Administrative Law and Regulation

The Roberts Court Wades into Products Liability Preemption Waters: *Riegel v. Medtronic, Inc.*

*By Catherine M. Sharkey**

With *Riegel v. Medtronic, Inc.* (06-179), the Roberts Court makes its inaugural foray this term into the realm of federal preemption of state-law products liability claims.[1] The Supreme Court's products liability preemption jurisprudence is a small but expanding area that can trace its beginnings to the early 1990s with *Cipollone v. Liggett Group, Inc.*,[2] and continues, most recently, through the 2005 decision of *Bates v. Dow Agrosciences, LLC*.[3] The regulation of public health and safety via common law tort actions falls within the traditional purview of the states. In recent decades, however, the federal government has played an increasingly significant role in the regulation of products. In 1976, Congress enacted the Medical Device Amendments (MDA) "to provide for the safety and effectiveness of medical devices intended for human use."[4]

The Court granted certiorari in *Riegel* to decide:

> [w]hether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

Returning to the field of medical devices, the Court will answer a question left open by its decade-old opinion in *Medtronic v. Lohr*,[5] which held that state-law tort claims as to medical devices subject to a less rigorous pre-market notification process (as opposed to pre-market approval) were *not* preempted.

The fractious opinion in *Medtronic* sets the scene for the issues pending before the Court in *Riegel*. The Court will decide whether the FDA's pre-market approval process for medical devices creates federal preemptive "requirements" sufficient to preempt state common-law tort actions. Tasked with interpreting the language and scope of the express preemption provision of the MDA, the Roberts Court returns to a contentious area of jurisprudence. The Court is presented with an opportunity to resolve looming tensions between competing canons of statutory interpretation: the presumption against preemption and *Chevron* deference to federal agency interpretations of ambiguous statutes.

I. Facts and Procedural Posture

Riegel involves Charles Riegel, a cardiac patient who sued Medtronic, Inc., the manufacturer of a balloon catheter used during his angioplasty. The balloon catheter, a "Class III" medical device, received premarket approval from the FDA in 1994.[6] The catheter ruptured after being over-inflated, causing Riegel extensive injuries and permanent disabilities. Riegel, joined by his wife,[7] brought a number of state-law claims against the medical device manufacturer, including negligent design, testing, manufacture, distribution, labeling, marketing, and sale of the catheter; strict liability; breach of express warranty; breach of implied warranty; and loss of consortium.

The Second Circuit affirmed (2-1) the district court's grant of summary judgment in favor of Medtronic, holding that the majority of Riegel's claims were preempted.[8] According to the court, because the FDA had expressly found the design of the device safe and effective, and approved the precise wording on the label, the plaintiffs' claims were preempted, except insofar as they alleged manufacturer did not adhere to specs submitted to the FDA in manufacturing the specific device used in his operation.[9]

II. Split in the Circuits

With its pro-preemption holding, the Second Circuit joined the large majority of federal circuits to have decided the issue. The Third, Fifth, Sixth, Seventh, and Eighth Circuits have all held that pre-market approval of a medical device preempts state tort claims that challenge the safety or efficacy of a product that was designed, manufactured, and labeled in conformity with PMA.[10] The Eleventh Circuit is the outlier, having found that comparable state law claims were not preempted.[11]

The Solicitor General counseled the Court against granting review on the grounds that the Second Circuit's decision was correct and the only cases on the short end of the lopsided split "predate most of the other cases addressing the question, and they were issued without the benefit of the FDA's current judgment that premarket approval of a Class III device imposes federal "requirements" that should be given preemptive effect."[12] Indeed, in *Goodlin*, the Eleventh Circuit took note of a 1997 FDA proposed rule (later withdrawn)[13] that would have enshrined the FDA's earlier anti-preemption view, and found it "unsettling that the agency charged with conducting PMA review has doubts regarding whether an approval pursuant to that process should preclude subsequent state tort liability."[14] Moreover, the Solicitor General reminded the Court that it had "repeatedly denied certiorari petitions that presented questions concerning the preemptive effect of the FDA's issuance of premarket approval for Class III medical devices."[15]

III. MDA Express Preemption and *Medtronic v. Lohr*

The starting point to understanding the issues at stake in *Riegel v. Medtronic, Inc.*, as with its forbear, *Medtronic v. Lohr*, is the express preemption provision set forth in Section 360k(a) of the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA). Section 360k(a) directs preemption of "any [state] *requirement*" "which is different from, or in addition to, any *requirement* applicable under [the FDCA] to the device."[16]

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The express preemption clause raises two interpretive issues. First, does the domain of state-law "requirements" that are potentially subject to preemption include common-law tort actions as well as positive enactments of statutory or regulatory law? Second, what precisely constitutes a federal "requirement applicable... to the device" sufficient to preempt state law?

