

1 of 285 DOCUMENTS

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Mealey's Emerging Drugs & Devices

February 16, 2006

*11-4 Mealey's Emerg. Drugs & Devices 27 (2006)***SECTION:** Volume 11, Issue #4**HEADLINE:** Preamble To FDA Final Rule: FDA's Latest Effort To Immunize Drug Manufacturers From Tort Liability At The Expense of Consumer Safety**BODY:**

By Karen Barth Menzies

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**EDITOR-NOTE:**

Editor's Note: Karen Barth Menzies is an attorney at Baum Hedlund in Los Angeles. For more than a decade she has been involved in litigating claims involving injuries stemming from selective serotonin reuptake inhibitors such as Prozac, Paxil, Zoloft and, more recently, Lexapro/Celexa. Heading a team of Baum Hedlund attorneys, she has successfully defeated Pfizer's and the FDA's preemption arguments in a number of cases, including *Motus v. Pfizer* (Nos. 02-55372 & 02-55498 9th Cir. ) and *Witczak v. Pfizer* (No. 04-2819 D. Minn. ). Ms. Menzies is Lead Counsel for the Plaintiffs Steering Committee (MDL-1574) Paxil Products Liability Litigation. In addition to her court activities, she has testified about the dangers of SSRIs before the California State Assembly and the Food and Drug Administration's Psychopharmacologic Drugs Advisory Committee and met with members of the House and Senate regarding the risk of antidepressant induced suicidality and preemption issues. Ms. Menzies was named Lawyer of the Year by *Lawyer's Weekly*, California Lawyer of the Year by California Lawyer magazine and one of The National Law Journal's Top 40 Under 40 for her extraordinary achievements and impressive track record for stepping up her fight in the past few years, advocating that pharmaceutical companies should warn about the alleged risks of antidepressant drugs. Copyright 2006, the author. Replies to this commentary are welcome.

**I. Introduction**

On Wednesday, Jan. 18, 2006, the Food and Drug Administration issued new regulations regarding the labeling of prescription drugs, including regulations aimed at providing doctors and patients with clearer information about the risks associated with prescription drugs. However, in the preamble to these new regulations, the FDA inserted conclusory and legally unsupported statements that tort lawsuits alleging a failure to warn of known or reasonably knowable safety risks are preempted by federal law. This attempted power-grab by the FDA wholly ignores the prerogative of Congress, contradicts both statutory and case law precedent, disregards the parallel but distinct roles played by FDA and tort liability law, fails to provide an avenue through which consumers may be compensated for drug-induced injury, neglects any federal replacement of applicable state policing and enforcement procedures, and shirks constitutionally established principles of federalism which protect the jurisdiction granted to states in matters involving public safety and health.

By inserting preemption language into the Final Rule without an official consultation with state and local government groups concerning the preemption language, the FDA also violated Executive Order (E.O.) 13132. (When an executive department or agency proposes to act through adjudication or rule-making to preempt State law, the department or agency shall provide all affected States notice and an opportunity for appropriate participation in the proceedings. Exec. Order No. 13132, [4(e), 64 Fed.Reg. 43255, 43257 (1999)]. According to the National Conference of State Legislatures (NCSL), the preemption language inserted into the preamble of the Final Rule is a thinly veiled attempt on the part of FDA to confer upon itself authority it does not have by statute and does not have by way of judicial ruling. The NCSL called FDA's action an abuse of agency process and a complete disregard for our dual system of government.

It would appear that the FDA included the preemption language in the preamble, rather than the substantive portion of the rule, in order to avoid E.O. 13132 and the required comment period. (The FDA also failed to provide the requisite comment period related to the preemption language.) Presuming this is the case, the FDA's statement is nothing more than the policy position of appointed officials with an agenda unrelated to public safety. As such, it should have zero preemptive effect.

