SAYING GOODBYE TO IMPLIED-FEDERAL PREEMPTION: THE CONTEMPORARY SCOPE OF FEDERAL PREEMPTION IN LIGHT OF *GEIER*, *RIEGEL*, AND *WYETH*

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I. INTRODUCTION

A. The Perfect Monday Morning?

Imagine you are sitting in a law office. It is eight o'clock in the morning on a Monday. Sipping a freshly brewed cup of Folgers coffee, your mind is racing about the massive amount of work that the week has in store. The stress you feel in your back due to the upcoming week is alleviated as you become absorbed into the warm cushion of the latest ergonomic chair created by Brookstone. You intently stare at the computer screen, responding to the dozens of e-mails, checking the calendar for upcoming deadlines, and furiously typing away on your keyboard. Your elbows rest on the thick and heavy wooden desk. Typical Monday morning.

As you are flipping through one of your oldest case files, a loud knock resonates throughout the office. Your head immediately snaps up from the case file, you set the file down, and you ask your secretary what's going on. Just like every other Monday morning, your secretary informs you that you have prospective clients who will be in for a consultation throughout the day.

The first prospective client, your secretary tells you, is a young woman who recently crashed her Honda Accord into a tree.[1] Upon impact, the woman was severely injured because an airbag did not deploy.[2] The reason? The Honda Accord was not equipped with an airbag.[3]

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[1] Geier v. Am. Honda Motor Co., 529 U.S. 861, 865 (2000).

[2] *Id.*

[3] *Id.*

The second prospective client is an older gentleman who recently suffered a heart attack.[4] During surgery, the doctor inserted an Evergreen Balloon Catheter into the gentleman's clogged heart artery in order to encourage blood flow.[5] While the catheter was lodged in the man's heart valve, the catheter exploded, rupturing the valve and requiring immediate emergency surgery.[6]

The third prospective client is a middle-aged woman, who also happens to be a professional musician.[7] Your secretary tells you that the woman went to a local clinic to receive treatment for a migraine headache.[8] The doctor injected a drug, Phenergan, into her right forearm vein in order to treat the migraine.[9] Shortly after this injection of Phenergan, the woman developed gangrene in her right arm, requiring the amputation of her right hand first, and then eventually her entire forearm.[10]

Your secretary rises from her chair, you thank her, and she leaves the room. As you sit in your ergonomic chair, you are dumbstruck by the gravity of the injuries that these prospective clients sustained. Like any good plaintiff's lawyer, you are beyond excited to begin pursuing justice (and a potentially hefty recovery) for each client. All three clients were injured by an allegedly defective product or the negligence of some defendant or defendants. You start brainstorming how the petitions or complaints are going to look—negligence and strict liability—no problem, right?

Well, what many practitioners do not understand is: What happens to that "perfect case" when the simplicity of state tort law no longer exists? What happens to that seatbelt case when you learn that Honda consciously chose not to install an airbag because the Federal Motor Vehicle Safety Standard said the airbag was unnecessary?[11] What happens to that negligence and strict liability cause of action when the Food and Drug Administration (FDA) already deemed the Evergreen Balloon Catheter "safe"?[12] What happens to your one-armed professional musician when the

[4] Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1005 (2008).

[5] *Id.*

[6] *Id.*

[7] Wyeth v. Levine, 129 S. Ct. 1187, 1191 (2009).

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] *See* Geier v. Am. Honda Motor Co., 529 U.S. 861, 865 (2000).

[12] *See* Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1005 (2008).

defendant's lawyer in her state-law tort case files a motion for summary judgment claiming that your client's causes of action are preempted by federal law?[13] Negligence and strict liability—no problem, right?

The answers to the above questions will not be found in a casebook, statute, or regulation. It is only after decades of litigation and strained interpretations of the United States Constitution, federal statutes, and agency regulations that the Supreme Court of the United States has "answered" these questions. If contemporary practitioners think the "answers" to these questions will be clear after pouring through eloquent opinions authored by the likes of Justices Breyer, Scalia, and Stevens, they might be wise to think again.

B. Scope of the Article

The Author hopes this article will clear up some confusion that recent litigation has created. This article includes a brief look at the constitutional basis for federal preemption and an overview of the three most recent and relevant cases on federal preemption of state tort law: *Geier v. American Honda Motor Co.*, *Riegel v. Medtronic*, and *Wyeth v. Levine*.

These cases will detail exactly what implied-conflict preemption and express federal preemption entail. The Author hopes that after detailing the facts and holdings of these three cases, it will become clear that implied-conflict preemption is on its death bed.

II. CONSTITUTIONAL BASIS FOR FEDERAL PREEMPTION

In order to "reduce the risk of tyranny and abuse," the Framers of the United States Constitution constructed a "federalist structure of joint sovereigns."[14] Under this system, "the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause."[15] The Supremacy Clause provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the

[13] *See Wyeth*, 129 S. Ct. at 1192 (defendant filed motion for summary judgment arguing plaintiff's failure-to-warn claims were pre-empted by federal law).

[14] Gregory v. Ashcroft, 501 U.S. 452, 458 (1991).

[15] Tafflin v. Levitt, 493 U.S. 455, 458 (1990); *see also* U.S. Const. art. VI, cl. 2 (the Supremacy Clause).

> United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.[16]

It was the intent of the Framers that the Supremacy Clause would have the effect of giving the federal government "a decided advantage in [a] delicate balance" between the federal and state sovereigns.[17] If a law is made "in pursuance" of the Constitution, such as a law promulgated by Congress, then the Supremacy Clause attaches, and the law will be the "supreme law of the land."[18] "As long as it is acting within the powers granted it under the Constitution, Congress may impose its will on the States."[19]

Notwithstanding the Supremacy Clause, the Tenth Amendment allows the states to retain all powers not delegated to the United States by the Constitution.[20] This reservation by the states is taken seriously.[21] It has long been held that "the preservation of the States, and the maintenance of their governments, are as much within the design and care of the Constitution as the preservation of the Union and the maintenance of the National government."[22] If, however, a federal law promulgated by Congress is made in pursuance of the powers delegated to it by the Constitution, a contrary state law will be preempted by the supreme federal law.[23]

Throughout the history of American jurisprudence, two "structural limitations" have been placed on federal laws made in pursuance of the

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[16] U.S. CONST. art. VI, cl. 2.