In *Medtronic*, five of the Justices (represented by the concurring and dissenting Justices) answered "yes" to the first question, concluding that the MDA will sometimes preempt state-law tort causes of action. Any ambiguity on this question[17] has arguably now been put to rest in *Bates v. Dow Agrosciences, LLC.*,[18] where the Court reiterated that "the term 'requirements' in [the express preemption provision of the Federal Insecticide Fungicide and Rodenticide Act] reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties."[19] On the second question, the *Medtronic* Court's majority held that the FDA's pre-market notification process—to which the medical device, a pacemaker, had been subjected—did not create preemptive federal "requirements" applicable to the device.

IV. Preemption Analysis

Preemption is the fiercest battle in products liability litigation today. With the stroke of a pen, Congress could definitively determine when its product regulations displace state common law. But instead, time and again, Congress punts, leaving open the key question of the extent to which federal standards and regulations preempt state common-law remedies. A textualist statutory interpretation approach to preemption will likely come up short. Instead, the products liability preemption inquiry is multidimensional, involving layers of legal and policy issues, beginning with interpretation of the statutory language, but reaching beyond to issues of regulatory policy, federalism, and the level of deference accorded federal agency actions and interpretations.

It is difficult to demonstrate that any consistent principle or explanatory variable emerges from the Supreme Court's products liability preemption jurisprudence. As Professor Jack Goldsmith has aptly summed up: "The [statutory interpretation] canons have an uncertain justification… and they probably conceal more than they enlighten about what drives the judicial decision to preempt or not."[20] Even the "presumption against preemption"—perhaps the leading contender for consistency in the traditional state realm of torts—breaks down in the products realm, rearing its head with gusto in some cases, but oddly quiescent in others. Strangely eluding detection to date, the influence of the position of the relevant federal agency may provide a tighter explanatory fit. To be sure, the Supreme Court has been less than forthcoming about its reliance upon the views of the agency, sometimes put forward in official regulations, but more often simply in amicus briefs submitted by the Solicitor General (which may or may not get explicit mention by the Court).

The Roberts Court ducked an opportunity last term to provide guidance on the potential clash that arises in preemption cases between the presumption against preemption and *Chevron* deference to agency interpretation. The Court granted certiorari in *Wachovia Bank, N.A. v. Watters* on whether the interpretation of the Comptroller of the Currency that its regulation preempted state laws regulating mortgage lending as applied to operating subsidiaries of national banks was entitled to *Chevron* deference.[21] The Court dodged the issue, holding that state laws were preempted by the National Banking Act, independent of the OCC's regulation,[22] prompting a vigorous dissent from Justice Stevens (joined by Chief Justice Roberts and Justice Scalia) that "[w]hatever the Court says, this is a case about an administrative agency's power to preempt state laws."[23] And so, the contentious *Chevron* deference issue was put off for another day.

A. The Presumption Against Preemption

The touchstone of conventional preemption analysis is congressional intent. The "presumption against preemption" in areas "traditionally occupied by the States" has acquired preeminent status as an interpretive canon. Given Congress' track record in failing to address squarely the question of preemption in the products realm, interpretive canons such as the presumption against preemption should, at least in theory, take on added significance.