Pharmaceutical industry lobbying efforts and zealot tort reformers have sired a new wave of brazen attempts to shield drug manufacturers from tort liability. The preemption language in the preamble to the Final Rule is but the latest attempt. Preemption has become the argument du jour and politically appointed regulatory officials the mouthpieces. The crafty messages sound of consumer protection, but are just the opposite. Limiting the liability of drug companies will not improve public safety. The FDA's purported position on preemption assumes that the FDA is infallible and that negligent misconduct by pharmaceutical companies should be the sole purview of FDA. Recent regulatory failures demonstrate that FDA is neither infallible nor does it have the capability of policing drug manufacturers' negligent misconduct.

The use of regulatory officials to protect pharmaceutical companies from tort liability began with the FDA's submission of amicus briefs in civil cases which, like the preamble to FDA's Final Rule, argued that state tort failure-to-warn lawsuits should be preempted because the FDA is the final arbiter of prescription drug labeling. These attempts have largely failed and for good reason. In the more than 65 years since the enactment by Congress of the Food, Drug and Cosmetics Act (FDCA), U.S. courts have held, virtually without exception, that the FDCA does not preempt state tort failure-to-warn lawsuits against prescription drug manufacturers. Apparently, the backers of preemption hope that, if they say something often enough, it will eventually come true. For the same reasons the FDA amicus briefs have failed, the preamble in the FDA's Final Rule should hold no authoritative weight. Unfortunately, some judges may fall prey to these deceptive efforts by FDA bureaucrats to confer authority upon FDA that Congress never granted.

## II. FDA's Position Is Legally Unsupportable

The FDA makes a number of assertions regarding preemption in the preamble to these new regulations, most of which do not withstand scrutiny. First, FDA asserts that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law. <sup>1</sup> The FDA states that this position represents the government's long standing views on preemption, with a particular emphasis on how that doctrine applies to State laws that would require labeling that conflicts with or is contrary to FDA-approved labeling. <sup>2</sup> However, Congress has never conferred upon FDA the authority to preempt state tort lawsuits involving prescription drugs and, as demonstrated by decades of FDA Commissioners' statements, this is not the FDA's long standing position. In fact, the FDA's longstanding position, at least prior to 2001, has been just the opposite.

The FDA argues in the preamble that state law actions threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. <sup>3</sup> The FDA defends its position by stating that it makes approval decisions based not on an abstract estimation of the product's risks and benefits under the conditions of the use prescribed, recommended, or suggested in the labeling. The Congressional testimony of Dr. David Graham related to the FDA's standard for concluding that a safety risk exists, discussed more fully below, should disabuse anyone of this notion. The FDA's history of drug safety failures serve to highlight the fallacy of this argument.

The FDA also rejects the long established view that its regulations are minimum safety standards. Instead, the FDA states that it interprets the act to establish both a floor and a ceiling, such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false and misleading. <sup>4</sup> The FDA's position is inconsistent with decades of case law, ignores the limitations of its drug approval process and its post-marketing surveillance, and contradicts statutory authority.

The FDA's assertion that a manufacturer will be subjected to liability if it strengthens a drug's label in a manner that makes the label false or misleading or is unsubstantiated or otherwise false or misleading <sup>5</sup> is a red herring. Clearly, the FDCA contemplates liability for misbranding, in the context of drug warnings, when a drug's label fails to include necessary information. It is patently absurd to argue that a drug would be misbranded in violation of the FDCA if it over-warned about a particular pathological condition, particularly one involving a serious risk that could result in death. In fact, to our knowledge, the FDA has never in its history brought a misbranding action against a manufacturer for providing stronger warnings than were required by the FDA at the time of the drug's approval. And liability for a misleading label only attaches when the label fails to reveal facts material in light of other representations contained in the label. <sup>21</sup> U.S.C. [321(n)].

Essentially, the government's argument would create a scenario where manufacturers are encouraged not to act quickly in the face of evolving information when a serious safety issue is suspected with a marketed drug. Indeed, manufacturers would be better off to not act at all and simply wait for the FDA to do something. That is not, and cannot, be the state of the law in this area. See *United States v. Dotterweich*, 320 U.S. 277, 282 (1943) (FDA's primary objective is the protection of consumers). Thus, the government's interpretation of the FDCA is misguided, if not downright dangerous, and at odds with the plain language of the statutes at issue.

