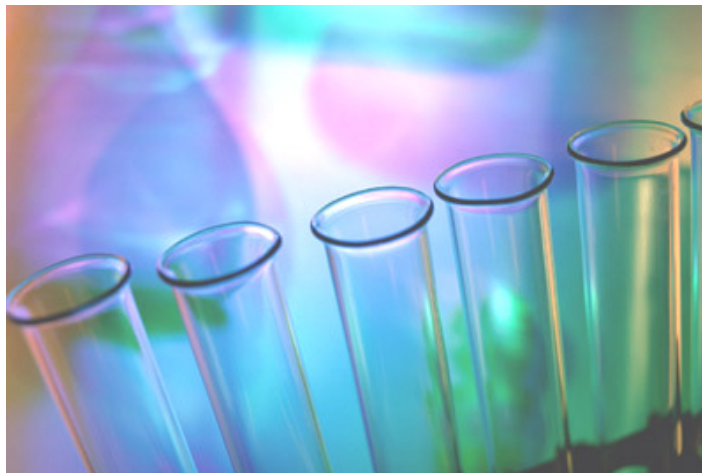




# **INVESTIGATIONAL DEVICES**

## AND THE DEFENSES THAT PROTECT THEM



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## I. The People's Preemption

The Supremacy Clause of the United States Constitution provides that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof ... shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."<sup>1</sup>

For over one hundred and fifty years, it has been settled that state law that conflicts with federal law is "without effect."<sup>2</sup> Consideration of issues arising under the Supremacy Clause "starts with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress."<sup>3</sup> Accordingly, "the purpose of Congress is the ultimate touchstone" of preemption analysis.<sup>4</sup> Congress has exercised this constitutional authority to supersede state regulation of medical devices.

In enacting the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §360c *et seq*, Congress swept back some state obligations and imposed a regime of detailed federal oversight.<sup>5</sup> To give the necessary authority to its new law and the regulations to be developed by the Federal Food and Drug Administration ("FDA"), the MDA includes an express pre-emption 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.

(1) which is different from or in addition to, any requirement applicable under this Act 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 Act.<sup>6</sup>

## II. Device Regulation under the MDA

Until the enactment of the MDA, the introduction of new medical devices was left largely for the States to supervise as they saw fit. The MDA established a regulatory regime imposing three levels of federal oversight for medical devices depending upon the potential risks they pose to the public.

Class I devices are subject to minimal controls by the FDA because of their generally accepted safety standards. Class II devices are subject to more specialized controls, such as performance standards or specific guidelines due to the fact that they are potentially more harmful in nature. Class III includes devices used in supporting or sustaining human life and those that present the greatest risk of causing injury.<sup>7</sup>

Class III devices are subject to the highest level of federal oversight. A Class III device that receives pre-market approval ("PMA") under the MDA has undergone a rigorous process, including the execution of intensive clinical trials.

PMA is an exhaustive process. Device manufacturers submit detailed information regarding the safety and efficacy of their devices to the FDA. The FDA then spends an average of 1,200 hours reviewing each submission.<sup>8</sup>

As part of the premarket approval application, a manufacturer must submit what is typically a multivolume application that includes, among other things:

- a full report of all studies and investigations of the device's safety and effectiveness;
- a full statement of the device's components, ingredients, and properties and of the principle or principles of operation;
- a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of such device;
- samples or device components required by the FDA; and
- a specimen of the proposed labeling.<sup>9</sup>

PMA imposes requirements under the MDA and is specific to individual devices.<sup>10</sup> As a result, premarket authorization preempts claims that seek to impose state requirements “different from, or in addition to” federal requirements. State common law claims are preempted for those devices having obtained PMA.<sup>11</sup>

### III. Finding Innovation

Congress also left room in the MDA to clear a path for innovation of medical

technology. Recognizing that new devices, by their very nature, cannot meet the requirements applicable to marketed devices, the FDA may grant exemptions to free promising new experimental devices from the usual PMA constraints. The Investigational Device Exemption (“IDE”) process is the FDA’s safety and efficacy review of investigational devices before the device manufacturer submits its PMA application. Under the IDE process, a device may be made available for use through a limited and controlled clinical trial. The FDA explains the purpose of the IDE process as follows:

to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end, to maintain optimum freedom for scientific investigators in their pursuit of this purpose.<sup>12</sup>