To date, however, the Court's application of the presumption has been haphazard at best. The presumption appears to do the yeoman's work in some products cases, while eluding mention altogether in others.[24] The *Medtronic* Court, for example, began its preemption analysis with an invocation of the presumption: "[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action."[25] Paradoxically, the Court has applied the presumption when interpreting express preemption provisions (as in *Medtronic*), but not when called upon to engage in implied preemption analysis, where it would seem more warranted given the absence of express statutory language.[26] And it is striking that in the single implied preemption case in which it is invoked (*Buckman Co. v. Plaintiffs' Legal Committee*) it is involved for the purpose of disavowing it, given the primacy of the federal interest at stake.[27]

Moreover, the subdued role played by the presumption against preemption fits a wider empirical pattern, whereby, for decades, roughly fifty-fifty odds have prevailed in Supreme Court preemption decisions.[28] Moreover, the preemption rate actually *increases* (to greater than 60% odds) when considering preemption of state common law tort claims—a realm in which the putative anti-preemption presumption should be at its zenith.[29]

B. Deference to the FDA

With the presumption against preemption playing a mixed interpretive role at best, deference to the relevant federal agency charged with administering a particular statute emerges as a contender. The role played by the FDA might be significant in two different respects. First, there is the level of scrutiny to which it subjects medical devices before manufacturers are allowed to market them, and the relationship between this regulatory action and the creation of federal preemptive "requirements." Second, the FDA plays a distinct interpretive role as administer of the MDA, and has a variety of means at its disposal to express its position on preemption, from formal

notice-and-comment rulemaking to less formal interpretive statements and preambles to litigation briefs.

V. FDA Regulatory Action

Both the pacemaker at issue in *Medtronic* and the balloon catheter at issue in *Riegel* are "Class III" medical devices regulated by the FDA. A crucial distinction, nonetheless, emerges with respect to the stringency of FDA regulatory review of the respective medical devices.

The FDA's review of the pacemaker at issue in *Medtronic* consisted solely in its determination that the device was "substantially equivalent" to a device that was on the market before 1976 (the effective date of the MDA). Known as the "premarket notification" process (or, alternatively, § 510(k) process), the FDA's review focuses narrowly on equivalence as opposed to safety and effectiveness. It is a streamlined process, completed in an average of twenty hours, that allows manufacturers to avoid the more stringent pre-market approval [PMA] process as a kind of accommodation "to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market."[30] Although designed as a limited exception, in practice most new medical devices are approved via the pre-market notification process.[31]

The balloon catheter at issue in *Riegel* was subjected to the full-bodied pre-market approval process mandated for Class III devices that do not fall within the grandfathering exception. In stark contrast to the pre-market notification process, the PMA process is rigorous, requiring manufacturers to submit detailed information regarding the safety and efficacy of the medical device and demanding an average of 1200 hours of FDA review time per submission:

> [A] manufacturer must submit a PMA application containing full reports of investigations of the device's safety and effectiveness; a statement of the components and principles of operation of the device; a comprehensive description of the methods of manufacture, processing, packing, and installation of the device; and the proposed labeling for the device. In determining whether to approve a PMA application, the FDA considers the information submitted by the manufacturer as well as other information known to the agency. The FDA may also request additional information from the manufacturer, and it may consult with a scientific advisory committee made up of outside experts.[32]

The PMA process culminates in a finding by the FDA that there is a "reasonable assurance" that the device is both safe and effective, so long as the device is used in accordance with any conditions of use included in the proposed labeling.[33]

A. FDA Interpretation

But the FDA's role in regulating medical devices goes beyond that of conducting the risk-risk analyses and assuring the safety of medical devices. It has also assumed the mantle of statutory interpreter of the MDA. Such a role was justified, in the eyes of the *Medtronic* Court, "[b]ecause the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is 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, whether it should be pre-empted."[34]

The FDA issued formal regulations construing the scope of the express preemption provision, which cabin its preemptive force to instances where the FDA has established "specific counterpart regulations or... other specific requirements applicable to a particular device."[35] The regulation further provides that the MDA "does not preempt State or local requirements of general applicability where the purpose of the requirements relates either to other products in addition to devices."[36]

In addition, the FDA often weighs in contemporaneously on factors that arguably determine the preemptive effect of its regulatory actions. In *Medtronic*, for example, at the time the FDA issued its "substantial equivalence" letter to the manufacturer, "[t]he agency emphasized... that this determination should not be construed as an endorsement of the pacemaker lead's safety."[37]

Finally, the FDA has shared its views before courts (including the Supreme Court) tasked with deciding preemption questions. In *Medronic*, the FDA adopted a narrowly constricted view of its preemptive power: "Neither the FDCA nor the FDA's regulations prescribe criteria for the design of devices. The design of a device originates with its manufacturer."[38] In other words, in this instance—where its review consisted solely of a "substantial equivalence" finding—it ceded regulation of the design of medical devices to state common law.

