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Federal Pre-Emption Under The Food, Drug & Cosmetic Act From Medtronic, Inc. V. Lohr; Pliva, Inc. V. Mensing

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INTRODUCTION

Beginning in 1996, the United States Supreme Court took a series of cases related to Federal pre-emption of state law claims for products approved by the United States Food and Drug Administration ("FDA"). 1 In some instances, these courts found federal law pre-empted state law claims. In other cases, the court found that no federal pre-emption existed and allowed the state law claims to proceed. This article examines the reasoning in each of these five cases as well as two state court cases related to federal pre-emption. 2 In doing so, this article describes the current landscape of federal pre-emption for products approved by the FDA.

I. Federal Pre-Emption

The theory of federal pre-emption rests on the Supremacy Clause of the United States Constitution. 3 The Supremacy Clause provides that federal law is "the supreme law of the land; ... anything in the constitution or laws of any state to the contrary notwithstanding." 4 Therefore, a state law that conflicts with federal law is pre-empted and has no effect. 5

Federal law pre-empts state law in three circumstances. Congress may expressly pre-empt state law. 6 Alternatively, "state law is pre-empted where it regulates conduct in a field that Congress intended the federal government to occupy exclusively." 7 Courts may imply pre-emption to the extent a state law actually conflicts with federal law. 8 Implied conflict pre-emption exists where a private party cannot comply with state and federal requirements or the state law obstructs accomplishing and executing Congress's objectives. 9 To understand under which theory the Court analyzed the pre-emption arguments in each of the cases discussed below and how it reached its decision, a brief discussion of the approval process for innovator drug products, generic drug products, over-the-counter drug products, and medical devices is necessary.

II. Approval Pathways for Medical Devices, Innovator Drug Products, Generic Drug Products, and Over-the-Counter Drug Products

Medical devices, innovator drug products, generic drug products, and over-the-counter drug

product each have separate approval paths for sale in the United States. The following section describes, in brief, those approval paths.

A. Approval Pathway for Medical Devices

In 1976, Congress passed the Medical Device Amendments Act ("MDA") amending the Food, Drug and Cosmetic Act ("FDCA"). The MDA provides for three categories of medical devices based on the risks they pose to the public health. Class I devices provide no unreasonable risk of illness or injury to the public and are subject only to "general controls." 10 Class II devices are potentially more harmful. Class II devices may be marketed without advance approval, however, manufacturers must comply with special controls. 11 Class III devices are those that "present a potential unreasonable risk of illness or injury," or are "purported or represented to be for the use in supporting or sustaining human life or for the use which is of substantial importance in preventing impairment of human health." 12

In order to introduce a Class III medical device into the market, the manufacturer must provide the FDA with "reasonable assurance that the device is safe and effective." 13 Providing "reasonable assurance" that the product is "safe and effective" is a rigorous process during which the manufacturer must submit a detailed application for approval that includes,

among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; 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. § 360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a) (2007), and may request additional data from the manufacturer, § 360c(c)(1)(G). 14

FDA averages 1200 hours reviewing each submission. 15 During the review process, the agency weighs any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. 16 The FDA may approve devices that present significant risk if the device offers great benefit in light of the available alternatives. 17 Pre-market approval also encompasses a review of the device's labeling. 18 That review includes assuring that the device's use is safe and effective under the conditions set forth on the label, which must be neither false nor misleading. 19 After completing its review, the FDA either grants or denies pre-market approval. Once a device has received pre-market approval, the MDA prohibits the manufacturer from changing the design specifications, manufacturing process, labeling, or any other attribute of the device that would affect safety or efficacy. 20 If a manufacturer wants to make a change that affects safety or effectiveness, it must file a supplemental pre-market approval application with the FDA subject to similar review procedures. 21 In addition, after it receives approval, a manufacturer is subject to reporting requirements including an obligation to inform the FDA of new clinical investigations concerning the device and to report adverse events related to the device if that adverse event contributed to death or serious injury. Finally, a manufacturer must

report any malfunctions of the device that are likely to cause or contribute to death or serious injury. 22 The FDA may withdraw pre-market approval if it determines the device is unsafe or ineffective based on newly reported data or existing information.