[17] *Gregory*, 501 U.S. at 460.

[18] *See* 3 JOSEPH STORY, COMMENTARIES ON THE CONSTITUTION OF THE UNITED STATES § 1831, at 694 (Boston, Hilliard, Gray, & Co. 1833).

[19] *Gregory*, 501 U.S. at 460.

[20] U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.").

[21] *See, e.g.*, Alden v. Maine, 527 U.S. 706, 760–62 (1999) (Souter, J., dissenting) (involving arguments by Maine that a state's sovereign immunity from individual suits is a "fundamental aspect" of state sovereignty "confirm[ed]" by the Tenth Amendment and that it should not be forced to consent to suit).

[22] Texas v. White, 74 U.S. (7 Wall.) 700, 725 (1868).

[23] *See* 3 STORY, *supra* note 18, at 363–64 ("If a number of political societies enter into a larger political society, the law, which the later may enact, pursuant to the powers entrusted to it by its constitution must necessarily be supreme . . . .").

Constitution such that "the Federal Government does not amass too much power at the expense of the States."[24] The first structural limitation is "the Constitution's conferral upon Congress of not all governmental powers, but only discrete, enumerated ones."[25] The second structural limitation is contained in the provisions of Article I of the United States Constitution, which are "integral parts of the constitutional design of separation of powers."[26] Specifically, clauses two and three of Article I, Section 7, of the Constitution set forth the Bicameral and Presentment Clauses, which "serve essential constitutional functions."[27] Combined, these clauses require that legislation undergo "a step-by-step, deliberate and deliberative process,"[28] that was "finely wrought and exhaustively considered" by the Framers."[29] If a federal law complies with the two structural requirements, then the Supremacy Clause will be operative and any contrary state law will be preempted.[30]

[24] *See* Wyeth v. Levine, 129 S. Ct. 1187, 1206 (2009).

[25] *See* Printz v. United States, 521 U.S. 898, 919 (1997); *see also* Marbury v. Madison, 5 U.S. (1 Cranch) 137, 176 (1803) ("The powers of the legislature are defined, and limited; and that those limits may not be mistaken, or forgotten, the constitution is written.").

[26] *See* INS v. Chadha, 462 U.S. 919, 946 (1983).

[27] *Id.* at 951; *see also* U.S. Const. art. I., § 7, cls. 2–3 ("Every Bill which shall have passed the House of Representatives and the Senate, shall, before it become a Law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it, with his Objections to that House in which it shall have originated, who shall enter the Objections at large on their Journal, and proceed to reconsider it. If after such Reconsideration two thirds of that House shall agree to pass the Bill, it shall be sent, together with the Objections, to the other House, by which it shall likewise be reconsidered, and if approved by two thirds of that House, it shall become a Law. But in all such Cases the Votes of both Houses shall be determined by Yeas and Nays, and the Names of the Persons voting for and against the Bill shall be entered on the Journal of each House respectively. If any Bill shall not be returned by the President within ten Days (Sundays excepted) after it shall have been presented to him, the Same shall be a Law, in like Manner as if he had signed it, unless the Congress by their Adjournment prevent its Return, in which Case it shall not be a Law. Every Order, Resolution, or Vote to which the Concurrence of the Senate and House of Representatives may be necessary (except on a question of Adjournment) shall be presented to the President of the United States; and before the Same shall take Effect, shall be approved by him, or being disapproved by him, shall be repassed by two thirds of the Senate and House of Representatives, according to the Rules and Limitations prescribed in the Case of a Bill.").

[28] *Chadha*, 462 U.S. at 959.

[29] *Id.* at 951.

[30] *See* Wyeth v. Levine, 129 S. Ct. 1187, 1206–07 (2009).

III. THE CONTEMPORARY SCOPE OF FEDERAL PREEMPTION OF STATE LAW

A. Geier v. American Honda Motor Co.: *Implied-Conflict Preemption*

In 1992, Alexis Geier owned a 1987 Honda Accord.[31] The Accord was equipped with shoulder and lap seatbelts, known as active restraints.[32] The Accord collided with a tree, and though wearing her seatbelt, Geier was seriously injured.[33] At the time of the collision, however, the Accord was not equipped with airbags or any other passive restraint devices.[34]

Geier and her parents (Geier) filed a lawsuit against the manufacturer of the Accord, the American Honda Motor Company, under District of Columbia tort law.[35] Geier claimed that Honda "had a duty to design, manufacture, distribute and sell a motor vehicle with an effective and safe passive restraint system, including, but not limited to, airbags."[36] Honda argued that Geier's "no airbag" lawsuit was preempted by the Federal Motor Vehicle Safety Standard 208 (FMVSS) which, at the time, gave car manufacturers a choice as to whether to install airbags in certain vehicles.[37]

The district court agreed with Honda and determined that Geier's state-law claims were expressly preempted by a provision of the FMVSS which preempts "any safety standard" that is not identical to a federal safety standard applicable to the same aspect of performance.[38] The court of

[31] Geier v. Am. Honda Motor Co., 529 U.S. 861, 865 (2000).

[32] *Id.* An active restraint is a device which is not effective unless some action is taken by the occupants of a vehicle, such as fastening a seat belt. Chrysler Corp. v. Dep't of Transp., 472 F.2d 659, 664 (6th Cir. 1972). A passive restraint does not depend for its effectiveness upon any action taken by the occupants beyond that necessary to operate the vehicle. *Id.* (citation omitted). An airbag is a passive inflatable restraint system. *Id.*

[33] *Geier*, 529 U.S. at 865.