Next, the FDA does not have the authority to declare a drug misbranded. The FDCA has set up an enforcement procedure, which requires the FDA to initiate a misbranding action in federal court. 21 U.S.C. §§ 331 (misbranding prohibited), 332 (jurisdiction in federal court to order injunctive relief), 333 (criminal penalties for violations of section 331), 334 (seizure authorized for misbranded drugs), 335 (FDA Secretary shall afford defendant hearing before referring to United States Attorney), 336 (Secretary may utilize written notice or warning in lieu of referral for prosecution for minor violations), and 337 (actions by the FDA shall be brought in the name of the United States). The court in *Witczak v. Pfizer*, 377 F. Supp. 2d 726; 2005 U.S. Dist. LEXIS 14608 (D. Minn. July 20, 2005), in denying Pfizer's motion for summary judgment regarding federal preemption, specifically stated that the FDA has no authority to declare, *ipse dixit*, that a label is false and misleading. Rather, the government must initiate an enforcement action to establish that the drug is in fact misbranded. 377 F.Supp.2d at 730. Thus, while the FDA may believe a drug's label is false or misleading, such belief, if any, does not have the force and effect of law unless and until the FDA is successful in an enforcement action under the FDCA. It is only then that it can be said that a conflict exists.

The FDA uses the context of the Final Rule (re improved labeling) to argue that drug labels have become legal disclaimers rather than a useful tool for physicians and their patients, and that drug companies place speculative risks in the label in order to avoid tort liability. What the FDA ignores, however, is that companies are not liable when they disclose known or reasonably knowable risks associated with their drugs. Nor are they liable for failing to disclose unsubstantiated risks.

The FDA's preemption arguments also ignore that the state law standards for proof actually exceed the standard provided for in FDA's own regulations. FDA regulation 21 C.F.R. [201.57(e) states that manufacturers must include a safety warning whenever there is reasonable evidence of an association between a particular hazard and the drug; a causal relationship need not have been proved. <sup>6</sup> However, all states require a plaintiff in a prescription drug failure to warn case to prove that, in fact, it is more likely than not that the drug caused the particular injury at issue.

#### A. FDA Does Not Have Preemptive Authority

Congress has not granted FDA the authority to preempt state tort law with respect to prescription medication. In fact, once a drug has been approved, there are no provisions in the FDCA which grant the FDA authority to require drug manufacturers to change their drug's labeling. The March 1, 2005 congressional testimony of FDA's deputy director for the Office of New Drugs, Dr. Sandra Kweder confirms this point. Dr. Kweder testified under oath at a hearing before the Senate Committee on Health, Education, Labor and Pensions regarding improving drug safety in the wake of the Vioxx debacle.<sup>7</sup>

The Committee was seeking information regarding what legislative changes may be necessary to strengthen the FDA's ability to protect the public against dangerous drugs.<sup>8</sup> When asked about the FDA's authority to require a drug company to change its label, Dr. Kweder testified that the FDA does not have the authority to tell a company this is how your label has to look. This is the language that needs to go in your label, here's where it goes, end of story. We have to negotiate with the company the specific language of how things should be worded, placement, those kinds of things . . .<sup>9</sup>

Sen. Patty Murray (D-Wash.) asked Dr. Kweder whether the FDA had the authority to change a drug's label. Dr. Kweder testified that the FDA does not have the authority to require a specific label change. Dr. Kweder further testified that stronger ability to require changes in labeling would be very helpful. <sup>10</sup>

This testimony confirms that the FDA could not preempt stronger state laws regarding prescription drug warnings, even if it wanted to. In effect, what Dr. Kweder is admitting is that once a drug is approved for sale in the United States, the FDA has no direct power to require the manufacturer to change its label to add additional or stronger warnings. Indeed, there is no provision of the FDCA which grants the FDA plenary authority over drug labeling. Instead, the FDCA simply sets up a system whereby manufacturers must apply for approval of their drug, including the drug's label, prior to marketing the drug.

