[the Suspension Clause] must not be subject to manipulation by those whose power it is designed to restrain."[79]

## II. FEDERAL JURISDICTION AND PROCEDURE

### *A. Federal Preemption of State Law*

*Preemption of State Common Law Claims.* — Recent Supreme Court preemption decisions have been decried in the press as pro-business and detrimental to injured consumers' ability to receive compensation.[1] In the context of medical devices, Congress has enacted prospective safety regulations, but it has been said to "all but ignore[] the remedial side" if such devices cause injury.[2] Last Term, in *Riegel v. Medtronic, Inc.*,[3] the Supreme Court held that the preemption provision in the Medical Device Amendments of 1976[4] (MDA) preempted state common law claims brought after a medical device subject to the most stringent level of federal regulation caused injury. Despite criticisms that it leaves tort victims uncompensated, preemption is necessary to ensure that federal regulatory agencies, like the Food and Drug Administration (FDA), are the only governmental actors able to impose requirements on manufacturers — thereby ensuring a nationally standardized system of safety regulations without myriad local variations. *Riegel* extends an evolving MDA jurisprudence that empowers this federal system, while preserving common law claims when the regulation systematically provides inadequate safety assurances, but it leaves open the question of how courts should treat claims alleging fraud in fulfilling FDA requirements. However, the rationale that underlies the Court's MDA jurisprudence — that state law claims are only preempted when federal regulation has been complied with — indicates that courts should permit some fraud-based tort claims.

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[79] *Id.* at 2259.

[1] *See, e.g.*, Erwin Chemerinsky, *A Troubling Trend in Preemption Rulings*, TRIAL, May 2008, at 62; Jeffrey Rosen, *Supreme Court, Inc.*, N.Y. TIMES, Mar. 16, 2008, § 6 (Magazine), at 38, 66 ("[T]he business community . . . is trying to ensure that these consumers often have no legal remedy for their injuries. And the Supreme Court has been increasingly sympathetic to the business community's arguments."); *cf.* James T. O'Reilly, *Drug Review "Behind the Curtain": A Response to Professor Struve*, 93 CORNELL L. REV. 1075, 1077–78 (2008) ("[S]ome patients will inevitably become victims of unreasonably harmful or badly-prescribed drugs and medical devices . . . [but p]recluding compensation to victims decreases drug sponsors' insurance costs, and thus increases the potential profitability of engaging in the high-risk quest of making novel, effective drugs." (footnote omitted)).

[2] Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 451 (2008).

[3] 128 S. Ct. 999 (2008).

[4] Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 and 42 U.S.C.).

In response to the perceived "inability of the common law tort system"[5] to respond to dangerous medical devices and in order to impose federal regulation on the field, Congress amended the Federal Food, Drug, and Cosmetic Act[6] (FDCA) with the MDA. The MDA contains "an express pre-emption provision"[7] prohibiting state or local governments from implementing "any requirement . . . which is different from, or in addition to," federal statutory requirements.[8]

The MDA created a three-tiered system of FDA oversight, requiring greater supervision for riskier medical devices.[9] A device is assigned to Class III if there is "insufficient information" to guarantee that either the Class I or Class II controls "provide reasonable assurance of its safety and effectiveness."[10] Class III devices are subject to "a rigorous regime of premarket approval."[11] Review of each application averages 1200 hours and approval is granted if the FDA finds "reasonable assurance" of safety and that "any probable benefit to health from the use of the device [outweighs] any probable risk of injury or illness from such use."[12] Once a device is approved, it is "subject to reporting requirements" on new studies or incidents involving malfunction risking serious injury or death.[13]

In 1996, during a coronary angioplasty, Charles Riegel's doctor inserted an Evergreen Balloon Catheter into his artery in order to dilate it, although the catheter's labeling warned against use in calcified ar-

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[5] *Riegel*, 128 S. Ct. at 1003.

[6] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

[7] *Riegel*, 128 S. Ct. at 1003.

[8] The preemption provision reads:

> 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) (2006). Subsection (b) allows exemption from preemption for certain more stringent or locally tailored state and local requirements. *See id.* § 360k(b).

