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Mealey's Litigation Report
Antidepressant Drugs

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Take me to the Top

GSK: Experts' Opinions On Paxil Dependence Should Be Barred

LOS ANGELES — Expert testimony regarding Paxil's alleged addictive nature and ability to induce dependence is inadmissible because any attempt to equate withdrawal symptoms with addiction is not generally accepted in the scientific community, the manufacturer of the antidepressant argues in a recently filed motion (In re: Paxil Products Liability Litigation, MDL No. 1574, C.D. Calif.)

(**Motion available.** Document #75-050325-012M.)

In fact, plaintiffs' experts have admitted in their depositions that Paxil is not habit-forming and does not meet the criteria for substance dependence as defined by medical literature, GlaxoSmithKline (GSK) says in its Feb. 18 motion, which seeks to exclude the testimony of five experts from all cases proceeding in the Paxil withdrawal MDL.

The manufacturer also asks the U.S. District Court for the Central District of California to strike the expert report of British psychiatrist and psychopharmacologist David Healy, M.D., because it contains confidential data from other manufacturers of selective serotonin reuptake inhibitors (SSRIs) that GSK does not have access to. As a result, the manufacturer contends that it cannot refute Healy's opinions.

Maladaptive Behavior

According to the manufacturer, Paxil is not addictive and does not induce substance dependence based on the definition of the term addiction and because it does not cause substance dependence, which is classified by the Diagnostic and Statistical Manual — Fourth Edition (DSM-IV) as signs or symptoms that a person continues to use a substance compulsively and maladaptively, despite significant problems associated with the use.

GSK notes that its own witness, Dr. Charles O'Brien, was a member of a committee established in the 1980s by the American Psychiatric Association and World Health Organization to review the definition of addiction and that committee concluded that one of the main characteristics of addiction was a loss of control over drug use, resulting in compulsive drug-taking behavior.

"In other words, one who is 'addicted' uses a drug despite antisocial consequences," the manufacturer says pointing to the committee's finding. "The outcome of the drug is harmful, not helpful."

According to the manufacturer, addiction is best characterized by abusers of opiates, who demonstrate maladaptive behavior, use the substance in order to get "high" and use the drug in excess of therapeutic doses to achieve other than a therapeutic effect. Such is not the case with Paxil.

"On the contrary, the most common dosage issue with antidepressants in general, and Paxil in particular, is that physicians often prescribe dosages that are too low to achieve maximum therapeutic benefits," GSK says. "Nor is there any evidence of a 'street market' value for Paxil, or any indication that patients forge prescriptions in order to obtain Paxil, or otherwise experience 'uncontrolled craving.'"

Experts Agree

GSK further argues that even the plaintiffs' experts agree that Paxil is not a drug of addiction, is not habit-forming and does not meet the definition or the criteria for substance dependence listed in the DSM-IV.

For example, Drs. Richard Kapit, Cherly Blume, George Glass and Joseph Glenmullen each stated in their depositions that Paxil does not meet the criteria for substance dependence characterized by the DSM-IV.

Similarly, Healy has written articles in which he states that Paxil and other SSRIs are not addictive, habit-forming or associated with substance dependence, GSK says.

Regulatory Agencies

In addition, both the Food and Drug Administration and the European Medicines Agency (EMEA) have found that there is no evidence demonstrating the SSRIs have addictive properties.

Dr. Robert Temple, director of the FDA's Office of Medical Policy and acting director of the Office of Drug Evaluation, stated in September 2002 that GSK's use of the phrase "Paxil is not habit-forming" is not misleading, finding that the fact a drug causes discontinuation syndrome does not mean it is habit-forming.

Also, an April 12, 2000, report prepared by the EMEA's Committee for Proprietary Medicinal Products (CPMP) found no evidence that SSRIs were drugs of dependence, GSK says.

Moreover, mental health organizations such as the National Institute of Mental Health and the National Depressive and Manic-Depressive Association have each said on their Web sites that antidepressants are not habit-forming or mind-altering, the company notes.

No Authority

The opinions of the plaintiffs' experts are baseless, GSK contends, because their theories have not been tested and are not supported by scientific literature.

"GSK is unaware of any published peer-reviewed literature reaching the conclusion that SSRIs in general, or Paxil in particular, are addictive, habit-forming or meet the criteria for substance dependence under DSM-IV," GSK asserts. "Indeed, plaintiffs' own experts are unable to cite such literature."

However, two published studies have concluded that SSRIs, notably Zoloft and Paxil, show little evidence of abuse potential when compared to methamphetamines, the manufacturer notes.

Conversely, none of plaintiffs' experts' opinions has been subject to peer review, GSK says.

Counsel

Thomas M. Moore, David J. Fleming and Mario Horwitz of Drinker, Biddle & Reath in Los Angeles and Chilton D. Varner, Andrew T. Bayman and Todd P. Davis of King & Spalding in Atlanta are counsel for GSK.

Karen Barth Menzies of Baum Hedlund in Los Angeles, Christopher Coffin of the Pendley Law Firm in Plaquemine, La., Donald J. Farber of the Law Offices of Donald J. Farber in San Rafael, Calif., and Kevin J. Yourman and Jennifer Liakos of Yourman, Alexander & Parekh in Manhattan Beach, Calif., represent the plaintiffs.

Take me to the Top

GSK Moves To Exclude Testimony About Paxil-Induced Suicidality

LOS ANGELES — The testimony of three experts concerning alleged suicidal behavior caused by Paxil discontinuation should be excluded from all MDL cases because there is no reliable scientific evidence to support their opinions, manufacturer GlaxoSmithKline (GSK) says (In re: Paxil Products Liability Litigation, MDL No. 1574, C.D. Calif.).

(**Motion available.** Document #75-050325-011M.)

The company contends in its Feb. 18 motion that the opinions of British psychiatrist and psychopharmacologist David Healy, M.D., Ph.D.; Harvard psychiatrist Joseph Glenmullen, M.D.; and Houston psychiatrist George Glass, M.D., are inadmissible under Daubert because their theories have not been adequately or objectively tested and the methodology of their research is not generally accepted in the scientific community.

Healy proffers general testimony regarding the alleged relationship between Paxil discontinuation and suicidal behavior, while Glenmullen opines that plaintiff James Meythaler's suicidal ideation was caused by Paxil withdrawal syndrome. Glass' testimony would support Andrew Barton's assertion that taking Paxil caused him to become suicidal.

The manufacturer is seeking to block the testimony of the plaintiffs' experts from all cases pending in the Paxil withdrawal MDL.

Association

GSK asserts that Healy fails to satisfy the burden of proof to establish the admissibility of his testimony. Specifically, the manufacturer argues that there is insufficient epidemiological evidence to support the expert's opinion in which he suggests that there is an association between Paxil use and suicidal behavior

In support of his opinion, Healy submitted a supplemental expert report that reviews epidemiological studies conducted by antidepressant manufacturers and regulatory agencies such as the Food and Drug Administration and the U.K.'s Medicines and Healthcare Products Regulatory Agency (MHRA). Healy asserts that the data shows claim that there is an association between Paxil and suicidal behavior.

According to the manufacturer, an association in epidemiological terms is not the equivalent of a causal relationship because associations in epidemiological studies can result from factors such as bias, chance, confounding or cause and effect.

The company also refers to a report filed by its expert, Anthony Rothschild, M.D., a professor of psychiatry at the University of Massachusetts, in which he says that an association is meaningful only if differences between study groups reach statistical significance.

Both Healy and Glenmullen also base their opinion on case reports and case series that describe individual adverse reactions, GSK says. However, case reports and case series are not reliable forms of evidence because there are no controls, which aid in the assessment of the relationship between exposure or treatment and disease or outcome. Moreover, the manufacturer points out that many courts have held that case reports are not sufficient to support an expert opinion under Daubert.

Agencies' Findings

GSK further argues that neither the FDA nor the MHRA has found that Paxil or any other antidepressant increases the risk of suicide in adults. In fact, after mandating stronger warnings for antidepressants prescribed to children and adolescents based on finding an increased risk of suicidality, the FDA declared that no similar finding had been made as to whether the risk extends to adults, the company says.

"During the course of the hearings leading to the pediatric label change, FDA stated on several occasions that it has examined the suicidality data in adults in a number of different ways and has found no evidence of any increased risk in adults," GSK states.

Similarly, the U.K's Committee on the Safety of Medicines (CSM), an advisory body to the MHRA, empanelled a so-called Expert Working Group (EWG) on the Safety of Selective Serotonin Reuptake Inhibitors (SSRIs) to study the risk of suicidality in the adult population. GSK says that the EWG on Dec. 6, 2004, issued a report that addressed pediatric and adult suicidality associated with SSRIs that found the incidence of possible suicide-related events was similar in the Paxil and placebo groups. In addition, the EWG concluded that "[t]here is no clear evidence that there is an increased risk of self-harm and suicidal thoughts when SSRIs are discontinued.

Healy

GSK further argues that Healy's analysis of data from studies included in Paxil's 1989 New Drug Application (NDA) in his supplemental expert report is unreliable because it is "non-transparent, methodologically flawed and unverifiable." Moreover, the manufacturer asserts that the numerous tables in his report referring to data from other analyses are inadmissible based on the methodology.