Reliance upon federal agency interpretation at each of these three levels—issuance of regulations regarding preemptive scope; contemporaneous views interpreting regulatory action; and expressions of views in amicus briefs before courts—is contentious (with increasing degrees in the move from formal regulations to less formal interpretive positions). In deciding products liability preemption issues, the Supreme Court has been influenced by agency positions, but has not always been upfront about the degree to which the agency's view is dispositive.

The *Medtronic* Court, for example, resisted the idea that the language of the express preemption provision of the MDA decided the preemption issue, given the inherent ambiguity over what is meant by the statutory term "requirement." In the words of Justice Breyer (in concurrence): "Congress must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so."[39] Here, the Court turned to the FDA—the federal agency charged with administering the MDA[40]—for guidance: "The ambiguity in the statute... provide[s] a sound basis for giving *substantial weight* to the agency's view of the statute."[41]

In reaching its ultimate posture against preemption of the Lohrs' state-law claims, the Court relied upon the fact that "[t]he FDA regulations interpreting the scope of § 360k's pre-emptive effect support the Lohrs' view, and our interpretation of the pre-emption statute is *substantially informed* by those regulations."[42] The *Medtronic* plurality emphasized the "critical importance of device specificity" in its understanding of the MDA preemption scheme.[43]

In dissent, Justice O'Connor (joined by then-Chief Justice Rehnquist and Justices Thomas and Scalia) railed against the Court's analysis, noting that its opinion neither explicitly relied on the FDA regulations nor offered "any sound basis for why deference would be warranted."[44] Sharpening its disagreement, the dissent elaborated:

> Apparently 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. It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference, but one pertaining to the clear statute at issue here is surely not.[45]

The Second Circuit, in *Riegel,* deferred to the FDA in both its regulatory and interpretive capacities. With respect to state law, the court held that the common law tort actions would impose state-law requirements "different from, or in addition to" the federal requirements.[46] With respect to federal law, the court construed the term "requirement" to encompass product specifications set forth in the PMA application that is submitted by the manufacturer and approved by the FDA.[47] The court reasoned that "[o]nce the PMA process is complete, all PMA-approved devices are subject to the same federal device-specific regulation: complying with the standards set forth in their individual approved PMA applications."[48] Moreover, whereas substantial-equivalence "does not reflect the FDA's determination that the device should 'take any particular form for any particular reason,' the PMA process expressly provides the FDA with the power to require the device to take a particular form in order to be approved as safe and effective."[49] Finally, the court noted that its pro-preemption conclusion was "further supported by the FDA's recent determination that preempted is warranted with respect to this universe of cases, as indicated by the content of the May 14, 2004 amicus brief that the FDA submitted upon request to the Third Circuit in connection with the *Horn* case."[50]

V. Questions for the Roberts Court

The issue before the Roberts Court is whether the PMA process gives rise to specific federal manufacturing and labeling requirements in conflict with state common law actions. In *Medtronic*, the presumption against preemption and deference to the FDA pointed in the same anti-preemption direction. In *Riegel*, the potential clash rises to the fore, given the FDA's pro-preemption position.

One threshold question—as yet unanswered by the Supreme Court—is whether the FDA's position on preemption matters, and, if so, whether the formality with which it conveys its view affects the level of deference courts should accord. It is certainly an understatement to suggest that the degree to which courts regard the FDA's position as dispositive or persuasive remains unclear. In *Horn* and *Riegel*, the Third and Second Circuits, respectively, deferred to the FDA's position,[51] while in *McMullen* the Seventh Circuit disclaimed reliance on the FDA's position in support of its pro-preemption holding.[52] Moreover, the dissents in *Horn* and *Riegel* sharply criticized judicial reliance on informal agency views.[53]

To the extent the issue surfaced in *Medtronic*, the Court was deeply divided. The plurality accorded some degree of deference to the FDA's formal regulation; Justice Breyer would apparently give wide berth to federal agencies to communicate their views on preemption formally via regulations or more informally via preambles and the like:

> [T]his Court has previously suggested that, in the absence of clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect…. It can communicate those intentions, for example, through statements in "regulations, preambles, interpretive statements, and responses to comments[.]"[54]

While agency briefs and preambles arguably lack "the force of law" necessary to warrant *Chevron* mandatory deference,[55] the doctrine on deference to agency preambles and amicus briefs—particularly in the realm of preemption—is far from pellucid.