[9] *Riegel*, 128 S. Ct. at 1003. For an explanation and examples of the three classes, see U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, Device Advice — Device Classes, http://www.fda.gov/cdrh/devadvice/3132.html (last visited Oct. 5, 2008).

[10] 21 U.S.C. § 360c(a)(1)(C)(i).

[11] *Riegel*, 128 S. Ct. at 1004. The approval process requires "a multivolume application" containing "full reports of all studies and investigations of the device's safety and effectiveness," a full description of the device and its manufacturing process, and "proposed labeling." *Id.* (citing 21 U.S.C. § 360e(c)(1)). Premarket approval applies to new devices; many devices on the market when the MDA was enacted were grandfathered in, and new devices found to be "substantially equivalent" to grandfathered devices are also exempt. *Id.* (quoting 21 U.S.C. § 360c(f)(1)(A)).

[12] *Id.* (quoting 21 U.S.C. §§ 360e(d), 360c(a)(2)(C)) (internal quotation marks omitted).

[13] *Id.* at 1005 (citing 21 U.S.C. § 360i).

teries.[14] The catheter, a Class III device marketed by Medtronic, Inc., had "received premarket approval from the FDA in 1994."[15] The catheter ruptured as the doctor inflated it to a pressure of ten atmospheres — two beyond "its rated burst pressure."[16] Riegel developed a heart block, was put on life support, and had emergency bypass surgery.[17]

In 1999, Riegel and his wife Donna[18] brought suit against Medtronic in federal district court, alleging that the "catheter was designed, labeled, and manufactured in a manner that violated New York common law and caused Riegel to suffer severe and permanent injuries."[19] The court held that the MDA preempted the Riegels' strict liability and breach of implied warranty claims, and most of their negligence claims.[20] The court also found that the federal statute would preempt a claim for negligent manufacturing "insofar as [the claim] was not premised on the theory that Medtronic violated federal law."[21]

The Second Circuit affirmed,[22] concluding that Medtronic was "clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved" premarket approval process.[23] The panel stated that the Riegels' state common law claims "would, if successful, impose state requirements that differed from, or added to" the federal requirements.[24]

Justice Scalia delivered the opinion of the Court,[25] affirming the Second Circuit. As a threshold question, the Court had to determine whether the MDA imposed device-specific requirements on the Medtronic catheter.[26] The Court had previously interpreted the MDA's preemption provision in *Medtronic, Inc. v. Lohr*,[27] which in turn had relied on an FDA regulation stating that preemption occurs "only

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[14] *Id.*

[15] *Id.* The FDA approved supplemental label changes to the catheter in 1995 and 1996. *Id.*

[16] *Id.*

[17] *Id.*

[18] Charles Riegel died before the case was decided by the Supreme Court, leaving Donna Riegel as petitioner both as administrator of his estate and on her own behalf. *Id.* at 1006 n.3.

[19] *Id.* at 1005; *see also* Riegel v. Medtronic, Inc., No. 99-CV-0694 (LEK/RWS), 2002 WL 34234093, at *1 (N.D.N.Y. Mar. 18, 2002).

[20] *Riegel*, 2002 WL 34234093, at *6–7.

[21] *Riegel*, 128 S. Ct. at 1006. Donna's loss of consortium claim was also preempted insofar as it derived from the preempted claims. *Riegel*, 2002 WL 34234093, at *7 & n.2.

[22] Riegel v. Medtronic, Inc., 451 F.3d 104 (2d Cir. 2006). Judge Katzmann wrote the opinion for the panel, in which Judge Parker joined. Judge Pooler dissented from the preemption holding.

[23] *Id.* at 118.

[24] *Id.* at 121.

[25] Chief Justice Roberts and Justices Kennedy, Souter, Thomas, Breyer, and Alito joined the opinion in full. Justice Stevens joined in part.

[26] *Riegel*, 128 S. Ct. at 1006 (citing 21 U.S.C. § 360k(a)(1)).

