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FDA POSITION ON FEDERAL PREEMPTION CONSISTENT WITH LAW AND PUBLIC HEALTH

by

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The Food and Drug Administration (FDA) has come under political fire in recent years for its assertion of plenary authority over the labeling of FDA-regulated products, including prescription drugs. FDA has undergone particular attack for asserting in a number of court proceedings that its labeling determinations should be given preemptive effect over state law. FDA has argued that *ad hoc* jury awards based on conflicting lay determinations have undercut its carefully-balanced scientific conclusions regarding warnings that inform medical professionals without discouraging useful medical treatments.

Opponents of this position have contended that FDA has embarked in a radical new direction that is contrary to its history and legal precedent. These contentions are without merit. FDA's recent actions are consistent with its historical role in protecting public health and reflect increasing judicial recognition of the importance of federal preemption of litigation involving FDA-regulated products.

FDA Has Recently Provided Amicus Assistance to the Courts Explaining the Need for Preemption. FDA has set forth its preemption position in *amicus* briefs filed in a number of state and federal cases over the past few years.¹

In *Motus*, FDA defended its regulatory authority to determine proper warnings about alleged suicide risks for prescription antidepressant drugs, and opposed tort plaintiffs' claims that manufacturers be held liable for following FDA's direction. FDA explained that preemption was needed for two reasons. *First*, allowing plaintiffs to proceed under state law based on a claim that the defendant should have provided warnings different than those required by FDA would impermissibly compel that "the manufacturer of a drug choose either to avoid tort liability or comply with the FDCA [Food, Drug & Cosmetics Act]." *Motus Amicus Br.* at 12. *Second*, "imposition of liability on the basis of a failure to warn would thwart the FDCA's objectives of ensuring a drug's optimal use by requiring that manufacturers disseminate only truthful information as to its effects." *Id.* at 14-15. FDA explained that drug labels are intended not only to inform patients of adverse health risks but also to encourage drug use by the patients who need them:

Under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly life-saving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects. Further,

¹See *Amicus Brief for the United States, Motus v. Pfizer, Inc.*, Nos. 02-55372 & 02-55498 at 2 (9th Cir. Sept. 19, 2002) ("*Motus Amicus Br.*"); *Amicus Curiae Letter Brief for the United States in Horn v. Thoratec*, No. 02-4597 (3d Cir. May 14, 2000); *Amicus Brief for the United States, Dowhal v. SmithKline Beecham Consumer Health Care, LP, et al.*, No. S109306 (Cal. July 21, 2003) ("*Dowhal Amicus Br.*"); Statement of Interest in Support of Defendant Pacesetter's Petition for Certification for Interlocutory Appeal of the United States in *Murphree v. Pacesetter, Inc.*, No. 005429-00-3 (Tenn. Circuit Ct. Dec. 12, 2003).

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allowing unsubstantiated warnings may also diminish the impact of valid warnings by creating an unnecessary distraction and making even valid warnings less credible.

Id. at 23-24²

In *Dowhal*, FDA opposed a private plaintiff's efforts to require pregnancy warnings on over-the-counter nicotine replacement products despite FDA's directive not to provide such warnings. FDA had rejected such warnings because they might discourage use by pregnant women unable to quit smoking without these products.³ In its *amicus* brief before the California Supreme Court, FDA explained:

FDA's determination concerning appropriate warning labeling reflects the agency's application of its established expertise to the relevant data in light of the FDCA's requirements. Because Congress has entrusted FDA to make any necessary judgments concerning what labeling content provides the warnings necessary to avoid misbranding a product, a state court should defer to FDA's assessment.

Dowhal Amicus Br. at 5. FDA noted that by enacting the FDCA, Congress established a comprehensive regulatory plan designed to ensure the safety and effectiveness of drugs. Congress gave FDA plenary authority to regulate the labeling of drug products. "State law must be applied so as to preserve the latitude necessary for the federal regulatory scheme to operate as Congress intended." *Id.*⁴

In *Horn*, the Third Circuit requested FDA's views on whether state tort claims of design defect, strict liability, negligence, and failure to warn should be preempted in light of FDA review and approval of Class III medical devices. Consistent with its position in the drug cases *Motus* and *Dowhal* (and in another medical device case *Murphree*), FDA explained the need for preemption in these circumstances:

State common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling. State actions are not characterized by centralized expert evaluation of device regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of FDA – sometimes on behalf of a single individual or group of individuals.

