Oklahoma Journal of Law and Technology

Volume 9 | Number 1

January 2013

When the Feds Have Taken the Field: Federal Field Preemption of Claims Against Manufacturers Whose Medical Devices Have Received Premarket Approval by the FDA

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9 Okla. J.L. & Tech. 65 (2013)
www.okjolt.org

WHEN THE FEDS HAVE TAKEN THE FIELD: FEDERAL FIELD PREEMPTION OF CLAIMS AGAINST MANUFACTURERS WHOSE MEDICAL DEVICES HAVE RECEIVED PREMARKET APPROVAL BY THE FDA

Imagine a neurology patient who is a long term sufferer of Parkinson's Disease. Parkinson's is caused by a deficiency of the neurotransmitter dopamine in the brain. Its symptoms include stiffness in motion, droopy posture, and rhythmic muscle tremors that can make even the most mundane of tasks nearly impossible to perform without assistance.[1] Now imagine that persons' neurologist offering a solution to his chronic condition: a pair of tiny electrodes implanted in both hemispheres of the brain that would stimulate the brain tissue, resulting in diminished symptoms. The patient seizes the opportunity to reduce, or possibly even end, years of misery caused by his condition. After the surgery, the results are fantastic. The Parkinsonian tremors and other symptoms are not completely gone, but they are greatly improved. As it turns out, there's just one problem—and it's a big one. The instructions and warnings contained in the device packaging failed to warn that patients should avoid all procedures that involve any form of electrocautery or diathermy. Uninformed of this risk, the patient schedules a dental procedure which involving diathermy or electrocautery. Thereafter, the patient shows deterioration in the control of his symptoms, and, despite undergoing more surgeries to fix or replace the electrodes in his brain, he still continues to experience reduced control of his Parkinsonian symptoms. The patient sues the manufacturer of the electrodes in a

[1] *Parkinsonism*, STEDMAN'S MEDICAL DICTIONARY 1301 (Elizabeth Randolph et al. eds., 26th ed. 1995).

state and common law strict products liability action, for failure to warn of the danger posed by diathermy or electrocautery. In addition to the reduction in control of his Parkinsons symptoms, the patient believes that the implanted electrodes caused damage to his surrounding brain tissue. Unfortunately, the patient finds that the federal regulations under which the device was certified as reasonably safe, do not require the manufacturer to provide further warnings about product safety. This result is true even where the manufacturer knows of a similar fact situation in which nearly the same damage was done to another patient. Since there was no duty to warn the patient under the federal statutes, the patient's state and common law claims for failure to warn were preempted by federal law, leaving the brain damaged man with no legal recourse by which he could attempt to recover damages for the injuries he sustained from the device.[2] This sad story has been repeated, again and again, with much the same disastrous results.

Products Liability Theory and Application

The field of products liability traces its roots at least as far back as the English common law. Products liability is a tort theory that arises when a manufacturer or seller's defective product causes injury to a consumer or bystander.[3] It is currently an incredibly diverse and complicated group of legal tort theories which have become deeply engrained within federal and state codes and regulations, as well as in the common law at all levels of governmental activity.

Within the area of products liability lies another set of theories, known as strict product liability, which is defined as: "liability arising when the buyer proves that the goods were unreasonably dangerous and that (1) the seller was in the business of selling

[2] For Parkinson's sufferer Jack McMullen, this scenario became an unfortunate reality in May of 2000. *See* McMullen v. Medtronic, Inc., 421 F.3d 482, 485-86 (7th Cir. 2005).
[3] *Products Liability*, BLACK'S LAW DICTIONARY 1245-46 (8th ed. 2009).

goods, (2) the goods were defective when they were in the seller's hands, (3) the defect caused the plaintiff's injury, and (4) the product was expected to and did reach the consumer without substantial change in condition."[4]

The theory of strict products liability, with its own special requirements, is applicable to a wide range of products and their manufacturers. In few places is it as prevalent, and as hotly disputed, as in the legal theories surrounding a manufacturer's strict liability for damages arising from defects or deficiencies in drugs and medical devices supplied for use on human beings.