[27] 518 U.S. 470 (1996) (finding no preemption of state law claims relating to a pacemaker that had not gone through the full premarket approval process).

when the Food and Drug Administration has established *specific* counterpart regulations or there are other *specific* requirements applicable to a particular device."[28] The premarket approval process to which the catheter had been subjected "impose[d] 'requirements' under the MDA" that were "specific to individual devices."[29] Once a device is approved, it must "be made with almost no deviations from the specifications in its approval application," which have been determined to provide "a reasonable assurance of safety and effectiveness."[30]

The Court then turned to the second question: whether the New York claims were based on tort duties imposing safety and effectiveness requirements that were different from or additional to those in the MDA.[31] Citing *Lohr*, and two other cases in which statutes' preemption provisions were found to preempt state common law claims,[32] Justice Scalia explained that "common-law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation."[33] To exclude such state common law duties from preemption "would make little sense," as such obligations "disrupt[] the federal scheme no less than state regulatory law to the same effect."[34] To hold otherwise would illogically give greater power to juries than to state legislators; although state legislatures would likely conduct a cost-benefit analysis before regulating, the jury is concerned only with "the cost of a more dangerous design, and is not concerned with its benefits."[35]

Responding to Justice Ginsburg's dissent, Justice Scalia stated that the MDA preemption clause does "'remove all means of judicial recourse' for consumers."[36] Justice Scalia distinguished the treatment of

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[28] *Riegel*, 128 S. Ct. at 1006 (emphases added) (quoting 21 C.F.R. § 808.1(d) (2008)). The comparison of the generally applicable federal manufacturing and labeling requirements and the state common law claims at issue in the *Lohr* case led the Court to conclude that the state claims were not preempted because the requirements were not device-specific. *Id.* at 1006–07.

[29] *Id.* at 1007. The Court distinguished the pacemaker at issue in *Lohr*, which was exempted from premarket approval as a result of "substantial-equivalence review" under the grandfather provision of the MDA; the Court stated that the need for the device to "remain [the] substantial equivalent[] of the relevant pre-1976 device[] [was] a qualification for an exemption rather than a requirement." *Id.* (citing *Lohr*, 518 U.S. at 493–94). In contrast, the premarket approval process "is in no sense an exemption from federal safety review — it *is* federal safety review." *Id.*

[30] *Id.*

[31] *Id.*

[32] *See id.* at 1007–08 (citing *Lohr*, 518 U.S. 470; Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005); Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992)).

[33] *Id.* at 1008 (quoting *Cipollone*, 505 U.S. at 522 (plurality opinion)).

[34] *Id.*

[35] *Id.*

[36] *Id.* at 1009 (quoting *id.* at 1015 (Ginsburg, J., dissenting)). Justice Scalia stated that the text of the MDA indicated that concern for the injured "was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Id.* Although he found the text unambiguous enough

drug, food, and color additive approvals under the FDCA, noting that it was not established whether tort claims related to those products were preempted; the preemption clause applied only to medical device approval, not to the entire FDCA.[37]

The Court rejected the claim that "general common-law duties are not requirements maintained 'with respect to devices,'"[38] because "[n]othing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices."[39] The Riegels appealed to an FDA regulation exempting from preemption any state or local "requirements of general applicability" not specifically targeting devices.[40] The Court felt, however, that, assuming that this regulation was applicable, the FDA's interpretation of its rule — "that the regulation does not refer to general tort duties of care," but only to requirements incidentally related to medical devices — was "entitled to substantial deference."[41] The Court concluded that FDA regulations did not change its textual interpretation.[42] Finally, the Court declined to address the Riegels' contention that their claims were "parallel" — that is, that the damages remedy was premised on the FDA regulation violation — and thus not preempted, because of their failure to raise the argument below.[43]

Justice Stevens concurred in part and in the judgment. Although he agreed with Justice Ginsburg on the congressional intent behind the MDA, he concluded that the text did preempt the state law at issue.[44] In his view, Congress sought to protect consumers and preempt conflicting state premarket regulatory regimes, not to preempt common law duties or to pass judgment on their costs and benefits.[45] However, some common law rules, although not all, would count as requirements, including causes of action for negligence and strict liability, as

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to preclude the need for *Skidmore* deference to the agency, Justice Scalia nonetheless noted that the FDA agreed with the Court's view; the FDA's earlier position was not entitled to weight because it had reversed its stance. *Id.* (citing Skidmore v. Swift & Co., 323 U.S. 134 (1944)). The FDA had previously stated that not all state common law claims ought to be preempted. *Id.* at 1015–16.

