



PHARMACEUTICAL
AND
MEDICAL DEVICE
GROUP

PARTNERS

DANIEL J. COHEN
NEIL M. DAY
TIMOTHY I. DUFFY
MICHAEL J. SULLIVAN

OF COUNSEL

LORNA A. DOTRO
H. LOCKWOOD MILLER, III

COUGHLIN DUFFY LLP
P.O. Box 1917
350 Mount Kemble Avenue
Morristown, New Jersey 07962
Tel (973) 267-0058
Fax (973) 631-6442

Wall Street Plaza
88 Pine Street, 5th Floor
New York, New York 10005
Tel (212) 483-0105
Fax (212) 480-3899

www.coughlinduffy.com

An Update from the Pharmaceutical
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PRODUCTIVELY Thinking

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DRUG MAKERS WIN LIMITED PREEMPTION VICTORY IN THIRD CIRCUIT

On April 8, 2008, a divided three-judge Third Circuit panel awarded a limited preemption victory to prescription drug manufacturers facing state failure-to-warn product liability suits. The decision, released in Colacicco v. Apotex Inc. and McNellis v. Pfizer Inc., ___ F.3d. ___ (2008) held that plaintiffs' failure-to-warn claims were preempted by the FDA's approval of the respective drugs' labeling.

Colacicco involved Paxil, a prescription SSRI used to treat depression. Plaintiff's decedent had taken a generic version of Paxil prior to his death by suicide, and plaintiffs brought suit against the generic manufacturer and GSK (the maker of Paxil), alleging that the drug failed to carry a warning of the increased risk of suicide. McNellis involved Zoloft, another SSRI used to treat depression, which plaintiffs also claimed failed to carry an increased suicidality warning. Whereas the Colacicco defendants had successfully moved to dismiss plaintiffs' claims in the Eastern District of Pennsylvania on preemption grounds, a similar motion to dismiss by the McNellis defendants was denied in the District of New Jersey. Because both cases raised the same issue – "whether actions taken by the FDA pursuant to its authority under the Federal Food, Drug and Cosmetic Act . . . and the corresponding regulatory scheme preempt the plaintiffs' state-law failure-to-warn claims" – the Third Circuit considered and decided both cases together.

Writing for the two-judge majority, Judge Sloviter concluded that plaintiffs' claims were preempted under conflict preemption. Judge Sloviter recognized the applicability of the so-called "presumption against preemption" but also noted that "the lack of a Congressional

directive expressly approving or rejecting preemption in the context of drug labeling regulations is not determinative." She gave deference to the pro-preemption position of the FDA, as stated through an amicus filing, that the FDA had considered and rejected the very warning that plaintiffs were arguing should have been given by the manufacturers, and she observed that "[a]bsent a determination that the FDA-approved labeling and the FDA's refusal to require the warnings suggested by plaintiffs in this case preempt state tort actions, the manufacturers may be subjected to considerable liability based on varying standards, with no benchmark that they should follow."

Although plaintiffs argued that, because FDA regulations "allow[] drug manufacturers to strengthen and augment warnings on drug labels without prior FDA approval, the FDA labeling requirements constitute mere minimum standards for the information that may be required in their labeling[.]" Judge Sloviter rejected this argument because FDA had "repeatedly rejected the scientific basis for the warnings that [plaintiffs asserted] . . . should have been included in the labeling." Because the FDA had "concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading," and because "the FDCA authorizes the FDA to prohibit false or misleading labeling[.]" Judge Sloviter concluded that "a state law obligation to include a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA's oft-repeated conclusion that the evidence did not support such an association." Under these circumstances, plaintiffs' failure-

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to-warn claims were held to be in conflict with, and thus preempted by, federal law.

In a lengthy dissent, Judge Ambro disagreed with the majority's finding of an actual conflict between federal regulation and plaintiffs' state-law failure-to-warn claims, finding instead that state law and federal regulation could work together to balance "safety and efficacy in the pharmaceutical industry while compensating victims of wrongful injuries."

IMPACT ON NEW JERSEY DEFENDANTS

Following on the heels of *Riegel v. Medtronic*, 522 U.S. ____ (2008), *Colacicco* represents a clear victory for the pharmaceutical industry. However, the Third Circuit's decision is explicitly confined to factual situations such as that before the court – in other words, situations in which the FDA "clearly and publicly stated its position prior to the prescriptions and deaths at issue [.]" Expressly not decided by the court, and thus still at issue in the preemption debate, was "whether the FDA's mere approval of drug labeling is sufficient to preempt state-law claims alleging that the labeling failed to warn of a given danger, whether FDA approval of drug labeling constitutes minimum standards in the absence of the FDA's express rejection of a specific warning, or whether actions against generic drug manufacturers are preempted on the basis of their obligations under the Hatch-Waxman Amendments." Accordingly, this decision from the Third Circuit will only focus even more attention on the eagerly awaited drug preemption decision from the United States Supreme Court in *Levine v. Wyeth*, expected later this year.

Authored by H. Lockwood Miller, III, Esq.

Current Mass Torts in New Jersey

<i>Accutane</i>	<i>J. Higbee, Atlantic County</i>
<i>Asbestos</i>	<i>J. McCormick, Middlesex County</i>
<i>Bextra/Celebrex</i>	<i>J. Higbee, Atlantic County</i>
<i>Ciba-Geigy</i>	<i>J. McCormick, Middlesex County</i>
<i>Depo-Provera</i>	<i>J. Harris, Bergen County</i>
<i>HRT</i>	<i>J. Happs, Middlesex County</i>
<i>Mahwah Toxic Dump Site</i>	<i>J. Harris, Bergen County</i>
<i>Ortho Evra</i>	<i>J. Happs, Middlesex County</i>
<i>Risperdal/Seroquel/Zyprexa</i>	<i>J. Happs, Middlesex County</i>
<i>Vioxx</i>	<i>J. Higbee, Atlantic County</i>
<i>Zometa/Aredia</i>	<i>J. Higbee, Atlantic County</i>

The Coughlin Duffy Pharmaceutical and Medical Device Group

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