[34] *Id.*

[35] *Id.*

[36] *Id.* at 881.

[37] *Id.* at 865.

[38] *Id.*; *see also* 15 U.S.C. § 1392(d) (1988) (recodified at 49 U.S.C. § 30101 (1994)). In 1988, the statute that the district court held expressly preempted Geier's claims read as follows:

> (d) Supremacy of Federal standards; allowable higher standards for vehicles used by Federal or State governments.
>
> Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor

appeals affirmed the trial court's decision on different grounds.[39] The court of appeals noted that a "saving[s] clause" provision of the FMVSS could allow a "no airbag" lawsuit to continue; however, the court did not resolve that question as it determined that Geier's state-law claims impliedly posed an obstacle to the accomplishment of the FMVSS's objectives.[40] The Supreme Court of the United States granted certiorari to determine "whether the [FMVSS] pre-empts a state common-law tort action in which the plaintiff claims that the defendant auto manufacturer, who was in compliance with the standard, should nonetheless have equipped a 1987 automobile with airbags."[41]

The Supreme Court first asked whether the FMVSS expressly preempted Geier's claims, as the district court held.[42] At the time of this case, the FMVSS, in relevant part, read:

> Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.[43]

On its face that statute appears to expressly preempt Geier's claims; however, the Court held that a "saving[s] clause," located in the FMVSS, operates in a manner that saves a significant number of common-law liability cases from being summarily dismissed because of preemption

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vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard. Nothing in this section shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a safety requirement applicable to motor vehicles or motor vehicle equipment procured for its own use if such requirement imposes a higher standard of performance than that required to comply with the otherwise applicable Federal standard.

15. U.S.C. § 1392(d).

[39] *Geier*, 529 U.S. at 865.

[40] *See id.* at 865–66.

[41] *Id.* at 865.

[42] *Id.* at 867.

[43] 15 U.S.C. § 1392(d).

considerations.[44] The savings clause provision states "compliance with" a federal safety standard "does not exempt any person from liability under common law."[45] Because of the existence of the savings clause, the Court determined that the requirements imposed by the express preemption provision were "federal law" that created "only a floor," while leaving state tort law adequate room to operate.[46] The Court reasoned that a broad reading of the "express preemption" provision, without the savings clause, would allow the preemption provision to preempt all "standards imposed in common-law tort actions, as well as standards contained in state legislation or regulations."[47] The Court referred to the express preemption provision as a federally established "minimum standard" of preemption, but concluded that the record contained insufficient evidence to prove Congress's intent to preempt state statutes, regulations, and common-law tort claims.[48] Thus, the Court concluded that the FMVSS did not, in fact, expressly preempt Geier, as the district court held.[49]

Unfortunately for Geier, the Court was unwilling to stop its analysis with express preemption and asked whether the state-law tort action impliedly conflicted with the FMVSS.[50] More specifically, the Court examined whether the savings clause, by itself, barred the ordinary working of implied conflict preemption principles because the clause can operate in a way to save some state-law tort claims.[51] The Court noted that "nothing in the language of the saving[s] clause suggests an intent to save state-law tort actions that conflict with federal regulations."[52] Additionally, the "Court has repeatedly 'decline[d] to give broad effect to saving[s] clauses where doing so would upset the careful regulatory scheme established by federal law.'"[53] The Court concluded that not only does the savings clause fail to foreclose federal preemption on state-law tort claims, but rather the

[44] *Geier*, 529 U.S. at 867–68; *see also* 15 U.S.C. § 1397(k) (1988) (repealed 1994).

[45] *Geier*, 529 U.S. at 868.

[46] *Id.*

[47] *Id.*

[48] *See id.*

[49] *Id.* at 868.

[50] *Id.* at 869.

[51] *Id.* at 869–70.

[52] *Id.* at 869.

[53] *Id.* at 870 (quoting United States v. Locke, 529 U.S. 89, 106–07 (2000)); *see also* AT&T v. Cent. Office Tel., Inc., 524 U.S. 214, 227–28 (1998); Tex. & Pac. Ry. Co. v. Abilene Cotton Oil Co., 204 U.S. 426, 446 (1907).

savings clause foresees preemption in cases where state-law tort claims impliedly conflict with established federal safety standards.[54] In essence, the Court determined that the savings clause demonstrates Congress's intent to let a jury compensate a plaintiff for the "occasional nonuniformity" of federal safety standards when motor vehicle companies have failed to comply with the FMVSS[55]; however, the express preemption provision and the savings clause are harmonized by the Court as it determined that the federal safety standard will preempt the jury-imposed safety standard when the manufacturer complies with the FMVSS.[56]

Before addressing the ultimate issue, the Court noted two types of conflict preemption: "frustration-of-purpose" conflict preemption, whereby a state rule would prevent or frustrate the accomplishment of a federal objective; and "impossibility" conflict preemption, whereby it would be impossible for a party to comply with both federal and state law.[57] Both forms of preemption, the Court said, nullify conflicting state law under the Supremacy Clause of the United States Constitution.[58] After laying out this framework, the Court said the true question was whether the state-law "no airbag" claim that Geier brought conflicts with the federal safety standard.[59]

Geier and the dissenters argued that the state-law claim in no way conflicted with the federal regulation because the FMVSS merely establishes a "minimum airbag standard."[60] The Secretary of the Department of Transportation, however, made clear that the FMVSS deliberately provided auto manufacturers a wide range of choices among different passive restraint devices.[61] The Secretary said that the airbags were one of "several equally acceptable" devices and that the Department of Transportation neither "favored" nor expected the introduction of airbag systems, and at no point did the Department of Transportation formally require the use of airbags at the time of Geier's collision.[62] In fact, the

[54] *Geier*, 529 U.S. at 870.