[37] *Id.*

[38] *Id.* (quoting Brief for Petitioners at 34–36, *Riegel*, 128 S. Ct. 999 (No. 06-179), 2007 WL 2456946).

[39] *Id.* at 1010.

[40] *Id.* (quoting 21 C.F.R. § 808.1(d)(1) (2008)).

[41] *Id.* (citing Auer v. Robbins, 519 U.S. 452, 461 (1997)). Although the FDA's "explanation [was] less than compelling," another regulation provided support: the MDA preempts state duties "having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*)." *Id.* (quoting 21 C.F.R. § 808.1(b) (emphasis added)) (internal quotation marks omitted).

[42] *Id.* at 1011.

[43] *Id.*

[44] *Id.* (Stevens, J., concurring in part and concurring in the judgment).

[45] *Id.* at 1012.

identified by *Lohr*.[46] Although Justice Stevens agreed with the Court that these New York common law duties were different requirements from those imposed by federal law, he did not join the Court's discussion that "requirements" encompassed all common law duties or of the congressional policy judgment to include a preemption provision.[47]

Justice Ginsburg dissented, arguing that the Court's construction of the MDA "cut deeply into a domain historically occupied by state law," and that Congress "did not intend . . . to effect a radical curtailment of state common-law suits."[48] She stated that the "presumption against preemption is heightened 'in fields of traditional state regulation'" like health and safety.[49] Furthermore, the FDA had previously stated that its "approval and state tort liability usually operate independently . . . . Preemption of all such claims would result in the loss of a significant layer of consumer protection . . . ."[50]

Noting that "Congress'[s] experience regulating drugs and food additives informed, and in part provided the model for, its regulation of medical devices," Justice Ginsburg pointed out that FDA preclearance requirements for new drugs and later additives had coexisted with state common law suits for decades.[51] The MDA applied a preemption provision to medical devices only in order "to exercise control over state premarket approval systems" that predated the federal system; such comparable regimes were lacking in drug and additive regulation.[52] Finally, Justice Ginsburg pointed out that under her reading of the MDA preemption provision, medical device manufacturers could still argue conflict preemption or "a regulatory compliance defense based on the FDA's approval of the premarket application."[53]

*Riegel* is the most recent step in a body of preemption precedent pertaining to medical devices; these cases must balance the effective regulatory power of the federal government and the ability of tort victims to seek compensation for their injuries. While acknowledging the supremacy of federal regulation, the Supreme Court's preemption ju-

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[46] *Id.*

[47] *Id.* at 1012–13.

[48] *Id.* at 1013 (Ginsburg, J., dissenting).

[49] *Id.* (quoting N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995)). Because the MDA was enacted in the wake of a "series of high-profile medical device failures" and resulting litigation, *id.*, she found that its "failure to create any federal compensatory remedy for [injured] consumers further suggests that Congress did not intend broadly to preempt state common law suits," *id.* at 1015.

[50] *Id.* at 1015 (quoting Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997)) (internal quotation mark omitted). Justice Ginsburg acknowledged that the FDA had reversed this position in its amicus brief, but concluded that this "new position is entitled to little weight." *Id.* at 1016 n.8.

[51] *Id.* at 1016–17.

[52] *Id.* at 1017.

[53] *Id.* at 1020.

risprudence has recognized that the FDA does not strictly regulate all medical devices on the market, nor can it ensure safety in all situations. Common law claims have thus been allowed to proceed when the federal regulatory system is systematically avoided — as when the device is not subject to regulation — or when it is unable to protect the public — as with manufacturer noncompliance. The Court has repeatedly decided cases according to the underlying principle that state law claims are only precluded if federal safety requirements have been satisfied; this principle should guide courts confronting the open question of the preemptive force of the MDA in the face of claims arguing that FDA approval was secured by fraud to allow such claims when they would not undermine federal regulatory supremacy.