The regulations pertaining to the medical devices at issue serve three purposes: to encourage medical experimentation, to protect public health, and to ensure that interstate commerce is not unduly burdened.<sup>13</sup>

The FDA uses the IDE process to ensure that a new, experimental device is reasonably safe to commence a clinical trial. The parameters of the trial are designed with patient safety in mind, while providing the opportunity to test the efficacy of the new device.

Like the PMA application, a device manufacturer's IDE application must include detailed information about the new device and clinical study, including:

- Plan for studying its use in human subjects during the experimental period;
- Reports of all studies and investigations of the device's safety and effectiveness;
- Statement of the device's components, ingredients and properties and the principle of operation;
- Description of the methods used in and facilities and controls used for manufacture, processing and packaging;
- Samples or device components required by the FDA; and
- Samples of the proposed labeling.<sup>14</sup>

The FDA reviews the application, which it must approve along with the Institutional Review Board (IRB) of each study center before the trial can begin.<sup>15</sup> Along with the FDA, the IRB must continue to monitor the clinical trial during the course of the study.<sup>16</sup> Any changes to the medical device or the clinical protocol must be reviewed and approved by the FDA.<sup>17</sup> These detailed regulations ensure that the design of the device and the protocol is sufficiently safe and effective to allow experimental use on human beings.<sup>18</sup>

#### **IV. The Power of the FDA**

In enacting the MDA, Congress specifically empowered the FDA to develop requirements to encourage innovation in new experimental devices. Consequently,

Congress specifically reserved to the federal government the role of setting requirements for safety and effectiveness of new devices intended for human use. Courts have found this intent in the general language of 21 U.S.C. §360j(g)(1), 21 C.F.R. § 812.1(a), and the specific language of 21 U.S.C. § 360k(a), which precludes state requirements that impose inconsistent or additional standards than does the MDA, including situations in which the device is being used subject to an FDA approved IDE.<sup>19</sup>

This Congressional intent preempts state common law claims if the FDA has approved a device under an IDE application, such as the IDE approvals for intraocular lenses,<sup>20</sup> hip stems,<sup>21</sup> and pacemakers.<sup>22</sup> Courts found that the plaintiffs' standard legal theories – strict liability, negligence, and/or breach of implied warranty of merchantability – directly collided with federal policy, because the FDA had already decided, rightly or wrongly, that a particular device could be sold, subject only to the FDA's requirements designed to show that the conditional distribution was in pursuit of a worthwhile experiment.

#### **V. IDE and PMA: Equal in the Eyes of Preemption**

In the 2008 U.S. Supreme Court decision *Riegel v. Medtronic, Inc.*, the Court addressed the issue of the preemptive effect of the MDA and held that the language contained in the MDA precluded state law tort claims against medical device manufacturers in the context of a Class III PMA approved device. Since that time, many courts have found preemption of state law claims in the context of Class III devices which received clearance pursuant

to the investigational device exemption.<sup>23</sup>

Post-*Riegel*, courts have consistently applied preemption to cases involving investigational devices. The FDA's regulation of IDE devices provides manufacturers the same extensive preemption afforded a drug that has PMA status, as discussed in *Riegel*.<sup>24</sup>

By its very nature, an investigational approval recognizes that the device may be neither safe nor effective, but the public interest may be served by using the device consensually to determine whether the benefits to be achieved through its use outweigh safety or effectiveness issues. A purpose of the IDE process is to encourage experimentation. IDE approval is within the express purview of the MDA, is a step on the way to potential PMA, and courts usually apply preemption provisions equally to IDE approvals.<sup>25</sup>

