“After You, My Dear Alphonse!”: Should the Courts Defer to the FDA’s New Interpretation of § 360k(a) of the Medical Device Amendments?

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"After You, My Dear Alphonse!": Should the Courts Defer to the FDA's New Interpretation of § 360k(a) of the Medical Device Amendments?

Richard C. Ausness*

Under the provisions of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act, certain medical devices are subject to premarket approval of the Food and Drug Administration (FDA). Section 360k(a) of the MDA provides that states may not establish "any requirement" which relates to safety or effectiveness of a medical device and "which is different from, or in addition to" any requirement imposed by the FDA. Until recently, the FDA maintained that § 360k(a) did not preempt most common law tort claims; however, in recent amici briefs, the FDA has aggressively asserted that most, if not all, common law tort claims should be preempted for medical devices that had received PMA approval. This Article discusses the implications of the FDA's new interpretation, and assesses the wisdom of promulgating such an interpretation in amici briefs, rather than in the formal notice-and-comment procedure.

* Ashland Oil Professor of Law, University of Kentucky. LL.M. 1973, Yale University; J.D. 1968, University of Florida. According to Merriam-Webster's Dictionary of Allusions, the expression, "After You, My Dear Alphonse," originated with the comic strip characters, Alphonse and Gaston:

[Two] Frenchmen who did everything with absurd, exaggerated politeness. They were created by Frederick Burr Opper (who also originated "Happy Hooligan") in 1905. According to Coulton Waugh, in The Comics, they were national figures, and their elaborate courtesies became catch phrases: "After you, my dear Alphonse!" and "No, after you, my dear Gaston!"

Elizabeth Webber & Mike Feinsilber, Merriam-Webster's Dictionary of Allusions 12 (1999). I would like to thank my wife, Robin Gwinn, for giving me the idea for this title.
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I. INTRODUCTION: THE PREMARKET APPROVAL PROCESS

The Food and Drug Administration (FDA) regulates medical devices under the provisions of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA). The MDA has established three classes of medical devices and requires the most dangerous, known as Class III devices, to undergo premarket approval

(PMA), a rigorous and thorough process.\textsuperscript{2} Section 360k(a) of the MDA provides that states may not establish "any requirement" which relates to safety or effectiveness of a medical device and "which is different from, or in addition to" any requirement imposed by the FDA.\textsuperscript{3} For many years, courts have split over whether § 360k(a) expressly preempts product liability claims against manufacturers whose medical devices have been approved for marketing by the FDA pursuant to the PMA process.\textsuperscript{4} In Medtronic, Inc. v. Lohr, the United States Supreme Court held that § 360k(a) did not preempt tort claims in cases where Class III devices were approved by the FDA under its less rigorous § 510(k) "substantial equivalence" review.\textsuperscript{5} However, the Medtronic Court did not indicate whether its reasoning could be extended to medical devices that had undergone PMA approval.\textsuperscript{6}

Until recently, the FDA maintained that § 360k(a) did not preempt most common law tort claims; however, in 2002, the FDA's Chief Counsel announced that the Agency now believed that most, if not all, common law tort claims should be preempted for medical devices that had received PMA approval.\textsuperscript{7} The Agency has espoused this new interpretation of § 360k(a) aggressively in amici curiae briefs that it filed in a number of MDA preemption cases.\textsuperscript{8} Recently, in Horn v. Thoratec Corp., a federal appeals court relied heavily on these amicus briefs to conclude that state-law tort claims against the manufacturer of an FDA-approved medical device were preempted by § 360k(a).\textsuperscript{9}

The Horn court's reliance on the FDA's revised interpretation of § 360k(a) raises a number of interesting questions about judicial deference to agency interpretations in preemption cases and this Article will address most of them. Part II discusses the MDA and the FDA's regulation of Class III medical devices. Part III reviews the doctrine of federal preemption and examines a number of Supreme Court decisions on preemption and common law tort claims. Part IV

\begin{thebibliography}{9}
\bibitem{infra} See infra Part I.B.
\bibitem{infra} 21 U.S.C. § 360k(a).
\bibitem{infra} See infra Part III.
\bibitem{at} 518 U.S. 470, 503 (1996).
\bibitem{at} Id. at 502-03.
\bibitem{at} 376 F.3d 163, 178, 180 (3d Cir. 2004).
\end{thebibliography}
analyzes the *Medtronic* case and some of the MDA preemption cases that have been decided since *Medtronic*. Part V considers whether courts should defer to the FDA's new interpretation of § 360k(a). This portion of the Article sets forth the FDA's former and current interpretations and also describes the principle of judicial deference. It then examines the *Horn* decision in some detail. In addition, Part V considers a number of deference issues. The first issue is whether a court should show less deference to an agency when it changes a longstanding interpretation. A second concern is whether a court should defer to an agency when it interprets its own preemption statute. A third consideration is whether the *Medtronic* Court's apparent endorsement of 21 C.F.R. § 808.1(d) prevents the FDA from changing its mind on the scope of preemption. A fourth issue is whether an amicus brief is sufficiently formal to justify deference under the *Chevron* doctrine. Part V concludes that the courts probably should not give *Chevron* deference to statutory interpretations in amicus briefs, but should defer to the FDA's interpretation under a weaker form of deference formulated by the Court in *Skidmore v. Swift & Co.* The Article concludes that the FDA is right on the merits, but that it should promulgate its new interpretation of § 360k(a) by revising 21 C.F.R. § 808.1(d) in a formal notice-and-comment rulemaking proceeding.

II. FDA REGULATION UNDER THE MEDICAL DEVICE AMENDMENTS: THE PREMARKET APPROVAL PROCESS

The MDA to the FDCA authorize the FDA to subject medical devices to PMA approval. The MDA defines three classes of medical devices, which receive different levels of regulation, based on the degree of danger posed by the medical device to the public. Class I devices are subject to "general controls," which are concerned with "adulteration, misbranding, registration, premarket notification, good manufacturing practices, and reporting." Class I devices include such things as surgeon's gloves, eye pads, and ice bags. Class II devices

14. Id. § 360c(a)(1)(A).
are those for which "the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device." The FDA is required to impose any special controls necessary to provide adequate assurance of the device's safety. Class II devices include such things as tampons, syringes, and neonatal incubators.

Class III devices are subject to the most stringent regulatory controls of all device classes. Class III medical devices are those: (1) for which there is insufficient information to determine that general controls and special controls are adequate to provide reasonable assurance of safety and effectiveness and (2) that are "purported or represented to be for a use in supporting or sustaining human life or for a use . . . of substantial importance in preventing impairment of human health, or [that] present[] a potential unreasonable risk of illness or injury." Pacemakers and heart valves are examples of Class III devices.

Ordinarily, the manufacturer of a Class III medical device must submit a PMA application to the FDA before marketing the device in interstate commerce. This application must contain a full report of any clinical investigations that concern the safety or effectiveness of the device. The application must also contain "a full statement of the components, ingredients, properties, and . . . principles of operation, of [the] device." It must include "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, [the] device." The PMA application must identify, discuss, and analyze any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience.

18. Id.
23. Id. § 360e(c)(1)(A); 21 C.F.R. § 814.20(b)(6)(ii).
25. Id. § 360e(c)(1)(C).
Even unpublished information must be included in the PMA application if it is possessed or reasonably obtainable by the applicant. 27 Finally, the PMA application must include "specimens of the labeling proposed to be used for the device." 28

As part of the PMA review, FDA scientists carefully evaluate all of the data and information submitted by the manufacturer; and the manufacturer periodically must update the application dating the review process with any significant new safety and effectiveness information. 29 The FDA may request additional information as necessary to provide a complete and accurate picture of the product, and may supplement the expertise of its in-house scientific personnel with advice from scientific advisory committees of outside experts. 30 Once the FDA approves the medical device for marketing, it issues an approval order, which takes the form of a letter to the manufacturer, and which contains any conditions for approval. 31 The Agency's approval of a PMA application reflects its conclusion that there is a "reasonable assurance of safety and effectiveness" of the device under the conditions set forth in the labeling for the product. 32 In addition, application approval means that the FDA has determined that the proposed labeling for the device complies with the all labeling requirements and is "neither false nor misleading." 33

Once the FDA approves a Class III medical device, the holder of the approval may not change the design of the device in a manner affecting its safety or effectiveness without FDA approval through a PMA supplement. 34 The FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific process utilized for review of the original PMA application. 35 Changes to the design of a device that affect safety or effectiveness are approved only if "nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device," and if "clinical data provide a reasonable assurance of safety and effectiveness for the changed . . . device" under the conditions in the

27. Id. § 814.20(b)(8)(iii).
29. 21 C.F.R. § 814.20(e).
30. Id. § 814.20(b)(13).
31. Id. § 814.44(e).
33. Id.; 21 C.F.R. § 814.44(d)(1).
34. 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39.
labeling.\textsuperscript{36} The FDA may "require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness."\textsuperscript{37} Certain labeling changes that enhance safety without a corresponding impact on effectiveness are eligible for implementation without prior FDA approval; additionally, some manufacturing changes are also accorded special treatment.\textsuperscript{38} Even under these circumstances, the Agency may disapprove a change after it has been implemented.\textsuperscript{39}

Most medical devices do not undergo the FDA PMA process. Class I and II devices are not subject to the PMA requirements.\textsuperscript{40} Also, a Class III medical device is not subject to the PMA requirement if it was marketed prior to the MDA's enactment and a regulation requiring submission of PMA application has not been issued for the device, or if it is "substantially equivalent" to such a device marketed prior to the MDA's enactment.\textsuperscript{41} A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the Agency in accordance with § 510(k) of the FDCA.\textsuperscript{42} A device found to be "substantially equivalent" to a predicate device is said to be "cleared" by the FDA (as opposed to "approved" by the Agency under a PMA).\textsuperscript{43} A premarket notification submitted under § 510(k) is thus entirely different from a PMA application, which must include data sufficient to demonstrate to FDA that the device is safe and effective.\textsuperscript{44} Another exception to the PMA process permits a Class III device that obtains an Investigational Device Exemption (IDE) to be tested on human subjects without obtaining FDA approval.\textsuperscript{45}

III. THE DOCTRINE OF FEDERAL PREEMPTION

Although the states are regarded as sovereign entities within the federal system,\textsuperscript{46} the federal government can prevent the states from regulating in certain areas if it so chooses. The principle by which federal law overrides state law in this manner is known as preemption.

\textsuperscript{37} Id. § 360e(d)(6)(B)(ii).
\textsuperscript{38} 21 C.F.R. §§ 814.39(d), (f).
\textsuperscript{39} 21 U.S.C. § 360e(e).
\textsuperscript{40} Id. § 360e(a).
\textsuperscript{41} Id. §§ 360e(b)(1)(A)-(B), 360j(a).
\textsuperscript{42} 21 U.S.C. §§ 360(k), 360e(f)(4).
\textsuperscript{43} Horn v. Thoratec Corp., 376 F.3d 163, 167 (3d Cir. 2004).
\textsuperscript{44} Medtronic, Inc. v. Lohr, 518 U.S. 470, 478-79, 493 (1996).
\textsuperscript{45} 21 U.S.C. §§ 360e(a), 360j(g).
\textsuperscript{46} Parker v. Brown, 317 U.S. 341, 351 (1943) (characterizing the federal system as "a dual system of government in which, under the Constitution, the states are sovereign").
According to conventional wisdom, the power of Congress to preempt state law derives from the Supremacy Clause of the United States Constitution. The power to preempt ensures that federal law will prevail over conflicting state statutes, local ordinances, and even state common law doctrines. In general, the party seeking to invoke federal preemption as a defense carries the burden of proof on this issue. Furthermore, the Court has declared that it will presume that Congress would not preempt state law in traditional areas of state concern, such as public health and safety, unless Congress makes its intent to supersede state law "clear and manifest." Courts and commentators typically divide preemption into two basic categories, express and implied, and further subdivide implied preemption into field preemption and conflict preemption.