[55] *See id.* at 871.

[56] *See id.* at 881.

[57] *Id.* at 873–74.

[58] *Id.*; *see also* Fid. Fed. Sav. & Loan Ass'n v. De la Cuesta, 458 U.S. 141, 152–53 (1982); English v. Gen. Elec. Co., 496 U.S. 72, 78–79 (1990).

[59] *See Geier*, 529 U.S. at 874.

[60] *See id.*

[61] *Id.* at 875; *see* Occupant Crash Protection, 49 Fed. Reg. 28,962, 28,965 (July 17, 1984) (to be codified at 49 C.F.R. pt. 571).

[62] *Geier*, 529 U.S. at 875–76; *see also* Occupant Crash Protection in Passenger Cars,

Department of Transportation specifically rejected a proposed FMVSS "all airbag" standard, opting to go with a variety of passive restraint device systems that the manufacturers had the option of implementing in their vehicles.[63]

Geier's tort action alleged, and depended on, Honda's duty to install airbags in its vehicles.[64] The Court determined that if such a case went to a jury and the jury was to impose that duty upon Honda, the outcome would be an imposed rule of state tort law forcing Honda to install airbags in all of its vehicles.[65] This result would clearly conflict with the "alternative options" approach that the FMVSS provided Honda at the time.[66] "Because the rule of law for which petitioners contend would have stood 'as an obstacle to the accomplishment and execution of' the important means-related federal objectives that [the Court has] just discussed, [Geier's claims] are preempted."[67]

Geier is the first of an important trilogy of preemption cases.[68] Not only does the *Geier* opinion clearly set forth the parameters of implied-conflict preemption—as of the year 2000—it also provides the reader with an important paragraph of dicta from Justice Breyer:

> One final point: We place some weight upon DOT's interpretation of FMVSS 208's objectives and its conclusion . . . that a tort suit such as this one would "'stan[d] as an obstacle to the accomplishment and execution'" of those objectives. Congress has delegated to DOT authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is "uniquely qualified" to comprehend the likely impact of state requirements . . . In these

Multipurpose Passenger Vehicles, Trucks, and Buses, 35 Fed. Reg. 16,927, 16,927 (Nov. 3, 1970) (to be codified at 49 C.F.R. pt. 571).

[63] *See Geier*, 529 U.S. at 878–79; *see also* Occupant Crash Protection, 49 Fed. Reg. at 28,965.

[64] *Geier*, 529 U.S. at 881.

[65] *Id.*

[66] *See id.*

[67] *Id.* at 881 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

[68] *See id.*

> circumstances, the agency's own views should make a difference.[69]

This dicta arises again in *Wyeth v. Levine*, and it is interesting to see how the *Wyeth* majority clearly tap dances around this insight.[70] This Author believes that the implied-conflict preemption law set forth in *Geier* is nearly eradicated by the Court in *Wyeth.*[71]

B. Riegel v. Medtronic, Inc.: *Express Federal Preemption*

Eight years after the Supreme Court laid out the parameters of implied-conflict preemption in *Geier*, the Court granted certiorari in an express preemption case: *Riegel v. Medtronic, Inc.*[72]

In 1996, Charles Riegel suffered a myocardial infarction, commonly known as a heart attack.[73] After suffering this heart attack, Riegel underwent a procedure called a coronary angioplasty,[74] which is a procedure used to open clogged heart arteries.[75] In order to do this, a doctor temporarily inserts a tiny medical balloon into the clogged arteries to help widen the artery which allows blood to flow more easily.[76] Riegel's right coronary artery was diffusely diseased and heavily calcified,[77] so his doctor inserted an Evergreen Balloon Catheter into the artery in an attempt to dilate, or widen, Riegel's artery.[78]

The Evergreen Balloon Catheter was marketed by Medtronic, Inc.[79] Companies that market medical devices must have "premarket" approval by

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[69] *Id.* at 883 (citations omitted).

[70] 129 S. Ct. 1187, 1201 (2009).

[71] *Id.*

[72] 128 S. Ct. 999, 1006 (2008).

[73] *Id.* at 1005; *see also* Mayo Clinic, Acute Myocardial Infarction (Heart Attack), http://www.mayoclinic.org/quality/ami.html (last visited Oct. 11, 2009).

[74] *Riegel*, 128 S. Ct. at 1005.

[75] Mayo Clinic, Coronary Angioplasty and Stents, http://www.mayoclinic.com/health/angioplasty/MY00352 (last visited Oct. 11, 2009).

[76] *Id.*

[77] A diffusely diseased and heavily calcified coronary artery is a problem with the heart. Specifically, it is a build-up of calcium deposits on the aortic valve in the heart, leading to heart murmurs. *See* Martha Grogan, Mayo Clinic, Aortic Valve Stenosis, http://mayoclinic.com/health/aortic-valve-calcification/HQ00245 (last visited Oct. 11, 2009).

[78] *Riegel*, 128 S. Ct. at 1005.

[79] *Id.*

the Food and Drug Administration (FDA) prior to marketing the product.[80] Although the regulation of new medical devices was an obligation typically regulated by the states,[81] in 1976 Congress passed the Medical Device Amendments of 1976 (MDA) "which swept back some state obligations and imposed a regime of detailed federal oversight."[82] The MDA includes an express preemption provision that states:

> 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-
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> > (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.[83]

The MDA established three levels of oversight for medical devices, depending on the risks the device presented.[84] A Class I device—which includes elastic bandages and doctor examination gloves—is subject to the lowest level of federal oversight under the MDA, while a Class III device—which includes replacement heart valves and pacemaker pulse generators—is subject to the heaviest premarket approval regulations under the MDA.[85]

The Evergreen Balloon Catheter was deemed a Class III medical device by the federal government.[86] In order for a Class III medical device to be given premarket approval by the FDA, the device undergoes a "rigorous" process,[87] including a 1,200-hour application review by the FDA, a full statement of the device's components, a referral to outside experts, and a duty to update the FDA on any changes in design specifications,

[80] *See id.* at 1002.