A second question is to what extent is an agency's change in position relevant to the deference issue. At the time of its intervention in *Medtronic* (1996), the FDA recommended that the Court leave open the issue whether the PMA process (as opposed to the pre-market notification process) engendered preemptive federal requirements.[56] In fact, the FDA had already taken the position that the PMA process did *not l*ead to preemption of state common law claims.[57] And a year after *Medtronic*, in an amicus brief urging the Court to grant certiorari in another medical devices case (where the catheter device at issue had gone through the full PMA process), the FDA maintained its view that "Section 360k does not... preempt respondents' common law tort claims."[58] The FDA's position at that time (as defended by then-FDA Chief Counsel) was driven by a view that "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection…. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product."[59]

The FDA subsequently changed its view and first articulated its new pro-preemption position for PMA devices in 2004 in an amicus brief before the Third Circuit Court of Appeals in *Horn v. Thoratec Corp*. To justify its change in position, the FDA explained:

> [B]ased on further analysis of the relevant legal and policy issues by FDA, the agency charged with administering the MDA and implementing its preemption provisions—as well as the recent rulings by several courts of appeals and state courts—the Government has instead determined that state tort claims such as those raised here are indeed preempted with respect to FDA-approved devices.[60]

According to the FDA, the PMA process creates specific federal requirements because, following approval, the device's "attributes are fixed in place, as they can be materially changed only with FDA approval."[61] The Third Circuit relied heavily on the FDA's views in holding plaintiff's state law claims preempted.[62] Since that time, while the FDA has steadfastly maintained its pro-preemption position, it has not attempted to embody its view in a new regulation or else amend the prior

regulation (§ 808.1(d)) that provided justification for the *Medtronic* Court to construe the MDA's express preemption clause narrowly to imbue only "device specific" requirements with preemptive effect.

This inconsistency appeared to be relevant to the Court's anti-preemption position in *Bates v. Dow Agrosciences, LLC*.[63] The Court reasoned that "[t]he notion that FIFRA contains a nonambiguous command to pre-empt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."[64] However, in *National Cable & Telecommunication Association v. Brand X Internet South*, a fairly recent decision (post-dating the Court's line of products liability preemption cases), the Court held that agency inconsistency is not relevant to a court's decision whether to accord *Chevron* deference to an agency interpretation.[65] Instead, the Court continued, "[u]nexplained inconsistency is, at most, a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act."[66] Three years prior, in *Barnhart v. Walton*, however, the Court stated: "The Agency's regulations also reflect the Agency's own longstanding interpretation... [and thus] should be accorded particular deference."[67] While the relevance of agency consistency as a factor in applying *Chevron* deference is somewhat ambiguous, there is no doubt as to its relevance in applying the weaker "power to persuade" *Skidmore* deference.[68]

In *Riegel*, the Second Circuit was not troubled by the FDA's change of heart; as it explained: "It is certainly true that the FDA previously took a different view, but as the Third Circuit noted in *Horn*, 'an agency may change its course so long as it can justify its change with a "reasoned analysis,"' a standard satisfied here."[69] In its amicus brief filed at the petition stage, the Solicitor General explained: "The FDA has since reexamined the issue and determined that the position it announced at the time of the filing in *Kernats* was erroneous."[70] In addition to embracing the reasons set forth in the *Horn* amicus brief, the Solicitor General claimed that "[t]he government's position in *Kernats* is also inconsistent with the risk-management principles that the FDA currently follows."[71]