Medical products have the potential to not only ease pain and suffering, but to improve a person's overall quality of life, or simply allow them to live and function in everyday society. If misused, mislabeled, or improperly handled, these same lifesaving products also have the potential to create great pain and suffering, create further, and more pronounced disability, or even cause the untimely death of the patient to whom they are marketed.

Due to the potentially hazardous nature of medical products marketed for human use, it is necessary that the production, testing, marketing, and post-market performance of such products be vigilantly monitored. The complex task of monitoring, assessing, and approving products proposed for use in the treatment of human beings falls primarily within the purview of the United States Food and Drug Administration ("FDA").[5]

While the FDA generally does a good job of screening out hazardous products and protecting consumers, there are several prevalent and unfortunate side effects of

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[4] *Id.*

[5] *See* Carol Rados, *FDA Medical Device and Radiological Health Regulations Come of Age*, FDA.GOV, http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/MedicalDeviceandRadiologicalHealthRegulationsComeofAge/default.htm (last visited July 3, 2013).

having a congressionally created and empowered entity in control of examining and approving new medical devices intended for human use. One of the biggest problems involves the current trend of judicial interpretation regarding medical products liability after the FDA has granted a product premarket approval ("PMA"). Pursuant to this trend, patients who are later injured by an undiscovered problem with the device are often barred from recovering damages on theories of product liability or strict products liability.[6] These dismissals of what would ordinarily be perfectly valid, good faith products liability claims are due to preemption of the claim by federal laws and statutes.[7]

Federal claim preemption can occur in many areas of the law, but it has become particularly prevalent in litigation. It is likely that this prevalence is due to Congress including a very specific preemption provision in the 1976 Medical Device Amendments (MDA), which states in part:

> §360k. "State and local requirements respecting devices
>
> (a) General rule. Except as provided in subsection (b) of this section no State or political subdividion 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."[8]

[6] *See generally* Kemp v. Medtronic, Inc., 231 F.3d 216, 230 (6th Cir. 2000) (finding that plaintiff's state law negligence per se claim is preempted, because the state law places an additional requirement not imposed by the federal law).
[7] *Id*.
[8] 21 U.S.C. § 360k(a) (2012).

It has long been a recognized fact that laws enacted by the state legislatures and maintained in the common law must give way to federal law or statute that is valid and on point.[9] If an injured party asserts a claim, and seeks damages for that harm under state or common law theories of products liability, strict liability, or a host of other state or common law tort theories, the state and common law claims will often be preempted by federal law. This is because the Framers of the Constitution, in seeking to create a strong national government, determined that the federal government, and its laws and treaties, would override any state law or statute which runs contrary to the federal law enacted in the same area. This was accomplished via the Supremacy Clause of the United States Constitution, which states: "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 United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the constitution or laws of any state to the contrary notwithstanding.[10]

To better understand how and why such a situation arises in cases where a medical device receives FDA premarket approval, it is necessary to first examine the role the FDA plays in awarding premarket approval to a potential medical product. This note reviews the history of the FDA, the method of classification used by the FDA for medical devices, and the actual premarket approval process. This note also examines the Supremacy Clause of the United States Constitution, and discusses how the Clause functions to preempt claims for damages against manufacturers of medical devices that

[9] Altria Group v. Good, 555 U.S. 70, 76 (2008) ("Consistent with that command, we have long recognized that state laws that conflict with federal law are 'without effect.'") (citing Maryland v. Louisiana, 451 U.S. 725, 746 (1981)).
[10] U.S. CONST. art. VI, cl. 2.

have received premarket approval. Finally, this note will discuss the possibility of improvements to the existing system, and any possible improvements that might be made.

Origin, History, and Function of the United States Food and Drug Administration

Prior to the creation of the Food and Drug Administration, control of the production and distribution of domestic food and the availability of consumer remedies were considered to be the responsibility of the individual states.[11] As a result, remedies were enforced at best in an inconsistent manner, and at worst barely or not at all.[12]

The FDA saw the first hiccups of creation around 1848, when Lewis Caleb Beck was appointed to the U.S. Patent Office to perform chemical analysis of agricultural products.[13] Although not called the Food and Drug administration at that time, the "Bureau of Chemistry" was the "oldest comprehensive consumer protection agency in the U.S. Federal Government."[14]

The first real assignment of regulatory authority came to the FDA through the passage of the Pure Food and Drug Act of 1906.[15] This law prohibited the "manufacture, sale, or transportation of adulterated or misbranded" food and drugs.[16] For the first time in United States History, consumers experienced an unprecedented level of governmental involvement and protection in the regulation of food and drug quality.