Neither 21 U.S.C. [352 nor 355 gives the FDA the authority that it is attempting to confer upon itself.<sup>11</sup> 21 U.S.C. [352 prohibits drug manufacturers from distributing drugs with labels which are false or misleading in any particular. However, this authority only allows the FDA to initiate an action against a manufacturer for misbranding its drug and, in that instance, it is the court that decides the case, not FDA. That is precisely what plaintiffs do when they sue a company for drug-induced injuries or death.<sup>12</sup> Just as a plaintiff has no authority to require a manufacturer to change its label by way of a lawsuit, so, too, the FDA does not acquire authority to require manufacturers to change their label simply by having the power to initiate an enforcement action.

21 U.S.C. [355 gives the FDA the authority to approve a new drug application or an abbreviated new drug application. Subsection (e) of [355 allows the FDA to withdraw its previously approved application for the drug if the FDA learns the drug is unsafe for use. Dr. Kweder confirmed that, although convoluted, the FDA does have this authority. Thus, as the FDA itself recognizes, there is a clear distinction between the authority to withdraw a drug from the market and the authority to require a manufacturer to change its label. Indeed, it makes common sense that there will be instances where the FDA would like to strengthen a drug's label but does not want to remove it from the market.

Accordingly, there is no statute that grants the FDA the authority to require manufacturers to change a drug's label. The FDA admits that it does not have this authority. Without the authority to require manufacturers to make a label change, how could anything the FDA did regarding a prescription drug have the effect of preempting stronger state laws? It cannot. FDA's regulations and the FDCA set forth minimum standards to which manufacturers must adhere.

As the U.S. Supreme Court held in *Louisiana Public Service Commission v. Federal Communications Commission*, 476 U.S. 355, 374-75 (1986), a n agency literally has no power to act, let alone preempt the validly enacted legislation of a sovereign state, unless and until Congress confers power on it . . . an agency may not confer power upon itself. To permit an agency to expand its powers in the face of Congressional limitations on its jurisdiction would be to grant to the agency power to override Congress. (Emphasis added.)

### III. FDA's Regulations And Actions Demonstrate That It Employs A Minimum Standards Approach

The FDA's attempt, through the Final Rule's preamble, to reject the minimum standards approach (which simply means state law can require stronger warnings) is wholly unsupported. Recognition of this longstanding policy has been a fundamental basis on which courts have rejected the FDA's previous attempts to argue preemption through amicus briefs. The FDA is well aware of this and, accordingly, included language in the preamble asserting that FDA's standard is no longer a minimum standard, but rather establishes both the floor and ceiling. This position lacks any authority and in fact conflicts with FDA's purpose.

Congress primary goal in enacting the FDCA was to protect consumers from dangerous products. *United States v. Sullivan*, 332 U.S. 689, 696 (1948). At the time the FDCA was enacted, Congress stated intent was that the FDCA must not weaken the existing laws, but on the contrary it must strengthen and extend that law's protection of the consumer. *Dotterweich*, supra, 320 U.S. at 282. Consistent with this intent, the FDA has traditionally enacted regulations which reflect a minimum standards approach to prescription drugs; in other words, the FDA sets the floor for labeling with which manufacturers must comply, however, states are free to impose stronger standards for the protection of consumers. See *Hill v. Searle Laboratories, Inc.*, 884 F.2d 1064, 1068 (8th Cir. 1989).

Since 1965, the FDA's regulations have permitted a manufacturer to add or strengthen a contraindication, warning, precaution, or adverse reaction, without prior approval by the FDA. 21 C.F.R. [314.70(c)(6)(iii)(A); *In re Tetracycline Case*, 747 F. Supp. 543, 549-50 (W.D. Mo. 1989).<sup>13</sup> Thus, FDA's position regarding stronger warnings by drug manufacturers, as expressed through its own regulations, is that a manufacturer could, and should, provide stronger warnings as soon as such a warning is warranted. Clearly, FDA's regulations in this area, virtually unchanged for 40 years, demonstrate that the agency takes a minimum standards approach to prescription drugs.