Through the MDA, Congress created a superseding federal system of regulation to ensure the safety of medical devices. In so doing, Congress vested the FDA with the power to approve — through a rigorous process — new devices before they may be marketed. Through its express preemption, the MDA made the FDA the only arbiter of appropriate regulation.[54] (In fact, some commentators have suggested increasing the role of the FDA in determining the outcome of product liability suits.[55]) As Justice Scalia argued, to allow state common law claims to proceed against a properly screened medical device in the face of the preemption provision would grant a single jury greater power than even state legislatures — a "perverse distinction" not mandated by the MDA.[56] By precluding some tort suits, *Riegel* accepted that some consumers hurt by pre-approved products will be uncompensated, which is a necessary cost of prioritizing the federal system.

However, preemption does not automatically apply to all medical devices. As a threshold matter, the MDA does not preempt suits relating to devices that are not subject to the extensive federal regulation at issue in *Riegel*. If the device was not required to comply with the most stringent federal safety requirements, its manufacturer cannot use FDA approval as a liability shield. As the *Riegel* majority discussed,[57] the *Lohr* Court preserved causes of action against products that did not go through the premarket approval process, but only through

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[54] *But cf.* O'Reilly, *supra* note 1, at 1087 ("[T]he expensive, messy, and difficult process of civil discovery does a better job of uncovering flaws in drug approval decisions than does the FDA's time-sensitive drug review process.").

[55] *See, e.g.*, Sharkey, *supra* note 2 (advancing an "agency reference model" for adjudication of product liability preemption cases); Catherine T. Struve, *Greater and Lesser Powers of Tort Reform: The Primary Jurisdiction Doctrine and State-Law Claims Concerning FDA-Approved Products*, 93 CORNELL L. REV. 1039 (2008) (describing the use of the primary jurisdiction doctrine to refer some products liability questions to the FDA for determination).

[56] *Riegel*, 128 S. Ct. at 1008.

[57] *See id.* at 1006–07.

"substantial equivalence" review under the MDA's grandfather provision — a procedure not primarily concerned with safety assurances.[58] Instead, the MDA exemption process was intended to "maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents[, which] included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design."[59] Thus, if the federal regulatory system has not approved the medical device, regulation through common law claims is allowed — and expected — to fill this gap.

Even if a device has been screened by the premarket approval process, the tort system catches some cases that fall through the cracks in federal safety regulation — if the cracks are the result of manufacturer noncompliance. Manufacturers are not immunized from tort suits if they violate FDA regulations. Importantly, the MDA does not preempt "parallel" state claims; nothing in the statute "prevent[s] a State from providing a damages remedy for claims premised on a violation of FDA regulations."[60] However, a successful claim may only be based on federal, not state, regulations. This combination of federal regulation and corresponding state liability continues after the initial premarket approval. Manufacturers are required to obtain FDA permission to make changes in design, manufacture, or labeling after initial approval[61] and to report the results of new scientific studies or incidents of malfunction or injuries resulting from the device[62] — and the FDA reserves the power to withdraw approval.[63] Coupled with these limits, tort liability for violations of FDA regulations provides an ongoing common law check on manufacturers' compliance.

*Riegel* and related preemption cases leave open an important question: how to treat the preemptive force of FDA regulation if agency approval is obtained by fraud? The case law is unsettled on this question. However, the Supreme Court has not foreclosed tort suits in all situations of fraud, and the rationale of its preemption decisions ought to be applied to fraud cases. The situations in which fraud claims are likely to be allowed reflect the same balance of federal supremacy and safety assurances that pervades the MDA preemption jurisprudence.

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58 Medtronic, Inc. v. Lohr, 518 U.S. 470, 493–94 (1996).

59 *Id.* at 494.

60 *Riegel*, 128 S. Ct. at 1011; *accord Lohr*, 518 U.S. at 495. *But see* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001) ("[A]lthough *Medtronic* [*v. Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.").

61 *See* 21 U.S.C. § 360e(d)(6) (2006).

62 *See id.* § 360i; 21 C.F.R. § 814.84(b)(2) (2008).

63 *See* 21 U.S.C. §§ 360e(e)(1), 360h(e) (describing the FDA's recall authority).

