Court's holding in Medtronic). The court noted, "[t]he general obligations imposed by the state common law relied upon by Lohr were no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce." Id.

114. See id. at 829 (including no language limiting pre-emption holding to fraudulent misrepresentation).

115. See id. at 826 (agreeing with general principles of Supreme Court's holding in Medtronic and suggesting MDA pre-empts no tort claims).

116. See id. at 824-25 (disagreeing with each of Buckman's arguments and holding in particular that Medtronic precludes agreeing with Buckman's pre-emption arguments).

117. See Fraud-On-FDA, supra note 112, at 25 (reporting pedicle screw decision and noting its possible impact on diet drug litigation accordingly, "Editor's Note: Although this is not a diet drug case, the issues involving fraud allegations are significant and coverage is provided as a service to our readers").

118. See, e.g., Symens v. SmithKline Beecham Corp., 152 F.3d 1050, 1054 (8th Cir. 1998) (holding that state law claims were pre-empted by Animal and Plant Health Inspection Service Regulations); Kuiper v. American Cyanamid Co., 131 F.3d 656, 660-61 (7th Cir. 1997) (holding that manufacturer might argue that Federal Insecticide, Fungicide, and Rodenticide Act pre-empted claims), cert. denied, 118 S. Ct. 1839 (1998); Grenier v. Vermont Log Bldgs., Inc., 96 F.3d 559, 564-65 (1st Cir. 1996) (holding that Federal Insecticide, Fungicide and Rodenticide Act pre-empted builder's failure to warn claims); Wilson v. Bradlees, Inc., 96 F.3d 552, 553 (1st Cir. 1996) (holding that Flammable Fabrics Act did not pre-empt common-law products liability claims).

119. Compare Gelsinger, supra note 8, at 682 (criticizing Medtronic ruling and noting "the Court appears to have overlooked the tremendous public benefit
One point of view posits that the possibility of liability harms consumers through its deterrent effect on drug and device development and marketing. The financial risk of tort actions involving drugs and devices approved and regulated by the FDA may cause drug companies to alter their long-term business planning. Further, tort actions involving FDA-regulated drug products have at times caused manufacturers to discontinue production of their approved products, such as the CU-7 Intrauterine device and childhood vaccines.

Gleaned from advances in the medical devices field. Under the particular circumstances of the Medtronic case, the Court's individualistic view of public health and safety could have a devastating effect on the medical devices industry and, in turn, on the public at large.), with Kenneth J. Witzel, Comment, Medtronic, Inc. v. Lohr and the Power of Preemption: A Pennsylvania Guide to the Preemption of Common Law Tort Claims by the Medical Device Amendments of 1976, 102 DICK. L. REV. 865, 878 (1998) ("Medtronic serves to reopen an avenue of relief for injured device recipients that has not been available for many recipients in recent years.").

120. See Donato & Neraas, supra note 2, at 318-19 (arguing for pre-emptive effect of MDA and asserting "these courts [that do not find pre-emption] ignore public policy which favors a finding of implied federal preemption in the drug area"); Margaret Gilhooley, Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice, 24 SETON HALL L. REV. 1481, 1482 (1994) ("Concerns have been raised, however, that the tort process, because of its uncertain standards, produces the unintended consequence of discouraging worthwhile innovation. Prescription drug manufacturers maintain that liability risks may cut into their innovative efforts."); W. Kip Viscusi, The Social Costs of Punitive Damages Against Corporations in Environmental and Safety Torts, 87 GEO. L.J. 285, 325-27 (1998) (asserting that punitive damage awards suppress innovation).


121. See Scarlett, supra note 120, at 38 (demonstrating effect of multi-million dollar liability awards on drug production). One commentator states:

It does not take many such awards before there is a real possibility that the process for developing, approving, and regulating drugs will be affected in undesirable ways.

Among the visible effects of large product liability awards, actual or threatened, is the discontinuation of specific products. A less visible, but probably real, effect is to deflect drug development away from product categories in which large judgments have made anticipated revenues seem too small to justify the investment necessary to bring a product to market.