A. Express Preemption

Express preemption occurs when a federal statute specifically excludes state regulation in a particular area. For example, in Rice v.


53. Gade, 505 U.S. at 98.
**Santa Fe Elevator Corp.**, the Supreme Court ruled that the language of the federal Warehouse Act manifested a congressional intent to displace state jurisdiction over federally licensed warehouse operators. Federal agencies acting within the scope of their delegated authority may also preempt state law by regulation. This principle is illustrated by *Fidelity Federal Savings & Loan Ass'n v. de la Cuesta*, where the Court concluded that the state of California could not limit the use of the Federal Loan Bank Board’s authorization of “due-on-sale” clauses in home mortgage contracts because such clauses had been authorized by the Federal Loan Bank Board.

**B. Implied Preemption**

Congress may impliedly preempt state law when a federal regulatory scheme effectively occupies the field and leaves no room for state regulation or when state-law conflicts in some way with federal law. Field preemption involves federal regulations that are so pervasive that courts assume that Congress intended to occupy the field and to exclude any state regulation. In *Schneidewind v. ANR Pipeline Co.*, for example, a public utility claimed that the federal Natural Gas Act preempted a Michigan statute that required companies to obtain approval of the state public service commission before issuing long-term securities. The Court found that the Michigan

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statute constituted an attempt to regulate natural gas company rates and facilities, and thus encroached upon a regulatory area already fully occupied by the Federal Energy Regulatory Commission.\footnote{Id. at 310.}

Another form of implied preemption is known as conflict preemption and may occur when it is impossible to comply with both state and federal law or where state law stands as an obstacle to the achievement of federal regulatory objectives. Impossibility is illustrated by \textit{McDermott v. Wisconsin}, where syrup that met the federal labeling standards was considered mislabeled under state law.\footnote{228 U.S. 115, 127, 136-37 (1913).} The Court found that the defendant could not satisfy the requirements of both the state and federal statutes and, therefore, invalidated the state statute.\footnote{Id. at 137.}

\textit{Michigan Canners \& Freezers Ass'n v. Agricultural Marketing \& Bargaining Board} demonstrates the concept of obstacle preemption.\footnote{467 U.S. 461, 478 (1984); see also Boggs v. Boggs, 520 U.S. 833, 844 (1997) (holding that state community property law interfered with objectives of ERISA); Int'l Paper Co. v. Ouellette, 479 U.S. 481, 491 (1987) (holding that applying affected-state, rather than source-state, common law in private nuisance actions against out-of-state polluters was not compatible with the regulatory objectives of the Clean Water Act).} In that case, a Michigan law organized and certified growers' associations as exclusive bargaining agents for all producers of a particular agricultural commodity.\footnote{See \textit{Michigan Canners}, 467 U.S. at 468 (referring to \textsc{Mich. Comp. Laws Ann.} \textsection 290.701-290.726 (West 1984)).} A group of asparagus farmers and processors challenged the Michigan statute because it required nonmember growers to pay service fees and adhere to contracts negotiated by the growers' association.\footnote{Id.} The Court noted that both the federal act and the Michigan statute were intended to facilitate collective action among producers in order to protect them against coercive action by processors.\footnote{Id. at 464-66.} However, the federal act was also enacted to protect individual producers against associations of producers.\footnote{Id. at 464-65.} Consequently, the Court held that the Michigan law stood "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" insofar as it enabled producers' associations to determine the prices individual growers would receive for their products.\footnote{Id. at 478.}
C. Preemption of Common Law Tort Claims

Until recently, defendants did not often invoke federal preemption as a defense against tort liability. Some early examples of preemption raised in tort cases include San Diego Building Trades Council v. Garmon,70 Silkwood v. Kerr-McGee Corp.,71 International Paper Co. v. Ouellette,72 and English v. General Electric Co.73 In Garmon, the Court held that the National Labor Relations Act preempted unfair labor practices claims by a lumber supplier against a number of labor unions.74 In contrast, the Silkwood Court concluded that the Atomic Energy Act did not preempt a punitive damage claim by an injured worker against a plutonium fuel rod manufacturer.75 However, in Ouellette, the Court determined that the Clean Water Act preempted a common law nuisance claim against an out-of-state paper mill.76 Finally, the Court in English declared that the Energy Reorganization Act of 1974 did not preempt a tort claim for intentional infliction of emotional distress.77 Cipollone v. Liggett Group, Inc.78 and Geier v. American Honda Motor Co.79 are two of the Supreme Court’s most significant preemption cases in recent years. The Cipollone case concerned the preemptive effect of federal labeling requirements on tort claims against tobacco companies.80 The Court concluded that the 1969 Federal Cigarette Labeling and Advertising Act expressly preempted the plaintiff’s failure-to-warn claims, but did not preempt claims based on breach of express warranty, misrepresentation, or conspiracy.81 The Cipollone Court also made several observations about preemption methodology. First, the Court acknowledged that it must construe the statute’s preemptive language “in light of the presumption against the pre-emption of state police power regulations.”82 Second, the Court declared that when a statute’s express preemption provision provided a “reliable indicium of congressional intent with respect to state authority, there is no need to infer

73. 496 U.S. 72, 78 (1990).
75. *Silkwood*, 464 U.S. at 257-58.
76. *Ouellette*, 479 U.S. at 500.
77. *English*, 496 U.S. at 90.
80. *Cipollone*, 505 U.S. at 509.
81. Id. at 524-30.
82. Id. at 518.
congressional intent to preempt state laws from the substantive provisions of the legislation.\footnote{83} In other words, the Court should limit itself to an express preemption analysis, and not engage in implied preemption analysis, when the statute in question contain an express preemption provision.\footnote{84} Third, the \textit{Cipollone} Court reiterated its position that common law tort doctrines could have the same coercive effect as statutes, ordinances, and administrative regulations.\footnote{85} Moreover, contrary to the position that it had taken in \textit{Silkwood}, the \textit{Cipollone} plurality opinion stated that a statute did not have to mention tort remedies specifically in order to preempt them; instead, general language would be sufficient to preempt common law tort claims.\footnote{86} Finally, the Court chose to examine the plaintiff’s tort claims on an individual basis, dismissing some as preempted and upholding others.\footnote{87}

Perhaps the most significant of these post-\textit{Cipollone} decisions was \textit{Geier}.\footnote{88} In that case, the Court held that Federal Motor Vehicle Safety Standard 208 (FMVSS 208), promulgated by the Department of Transportation (DOT) under the authority of the National Transportation Motor Vehicle Safety Act (NTMVSA), preempted design defect claims based on a failure to equip motor vehicles with airbags.\footnote{89} The NTMVSA expressly preempted “any safety standard” established by a state that was “applicable to the same aspect of performance of [a motor] vehicle or item of equipment” unless it was identical to the federal standard.\footnote{90} The NTMVSA also contained a “saving clause” that declared that compliance with federal safety standards would not “exempt any person from any liability under common law.”\footnote{91} FMVSS 208 provided for a gradual phase-in of airbags by requiring automobile manufacturers to equip some, but not

\footnote{83. \textit{Id.} at 517 (internal citations and quotations omitted).}
\footnote{85. \textit{See Cipollone}, 505 U.S. at 521; \textit{see also} Raeker-Jordan, \textit{supra} note 52, at 1409-10.}
\footnote{88. 529 U.S. 861 (2000).}
\footnote{89. \textit{Id.} at 865 (citing the National Traffic and Motor Vehicle Safety Act of 1966, 80 Stat. 718 (currently codified in various sections of 49 U.S.C.)).}
\footnote{91. \textit{Id.} § 1397(k) (current version at 49 U.S.C. § 30,103(e) (2000)).}
all, of their vehicles with airbags each year.92 The Court first
determined that the savings clause required the Court to interpret the
preemption clause more narrowly than it otherwise would.93
Consequently, it declared that the federal safety standard did not
expressly preempt the plaintiff’s design defect claim.94 However, the
Court then concluded that the “no airbag” claim was impliedly
preempted because it conflicted with DOT’s policy of providing
automobile manufacturer’s with “a range of choices among different
passive restraint devices.”95

D. Preemption Under the MDA

The FDCA does not include an express preemption provision.96
The MDA, however, does contain such a provision, § 360k(a), which
declares:

[N]o 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
relates to the safety or effectiveness of the device or to any other matter
included in a requirement applicable to the device under this chapter.97

The Supreme Court interpreted this language to mean that only federal
design requirements specific to a device, focusing on safety and
effectiveness, can preempt state law.98

While § 360k(a) clearly preempts state statutes, municipal
ordinances, or administrative regulations that purport to subject
medical devices to safety standards that are additional to or different
from those mandated by the FDA, it is less clear whether this provision
also preempts common law tort claims against manufacturers of FDA-
approved medical devices. It should be noted that the MDA contains a
savings clause which declares that “[c]ompliance with an order issued
under this section shall not relieve any person from liability under

93. Id. at 868.
94. Id.
95. Id. at 875.
96. David R. Geiger & Mark D. Rosen, Rationalizing Product Liability for
Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform
Pharmaceutical Safety Standards, 45 DePaul L. Rev. 395, 400 (1996); Sasha B. Rieders,
Note, State Law Tort Claims and the FDA: Proposing a Consumer-Oriented Prescription in
Federal or State law." However, the purpose and effect of this provision is clouded by the fact that it appears in a section of the MDA that deals with the FDA's authority over a medical device when it discovers that the device "presents an unreasonable risk of substantial harm to the public health." 

In addition, the FDA has adopted a regulation which declares that § 360k(a) will preempt common law tort claims in certain circumstances. This regulation provides:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

Unfortunately, the phrases "specific counterpart regulations" and "other specific requirements applicable to a particular device under the act" are ambiguous and both the courts and the FDA have interpreted them differently over the years.

IV. Medtronic and Its Progeny

A. MDA Preemption Before Medtronic

Prior to Medtronic, most courts held that the MDA preempted common law tort claims against the manufacturers of PMA-approved medical devices. However, a few courts refused to find that common

100. Id. § 360h(a)(1); see also Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1378-79 (11th Cir. 1999).
law tort claims were preempted. Michael v. Shiley, Inc. and Kennedy v. Collagen Corp. illustrate the respective reasoning behind these contrasting lines of authority.