Two significant exceptions exist to the requirement of pre-market approval for a Class III device:

1. The MDA includes a grandfathering clause which permits pre-1976 devices to remain on the market without FDA approval until the FDA initiates and completes a PMA; and 23
2. The MDA also permits devices that are "substantially equivalent" to existing devices to avoid the pre-market approval process. 24

Under the "substantially equivalent" process, a sponsor submits a "pre-market notification to the FDA of its intent to market the product (the "510(k) process"). If the FDA concludes, based on the 510(k) notification, that the device is "substantially equivalent," the product can be marketed without submitting a PMA. The information required as part of the 510(k) application is significantly less than that required under a PMA application. In addition, the FDA generally completes its review in 20 hours as opposed to 1200 hours. Not surprisingly, the 510(k) process has become the means by which many Class III medical devices were approved.

B. The New Drug Approval Process

Under the FDCA, a manufacturer may not market a "new drug" until submitting a New Drug Application ("NDA") and receiving approval. 25 The NDA must provide, among other things, the proposed labeling, full reports of all investigations to show whether the drug is safe and effective, and the "discussion on why the benefits exceed the risks under the conditions stated in the labeling." 26 The FDA will only approve a drug if it finds, among other things, that the drug is "safe and effective for use under the conditions prescribed, recommended or suggested in the proposed labeling and that the proposed labeling is not 'false or misleading in any particular.'" 27 In general, a manufacturer may not change a drug's labeling after the FDA approves the NDA absent a supplemental application. 28 However, FDA regulations permit a manufacturer to make certain changes to the labeling under the "Changes Being Effected" regulation ("CBE"). 29 A manufacturer may change the label to add or strengthen a contra-indication 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 product." 30 The manufacturer may make that change upon filing a supplemental application to change the labeling and does not need to wait for FDA approval to do so. 31

C. Approval of Generic Drug Product

In contrast to innovative "new drugs," a generic product is approved pursuant to an Abbreviated New Drug Application ("ANDA"). Pursuant to the Hatch-Waxman Amendments to the FDCA, "generic drugs" can gain FDA approval if they show "equivalence to a reference listed drug that already has an approved NDA." In general, the generic drug manufacturer must show that the drug is bio-equivalent and has the same active ingredient as the reference listed drug. The FDCA

also requires the generic drug manufacturer to use the same labeling as that approved for the branded drug. 32 In addition, unlike branded drug manufacturers, generic drug manufacturers may not use the CBE process to strengthen the warning labels. 33

D. Approval of Over-the-Counter Drug Product

The FDCA provides two systems for approving over-the-counter (OTC) drug product. First, a manufacturer can file an NDA or ANDA as discussed above. Additionally, the manufacturer can comply with the "monograph" for the OTC drug product. 34 The NDA and ANDA process is similar to those described above. However, at the time of the enactment of the Drug Amendments of 1962 which added the requirement that a drug be "effective" and that the labeling not be false or misleading in order to obtain approval, there were thousands of OTC drugs already on the market which would now require approval. 35 To address this issue, the FDA retained the National Academy of Sciences to create expert panels to assist in evaluating the between 100,000 and 500,00 OTC drugs that were already on the market. The Academy convened 17 expert advisory panels to review 26 categories of OTC drugs. OTC drug products were then reviewed in four phases known as the "monograph process." 36 First, the panel reviewed existing test data and made recommendations of a form of monograph under which an OTC drug can be marketed without an NDA. Then, the FDA reviewed the monographs and published them in the Federal Register for public comment. 37 The FDA then reviewed the comments and published a tentative final monograph to which the public could object in writing or at a public hearing. 38 The FDA then promulgated a regulation containing the final monograph establishing the conditions under which an OTC drug is "safe and effective and not misbranded." 39 If the product does not conform to the monograph, then the drug may be treated as an unapproved new drug. The monograph regulations include labeling requirements. 40