Horn Amicus Br. at 25-26. FDA rejected the argument often made by tort plaintiffs that regulatory decisions impose only minimum standards, again explaining that FDA approval "sets a ceiling as well as a floor":

Risk minimization measures, such as labeling warnings and market withdrawal, may actually present substantial disadvantages. More warnings can discourage appropriate product use. Market withdrawal can deprive patients of a useful therapeutic product. Therefore, FDA review of a PMA focuses not only on identifying the risk minimization appropriate for a device, but also on ensuring that the measures selected do not present their own public health disadvantages. By imposing additional risk minimization measures, state co-regulation may disrupt the careful balancing performed by FDA in the PMA process.

Id. at 29. FDA further noted that its regulatory scheme "offer[s] far more immediate protection for consumers than does the tort system" which "normally takes years to reach resolution, and the resolutions it reaches are often not consistent with the broader risk-benefit calculus the agency makes." *Id.* at 26 n.5.

FDA's Amicus Efforts in Support of Preemption Are Consistent with Historical Precedent and Necessary to its Continued Ability to Protect the Public Health. In July 2004, Representative Maurice

² The Ninth Circuit affirmed summary judgment for the defendants on an alternative ground and accordingly did not reach the preemption issue. See *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004).

³ The plaintiff argued that such warnings were required under California's Proposition 65.

⁴ The California Supreme Court agreed with FDA and held plaintiff's claim to be preempted. See *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004).

Hinchey of New York generated headlines by introducing a bill in the House of Representatives stripping \$500,000 from the FDA Chief Counsel's office as a punishment for FDA's position in the *Motus*, *Dowhal*, *Horn*, and *Murphree* cases. Congressman Hinchey accused FDA of having embarked in "a radical new direction" through its *amicus* efforts in support of preemption and of having engaged in a "pattern of collusion between the FDA and the drug companies and medical device companies" in a way that had "never happened before." 150 Cong. Rec. H5598-H5599 (July 13, 2004).

In response, a bipartisan group of former FDA Chief Counsels issued a statement defending FDA's *amicus* efforts as not "radical or even novel." 150 Cong. Rec. E1506 (July 22, 2004). The Chief Counsels explained that FDA has filed *amicus* briefs asserting its primary responsibility over new drug issues since the early 1970s, that FDA had submitted *amicus* briefs in private tort litigation during the Clinton Administration that similarly argued for preemption of inconsistent state court determinations regarding FDA drug product labeling, and that these *amicus* efforts were necessary "to protect a uniform national system of food and drug law." *Id.* at E1505-1506.

The Chief Counsels made clear that FDA's *amicus* efforts in support of preemption of state tort law claims are crucial to FDA's continued ability to protect the public health:

The *amicus curiae* briefs ... protect FDA's jurisdiction and the integrity of the federal regulatory process. There is a greater need for FDA intervention today because plaintiffs in courts are intruding more heavily on FDA's primary jurisdiction than ever before. In our judgment, [these] actions are in the best interests of the consuming public and FDA. If every state judge and jury could fashion their own labeling requirements for drugs and medical devices, there would be regulatory chaos for these two industries that are so vital to the public health, and FDA's ability to advance the public health by allocating scarce space in product labeling to the most important information would be seriously eroded.

Id. at E1506.

FDA's Amicus Efforts Reflect Increased Judicial Recognition of the Need for Preemption of Tort Claims Involving FDA-Regulated Products. FDA's understanding of the preemptive effect of its regulatory determinations is entitled to deference and its recent *amicus* efforts have and will continue to have an impact on state tort law litigation.⁵ The United States Supreme Court has repeatedly stated that courts should defer to FDA's views regarding preemption, going so far in one case as to find such views "dispositive."⁶ However, Representative Hinchey's insinuation that FDA has been leading the charge on preemption is not accurate. Rather, FDA has been responding to an increasing judicial awareness that state tort law claims involving FDA-regulated products are intruding upon FDA authority. This judicial awareness is highlighted by two United States Supreme Court opinions, both of which have led to preemption rulings in prescription drug litigation wholly unrelated to the FDA *amicus* efforts.

In *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court first addressed the question of FDA preemption in connection with a claim brought against a grandfathered medical device approved under the §510(k) "substantial equivalence" process.⁷ The Court held that state tort law claims were not preempted because FDA does not impose product-specific requirements on §510(k) devices. However, a majority found that such claims would be preempted in cases involving products that had undergone FDA safety and efficacy review. *See id.* 518 U.S. at 506 (Breyer, J., concurring). Following *Lohr*, the clear majority of

⁵See *Needleman v. Pfizer, Inc.*, No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004) (citing to FDA *Motus Amicus* Brief in finding plaintiffs' claims in prescription drug case preempted); *Dusek v. Pfizer Inc.*, No. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004) (same).

⁶*Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714 (1985). *See also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) (FDA "is uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress and, therefore, whether it should be preempted.") (internal quotation and footnote omitted).