For example, Healy allegedly misrepresented data from the FDA's analysis of suicides in adult placebo-controlled depression trials, which was conducted by FDA investigator Dr. Tarek Hammad, and an analysis conducted by the British General Practice Research Database.

In addition, the manufacturer says that Healy's most recent analysis is inadmissible because it has not been peer-reviewed and that his opinions must be excluded because they depend on information from other SSRI manufacturers that is not available to GSK.

Glenmullen And Glass

Finally, GSK claims that the opinions of Glenmullen and Glass are inadmissible because they fail to cite evidence to support their assertion that Paxil caused the suicidal ideation allegedly experienced by Meythaler and Barton, respectively.

Specifically, Glenmullen could not identify a single study reporting increased suicidality or deliberate self-harm associated with discontinuing Paxil, had done no independent evaluation of the Paxil clinical trials data and conceded that he is not in a position to refute the analysis of suicidality done by the FDA, which found no association between Paxil and suicidality in adults.

Similarly, Glass should not be able to testify regarding the alleged association between Paxil withdrawal and suicidal behavior because he too was unable to a study finding a statistically significant increased incidence of suicidality associated with either taking or discontinuing Paxil.

Take me to the Top

GSK: Pollster's Opinions Are Irrelevant, Unreliable

LOS ANGELES — A proposed expert's testimony regarding the findings of a poll conducted to determine whether GlaxoSmithKline's (GSK) use of the phrase "non-habit forming" in its advertisements for Paxil is inadmissible because it prevents jurors from making their own analysis on the issue, the manufacturer says in a recently filed motion (In re Paxil Products Liability Litigation, MDL No. 1574, C.D. Calif.).

(**Motion available.** Document #75-050325-008M.)

GSK further argues in the Feb. 18 motion that Kelly Anne Conway's testimony regarding the results of her research is inadmissible because it is unreliable and irrelevant to the claims of five trial plaintiffs because they could not possibly have seen or relied on the advertisements before deciding to take Paxil.

Conway conducted a telephone survey of consumers to evaluate how the public understood GSK's use of the phrase "Paxil is non-habit forming" in a direct-to-consumer (DTC) advertising campaign that began airing in October 2001. Conway unveiled the findings of her research in a Sept. 23, 2002, declaration, but GSK contends that her methodology contradicted what she told the court was the purpose of her poll.

For example, GSK asserts that Conway removed any reference to Paxil from the questions she asked participants in the survey and that the poll never asked respondents to comment on the exact language in the DTC advertisement. In addition, her questions to participants were often "suggestive and leading to reach its results."

Unqualified

GSK further argues that Conway, the president of The Polling Co. Inc., is not qualified to render an expert opinion whether its DTC advertisements were truthful and nonmisleading because she has a Bachelor of Arts degree in political science and a Juris Doctor and has no scientific, medical or regulatory training or knowledge.

However, the manufacturer points out that in her deposition, Conway was unable to identify the Food and Drug Administration regulation that applies to DTC advertisements. Conway also stated in her deposition that GSK did not violate any Food and Drug Administration regulations by airing the DTC advertisements.

"She cannot, on the one hand, state that GSK complied with the law and then on the other state that GSK acted inappropriately," GSK argues. "What is most striking, however, is that this pollster wishes to give this contradicting testimony based solely upon a 15-minute telephone poll of unnamed and unknown respondents that GSK cannot examine to determine why they arrived at their responses to the poll."

Unreliable

Aside from the irrelevance of the proffered testimony, Conway's opinion is also unreliable because the methodology of her poll failed to satisfy the requirements of Daubert. GSK notes that in her deposition, Conway admitted that the results of the poll would have been different if she had mentioned Paxil specifically.

Similarly, GSK argues that Conway's poll was not conducted in accordance with the accepted principles of polling research.

Finally, Conway's opinions are suspect because she formed them solely as a result of litigation and has shared them only with lawyers involved in the litigation.

Take me to the Top

GSK Challenges Admissibility Of 'Addictionologist's' Testimony

LOS ANGELES — The opinions of a psychiatrist and self-described "addictionologist" regarding Paxil's effects on a person's drinking habits are inadmissible, manufacturer GlaxoSmithKline (GSK) says, because the expert's proffered testimony is not supported by reliable scientific evidence (In re: Paxil Products Liability Litigation, MDL No. 1574, C.D. Calif.).

(**Motion available.** Document #75-050325-009M.)

The company also argues in its Feb. 18 motion that the opinions of Dr. William Glass M.D., should not be allowed during trial because his postulations are derived solely for the purposes of litigation and because the assertion that plaintiff Andrew Barton's alcohol consumption was affected by his use of Paxil was not contained in his Dec. 30, 2004, expert report.

Glass, a Houston-based psychiatrist, was designated by five trial plaintiffs as an expert specializing in addiction, dependence and withdrawal to proffer testimony regarding adverse reactions Barton, Kenneth Borenstein and Gerri Marin experienced as a result of using Paxil. Specifically, Glass opines that Barton's use of the antidepressant caused him to increase his consumption of alcohol.

No Opinion

However, GSK contends that based on his expert report and deposition testimony, Glass has not opined that Paxil caused any changes in Barton's drinking habits. Rather, Glass in his deposition only affirmed Barton's belief that Paxil was causing him to drink more and did not offer any scientific support by way of research or journal articles to bolster the allegation.

According to GSK, Barton has a medical history of alcoholism that began at age 16 and has been unable to accurately recall how much and how often he consumes alcohol. Although Glass admitted in his deposition testimony that Barton's lack of reliability in reporting his drinking habits stems from his alcoholism, the psychiatrist maintains that Barton's alcohol abuse became worse when he was using Paxil.

"Dr. Glass clearly lacks any reliable underlying data or objective findings to support such a novel theory," GSK avers. "Dr. Glass has not identified another doctor or scientist who espouses the 'Paxil-makes-him-drink-more' hypothesis. His only data, the past self-reports of Plaintiff Barton's increased alcohol abuse, are, as Dr. Glass admits, inconsistent and less than reliable because Plaintiff is an alcoholic with a propensity to distort his alcohol consumption."

Remaining Plaintiffs

GSK asserts that Glass' opinions regarding Borenstein and Marin should also be excluded as unreliable and irrelevant because he holds his opinions that Paxil caused plaintiffs' withdrawal symptoms with the requisite degree of legal certainty.

The manufacturer notes that in his deposition, Glass could not state any case-specific causation issues with regarding to Borenstein's and Marin's claims.

"At best, Dr. Glass' case-specific causation testimony amounts to mere speculation and conjecture that is utterly unhelpful to a jury because it fails to meet the legal to prove causation," GSK concludes.

Take me to the Top

English Professor Unqualified To Discuss Adequacy Of Ads, GSK Argues

LOS ANGELES — GlaxoSmithKline (GSK) has asked a federal court to exclude from trial the opinions of an English professor who opines that language appearing in the company's advertisements and brochures for Paxil was false and misleading with regard to the antidepressant's potential for dependence and withdrawal symptoms on grounds that the expert is unqualified and the testimony is irrelevant (In re: Paxil Products Liability Litigation, MDL No. 1574, C.D. Calif.).

(**Motion available.** Document #75-050325-010M.)

William Lutz, an English professor at Rutgers University in Camden, N.J., and a self-proclaimed expert on "plain English," does not have the qualifications to proffer his opinions because he has no expertise with Food and Drug Administration regulations, GSK says in a Feb. 18 motion.

Lutz said during his deposition that the language in the FDA-approved package insert for Paxil "is extremely difficult to read," "is not a clear communication of information," "is not arranged in a hierarchy of importance to communicate to doctors" and "violates just about every principle of information design." In addition, the professor proclaims that the use of the phrase "Paxil is non habit-forming" in television advertisements is misleading because it essentially told consumers that the antidepressant is not addictive, GSK says.

However, GSK notes that although Lutz has published several books and papers, the subject matter of these materials does not relate to the issue about which he is proffering testimony. Furthermore, Lutz's inexperience in developing a warning label or advertisement for a pharmaceutical drug and his lack of training in the regulations governing the wording of direct-to-consumer (DTC) advertisements demonstrate that he is unqualified to proffer his opinion, the manufacturer asserts.

"Lutz may have 'opinions' on the appropriateness of the Paxil package insert and GSK's promotional activities," GSK says. "He may be a critic of those activities. But, he hardly has the 'specialized' or 'scientific knowledge' required by Federal Rule of Evidence 702." Shepardize

Relevance

GSK also claims that Lutz's testimony should be excluded because it is irrelevant to the plaintiffs' claims because they did not rely upon the advertisements in question when they were prescribed Paxil for the first time. In support of its assertion, GSK looks to the depositions of trial plaintiffs Andrew Barton, Kenneth Borenstein, Gerri Marin, Trishia Medema and James Meythaler, who each stated that they did not specifically recall the Paxil advertisements.

"If these five plaintiffs did not see or rely on GSK's advertising — as they did not — Lutz's proposed expert testimony can provide nothing probative that would be relevant to any issue in this case," GSK asserts.

Furthermore, Lutz's opinions invade the province of the jury, GSK claims.

"Whether or not GSK's promotional statements about Paxil are misleading is precisely the type of question that the jury is fit to answer," the company contends. "The proper question is not what possible connotation this phrase may have to a Rutgers English professor and linguist, but what the jury understands this phrase to mean. The danger in allowing such inappropriate expert testimony is that it may lead jurors to suspend their own independent analysis."