Michael involved the Bjork-Shiley Heart Valve, which allegedly failed as the result of a weak strut mechanism and poor manufacturing standards at the defendant’s plant. The plaintiff raised a number of liability theories, including negligence, strict products liability, and breach of warranty. However, the trial court granted summary judgment in favor of the defendant, concluding that her claims were preempted by the MDA. On appeal, the federal circuit court considered whether state common law doctrines could impose “requirements” on the defendant and whether the FDA’s PMA process imposed any conflicting “requirements.” Relying on its earlier decision in Gile v. Optical Radiation Corp., the court in Michael summarily concluded that claims based on general common law doctrines could be requirements. The court rejected the plaintiff’s contention that 21 C.F.R. § 808.1(d)(1), which excludes state or local requirements of general applicability from preemption, defeated the preemption defense; the court looked instead to § 360k(a), which did not limit the scope of MDA preemption in this manner. Turning to the second issue, the court in Michael concluded that the FDA’s labeling and post market notification requirements, as well as its good manufacturing practices, constituted “specific requirements applicable to a particular device under the act,” even though they were general requirements and not specific to heart valves. Consequently, the court affirmed the lower court’s grant of summary judgment as to the plaintiff’s negligence, strict liability, and implied warranty claims.
The federal appeals court in *Kennedy* took a narrower view of MDA preemption than its colleagues in *Michael*.115 The plaintiff in *Kennedy* developed systemic lupus erythematosus, an autoimmune disease, after being injected with Zyderm, a collagen implant.116 The plaintiff brought suit against Zyderm’s manufacturer, claiming, inter alia, negligence, strict liability, and breach of warranty.117 The district court granted the defendant’s motion for summary judgment on the grounds that § 360k(a) preempted plaintiff’s claims.118

As in the *Michael* case, the federal appeals court in *Kennedy* examined two issues: “(1) what constitutes a ‘State . . . requirement’ and (2) what constitutes a ‘requirement’ under the MDA.”119 In the absence of any clear direction in § 360k(a), the court turned for guidance to 21 C.F.R. § 808.1(d).120 As far as the first issue was concerned, the court noted that 21 C.F.R. § 808.1(d)(1) declared that the MDA would not preempt laws of general applicability.121 Because state common law is a law of general applicability, the court reasoned, it should not be preempted by the MDA.122 Furthermore, the fact that state common law could have an indirect regulatory effect would not justify treating it as a specific requirement applicable to a particular device.123

The court also concluded that the PMA process did not qualify as a specific requirement applicable to a particular device.124 According to the court, the fact that the FDA might impose specific requirements upon a particular manufacturer as a condition to allowing it to market its device was distinguishable from the fact that PMA was required before a device could be marketed.125 The *Kennedy* court also observed that in cases involving Class II medical devices, courts have refused to find preemption unless the FDA had adopted requirements that were specifically tailored to the device in question.126

116. *Id.* at 1454-55.
117. *Id.* at 1454.
119. *Kennedy*, 67 F.3d at 1457.
120. *Id.*
121. *Id.* at 1459.
122. *Id.*
123. *Id.*
124. *Id.*
125. *Id.*
126. *Id.* at 1458 (citing Anguiano v. E.I. Du Pont de Nemours & Co., 44 F.3d 806, 810 (9th Cir. 1995); Moore v. Kimberly-Clark Corp., 867 F.2d 243, 246 (5th Cir. 1989)).
The court in *Kennedy* clearly felt that it should interpret § 360k(a) narrowly. First, it applied the presumption against preemption to justify a narrow construction of the MDA’s preemption provision.127 Second, the court echoed *Silkwood* when it expressed doubts that Congress would enact consumer protection legislation while at the same time stripping consumers of their existing tort remedies.128 Finally, the court in *Kennedy* observed that the PMA process was supposed to protect consumers from unsafe products, “not create a rose garden, free from liability, for manufacturers.”129 Consequently, allowing § 360k(a) to preempt common law tort claims would be contrary to the MDA’s overall purpose and objectives.130

**B. Medtronic, Inc. v. Lohr**

*Medtronic, Inc. v. Lohr*, decided in 1996, was the first and only Supreme Court case to consider whether § 360k(a) preempts common law tort claims.131 The plaintiff in that case, a heart patient, required emergency surgery when her cardiac pacemaker failed.132 She brought suit against the manufacturer, alleging defective manufacture and design, as well as failure to warn.133 According to the plaintiff, a defect in the pacemaker’s Model 4011 lead caused it to malfunction.134 The FDA had designated the pacemaker as a Class III device; however, the pacemaker had not undergone PMA by the FDA, but instead had been approved for marketing after a § 510(k) review.135 Medtronic claimed that § 360k(a) expressly preempted all of the plaintiff’s claims.136 The trial court accepted the defendant’s preemption argument and granted its motion to dismiss.137 On appeal, the United States Court of Appeals for the Eleventh Circuit concluded that the plaintiff’s negligent manufacturing and failure-to-warn claims

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127. *Id.* at 1456.
128. *Id.* at 1459 (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).
129. *Id.* at 1460.
130. *Id.*
132. *Id.* at 480-81.
133. *Id.* at 481.
134. *Id.* at 480-81. The lead is the portion of the pacemaker that transmits an electrical signal from the pulse generator to the heart. *Id.* at 480.
135. *Id.*
136. *Id.* at 481-82.
137. *Id.* at 483.
were preempted, but her design defect claims were not.\textsuperscript{138} The Supreme Court granted certiorari and agreed to review the case.\textsuperscript{139}

Justice Stevens, joined by Justices Kennedy, Souter, and Ginsburg, wrote the plurality opinion, which concluded that § 360k of MDA did not preempt common law tort claims.\textsuperscript{140} This opinion contained seven parts. Part I described the MDA's classification system and licensing processes.\textsuperscript{141} Part II gave the facts and procedural history of the case, while part III described the law of federal preemption.\textsuperscript{142} Part IV of the plurality opinion concluded that § 360k would preempt few, if any, common law tort claims.\textsuperscript{143} Part V declared that none of the plaintiffs' claims were preempted.\textsuperscript{144} In part VI, the plurality determined that the statement that state requirements established by court decision in the FDA's regulations could be preempted referred only to court decisions that purported to interpret state statutes and regulations.\textsuperscript{145} Finally, part VII set forth the decision of the Court.\textsuperscript{146}

Justice Breyer concurred in the judgment and in parts I, II, III, V, and VII of the plurality opinion.\textsuperscript{147} However, he expressly declined to join in parts IV and VI of the plurality opinion.\textsuperscript{148} Justice O'Connor, joined by Chief Justice Rehnquist and Justices Scalia and Thomas, dissented in part and concurred in part.\textsuperscript{149} They agreed that § 360k would not preempt the plaintiffs' design defect claim, but concluded that it would preempt their failure-to-warn and defective manufacturing claims.\textsuperscript{150} Thus, \textit{Medtronic} can be characterized as a "dual majority" case because Justice Breyer joined with the plurality to support the result, but agreed with the dissent that § 360k could preempt common law tort claims.\textsuperscript{151}

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{138} Lohr v. Medtronic, Inc., 56 F.3d 1335, 1349, 1350-52 (11th Cir. 1995).
\item \textsuperscript{139} Medtronic, Inc. v. Lohr, 516 U.S. 1087 (1996).
\item \textsuperscript{140} \textit{Medtronic}, 518 U.S. at 513-14.
\item \textsuperscript{141} \textit{Id.} at 475.
\item \textsuperscript{142} \textit{Id.} at 480, 484.
\item \textsuperscript{143} \textit{Id.} at 486.
\item \textsuperscript{144} \textit{Id.} at 492.
\item \textsuperscript{145} \textit{Id.} at 502.
\item \textsuperscript{146} \textit{Id.} at 503.
\item \textsuperscript{147} \textit{Id.} at 503-08 (Breyer, J., concurring in part and concurring in the judgment).
\item \textsuperscript{148} \textit{Id.} at 508 (Breyer, J., concurring in part and concurring in the judgment).
\item \textsuperscript{149} \textit{Id.} at 509-14 (O'Connor, J., concurring in part and dissenting in part).
\item \textsuperscript{150} \textit{Id.} at 514 (O'Connor J., concurring in part and dissenting in part).
\item \textsuperscript{151} Horn v. Thoratec Corp., 376 F.3d 163, 176 n.18 (3d Cir. 2004).
\end{enumerate}
\end{footnotesize}
1. Common Law Tort Rules as “Requirements”

In the plurality opinion, Justice Stevens considered whether any common law claim would constitute a “requirement” within the meaning of § 360k(a) that imposes duties upon the manufacturer that are “different from, or in addition to” those imposed by the FDA. Justice Stevens, the proposition that common law tort claims could be considered to be “requirements” was “unpersuasive” and “implausible” because it would leave consumers without any remedy if they were injured by a defective medical device. Quoting from the Silkwood case, Justice Stevens declared that if Congress wished to take away state-law remedies, it would have to express itself more clearly. Justice Stevens further observed that “requirement” was a “singularly odd word” for Congress to use if it wanted to preclude common law claims. Justice Stevens distinguished Cipollone by arguing that the term “requirement,” as used in the 1969 Cigarette Labeling Act, could reasonably include common law tort actions because that statute preempted only a narrow class of claims and, therefore, did not seriously interfere with any important state interest. Justice Stevens also relied on the MDS’s legislative history to support his conclusion that § 360k(a) did not preempt all common law claims.

In a concurring opinion, Justice Breyer expressed his support for Cipollone’s finding that the term “requirement” could refer to a duty imposed upon product manufacturers by principles of state tort law. Justice O’Connor, joined by three other members of the Court, also embraced the Cipollone Court’s finding that common law tort actions could impose “requirements” on product manufacturers. Thus, five members of the Court agreed that common law tort doctrines could be “requirements” and that § 360k(a) could preempt some common law claims.

152. Medtronic, 518 U.S. at 486.
153. Id. at 487.
154. Id.
155. Id.
156. Id. at 488.
157. Id. at 490-91.
158. Id. at 504 (Breyer, J., concurring in part and concurring in the judgment).
159. Id. at 510 (O’Connor, J., concurring in part and dissenting in part).
2. Specific Federal Requirements

The FDA regulation, 21 C.F.R. § 808.1(d), provided that § 360k(a) would preempt state and local requirements only when the FDA had established specific counterpart regulations or other regulations that are specific to a particular device. In the plurality opinion for the Court, Justice Stevens considered whether any specific federal requirements existed that might conflict with any of the plaintiff's claims. As far as the plaintiff's defective design claim was concerned, Justice Stevens concluded that the FDA focused more on equivalence than safety in its § 510(k) process; since the Agency's requirements were not related to the safety of the product's design, there was no overlap between those requirements and the standards applicable to manufacturers under state tort law. Next, Justice Stevens determined whether § 360k(a) preempted the plaintiff's claims based on defective manufacturing or inadequate labeling. He acknowledged that one set of regulations that required manufacturers of medical devices to include a label with each device that contained "information for use . . . and any relevant hazards, contraindications, side effects, and precautions." Another set of regulations required manufacturers to comply with "Good Manufacturing Practices" were described by the FDA in considerable detail. Justice Stevens concluded that the FDA's manufacturing and labeling requirements reflected "important, but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." Consequently, Justice Stevens concluded that none of the plaintiff's claims based on defective manufacturing or labeling were preempted.

Justice Breyer also agreed that only FDA regulations that were "specific" to the device in question would preempt common law tort claims. He then concluded that none of the FDA requirements involved in the case were sufficiently specific to preempt any of the

161. Medtronic, 518 U.S. at 489.
162. Id. at 492-94.
163. Id. at 492.
164. 21 C.F.R. § 801.109(b)-(e).
165. Id. § 820.
166. Medtronic, 518 U.S. at 501.
167. Id. at 502.
168. Id. at 506 (Breyer, J., concurring in part and concurring in the judgment).
plaintiff's common law tort claims.\textsuperscript{169} Justice O'Connor did not agree that under § 360k(a) only specific FDA regulations would be given preemptive effect.\textsuperscript{170} As she pointed out, § 360k(a) did not declare specificity to be a requirement so there was no reason for the Court to impose such a requirement.\textsuperscript{171} Nevertheless, she agreed that the plaintiff's design defect claims were not preempted.\textsuperscript{172} At the same time, Justice O'Connor did conclude that other claims imposed state requirements upon the defendant that were "different from, or in addition to" requirements contained in FDA regulations on labeling or Good Manufacturing Practices.\textsuperscript{173}

3. Specific State Requirements

The second issue concerned whether common law tort doctrine could be considered "state and local requirements of general applicability" and thereby saved from preemption by 21 C.F.R. § 808.1(d). Justice Stevens declared that for state requirements to be preempted, they must be "with respect to" medical devices.\textsuperscript{174} Justice Stevens concluded that "the general state common law requirements in this suit were not specifically developed 'with respect to' medical devices" and, therefore, "are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements."\textsuperscript{175}

Justice Breyer, on the other hand, agreed with Justice O'Connor that tort doctrines establishing a standard of conduct could have the same regulatory effect as statutes, ordinances, and administrative regulations.\textsuperscript{176} He also observed that standards established by tort law could conflict with standards established by regulation under the MDA.\textsuperscript{177} According to Justice Breyer, if the MDA preempted a state requirement embodied in legislation or administrative regulation, "it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action."\textsuperscript{178} Thus, Justice Breyer apparently rejected the argument that § 360k(a)

\textsuperscript{169} Id. at 507 (Breyer, J., concurring in part and concurring in the judgment).
\textsuperscript{170} Id. at 512 (O'Connor, J., concurring in part and dissenting in part).
\textsuperscript{171} Id. (O'Connor, J., concurring in part and dissenting in part).
\textsuperscript{172} Id. at 513 (O'Connor, J., concurring in part and dissenting in part).
\textsuperscript{173} Id. at 514 (O'Connor, J., concurring in part and dissenting in part).
\textsuperscript{174} Id. at 500.
\textsuperscript{175} Id. at 501.
\textsuperscript{176} Id. at 504 (Breyer, J., concurring in part and concurring in the judgment).
\textsuperscript{177} Id. (Breyer, J., concurring in part and concurring in the judgment).
\textsuperscript{178} Id. at 504-05 (Breyer, J., concurring in part and concurring in the judgment).
only preempted state requirements that were specific to the device in question.