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[11] John P. Swann, *FDA's Origin*, FDA.GOV, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm (last visited July 3, 2013) [hereinafter *FDA's Origin*].
[12] *Id.*
[13] *An Introduction to CVM*, FDA.GOV, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/NewEmployeeOnboarding/ucm222941.htm (last visited July 3, 2013).
[14] *About FDA: History*, FDA.GOV, http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm (last visited July 3, 2013).
[15] Pure Food and Drug Act of 1906, Pub. L. 59-384, 34 Stat. 768 (1906).
[16] *Id.*

In 1927, the Bureau of Chemistry had its name changed to the Food, Drug, and Insecticide Administration.[17] It transferred its research responsibilities to other agencies,[18] and began its sole task as a regulatory department.[19] In 1930, the name changed to The United States Food and Drug Administration.[20]

The scope of the authority the FDA was able to exercise over drugs and other medical products increased sharply within the decade. In 1938, a public outcry resulted over the deaths of more than 100 people due to a poisonous additive in a sulfa drug.[21] Prompted by this public response, Congress acted to expedite the Food, Drug, and Cosmetic Act. The bill, which was directed at preventing such catastrophes from occurring, had previously been ignored by Congress for over five years.[22] In the aftermath of the tragedy, however, the bill rocketed through both the House of Representatives and the Senate, and was signed into law by President Franklin D. Roosevelt on June 25, 1938.[23]

The new Act charged the FDA with overseeing the prescription, regulation, approval, and labeling of all drugs introduced for sale.[24] More importantly, the Act also brought medical devices under the control and regulation of the FDA. [25] At this time,

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[17] *FDA's Origin*, *supra* note 11.
[18] *Id*.
[19] *This Week in FDA History—June 30, 1906 and June, 25 1938*, FDA.GOV, http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117833.htm (last visited July 2, 2013).
[20] *FDA's Origin*, *supra* note 11.
[21] The term sulfa drug is used to describe any of a number of synthetic chemical substances derived from sulfanilamide or para-aminobenzenesulfonamide. Sulfa drugs are used to treat a wide variety of bacterial infections by inhibiting the actions of the physiological substance para-aminobenzoic acid, which bacteria require to synthesize folic acid. *Sulfa Drug*, TABER'S CYCLOPEDIC MEDICAL DICTIONARY 2086 (Donald Venes, M.D., M.S.J. et al. eds., 19th ed. 1997).
[22] *FDA History—Part II*, FDA.GOV, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm (last visited July 2, 2013).
[23] *Id*.
[24] *Id*.
[25] *Id*.

however, the Act did not require or provide for premarket approval of medical devices by the FDA.[26]

From the 1938 passage of the Act well into the early 1960s, the vast majority of the regulatory and investigative functions employed by the FDA as to medical products dealt with claims and complaints by citizens concerning the practice of quackery and charlatanism.[27] Following WWII, advancements in technology provided a greater potential for bona fide improvements in medical products for the benefit of society. At the same time, however, it opened the door to the introduction into the consumer marketplace of a great variety of outlandish and outright bogus therapeutic devices. In response to this, a push began in the 1960s to enact laws enabling the FDA to more carefully regulate the introduction of medical devices into the market.[28]

Once again, proposed legislation aimed at allowing the FDA stricter control of medical devices remained largely unexplored and ignored. As in 1938, Congressional reluctance once again changed when another tragedy galvanized Congress into action. After thousands of women were injured by a birth control product called the Dalkon Shield intrauterine device, Congress quickly passed the Medical Device Amendments Act,[29] creating and defining three classes of medical devices.[30] Each of these classes required a different level of regulatory scrutiny. The most stringent scrutiny ultimately became the premarket approval requirement for proposed medical devices.[31]

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[26] Rados, *supra* note 5.
[27] *FDA History—Part IV*, FDA.GOV, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055137.htm (last visited July 2, 2013).
[28] *See id*.
[29] *Id*.
[30] Medical Device Amendments Act of 1976, Pub. L. 94-295, 90 Stat. 539.
[31] *Premarket Approval (PMA)*, FDA.GOV, http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/default.htm (last visited June 2, 2013).

