Legal Backgrounder

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COURTS' MISAPPLICATION OF FDA PREEMPTION POLICY CREATES QUANDARY FOR DRUG PRODUCERS

by

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A year ago, the Food & Drug Administration (FDA) set off a firestorm of debate in courtrooms across the nation when it adopted new drug labeling rules. At the center of the controversy is FDA's position that federal labeling requirements have preemptive effect and courts applying state law must not second-guess FDA labeling determinations:

> FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in [drug] labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.[1]

Now, one year later, a troubling trend has emerged. While several courts have agreed that state law must yield when it directly conflicts with FDA labeling determinations, other courts have refused to dismiss failure-to-warn claims on conflict preemption grounds. What is particularly startling is that failure-to-warn lawsuits have been allowed to proceed even where FDA specifically rejected including a particular risk in the drug label.

For instance, in September 2006, the court in *McNellis v. Pfizer, Inc.* denied a motion to dismiss plaintiff's claim that the SSRI (selective serotonin reuptake inhibitor) antidepressant Zoloft should have carried additional warnings concerning suicide – despite FDA's refusal to change the existing suicide

[1]Preamble, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (the "Preemption Preamble").

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warnings because, in the agency's considered judgment, it was scientifically unfounded at that time.[2]

Four months earlier, the opposite conclusion was reached in *Colacicco v. Apotex, Inc.*, which also involved SSRI antidepressants. The *Colacicco* court appropriately dismissed plaintiff's state law failure-to-warn claims, finding that FDA "repeatedly determined that there was inadequate evidence of an association between adult use of SSRIs and suicidality."[3] The *Colacicco* court relied in part on an FDA *amicus* brief that explained the regulatory history of SSRI labeling and emphasized that labeling inconsistent with the agency's directives would have been "false and misleading" and thus contrary to law.[4]

Surprisingly, the *McNellis* court rejected *Colacicco*'s holding, FDA's *amicus* brief, and the Preemption Preamble, and held preemption inapplicable. The effect of the *McNellis* ruling is that the court would permit a jury to decide that a drug company should have ignored the FDA's labeling directives and unilaterally changed the Zoloft labeling.[5]

This creates an impossible quandary. Drug companies must comply with FDA labeling directives. Such directives are based on FDA's expert scientific evaluation of a drug's risks and benefits. As FDA has articulated, to allow plaintiffs and lay juries to second-guess the agency's scientific assessment of a specific drug threatens FDA's congressionally-mandated role:

> If . . . judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.[6]

The *Colacicco* court recognized this, concluding that "it is not the function of this Court, or for a jury . . . to substitute its judgment for the FDA's" concerning drug labeling.[7] As another court applying preemption in a case involving SSRIs, *Ackermann v. Wyeth Pharmaceuticals*, explained, "[a]llowing each state to require different standards for drug labeling promotes confusion," and "[t]o usurp the FDA's regulation in this area offers the potential for far more harm than benefit to patients."[8]

The *McNellis* outcome is troubling because the court, by allowing the lawsuit to proceed, will essentially permit a jury to reject FDA's labeling mandates. The drug company is left in the untenable

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[2] *McNellis v. Pfizer, Inc.*, 2006 U.S. Dist. LEXIS 70844 (D.N.J. Sept. 26, 2006), *appeal docketed*, No. 06-8056 (3d Cir. 2006).

[3] *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d. 514, 524 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. Jun. 21, 2006).

[4] *Id.*

[5] Both *McNellis* and *Colacicco* are on appeal to the United States Court of Appeals for the Third Circuit. The appeals have been consolidated and will be heard by the same panel.

[6] 71 Fed. Reg. 3969; *see also id.* at 3934-35.

[7] *Colacicco*, 432 F. Supp. 2d. at 530.

[8] *Ackermann v. Wyeth Pharms.*, 2006 U.S. Dist. LEXIS 64499, 19, *adopted by, summary judgment granted*, 2006 U.S. Dist. LEXIS 88456 (E.D. Tex. 2006).