Id.

122. See Donato & Neraas, supra note 2, at 318-19 (noting effect of tort actions on market distribution of Bendectin, CU-7 intrauterine devices and childhood vaccines); Viscusi, supra note 120, at 326 (demonstrating relationship between punitive damage awards and vaccine production, price and use). For example, when childhood vaccine manufacturers halted production of certain vaccines following several costly tort actions, the vaccine supply decreased so significantly that the nation's immunization supply was put in jeopardy. See Donato & Neraas, supra note 2, at 318-19. In a footnote, the commentators observed, "[t]his vaccine liability crisis prompted Congress to pass the National Childhood Vaccine Injury Act which established the National Vaccine Injury Compensation Program, a no-fault
Another perspective suggests that this threat of liability is favorable to consumers.\textsuperscript{123} According to this theory, \textit{Medtronic} has enabled injured consumers to bring common law tort suits against manufacturers and counter manufacturers' pre-emption defense under the MDA.\textsuperscript{124} The ensuing benefit to consumers is therefore two-fold: first, the injured have greater opportunity for redress, and second, it may be presumed that manufacturers will seek to produce safer products when threatened with damages to this degree.\textsuperscript{125}

\section*{IV. Conclusion}

In the wake of the Third Circuit's recent ruling in \textit{Bone Screw Litigation}, the effect on consumers as well as pharmaceutical and medical device manufacturers has yet to be determined. The fact that litigation strategy will be altered, however, by both plaintiffs' and defendants' counsel is quite certain.\textsuperscript{126}

\textit{Elizabeth G. Harkins}

\footnotesize{nontort compensation alternative for individuals injured by compulsory childhood immunization.} \textit{Id.} at 319 n.94.

\textsuperscript{123} \textit{See} Tumidolsky, \textit{supra} note 1, at 268 (crediting Supreme Court's ruling in \textit{Medtronic} with providing increased safety for consumers).

\textsuperscript{124} \textit{See} id. (attributing change in litigation landscape for consumers to \textit{Medtronic}); Witzel, \textit{supra} note 119, at 879-86 (citing examples of medical device cases that "demonstrate how the Supreme Court's ruling in \textit{Medtronic} has resulted in eventual relief for some victims and their families").

\textsuperscript{125} \textit{See} Tumidolsky, \textit{supra} note 1, at 268 (explaining benefit to consumers not simply from litigation perspective but also from improved manufacturing techniques); Robert J. Katerberg, \textit{Note}, \textit{Patch ing the "Crazy Quilt" of Gipollone: A Divided Court Rethinks Federal Preemption of Products Liability in Medtronic, Inc. v. Lohr, 75 N.C. L. REV. 1440, 1495-96 (1997)} ("The holding of \textit{Medtronic} clearly means that most plaintiffs' claims will not be preempted by the MDA. Until \textit{Medtronic}, the preemption defense carried many defendants' summary judgment motions in the federal district courts."); Witzel, \textit{supra} note 119, at 878-79 (asserting that \textit{Medtronic} ruling provides incentive to produce safer products and strictly comply with FDA procedures).

\textsuperscript{126} \textit{See}, e.g., Tumidolsky, \textit{supra} note 1, at 268 (noting dramatic effect of \textit{Medtronic} on federal product liability actions); Angela Woodley Kronenberg, \textit{Note}, King v. Collagen Corporation: \textit{FDA Approval Insulates Medical Device Manufacturers From State Common Law Liability}, 11 J. CONTEMP. HEALTH L. \\ & POL'Y 563, 565 (1995) (explaining effect of \textit{King} on medical device litigation on First Circuit); see also Brad Kenneth Lindow, \textit{Recent Case}, \textit{Medical Device Amendments Act Does Not Preempt All State Law Claims}, 10 LOY. CONSUMER L. REP. 32, 32-33 (1998) (demonstrating effect of similar Seventh Circuit ruling pursuant to \textit{Medtronic}).