Reliability

Finally, the manufacturer says that Lutz's opinions are not reliable because they fail to satisfy the standards of Daubert, which requires that expert testimony be derived from research using a methodology that is generally accepted in the scientific community.

GSK points out that this is Lutz's first attempt at pharmaceutical work and that it was prepared solely for the purpose of litigation.

"Lutz's methodology in this litigation defies description; indeed it is nonexistent, let alone reliable," GSK argues. "Lutz's failure to follow a rigorous scientific approach is consequent to his lack of experience and familiarity with medical research and pharmaceutical medications subject to rigorous requirements imposed by the FDA."

Take me to the Top

GSK Seeks Dismissal Of 5 Trial Plaintiffs' Claims

LOS ANGELES — Paxil manufacturer GlaxoSmithKline (GSK) seeks to dismiss with prejudice the claims of five plaintiffs whose cases are scheduled for trial in May, arguing that their causes of action are barred by the learned intermediary doctrine and preempted by federal law (In re: Paxil Products Liability Litigation, MDL No. 1507, C.D. Calif.).

(**Barton motion available.** Document #75-050325-002M. **Borenstein motion available.** Document #75-050325-003M. **Marin motion available.** Document #75-050325-004M. **Medema motion available.** Document #75-050325-005M. **Meythaler motion available.** Document #75-050325-006M.)

In five separate motions filed Feb. 18, the manufacturer further asserts that Andrew Barton, Kenneth Borenstein, Gerri Marin, Trishia Medema and James Meythaler failed to proffer evidence that Paxil caused their alleged injuries and have not produced any expert testimony on the existence or amount of their economic damages.

The plaintiffs, who were randomly selected to have their cases tried first, seek damages for withdrawal symptoms they allegedly suffered when stopping or tapering their use of Paxil. They assert claims of fraud, negligence, strict products liability, breach of express and implied warranties and violation of California's unfair competition law.

Learned Intermediary Doctrine

GSK argues that the language on the Paxil label when the plaintiffs used the drug sufficiently explained the risk of withdrawal symptoms and that plaintiffs' prescribing physicians understood the risk when they prescribed the drugs.

The manufacturer further contends that each of the plaintiffs' prescribing physicians has stated in depositions that he or she was aware of Paxil's association of withdrawal symptoms upon discontinuation of the antidepressant. As a result, the plaintiffs' fraud, negligence and strict liability claims are barred by the learned intermediary doctrine.

In addition, the plaintiffs' cannot rely on the California's Supreme Court ruling in Stevens v. Parke, Davis (9 Cal. 3d at 51 Shepardize, 107 Cal. Rptr. 45 [Calif. Sup. 1973]) to support their assertion that the learned intermediary does not apply in cases where the company overpromoted the drug, GSK asserts.

"Here, unlike there, plaintiff has no evidence to support any contention that GSK's sales representatives 'overpromoted' Paxil or minimized scientifically-supported facts about discontinuation symptoms plainly included in Paxil's labeling or package insert," the drug company says.

Causation

The plaintiffs' claims should also be dismissed with prejudice because they fail to proffer evidence demonstrating that Paxil is capable of causing their alleged injuries or did in fact cause their injuries.

Specifically, GSK argues that Meytheler fails to provide expert testimony to support his allegation that Paxil can cause suicidality and whether it is addictive or causes substance dependence or abuse. Similarly, the company contends that Medema cannot prove that the antidepressant is addictive because she was never diagnosed with substance dependence as defined by the Diagnostic and Statistical Manual of Mental Disorders — Fourth Edition (DSM-IV).

Moreover, the remaining plaintiffs do not have reliable expert testimony to prove that Paxil caused their injuries. For example, Barton's injuries could have been the result of his history of alcohol dependence, GSK says.

GSK also states that the testimony of the plaintiffs' designated experts is unreliable under Daubert and points out that it has filed separate motions in which it argues that the experts' testimony should be deemed inadmissible (See Page X).

The company further argues that plaintiffs' proffered expert testimony on economic damages is inadmissible.

Statute Of Limitations

Furthermore, GSK notes that in 2002 the California Legislature extended the statute of limitations for personal injury cases from one year to two years. However, the claims of Barton and Meytheler are time-barred because they failed to file their complaints within the one-year statute of limitations in effect and the time their claims accrued and because the Legislature allowed the new statute of limitations to retroactively apply only to victims of the Sept. 11, 2001, terrorist attacks.

Barton and Meytheler also stated in their depositions that they had reasonable belief that their alleged injuries were the result of their discontinuation of Paxil more than one year before they filed suit, GSK asserts.

Alleged Misrepresentations

In their complaints, the plaintiffs contend that GSK misrepresented to consumers and the medical community the scope and severity of withdrawal symptoms caused by Paxil. For example, the plaintiffs assert that GSK said in its advertisements that the antidepressant was non-habit forming. In addition, GSK told its sales representatives to distort the findings of studies that found that rates of withdrawal symptoms were higher in patients receiving Paxil than other selective serotonin reuptake inhibitors (SSRIs) to focus on a classwide effect.

Although plaintiffs use these allegations to support their fraud and breaches of warranties claims against GSK, the manufacturer avers that the allegations fail because the plaintiffs cannot show that they or their physicians detrimentally relied on the alleged misrepresentations.

To recover damages for their breach of warranty claims, the plaintiffs would be required to show that the manufacturer's alleged misrepresentations became part of the basis of the bargain and demonstrate that Paxil failed to conform to the promises or affirmations made on its label.

The plaintiffs must also show that their physicians relied on the company's alleged misrepresentations when deciding to prescribe the drug, GSK says.

Preemption

GSK further argues that plaintiffs' claims are preempted by the supremacy clause of the U.S. Constitution because their failure to warn claims conflict with the Food, Drug and Cosmetic Act (FDCA).

Finally, the manufacture asserts that the plaintiffs' failure to show a causal link between Paxil and their injuries and their inability to demonstrate reliance upon the alleged misrepresentations warrant judgment in its favor on the plaintiffs' claims for unfair competition.

Counsel

Thomas M. Moore, David J. Fleming and Mario Horwitz of Drinker, Biddle & Reath in Los Angeles and Chilton D. Varner, Andrew T. Bayman and Todd P. Davis of King & Spalding in Atlanta are counsel for GSK.

Karen Barth Menzies of Baum Hedlund in Los Angeles, Christopher Coffin of the Pendley Law Firm in Plaquemine, La., Donald J. Farber of the Law Offices of Donald J. Farber in San Rafael, Calif., and Kevin J. Yourman and Jennifer Liakos of Yourman, Alexander & Parekh in Manhattan Beach, Calif., represent the plaintiffs.

Take me to the Top

Minnesota AG: Federalism, State's Interest Oppose Preemption

MINNEAPOLIS— Minnesota Attorney General Michael Hatch has filed an *amicus curiae* brief opposing Pfizer Inc.'s motion for summary judgment in a Zoloft suicide case, arguing that the state has a strong interest in protecting consumers who have sustained injuries as a result of prescription medications (Kimberly Witczak v. Pfizer Inc., No. 04-CV-2819, D. Minn. See January 2005, Page 9).

(**Brief available.** Document #75-050325-107B.)

In the brief, which was filed March 21 in the U.S. District Court for the District of Minnesota, Hatch argues that a ruling agreeing with Pfizer's assertion that Kimberly Witczak's state law failure to warn claims are preempted by federal law would adversely affect Minnesota because it often litigates claims against drug manufacturers that overcharge state-funded prescription drug benefit and insurance programs such as Medicaid.

Preemption Argued

Witczak claims in her lawsuit against Pfizer that its failure to sufficiently warn consumers regarding Zoloft's ability to induce suicidal behavior caused her husband to take his own life days after he began using the antidepressant. In its Jan. 20 motion for summary judgment, Pfizer argues that the Food, Drug and Cosmetic Act (FDCA) preempts her claims.

Hatch asserts that Pfizer's preemption argument is flawed because there is a strong presumption against preemption in the principles of federalism and that the presumption against preemption applies with particular strength when the federal regulatory scheme intrudes upon a field that the states have traditionally occupied.

"Here, the presumption against preemption is especially compelling given Pfizer's argument that the preemptive effect of the FDCA is to preclude not only the Plaintiff's failure to warn claim, but also *all* of the other Plaintiff's claims, thereby leaving Plaintiff without any remedy," Hatch says.

FDCA

Hatch further contends that Congress did not intend to allow the FDCA to preclude state law failure to warn claims.

"Despite numerous amendments to the FDCA in the 67 years since Congress first enacted the statute, Congress has *never* seen fit to add an express preemption clause regarding state regulation of prescription drugs, nor to include an express preemption clause barring state tort claims for injuries to consumers from any FDCA-related product," Hatch argues. "Moreover, Congress' refusal to preempt state law claims involving prescription drugs cannot be ascribed to its ignorance. Congress has shown that it can and will add an express preemption clause to the FDCA when it deems one necessary, as it has done for the labeling of medical devices and over-the-counter drugs."

In addition, the FDCA does not prohibit drug manufacturers from strengthening warnings without the approval of the Food and Drug Administration, despite Pfizer's contention that doing so would be "false and misleading," Hatch contends.