Medical device classification by the FDA

The FDA devised a system of classification for medical devices that consists of three classes.[32] Class I devices are uniformly non-invasive devices, and are generally designed for use as blood or fluid barriers or in simple diagnostic procedures involving insertion of the device into the mouth, nose, or ears.[33] Examples of such devices are tongue depressors, bandages, and gloves. With few exceptions, these devices are generally exempt from the FDA requirement for a marketing application.[34] The manufacturer need only show that it adheres to good manufacturing practice standards.[35]

Class II devices are more complicated; they commonly breach the skin, or are inserted into the body at a greater depth than Class I devices.[36] Examples of Class II devices are syringes, urinary catheters, and auditory testing equipment which can be inserted into the ear as far as the eardrum or beyond. Class II devices do not include any device inserted into the body for the purpose of supporting or sustaining life. Devices which qualify as Class II generally require premarket notification, and may be required to meet other specific performance standards set forth by the FDA.[37]

Class III devices are designed to sustain or support life.[38] One of the important distinctions that determines if a device will be qualified as Class III is whether its failure is potentially catastrophic or life-threatening. Examples of Class III devices are

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[32] *Classify Your Medical Device*, FDA.GOV, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm (last visited July 3, 2013); *see also* Medical Device Amendments Act of 1976, Pub. L. 94-295, 90 Stat. 539.
[33] *See 2008-04 FDA Device Classification*, LEEDER GROUP.COM, http://leedergroup.com/bulletins/fda-device-classification (last visited July 3, 2013).
[34] *Id*.
[35] *Id*.
[36] *Overview of Medical Devices and Their Regulatory Pathways*, FDA.GOV, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm203018.htm (last visited July 4, 2013).
[37] *Id*.
[38] *Id*.

anesthesia machines and equipment, internal/external defibrillators, and prosthetics designed for permanent implantation. These devices are subject to the most stringent standards the FDA employs, and are generally required to receive premarket approval prior to being introduced into the market.[39]

For a product to receive premarket approval by the FDA, a device must undergo extensive and exacting levels of testing, followed by clinical trials. To allow time for the submitting company to perform the requisite testing and clinical trials that establish the safety and effectiveness of the proposed device, the FDA provides for an Investigational Device Exemption (IDE).[40] The IDE is a temporary classification which is ultimately withdrawn in two situations: 1) where the product proves to be unreasonably dangerous, and 2) once the trials and testing have been safely and successfully completed, and the application evolves into premarket approval.

In order to obtain premarket approval from the FDA, Class III devices must be reviewed carefully for their safety and efficacy. Often, this requires review by a medical advisory board as well.[41] The manufacturer's application for approval by the Secretary of Health, Education, and Welfare must follow the requirements found in 21 U.S.C. § 360c(a), and must contain the following information:

1. "Full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective."[42]

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[39] *Id.*
[40] *See* 21 C.F.R. § 812.1 (2013) (permitting a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device).
[41] 21 U.S.C. § 360e(g)(2)(A) (2012).
[42] *Id.* § 360e(c)(1)(A).

2. "[A] full statement of the components, ingredients, [] properties and of the principle or principles of operation, of such device."[43]

3. "[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, [sic] such device."[44]

4. "[A]n identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard."[45]

5. "[S]uch samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing."[46]

6. "[S]pecimens of the labeling proposed to be used for such device."[47]

7. "[T]he certification required under section 282(j)(5)(B) of Title 42 . . . ."[48]

8. "[S]uch other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require."[49]

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[43] *Id*. § 360e(c)(1)(B).
[44] *Id*. § 360e(c)(1)(C).
[45] *Id*. § 360e(c)(1)(D).
[46] *Id*. § 360e(c)(1)(E).
[47] *Id*. § 360e(c)(1)(F).
[48] *Id*. § 360e(c)(1)(G).
[49] *Id*. § 360e(c)(1)(H).