Justice O’Connor and the other dissenters rejected the FDA’s interpretation of § 360k(a) insofar as it purported to give preemptive effect only to “specific counterpart regulations.” She also rejected the notion that § 360k(a) would only preempt device-specific tort doctrines, declaring that it did not mandate that a requirement be specific “either to pre-empt or be pre-empted.” Instead, § 360k(a) would preempt a common law tort doctrine if it imposed “any requirement” that was “different from or in addition to” any FDA requirement applicable to the medical device in question.

C. MDA Preemption After Medtronic

Since Medtronic, courts have continued to disagree about whether § 360k(a) pre-empts tort claims against manufacturers whose medical devices have received FDA approval. A substantial number of courts have refused to find preemption in such cases. However, many other courts have concluded that tort claims are pre-empted, and this position appears to be gaining ground. As might be expected, courts on both sides of the issue have relied heavily on the Medtronic court’s analysis to support their conclusions.

Goodlin v. Medtronic, Inc. is illustrative of this first view. In this case, the plaintiff argued that the defendant negligently and defectively manufactured the 4004/M cardiac pacemaker lead.

179. Id. at 512 (O’Connor, J., concurring in part and dissenting in part).
180. Id. at 514 (O’Connor, J., concurring in part and dissenting in part) (emphasis added).
181. Id. (O’Connor, J., concurring in part and dissenting in part).
184. See, e.g., Kemp, 231 F.3d at 223-24; Goodlin, 167 F.3d at 1371-74.
185. Goodlin, 167 F.3d at 1367.
186. Id. at 1369.
According to the plaintiff, the design created a high risk that the lead would fail because of degradation of the polyurethane insulating material that surrounded it. The FDA approved the 4004/M lead for marketing in 1989 after it successfully completed the PMA process. The manufacturer contended that the plaintiff’s design-based claims were preempted and the trial court granted summary judgment in its favor.

Although the Goodlin court declared that Medtronic provided “little more than a rudimentary analytical framework to guide our resolution of Medtronic’s preemption claims in this case,” it cited Medtronic for the proposition that “‘presumptions about the nature of pre-emption’ inform the interpretation of section 360k(a).” Specifically, the court declared that “[t]he purpose of Congress [was] the ultimate touchstone” in every pre-emption case [and] deference to state sovereignty . . . require[d] an assumption that Congress will not supersede the ‘historic police powers’ of the states . . . without making that purpose ‘clear and manifest.’” The court also relied on Medtronic to determine whether the defendant had identified any “specific federal requirement imposed on its particular device that would preempt any conflicting or additional state requirement inherent in a jury verdict in Goodlin’s favor.” It rejected the argument that the FDA’s approval of the 4004/M lead, standing alone, imposed a specific requirement on the device. While acknowledging that the FDA’s approval was specific to the device under review, the court declared that the approval itself did not reveal or impose any ascertainable substantive prerequisite that the court could compare with an arguably conflicting state requirement. Thus, the court concluded, the FDA’s approval of Medtronic’s device did not meet § 360k(a)’s standard of a specific federal requirement. Finally, the Goodlin court found that the FDA’s “Conditions for Approval,” as distinguished from the approval itself, also did not satisfy the statutory standard. Although the court agreed that these conditions amounted to specific federal

187. Id. at 1368.
188. Id.
189. Id. at 1369.
190. Id. at 1371 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).
191. Id. at 1372 (quoting Medtronic, 518 U.S. at 485).
192. Id.
193. Id. at 1376.
194. Id.
195. Id.
196. Id.
requirements, it concluded that they were too generic in nature to be "applicable under this chapter to the device."197 According to the court, the FDA did not impose any conditions that were specific to pacemaker leads, but instead merely imposed generic conditions that were applicable to every medical device that went through the PMA process.198

*Kemp v. Medtronic, Inc.* also involved Medtronic's model 4004/M pacemaker lead.199 In *Kemp*, however, the court held that the plaintiff's common law tort claims were preempted.200 The plaintiff in that case was injured when her pacemaker malfunctioned, apparently due to degradation of the lead's polyurethane insulation.201 She brought suit against Medtronic, alleging defective design, failure to warn, breach of warranty, fraudulent misrepresentation or "fraud on the FDA," and negligence per se based on defective manufacture.202 The trial court, however, granted the defendant's motion for summary judgment and the plaintiff appealed.203

As in *Goodlin*, the court in *Kemp* looked to the Supreme Court's decision in *Medtronic* for guidance.204 The first issue the court addressed was whether the FDA established specific federal requirements for the Model 4004/M lead through the PMA process.205 The *Kemp* court acknowledged that *Goodlin* had concluded that the PMA process had not established such requirements.206 However, the court in *Kemp* rejected *Goodlin*'s analysis, in part because it had previously held that the IDE process, which was similar to the PMA process, did impose specific requirements on medical device manufacturers.207 In *Kemp*, the specific federal requirement issue

197. *Id.* (quoting 21 U.S.C. § 360k(a)(1) (1994)).
198. *Id.* at 1377. The court in *Goodlin* declined to consider whether common law tort doctrines were too general in nature to constitute specific state requirements. *Id.* at 1371 n.7. However, several other courts have done so. For example, in *Walker v. Johnson & Johnson Vision Products, Inc.*, a Michigan intermediate appellate court held that state common law is a law of general applicability and for this reason would not be preempted by § 360k(a). 552 N.W.2d 679, 686 (Mich. Ct. App. 1996). A Washington appeals court reached a similar conclusion where a state products liability statute imposed strict liability on products generally. *Wutzke v. Schweigeler*, 940 P.2d 1386, 1391-92 (Wash. Ct. App. 1997).
199. 231 F.3d 216, 218-19 (6th Cir. 2000).
200. *Id.* at 218.
201. *Id.* at 218-19.
202. *Id.* at 219-20.
203. *Id.* at 221.
204. *Id.* at 223.
205. *Id.* at 225.
206. *Id.* at 225-26.
207. *Id.* at 226 (citing *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997)).
involved a PMA supplement rather than the original PMA process itself. Nevertheless, the court concluded that the FDA did establish specific federal requirements for Medtronic’s pacemaker lead when it approved the defendant’s PMA supplement, even though the Agency had not promulgated any specific regulations governing pacemakers. According to the court, “the specific requirements applicable to the Model 4004M include the entire relevant PMA and accompanying PMA Supplement.” The court in *Kemp* then considered whether any of the plaintiff’s claims imposed state-law requirements which were “different from, or in addition to” the federal requirements established by the FDA through its PMA process. It concluded that federal law preempted the plaintiff’s state-law basis per se negligence claim because it assumed that the lead’s platinum sputter barrier must have a uniform thickness of 500 angstroms while the PMA did not contain any thickness requirement. The court also held that federal law preempted both the plaintiff’s “fraud on the FDA” and inadequate warning claims.

Finally, in *McMullen v. Medtronic, Inc.*, a federal appeals court held that the MDA expressly preempted a state law failure-to-warn claim. The plaintiff in that case alleged that a device implanted in his brain to control the symptoms of Parkinson’s Disease caused severe brain damage after he underwent diathermy during a dental procedure. According to the plaintiff, the manufacturer breached its postsale duty to warn by not informing him about this risk in a timely manner once it received information about a similar injury to another user. The device in questions, known as the Medtronic Activa Tremor Control System, had been licensed by the FDA after undergoing full PMA review in 1997. The court determined that any common law postsale duty to warn amounted to a state requirement. Furthermore, the diathermy/electrocautery warning approved by the

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208. *Id.* at 225-26.
209. *Id.* at 227-28.
210. *Id.* at 228.
211. *Id.* at 228-29.
212. *Id.* at 228-32.
213. *Id.* at 232-37.
214. 421 F.3d 482 (7th Cir. 2005).
215. *Id.* at 490.
216. *Id.* at 485-86.
217. *Id.* at 486.
218. *Id.* at 484.
219. *Id.* at 487.
FDA as part of the PMA process was a specific federal requirement.\(^{220}\) Finally, the court concluded that the postsale duty imposed under state tort law was different from or in addition to the FDA warning mandated by the FDA.\(^{221}\) This was true even though FDA regulations permitted a manufacturer to amend its existing warning temporarily pending FDA approval of the proposed change.\(^{222}\) Consequently, the court concluded that § 360k(a) expressly preempted the plaintiff’s state law postsale failure-to-warn claim.\(^{223}\)

V. JUDICIAL DEFERENCE TO THE FDA’S INTERPRETATION OF § 360K(A)

In 1978, the FDA promulgated a regulation, 21 C.F.R. § 808.1(d), that interpreted § 360k(a) in a way that seemed to limit its preemptive effect on common law tort actions. However, in 2002, the FDA’s Chief Counsel announced that the Agency now believed that most, if not all, common law tort claims should be preempted for medical devices that had undergone the PMA process.\(^{224}\) The Agency also espoused this new interpretation of § 360k(a) in amici curiae briefs that it filed in a number of MDA preemption cases.\(^{225}\) Recently, in *Horn v. Thoratec Corp.*, a federal appeals court relied heavily on these amici briefs to conclude that claims against the manufacturer of an FDA-approved medical device were preempted by § 360k(a).\(^{226}\)

The *Horn* court’s reliance on the FDA’s revised interpretation of § 360k(a) raises a number of questions about judicial deference to agency interpretations in preemption cases. First of all, should a court show less deference to an agency when it changes a longstanding interpretation? Second, should a court defer to an agency when it interprets its own preemption statute? Third, does the *Medtronic* Court’s apparent endorsement of 21 C.F.R. § 808.1(d) prevent the FDA from changing its mind on the scope of preemption? Finally, is an amicus brief sufficiently formal to justify deference under the *Chevron* doctrine, or should a court apply a weaker form of deference as exemplified by the *Skidmore* approach?

\(^{220}\) *Id.* at 487-88.

\(^{221}\) *Id.* at 488.

\(^{222}\) *Id.* at 489; see also 21 C.F.R. § 814.39 (2005) (authorizing manufacturers temporarily to amend an FDA-approved warning).

\(^{223}\) *Id.* at 490.


\(^{225}\) See Clune, *supra* note 8, at 1.