III. A Look at Pre-Emption Cases

Beginning in 1996, the Supreme Court began looking at the approval process and labeling requirements for various products approved by the FDA pursuant to the FDCA and how that process affected federal pre-emption of state law claims. In the first case, the Court determined that the MDA did not pre-empt state law claims for products approved pursuant to the 510(k) process. 41 The decision in *Lohr* turned on an interpretation of 21 U.S.C. § 360k(a) which provides:

(a) General rule

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

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

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The central question in *Lohr* was whether state law tort claims were a different "requirement" than those applied under the FDCA to products approved under the 510(k) process. The majority of the Court determined that they were not, because "the 510(k) process is focused on equivalence, not safety." 42 Moreover, the Court determined that the manufacturing and labeling claims brought by the *Lohrs* were not pre-empted because, under the 510(k) process, "[t]he Federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." 43 Justice Stevens was not, however, successful in convincing a majority of the Court that Section 360(k) could never pre-empt any common law claims related to medical devices. 44

Justice O'Connor, in her opinion (concurring in part and dissenting in part), argued that while the *Lohrs'* defective design claims were not pre-empted under the 510(k) process, their manufacturing and labeling claims should be because of the extensive requirements set forth in the FDCA related to good manufacturing practices and labeling. 45 As we will see, Justice O'Connor's position carried the day in *Riegel*.

The Court next dealt with the pre-emption of claims under the FDCA in *Buckman Co. v. Plaintiffs' Legal Comm.* In *Buckman*, the plaintiffs claimed that *Buckman* committed "fraud on the FDA" as part of its attempt to obtain approval for orthopedic bone screws pursuant to the 510(k) process. 46 The *Buckman* Court determined that the FDCA impliedly pre-empted state fraud on the FDA claims because

Petitioner's dealings with the FDA were prompted by the MDA, and the very subject matter of petitioner's statements were dictated by that statute's provisions. Accordingly—and in contrast to situations implicating "Federalism concerns and the historic primacy of state regulation of matters of health and safety," *Medtronic*, 518 U.S., at 485, 116 S.Ct. 2240—no presumption against pre-emption obtains in this case. 47

In addition, the Court pointed out that the FDA has numerous powers to investigate fraud, and may seek injunctive relief and civil penalties in the cases of fraud. Further, the FDA may seize the device and pursue criminal prosecutions in cases of fraud. The Court went on to state:

State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants' burdens not contemplated by Congress in enacting the FDCA and the MDA. 48

Finally, the Court drew away from the broad no pre-emption decision of *Lohr*.

Notwithstanding the fact that *Medtronic* did not squarely address the question of implied pre-emption, it is clear that the *Medtronic* claims arose from the manufacturer's alleged

failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. See 518 U.S., at 481, 116 S.Ct. 2240. 49

The day before issuing its opinion in *Buckman*, the Court determined in *Riegel* that state law tort claims were pre-empted under Section 360(k) for devices approved pursuant to the pre-market approval process. In that decision, the Court determined that Section 360(k) directly pre-empted *Riegel's* state law tort claims that a Medtronic catheter which injured him was "designed, labeled and manufactured in a way that violated New York common law." 50 In contrast to the decision in *Lohr*, the Court determined that pre-market approval does impose "requirements" on the manufacturer that obtains pre-market approval because pre-market approval is focused on safety, not equivalence. 51 The Court pointed out that unlike instances in the 510(k) process, the FDA requires a device that has received pre-market approval to be made with "almost no deviations from the specifications in its approval application." 52 The Court reasoned that allowing state law claims to proceed would require a device manufacturer to produce products that are "safer, but hence less effective." 53 The Court did note, however, that Section 360(k) does not prevent a state from providing claims that are premised on a violation of FDA regulation. 54 Presumably, these are cases involving a violation of good manufacturing practices. They would, however, not involve a design defect or labeling claim.

The Court next turned to pre-emption under the FDCA in March of 2009, when it decided *Wyeth v. Levin*. *Wyeth* involved a failure to warn claim related to the labeling of a branded drug product marketed pursuant to an NDA. 55 Because the sections of the FDCA that relate to new drug approvals do not contain pre-emption language similar to the § 360(k) language for medical devices, *Wyeth* had to rely on implied pre-emption. *Wyeth* argued that it would be impossible for it to comply with both the state law duties imposed for improved labeling and its federal labeling duties because its labeling had to be approved by the FDA as part of the NDA process. 56 However, Justice Stevens, writing for the Court, rejected that argument. He did so because *Wyeth* could have revised its label pursuant to the CBE process. 57 Justice Stevens also pointed out that Congress specifically did not include direct pre-emption language, which it certainly could have given that it had done so when it enacted the MDA.