⁷Under Section 510(k), medical devices that are substantially equivalent to medical devices already on the market when the Medical Device Act was enacted are not required to go through the full PMA safety and efficacy process.

federal circuit courts have held that state tort law claims involving Class III medical devices subject to the full Pre-Marketing Approval (“PMA”) process are preempted.⁸

While the medical device cases were decided in the context of an express preemption provision in the Medical Device Act, the holdings turn on the conflict between state tort law claims and FDA’s rigorous review of the safety and labeling of Class III medical devices through the PMA process, the same conflict that would independently require a finding of implied preemption.⁹ The PMA process was patterned after, and is substantively identical to, the NDA process used to approve prescription drugs. Accordingly, a number of courts have held that the same reasoning underlying the preemption rulings in medical device cases requires implied preemption of state tort law claims involving prescription drugs.¹⁰

The Supreme Court revisited FDA preemption in *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001), in which it impliedly preempted claims that a manufacturer had committed fraud on the FDA as part of the regulatory approval process. The Court found that allowing tort damages based on alleged fraud on the FDA would cause manufacturers “to fear that their disclosures to the FDA, although deemed appropriate by the Administration, would later be judged insufficient in state court.” 531 U.S. at 351. Such claims would deprive the FDA of control over its regulatory responsibilities, both by “dramatically increas[ing] the burdens” facing regulated entities that would be forced to “comply[] with the FDA’s detailed regulatory regime in the shadow of 50 States’ tort regimes,” *id.* at 350, and by imposing “additional burdens” on the FDA, because regulated entities would “have an incentive to submit a deluge of information that the Administration neither wants nor needs,” *id.* at 351. The Court also explained that allowing state tort law claims based on alleged fraud on the agency would deprive the FDA of “flexibility” to respond to such fraud as it deems appropriate, which the Court explained was “a critical component of the statutory and regulatory framework under which FDA pursues difficult (and often competing) objectives.” *Id.* at 349.

While *Buckman* addressed claims arising from alleged fraud on FDA, its implications extend more broadly. One of plaintiffs’ key arguments to sidestep the conflict between state tort law claims and FDA regulation of medical devices and drugs is the claim that FDA was misled by the product manufacturer. Under *Buckman*, that argument is no longer available. Moreover, while *Buckman* involved a medical device, the decision turned on implied preemption and has subsequently been applied in a number of prescription drug cases as well.¹¹

Conclusion. In recent years, a trend has developed in drug and medical device litigation towards federal preemption of state tort actions. FDA’s decision to encourage and further this trend is consistent with its history and protective of the public health and it should thus continue in its efforts.

⁸See *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. *en banc* 2001); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 584-85 (5th Cir. 2001), *cert. denied*, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998). *But see Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375 (11th Cir. 1999).

⁹See *R.F. v. Abbott Laboratories*, 745 A.2d 1174, 1192-93 (N.J. 2000) (“An examination of those [MDA] cases discloses that much of the reasoning of the courts is consistent with an implied preemption analysis.”).

¹⁰See *Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) (finding “same rationale” for preemption in medical device cases applies to prescription drug claims), *aff’d on other grounds*, 367 F.3d 1013 (8th Cir. May 18, 2004); *Dusek*, 2004 WL 2191804, at *9 n.34 (FDA scrutiny of prescription drugs parallels that required for medical devices “suggesting a finding of preemption is appropriate here despite the absence of an express preemption clause”); *Kanter v. Warner Lambert Co.*, 122 Cal. Rptr. 2d 72, 83 (Ct. App. 2002) (“The substantial similarity between the premarket approval process [for medical devices] and new drug application processes compels the conclusion that the latter also establishes a federal requirement with respect to labeling that can have preemptive effect.”). For additional analysis of the parallels between medical device and prescription drug preemption, see Eric Lasker, *A Winding Brooks: The Eighth Circuit Reverses Course and Carves a Route to Implied Preemption in Prescription Drug Cases*, DRI INDUSTRYWIDE LIABILITY NEWS 8 (Winter 2003).

¹¹See *Garcia v. Wyeth Ayerst Labs*, No. 03-1712, 2004 WL 2256044 (6th Cir. Oct. 7, 2004) (rejecting drug product liability claim that was based on assertion that FDA acted improperly due to defendant’s failure to provide FDA accurate information); *Flynn v. American Home Prods. Corp.*, 627 N.W.2d 342 (Minn. Ct. App. 2001) (same). Further analysis of the potential impact of *Buckman* on preemption in prescription drug litigation can be found at Eric G. Lasker, *The U.S. Supreme Court Expands the Scope of Federal preemption of Product Liability Claims Involving FDA Regulated Products*, 37 TORT & INS. L. J. 129-145 (Fall 2001).