A Jan. 12, 2006, editorial published in the *New England Journal of Medicine*, by Wayne A. Ray and C. Michael Stein, explains why FDA standards must be viewed as minimum standards and why drug approval should not preempt state tort lawsuits:

The current regulatory process does not have systematic provisions for obtaining important data needed to guide clinical practice. Planned data collection occurs almost exclusively during premarketing testing. The FDA approves medications on the basis of studies of limited duration that include relatively small numbers of patients who are often healthier than the target population for the new drug. Although many important effects of a new medication almost certainly will be unknown at the time of licensing, there are no systematic provisions for post-marketing studies. Thus, there often is insufficient information on several topics: the safety of widely used drugs, the effects of long-term

exposure, the frequency of rare adverse effects, the effects in special populations or for indications not studied before marketing, the efficacy of a new drug with respect to clinical (as opposed to surrogate) end points, and the efficacy of the new drug relative to others for the same indication.

The present system of drug regulation is susceptible to the influence of conflicts of interest . . . , may promote hasty approvals, divert resources from post-marketing surveillance, and foster the perception that the pharmaceutical industry is the FDA's customer. Conflicts of interest created by the obvious economic motivations of the manufacturer and the FDA's potential reluctance to reverse a previous drug-approval decision may impede the response to signs of potential adverse drug effects, such as those indicated by the results of the Vioxx Gastrointestinal Outcomes Research (VIGOR) trial of rofecoxib. There is evidence of bias in the design and conduct of post-marketing studies funded by the pharmaceutical industry, as well as evidence of selective reporting and selective publication of data.

After drug approval, the FDA's statutory authority is limited to requesting changes to the label, negotiating restrictions to distribution with the manufacturer, or petitioning for the withdrawal of the drug. There is no defined process for answering the many questions that cannot be addressed in premarketing studies. . . . Medications approved on the basis of studies of a few thousand patients are rapidly marketed to millions of patients, setting the state for drug disasters. 14

Over the years, and very recently, the FDA has taken a number of actions which affirmatively demonstrate that it views its regulations as being minimum standards. Essentially, the FDA allows a drug to come to the market based on a minimum showing of safety and efficacy.<sup>15</sup> The FDA's approval and post-marketing review process is something of a one-way ratchet, allowing drugs to come to market without all the safety data about those drugs and slowly adding additional or stronger warnings in the future as it deems them necessary. The following examples illustrate the FDA's approach in this area.

#### A. SSRI Antidepressants

Currently, the FDA has approved a number of selective serotonin reuptake inhibitor (SSRI) antidepressants for use with adults, and certain ones for particular indications in pediatric patients. There have been numerous reports in the medical literature over 15 years regarding a potential increased risk of suicide associated with the use of many of these antidepressants. This risk was recently confirmed in a Canadian study which compared the use of SSRIs with placebo in over 700 clinical trials.<sup>16</sup> However, instead of withdrawing its approval of these drugs, requiring immediate studies of this potentially deadly risk or demanding that the label be changed, the FDA took no regulatory action, until recently. In fact, it was not until late 2003, after British regulators raised the red flag on the issue in relation to children and adolescents that the FDA finally began to formally look into this association and examine the situation further.<sup>17</sup> Once the FDA decided to reevaluate the data regarding children and adolescents, it determined that a black box warning regarding the risk of suicidality was appropriate.<sup>18</sup> A black box warning is the strongest warning provided for by FDA's regulations. 21 C.F.R. [201.57(e)]. This demonstrates that the approach taken by the FDA regarding the issue of suicidality and SSRIs is a minimum standards approach: FDA opted to wait for additional or conclusive data before requiring manufacturers to provide doctors and patients with suicidality warnings.

