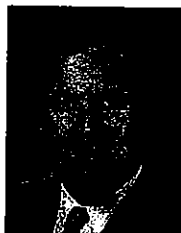


PAXIL, SUICIDE, AND CHILDREN

By D. Andrew List

"There is nothing worse that you can do to a [child] in America today than give them a mental illness kind of label and tell them they need drugs."

— Peter R. Breggin, M.D.



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Since 1990, the number of children in the United States taking antidepressants has more than doubled. At the same time, the class of antidepressant drugs known as selective serotonin reuptake inhibitors ("SSRI's") began to dominate the market.

Although the FDA has never approved most of the SSRI drugs (including Celexa, Effexor, Paxil or Zoloft) for patients under the age 18, "off label" prescriptions of these drugs to minors continue to increase. Indeed, in 2002, more than two million pediatric prescriptions were written for Paxil (paroxetine) alone.

Unfortunately, pediatric clinical trials of Paxil have demonstrated an increased risk of suicidal behaviors among children and teenagers. Given the increasing usage of SSRI drugs in general – and Paxil in particular – many attorneys have been contacted (or will be contacted) by someone whose child has ingested Paxil and has attempted suicide. Before undertaking the representation, all of us should follow several initial steps to determine whether the claim is viable.

First, we need a basic understanding of how these drugs impact children. Generally, an SSRI medicine, such as Paxil, acts upon the chemicals that allow nerves in

the brain to communicate with each other. These chemical messengers are called neurotransmitters. Neurotransmitters are released by one nerve and taken up by other nerves. When neurotransmitters are released, but not taken up by other nerves, they return to the nerves that released them (reuptake).

Many experts believe that an imbalance caused by reuptake causes depression. Accordingly, Paxil and other SSRI drugs seek to stop the reuptake process. Although experts differ as to how this process contributes to suicidal behaviors, one theory suggests that SSRI drugs quickly reverse the lethargy associated with depression, but then take several weeks to ease the depression itself. During the time before the underlying depression is resolved, young patients have increased energy to contemplate or carry through suicide attempts.

As a result, parents and professionals (both legal and medical) should be especially attentive to behavioral changes when a child or teenager first begins taking Paxil, or when a change in dosage occurs.

Additionally, lawyers representing families in Paxil cases – and all other pharmaceutical cases – must be aware of preemption. In most pharmaceutical litigation, drug manufacturers argue that FDA labeling rules preempt any claim for failure to warn under state tort laws. And, the preemption landscape is rapidly changing.

On January 24, 2006, the FDA issued its rulemaking for labeling requirements. The rules became effective June 30, 2006. In a preamble to the rules, the FDA stated that "under existing preemption principles, FDA approval of labeling under the act *** preempts conflicting or contrary state law."

While it is too early

to predict the final implications of the FDA preamble on preemption, at least one court has decided in favor of a manufacturer. In *Colacicco v. Apotex*, LEXIS 34127 (E.D. Pa., May 25, 2006), plaintiff filed suit against GlaxoSmithKline (the manufacturer of Paxil) and Apotex (the manufacturer of a generic equivalent of Paxil) after his wife committed suicide while taking the generic version of the drug. The plaintiff argued that the defendants' FDA-approved label failed to warn the decedent or her doctor of the risk of suicide.

After considering an amicus brief filed by the FDA, as well as the preamble to the new drug labeling regulations, the court held that plaintiff's failure to warn claims were preempted. The court expressly stated that:

[W]hen Congress passed the Food, Drug and Cosmetic Act ..., it vested the FDA with authority to regulate the specifics of drug labeling, making important judgments of what is required for safety of the consuming public, what new drugs may appear in the marketplace, and what warnings their instructions and labels must carry.

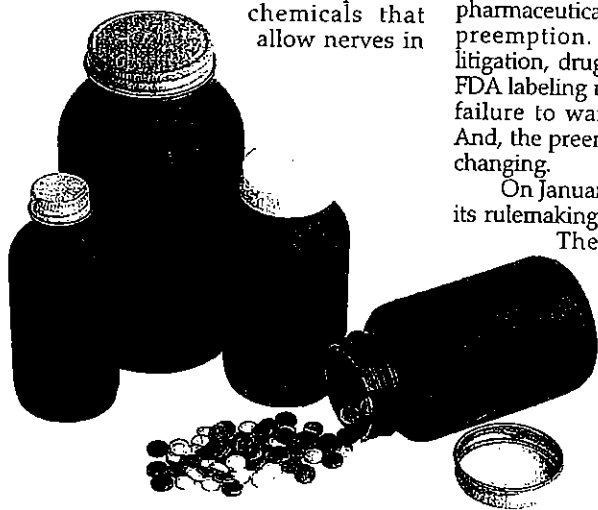
At least one other court has found against preemption. Judge Carol Higbee – the judge presiding over all Vioxx cases filed in state court in New Jersey – recently referred to the preamble as "a political statement by the FDA." During a hearing on June 6, 2006, Judge Higbee rejected defendant's preemption argument, stating that the preamble has "**** nothing to do with science *** It is contrary to the U.S Supreme Court's decisions. It is contrary to all the law on preemption."

Although the future of "preamble preemption" is uncertain, lawyers representing plaintiffs in all pharmaceutical cases must be prepared to vigorously litigate this issue.

Finally, as is true in any case, lawyers representing families in Paxil cases must remember that a viable claim is viable only against a responsible party. Generally, pursuing claims against physicians, pharmacists or other medical providers is unjustified in Paxil cases because GlaxoSmithKline failed to disclose the risks of Paxil to the medical community, just as it failed to warn American parents and consumers.



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