Notably, MDA preemption for a device is stronger than preemption afforded to drug manufacturers under the Supreme Court's decision in *Wyeth v. Levine*.<sup>26</sup> Drug manufacturers have had to rely upon *implied* preemption since there is no similar express preemption by Congress.<sup>27</sup> Drugs approved for sale under the Food, Drug, and Cosmetic Act ("FDCA"), are deemed "safe and effective" along with the exact language of the label and the packaging inserts. After *Levine*, a drug manufacturer must prove that the FDA would not have approved a change to the drug's label to take advantage of the implied preemption argument.<sup>28</sup> If a drug manufacturer cannot meet this burden, a state may impose requirements "in addition to" the FDA's mandates.<sup>29</sup>

Devices approved through the IDE process have strong preemption defenses that have remained intact despite *Levine*.<sup>30</sup> Plaintiffs cannot seek state relief for regulations "different from, or in addition to" the FDA's requirements. This is true even during the investigational stage, when the medical device at issue is undergoing a clinical trial subject to an FDA approved IDE application.

## VI. The FDA's Balancing Act

The determining factor in the preemption analysis is the rigorous demands of the FDA approval process – federal requirements which the applicant must follow. In granting IDE applications, the FDA exercises its authority to ensure the device was as safe and effective as possible before giving the clinical trial the green light.

The FDA is an active regulatory agency, not merely a passive administrative body that rubber-stamps suggested changes. It imposes operational safeguards on the conduct of clinical trials and can also mandate restrictions to the device's design, even requiring manufacturers to obtain approval for design changes that the manufacturer itself suggests.

IDE applications include specific information about design, labeling, informed consent language, reliability testing, data on prior clinical trials and available scientific literature. The FDA can impose further testing and compatibility requirements before granting its approval to proceed with the change. An approved IDE application is not an invitation to experiment wildly. Instead, the device and clinical trial are subjected to great scrutiny.<sup>31</sup> The FDA reviews, manages, and approves all aspects of the clinical trials to ensure that a

proposed new medical device and the clinical trial plan delicately balance safety and effectiveness with innovation and the potential benefit for public health.

Plaintiffs bringing claims for improper design contend that the FDA imposes no requirements over a particular device's design, and thus, there is no direct federal regulation and section 360(k) preemption does not apply. This argument assumes that the only federal requirement that might relate to the safety or effectiveness of a medical device's design would be an actual specification of that design. This cramped interpretation of section 360(k) would cripple the exemption for investigational devices. The FDA hardly can be expected to specify the safe and effective design of an investigational device.<sup>32</sup> If there was a known safe and effective design, there would be no experiment. The point of the experiment is to find out whether it is safe and effective.<sup>33</sup> The FDA determined, by granting the IDE application, that the device had sufficient promise of being proven safe and effective to justify the risk of its use on human beings. A finding that the device was not sufficiently safe and effective would directly conflict with the FDA's judgment.

## **VII. The Trump Card**

State common-law liability is "premised on the existence of a legal duty," and a tort judgment establishes that the defendant has violated a state-law obligation.<sup>34</sup> While the common-law remedy is limited to damages, a liability award is the state's exercise of governing conduct and controlling policy. A jury's decision, resting upon only those limited facts that can be presented in a trial, cannot replace the

conclusion of numerous FDA scientists, physicians, consultants, and experts who have virtually no restrictions on the information and data available to them for review, who conduct a detailed cost-benefit analysis for each new medical device considered, and who determine how many lives will be saved by the device which, along with greater effectiveness, may bring a greater risk of harm. The state cannot find that the FDA's intricate review and ultimate judgment violated a state obligation. The Constitution precludes it.

As a practical matter, FDA approved clinical trials take place throughout the United States to generate sufficient data to evaluate the safety and efficacy of the new device. If each state could impose its own requirements for the design of the device or for conducting the clinical trial, it would render the process infeasible and the market would be starved of new and innovative devices.

To investigate and meet the various requirements for safety and effectiveness each state might impose would be prohibitively expensive. Additionally, the data generated by clinical trials conducted simultaneously in various states with different standards would generate inconsistent data and would render scientifically invalid results. Such a decentralized regulatory scheme would completely undermine and ultimately defeat the process established by Congress that is meant to encourage, rather than to discourage, innovation. Congress has the constitutional power to displace state tort law remedies, and, for the reasons discussed above, clearly did so by enacting the MDA.