\(^{226}\) 376 F.3d 163, 170-73, 177-79 (3d Cir. 2004).
A. The FDA’s Interpretation of § 360k(a)

1. The FDA’s Original Interpretation

Until 2002, the FDA maintained that § 360k(a) would not prohibit common law tort claims against medical device manufacturers in most cases. As early as 1978, the FDA codified this view in its regulations.\(^{227}\) 21 C.F.R. § 808.1(d) provided that state requirements would be preempted only when the FDA had established “specific counterpart regulations” or “other specific requirements” that were “applicable to a particular device.”\(^{228}\) Both Justice Steven’s plurality opinion for the Court and Justice Breyer’s concurring opinion in \textit{Medtronic} accepted this interpretation of § 360k(a) for purposes of determining whether the MDA preempted common law tort claims.\(^{229}\) The FDA’s regulations also declare that § 360k(a) would not preempt “state or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices.”\(^{230}\) The \textit{Medtronic} Court accepted this limitation on the preemptive scope of § 360k(a),\(^{231}\) leading Justice Stevens to conclude that “it is apparent that few, if any, common-law duties have been pre-empted by this statute.”\(^{232}\) In 1984, the FDA issued an Advisory Opinion which concluded that state rules or requirements governing the legal remedies were not “requirements with respect to a device” within the meaning of § 360k(a).\(^{233}\) The Agency subsequently filed several amicus briefs that argued for a narrow interpretation of § 360k(a). For example, in 1995, the FDA filed an amicus brief with the United States Court of Appeals for the First Circuit in \textit{Talbott v. Bard Inc.},\(^{234}\) a fraud on the FDA case, arguing that the plaintiffs’ claims should not be preempted if they were premised on the same deficiencies that resulted in a federal enforcement action since tort liability would not impose any requirement that was in addition to or different from requirements

\(^{228}\) 21 C.F.R. § 808.1(d) (1978).
\(^{230}\) 21 C.F.R. § 808.1(d)(1).
\(^{231}\) \textit{Medtronic}, 518 U.S. at 498-500.
\(^{232}\) \textit{Id.} at 502.
\(^{233}\) Porter, \textit{supra} note 227, at 8.
\(^{234}\) 63 F.3d 25 (1st Cir. 1995).
imposed by federal law. The FDA also submitted a brief to the Supreme Court in the Medtronic case. In this brief, the FDA maintained that § 360k(a) generally does not preempt state tort claims and that it had consistently construed the term "requirement" to refer to substantive, not remedial, provisions.

As late as 1997, Margaret Jane Porter, the FDA's Chief Counsel, wrote:

Since the passage of the Medical Device Amendments of 1976 (MDA), it has been the agency's position that the scope of preemption under section 521 [360k(a)] should be interpreted narrowly, with a presumption against preemption. This is true particularly when the effect of preemption would be to override a state scheme offering greater consumer protection than that currently afforded under the FDCA.

In addition, Ms. Porter declared that the "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." Thus, the FDA visualized tort law as complementing, rather than conflicting with, its regulatory objectives.

The FDA adhered to this view in a 1997 amicus brief that it submitted to the Supreme Court in Kernats v. Smith Industries Medical Systems, Inc. The Illinois intermediate appellate court in Kernats held that § 360k(a) did not preempt a products liability claim against the manufacturer of a chorionic villus sampling (CVS) catheter because it concluded that state tort law doctrines were not developed specifically with respect to medical devices. Arguing in support of the plaintiff's position, the FDA agreed that § 360k(a) would not preempt common law tort claims against the manufacturers of FDA-approved medical devices. The FDA stated that the mere decision to grant PMA did not establish specific federal requirements for the

235. Porter, supra note 227, at 9 (citing Brief for the United States as Amicus Curiae at 13-14, Talbott v. Bard, Inc., 63 F.3d 25 (1st Cir. 1995)).
237. Id. at 12-13.
238. Porter, supra note 227, at 7.
239. Id. at 11.
241. Id. at 1309.
device within the meaning of § 360k(a). According to the FDA, "the manufacturer may select any design, manufacturing, and labeling features that will satisfy the general minimum standards in the Act and regulations, and it may obtain an IDE or PMA on the basis of that selection if the FDA approves the application." However, "[b]ecause the FDA has not imposed any specific substantive requirements on petitioner's design of the CVS in the course of the review process, that design does not represent a specific federal requirement that preempts state common law requirements." In the FDA's view, state law would be preempted only if the FDA supplemented these generalized minimum standards with "additional federal requirements respecting the particular device" and only if state-law imposed requirements that were "different from, or in addition to" these additional federal requirements. Finally, the FDA declared that § 360k(a) would not preempt the plaintiffs' claims "because petitioner has not shown that Illinois common law imposes a substantive requirement specifically with respect to the medical devices at issue here."

2. The FDA's Current Interpretation of § 360k(a)

Recently, the FDA changed its position and now believes that most common law tort claims are preempted by § 360k(a). The chief architect of the FDA's new policy toward preemption was Daniel E. Troy, who served, until recently, as the Agency's Chief Counsel. Speaking in September, 2002 at the Food and Drug Law Institute's (FDLI) annual Advertising and Promotion Conference, Mr. Troy declared that allowing state judges and juries to impose additional requirements on the manufacturers of pharmaceutical products would conflict with FDA determinations of what was necessary for safe product design and labeling. Furthermore, he warned, the FDA would "participate in product liability lawsuits brought under state law as necessary to safeguard its considerable expertise in regulating the content of drug labeling and advertising."
Since then, the FDA has filed amici briefs in at least five cases. In a 2002 brief filed before a federal district court in *Bernhardt v. Pfizer*, the FDA contended that its prescription drug labeling regulations preempted common law failure-to-warn claims. The *Bernhardt* case was eventually decided on primary jurisdiction grounds, rather than preemption grounds. That same year, the FDA submitted an amicus brief to a California intermediate appellate court in *Dowhal v. SmithKline Beecham Consumer Healthcare*. The plaintiff in that case claimed that the California Safe Drinking Water and Toxic Enforcement Act, otherwise known as Proposition 65, required the manufacturers of over-the-counter nicotine replacement products to include certain warnings on its packages. In its brief, the FDA contended that Proposition 65 was impliedly preempted because it would compel the manufacturer to change FDA-approved labeling without the Agency's permission. Furthermore, the FDA argued, the warnings required by state law would discourage pregnant women from using nicotine replacement products, a consequence that was at odds with the FDA's policy of encouraging the use of such products as an alternative to smoking. Although the intermediate appellate court rejected the FDA's preemption argument, the FDA's view ultimately prevailed in the California Supreme Court.

Later that year, the FDA intervened in *Motus v. Pfizer, Inc.*, a case that involved the prescription antidepressant drug, Zoloft. The trial court granted summary judgment for the defendant, concluding that the plaintiff would have taken the drug even if it had contained a stronger warning. In a brief submitted to the United States Court of Appeals for the Ninth Circuit, the FDA argued that the plaintiff's failure-to-warn claim about the risk of violent behavior or suicide was impliedly preempted because such a warning would have been in

251. *See infra* notes 252-272 and accompanying text.
252. Bert W. Rein et al., *Addressing the Conflict: FDA v. Torts*, 3 PHARMACEUTICAL & MED. DEVICE L. BULL., May 2003, at 1-2 (discussing the FDA's view as argued by the DOJ in Statement of Interest of the United States at 5-6, *Bernhardt v. Pfizer, Inc.*, Nos. 00 CIV. 4042 LMM, 00 CITV 4379 LMM (S.D.N.Y. filed Nov. 13, 2000)).
253. *Id.* at 1.
254. *Id.* (discussing the FDA's amicus brief in *Dowhal v. SmithKline Beecham Consumer Healthcare*, 122 Cal. Rptr. 2d 246 (Cal. Ct. App. 2002)).
255. *Dowhal*, 122 Cal. Rptr. 2d at 248; *see also* Rein, *supra* note 252, at 1-2.
257. *Id.*
violation of federal labeling requirements, as the Agency had evaluated this risk and concluded that it was scientifically unsubstantiated. The FDA also argued that the plaintiff's failure-to-warn claim was preempted because such warnings would unreasonably discourage use of the drug and thus thwart the federal objective of optimal use of beneficial drugs. The Ninth Circuit, however, sidestepped the preemption issue and affirmed the lower court's ruling that the plaintiff had failed to prove causation.

The FDA also submitted a brief in a class action involving another antidepressant prescription drug, Paxil. The plaintiffs in that case sought to enjoin Paxil's manufacturer from claiming in its television advertising that Paxil was "nonhabit forming." In response, the FDA maintained that the Paxil advertisements were not inaccurate or misleading. The FDA also contended that the plaintiff's claim was preempted. The court rejected the FDA's preemption theory, but gave greater weight to the FDA's argument that the advertisements were not misleading.

The FDA also has filed amici briefs in two cases involving medical devices. The first of these was Murphree v. Pacesetter, Inc., a case brought in a Tennessee state court in 2003. In its brief in Murphree, the FDA argued that it has the responsibility and the expertise to determine whether a medical device satisfied the PMA approval standard; according to the FDA, lay juries did not have the requisite scientific knowledge or technical expertise to make such judgments. Furthermore, the FDA declared: "[T]he prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place

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263. \textit{Motus v. Pfizer, Inc.}, 358 F.3d 659, 660 (9th Cir. 2004).

264. \textit{Clune, supra} note 8, at 5.

265. \textit{id}.

266. \textit{See id}.

267. \textit{id} at 5-6.

268. \textit{id} at 6, 14 n.86.

269. \textit{id} at 4 (discussing the unpublished case, No. 005429-00-3 (Tenn. Cir. Ct., Dec. 12, 2003)).

and charged the FDA with implementing. According to the FDA, this situation, which would create considerable uncertainty about the status and safety of FDA-approved medical devices, "would create chaos for both the regulated industry and FDA."

Finally, the FDA filed an amicus brief in *Horn v. Thoratec Corp.*, which contended that the plaintiff's design and warning claims should be preempted. The FDA amicus brief declared unequivocally that any conditions imposed upon the defendant TCI through the PMA process qualified as specific federal requirements. In addition, the FDA's brief concluded that the plaintiff's common law tort claims attempted to impose requirements upon TCI that were different from the requirements imposed by the FDA with respect to the design, labeling, and manufacture of the defendant's medical device. The FDA's brief also described some of the adverse effects tort claims would have on its regulatory scheme. First, lawsuits would "encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population—the central role of the FDA—sometimes on behalf of a single individual or group of individuals." The threat of tort liability would also put pressure on device manufacturers to add warnings that the FDA did not believe were scientifically justified or to withdraw FDA-approved devices from the market, notwithstanding the fact that the FDA had found them to be safe and effective. The FDA's brief concluded that this would "harm the public health by retarding research" and development, promoting unscientific warnings, and causing the "underutilization of beneficial treatments."

B. The Meaning of Judicial Deference

The principle of judicial deference is concerned with how much courts should defer to agency interpretations of ambiguous statutes.

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271. *Id.*
272. *Id.*
273. 376 F.3d 163 (3d Cir. 2004). The defendant, Thoratec Corp., was previously known as Thermo Cardiosystems, Inc. (TCI); the court of appeals chose to retain this nomenclature as it was used by both parties as well as the district court. *Id.* at 164 n.1.
274. *Id.* at 171.
275. *Id.* at 171-72; FDA Amicus Curiae Letter Brief, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597) [hereinafter FDA Letter Brief].
Deference to an agency administering its own statute varies with the circumstances and courts have looked to a variety of factors to determine how much weight to give to an agency’s interpretation. Under the strong version of judicial deference, the deferential review model, the court is required to accept the Agency’s interpretation as long as it is reasonable. The weaker form, the independent review model, allows the court to make its own examination of the statute and to treat the Agency’s interpretation merely as a factor for consideration. Commentators argue that judicial deference, particularly in its strong version, is beneficial because it reduces the power of courts to employ statutory interpretation as a tool to implement their own policy agendas. It also promotes uniform interpretations of federal law and provides expertise to the interpretation of complex and highly technical regulatory schemes. The strong version of judicial deference is exemplified by Chevron and its progeny; the weaker version is illustrated by the Skidmore decision.