Once the FDA receives the application, the application is referred to the appropriate review panel,[50] where it is vigorously tested and scrutinized. Due to the dangerous nature of Class III medical devices, the application very often takes a considerable amount of time to process. Potential product manufacturers must submit a significant amount of testing and clinical research data to the FDA for review.[51] This cannot be done without trials conducted over the course of several months, or more often years.[52] By this time, the applicant usually has a substantial amount of time, money, and other resources committed to the development, testing, and approval of the device.

Medical device manufacturers who have previously received premarket approval may bypass this lengthy and expensive process[53] with a request for accelerated premarket approval. Accelerated approval applies where the new design is substantially similar to a previously approved device. These substantially similar devices are usually a design improvement on an original or continuing model. In order for the manufacturer to receive this accelerated form of premarket approval, it must submit a 510(k) request for FDA market clearance of the similar device. This strategy is commonly employed by large manufacturing companies, in order to avoid increased research and testing costs, and to hurry a new model of an older product to the market.[54]

To fully understand the stringency of the premarket approval process, and the lengths to which manufacturers will go to avoid the time and expense required to secure premarket approval, one need only compare the number of FDA product market

[50] *See id.* § 360e(c)(3).
[51] *See generally id.* § 360e(c) (listing information and data requirements for premarket approval applications).
[52] *See generally* 21 C.F.R. § 814.20 (2013) (stating purpose of premarket approval investigation is to establish, *inter alia*, a "thorough device review process")
[53] 21 U.S.C. § 360e(b)(1)(B).
[54] Horn v. Thoratec Corp., 376 F.3d 163, 167 (3d Cir. 2004) (citing one example in which the "substantial equivalence" approval process was used to bypass the more rigorous PMA approval procedures).

clearances to the number of premarket approvals for the same year.[55] These figures strongly indicate that manufacturers prefer the less time-consuming, less expensive market clearance option.

The Supremacy Clause and Preemption of Claims

The Supremacy Clause of the United States Constitution states that "all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land."[56] This means that the statutes and regulations contained in the Code of Federal Regulations (CFR) and the United States Code (USC), having been enacted by the United States Congress, cannot be overridden or contradicted by any law put in place by a state entity.

Since the responsibilities of the FDA for overseeing the introduction of potentially dangerous medical devices into the stream of commerce have been statutorily authorized by Congress, the authority of the FDA to act in this area of regulation cannot be superceded by any state or local law. This has the effect of expressly preempting any state law or common law theory that happens to be in conflict with these regulations. The section of the statutes responsible for this specifically states the following device requirements:

> 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

[55] *See, e.g., id.* The number of medical devices that receive PMA review each year is dwarfed by the number of those that are marketed pursuant to cleared Section 510(k). In fiscal year 2003, for example, original PMAs represented only fifty-four of the 9872 major submissions received. The previous fiscal year, original PMAs accounted for forty-nine of 10,323 total submissions. *Id.*
[56] U.S. CONST. art. VI, cl. 2.

> device or to any other matter included in a requirement applicable to the device under this chapter.[57]

Cases Establishing and Reinforcing Claim Preemption for Medical Device Claims

Medtronic, Inc. v. Lohr[58] was the initial case to deal specifically with the question of whether states could enact stricter requirements for medical devices than those propounded by the FDA. In that case, decided in 1996, Lohr was the recipient of a pacemaker designed by Medtronic, which was grandfathered in via the "substantially equivalent" preexisting device exception to PMA requirements.[59] Lohr's device failed, causing severe distress, and requiring emergency surgery to correct a faulty lead from the device directly to the patient's heart.[60] Lohr brought suit on theories of negligence and strict liability.[61] The Supreme Court declined to allow claim preemption, holding, *inter alia*, that the state laws did not directly conflict with any applicable federal standard, since the state and common laws did not describe "a substantive requirement for a specific device."[62] The Court based its findings on its reading of § 360k.[63] The Court, however, declined to address a further definition of what would constitute a requirement under § 360k, saying:

