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Does FDA Approval Provide Safe Harbor?

Courts are split on manufacturers' obligation to independently update drug labels

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There is a significant controversy in the courts nationally and now in New Jersey concerning the obligations of a pharmaceutical manufacturer to update drug warnings *sua sponte*.

The label, including the warning that the public receives as a package insert and which is largely reproduced in the *Physician's Desk Reference*, must be approved by the FDA. Some state and federal courts have determined that the manufacturer is obligated to make warning enhancements, irrespective of FDA approval of the warning. Other state and federal courts have rejected this view and have found that FDA approval pre-empts state law from imposing any additional requirements. Still other courts have found that while pre-emption exists concerning the language of the warning, federal law still will permit a state to impose additional liability beyond that described in the Federal Food, Drug and Cosmetic Act (FDCA) or the medical device amendments thereto. The FDA has expressed itself

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clearly on this subject in a preamble to recent amendments to the FDA regulations (published Jan. 24, 2006, and effective June 30, 2006), discussing in-depth the pre-emptive effect of FDA drug warning approvals. See 21 Fed. Reg. 3922, 3933-36, 3967-69.

For a detailed discussion of the varying court views on pre-emption and the growing trend of plaintiffs to add allegations of Consumer Fraud Act violations (or similar acts), to avoid direct confrontation with a product liability failure to warn preclusion, see William Dreier, "Liability for Drug Advertising, Warning and Frauds," 58 Rutgers L. Rev. 615 (2006). The article, published when the FDA changes were promulgated, suggests that at the very least, courts should defer to the primary jurisdiction of the FDA to pass upon any claim that particular language should have been added to a manufacturer's warning. Individual juries should not be able to impose requirements that would be unacceptable to the FDA or that may have been specifically rejected after months or years of study.

After publication of the amended FDA regulations and preamble, an addendum was added to the article, outlining the effect of the federal action and describing some of the more recent decisional law giving effect to or rejecting the pre-emption statements in the pre-

amble.

This issue is of significant importance in light of a recent federal district court decision in *McNellis v. Pfizer, Inc.*, 2006 WL 2819046 (D.N.J. Sept. 29, 2006) (*McNellis II* or *McNellis*), adhering to the court's prior decision at 2005 WL 3752269 (D.N.J. Dec. 29, 2005) (*McNellis I*), but staying the effect of that decision and certifying the issue to the Third Circuit under 28 U.S.C. § 1292(b) for interlocutory appeal. In the later opinion, the court collected the authority to that date and in effect directly challenged the FDA's authority. The court refused to follow the specific expressions of pre-emptive intent in the Preamble, noting that they might force a violation of other FDA regulations. The court also questioned the FDA's power to issue such pre-emptive regulations, citing to the FDA's inconsistent interpretations of the FDCA and regulations over the years.

There are at least three problems with this analysis. First, the court overlooked completely that it will be applying New Jersey substantive law to this case. Second, the court did not consider the concept of primary jurisdiction. Third, the court mistakenly considered the consistency of FDA interpretations since 2000.

As noted in the *Rutgers Law Review* article, the New Jersey Supreme Court

has expressed in detail its adherence to the proposition that a manufacturer's compliance with an FDA-approved warning will, except in the rarest case, preclude a claim that the warning was defective under New Jersey's Product Liability Act, N.J.S.A. 2A:58C-1 to 7. See *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1 (1999). Although *Perez* principally involved direct-to-consumer advertising, the Court made it clear that the decision applied to all warning defect cases. The Court's treatment of an FDA-approved warning could not have been more definitive. It stated:

FDA Regulations are pertinent in determining the nature and extent of any duty of care that should be imposed on pharmaceutical manufacturers with direct-to-consumer advertising.... Presently, any duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling. See N.J.S.A. 2C:58-4. That presumption is not absolute.... Nevertheless, FDA Regulations serve as *compelling evidence* that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product. (Emphasis added.)

The Court did state that the presumption was not absolute, citing *Feldman v. Lederle Labs., Inc.*, 125 N.J. 117, 156-57 (1991), cert. denied, 505 U.S. 1219 (1992), but it then went on to reshape the effect of this presumption. It first noted that the same presumption will apply to both warnings to the physician and direct-to-consumer advertising. It then stated the scope of this new presumption as follows:

For all practical purposes, absent deliberate concealment or non-disclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be *virtually*

dispositive of such claims.

The Court concluded its discussion on this point by noting that there could be no punitive damages if there was compliance with FDA labeling, and that there would be compensatory damages only in "those rare cases where the presumption is overcome." As noted earlier, these "rare cases" were defined as "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." Certainly, the exception was not meant to include issues that had actually been brought to the attention of the FDA (as in *McNellis*) or were disclosed to the public through the manufacturer's Web sites or in public FDA submissions.