The source of Chevron deference is the Supreme Court’s decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* In that case, the Natural Resources Defense Council (NRDC) challenged the Environmental Protection Agency’s (EPA) interpretation of “stationary source,” as used in the Clean Air Act. The EPA regulations authorized the states to use a “bubble concept” under which all pollution sources in a plant would be treated as though they came from a single source; this allowed emissions to be aggregated and netted in order to more easily comply with federal emission standards. The Court held that courts must defer to agency interpretations when Congress has left gaps or ambiguities in the

285. The issue of judicial deference usually arises when someone challenges agency action. However, it can also arise in cases between two private parties. See, e.g., Mead Corp. v. Tilley, 490 U.S. 714, 722 (1989) (illustrating a suit by retirees against former employer under ERISA).
287. *Id.* at 840.
288. *Id.*
statute that the Agency administers.\textsuperscript{289} \textit{Chevron} is a strong deference doctrine because courts are required to accept the Agency’s interpretation, if reasonable, whether they agree with it or not.\textsuperscript{290}

\textit{Chevron} outlined a two-step process to determine whether a court should defer to an agency’s interpretation.\textsuperscript{291} In step one, the court must determine whether the statute is unambiguous on the particular issue before it.\textsuperscript{292} If the court concludes that the statute is unequivocal, it has no choice but to carry out Congress’s intent.\textsuperscript{293} Once the court finds the statute to be ambiguous, it then proceeds to step two, which involves a determination of whether the agency’s interpretation of the statute is reasonable.\textsuperscript{294}

Courts and scholars have offered a number of justifications for the principle of judicial deference: implicit delegation by Congress of the power to interpret the statute in question, political accountability, and agency expertise.\textsuperscript{295} The implied delegation theory assumes that Congress cannot enact enough laws in the regulatory area to be effective on their own and, therefore, relies upon administrative agencies to resolve ambiguities and fill in the gaps in its statutory scheme.\textsuperscript{296} Political accountability provides another rationale for \textit{Chevron}-style judicial deference. According to this theory, because administrative agencies are part of the executive branch of government, they are more politically accountable to the people than unelected federal judges and, therefore, these agencies are better suited than courts to make controversial policy choices.\textsuperscript{297} Finally, agencies

\begin{itemize}
\item \textsuperscript{289} \textit{Id.} at 843-44.
\item \textsuperscript{290} Robert A. Anthony, \textit{Which Agency Interpretations Should Bind Citizens and the Courts?}, 7 \textit{Yale J. on Reg.}, 1, 26-27 (1990). Factors that affect “reasonableness include ... agency expertise in a technical or complex area, detailed ... consideration by the agency, the need to reconcile conflicting policies, congressional grant ... of explicit rulemaking authority [to the agency],” whether the interpretation occurs at the same time the agency implements the statute, evidence that Congress is aware of the agency’s position and has rejected attempts to override it, and whether the agency has consistently adhered to its interpretation. \textit{Id.} at 29.
\item \textsuperscript{292} \textit{Chevron}, 467 U.S. at 842-43.
\item \textsuperscript{293} \textit{Id.} at 843 n.9.
\item \textsuperscript{294} \textit{Id.} at 845.
\item \textsuperscript{295} David M. Gossett, Comment, \textit{Chevron, Take Two: Deference to Revised Agency Interpretations of Statutes}, 64 U. Chi. L. Rev. 681, 688-90 (1997).
\item \textsuperscript{296} \textit{Chevron}, 467 U.S. at 840; see also Kenneth A. Bamberger, \textit{Provisional Precedent: Protecting Flexibility in Administrative Policymaking}, 77 \textit{N.Y.U. L. Rev.} 1272, 1279-80 (2002).
\item \textsuperscript{297} \textit{Chevron}, 467 U.S. at 865-66; see also Marshall, supra note 291, at 266.
\end{itemize}
are more likely than courts to interpret complex and technical statutes correctly because they have specialized personnel and superior investigative capabilities.\footnote{Chevron, 467 U.S. at 844; see also Jeffrey E. Shuren, The Modern Regulatory Administrative State: A Response to Changing Circumstances, 38 Harv. J. on Legis. 291, 318 (2001).} Over the years, courts have recognized a number of exceptions to the \textit{Chevron} doctrine. Obviously, deference is not appropriate if the statute in question is clear and unambiguous.\footnote{Gossett, supra note 295, at 690-91.} In addition, courts usually refuse to defer to agency interpretations that are adopted for tactical purposes during the course of litigation.\footnote{Anthony, supra note 290, at 60-61.} Moreover, courts are reluctant to defer to self-serving interpretations of statutes that define the Agency's jurisdiction.\footnote{Michael Herz, Deference Running Riot: Separating Interpretation and Lawmaking Under \textit{Chevron}, 6 Admin. L.J. Am. U. 187, 216-21 (1992).} Finally, the \textit{Chevron} doctrine is not applicable to agency interpretations that raise constitutional issues.\footnote{Eric M. Braun, Note, Coring the Seedless Grape: A Reinterpretation of \textit{Chevron} U.S.A. Inc. v. NRDC, 87 Colum. L. Rev. 986, 1002-03 (1987).}

As the Supreme Court pointed out in \textit{United States v. Mead Corp.}, if an agency interpretation fails to qualify for \textit{Chevron} deference, it may still “claim respect according to its persuasiveness” under the principles of \textit{Skidmore}.\footnote{533 U.S. 218, 221 (2001).} \textit{Skidmore v. Swift & Co.} involved a Fair Labor Standards Act (FLSA) dispute over whether firemen were entitled to overtime pay for time when they were “on call” but not actually working.\footnote{323 U.S. 134, 135-36 (1944).} Having concluded that FLSA did not authorize the Administrator to make binding decisions about the applicability of the Act, the Court went on to conclude that it was proper for courts and litigants to turn to these decisions for guidance.\footnote{Id. at 140.} \textit{Skidmore}-type deference is a weaker form of judicial deference than the \textit{Chevron}-type variety because the court is not bound by the Agency’s interpretation.\footnote{Anthony, supra note 290, at 13.} Instead, the weight that a court gives to an agency’s interpretation will depend on its “power to persuade,”\footnote{Skidmore, 323 U.S. at 140.} which in turn depends upon such “factors” as “the degree of the agency’s care, its consistency, formality, and relative expertness.”\footnote{Mead, 533 U.S. at 228.} Thus, the \textit{Skidmore} approach acknowledges the importance of the Agency’s expertise and ensures

\begin{thebibliography}{99}
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\item 299. Gossett, supra note 295, at 690-91.
\item 300. Anthony, supra note 290, at 60-61.
\item 303. 533 U.S. 218, 221 (2001).
\item 304. 323 U.S. 134, 135-36 (1944).
\item 305. Id. at 140.
\item 306. Anthony, supra note 290, at 13.
\item 307. \textit{Skidmore}, 323 U.S. at 140.
\item 308. \textit{Mead}, 533 U.S. at 228.
\end{thebibliography}
that its views are given fair consideration, but, nevertheless, does not treat the Agency’s interpretation as binding.\footnote{Robert A. Anthony, \textit{Three Settings in Which Nonlegislative Rules Should Not Bind}, 53 \textit{Admin. L. Rev.} 1313, 1316 (2001).}

\section{Judicial Deference to the FDA in \textit{Horn}}

In \textit{Horn v. Thoratec Corp.}, the United States Court of Appeals for the Third Circuit held that § 360k(a) of the MDA expressly preempted the plaintiff’s common law design and warning claims.\footnote{376 F.3d 163, 180 (3d Cir. 2004).} The case involved the HeartMate, a cardiac pump manufactured by the defendant, TCI, and approved for marketing by the FDA pursuant to its PMA process.\footnote{Id. at 164, 167.}

\subsection{The Court’s Opinion in \textit{Horn}}

The first issue the court in \textit{Horn} addressed was whether any of the conditions imposed on TCI by the FDA as part of the PMA process were the sort of federal “requirements” contemplated by the Court in \textit{Medtronic} or by the FDA regulations promulgated in 21 C.F.R. § 808.1(d). The \textit{Horn} court described the HeartMate device’s lengthy journey through the PMA process.\footnote{Id. at 169-70. According to the court, the market approval process began in 1975, when the HeartMate underwent ten years of live animal and human cadaver studies. \textit{Id.} In 1985, the FDA granted TCI an Investigational Device Exemption so that it could conduct clinical trials. \textit{Id.} at 170. During the next seven years, TCI submitted more than ninety supplements to the FDA and responded to numerous inquiries from the agency about the progress of the clinical trials. \textit{Id.}} During this period, the FDA approved several design changes intended to reduce the risk of leakage from the HeartMate’s screw ring.\footnote{Id.} TCI submitted its PMA application to the FDA in 1992 and supplemented it during the next three years with additional amendments and responses to FDA questions.\footnote{Id.} After extensive review, the FDA approved the HeartMate for commercial sale in 1994.\footnote{Id.} In the court’s view, the conditions imposed by the FDA on the design and labeling of the HeartMate involved more than generic concerns and were specifically applicable to that particular device.\footnote{Id.} The court in \textit{Horn} also considered whether state tort doctrine upon which the plaintiff’s claims were based could be “state
requirements with respect to the HeartMate which are different from, or in addition to, the federal requirements.\textsuperscript{317} There was no dispute that the plaintiff’s tort claims were not specific to medical devices, but based on “general requirements stemming from state common law.”\textsuperscript{318} The question, therefore, was whether § 360k(a) could preempt claims based on “nonspecific” common law tort doctrines, and if so, under what circumstances. As the Third Circuit acknowledged, the Medtronic Court in its plurality opinion concluded that the plaintiffs’ claims in that case escaped preemption, “not because the source of the duty is a judge-made common law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be ‘with respect to’ specific devices such as pacemakers.”\textsuperscript{319} This requirement, if taken at face value, would have insulated most common law tort claims from the preemptive reach of § 360k(a). However, the court in Horn looked to the reasoning of Justice Breyer’s concurring opinion instead of relying on the plurality’s analysis.\textsuperscript{320} Justice Breyer favored a more flexible approach that invited the court to “carefully examine the state common law claim in order to determine whether that claim would impose a substantive requirement that conflicts with, or adds a greater burden to, a specific federal requirement.”\textsuperscript{321} Using Justice Breyer’s approach, the court in Horn concluded that Medtronic did not require common law tort doctrines to be device specific in order to be preempted.\textsuperscript{322}

Having determined that § 360k(a) might preempt the plaintiff’s common law tort claims, the court in Horn then considered whether any of these claims actually were preempted. The court first looked at

\begin{itemize}
\item \textsuperscript{317} Id. at 173 (emphasis omitted).
\item \textsuperscript{318} Id.
\item \textsuperscript{319} Id. at 174 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 502 (1996)).
\item \textsuperscript{320} Id. at 174-76.
\item \textsuperscript{321} Id. at 174. The court in Horn invoked the “narrowest grounds” principle to its reliance on the Breyer opinion. Id. at 175. Under the narrowest grounds rule, a lower court is required to follow the rationale “taken by those Members who concurred in the judgments on the narrowest grounds.” Gregg v. Georgia, 428 U.S. 153, 169 n.15 (1976); see also Marks v. United States, 430 U.S. 188, 192-93 (1977); Planned Parenthood of Se. Pa. v. Casey, 947 F.2d 682, 693 (3d Cir. 1991), modified on other grounds, 505 U.S. 833 (1992). Applying this approach, the Horn court concluded that Justice Breyer’s reasoning on this issue was narrower than that of Justice Steven’s plurality because “although the Lohrs’ claims were not preempted by § 360k(a), he was not prepared to join in Justice Stevens’ sweeping pronouncement that § 360k almost never preempts a state common law claim.” Horn, 376 F.3d at 175. The court also noted that the Justices who joined in Justice O’Connor’s opinion agreed with Breyer that state requirements did not have to be device specific in order to be preempted. Id. at 176.
\item \textsuperscript{322} Horn, 376 F.3d at 175.
\end{itemize}
the design defect claim.\footnote{323} The plaintiff’s husband received a HeartMate implant after he suffered a heart attack; about six months later, the suture on his HeartMate wore off and the screw ring disconnected.\footnote{324} This allowed an air embolus to travel to Mr. Horn’s brain, causing a fatal brain hemorrhage.\footnote{325} Horn’s widow claimed that the manufacturer failed to design the device so that either the suture would not wear out or that the screw rings would remain connected.\footnote{326} According to the court, this claim was preempted because if the plaintiff prevailed, it would “impose substantive requirements on TCI that would conflict with, or add to, the requirements imposed by the FDA” because to avoid future tort liability TCI would either have “to use an entirely different design than the screw ring to connect the outlet elbow to the pump, or to use different materials instead of a suture, or to place the eyelet in a different position.”\footnote{327} Thus, any device that complied with the plaintiff’s proposed design would be quite different from the actual device that was approved by the FDA. Furthermore, the court suspected, the designs approved by lay juries were not likely to be better than those approved by the FDA.\footnote{328}