> [W]e do not respond directly to this argument for two reasons. First, since none of the Lohrs' claims is pre-empted in this suit, we need not resolve hypothetical cases that may arise in the future. Second, given the critical importance of device specificity in our (and the FDA's) construction of § 360k, it is apparent that few, if any, common-law duties have been pre-empted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has "the effect of establishing a substantive requirement for a specific device." 21 CFR §

[57] 21 U.S.C. § 360k(a).
[58] 518 U.S. 470 (1996).
[59] *Id.* at 480.
[60] *Id*. at 481.
[61] *Id*.
[62] *Id*. at 500.
[63] *Id.* at 496-503.

808.1(d)(6)(ii) (1995). Until such a case arises, we see no need to determine whether the statute explicitly pre-empts such a claim.[64]

This case was decided by a mere four judge plurality, and was contentious enough that Justice Breyer, in spite of joining the plurality, wrote a separate concurrence to express his lack of conviction "that future incidents of [§ 360k(a)] pre-emption of common-law claims will be 'few' or 'rare.'"[65] As it turned out, Justice Breyer's words were uncannily prophetic, given the multitude of preemption cases that would follow.

The Courts Adopt a New View

As early as 2000, a new trend developed among the Courts in the interpretation of the requirements of § 360k. Courts began to interpret the statute as did the Sixth Circuit in *Kemp v. Medtronic*, to say that, rather than failure of a state or common law statute to name a specific device, affirmation by the FDA of a specific device during the PMA process must be shown in order to assert federal control over the laws governing the distribution of said device.[66]

In that case, Kemp's internal pacemaker malfunctioned. This caused her to faint and hit her head. As a result she incurred bilateral subdural hematomas, causing her to suffer headaches, facial pain, and neck pain.[67] Her injuries included loss of sight, speech, and cognitive and motor capabilities.[68] The Sixth Circuit held that a state or common law which held a medical device to a standard higher that that set for the device by the FDA

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[64] *Id*. at 502-03.
[65] *Id.* at 508.
[66] Kemp v. Medtronic, Inc., 231 F.3d 216, 227 (6th Cir. 2000) ("To preempt these claims, the federal requirements must be 'applicable to the device' in question . . . and 'specific' to a 'particular device.'") (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 500 (1996)).
[67] *Id.* at 218. A subdural hematoma is a hematoma located below the dura matter in the brain. These injuries are typically the result of a head injury. *Hematoma*, TABER'S CYCLOPEDIC MEDICAL DICTIONARY 2086 (Donald Venes, M.D., M.S.J. et al. eds., 19th ed. 1997).
[68] *Kemp*, 231 F.3d at 218.

placed a requirement upon the product which the FDA did not, and was therefore expressly preempted by § 360k.[69]

This line of reasoning re-interpreted the plurality decision in *Lohr*. In *the Lohr* case, the Court held that if a product was not specifically named within the text of a state or common law, then the statute or law did not place a specific requirement on the device which would run contrary to the requirements placed upon it by the FDA. For this reason, products liability claims based on such theories were not subject to express claim preemption based on § 360k.

Viewed from the *Kemp* perspective, when a device passes the FDA's rigorous PMA standards, it reaches the pinnacle of what may be required of it in terms of safety. In *Horn v. Thoratec* the Third Circuit held that any products liability claim arising from state or common law requirements which were "different from, or in addition to, [] specific federal requirements" would fail due to federal claim preemption. [70] Once *Horn* was decided by the Third Circuit, an apparent chain reaction followed, with other circuit courts following suit over the next several years.[71]

In April of 2005, the Sixth Circuit reaffirmed its decision in *Kemp,* when it denied a plaintiff leave to amend her original complaint to include claims not preempted by federal law.[72] In the opinion, Circuit Judge Kennedy wrote

> Plaintiff's proposed amended claims themselves undermine their preemption arguments, because those claims assert that Defendant has duties 'independent of any obligations . . . to comply with applicable federal regulations.' Such independent duties are, at the very least, 'in