Reliance

In its summary judgment motion, Pfizer states that the FDA has made statements in support of its position that plaintiffs' state court failure to warn claims are preempted by the FDCA. However, Hatch asserts that the court should afford little weight to Pfizer's reliance upon informal FDA statements regarding Zoloft and other antidepressants and *amicus* briefs filed on behalf of the FDA in other drug cases that articulate the agency's views on the FDCA's preemptive effect.

"These statements simply do not justify a finding of implied preemption given the analysis above, including the fact that the FDCA does not prohibit state common law liability based upon the absence of additional warnings not required by the FDA and the fact that the decision as to whether state common law liability lies because of the absence of such additional warnings is not the FDA's to make," Hatch says.

Hatch further argues that the FDA's *amicus* briefs are of little value because the agency is not specialized in making legal determinations of this kind, the views the agency espouses in the briefs are inconsistent with other pronouncements by the agency and because of the FDA's close ties with the pharmaceutical industry.

Finally, the Minnesota attorney general asserts that denying Pfizer's preemption defense would further the public safety goal embodied in the FDCA.

Counsel

Hatch and Minnesota Assistant Attorney Generals Michael Vanselow and Paul B. Civello in St. Paul, Minn., submitted the brief. Karen Barth Menzies, Jessica R. Dart George Murgatroyd III and Robert Brava-Partain of Baum Hedlund in Los Angeles and James Ryan of the Ryan Law Firm in Minneapolis represent Witczak.

Joseph M. Price and Peter J. Gross of Faerge & Benson in Minneapolis and Amy Padden and James E. Hooper Jr. of Wheeler Trigg Kennedy in Denver are counsel for Pfizer.

Take me to the Top

Widow Moves To Strike FDA's Amicus Brief In Zoloft Suicide Case

MINNEAPOLIS — An Food and Drug Administration *amicus curiae* brief that supports Pfizer Inc.'s assertion that a widow's state law failure-to-warn claim is preempted by federal law should be stricken because it is nothing more than inadmissible hearsay, a woman says in opposition to the manufacturer's submission of the document in support of its motion for summary judgment (Kimberly Witczak v. Pfizer Inc., No. 04-CV-2819-JMR-FLN, D. Minn.).

(**Motion available.** Document #75-050325-018M.)

Kimberly Witczak, who claims that Pfizer is liable for her husband's Aug. 6, 2003, suicide, also argues in her March 14 motion to strike that the FDA's *amicus* brief in Motus v. Pfizer (Nos.02-55372 & 02-55498 [9th Cir.]) is not competent evidence and irrelevant to her claims.

Although the Ninth Circuit found in favor of Pfizer in Motuson the basis of expert testimony, the federal appeals court did not address its preemption defense, Witczak points out.

Pfizer has held that the brief, which was written by then FDA Chief Counsel Daniel Troy, supports its argument that stronger warnings regarding Zoloft's alleged ability to cause suicidal behavior would be false and misleading due to insufficient scientific evidence, thereby deeming the drug misbranded under

the Food, Drug and Cosmetic Act. However, Witczak contends that because the brief contains unsworn statements, its contents are hearsay and therefore inadmissible.

In addition, Witczak says that though the brief is not subject to the hearsay exceptions of Federal Rules of Evidence 803 Shepardize(a), it is still inadmissible because it does not set forth factual findings resulting from any type of investigation nor was it prepared in the normal course of the FDA's business.

Speculation

Witczak further argues that the brief is not competent evidence on the ground that it does not demonstrate that the authors had "any personal knowledge of the factual assertions made in the brief or that it contains the policy of the FDA."

"Additionally, most of the statements contained in the brief are sheer speculation, improper opinions and conclusions," Witczak avers.

Moreover, Witczak notes that two high-ranking FDA officials, Drs. Robert Temple and Russell Katz, admitted at a Feb. 2, 2004, press conference after an advisory committee meeting concerning the risk of suicidality associated with antidepressants, that they were unaware of the agency's *amicus* brief in Motus.

Irrelevant

The FDA's assertions in the brief are also irrelevant to the present case, Witczak says, because since the filing of the document in 2002, the agency allowed Wyeth in August 2003 to strengthen its warning regarding the risk of suicidality associated with the antidepressant Effexor.

"The FDA did not take any action to make Wyeth withdraw this warning as 'false and misleading,'" Witczak contends. "To the contrary, the FDA stated that Wyeth's action in this regard was acceptable and proper."

Witczak also contends that consideration of the brief would violate her Fifth Amendment right to due process because she should be allowed to challenge the statements in the brief through cross examination. In addition, the FDA's recent decision to require manufacturers of antidepressants to add a black box warning regarding the risk of suicidality in package inserts demonstrates that the contents of the brief are not correct.

Although courts in some instances should consider an agency's declarations regarding it regulations, Witczak argues that the FDA's brief should not be considered because it does not satisfy the requirements of the Administrative Procedures Act (APA) and contains no regulatory or statutory interpretation.

"Indeed, the brief is totally devoid of any reference to official FDA action — there are no citations to the Federal Register regarding this purported action, no exhibits which reflect consideration of this action and no evidence of reasoned analysis, any of which would be sufficient to satisfy the APA's requirements," Witczak says.

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Plaintiffs: Disclaimer Did Not Waive Confidentiality

SAN FRANCISCO — A disclaimer at the end of a law firm's online questionnaire did not waive the confidentiality of information supplied by prospective clients even though it did not establish an attorney-client relationship, plaintiffs argue in a March 1 petition for a writ of *mandamus*seeking the reversal of a

federal judge's ruling (Andrew Barton, et al. v. U.S. District Court for the Central District of California, No. 05-71086, 9th Cir. See February 2005, Page 12).

(**Petition available.** Document #68-050318-104X.)

The five plaintiffs, who are involved in the Paxil withdrawal MDL and have a trial scheduled for May 2, are asking the Ninth Circuit U.S. Court of Appeals to overturn U.S. Judge Mariana Pfaelzer of the Central District of California's Jan. 28 order requiring the production of online questionnaires submitted to their attorneys before they were clients.

Judge Pfaelzer found that although the questionnaires constituted preliminary consultations that the Ninth Circuit has held are privileged, the plaintiffs waived their right to confidentiality when agreeing to the disclaimer at the end of the questionnaire.

The plaintiffs, led by Andrew Barton, assert that numerous law firms use the Internet to market their services and that Judge Pfaelzer's ruling, if it stands, could have a tremendous impact on how attorneys advertise.

"If the District Court's order is upheld, it could have the effect of chilling communications between attorneys and potential clients," the plaintiffs say. "In effect, the District Court's order turns California law upside down and shifts the presumption of confidentiality for internet communications to the proponent of the privilege."

Disclaimer

The plaintiffs note that disclaimers appearing on law firms' Web sites are not uniform. Although most disclaimers state that submitting information does not form an attorney-client relationship, the topic of confidentiality varies in three ways. For example, some law firms' disclaimers expressly state that the information will not be treated as confidential, while others assure the potential client that the information will be protected.

In the present case, the disclaimer on plaintiff counsel Baum Hedlund's Web site is silent on the issue of confidentiality, the plaintiffs note.

"Although the disclaimer clearly and expressly disclaims the formation of an attorney-client relationship by the mere fact of transmitting the answers on the intake questionnaire to counsel, it never mentions the confidentiality of the information being sent to counsel," the plaintiffs say. "And the disclaimer certainly does not say that, by submitting the information, the potential client is agreeing that their information is no longer confidential."

In addition, the plaintiffs say the main reason the disclaimer appears is to avoid any conflicts of interest and protect from client confusion and malpractice.

"These issues of possible client confusion, malpractice, potential conflicts of interest, and other jurisdictions highlight the need for attorneys who maintain a presence on the internet to disclaim any formation of an attorney-client relationship or the rendering of legal advice based solely on the potential client's visit to the Web site or submission of information to the firm," the plaintiffs argue. "Indeed, any failure by Petitioners' counsel to have such a disclaimer would have inevitably led to numerous issues of possible malpractice given the large number of potential clients which Petitioners' counsel chose *not* to represent [emphasis original]."

Preliminary Communications

The plaintiffs further assert that California law holds generally that preliminary communications between potential clients and attorneys are privileged.

"Here, Petitioners submitted to Petitioners' counsel answers to an intake questionnaire which sought information that enabled counsel to determine whether Petitioners had a legal claim against GSK (GlaxoSmithKline) for which counsel could represent them," the plaintiffs say. "That Petitioners were contemplating legal representation when they transmitted the information to counsel is not in dispute. Clearly, then, these communications were preliminary discussions between attorney and a potential client seeking legal representation, which the District Court so held."

Moreover, the information submitted to the firm included sensitive information regarding the plaintiffs' medical history and use of the antidepressant Paxil, the plaintiffs say.

Karen Menzies and Robert Brava-Partain of Baum Hedlund in Los Angeles; Christopher Coffin of the Pendley Law Firm in Plaquemine, La.; Donald Farber of the Law Offices of Donald Farber in San Rafael, Calif.; and Kevin Yourman of Yourman, Alexander & Parekh in Manhattan Beach, Calif., are counsel for the plaintiffs.

David J. Fleming of Drinker, Biddle & Reath in Los Angeles and Todd Davis and Chilton Varner of King & Spalding in Atlanta represent real party in interest SmithKline Beecham.