Having disposed of the plaintiff’s design claims, the court in Horn went on to consider whether her failure-to-warn claim was preempted. The plaintiff argued that TCI should have warned doctors, either through revisions in the product labeling or by means of “Dear Doctor” letters, that they should not use the HeartMate if the suture, as placed in the device, would face the patient’s sternum.\footnote{329} However, the court observed that the manufacturer was prohibited by the PMA order from making such changes without first obtaining subsequent FDA

\footnote{323}{The HeartMate pump assisted blood flow between the heart’s ventricle and aorta. \textit{Id.} at 164. One tube, known as the inlet side tube is surgically attached to the heart and transports blood from the heart to the pump. Another tube, known as the outlet side tube transports blood from the pump to the aorta. Another tube is attached to the pump at one end and a console outside of the patient’s body at the other end. The console contains an air compressor that provides power to the pump. The connection between the pump and the outlet side tube, known as the “elbow,” is inserted into an adapter conduit, which is attached to the pump. A screw ring is secured over the elbow to ensure that it remains connected to the adapter conduit and the pump. A suture is tied over the screw ring and secured to the adapter conduit to ensure that it will not rotate. \textit{Id.}}

\footnote{324}{\textit{Id.} at 164-65.}

\footnote{325}{\textit{Id.} at 165.}

\footnote{326}{\textit{Id.} at 166.}


\footnote{328}{\textit{Id.}}

\footnote{329}{\textit{Id.} at 166 n.5.}
approval. Consequently, the court concluded that § 360k(a) preempted the plaintiff’s claim insofar as it was based on the alleged inadequacies of any warnings that were reviewed and approved by the FDA in its PMA order.

2. The Horn Court’s Deference to the FDA

The FDA filed an amicus brief in Horn which contended that the plaintiff’s design and warning claims were preempted. The FDA’s amicus brief declared unequivocally that any conditions imposed upon TCI through the PMA process qualified as specific federal requirements. The FDA distinguished between the § 510(k) process involved in Medtronic and the PMA process involved in Horn, claiming that “[u]nlike a section 510(k) clearance, which only determines whether two products are substantially equivalent, PMA process consummates an exhaustive inquiry into the risks and efficacy of a device.” According to the FDA, the PMA approval was “a very lengthy process involving thousands of pages of documentation and many hours of expert analysis, and often including substantial give-and-take between the agency and the manufacturer.” Furthermore, the PMA order for a new device typically contained “detailed specifications for its design, manufacture, performance, labeling and use.” Consequently, the FDA reasoned, Medtronic would not prevent a lower court from concluding that the PMA process imposed specific federal requirements even though the § 510(k) process did not.

Turning to the state requirement issue, the court declared that “[o]ur preemption conclusion is reinforced by the informed analysis found in the FDA’s amicus curiae brief.” The FDA brief stated that § 360k(a) would preempt common law claims if they imposed a requirement upon the manufacturer that was different from that imposed by the FDA in the PMA process. The FDA further concluded that the plaintiff in Horn had attempted to impose a requirement upon TCI that was different from the requirements

330. Id. at 176-77.
331. Id. at 177.
332. Id. at 171.
333. Id. at 171-72.
334. Id. at 172 (quoting FDA Letter Brief, supra note 275, at 23-24).
335. Id.
336. Id.
337. Id.
338. Id. at 177.
339. Id.
imposed by the FDA with respect to the design, labeling, and manufacture of the HeartMate.\textsuperscript{340} According to the FDA, "any finding of liability based upon TCI's failure to satisfy a standard different from those approved by FDA in the PMA process would necessarily rest upon an implicit requirement that this device be designed, manufactured or marketed in a way that differs from the way approved by FDA."\textsuperscript{341}

The court in \textit{Horn} also quoted, with apparent approval, portions of an amicus brief that the FDA had submitted in another case.\textsuperscript{342} In its brief, the FDA stated that it was "inappropriate for a jury to second-guess FDA's scientific judgment on such a matter that is within FDA's particular expertise" because juries lacked sufficient scientific knowledge and technical expertise to make correct decisions.\textsuperscript{343} In addition, the FDA complained that such second-guessing was inconsistent with the regulatory scheme for medical devices that Congress put in place when it enacted the MDA.\textsuperscript{344} Furthermore, the FDA declared, if tort claims were not preempted, the resulting "uncertainty as to the status of medical devices would create chaos for both the regulated industry and FDA."\textsuperscript{345}

Another issue in \textit{Horn} was whether the court should give less weight to the FDA's opinion because it had previously asserted that PMA did not require preemption. Responding to the dissent's claim that the FDA's current position was entitled to no deference or nothing more than "near indifference," the court relied on \textit{Chevron},\textsuperscript{346} which held that a court could rely on a revised interpretation of a statute or regulation by an agency because "[a]n initial agency interpretation is not instantly carved in stone."\textsuperscript{347} According to the \textit{Chevron} Court, an agency could change its interpretation as long as it could support its decision with a "reasoned analysis."\textsuperscript{348} The court in \textit{Horn} concluded that this standard had been met.\textsuperscript{349}

\textsuperscript{340} \textit{Id.}
\textsuperscript{341} \textit{Id.} at 177-78 (quoting FDA Letter Brief, \textit{supra} note 275, at 17-18 (emphasis omitted)).
\textsuperscript{342} \textit{Id.} at 178 (citing Statement of Interest of the United States of America, Murphree v. Pacesetter, Inc. (Tenn. Cir. Ct. Dec. 12, 2003) (No. 005429-00-3)).
\textsuperscript{343} \textit{Id.}
\textsuperscript{344} \textit{Id.} (quoting Statement of Interest, \textit{supra} note 342, at 7-9).
\textsuperscript{345} \textit{Id.}
\textsuperscript{346} 467 U.S. 837 (1984).
\textsuperscript{347} \textit{Id.} at 863.
\textsuperscript{348} \textit{Id.}
\textsuperscript{349} \textit{Horn}, 376 F.3d at 179.
D. Should Courts Defer to the FDA?

No doubt the FDA would like the *Chevron* doctrine to apply to its new interpretation of § 360k(a). However, there are a number of potential barriers. First, it may be significant that the FDA’s new interpretation deviates from its previous longstanding and consistent view of the preemptive scope of § 360k(a). Second, the strong version of judicial deference may not be applicable to agency interpretations in preemption cases. Third, under the doctrine of *stare decisis*, the *Medtronic* Court’s interpretation of § 360k(a) may foreclose a different interpretation by the FDA. Finally, agency interpretations that are communicated by speeches and amici briefs may not be entitled to *Chevron* deference.

1. Change in Interpretation

Unlike courts, administrative agencies are not bound by *stare decisis* and are, therefore, generally free to change their interpretation of statutes and regulations in response to changing policies and conditions. That being the case, must courts give revised agency interpretations the same sort of strong deference that they would give original interpretations? *Chevron* seems to support this position. First of all, *Chevron* itself involved a revised interpretation by the EPA of the term “source” in the Clean Air Act. Nevertheless, the Court held that the courts must defer to this revised interpretation. In the Court’s words: “The fact that the agency has from time to time changed its interpretation of the term ‘source’ does not . . . lead us to conclude that no deference should be accorded the agency’s interpretation of the statute. An initial agency interpretation is not instantly carved in stone.”


The *Chevron* Court went on to declare that it was desirable for federal agencies to reexamine their regulatory policies and interpretations on a continuing basis. 354 This suggests that the *Chevron* Court believed that changed interpretations were entitled to the same deference as original ones. 355

The *Chevron* Court’s position on revised agency interpretations appears to be correct. The policy rationales behind judicial deference, implied delegation, political accountability, and agency expertise arguably apply to revised interpretations as well as they do to original ones. 356 Moreover, as commentators have pointed out, there are a number of legitimate reasons why an agency may, or even should, change its interpretation of a statute. 357 For example, the Agency may find that its prior interpretation was not consistent with congressional intent; it may conclude that an alternative interpretation will avoid unintended side effects; or it may determine that a revised interpretation would be more consistent with new policy goals. 358

Nevertheless, in recent years, the Supreme Court has retreated somewhat from its earlier position and now appears to discount revised interpretations unless the Agency explains why it has changed its view. 359 Many lower federal courts have also required an agency to provide a “reasoned analysis” to justify its new interpretation. 360 Arguably, the FDA’s amicus brief in *Horn* satisfied this reasoned analysis requirement. In its brief, the FDA described how lawsuits against medical device manufacturers would interfere with its licensing process and discourage patients from using products that the

354. *Id.* at 863-64.
357. *Id.* at 702-03.
358. *Id.*
359. Smiley v. Citibank, 517 U.S. 735, 742 (1996) (stating that a court may refuse to accept a revised agency interpretation when it constitutes a “[s]udden and unexplained change, . . . or a change that does not take account of legitimate reliance on prior interpretation” (citations omitted)); Thomas Jefferson Univ. Hosp. v. Shalala, 512 U.S. 504, 515 (1994) (observing that an agency’s interpretation that conflicts with an earlier interpretation will be given “considerably less deference” than a consistently held one); Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993) (declaring that “the consistency of an agency’s position is a factor in assessing the weight that position is due”); INS v. Cardoza-Fonseca, 480 U.S. 421, 446 n.30 (1987) (suggesting that a revised agency interpretation should not be given as much weight as a longstanding one).
360. *E.g.*, Detroit/Wayne County Port Auth. v. ICC, 59 F.3d 1314, 1317 (D.C. Cir. 1995); Torrington Extend-a-Care Employee Ass’n v. NLRB, 17 F.3d 580, 589 (2d Cir. 1994); Mobil Oil Corp. v. EPA, 871 F.2d 149, 152 (D.C. Cir. 1989).
Agency had found to be safe and effective. Finally, the FDA's new interpretation was prompted by a change in administration. As the *Chevron* Court observed, an agency might "properly rely upon the incumbent administration's views of wise policy to inform its judgments." The FDA's former interpretation no doubt reflected the Clinton Administration's feeling that tort law complemented the FDA's regulatory scheme, while the Agency's current pro-preemption stance may be part of the Bush Administration's broader "tort reform" agenda. In any event, even if the FDA's new interpretation is politically motivated, *Chevron* would seem to require judicial deference if this new interpretation is reasonable.

2. Judicial Deference in Preemption Cases

A number of legal commentators have argued that *Chevron*-type deference should not be applied in preemption cases. The doctrinal basis for this argument is that the sort of deference mandated by *Chevron* is inconsistent with the "presumption against preemption" that the Court directed be applied to preemption claims in *Rice v. Santa Fe Elevator Corp.* The purpose of *Rice*’s presumption against preemption is to force Congress to consider state interests when it legislates. A potential conflict exists between *Rice* and *Chevron* when an agency interprets an ambiguous statute and concludes that it expressly preempts state law. *Rice* directs courts to resolve statutory ambiguity in favor of nonpreemption, while *Chevron* requires courts to defer to agency interpretations. One solution to this conflict is to conclude that *Chevron* deference is not required in preemption cases. Another proposal is to employ an "asymmetrical deference" approach where a court will apply *Chevron* deference only when an agency interprets its preemptive power narrowly.