[69] *Id*. at 235.
[70] Horn v. Thoratec Corp., 376 F.3d 163, 167 (3d Cir. 2004).
[71] *See, e.g.*, Cupek v. Medtronic, Inc., 405 F.3d 421 (6th Cir. 2005); McMullen v. Medtronic, Inc., 421 F.3d 482 (7th Cir. 2005); Gomez v. St. Jude Med. Diag Div., Inc., 442 F.3d 919 (5th Cir. 2006); Reigel v. Medtronic, Inc., 451 F.3d 104 (2d Cir. 2006) *aff'd,* 552 U.S. 312 (2008).
[72] *Cupek*, 405 F.3d at 425 (finding plaintiff's request to amend was futile because claims could not be distinguished from preempted claims).

> addition to' federal requirements, and may very well be 'different from' federal requirements.[73]

The decision of the Court further solidified the new theory that achievement of PMA insulated the recipient company from liability for later defects or failures to warn of discovered defects.

Thereafter, the Seventh Circuit issued a similar ruling, holding that a patient's common law liability claim for failure to warn was preempted by federal law.[74] This case involved the malfunction of a neurostimulation device, which was designed to improve the symptoms of Parkinson's Disease. During a dental procedure, the device malfunctioned, cauterized a portion of the patient's brain, and resulted in severe damage.[75]

The Fifth Circuit was the next Court to fall in line. In March of 2006, the Fifth Circuit held that, in the case of a failed arterial sealing device resulting in 99% blockage of a patient's femoral artery, state or common law claims for defective design, failure to warn, breach of implied warranty, and express warranty were all federally preempted.[76]

Following this growing trend, the Second Circuit held that a plaintiff's claims of negligence, strict liability and breach of implied warranty were all federally preempted.[77] This case involved the rupture of a balloon catheter during an angioplasty procedure, which resulted in complete heart block and required emergency coronary bypass surgery.[78] This Second Circuit case sounded the death-knell for any further changes in

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[73] *Id*. at 424-25.
[74] *McMullen*, 421 F.3d at 487.
[75] *Id*. at 486.
[76] *Gomez*, 442 F.3d at 933 ("These claims cannot be presented to a jury because, if successful, they would be inconsistent with the federal regulatory requirements.").
[77] *See Reigel*, 451 F.3d at 121.
[78] *Id*. at 106.

the lower court's positions when the United States Supreme Court granted certiorari to review the finding of the lower court, and affirmed in an 8-1 decision.[79]

The Consequences of the new Approach by the Courts

One of the most unfortunate aspects of this current line of judicial interpretation employed by the courts is that it dismisses out of hand the vast majority of good-faith state and common law tort claims presented by plaintiffs who have a legitimate injury, and who should be entitled to both compensation and justice. This line of jurisprudence places on a pedestal the research and development departments of major medical device manufacturers and the FDA, and provides for little or no accountability when damage is done to real human beings as a result of an overlooked flaw or a miscalculation of the risks and dangers associated with a medical device.

At this time, a plaintiff who wishes to recover from an injury caused by the alleged negligence of a medical device manufacturing company whose device has undergone the rigors of PMA screening by the FDA, is limited to only one theory of recovery. The aggrieved plaintiff must allege and demonstrate that the medical device manufacturer was negligent in manufacturing the product in violation of the standards set by federal law.[80] Unfortunately, even if the plaintiff alleges manufacturer negligence and an implied cause of action against the manufacturer for violation of the Federal Food, Drug, and Cosmetics Act,[81] that cause of action may be dismissed under the reasoning of some of the Circuit Courts. The Sixth Circuit has held that in drafting the FDCA, Congress preempted private causes of action against the manufacturer of a medical

[79] *See* Riegel v. Medtronic, 552 U.S. 312 (2008).
[80] *See id.* at 321 ("[T]he MDA pre-empt[s] a negligent manufacturing claim insofar as it [is] not premised on the theory that [the manufacturer] violated federal law.")
[81] *See* 21 U.S.C. §§ 301-399a (2012).

device that malfunctions, or is later found to be defective.[82] In *Kemp*, District Judge McKeague wrote: "Returning to answer this question when it was squarely before the Court, we held that no private cause of action exists for a violation of the FDCA. . . . States are not granted any authority to enforce compliance with the specific federal requirements Established by the PMA process."[83]

This limits a plaintiff's ability to recover damages and suffering caused by a faulty medical device to merely informing the FDA of the fault. There does not appear to be any statute in place providing relief to the injured party. If the law is allowed to stand in its current form, it will seriously abrogate the rights of persons who have a legitimate claim for injury against a medical products manufacturer. As a result, their ability to seek justice and reparations in the courts for injuries suffered will be significantly hampered.