### VIII. Persistent Plaintiffs, Informed Consent, and Preemption

In connection with the IDE application and approval process, the FDA reviews all aspects of a clinical trial including the design and manufacturing of the device, the structure of the study's protocols, the informed consent form, and patient and physician instructional materials before it gives approval for the trials to commence.

To participate in a clinical trial, medical device manufacturers and medical providers are required by specific FDA regulations to provide written informed consent to patients participating in the study. The form seeks to provide the patient information about possible benefits, risks and complications, and to assure the patient that consent to the procedure. The FDA approves the form and substance of each such informed consent document.

In the ever-present effort by the plaintiffs' bar to sidestep preemption, a novel niche of arguments has evolved surrounding the informed consent document. In one line of cases, the focus is on the following language in the form, "Nothing in this informed consent shall act to waive any of your legal rights..." This phrase, or language similar to it, prohibits any attempt to insert exculpatory provisions in the informed consent document and is mandated by the FDA.

Plaintiffs have argued that this "legal rights" language in the form effectively trumps the preemption language of other regulations and the statute. Put another way, defendants waive any and all procedural defenses, *including preemption*, based on that language contained in the form. This

argument suggests that by obtaining patient consent to the procedure, the patient acquires greater legal standing than is even available under the law. And, that a manufacturer or a hospital would forego certain legal 'rights' which they are powerless to waive at any stage of the litigation.

This approach is inconsistent with the fundamental rule in statutory construction - that all laws are presumed to be consistent with each other should be harmonized by courts whenever possible.<sup>35</sup> In fact, it is possible to harmonize the two arguably conflicting regulations. The consent regulation should be read to prevent patients from waiving legal rights *which are not preempted under federal law*, and courts have done just that.<sup>36</sup>

Although this waiver argument does not appear to be a strong one, it illustrates the climate of medical device litigation, and specifically the constant line of attack against preemption.

### IX. Conclusion

As medicine progresses and research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The committee wants to encourage their research and development. The committee also wants to be sure that the FDA has the proper authority to regulate that process so that Americans are not put at risk from the use of unsafe and ineffective medical devices.

The regulations, by placing substantial authority in the FDA to regulate medical devices and grant investigational exemptions, attempt to balance and satisfy these sometimes diverging goals.

Although preemption may permit a manufacturer to escape liability for an allegedly defective device and leave a plaintiff with no recourse for an injury or death, preemption also encourages future experimentation so that more individuals will have the opportunity to experience life saving treatments and products.

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<sup>1</sup> Art VI, clause 2.

<sup>2</sup> *McCulloch v. Maryland*, 17 U.S. 316, 4 Wheat 316, 427, 4 L. Ed. 579 (1819).

<sup>3</sup> *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 91 L. Ed. 1447, 67 S. Ct. 1146 (1947).

<sup>4</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608, 120 L. Ed. 2d 407, 422 (1992). *Accord Medtronic v. Lohr*, 518 U.S. at 485, 135 L. Ed. 2d 700, 116 S. Ct. 2240, 1996 U.S. LEXIS 4260 at \*27.

<sup>5</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1002-03 (2008).

<sup>6</sup> 21 U.S.C. § 360k(a). The exception contained in subsection (b) permits the FDA to except some state and local requirements from pre-emption.

<sup>7</sup> *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D. Pa. 1992), *citing* 21 U.S.C. § 360c(a)(1)(A)-(C).

<sup>8</sup> *Riegel*, 128 S.Ct. 999, 1004 (2008) (*citing Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240, 2247 (1996)).

<sup>9</sup> *Riegel*, 128 S. Ct. at 1004 (*citing* 21 U.S.C. § 360e(c)(1)) (internal quotations omitted).

<sup>10</sup> *Riegel*, 128 S. Ct. at 1007.

<sup>11</sup> *Id.*

<sup>12</sup> 21 U.S.C. §360j(g)(1); 21 C.F.R. § 812.1(a).