[81] *Id.*

[82] *Id.* at 1003.

[83] *Id.*; *see also* 21 U.S.C. § 360k(a) (2006).

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

[85] *Id.*

[86] *Id.* at 1005.

[87] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996).

manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness.[88]

As stated earlier, Riegel's right coronary artery was diffusely diseased and heavily calcified.[89] Even though the Evergreen Balloon Catheter's labeling stated that the device was contraindicated for patients with diffuse or calcified stenoses,[90] Riegel's doctor still utilized the device in attempt to dilate Riegel's arteries.[91] Additionally, the label on the catheter warned that the device should not be inflated beyond its burst pressure of "eight atmospheres," or roughly four inflations.[92] Despite the warning, Riegel's doctor inflated the catheter five times, or ten atmospheres.[93] Upon the fifth inflation of the Evergreen Balloon Catheter, the device ruptured inside of Riegel.[94] "Riegel developed a heart block, was placed on life support, and underwent emergency coronary bypass surgery."[95]

In April 1999, Riegel and his wife sued Medtronic in New York federal court, asserting claims of strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter.[96] At its core, Riegel's lawsuit alleged that the catheter was designed, labeled, and manufactured in a manner that violated New York common law, notwithstanding Medtronic's compliance with the FDA regulations.[97] In response, Medtronic pleaded that it had complied with the MDA's federal requirements and Riegel was federally preempted from suing the company.[98] The district court agreed, and even held that Donna Riegel, Charles' wife, was preempted from bringing a loss of consortium claim because it was derivative of her husband's preempted claims.[99] The Court of Appeals for the Second Circuit affirmed the decision, holding that the Riegels' claims were preempted because they "would, if successful, result in state 'requirements' that differed from, or

[88] *Riegel*, 128 S. Ct. at 1004–05; *see also* 21 U.S.C. § 360e(d)(6)(A)(i) (2006).

[89] *See supra* note 77 and accompanying text.

[90] *Riegel*, 128 S. Ct. at 1005.

[91] *Id.*

[92] *Id.*

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *Id.* at 1005–06.

[97] *Id.* at 1005.

[98] *See id.* at 1006.

[99] *Id.* at 1006.

added to [the device-specific federal requirements]."[100]

The Supreme Court noted that the MDA expressly preempts state "requirements" that are "different from, or in addition to any requirement applicable . . . to the device."[101] "Safety and effectiveness are the very subjects of the Riegels' common-law claims, so the critical issue is whether New York's tort duties constitute 'requirements' under the MDA."[102]

The Court cited *Medtronic, Inc. v. Lohr* while discussing the MDA's premarket approval process.[103] The MDA's premarket approval imposes "requirements," and the process is "in no sense an exemption from federal safety review—it *is* federal safety review."[104] Compliance with the MDA, and approval from the FDA, is certification that the device provides a reasonable assurance of safety and effectiveness.[105] In *Lohr*, the Court held that "common-law causes of action for negligence and strict liability do impose 'requirement[s],' and would be preempted by federal requirements specific to a medical device."[106] Because the Riegels argued that state-law tort liability was not a "requirement" under the MDA, the Court was charged with the responsibility of determining whether a tort victim's state-law claims are "requirements" that would be preempted by federal law[107]. With this in mind, the Court said that "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's 'requirements' includes its common-law duties."[108] The Court went on to say that if a jury-imposed sanction against a medical device manufacturer or marketer required the device to be "safer" than the model constructed by the FDA, then such a system would disrupt the carefully designed federal regulatory scheme.[109] Because a jury does not consciously conduct a cost-benefit analysis—weighing the safety of a device versus how effective it is—the Court said that "tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation," and is more readily

[100] *See* Riegel v. Medtronic, Inc., 451 F.3d 106, 120 (2d Cir. 2006).

[101] *Riegel*, 128 S. Ct. at 1006.

[102] *Id.* at 1007.

[103] *Id.*; *see* Medtronic, Inc. v. Lohr, 518 U.S. 470, 492–93 (1996).

[104] *Riegel*, 128 S. Ct. at 1007 (emphasis in original).

[105] *See id.* at 1007.

[106] *Id.* at 1007.

[107] *See id.*

[108] *Id.* at 1008.

[109] *See id.*

preempted.[110]

The dissent in *Riegel* vigorously argued that all tort suits falling under the Food, Drug, and Cosmetics Act (FDCA), such as drug or additive approval suits, will be preempted based upon the Court's holding.[111] The Court, however, was quick to diffuse the dissent and noted that the only types of lawsuits that Congress has expressly preempted are suits falling under the MDA.[112] More specifically, Congress has only expressed its intent to federally preempt suits against medical devices.[113]

Perhaps the most important part of *Riegel* is the lesson learned regarding express preemption: without an express preemption clause written into an act of Congress, the Court is unwilling to preempt a state-law tort claim.[114] The Riegels' claims, however, were claims against a marketer of a medical device and they were seeking to impose a state-law tort duty, or an "additional requirement," on a product that was expressly governed by the MDA.[115] Because the Riegels' claims fell within the purview of the MDA, they were preempted from recovering damages under New York tort law.[116]

The Court did note, however, that a state law providing a damages remedy against a manufacturer or marketer for violating the MDA would allow a plaintiff to recover damages because such a remedy would be "parallel" to the MDA and not "in addition to" the federal requirements.[117] Both the district court and the Supreme Court noted that such recovery for the Riegels would be possible if they were, in fact, only seeking a parallel remedy; however, the claims that the Riegels asserted against Medtronic were such that "Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements."[118] Because Medtronic marketed the Evergreen Balloon Catheter in compliance with the MDA, the Riegels were preempted.[119]

[110] *Id.* at 1008.