CONCLUSION

Riegel presents an opportunity for the Court not only to revisit *Medtronic* and the issue of express preemption under the MDA but also to begin to fashion a framework for preemption jurisprudence that reconciles the often competing demands of the presumption against preemption and deference to agency interpretations. Significantly, the Court will also hear a second products liability preemption case, *Warner-Lambert Co. LLC v. Kent*, a pharmaceutical drug case, where the argument for preemption lies in implied (as opposed to express) grounds, and which calls for the Court to interpret the scope of its previous holding in *Buckman* in preempting claims of fraud on the agency.[72] Finally, the Court has called for the views of the Solicitor General in a pharmaceutical drug preemption case, *Levine v. Wyeth*. Preemption in the pharmaceutical drug context is even more fraught than that of medical devices. Unlike the MDA, the FDCA contains no express preemption provision that pertains to drugs. The FDA has taken a similarly aggressive pro-preemption stance, expressing its views in a preamble to a rule on the form and content of drug labels as well as in amicus briefs before courts. The case presents a clash (analogous to that in *Riegel*) between the presumption against preemption and deference to agency views, but in a context that has not yet ripened in the lower courts.[73]

Endnotes

1 The Court has granted certiorari in a second products liability case, Warner-Lambert Co. LLC v. Kent (No. 06-1498), 2007 WL 1420397 (Sept. 25, 2007).

2 505 U.S. 504 (1992).

3 544 U.S. 431 (2005).

4 90 Stat. 539.

5 518 U.S. 470 (1996).

6 Class III medical devices "presen[t] a potential unreasonable risk of illness or injury" or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C).

7 Mr. Riegel in fact died in 2004. The Supreme Court granted the untimely motion of Donna Riegel (which was opposed by Medtronic) to be substituted in place of Charles Riegel. Chief Justice Roberts and Justice Scalia dissented on the ground that the motion was filed more than six months after petitioner's death, in violation of Supreme Court Rule 35.1.

8 Riegel v. Medtronic, Inc., 451 F.3d 104, 119 (2d Cir. 2006), *cert. granted*, 127 S. Ct. 3000 (2007).

9 *Id.* at 106.

10 Horn v. Thoratec Corp., 376 F.3d 163, 169 (3d Cir. 2004); Martin v. Medtronic, Inc., 254 F.3d 573, 585 (5th Cir. 2001), *cert. denied*, 534 U.S. 1078 (2002); Kemp v. Medtronic, Inc., 231 F.3d 216, 227-28 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001); McMullen v. Medtronic, Inc. 421 F.3d 482, 487-88 (7th Cir. 2005), *cert. denied*, 126 S. Ct. 1464 (2006); Brooks v. Howmedica, Inc., 273 F.3d 785, 798 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002).

11 Goodlin v. Medtronic, Inc. 167 F.3d 1367, 1382 (11th Cir. 1999).

12 Brief for the United States as Amicus Curiae at 8, Riegel v. Medtronic, Inc. (No. 06-179), 2007 WL 1511526 (May 23, 2007) [hereinafter U.S. *Riegel* Brief].

13 62 Fed. Reg. 65,384 (1997), *withdrawn*, 63 Fed. Reg. 39,789 (1998).

14 *Goodlin*, 167 F.3d at 1375 n.15.

15 U.S. *Riegel* Brief at 20.

16 The section provides in full:

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which 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.

21 U.S.C. § 360k(a).

17 There is some ambiguity with respect to the *Medtronic* plurality's take on

this point. The plurality (consisting of Justices Stevens, Kennedy, Souter, and Ginsburg) seems to accept, albeit grudgingly, that the MDA may preempt some common-law tort actions, when it states its view that "§ 360(k) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Medtronic*, 518 U.S. at 491. But the plurality ultimately reserves final judgment on this issue, reasoning:

[I]t is apparent that few, if any, common-law duties have been pre-empted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has "the effect of establishing a substantive requirement for a specific device." Until such a case arises, we see no need to determine whether the statute explicitly pre-empts such a claim.

Id. at 502-03.

Justice Breyer, in a separate concurrence, provides a clear "yes" response:

I believe that ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, 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. It is possible that the plurality also agrees on this point, although it does not say so explicitly.

Id. at 504-05 (Breyer, J., concurring). The dissent (Justice O'Connor, joined by then-Chief Justice Rehnquist, and Justices Scalia and Thomas) likewise have no difficulty reading "requirement" to include state-law causes of action. *Id*. at 509 (O'Connor, J., dissenting) ("I conclude that state common-law damages actions do impose 'requirements' . . . .").

18 544 U.S. 431 (2005).