Take me to the Top

9th Circuit Will Review Ruling On Disclaimers

SAN FRANCISCO — The Ninth Circuit U.S. Court of Appeal on March 23 said it will review a federal judge's finding that a disclaimer at the end of an online questionnaire waived the attorney-client privilege, sources told **Mealy Publications** (Andrew Barton, et al. v. U.S. District Court for the Central District of California, No. 05-71086, 9th Cir.)

(**Order available.** Document #75-050325-014R.)

In addition, the federal appeals court granted lead plaintiff Andrew Barton's motion seeking a stay of U.S. Judge Maria Pfaelzer of the Central District of California's Jan. 28 order compelling the production of online questionnaires from a law firm's Web site.

Plaintiffs completed the questionnaires before forming an attorney-client relationship with the Los Angeles-based firm Baum Hedlund, but Judge Pfaelzer ruled in her order that a disclaimer at the end of the questionnaire waived the confidentiality of the information. Plaintiffs each hired Baum Hedlund to represent them in their cases against GlaxoSmithKline (GSK) for injuries they allegedly sustained as a result of tapering or discontinuing the antidepressant Paxil.

The appeals court ordered GSK to file a response to plaintiffs' petition for a writ of *mandamus* within 10 days; the District Court can file a response if it so desires.

Plaintiffs will then have five days to file a reply, the appeals court ruled.

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Amicus Brief Supports Review Of Ruling On Disclaimers

SAN FRANCISCO — The Ninth Circuit U.S. Court of Appeals should review a federal judge's order requiring the disclosure of private information contained in online questionnaires because it jeopardizes the privileged and confidential nature of preliminary communications between attorneys and potential clients, attorneys from the Los Angeles County Bar Association (LACBA) say in a March 10 *amicus curiae* brief (Andrew Barton, et al. v. United States District Court for the Central District of California, No. 05-71086, 9th Cir.).

(**Letter available.** Document #68-050318-008X.)

Attorneys Daniel Koes and Pamela Dunn filed the brief on behalf of the more than 25,000 members of the LACBA and say allowing the ruling of U.S. Judge Maria Pfaelzer of the Central District of California to stand would have a chilling effect on the methods in which attorneys communicate with potential clients before the establishment of the attorney-client relationship.

Judge Pfaelzer ordered five plaintiffs selected for the nation's first Paxil withdrawal trials to disclose the contents of online questionnaires completed on Los Angeles-based law firm Baum Hedlund's Web site. In her Jan. 28 order, Judge Pfaelzer found that though the information was privileged under California law, a disclaimer at the end of the questionnaire that discharged the establishment of an attorney-client relationship also constituted a waiver of confidentiality (See February 2005, Page 12).

"The exception to confidentiality created by this ruling threatens to completely swallow the privileged nature of preliminary communications between lawyers and potential clients," the LACBA says. "Until the Court unravels the procedural pretzel created by this ruling, attorneys cannot safely advise potential clients that no attorney-client privilege exists — using the internet or any other means — without rendering all their pre-engagement communications open to discovery by their adversaries."

Unworkable Conundrum

The LACBA further urges the Ninth Circuit to review Judge Pfaelzer's ruling based on the effect her decision will have on attorneys across the country. Specifically, the ruling has created an "especially unworkable conundrum" because it allows sensitive information, such as prescription drug use and medical history, open for disclosure despite the presence of a disclaimer.

In addition, the ruling affects how attorneys will be able to use the Internet to communicate with potential clients.

"Many LACBA members have a presence on the internet that would be directly impacted by this ruling," the group says. "Many more regularly participate in pre-engagement communications with potential clients, often exchanging confidential information in anticipation of a future engagement. And it is likely that most have had some occasion to advise potential clients that no attorney-client relationship will arise until the parties' pre-engagement evaluation is complete and they have entered into a written engagement agreement."

Dunn and Koes of Dunn Koes in Pasadena, Calif., represent the LACBA.

Take me to the Top

Plaintiffs' Claims Should Be Tried Individually, GSK Argues

LOS ANGELES — The claims of five Paxil withdrawal plaintiffs should be tried separately because they do not share any common issues of law aside from their use of the antidepressant, manufacturer

GlaxoSmithKline (GSK) says in a March 3 motion (In re: Paxil Products Liability Litigation, MDL No. 1574, C.D. Calif.)

(**Motion available.** Document #75-050325-101M.)

For example, the company argues that each of the plaintiffs, who claim that they suffered withdrawal symptoms when tapering or discontinuing their use of the selective serotonin reuptake inhibitor (SSRI), used the antidepressant at different times and for different reasons. In addition, the plaintiffs do not share similar medical histories or methods for discontinuing Paxil, the company says.

Plaintiffs Andrew Barton, Kenneth Borenstein, Gerri Marin, Trishia Medema and James Meythaler were each randomly chosen to be the first Paxil withdrawal clients in the nation to go to trial. Each contends that GSK is liable for withdrawal symptoms they experienced when attempting to discontinue or taper their use of Paxil.

"This lone common thread — the consumption of Paxil — is similarly insufficient to meet the requirements for joinder or consolidation of trials (as opposed to pre-trial proceedings)," the company asserts.

Moreover, trying the plaintiffs' claims simultaneously would lead to jury confusion, GSK argues, because of the number of expert witnesses expected to testify. According to the motion, no less than 88 witnesses have been deposed by the parties and plaintiffs responded to the manufacturer's interrogatories by stating that they may call up to 166 witnesses during the trial.

Same Transaction

As a result of the highly individualized nature of each of the plaintiffs' claims, GSK contends that severance is warranted because the plaintiffs do not meet the standards for joinder or consolidation under Federal Rule of Civil Procedure 20(a). Under Rule 20(a), the joinder of plaintiffs is permitted only if the claims arise out of the same transaction or occurrence and if there are common questions of law or fact.

The manufacturer argues that plaintiffs' use of Paxil and alleged injuries stemming from discontinuing the drug do not satisfy the same transaction standard. Similarly, although the plaintiffs' cases share sufficient common facts to warrant the consolidation of pretrial proceedings, it does not lead to the conclusion that they should be joined or consolidated for trial.

In their motions for class certification, plaintiffs claimed that GSK's conduct in testing, marketing and labeling Paxil and the question of whether the drug is capable of producing withdrawal symptoms supported the commonality of their claims.

"It is well-established that alleging the same general theories of law against a defendant is not sufficient to satisfy the 'common question of law or fact' prong of Rule 20," GSK avers.

Prejudice

GSK further contends that a trial encompassing the claims of all five plaintiffs would be severely prejudicial because evidence concerning one plaintiff's case will inevitably bias the jury against GSK with respect to the other plaintiffs.

Also, jurors may not be able to keep track of which evidence applies to each particular plaintiff.

"This problem is two-fold," GSK says. "First, a jury might attribute to all plaintiffs evidence that is relevant only to one plaintiff's case, thereby essentially fabricating evidence that does not exist. Second, GSK's defenses — such as the statute of limitations, the learned intermediary doctrine and assumption of

the risk — must be decided as to each individual plaintiff. If the jury fails to apply the evidence to the appropriate plaintiff, these defenses will be meaningless."

Finally, the company asserts that a single trial would be no more efficient than holding separate trials.

Counsel

Thomas M. Moore, David J. Fleming and Mario Horwitz of Drinker, Biddle & Reath in Los Angeles and Chilton D. Varner, Andrew T. Bayman and Todd P. Davis of King & Spalding in Atlanta are counsel for GSK.

Karen Barth Menzies of Baum Hedlund in Los Angeles, Christopher Coffin of the Pendley Law Firm in Plaquemine, La., Donald J. Farber of the Law Offices of Donald J. Farber in San Rafael, Calif., and Kevin J. Yourman and Jennifer Liakos of Yourman, Alexander & Parekh in Manhattan Beach, Calif., represent the plaintiffs.

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Plaintiffs Seek Certification Of Class To Resolve Common Questions

LOS ANGELES — Plaintiffs in the Paxil withdrawal MDL have asked the court to certify a nationwide class to determine liability as to GlaxoSmithKline's (GSK) conduct regarding its alleged misrepresentations about Paxil's ability to induce dependence (In re: Paxil Products Liability Litigation, MDL No. 1574, C.D. Calif.).

(**Renewed motion available.** Document #75-050325-015M.)

In their Feb. 7 renewed motion for class certification, lead plaintiffs Katherine Keith and Dan Kabic say certification of a nationwide common issues class is necessary because although GSK has conceded that Paxil can cause withdrawal symptoms in some people, questions of law remain as to the manufacturer's motivation and conduct.

For example, the plaintiffs opine that questions regarding when GSK knew that Paxil could cause moderate to severe withdrawal symptoms, whether it misrepresented the degree of frequency and severity of withdrawal symptoms in its advertisements, marketing and labeling, whether GSK failed to warn physicians and the medical community regarding withdrawal reaction and whether its representations regarding Paxil's ability to cause withdrawal symptoms was misleading can all be resolved in a single forum, upon a single presentation and in front of a single fact finder.

"These questions only relate to the conduct and motivation of GSK," plaintiffs argue. "They are highly relevant not only to the plaintiffs' claims, but to determining the intentional nature of GSK's conduct."

The common issues class would include people who suffered withdrawal reactions as a result of discontinuing or tapering their use of Paxil.