This position was recently recognized in *Rowe v. Hoffmann-La Roche*, 383 N.J. Super. 442 (App. Div. 2006) (now on appeal to the Supreme Court on other issues). While recognizing that the presumption of compliance was not absolute, the court rejected plaintiff's claim that New Jersey had a reluctance to cede control to the FDA, by referring to the explanation of "the strength of New Jersey's statutory presumption as interpreted by *Perez* in Dreier, Keefe & Katz, *Current New Jersey Product Liability and Toxic Tort Law*, § 15.4 ([Gann] 2005)." The text contains a full explanation of the practically conclusive *Perez* presumption.

Other courts have similarly recognized that New Jersey employs this strong presumption. See *Merida Prods. Liability Litig. Steering Comm. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006). The court found that the New Jersey presumption was only "technically rebuttable," but that "for all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims."

McNellis failed to recognize that, absent the deliberate concealment or nondisclosure of after-acquired knowledge, New Jersey's law had already approached the pre-emption provisions of the FDA preamble years before the

preamble was issued. Absent these narrow exceptions, the failure to make such a change would not fall within a New Jersey cause of action, so long as the manufacturer was in compliance with its existing FDA approvals.

As recognized in *Rowe*, the New Jersey presumption, unlike that in Michigan, is not absolute. But in the *McNellis* situation, the differences are not material. In *McNellis*, the issues raised by the plaintiffs had already been brought to the attention of the FDA, which had not authorized the very changes for which the court was asked to permit liability to attach. Most important, the court failed to acknowledge, much less address, the crucial facts that (i) both before and after the plaintiff's decedent had been treated with the medication in issue, the FDA had mandated the exact labeling language challenged by the plaintiff as inadequate; (ii) both before and after the plaintiff's decedent had been treated with the medication in issue, the FDA had filed, in other cases involving the same medication and similar allegation, amicus curiae briefs explicitly stating that the manufacturer could not add different warnings without misbranding the product; and (iii) there was no allegation that, during the brief period between the two FDA mandates and between the two FDA briefs, the manufacturer had learned of and fraudulently concealed from the FDA any new information that warranted an additional warning.

Nonetheless, the court referred to an emergent power of the manufacturer under 21 CFR 314.70(c)(6) to enhance a previously approved warning, even in the face of the FDA's decision that there was no scientific evidence to support a different warning. Is there any question that under New Jersey law as expressed in *Perez*, no liability would attach to this conduct? This was not one of the "rare cases" in New Jersey where there could be compensatory damages. This could not be "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." If the FDA's actions were to be "virtually dispositive" as

required by New Jersey law, what would be left to present to a jury?

The second point overlooked by the court in *McNellis* was the concept of primary jurisdiction, often used by the federal courts concerning their relationship with administrative agencies. If there was any question in *McNellis* as to how the FDA would treat the allegedly inadequate warnings, the issue could have been referred to the FDA for an administrative ruling before the legal issue was sent to the Third Circuit. This was briefly discussed at oral argument, but was not treated in the court's opinion. For example, in *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000), the court explained that "under the doctrine of primary jurisdiction, a district court may refer a matter within its original jurisdiction to the appropriate administrative agency if doing so will 'promot[e] proper relationships between the courts and administrative agencies charged with particular regulatory duties.' *Nader v. Alleghany Airlines, Inc.*, 426 U.S. 290, 303 (1976)." The judge in *Bernhardt* then outlined the factors governing the referral of the matter to a regulatory agency, factors all present in *McNellis*. New Jersey state courts similarly permit such referrals. See *Unalachtigo Band of the Nanticoke-Lenni Lenape Nation v. State*, 375 N.J. Super. 330, 345-46 (App. Div.), cert. denied 184 N.J. 210 (2005).

Even if a referral procedure is not directly feasible in another state as it is in New Jersey and in the federal courts, a court could direct the parties to submit the issue to the FDA and apply for a letter ruling on the proposed warning language with the court being advised of the results. The case could be stayed pending this analysis so that state rulings by individual judges and juries would not overrule the national regulatory system governing drug warnings.

Submission to the FDA is a fact of life in the pharmaceutical industry. Manufacturers regularly make such referrals themselves. As is also noted in the *Rutgers Law Review* article, it would be a highly unusual case where a manufacturer would unilaterally change its

labeling in advance of FDA approval. 21 CFR 314.70(c)(6) does permit a manufacturer to strengthen label warnings pending FDA approval of a proposed change. But 21 CFR 201.57 requires that all new warnings must be based on "reasonable evidence of an association" between the medication in issue and the type of serious adverse event in issue. In addition, the regulations governing advertising require the disclosure of all warnings, and the warnings in the label are part of the pharmaceutical advertising.

As the *Rutgers Law Review* article explains, a manufacturer is permitted to obtain FDA comments on its proposed advertising, and favorable comments provide a safe harbor against future claims of inadequate disclosure. Deliberately inadequate or false disclosure can result in the product being considered misbranded, with grievous consequences. Only in cases where there is an immediate danger to the public, therefore, would a manufacturer run the risk of making such unapproved changes. This practice is explained in some detail in *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 2006 WL 2374742, *8 (N.D. Cal. Aug. 6, 2006). This emergency procedure is not used where the FDA is fully aware of the issue and has not directed that the change be made. A court's resort to the FDA advice would be a natural outgrowth of this submission process.