The most recent case in which the Court discussed federal pre-emption under the FDCA is *Pliva, Inc. v. Mensing*. *Pliva* involved failure to warn claims related to the labeling of a generic drug product. 58 Justice Thomas wrote the opinion for the Court and began by pointing out that "brand name and generic drug manufacturers have different failure to warn labeling duties." 59

He stated:

[a] brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. See, e.g. 21 U.S.C. §§ 355(b)(1),(d); *Wyeth*, supra at 570-571. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's. See, e.g. § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7). 60

Justice Thomas then summarized the requirements of both state and federal law. That is, state law placed a duty on all drug manufacturers to assure that labels were adequate and safe while

federal law required generic drug manufacturers to use the label approved by the FDA when it approved the NDA or any supplemental application. 61 He thus determined it was impossible for generic drug manufacturers to comply with both their state law duties and their federal law duties at the same time. Therefore, the Court found that federal law pre-empted state law failure to warn claims related to generic labeling. 62 The Court recognized that finding no pre-emption in Wyeth and pre-emption in Pliva may make little sense to a harmed consumer. 63 The Court concluded that the dissimilarly statutory schemes required dissimilar pre-emption outcomes. 64

While the Supreme Court has not dealt with pre-emption for over-the-counter drug products, the district courts have. Like the MDA, the section of the FDCA dealing with OTC drugs provides for federal pre-emption for "requirements of a state" that are in addition to, different from, or not identical with the requirements of the OTC statute. 65 Unlike the MDA, however, the OTC statute contains a savings clause for product liability which states "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 66 Thus, for OTC drug products, product liability claims are expressly not pre-empted. However, other types of state law claims are pre-empted.

In *Carter v. Novartis Consumer Health, Inc.*, and *Mills v. Warner Lambert Co.*, the district courts dealt with this distinction. In *Carter*, the plaintiffs brought a class action claim based on consumer fraud and unjust enrichment, false and misleading advertising, fraudulent concealment and the like based on the claim that OTC cold medicines "do not work." 67 In *Carter*, the Court determined that the consumer fraud claims would have imposed an additional "requirement" unrelated to product liability that would be different from or in addition to the requirements of federal law under the monograph because they had provided in the monograph age and dosing limits and perforce the FDA had to have determined the products were "effective." 68 In like manner, in *Mills*, the plaintiffs brought state law claims under the Texas Deceptive Trade Practices Act and implied warranty claims related to the labeling of OTC product intended to treat lice. 69 In essence, the plaintiff's claims were that the product simply did not work and it was deceptively advertised. The *Mills* Court determined that because the products at issue either had an approved NDA or an approved monograph which required the labeling to say it treated lice, the FDA must have determined the products were effective at treating lice. Therefore, the FDCA both impliedly pre-empted and directly pre-empted plaintiffs' claims.

Conclusion

While the cases set forth above illustrate apparently inconsistent pre-emption law under the FDCA, they actually make practical sense given the statutory framework. For example, a device manufacturer that submits a 510(k) application should not be able to avail itself of federal pre-emption since the FDA has not made any decision as to whether or not the product is "safe." In contrast, a manufacturer that avails itself with a more rigorous PMA process should be able to avail itself of the direct pre-emption set forth in Section 360(k) because the FDA had determined that the product is safe and effective as labeled. In like manner, because a manufacturer of branded product has control over its labeling and does not need FDA approval to make changes pursuant to the CBE process, it should be held liable for failing to do so. In contrast, because a generic drug manufacturer has no control over the labeling, and must rely on the branded drug manufacturer to make those changes, it should not. Finally, because drugs that are sold as OTC

product cannot be marketed in a way that does not conform with the monograph or NDA, an OTC manufacturer should be able to avail itself of the direct pre-emption set forth in Section 379r.