Consumer Class

The plaintiffs also ask the court to certify a class of California residents seeking mandatory injunctive relief and disgorgement based on GSK's alleged violation of California's Unfair Competition Law (UCL).

U.S. Judge Mariana Pfaelzer of the Central District of California on Aug. 29, 2003, rejected the plaintiffs' previous motion for a UCL class, noting that GSK said it was no longer claiming that Paxil was not habit-

forming. However, the plaintiffs point out in their current motion that as of Jan. 17, GSK's sales representatives were still telling doctors that the company had "taken care" of the withdrawal symptoms associated with Paxil and that there are "no problems . . . with discontinuation."

"The fact that GSK's sales representatives are still making these types of statements to physicians, when GSK has already admitted to this Court that it concedes that withdrawal symptoms do occur in some cases, is preposterous," the plaintiffs assert. "It is exactly these types of statements and conduct that plaintiffs respectfully request this Court to permanently enjoin."

Arguments on the motion are scheduled to be heard March 31 before Judge Pfaelzer.

Karen Barth Menzies of Baum Hedlund in Los Angeles; Christopher L. Coffin of the Pendley Law Firm in Plaquemine, La.; Donald J. Farber of the Law Offices of Donald J. Farber in San Rafael, Calif.; and Kevin J. Yourman, Jennifer R. Liakos and Angela S. Rupert of Yourman, Alexander & Parekh in Manhattan Beach, Calif., represent the plaintiffs.

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Judge Finds Prop 64 Bars Class Representative's Claims

LOS ANGELES — An unaffected plaintiff cannot maintain an action seeking restitution for a proposed class under California's Unfair Competition Law, a Los Angeles County Superior Court judge ruled, finding that Proposition 64 is retroactive to pending cases
(Roberta Madison, Dr., P.H.,et al. v. Pfizer Inc., et al., No. BC318871, Calif. Super., Los Angeles Co., See January 2005, Page 17).

(**Notice of Order.** Document #75-050325-113X.)

In a March 21 notice of ruling, Pfizer Inc. said Judge Kenneth R. Freeman granted its motion for judgment on the pleadings, which sought to remove lead plaintiff Roberta Madison from representing a proposed class of California consumers seeking restitution for monies spent on Zoloft based on the company's alleged concealment and suppression of safety data on Zoloft.

In a Jan. 5 joint case management conference statement, Madison, who initiated the action in July 2004 as a private attorney general, conceded that she had never purchased or used the selective serotonin reuptake inhibitor (SSRI).

(**Statement available.** Document #75-050128-017B.)

The parties also agreed that proceedings should be halted for the court to determine the applicability of amendments to Proposition 64, which limit private enforcement of Sections 17200 and 17500 of California's Unfair Competition Law to plaintiffs who have suffered injury in fact and have lost money or property and require plaintiffs seeking to represent consumers to comply with the class action requirements of Code of Civil Procedure Section 382.

Retroactivity

In support of its motion for judgment on the pleadings, Pfizer argued that the amendments to Proposition 64, which were passed by the California Legislature in November, were retroactive.

However, sources told **Mealey Publications** that the argument over the retroactive application of Proposition 64 is still hotly debated and that a majority of appeals courts have found that the amendments apply to cases filed before their enactment.

The plaintiffs will have 30 days to amend their complaint to find a new class representative that fits the requirements of Prop 64 or apply to the court to show cause why additional time should be permitted, the document states.

George Murgatroyd III, Karen Barth Menzies and Robert M. Brava-Partain of Baum Hedlund in Los Angeles represent Madison.

Pierce O'Donnell, Ann Marie Mortimer and Daniel C. Tepstein of O'Donnell & Schaffer in Los Angeles and Malcolm E. Wheeler of Wheeler Trigg Kennedy in Denver are counsel for Pfizer.

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FDA Seizes Avandamet, Paxil CR For Violations Of Manufacturing Practices

ROCKVILLE, Md. — The Food and Drug Administration announced March 4 that federal marshals seized Avandamet and Paxil CR tablets from two GlaxoSmithKline Inc. (GSK) plants for continuing violations of good manufacturing practices (United States of America v. Undetermined Quantities of Drugs, et al., No. 05-113, E.D. Tenn., Knoxville).

(**Complaint available.** Document #28-050310-022C.)

The U.S. attorney for the Eastern District of Tennessee filed a March 1 complaint in federal court for forfeiture *in rem* of Paxil CR and Avandamet drugs that he said were adulterated by not conforming to good manufacturing practice.

In a press release, the FDA said it found that some Avandamet tablets did not have an accurate dose of rosiglitazone, the active ingredient. It said Paxil CR tablets could split apart and patients could receive no active ingredient or active ingredient without the drug's time-release ingredient.

The FDA said it is unaware of any injuries and said it does not believe the seized drugs pose a significant health hazard. However, it said it is concerned that manufacturing practices could result in "poor quality drug products that could potentially pose risks to consumers." It urged patients taking the drugs to continue to do so but to talk with their health care providers about possible alternatives until the manufacturing problems have been corrected.

Violations Ongoing

The FDA indicated that violations of good manufacturing practices at GSK plants in Tennessee and Puerto Rico were ongoing. It said GSK had voluntarily recalled some affected lots but failed to recall all affected lots, resulting in the seizures.

In a press release, GSK stated only that the FDA had "halted" distribution of the two drugs because of "manufacturing issues." It said it believes the manufacturing issues do not pose health risks to patients.

GSK said it anticipated the seizure will result in a shortage of the two drugs.

U.S. Attorney Harry S. Mattice Jr. and Assistant U.S. Attorney Pamela G. Steele of the Eastern District of Tennessee represent the government.

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New Complaints

Paxil Caused Man To Commit Suicide, Estate Alleges In D.C. Suit

WASHINGTON, D.C. — The estate of a Maryland man filed suit in federal court March 18, alleging that his use of Paxil caused him to commit suicide (Amanda Paine v. GlaxoSmithKline, No. 1:05cv00574, D. D.C.).

(**Complaint available.** Document #75-050325-017C.)

Amanda Paine, representative of the estate of Gerry Paine, alleges that Paxil manufacturer GlaxoSmithKline (GSK) was negligent in its testing of the drug and in its failure to warn physicians of the risk of withdrawal or discontinuation symptoms. Gerry Paine committed suicide on March 18, 2003, after taking Paxil to combat depression.

'Vulnerable Subpopulation'

Paine alleges that GSK has known "for years" about "a vulnerable subpopulation of patients who are at risk of violence and suicide has a result of taking Paxil and other SSRI drugs" but "has failed to conduct any prospective tests to determine the frequency of this phenomenon or develop means of identifying and protecting those patients who are in this risk group. GSK has also failed "to warn prescribing physicians, pharmacists, and patients about this risk or to instruct them on the known ways to reduce or ameliorate the risk."

She also alleges that Paine's prescribing physician "was not warned about the dangers of Paxil induced violence/suicide and had not been instructed about the proper way to taper a patient off of Paxil."

The suit seeks $5 million in damages.

Paine is represented by Deairich R. Hunter of The Hunter Law Firm in Washington.

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Lilly Removes Pennsylvania Zyprexa Action To Federal Court

PHILADELPHIA — Citing diversity of citizenship and the amount in controversy, Eli Lilly and Co. on March 21 removed to federal court a complaint brought by the widow of a Kansas City, Mo., man alleging that her husband's suicide was related to his use of Lilly's Zyprexa antipsychotic drug (Debra Vanderwerf, et al. v. GlaxoSmithKline, PLC, et al., No. 2:05-CV-01315-MAM, E.D. Pa.).

(**Notice and complaint available.** Document #75-050325-016C.)

Debra Vanderwerf alleges in an action originally filed Feb. 18 in the Philadelphia County Court of Common Pleas that her husband, William Vanderwerf, committed suicide in February 2003 "as a direct and

proximate result" of his ingestion of Zyprexa and the antidepressant Paxil, manufactured by GlaxoSmithKline PLC.

According to the plaintiff, William Vanderwerf was taking 40 milligrams of Paxil daily when he was advised by his physician on Feb. 7, 2003, to begin taking Zyprexa and to see a psychologist. Shortly thereafter, the plaintiff states, William Vanderwerf experienced paranoia, delusions, hysteria and neuroleptic-induced akathisia. On Feb. 21, he shot himself to death.

The complaint asserts causes of action for strict liability, negligence, negligence *per se*, and breach of implied warranty.

In removing the action, Lilly argued that the amount in controversy exceeds $75,000 and that complete diversity exists among the parties.

Lilly is represented by Nina M. Gussack, Anthony C.H. Vale and Edward J. Sackman of Pepper Hamilton in Philadelphia. Vanderwerf is represented by Harris L. Pogust of Cuneo, Pogust & Mason in West Conshohocken, Pa.; Brian J. Madden of Wagstaff & Cartmell in Kansas City, Mo.; and Derek H. Potts of the Law Office of Derek Potts in Kansas City, Mo.

Take me to the Top

FDA Position On Federal Preemption Consistent With Law And Public Health

By Eric G. Lasker

[Editor's Note: Eric Lasker is a partner at the law firm of Spriggs & Hollingsworth in Washington, D.C., where he handles a variety of complex civil matters. Lasker has significant experience in pharmaceutical product liability claims as well as the federal preemption defense. Reprinted with permission of the Washington Legal Foundation, which originally published this article as part of its educational "Legal Backgrounder" series. Copyright 2005, Washington Legal Foundation. Replies to this commentary are welcome.]