The question of *Chevron*’s applicability to preemption cases remains unclear. In *Medtronic*, Justice Stevens acknowledged that his interpretation of § 360k(a) was "substantially informed" by the FDA

368. Id. at 717.
regulations and also declared that the FDA was "uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, ... should be preempts." Citing *Chevron*, Justice Stevens concluded that "[t]he ambiguity in the statute—and the congressional grant of authority to the agency on the matter contained within it—provide a 'sound basis' for giving substantial weight to the agency's view of the statute." However, although the *Medtronic* Court invoked *Chevron*, it did not actually engage in a *Chevron* two-step analysis. The Court applied the first step and concluded that statute was ambiguous, but it did proceed to step two and determine whether the FDA's interpretation was reasonable. Furthermore, nowhere in the *Medtronic* plurality opinion did the Court acknowledge that it was required to defer to the FDA's interpretation of § 360k(a). Instead, it merely declared that the FDA regulation "substantially informed" its preemption analysis without ever revealing what this ambiguous phrase meant. Justice O'Connor's dissenting opinion criticized the Court for equivocating on this issue. According to Justice O'Connor, "[a]pparently recognizing that *Chevron* deference is unwarranted here, the Court does not admit to deferring to these regulations, but merely permits them to 'infor[m]' the Court's interpretation." Justice O'Connor, citing *Smiley v. Citibank*, added that "[i]t is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference.

In addition, a majority of the Court (composed of the dissenters and Justice Breyer) appear to have rejected the "state ... requirements applicable to the device" part of § 808.1(d), something they could not

370. *Id.* at 496.
371. *Id.*; see also *Id.* at 487 (declaring that "it would take language much plainer than the text of § 360k to convince us that Congress intended that result"). Justice Stevens also stated that "[t]he different views expressed by the Courts of Appeals regarding the appropriate scope of federal pre-emption under § 360k demonstrate that the language of that section is not entirely clear." *Id.* at 495. Justice Breyer described § 360k(a) as "highly ambiguous." *Id.* at 505 (Breyer, J., concurring in part and concurring in the judgment). The dissent, on the other hand, concluded that *Chevron*-type deference was improper because § 360k(a) was not ambiguous. *Id.* at 512 (O'Connor, J., concurring in part and dissenting in part).
373. *Id.* at 749.
375. *Id.* (citing *Smiley v. Citibank*, 517 U.S. 735, 743-44 (1996)).
have done if *Chevron* were applicable.\textsuperscript{376} Finally, even if one concludes that the Court actually deferred to the FDA, it is possible to argue that *Medtronic* is merely an example of asymmetrical deference and would not compel *Chevron*-type deference in a case like *Horn* where the FDA was interpreting its preemptive power broadly instead of narrowly.

A few state courts have also have considered whether *Chevron* is applicable to MDA preemption cases. For example, in *Walker v. Johnson & Johnson Vision Products, Inc.*, a Michigan intermediate appellate court turned to *Chevron* for guidance.\textsuperscript{377} First, the court determined that § 360k(a) was ambiguous.\textsuperscript{378} Citing *Chevron*, the court then declared that it “should defer to a federal agency’s construction of the statute unless the agency’s interpretation is unreasonable.”\textsuperscript{379} Finally, the court interpreted 21 C.F.R. § 808.1(d) to conclude that the PMA process itself would not preempt common law tort claims because it was not a “specific requirement applicable to a particular device,” as required by the FDA regulation.\textsuperscript{380}

The Texas Supreme Court, on the other hand, in *Worthy v. Collagen Corp.*, observed that preemption is determined by Congress, not the FDA.\textsuperscript{381} At the same time, the court acknowledged that “the FDA is in a unique position to determine the scope of preemption because of its role in the creation of preemptive federal requirements.”\textsuperscript{382} The court then determined that the details of the FDA’s approval of the product in question, Zyderm, were sufficiently specific to have a preemptive effect.\textsuperscript{383}

Thus it remains unclear whether the Court would apply the strong version of judicial deference in a case where an administrative agency interpreted a statute to expand the scope of its preemptive power. Although the *Medtronic* Court agreed with the FDA’s interpretation of § 360k(a), it did not seem to consider itself bound by what the Agency said. The deference shown by the Court, if any, was more consistent with *Skidmore*-type deference than the more robust style of deference that was mandated by *Chevron*.

\textsuperscript{376} See *Horn v. Thoratec Corp.*, 376 F.3d 163, 176 (3d Cir. 2004).
\textsuperscript{378} Id. at 684.
\textsuperscript{379} Id.
\textsuperscript{380} Id. at 684-85.
\textsuperscript{381} 967 S.W.2d 360, 375 (Tex.), cert. denied, 524 U.S. 954 (1998).
\textsuperscript{382} Id.
\textsuperscript{383} Id. at 376.
3. **Stare Decisis**

The doctrine of *stare decisis* obligates a court to follow an earlier decision when the same issue arises again in litigation.\(^{384}\) It promotes consistency, coherence, and predictability in the law and also helps to legitimize the legal process.\(^{385}\) *Stare decisis* also limits the operation of the *Chevron* doctrine. Once the Supreme Court has interpreted an ambiguous statutory term, only Congress can change this interpretation.\(^{386}\) When the Supreme Court has made an interpretation, an agency cannot interpret the statute differently and then invoke *Chevron* to obtain the Court's deference to its new interpretation.\(^{387}\) The rationale for this rule is known as the incorporation theory of precedent.\(^{388}\) According to this theory, a judicial interpretation of a statute is incorporated into the statute and becomes part of the statutory scheme.\(^{389}\) What, then, is the precedential effect of *Medtronic* on the FDA? It might be argued that the *Medtronic* Court adopted the FDA's former interpretation of § 360k(a) as its own, thereby precluding the FDA from interpreting that statute more broadly. To be sure, there is a good deal of language in Justice Stevens' plurality opinion that may be inconsistent with the FDA's broad interpretation of § 360. For example, Justice Stevens declared that Congress was "primarily concerned with the problem of specific conflicting state statutes and regulations rather than the general duties enforced by common-law actions."\(^{390}\) Later in the *Medtronic* opinion, Justice Stevens stated that "nowhere in the materials relating to the Act's history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices."\(^{391}\) Finally, Justice Stevens concluded that "§ 360(k) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions."\(^{392}\)

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391. *Id.* at 490.
392. *Id.* at 491.
However, the argument that *Medtronic* prevents the FDA from reinterpreting § 360k(a) will almost certainly fail. First, the *Medtronic* Court acknowledged the significant difference between premarket notification review under § 510(k) and the PMA process and based its finding of “no preemption” on the fact that, unlike the PMA process, the § 510(k) notification process was concerned with equivalency, not safety. In addition, the plurality opinion’s endorsement of the “specific counterpart regulations” requirement in 21 C.F.R. § 808.1(d) did not receive the support of Justice Breyer and, therefore, could not be part of the holding of the case. Finally, *Medtronic* is such a fractured opinion, so its application as a binding precedent beyond its immediate facts is problematic. Therefore, the doctrine of *stare decisis* should not prevent the FDA from revising its interpretation of § 360k(a).

4. Amici Briefs

Agencies must interpret the statutes that they administer and these interpretations can be expressed in a variety of formats, including “legislative regulations, adjudicatory opinions, manuals, court briefs, interpretive rules, policy statements, staff instructions, opinion letters, audits, correspondence, informal advice, guidelines, press releases, testimony before Congress, internal memoranda, speeches, explanatory statements in the Federal Register, and others.” While agency interpretations contained in formal adjudication and notice-and-comment rulemaking qualify for deference under *Chevron*, less formal modes of interpretation may not. This means that courts may refuse to give *Chevron*-type deference to interpretations of § 360k(a) contained in FDA amici briefs.

The Supreme Court addressed this issue a few years ago in *Christensen v. Harris County* and *United States v. Mead Corp.* In *Christensen*, employees alleged that their employer violated the Fair Labor Standards Act (FLSA) by forcing them to take time off in order to reduce accrued compensatory time. The plaintiffs argued that the Court should defer to the Department of Labor’s interpretation of the

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393. *Id.* at 478-79 (declaring that “[t]he § 510(k) notification process is by no means comparable to the PMA process”).
394. *Id.* at 493.
395. *Id.* at 473.
399. *Christensen*, 529 U.S. at 578.
statute, expressed in an opinion letter, that an employer could not compel employees to take time off unless they had agreed to do so in advance.\textsuperscript{400} The Court, however, observed that the Labor Department's interpretation was not the product of formal adjudication or notice-and-comment rulemaking.\textsuperscript{401} Consequently, it held that "[i]nterpretations such as those in opinion letters--like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law--do not warrant \textit{Chevron}-style deference."\textsuperscript{402} Instead, interpretations contained in these formats were "entitled to respect" under \textit{Skidmore} to the extent that they had "the power to persuade."\textsuperscript{403} Justice Scalia, in a concurring opinion, claimed that the Court had accorded \textit{Chevron} deference "to authoritative agency positions set forth in a variety of other formats."\textsuperscript{404} He also pointed out that the Solicitor General of the United States and the Solicitor of the Department of Labor had filed an amicus brief which stated that the position set forth in the opinion letter was the position of the Department of Labor.\textsuperscript{405} According to Justice Scalia, "[t]hat alone, even without existence of the opinion letter, would in my view entitle the position to \textit{Chevron} deference."\textsuperscript{406}

One year later, in \textit{United States v. Mead Corp.}, the Court reaffirmed \textit{Christensen}.\textsuperscript{407} The plaintiff in that case challenged a tariff classification by the United States Customs Service.\textsuperscript{408} In \textit{Mead}, the Court considered whether the Custom Service's action, contained in a "ruling letter," was entitled to \textit{Chevron}-type deference.\textsuperscript{409} Holding that informal interpretations did not deserve \textit{Chevron} deference, the Court declared:

\begin{quote}
We hold that administrative implementation of a particular statutory position qualifies for \textit{Chevron} deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority. Delegation of such authority may be shown in a variety of ways, as by an agency's power to
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\textsuperscript{400} \textit{Id.} at 586.
\textsuperscript{401} \textit{Id.} at 587.
\textsuperscript{402} \textit{Id.}
\textsuperscript{403} \textit{Id.}
\textsuperscript{404} \textit{Id.} at 590 (Scalia, J., concurring in part and concurring in the judgment).
\textsuperscript{405} \textit{Id.} at 591 (Scalia, J., concurring in part and concurring in the judgment).
\textsuperscript{406} \textit{Id.} (Scalia, J., concurring).
\textsuperscript{407} \textit{United States v. Mead Corp.}, 533 U.S. 218, 225 (2001).
\textsuperscript{408} \textit{Id.} at 221.
\textsuperscript{409} \textit{Id.} at 231-34.
engage in adjudication or notice-and-comment rulemaking, or by some other indication of a comparable congressional intent.\textsuperscript{410}

As in Christensen, the Court went on to hold that the less formal agency interpretations were still entitled to some judicial deference under the Skidmore approach.\textsuperscript{411}

Later in the opinion, the Court observed that most Chevron deference cases involved interpretations that arose from notice-and-comment rulemaking or formal adjudication.\textsuperscript{412} Although the Court acknowledged that “as significant as notice-and-comment is in pointing to Chevron authority, the want of that procedure here does not decide the case, for we have sometimes found reasons for Chevron deference even when no such administrative formality was required and none was afforded.”\textsuperscript{413} This suggests that interpretations contained in other formats, such as interpretive rules or informal adjudications, may also be entitled to Chevron deference.\textsuperscript{414} However, it is difficult to see how interpretations communicated by public speeches or amici briefs would satisfy the criteria for Chevron deference set forth by the Court in Mead.

VI. CONCLUSION

In its amicus brief, the FDA made a strong argument that uncontrolled tort litigation threatens to undermine its comprehensive regulatory scheme. For this reason, courts should defer to the Agency’s interpretation of § 360k(a). However, this interpretation may not be entitled to Chevron-style deference because the Agency has announced it without allowing for public comment. Nevertheless, the FDA’s interpretation is sufficiently persuasive that it should be accepted by the courts under a Skidmore-type deference standard.

\textsuperscript{410} Id. at 226-27.
\textsuperscript{411} Id. at 227-28.
\textsuperscript{412} Id. at 230.
\textsuperscript{413} Id. at 230-31.
\textsuperscript{414} Merrill & Hickman, supra note 282, at 901-05.