[111] *Id.* at 1016–18 (Ginsburg, J., dissenting).

[112] *See id.* at 1009 (majority opinion).

[113] *Id.* at 1009.

[114] *See id.* at 1006–07.

[115] *Id.* at 1009.

[116] *See id.* at 1011.

[117] *See id.*

[118] *Id.* at 1011.

[119] *Id.*

C. Wyeth v. Levine: *No Federal Preemption—the Beginning of the End for Implied-Conflict Federal Preemption*

The *Wyeth* opinion is fairly complex. The preemption doctrines developed in *Geier* and *Riegel* can clearly be spotted throughout the opinion, which makes the reasoning by the Court surprising in the respect they did not rely on the precedent established by *Geier* for *Wyeth*, which appears to be a implied-conflict preemption case.

The Author believes the most interesting portion of *Wyeth* is the last paragraph of Justice Thomas's concurrence. In hindsight, this paragraph seems prophetic: the core of Thomas's beliefs mirror the message detailed by President Barack Obama in a directive issued by the White House a mere seventy-seven days after the Court decided *Wyeth.* This section will illustrate how the *Wyeth* opinion and the President's directive work in conjunction to essentially eliminate implied-conflict preemption.

1. *Wyeth:* The Majority Opinion

On previous visits to her local Vermont clinic for migraine headaches, Diana Levine received intramuscular injections of the drugs Demerol for migraine headaches and Phenergan for nausea.[120] During the morning of April 7, 2000, Levine visited the clinic for migraine treatment with those drugs.[121] Unfortunately, the treatment did not provide her relief and Levine returned later in the day for a second round of treatment with the same drugs.[122] This time, however, the physician's assistant administered the drugs via the "IV-push" method, by which the physician injected the drugs directly into Levine's veins in her right arm.[123] Tragically, the drug escaped from Levine's vein either because of a vein puncture or because the Phenergan came into contact with arterial blood.[124] It was not long before Levine, a professional musician, developed gangrene in her right arm.[125] The doctors performed immediate surgery, first amputating her right hand,

[120] Wyeth v. Levine, 129 S. Ct. 1187, 1191 (2009).

[121] *Id.*

[122] *Id.*

[123] *Id.*

[124] *Id.*

[125] *Id.*

and then her entire forearm.[126]

Levine brought suit against the local clinic, the clinician, and Wyeth, the company who manufactured the Phenergan, relying on common-law theories of negligence and strict liability.[127] Levine alleged that Wyeth should have provided a warning on the label of the Phenergan that clinicians should only administer the drug through the "IV-drip" method of administration—whereby the clinician injects the drug into an IV bag, rather than directly into the veins with the IV-push method—but consciously failed to do so.[128]

After Levine settled with the clinic and the clinician, Wyeth filed a motion for summary judgment alleging that Levine's "failure to warn" claims were preempted by federal law.[129] Wyeth claimed that the FDCA and the FDA preempted Levine's state-law tort claims.[130]

The trial judge denied the motion for summary judgment, and at trial, the judge instructed the jury that they could consider the evidence of Wyeth's compliance with FDA's regulations as evidence of an adequate warning, but that compliance alone was insufficient to prove adequacy.[131] Moreover, the trial judge instructed the jury, without objection from Wyeth, that the FDA regulations "permit a drug manufacturer to change a product label to add or strengthen a warning about its product without prior FDA approval so long as it later submits the revised warning for review and approval."[132] After these instructions, counsel for Levine told the jury during closing argument, without an objection from Wyeth, "Thank God we don't rely on the FDA to . . . make the safe[ty] decision. You will make the decision. . . . The FDA doesn't make the decision, you do."[133]

After the five-day jury trial, the Vermont jury returned a verdict in favor of Levine, with damages totaling $7,400,000.[134] The Vermont Supreme Court affirmed, holding that the FDA labeling requirements did not conflict with Vermont common law "because [Wyeth] could have warned against IV-push administration without prior FDA approval, and because federal

[126] *Id.*

[127] *Id.*

[128] *Id.* at 1191–92.

[129] *Id.* at 1192.

[130] *See id.* at 1192, 1195.

[131] *Id.* at 1192–93.

[132] *Id.* at 1193.

[133] *Id.* at 1218.

[134] *Id.* at 1193.

labeling requirements create a floor, not a ceiling, for state regulation."[135] Shortly after the Vermont Supreme Court's opinion, the FDA amended a preamble to a regulation, claiming that the FDCA created "both a 'floor' and a 'ceiling'" so that "FDA approval of labeling . . . preempts conflicting or contrary State law."[136] Additionally, the FDA preamble claimed that state-law "failure to warn" claims "threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs."[137]

On certiorari to the Supreme Court of the United States, Wyeth contended that the FDA requirements constitute both a floor and a ceiling for a manufacturer's duty for labeling products.[138] Wyeth advanced two "implied conflict" preemption arguments: first, that it would be impossible for it to comply with the state-law duty to modify the Phenergan drug label while complying with federal law; and second, that recognition of Levine's state-law tort claim would frustrate the "full purposes and objectives of Congress" because it substitutes a lay jury's opinion for the expertise of the congressionally enacted FDA.[139]

Wyeth first argued that it would be impossible to comply with both the state-law duties and its federal labeling duties under the FDCA because Wyeth could only change the label on the Phenergan without the FDA's initial approval if there is "newly acquired information" about the product.[140] The Court dismissed this argument because the FDCA contains a "changes being effected" regulation that provides a manufacturer the opportunity to make certain changes to the labeling of its product before receiving approval from the FDA.[141] This regulation allows a manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug

[135] *Id.* (citing Wyeth v. Levine, 944 A.2d 179, 184 (Vt. 2006)).

[136] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

[137] *Id.* at 3935.

[138] *See Wyeth*, 129 S. Ct. at 1193–94.