Lastly, the *McNellis* opinion failed to give weight to the preamble as the policy of the FDA expressed since 2000. In the new *McNellis* opinion, the court cited many pre-preamble cases to support its view. These cases, however, could not have considered the strong and definitive pre-emption language in the preamble. In some of the earlier cases, the FDA had filed amicus briefs to urge findings of pre-emption, a position accepted by many courts (see, e.g., *Riegel v. Metronic, Inc.*, 451 F.3d 104, 124 (2d Cir. 2006); *Horn v. Thoratec Corp.*, 376 F.3d 163, 177 n.23 (3d Cir. 2004); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 524-52 (E.D. Pa. 2006)),

but rejected by others as being ad hoc, and not general FDA policy expressed by regulations (see *McNellis I; Witczek v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 727-28 (D. Minn. 2005)). This defect, if it was one, is now cured by the preamble, and the contrary decisions should accordingly be given lesser weight.

There was a contrary policy statement in 2000, prior to the administration change in Washington; but since then, the FDA policy has been consistent. Although some earlier cases viewed FDA regulations as a floor but not a ceiling on warnings, the preamble now clearly provides that the FDA-approved language defines both a ceiling and a floor. 71 Fed. Reg. 3935. The FDA states:

FDA interprets the act to establish both a "floor" and a "ceiling" such that additional disclosures of risk can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use, exaggeration of risk could discourage appropriate use of a beneficial drug.

The FDA does permit some state actions to proceed, with the exception of "fraud on the FDA" claims specifically prohibited by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352-53 (2001). But the state law requirements must parallel FDA requirements. So long as the state law requirements merely provide specific remedies but do not regulate a manufacturer's or advertiser's conduct, states may still assert jurisdic-

tion outside of the area of “fraud on the FDA.” 71 Fed. Reg. 3936. Against the arguments in *McNellis*, the preamble states unequivocally: “In fact, the determination where the labeling revisions are necessary is, in the end, squarely and solely FDA’s under the act.”

Other courts have viewed these issues since the preamble was promulgated. See *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 524-52 (E.D. Pa. 2006) (appeal filed June 21, 2006), where, as noted in *McNellis II*, the court: (1) gave deference to the FDA’s interpretation (outlined in the preamble) of its own regulations; and (2) held that the regulations to the FDCA pre-empt state failure-to-warn tort claims. The *McNellis* court, however, rejected this analysis, as did the court in *Jackson v. Pfizer, Inc.*, 432 F. Supp. 1964 at 68, n.3 (D. Neb. 2006). See also, *Perry v. Novartis Pharma. Corp.*, 2006 WL 2979388, at *7, n. 16 (E.D. Pa. Oct. 16, 2006) (where the court distinguished cases in which the FDA declined to add a warning from cases in which a plaintiff claims that the company should add a warning while the FDA is considering the issue). *Colacicco* was followed in *Conte v. Wyeth, Inc.*, 2006 WL 2692469, *5 (Cal. Super. 2006), and in *In re Bextra and Celebrex, Marketing Sales*

Practices and Prods. Liability Litig., at *7.

The *McNellis* court took issue with the fact that the FDA had changed its position on the pre-emptive effect of its regulations between 2000, when it issued an earlier statement on pre-emption, and 2006, when it promulgated the new regulation with the preamble. Because of this change in position, the court concluded that it could give less deference to the FDA’s interpretation of its own regulations.

Federal precedent states that consistency of interpretation is one factor to be considered. But as noted in *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, the “180-degree reversal” of the FDA’s prior position does not diminish the effect of the present position. This is not a case of an agency giving inconsistent current decisions, but rather a studied change in position based on experience with the unworkability and lack of uniformity resulting from the earlier rule. The court stated:

[T]he Supreme Court has recognized that an agency’s view of the pre-emptive effect of its regulations may change over time as the agency gains more

experience with the interrelationship between its regulations and state laws. [citations omitted]. Moreover, the Supreme Court has never held that a court may not give weight to an agency’s view of the pre-emptive effect of its own regulations simply because that agency’s view changed contemporaneously with a change in administration. And as the *Colacicco* court notes, the FDA’s view has been consistent since 2000.

These three defects in the *McNellis* decision indicate that a different focus is needed when viewing a pharmaceutical manufacturer’s failure to give a particular warning urged by a plaintiff, as opposed to the warning approved by the FDA. Finders of fact, be they judge or jury, simply do not have the expertise to make this determination, except in the most egregious cases (which seldom appear). Manufacturers should not be exposed to the whim of each jury concerning the standard for the FDA-regulated warnings they must give to a national market. Hopefully, the Third Circuit will resolve this dilemma. ■