19 *Id.* at 443 ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules") (quoting *Cipollone*, 505 U.S. at 521 (plurality opinion)). Clouding the issue, however, the *Bates* Court retreated from its statement by concluding that "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." *Id.* at 432.

20 Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 Sup. Ct. Rev. 175, 200.

21 126 S.Ct. 2900 (No. 05-1342) (June 19, 2006).

22 127 S. Ct. 1559, 1572 (2007) (opining that the deference issue was "beside the point, for under our interpretation of the statute, the level of deference owed to the regulation is an academic question").

23 *Id.* at 1585 (Stevens, J., dissenting); *id.* at 1584 ("No case from this Court has ever applied such a deferential standard to an agency decision that could so easily disrupt the federal-state balance.")

24 *See, e.g.*, Freightliner Corp. v. Myrick, 514 U.S. 280 (1995) (no mention of presumption); Geier v. American Honda Motor Co., 529 U.S. 861 (2000) (same); Sprietsma v. Mercury Marine, 537 U.S. 51 (2002) (same).

25 *Medtronic*, 518 U.S. at 485. Most recently, the presumption reared its head again in *Bates*, 544 U.S. at 449 (quoting *Medtronic*); *id*. at 499 ("Even if Dow had offered us a plausible alternative reading of [the express preemption provision]—indeed, even if its alternative were just as plausible as our reading of that text—we would nevertheless have a duty to accept the reading that disfavors pre-emption.").

26 Thus, the presumption prevails in *Cipollone*, *Medtronic*, and *Bates*—all decided on express preemption grounds; but is not invoked in *Geier* or *Sprietsma*—the seminal implied preemption cases.

27 531 U.S. 341, 347-48 (2001) (refusing to apply presumption given that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" and "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law").

28 *See* Michael S. Greve & Jonathan Klick, *Preemption in the Rehnquist Court: A Preliminary Empirical Assessment*, 14 Sup. Ct. Econ. Rev. 43, 57 (2006) (in an empirical analysis of universe of 105 preemption decisions from the Rehnquist Court era, finding preemption in 52%); *accord* Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Decisions*, 120 Harv. L. Rev. 1604, 1605 (2007) ("Between the 1983 and 2003 Terms the Supreme Court decided 127 cases involving federal preemption of state law, finding state law preempted approximately half of the time.") (footnotes omitted).

29 Greve & Klick, *supra* note 29, at 52 (finding 62.5% preemption rate in 32 cases involving preemption of state common law claims; figure increases to 67.6% when cases are restricted to "Second Rehnquist Court," beginning in 1994).

30 *Medtronic*, 518 U.S. at 478 (citing 21 U.S.C. § 360e(b)(1)(B)).

31 *Id.* at 479 ("[T]he House reported in 1990 that 80% of new Class III devices were being introduced to the market through the § 510(k) process and without PMA review."); *see also* Richard C. Ausness, *After You, My Dear Alphonse!: Should the Courts Defer to the FDA's New Interpretation of § 360K(A) of the Medical Device Amendments?*, 80 Tul. L. Rev. 727, 733 (2006) ("Most medical devices do not undergo the FDA PMA process.").

32 U.S. *Riegel* Brief at 2.

33 21 U.S.C. § 360e(d)(2).

34 *Medtronic*, 518 U.S. at 496 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)); *id*. at 506 (Breyer, J., concurring) (FDA has a "special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether... state requirements may interfere with federal objectives").

35 21 C.F.R. § 808.1(d) (1995).

36 *Id.* § 808.1(d)(1).

37 *Medtronic*, 518 U.S. at 480.

38 Brief for the United States as Amicus Curiae Supporting Respondents at 20, Medtronic v. Lohr, 518 U.S. 470 (1996) (Nos. 95-754, 95-886), 1996 WL 118035 [hereinafter U.S. *Medtronic* Brief].

39 *Medtronic*, 518 U.S. at 505 (Breyer, J., concurring).

40 The FDCA vests authority in the Secretary of Health and Human Services, who subsequently delegated authority to the FDA, "to promulgate regulations for the efficient enforcement of" the Act. 21 U.S.C. § 371(a).

41 *Medtronic*, 518 U.S. at 496 (citing Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984); Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 714 (1985)).

42 *Id.* at 495 (emphasis added).

43 *Id*. at 503.