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position of potentially paying product liability damages for failing to add stronger suicide warnings despite that FDA did not consider those warnings appropriate based on the scientific data.[9] Over many years, FDA repeatedly concluded that the scientific data did not establish that SSRI use increased the risk of suicide. In fact, the *McNellis* court acknowledged that in June 2003 – several months *after* the decedent's suicide – FDA specifically found that data on suicidality did *not* support any labeling change.[10] Nevertheless, the *McNellis* court held that preemption did not apply because it viewed FDA regulations merely as "minimum standards" that do not prohibit a manufacturer from unilaterally strengthening a warning.[11]

In essence then, drug companies are stuck in a damned-if-you-do, damned-if-you-don't quagmire, facing conflicting federal and state law requirements. This is the exact setting in which conflict preemption *must* apply – *i.e.*, where it is impossible to comply with both state and federal law *or* where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[12]

The *McNellis* case is unfortunately not the only case in which a court has rejected preemption and thereby exposed a drug company to potential liability for using an FDA-mandated warning. In *Jackson v. Pfizer, Inc*., the plaintiff alleged that drug labeling for Zoloft and another SSRI antidepressant, Effexor, should have included additional suicidality warnings before decedent's suicide in October 2002.[13] The court acknowledged that "*FDA required that the antidepressants use the exact language specified by it with regard to suicide*."[14] Regardless, the *Jackson* court rejected preemption, following a line of cases viewing federal labeling requirements as mere minimum standards. With little analysis or explanation, the court ruled that FDA's requirements did not make it impossible for the drug company also to comply with state failure-to-warn law, nor did plaintiff's claim frustrate the purposes of the federal drug labeling scheme.[15]

The disturbing second-guessing of FDA drug labeling determinations is not limited to cases involving SSRI drugs either. For example, in *Rush v. Wyeth*, the plaintiff alleged that Prempro drug labeling should have included additional warnings regarding the risk of breast cancer with hormone therapy.[16] From 1995 to 2002, FDA evaluated the scientific data concerning hormone therapy and breast cancer, and required very specific language concerning breast cancer in the drug labeling. Moreover, FDA conclusively determined during the relevant time period that there was insufficient scientific evidence to substantiate a link between hormone therapy and breast cancer. Therefore, the drug company could not have included breast cancer warnings other than what was specifically required by FDA. Nevertheless, the *Rush* court – in a one-page order with no substantive analysis – rejected preemption out of hand.

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[9] *McNellis*, 2006 U.S. Dist. LEXIS 70844, 14.

[10] *Id*. at 20-21.

[11] FDA, in the Preemption Preamble, directly rejects the "misunderstanding" that its regulations are merely minimum standards, noting that "additional disclosures of risk information can expose a manufacturer to liability under the [FDCA] if the additional statement is unsubstantiated or otherwise false or misleading." 71 Fed. Reg. at 3934-35.

[12] *See Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873, 899 (2000).

[13] *Jackson v. Pfizer, Inc*., 432 F. Supp. 2d 964 (D. Neb. 2006).

[14] *Id*. at 968 (emphasis added).

[15] *Id*. at 968-69.

[16] *Rush v. Wyeth*, No. 4:05-00497 (E.D. Ark. June 15, 2006).

Cases such as *McNellis*, *Jackson*, and *Rush* impose the impossible on drug companies. In each of these cases, FDA specifically considered and rejected certain warnings as scientifically unsubstantiated and required use of particular labeling. FDA-mandated labeling necessarily reflects FDA's scientific conclusions regarding the risks and benefits of a given drug. Were a drug company to ignore FDA's determinations and unilaterally change mandated drug labeling, it would violate federal law.

There can be no doubt that in those circumstances, preemption must apply and conflicting state law must yield. Any other result permits judges and juries to second-guess FDA's "authoritative conclusions regarding the conditions under which the product can be used safely and effectively."[17] That outcome unquestionably disrupts and undermines the federal Food, Drug, and Cosmetic Act, and FDA's Congressionally-appointed authority.

The primary mission of drug companies is to research and develop therapies and cures to improve health and save lives. These purposes are defeated if drug companies can be hauled into court to defend failure-to-warn lawsuits even where FDA has specifically considered and rejected the warnings that plaintiffs allege should have been given. Such litigation requires the wasteful and unjustifiable commitment of substantial time, expense, and focus that should instead be devoted to innovation.

[17] *See* 71 Fed. Reg. at 3934.