If a state fraud claim interferes with FDA regulatory decisions, preemption is likely to be (correctly) found. In *Buckman Co. v. Plaintiffs' Legal Committee*,[64] the Supreme Court held that a state law claim of fraud in securing FDA approval was preempted.[65] The Court concluded that given the FDA's powers to detect and punish fraud against it, allowing state "fraud-on-the-FDA" claims would undermine the Administration's authority to pursue its chosen enforcement strategy.[66] In *Buckman Co.*, the medical device — a bone screw used in spinal surgery — was approved on the basis of an application for its component parts,[67] described as "plates and screws for use in the long bones of the arms and legs."[68] The spinal surgery use was thus "off-label," and the Court held that this sole basis of the fraud claim conflicted with the "accepted and necessary corollary of the FDA's mission to regulate . . . without directly interfering with the practice of medicine."[69] Acknowledging the value of off-label usage, the *Buckman* Court recognized the FDA's ability to decide how best to ensure safe medical devices — even if that decision meant choosing not to enforce its own disclosure requirements against fraud.

State law claims ought to proceed when the fraud allegation is unlikely to interfere with an FDA enforcement decision that balances the costs and benefits of punishing fraud. As an example, under Michigan law, a manufacturer may assert compliance with relevant regulation as a defense to tort liability.[70] However, an exception to this regulatory-compliance defense exists for situations in which the manufacturer "[i]ntentionally with[held] from or misrepresent[ed] to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, and the drug would not have been approved . . . if the information were accurately submitted."[71] The Sixth Circuit has reinforced the FDA's preemptive authority, holding that although

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[64] 531 U.S. 341 (2001).

[65] *See id.* at 348 & n.2 (finding implied preemption without reaching the question of express preemption under the MDA). The device at issue in *Buckman* had gone through the § 510(k) approval process and had been rejected until it was split into two component parts, which were then approved. *Id.* at 346. The combination of § 510(k) approval, off-label usage, and implied preemption renders unclear the impact of this decision on premarket approval cases.

[66] *Id.* at 348–50.

[67] The manufacturer had twice previously applied for and been denied § 501(k) approval for the aggregate device composed of the two individually approved parts. *Id.* at 346.

[68] *Id.* (quoting *In re* Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 820 (3d Cir. 1998)).

[69] *Id.* at 350. No defective design or manufacturing was alleged. *See* Transcript of Oral Argument at 3, *Buckman*, 531 U.S. 341 (No. 98-1768), *available at* http://www.supremecourtus.gov/oral_arguments/argument_transcripts/98-1768.pdf.

[70] *See* MICH. COMP. LAWS § 600.2946(5) (2004).

[71] *Id.* § 600.2946(5)(a) (internal citations omitted).

*Buckman* would require preemption if a state court found fraud against the FDA in a claim under the Michigan statute, the cause of action could proceed if "the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process."[72] The Second Circuit in *Desiano v. Warner-Lambert & Co.*[73] had a narrower conception of the preemption, holding that the Michigan statute was not preempted at all.[74] The court held that the plaintiffs' claims, like those in *Lohr*, "'*parallel* federal safety requirements' but are not premised principally (let alone exclusively) on a drug maker's failure to comply with federal disclosure requirements."[75]

Although the Supreme Court's decision in *Buckman* and the Second Circuit's decision in *Desiano* were both reached on implied preemption grounds, the concern for FDA objectives and the allowance of parallel claims both have relevance to the MDA's express preemption. While the Supreme Court has not clarified its stance on the Michigan statute, its 4–4 affirmation of the Second Circuit in *Desiano*, coupled with the views of the courts of appeals, suggests that courts are rightly receptive to some tort claims arising from manufacturer fraud in the FDA approval process. Such fraud undermines the effectiveness of federal requirements — an important consideration in *Riegel* — while also endangering consumer welfare, which hurts both sides of the federal regulatory and private compensation balance. Courts ought to allow these actions to go forward in situations that would not impede the FDA's ability to choose its own enforcement strategy; such claims would further encourage compliance with federal regulations.