Another unfortunate effect of the current line of reasoning by the Courts is implicated when medical device manufacturers become aware of a potential design flaw or failure, but elect notwithstanding, to continue to sell the existing device in order to reduce on-hand supplies. In this instance, federal preemption provides what amounts to a nearly impenetrable umbrella of liability protection to the medical device manufacturers, as they complete discontinuation of a faulty product by continuing to sell it to uninformed physicians. The doctors then use these faulty devices to treat patients, who then suffer, in some cases terribly, the aftereffects of these devices.

In *Blunt v. Medtronic, Inc.*,[84] which was decided by the Wisconsin Court of Appeals in July of 2007, Medtronic was aware of a defect in the battery design in one of its defibrillators. It applied to the FDA for permission, based upon the substantially

[82] Kemp v. Medtronic, Inc., 231 F.3d 216, 236 (6th Cir. 2000).
[83] *Id.*
[84] Blunt v. Medtronic, Inc., 738 N.W.2d 143, 145 (Wis. Ct. App. 2007).

similar exception, to implement three design changes to the defective battery.[85] Medtronic first became aware of the potential problem as early as January 2003, but did not apply for permission to change the design until October 2003.[86] There is no indication that Medtronic took any steps to inform physicians or patients of the potentially fatal flaw at this time.

Early in 2004, Medtronic received the first warnings from the marketplace alerting it to the battery failure problem.[87] Despite this information about the flaw, Medtronic neither issued any warnings to physicians, nor discontinued distribution of the flawed product. In fact, on May 19, 2004, long after Medtronic became aware of a potentially fatal flaw in the design of its defibrillator, the company supplied one of the original models, with the original flawed battery, to Blunt's physician for implantation into Blunt's body.[88]

The first indication that there might be a shorting problem with the original model of the defibrillator did not reach physicians and patients until February 2005, over two years after Medtronic became aware of the danger.[89] During those two years, Medtronic had ample time to clear out the remaining stock of the flawed original model, by providing those devices to physicians and patients who had not been informed of the potentially life-threatening design flaw. A line of jurisprudence which insulates companies from liability that so blithely and willingly continue to sell faulty life support devices, known by them to be potentially lethally defective, in order to protect its bottom line, is in serious need of re-examination.

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[85] *Id*.
[86] *Id*.
[87] *Id*. at 145 n.2.
[88] *Id*.
[89] *Id*.

Conclusion

In light of the serious potential for injustice, supported by the almost hermetic legal seal that the most recent line of medical device products liability jurisprudence places around the manufacturers of medical devices, it is time for a re-examination of the current policies adopted by the Courts. It would better serve justice, and the consumer public, if the Supreme Court, at the earliest opportunity, were to grant certiorari for another medical device products liability claim. The Court should determine a more compromising approach to such cases. Its solution should resolve the tension between the *Lohr* and *Reigel* lines of cases, and at the same time better balance the interests of medical service providers and the consumer public, so that the public's interest in the absolute safety and reliability of medical devices is more robustly protected. In the absence of such re-examination by the Court, it should be incumbent upon Congress itself to take action to clarify and re-define §360(k), such that courts will be able to interpret the statute to assure fair accountability of manufacturers and justice to consumers injured as a result of defective products. When the letter of the law defies its spirit, which should at all times keep protection of the people at the forefront of its interests, then perhaps it is time for those letters to be changed. These changes should be made in a cooperative effort by Congress and the judiciary, in order to protect our citizens, and to provide them with a means of redress, when they are injured by questionable manufacturer actions. When only Congress can act to protect the American people, as in the instances discussed above, it must act to ensure that protection.