FOOTNOTES:

Footnote 1. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Wyeth v. Levine*, 555 U.S. 555 (2009); *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011).

Footnote 2. *Mills v. Warner Lambert Company*, 581 F. Supp. 2d 772 (E.D. Tex. 2008); *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271 (C.D.CA., 2008).

Footnote 3. *Mills*, 581 F. Supp. 2d at 777.

Footnote 4. U.S. Const. art. VI, cl. 2.

Footnote 5. *Maryland v. Louisiana*, 451 U.S. 725, 747 (1981).

Footnote 6. *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992).

Footnote 7. *English v. General Elec. Co.*, 496 U.S. 79 (1990).

Footnote 8. *Id.*

Footnote 9. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

Footnote 10. 21 U.S.C. § 360c(a)(1)(A).

Footnote 11. 21 U.S.C. § 360c(a)(1)(B).

Footnote 12. 21 U.S.C. § 360c(a)(1)(C).

Footnote 13. 21 U.S.C. § 360e(d)(2).

Footnote 14. *Riegel*, 552 U.S. at 318.

Footnote 15. *Id.*

Footnote 16. 21 U.S.C. § 360c(a)(2)(C).

Footnote 17. *Riegel*, 552 U.S. at 318.

Footnote 18. 21 U.S.C. § 360c(a)(2)(B).

Footnote 19. 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A).

Footnote 20. 21 U.S.C. § 360e(d)(6)(A)(i).

Footnote 21. 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c).

Footnote 22. 21 C.F.R. §§ 814.84(b)(2), 803.50(a).

Footnote 23. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1).

Footnote 24. 21 U.S.C. § 360e(b)(1)(B).

Footnote 25. 21 U.S.C. § 355(a). A "new drug" is a term of art without significant relevance here.

Footnote 26. 21 U.S.C. § 355(b)(1)(F); § 355(b)(1)(A); 21 C.F.R. § 314.50(d)(5)(VIII).

Footnote 27. 21 U.S.C. § 355(d).

Footnote 28. *Wyeth*, 555 U.S. at 129.

Footnote 29. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C).

Footnote 30. *Id.*

Footnote 31. *Id.*

Footnote 32. 21 U.S.C. § 355(j)(2)(A)(v).

Footnote 33. 21 U.S.C. § 315.94(a)(8)(IV); *Pliva* (slip opinion page 8).

Footnote 34. *Mills*, 581 F. Supp. 2d at 781.

Footnote 35. *Id.* at 783.

Footnote 36. *Id.* at 784.

Footnote 37. *Id.*

Footnote 38. *Id.*

Footnote 39. *Id.*

Footnote 40. *Id.*

Footnote 41. *Lohr*.

Footnote 42. *Id.* at 492-93.

Footnote 43. Id. at 501.

Footnote 44. Id. at 471.

Footnote 45. Id. at 513 (O'Connor, J., concurring in part and dissenting in part).

Footnote 46. Buckman, 531 U.S. at 344.

Footnote 47. Id. at 347-48.

Footnote 48. Id. at 350.

Footnote 49. Id. at 352.

Footnote 50. Riegel, 552 U.S. at 320.

Footnote 51. Id. at 322-23.

Footnote 52. Id.

Footnote 53. Riegel, 552 U.S. at 325.

Footnote 54. Id. at 330.

Footnote 55. Wyeth, 129 S. Ct. at 1190-91.

Footnote 56. Id.

Footnote 57. Id.

Footnote 58. Pliva, 564 U.S., slip op. at 3.

Footnote 59. Id. at 6.

Footnote 60. Id.

Footnote 61. Pliva, slip op. at 12.

Footnote 62. Id.

Footnote 63. Id. at 19. As discussed below, however, the result makes perfect sense.

Footnote 64. Id.

Footnote 65. 21 U.S.C. § 379r(d).

Footnote 66. 21 U.S.C. § 379r(e).

Footnote 67. Carter, 582 F. Supp. 2d at 1276-77.

Footnote 68. Id. at 1286.

Footnote 69. Mills, 581 F. Supp. 2d at 776.