<sup>13</sup> *Hunsaker*, *citing* S. Rep. No. 33, 94th Cong., 2d Sess. 1070, 1071 (1976); H.R.Rep. No. 853, 94th Cong., 2d Sess. 45 (1976).

<sup>14</sup> 21 C.F.R. §812.20.

<sup>15</sup> 21 C.F.R. §812.20, §812.30 and §812.62.

<sup>16</sup> 21 C.F.R. §812.64.

<sup>17</sup> 21 C.F.R. §812.35.

<sup>18</sup> *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 545 (3d Cir.), *cert. denied*, 513 U.S. 965, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7<sup>th</sup> Cir. 1992).

<sup>19</sup> *See Chambers v. Osteonics Corp.*, 109 F.3d 1243 (7th Cir. 1997); *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997), petition for cert. filed, 65 U.S.L.W. 3755 (U.S. May 1, 1997) (No. 96-1749); *Gile*, 22 F.3d 540; *Slater*, 961 F.2d 1330; *Berish v. Richards Medical Co.*, 937 F. Supp. 181, 195-96 (N.D.N.Y. 1996).

<sup>20</sup> *Gile*, 22 F.3d 540 (recognizing that the MDA included an express preemption provision and the Congressional intent that the FDA should encourage the discovery and development of devices for human use); *see also Slater*, *supra*.

<sup>21</sup> *Chambers*, 109 F.3d 1243.

<sup>22</sup> *Martin*, *supra*.

<sup>23</sup> *Riegel*, 128 S. Ct. at 1008 (2008).



<sup>24</sup> See *Robinson v. Endovascular Technologies, Inc.* (No: 1-03-CV-009655, Cal. Super. Santa Clara Co., Dec. 2008); *Norks v. Endovascular Technologies*, (No: 1-03-CV-010668, Cal. Super. Santa Clara Co., Dec. 2008).

<sup>25</sup> *Robinson, supra*; *Nork, supra*. Another court dismissed with prejudice an entire MDL master complaint - more than 20 counts - finding that the MDA preempted **every** claim. *In re Medtronic*, 592 F. Supp. 2d 1147 (D. Minn. 2009).

<sup>26</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009).

<sup>27</sup> *Id.* at 1201.

<sup>28</sup> See *Baumgardner v. Wyeth Pharmas.*, No.05-5720 (E.D. Pa. Aug. 31, 2010).

<sup>29</sup> This is the pivotal difference between drug preemption and medical device preemption arguments: states in neither instance may impose regulations “different from” FDA requirements, but only medical device manufacturers have the assurance that states may not impose regulations “in addition to” FDA requirements.

<sup>30</sup> *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, No. 09-2290, 2010 U.S. Dist. LEXIS 21253, \*10 (8th Cir. Oct. 15, 2010) (“Congress did not extend the express preemption for medical devices in § 360k to prescription drugs.”).

<sup>31</sup> Indeed, a comparison between what is required for a PMA approval (21 U.S.C. §360e(c)(1); 21 U.S.C. §814.20) and what is required for FDA approval of an IDE (21 U.S.C. §812.20) reveals that the information and data required by the FDA is nearly the same.

<sup>32</sup> *Gile*, 22 F.3d at 544-45 (citing *Slater*, 961 F.2d at 1333). However, the FDA does exercise its authority over specific design requirements, including requirements for the structure and operation of the investigational protocol, reliability testing data, and the design of the device itself. It reviews design specifications, bench testing data, animal testing results, and the outcomes of any foreign clinical trial. The FDA grants the IDE application under the specific regulations it imposes, solidifying its determination that the device is safe and effective for use on human beings who agree to be a participant in a clinical trial.

<sup>33</sup> *Id.* See also *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1283 (D.C. Cir. 1983).

<sup>34</sup> *Riegel, supra* (citing *Cipollone*, 112 S. Ct. at 2608).

<sup>35</sup> *Hunsaker, citing* 73 Am.Jur.2d *Statutes* § 254 at 425.

<sup>36</sup> *Id.*, emphasis added.