Although *Riegel* appears to be a broad preemption precedent, its scope is couched within a system of supreme federal regulation and supplementary common law claims. The Court's finding that the MDA's express preemption provision precluded the Riegels' state tort claims was the next step in a jurisprudence that finds preemption when federal requirements have been satisfied. However, this preemption only applies to medical devices that undergo the extensive premarket approval process; manufacturers who do not comply or who perpetrate fraud are likely to find themselves still subject to tort liabil-

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[72] Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 966 (6th Cir. 2004). Of course, it is unclear how often the FDA would make this determination.

[73] 467 F.3d 85. *Desiano* involved the manufacture of drugs, which are not subject to an express preemption provision. The Court will address the issue of preemption of state law claims against drug manufacturers in the October 2008 Term. *See* Levine v. Wyeth, 944 A.2d 179 (Vt. 2006), *cert. granted*, 128 S. Ct. 1118 (2008) (mem.).

[74] *See Desiano*, 467 F.3d at 87. The Supreme Court affirmed *Desiano* by a divided 4–4 vote in *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (per curiam), thus creating no binding precedent.

[75] *Id.* at 95 (emphasis added).

ity. Rather than completely deprive consumers of the protection provided by state common law actions, the Supreme Court's MDA-related decisions have struck a balance — protecting consumer safety through a complementary system of federal regulation and state civil actions.

### *B. Habeas Corpus*

*Jurisdiction over Americans Held Overseas.* — The rule of non-inquiry is a judge-made doctrine that bars courts reviewing extradition decisions from "investigating the fairness of a requesting nation's justice system" or the "procedures or treatment which await a surrendered fugitive" once surrendered.[1] It was adopted by the Supreme Court in the early twentieth century, in *Neely v. Henkel*[2] and *Glucksman v. Henkel*,[3] and is grounded on concerns for international comity, the prevention of multiple pronouncements on foreign relations, and comparative institutional competence.[4] But its reach and scope remain uncertain.[5] Some courts have held that the rule does not always prevent them from investigating allegations that extradition will lead to torture,[6] while others have left such determinations solely in the hands of the Executive.[7] More recently, courts have disagreed as to whether the rationales underlying the rule of non-inquiry apply to the government's decisions to transfer Guantánamo detainees to their home countries,[8] where they may face mistreatment.

Last Term, in *Munaf v. Geren*,[9] the Supreme Court ruled that habeas corpus provided no relief to two American citizens who hoped to enjoin their transfer to the Iraqi justice system, holding that courts could not disturb the Executive's assessment of the adequacy of a foreign judicial process.[10] The decision was narrow, and the Court pre-

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1 *See* Hoxha v. Levi, 465 F.3d 554, 563 (3d Cir. 2006) (internal citation and quotation marks omitted).

2 180 U.S. 109 (1901).

3 221 U.S. 508 (1911).

4 *See* Matthew Murchison, Note, *Extradition's Paradox: Duty, Discretion, and Rights in the World of Non-Inquiry*, 43 STAN. J. INT'L L. 295, 304–08 (2007).

5 *See id.*

6 *See, e.g.*, Mironescu v. Costner, 480 F.3d 664, 672–73 (4th Cir. 2007); Gallina v. Fraser, 278 F.2d 77, 79 (2d Cir. 1960) ("We can imagine situations where the relator, upon extradition, would be subject to procedures or punishment so antipathetic to a federal court's sense of decency as to require reexamination of the [non-inquiry] principle set out above.").

7 *See, e.g.*, Hoxha v. Levi, 465 F.3d 554, 563–64 (3d Cir. 2006); Ahmad v. Wigen, 910 F.2d 1063, 1066–67 (2d Cir. 1990).

8 *Compare* Al-Anazi v. Bush, 370 F. Supp. 2d 188, 194–95 (D.D.C. 2005) (citing the rule of non-inquiry in declining to interfere in executive transfers from Guantánamo), *with* Alhami v. Bush, No. 05-359 (GK), at 3 (D.D.C. Oct. 2, 2007) (order granting preliminary injunction) (considering "evidence that [a Guantánamo habeas petitioner] would face a serious threat of torture if rendered to a Tunisian prison" in temporarily enjoining such a transfer).

9 128 S. Ct. 2207 (2008).

10 *Id.* at 2224–25.