[139] *Id.*; *see also* Hines v. Davidowitz, 312 U.S. 52, 67 (1941) (supporting the idea that federal law can preempt state laws that stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress).

[140] *See Wyeth*, 129 S. Ct. at 1196.

[141] *Id.*; *see also* 21 C.F.R. § 314.70(c)(6)(iii)(A)(C) (2006).

product."[142] Therefore, Wyeth could have strengthened the warning on the Phenergan and accomplished simultaneous compliance with its state-law and federal labeling duties.[143] Moreover, the Court dismissed Wyeth's "newly acquired information" argument because Wyeth was interpreting the term too narrowly—"newly acquired information," as defined by the FDA, encompasses new data and new analyses of previously submitted data.[144] Levine introduced evidence at trial of "at least 20 incidents prior to her injury in which a Phenergan injection resulted in gangrene and amputation."[145] Additionally, Levine put on evidence that, after the first incident, Wyeth contacted the FDA and reported the injury.[146] The Supreme Court determined that this would be a "new analys[i]s of previously submitted data," and thus, Wyeth could have strengthened the label to warn of the risks associated with the IV-push administration.[147]

Noting that "the manufacturer bears responsibility for the content of its label at all times,"[148] the Court said that "[i]mpossibility preemption is a demanding defense. On the record before us, Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements."[149]

Wyeth's second argument leaned heavily on implied-conflict preemption, or "purposes and objectives" preemption, as laid out by the Supreme Court in *Hines*,[150] and reiterated in *Geier*.[151] Wyeth argued that Congress entrusted the FDA to make drug labeling decisions that strike a balance between competing objectives.[152] Wyeth pointed to the FDA's preamble as evidence that the FDA standards are a floor and a ceiling for their drug labeling requirements,[153] and that based on this preamble, the

[142] *Wyeth*, 129 S. Ct. at 1196.

[143] *See id.*

[144] *See id.* at 1197; *see also* Changes to the January 2008 Rule, 73 Fed. Reg. 49,604, 49,604 (Aug. 22, 2008).

[145] *Wyeth*, 129 S. Ct. at 1197.

[146] *Id.*

[147] *See id.*

[148] *Id.* at 1197–98.

[149] *Id.* at 1199.

[150] *See supra* note 139 and accompanying text.

[151] *See* 529 U.S. 861, 873 (2000).

[152] *Wyeth*, 129 S. Ct. at 1199.

[153] *See id.; see also* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006) (to be

jury-imposed duty stemming from state law is an implied-conflict like we saw in *Geier*.[154]

The Court conceded that agency regulations have the force and effect of law and that it is possible that a regulation could preempt a state law requirement.[155] The Court also said that they will give "some weight" to an agency's view on how state tort law will impact its regulations when "the subject matter is technica[l] and the relevant history and background are complex and extensive."[156] Such a proclamation by a federal agency, however, will only be given "some weight" when the agency's statement is thorough, consistent, and persuasive, as opposed to a mere conclusion leading to preemption.[157] After proclaiming that the FDA preamble "does not merit deference," the Court cited to an FDA-issued notice of proposed rulemaking in December 2000, when the FDA said that the preamble would "not contain policies that have federalism implications or preempt State law."[158] More importantly, however, the Court placed heavy weight on the fact that Congress was silent about whether this preamble would preempt state-law claims.[159] The Court, noting the express preemption provision in *Riegel*, said:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.[160]

codified at 21 C.F.R. pts. 201, 314, 601).

[154] *Wyeth*, 129 S. Ct. at 1203.

[155] *Id.* at 1200; *see, e.g.*, *Geier*, 529 U.S. at 886.

[156] *Wyeth*, 129 S. Ct. at 1201 (citing *Geier*, 529 U.S. at 883).

[157] *See id.*

[158] *Id.*; *see also* Exec. Order No. 13,132, 65 Fed. Reg. 81,103, 81,103 (Dec. 22, 2000).

[159] *See Wyeth*, 129 S. Ct. at 1200.

[160] *Id.* (citations omitted). Although the citation was omitted in the above quote, the Court cited direct language from *Riegel*: "Congress could have applied the pre-emption clause to the

Wyeth and the dissent argued that the facts presented in this case were identical to the facts of *Geier*.[161] In fact, the dissent claimed that "[t]his case illustrates that tragic facts make bad law" and that the "result [the majority arrives to] cannot be reconciled with *Geier* or general principles of conflict preemption."[162] The majority, however, distinguished the FMVSS regulation in *Geier* from the FDA preamble in this case by noting that the Department of Transportation in *Geier* conducted a formal rulemaking, devised a plan to phase in passive restraint devices, and expressly enumerated the factors that they weighed and relied upon in coming to its conclusion that the FMVSS should have preemptive power.[163] The FDA preamble, on the other hand, was merely an agency's conclusion that conflicted with the goals of the FDA and was bare of analysis.[164] With regard to Wyeth's "purposes and objectives" implied preemption argument, the Court said that "Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight."[165]

The *Wyeth* Court, in a six-three decision, affirmed the Vermont Supreme Court, holding that "it is not impossible for Wyeth to comply with its state and federal law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA."[166]

2. *Wyeth*: Justice Thomas's Concurrence and President Obama's Directive

Justice Thomas was one of six members of the Court comprising the

entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices." Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1009 (2008). This is particularly intriguing because Wyeth was not arguing for express preemption, but rather for implied-conflict preemption as defined in *Geier*. The Court appears unwilling to apply an implied-conflict preemption analysis in this case, but rather wanted to see hard evidence from Congress, in the form of an express preemption clause, before determining that Levine was preempted.

[161] *See Wyeth*, 129 S. Ct. at 1203; *see id.* at 1217–31 (Alito, J., dissenting).

[162] *Id.* at 1217 (Alito, J., dissenting).

[163] *Id.* at 1203 (majority opinion).

[164] *See id.* at 1201–03.

[165] *Id.* at 1204.