44 *Id.* at 509 (O'Connor, J., concurring in part and dissenting in part).

45 *Id.* at 512 (O'Connor, J., concurring in part and dissenting in part).

46 Riegel v. Medtronic, Inc., 451 F.3d 104, 119 (2d Cir. 2006).

47 *Id*. at 119.

48 *Id.* at 118.

49 *Id.* at 121.

50 *Id*. at 124-25 (citing *Horn*, 376 F.3d at 177-79; *Medtronic*, 518 U.S. at 496).

51 *Horn*, 376 F.3d at 170-171; *Riegel*, 451 F.3d at 124-25 .

52 McMullen v. Medtronic, Inc., 421 F.3d 482, 489 n.3 (7th Cir. 2005) ("An agency's urging, however, does not change a permissive provision into a mandatory one.").

53 *Horn*, 376 F.3d at 182 (Fuentes, J., dissenting) ("[A]rguments advanced by the United States in a litigation brief are entitled to 'near indifference,' and are only as persuasive as their own merits dictate."); *Riegel*, 451 F.3d at 129 (Pooler, J. dissenting) ("[T]he idea that all state tort claims are unambiguously preempted is "particularly dubious" considering it appears that until relatively recently neither the industry nor the FDA thought such claims were preempted.").

54 518 U.S. 470, 505–06 (1996) (Breyer, J., concurring) (citations omitted).

55 *See* United States v. Mead Corp., 533 U.S. 218, 228 (2001) ("[A]dministrative implementation of a particular statutory provision qualifies

for *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.") (emphasis added).

56 U.S. *Medtronic* Brief at 20 n.14 ("There is no occasion in this case to consider the extent to which the PMA process may result in requirements applicable to a device under the FDCA that would trigger preemption under Section 521(a).").

57 *See, e.g.*, Brief for the United States as Amicus Curiae at 14 n.5, Talbott v. Bard, Inc., 63 F.3d 25 (1st Cir. 1995) (No. 94-1951) ("This Court previously indicated that premarket approval procedures that apply to Class III devices constitute 'specific requirements' within the meaning of 21 C.F.R. § 808.1(d). Although the FDA holds a contrary view of the effect of its regulations, these issues need not be addressed to resolve this appeal.").

58 Brief for the United States as Amicus Curiae at 13, Smith Indus. Med. Sys., Inc. v. Kernats, 522 U.S. 1044 (1997) (No. 96-1405), 1997 WL 33561767. According to the Solicitor General, "We have been informed by the FDA that it imposes such specific [federal] requirements on Class III devices only in extraordinary situations." *Id*. at 15.

59 Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 11 (1997).

60 Brief for the United States as Amicus Curiae at 3, Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004) (No. 02-4597), 2004 WL 1143720.

61 *Id*. at 16-17.

62 *Horn*, 376 F.3d at 170-71 ("[T]he Supreme Court has instructed us that the FDA's preemption determinations are significant and should inform our interpretation of § 360k(a).").

63 544 U.S. 431 (2005).

64 *Id.* at 450.

65 545 U.S. 967, 981 (2005) ("Agency inconsistency is not a basis for declining to analyze the agency's interpretation under the *Chevon* framework.").

66 *Id.*; *see also* 5 U.S.C. § 706(2)(A).

67 535 U.S. 212, 213 (2002).

68 *See, e.g.*, Gonzales v. Oregon, 546 U.S. 243 (2006) ("The weight of such a judgment in a particular case will depend upon the thoroughness evidence in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking the power to control.") (citing Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

69 *Riegel*, 451 F.3d at 125 (citing *Horn*, 376 F.3d at 179; Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 42 (1983)).

70 U.S. *Riegel* Amicus Brief at 17.

71 *Id.* The SG has offered somewhat more in the way of explanation than it did in *Bates*, where it disavowed its previous position, but provided no explanation. *See* Brief for the United States as Amicus Curiae Supporting Respondents at 20, Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005) (No. 03-388), 2004 WL 1205202 ("The United States has properly considered and disavowed its prior position that Section 136v(b) does not preempt state common-law duties.").

72 No. 06-1498, 2007 WL 1420397 (Sept. 25, 2007).

73 The Third Circuit is poised to be the first court of appeals to decide the preemption issue.