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 set forth its preemption position in *amicus* briefs filed in a number of state and federal cases over the past few years.1

Drug Warnings

In Motus v. Pfizer Inc.,(Nos. 02-55372 & 02-55498 [9th Cir. 2002]) 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, 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 23-2422

In Dowhal v. SmithKline Beecham Corp. (No. S109306 [Calif. Sup. 2001]), 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*

Medical Devices

In Horn v. Thoratec (No. 02-4597 [3rd Cir.]), 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 Motusand Dowhal (and in another medical device case Murphree v. Pacesetter (No. 005429-00-3 [Tenn. Cir.])), 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[Pre-Marketing Approval] 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.

Congressional Opposition

In July 2004, Representative Maurice 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 *Shepardize*.

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 *Shepardize*.

Impact On Litigation

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 Shepardize[U.S. Sup.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 Shepardize(Breyer, J., concurring). Following Lohr, the clear majority of federal circuit courts have held that state tort law claims involving Class III medical devices subject to the full 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 Shepardize[U.S. Sup. 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 Shepardize. 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 *Shepardize*, 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 *Shepardize*. 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 *Shepardize*.

While Buckmanaddressed 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

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.

Endnotes

1. *See 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).

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 Shepardize(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 Shepardize(Cal. 2004).

5. *See* 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 Shepardize(1985). *See also* Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 Shepardize(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 pre-empted.") (internal quotation and footnote omitted).

7. Under 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.

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

9. *See* R.F. v. Abbott Laboratories, 745 A.2d 1174, 1192-93 Shepardize(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.").

10. *See* Ehlis v. Shire Richwood, Inc., 233 F. Supp. 2d 1189, 1198 Shepardize(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 Shepardize(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 Shepardize(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).

11. *See* 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 Shepardize(Minn. Ct. App. 2001) (same). Further analysis of the potential impact of Buckmanon 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*, 37TORT & INS. L. J. 129-145(Fall 2001). ☐

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Preemption Issues And Prescription Drug Litigation

By Jessica R. Dart

[Editor's Note: Jessica Dart is attorney with the Los Angeles-based law firm Baum Hedlund, P.C., where she has argued and briefed federal preemption issues in a variety of cases including Motus v. Pfizer Inc., (Nos. 02-55372, 55498 [9th Cir.]); Ehlis v. Shire Richwood Inc. (No. 02-3933 [8th. Cir.]); In re Paxil Litigation, (No. CV-01-07937 MRP [C.D. Calif.]); Dusek v. Pfizer Inc. (No. H-02-3559 [S.D. Tex.])and Needleman v. Pfizer Inc. (No. 3:03-CV-3074-N [N.D. Tex.]). She is currently assisting in the litigation of six other Zoloft-induced suicide cases, including the case of Witczak v. Pfizer Inc. (No. 04-CV-2819-JMR-FLN, [D. Minn.]). Copyright 2005, the author. Replies to this commentary are welcome.]

> "Not only is the Defendant's argument based upon a flawed federal preemption analysis, but it would, if successful, have the extraordinary severe result of depriving Minnesotans injured by Defendant's drugs and culpable conduct of any ability to seek redress for their injuries."
>
> Mike Hatch, Minnesota Attorney General on Pfizer Inc.'s preemption argument in Witczak v. Pfizer Inc.(No. 04-CV-2819-JMR-FLN [D. Minn.]).

Just a few weeks ago, Minnesota's Attorney General, Michael Hatch, wrote to U.S. District Judge James M. Rosenbaum and requested permission to file a friend of the court brief in the case of Witczak v. Pfizer Inc.

The A.G.'s request came after Zoloft manufacturer Pfizer Inc. announced its intention to get plaintiff Kimberly Witczak's case dismissed by arguing that it could not be held liable for failing to warn about the side effects that led to her husband's death because the Food and Drug Administration wouldn't have allowed it to do so.

Pfizer's argument was not that it made the FDA aware of the need for a warning and the FDA refused to allow a warning anyway, but rather that *if* it had filed an application with the FDA containing the evidence justifying the need for a warning, the FDA would have discounted the evidence as non-credible and threatened Pfizer with a misbranding action if Pfizer had persisted in warning. Assuming *arguendo* that the FDA would have filed a misbranding action, and assuming *arguendo* that the FDA's misbranding action would have stood up in court, Pfizer's argument is belied by the simple fact that once the FDA did take a look at the evidence of SSRI-induced akathisia and suicidality, the FDA asked Pfizer to warn.

Warning Signs

Almost a year before Timothy Michael Witczak's death, the FDA had begun analyzing evidence linking Zoloft and other SSRI's with suicidality, akathisia and certain other neurological conditions associated with self harming behavior and a loss of impulse control. The FDA found that these drugs can increase the risk of suicidality in those 18 and under and that patients of all ages needed to be warned that they should be monitored closely for suicidal thoughts and actions during initial drug therapy and whenever a change in dose occurs. The FDA further found that because it had not previously looking at the clinical trial data in a sufficiently careful manner, they would need to re-analyze the data from adult clinical trials to see if even stronger warnings are needed then the ones it is currently requesting.

Regardless of what the FDA finds, the warnings currently in place would have been enough to save Mr. Witczak's life had Pfizer not assumed, *arguendo*, that the FDA wouldn't have allowed it to warn. Mr. Witczak (known as "Woody" to his friends and family) was 37 when he died. He was happily married to his wife of almost 10 years. He had no history of mental illness prior to taking Zoloft. His family doctor prescribed Zoloft after Woody asked if there was something he might take to help him sleep better.

Woody's formal diagnosis, to the extent there was one, was insomnia. He had not been prescribed Zoloft for depression. Prior to ingesting his first Zoloft, Woody's biggest concern had been to get better sleep so he could perform well in his job as Vice President of Sales at XE Energy, a new startup company that he and two business associates were building to supply industry with environmentally friendly lighting systems.

In the days preceding his death, Woody had thrown an engagement party for friends, booked his flight for a buddy's bachelor party and made reservations for a vacation with his wife and family. He and his wife, Kim, had been trying to get pregnant for some time so, just days before his death, they had decided that when Kim got back from her business trip they were going to schedule her *in vitro* appointment A.S.A.P. Instead, Kim got a call from her father at about 9:30 p.m. on Aug. 6, 2003. He had found Woody dead, hanging from the rafters in Kim and Woody's garage.

Kim is now a widow and if her husband had been hit by a drunk driver there would be no question about her right to have the driver's negligence determined in court. A defense of "but, the government wouldn't let me drive sober," submitted on the driver's behalf would go beyond offensive but that argument would be no different, and no less offensive, than the one Pfizer is asserting now.

FDA's Amicus Brief

Pfizer's position is contrary to well established law. Its position would be laughable but for the fact that it has recently obtained dismissal of two similar Zoloft suicide cases using the same, "the government wouldn't have let us warn" defense. See Dusek v. Pfizer Inc. (No. H-02-3559 [S.D. Tex.]) and Needleman v. Pfizer Inc. (No. 3:03-CV-3074-N [N.D. Tex.]) (appeals pending). These two cases have one thing in common with Mrs. Witczak's case. In all three cases, Pfizer has asked that the court defer to an *amicus* brief filed on its behalf in the Ninth Circuit Court of Appeals in another Zoloft-induced suicide case Motus v. Pfizer Inc. 127 F.Supp.2d 1085 Shepardize(C.D. Cal. 2000).

The *amicus* brief in Motus purported to present the position of the FDA and announced the agency's unqualified support of Pfizer's preemption defense. In the broadest possible terms the brief stated that had Pfizer attempted to warn about the possible causal relationship between Zoloft and suicide prior to Mr. Motus' death, "any warning, no matter how worded, that could reasonably have been read as describing or alluding to such a relation would have been false or misleading, and therefore in conflict with federal law[.]" See United States *Amicus* Brief in Motus v. Pfizer Inc., at p Shepardize. 2. The brief also stated that the FDA had done something no scientist familiar with the scientific method would ever claim go have accomplished. To secure Pfizer's legal success, the brief stated that the FDA had thoroughly "examined the matter" and "concluded" that a risk of Zoloft-induced suicide "does not exist." *See* FDA Brief at pgs. *Shepardize*2 & 16.

The Ninth Circuit did not adopt the FDA's *amicus* brief position in Motus, but it would later come out that Pfizer itself had solicited the brief by calling its former lawyer, the FDA's then-newly appointed Chief Counsel, Daniel E. Troy. When the FDA appropriations committee later questioned the amount of compensation Pfizer had paid Troy in the months prior to his joining the FDA, the agency responded that Troy had only worked about 80 hours per year for Pfizer. Troy's financial disclosures, obtained pursuant to a Freedom of Information Act (FOIA) request filed by United States Congressman Maurice Hinchey, painted a slightly different picture. Troy's late-reported financial disclosures revealed that Pfizer had given Troy and/or his firm, close to $400,000 in the months just preceding his formal appointment as the legal head of the FDA; thus making Troy's services roughly equal to $400,000 per hour.

Four thousand dollars an hour, however, has turned out to be a bargain deal for Pfizer. Troy, having resigned from the FDA, is now back representing drug companies and teaching them how to overcome and get around FDA regulation, something he specialized in prior to being appointed by the Bush Administration to run the FDA's legal department. And, Pfizer is still relying on the three-year old FDA *amicus* brief that Troy admits having initiated.