[166] *Id.*

majority in *Wyeth*.[167] Prior to *Wyeth*, Justice Thomas was becoming increasingly alarmed by the frequent use of the implied-conflict preemption doctrine.[168] Justice Thomas's frustrations came to a head in *Wyeth* as he wrote a concurring opinion that was almost equal in length to the majority's opinion.

Justice Thomas noted that he had "become increasingly skeptical of the Court's 'purposes and objectives' pre-emption jurisprudence" because "the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law."[169] Justice Thomas went so far as to call the recent implied-conflict preemption jurisprudence "inconsistent with the Constitution."[170] After surveying the facts of *Wyeth* and the history of federal preemption, Justice Thomas concluded his concurrence by taking a bold stance against implied-conflict preemption:

> The origins of this Court's "purposes and objectives" pre-emption jurisprudence in *Hines*, and its broad application in cases like *Geier*, illustrate that this brand of the Court's pre-emption jurisprudence facilitates freewheeling, extratextual, and broad evaluations of the "purposes and objectives" embodied within federal law. This, in turn, leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution and the agency actions authorized thereby. Because such a sweeping approach to pre-emption leads to the illegitimate—and thus, unconstitutional—invalidation of state laws, I can no longer assent to a doctrine that pre-empts state laws merely because they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of federal

[167] *See id.* (Thomas, J., concurring in judgment).

[168] *See* Bates v. Dow Agrosciences, L.L.C., 544 U.S. 431, 456–59 (2005) (Thomas, J., concurring in judgment in part and dissenting in part); Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 678 (2003) (Thomas, J., concurring in judgment) (referring to the "concomitant danger of invoking obstacle pre-emption based on the arbitrary selection of one purpose to the exclusion of others").

[169] *Wyeth*, 129 S. Ct. at 1205 (Thomas, J., concurring in judgment).

[170] *Id.*

law, as perceived by this Court.[171]

On March 4, 2009, Justice Thomas called the Court's holding in *Geier* a "broad application" of pre-emption and put the Court on notice that he is no longer on board with the implied-conflict preemption jurisprudence.[172] A mere seventy-seven days later, President Barack Obama issued an executive directive entitled "Preemption."[173] On May 20, 2009, the President—intentionally or inadvertently—aligned himself with Justice Thomas on the issue of implied-conflict preemption. The President's directive states:

> From our Nation's founding, the American constitutional order has been a Federal system, ensuring a strong role for both the national Government and the States. The Federal Government's role in promoting the general welfare and guarding individual liberties is critical, but State law and national law often operate concurrently to provide independent safeguards for the public. Throughout our history, State and local governments have frequently protected health, safety, and the environment more aggressively than has the national Government.
>
> An understanding of the important role of State governments in our Federal system is reflected in longstanding practices by executive departments and agencies, which have shown respect for the traditional prerogatives of the States. In recent years, however, notwithstanding Executive Order 13132 of August 4, 1999 (Federalism), executive departments and agencies have sometimes announced that their regulations preempt State law, including State common law, without explicit preemption by the Congress or an otherwise sufficient basis under applicable legal principles.
>
> The purpose of this memorandum is to state the general policy of my Administration that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis

[171] *Id.* at 1217.

[172] *See id.*

[173] *See* Preemption, 74 Fed. Reg. 24,693, 24,693–94 (May 22, 2009).

> for preemption. Executive departments and agencies should be mindful that in our Federal system, the citizens of the several States have distinctive circumstances and values, and that in many instances it is appropriate for them to apply to themselves rules and principles that reflect these circumstances and values. As Justice Brandeis explained more than 70 years ago, "[i]t is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[174]

To a reader with knowledge of the issues in *Wyeth*, it seems clear that the President's directive specifically singles out general declarations of preemption like the FDA attempted in its 2006 preamble. In order to discourage federal agencies from enacting regulations preempting state law without a sufficient legal basis, President Obama provided a three-pronged directive to the agencies:

> 1. Heads of departments and agencies should not include in regulatory preambles statements that the department or agency intends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation.
>
> 2. Heads of departments and agencies should not include preemption provisions in codified regulations except where such provisions would be justified under legal principles governing preemption, including the principles outlined in Executive Order 13132.
>
> 3. Heads of departments and agencies should review regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption. Where the head of a department or agency determines that a regulatory statement of preemption or

[174] *Id.* at 24,693.

> codified regulatory provision cannot be so justified, the head of that department or agency should initiate appropriate action, which may include amendment of the relevant regulation."[175]

One can surely make the argument that the timing of the *Wyeth* decision and the issuance of the President's directive is a coincidence; however, the directive and the Court's holding in *Wyeth* act in concert to drastically limit the preemption power of a federal agency in a way that is more than mere happenstance. After reading President Obama's directive, it appears that Justice Thomas was not the only person in the government who was becoming "increasingly skeptical" of the implied-conflict preemption jurisprudence.

IV. CONCLUSION

From a lawyer's perspective, the recent decisions of the Supreme Court—along with the presidential directive—allow a practitioner to give more definitive advice to clients. A defense lawyer can tell her corporate clients that the Supreme Court has held that a company must comply with both federal regulations and jury-imposed tort duties. A plaintiff's lawyer can tell a judge at a summary judgment hearing that mere compliance with a federal agency regulation does not insulate a defendant from liability. A lawyer working for a federal agency can inform her colleagues that the proposed preemption regulation will not pass muster unless it complies with President Obama's directive and the Supreme Court's specificity requirement developed in *Riegel* and *Wyeth*.

Although not always crystal clear, the contemporary state of implied-conflict preemption is coming into focus. The days when a federal agency, such as the FDA, can amend its preamble with boilerplate preemptive language are over. With the Court's holding in *Wyeth*, it appears that implied-conflict preemption is over as well. At least for the time being, it's time to say goodbye to implied preemption.

[175] *Id.* at 24,693–94.