Review Of FDA's Position

The Witczak case, however, may put an end to Pfizer's preemption defense. Since the brief was filed, the FDA has admitted that it had begun to reexamine the issue of SSRI-induced suicide in September 2002, the very month that Troy had the *amicus* brief filed in the Motus case. That reexamination led to new warnings and an FDA admission that, contrary to claims made in the Motus *amicus* brief, it had not looked carefully at the issue of SSRI-induced suicide for some time because it had not seen a signal in the data until 2002, approximately one year before Woody's death.

Even without these developments, however, Pfizer's preemption defense should fail. Recent admissions of FDA officials in charge of approving Zoloft's labeling, coupled with Congressional findings regarding the FDA's failure to issue timely suicide warnings confirm what the law has always provided:

(1) Prescription drug manufacturers have the right *and the duty* to warn about serious hazards associated without prior FDA approval "as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 CFR § 201.57 Shepardize(e)(Warnings);44 Fed. Reg. at 37,447, June 26, 1979); 21 C.F.R. §314.7 Shepardize(c)(2)(I) (*stating* that a change to labeling that "add[s] or strengthen[s] a contraindication, warning, precaution, or adverse reaction" is within the category of changes that "may be made before FDA approval.").

(2) Prescription drug manufacturers have state law duties, as well as federal ones, to act as reasonable corporations would, in like circumstances, when they know that their product can cause injury and death; and

(3) *Amicus*briefs filed by captured federal agencies, or their lawyers, are not entitled to deference when they are inconsistent with Congressional intent and the federalist right of states to protect the health, welfare and legal rights of their citizens.

Types Of Preemption

As the Minnesota Attorney General has pointed out, Pfizer's federal preemption analysis is "flawed." Generally speaking, there are three main types of federal preemption: field preemption, express preemption, and implied conflict preemption. Field preemption is not at issue in the Witczak case, but applies whenever Congress has given a federal agency the right to regulate an area so completely that no power or authority is left to the states. Only a few federal agencies have field preemption authority and it is well established that the FDA is not one of them when it comes to prescription drugs.

The express preemption doctrine, also not at issue in the Witczak case, requires no real attention in this article because lawyers litigating a prescription drug injury or death case will have no occasion to deal with it directly. Congress has never passed an express preemption clause applicable to the FDA's regulation of prescription drugs. In contrast, Congress has amended the Food, Drug and Cosmetics Act (FDCA) several times to add express preemption clauses to the portions of the act dealing with FDA regulation of certain other products such as medical devices or over-the-counter products. These preemption clauses "expressly" give the FDA the authority to prevent states from passing laws or regulations which impose "additional or differing" requirements upon manufacturers than those imposed by the FDA. Sometimes the express preemption clause does not use the "additional or differing" terminology and merely states that no state shall impose requirements on manufactures that are "non-identical" to the FDA's own regulations.

Even though Congress has not given the FDA the authority to prevent states from imposing additional or differing (or non-identical) requirements on prescription drug manufacturers, it is still important to understand the doctrine when litigating a prescription drug case. This is because what qualifies as a conflict for purposes of the conflict preemption doctrine is different than what will qualify as a conflict in a case where the FDA has express preemption authority.

Arguing Against Preemption

If you are a plaintiff's lawyer facing a "conflict preemption" defense in a prescription drug case, the defendants will likely assert that a conflict exists if there is any risk that a verdict in your client's failure will result in a "requirement" that will "add to" or "differ from" what the FDA has required. But, that is not the test for a conflict in a prescription drug case. In a prescription drug case, you do not look to see if a verdict in your clients favor will "require" the manufacturer to do anything "in addition to," or "differing

from" what the FDA has required because Congress has never given the FDA the authority to prevent such state requirements for prescription drug manufacturers. In a prescription drug case, you look to see if your case would require the manufacturer to do anything that would "stand as obstacle" or "conflict" with an existing federal law or FDA regulation.

The conflict preemption defense cannot properly be invoked in a prescription drug case on the basis of hypothetical or speculative conflicts. Unless a verdict in your client's favor will actually conflict with an *existing* federal law, regulation, or other final rule or adjudication qualifying as federal "law" for purposes of invoking Supremacy Clause status, the conflict preemption doctrine will not apply. Because express and implied preemption doctrines are thought to derive their authority from the Supremacy clause, something must actually constitute "federal law" in order to pose a conflict with an alleged state "requirement." Informal FDA determinations do not qualify as federal law, a telephone call or a letter from an FDA official does not qualify as federal law, and even an amicus brief written by FDA lawyers does not qualify as federal law.

To become federal law, the FDA, at a minimum, must follow the dictates of the Administrative Procedures Act (APA) and its own regulations on regulation and rule making. Under both statutory frameworks, states must be given notice and the right to comment if the FDA proposes to enact a regulation or rule that has the effect of preempting state law. As the state of Minnesota made clear in its *amicus* brief in the Witczak case, "the law is clear that the type of informal pronouncements upon which Pfizer relies are not entitled to any preemptive effect. First, courts and commentators have correctly reasoned that federal preemption based on agency action or pronouncements is suspect, given that federal agencies are a clear step removed from Congress and that their interpretations, therefore, should not constitute a substitute for clear and unmistakable expression of *congressional* intent. The relevant inquiry in a federal preemption analysis is the clear unmistakable intent of Congress–not the intent of an unelected agency." *See* Memorandum of *Amicus*Curiae State of Minnesota in Opposition to Defendant Pfizer Inc.'s Motion for Summary Judgment (Preemption) in Witczak, at pg. 21.

In the case of FDA's regulation of Zoloft, the agency has *never* told Pfizer that it may not warn of Zoloft's association with suicidality, and no law, FDA regulation, final rule or formal adjudication exists to demonstrate otherwise. The only thing that had occurred prior to the filing of the FDA *amicus*brief in Motus was FDA approval of Pfizer-drafted drug labeling and some informal and uncompleted FDA queries into the issue of Zoloft-induced suicidality. The FDA *amicus* brief statement that it "would have" told Pfizer it could not warn, had Pfizer ever attempted to do so, is a speculative statement about a hypothetical situation that only became non-hypothetical when the FDA recently did the opposite and asked Pfizer to warn.

Impact On Federalism

The mere ability of Pfizer to procure an FDA *amicus* brief to support its attempts to escape liability in the Motus case, however, stands as a substantial threat to our legal rights as citizens, and to our system of checks and balances. Given that Congress has never seen fit to give the FDA express preemption authority in the prescription drug arena, the FDA's position in the Motuscase was nothing more than a backdoor attempt to obtain for the FDA the very same preemptive authority that Congress has repeatedly refused to provide.

In the Witczakcase, judicial adoption of the FDA's *amicus* brief position in Motuswould amount to a judge-made amendment to the FDCA that would violate the separation of powers doctrine. Such a ruling would also run afoul of long-held principles of federalism, which preserve the historic police power of the states to govern matters of health and safety. Accepting the Motus *amicus*brief arguments would effectively give

the FDA (or rather its politically appointed lawyers) the *ipse dixit* authority to remove the *subject matter* of its regulatory actions, or lack thereof, from any form of judicial scrutiny.

Such a legal development would effectively close the gap for consumers injured by prescription drugs. While Daniel Troy's resignation from the FDA is likely to reduce the ability of drug companies to get free legal help from the U.S. government, judicial adoption of the Motus *amicus* brief would pave the way for drug manufacturer wanting to escape accountability for their violations of state negligence and strict liability laws. Using the case of Zoloft as example, all such companies will need to do is demonstrate that the FDA had approved its drug labeling — and that despite some initial queries, had not yet gotten around empirically investigating their drugs risks and asking them to warn.

Woody Witczak died approximately one year after the FDA got around to following up on earlier signals of Zoloft's association with akathisia and suicidality. The FDA requested that Pfizer immediately warn doctors, patients and their families of Zoloft's risks approximately one year after that. Pfizer has yet to provide truly adequate warnings about Zoloft risks and even after the FDA asked it to warn, it wrangled with the agency and watered down the requested wording. While sitting in a doctor's office the other day, waiting to begin a deposition, I ran into two Pfizer sales representatives hoping to squeeze in a meeting with the doctor before we began. Not knowing that I was there to depose the doctor, and maybe assuming I was another drug representative, they asked me if I was waiting to see the doctor too. I said yes and asked them what they thought about the new warnings the FDA was requesting regarding Zoloft and suicide. The response from the first, young 20-something drug rep was, "Oh, we are not supposed to talk about that." "Even when doctors ask?" I inquired. "Well, if they ask," she replied, "we are just supposed to give them a number to call." Pfizer's lawyer then promptly told them to shut up.

Congress' investigation into the FDA's failure to request timely warnings is a sign that it would never leave the public's health and safety entirely up to the FDA, but this is of little consolation to Kim Witczak. Had Pfizer warned when it first knew of Zoloft's association with akathisia and suicidality Woody, and countless others, would still be here today.

Woody's life and death inspired his friends and family to do what Woody would have done if one of them had died as a result of Pfizer's failure to warn. Their Web site, celebrating Woody and detailing the facts regarding the issue of SSRI-induced suicidality, can be found at *www.woodymatters.com*.

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