#### B. Vioxx

In October 2004, Merck & Co. Inc., the manufacturer of Vioxx, withdrew the arthritis drug from the market following an analysis conducted by FDA scientist Dr. David Graham in which he discovered a significant increased risk of heart attacks in those taking Vioxx. Numerous reports, both within and outside of the FDA, suggested that the FDA wanted to suppress this report and delay its release. When the report did become public, the FDA took no regulatory action in response. Instead, the manufacturer itself decided to pull the drug off of the market. When the FDA recently convened a panel of scientists to determine whether Vioxx should remain on the market, the panel voted to continue FDA's approval of the drug, notwithstanding the fact that the manufacturer, itself, no longer sells this drug. This example clearly shows that, even in the face of concrete evidence regarding a serious safety hazard associated with a widely used drug, the FDA waits before taking action regarding a drug's risks.

Clearly, this demonstrates a minimum standards approach to regulation.

#### C. Civil Actions Complement FDA's Purpose

It makes sense that not all safety risks associated with a new drug will be known at the time of approval. Broader use in the market and further research provide additional information about a drug's efficacy and safety. On this front, FDA regulations allow for additional indications for a drug's use as well as stronger or additional warnings when

deemed appropriate. By contrast, what if a drug manufacturer is aware of or should have known of a safety risk before it was revealed through post-marketing surveillance and/or further research in the field? And what if that drug manufacturer failed to disclose this potential risk to physicians and patients, or indeed actually took measures to hide or cover up this risk. Discovery of this kind of negligent and/or wrongful conduct can only be obtained through private civil lawsuits. Our judicial system provides the procedures for discovery, the standard of proof, and compensation to victims of negligent or wrongful conduct. The language in the preamble is an attempt by appointed federal regulators to entirely trump the judicial process.

#### IV. Courts Have Consistently Held That The FDA's Regulations Regarding Prescription Drugs Set Forth Minimum Standards

Courts have held that the FDCA and its associated regulations are minimum standards of conduct to which manufacturers must adhere.<sup>19</sup> Minimum safety standards should not preempt a state tort action . . . .<sup>20</sup> In fact, the FDA has set up a framework for regulation which confirms this minimum standards approach for prescription drug labeling. 21 C.F.R. [201.57(e) requires a manufacturer to provide warnings in a drug's label as soon as there is reasonable evidence of an association of a serious hazard with a drug . . . .<sup>21</sup> That regulation also sets the bar for a warning inclusion fairly low by stating that the warning must be added even if a causal relationship between the serious hazard and the drug has not been proved.<sup>22</sup> And manufacturers do not need to wait for FDA approval to make these changes to their drugs labels. FDA regulation 21 C.F.R. [314.70(c)(6)(iii)(A) explicitly allows a manufacturer to add or strengthen a contraindication, warning, precaution, or adverse reaction in a drug's label without prior FDA approval.<sup>23</sup> One commentator has described this section as a safety valve, or a device that lessens the risk of a conflict or an obstacle in a situation that could otherwise cause harm.<sup>24</sup> Many courts have recognized that these two regulations read together defeat any claim that it would be impossible to comply with both state law and federal law regarding drug labeling.<sup>25</sup>

A drug label is always subject to change and rarely current. As the court in *Globetti v. Sandoz Pharm. Corp.*, 2001 U.S. Dist. LEXIS 2391, (N.D. Ala. 2001), stated:

To argue that, once the FDA approves a drug's label, the defendant has no further duty to give adequate warning creates an incentive for pharmaceutical companies to oppose all efforts by the FDA to secure clearer drug labels. If that were the case, drug manufacturers could avoid liability simply by resting on the formerly approved label (regardless of how long ago the approval occurred and how much information about the drug had changed) and resist all efforts to change it. The FDA approval of the label becomes a complete bar to liability, regardless of how inadequate it may have become over time.

#### V. History Of Preemption For Prescription Drugs

In 1962, Congress enacted one of the most sweeping changes to the FDCA in the history of the Act.<sup>26</sup> At that time, Congress included within this new legislation a specific statement regarding the FDCA's Effect on State Laws :

Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.<sup>27</sup>

Although it is difficult to find congressional intent from an absence of legislation or congressional history, it is striking that Congress has never seen fit, in over 43 years, to enact an express preemption clause for prescription drugs.<sup>28</sup>

Congress 1962 statement that only direct and positive conflicts should override state law is consistent with the historical presumption against preemption in matters dealing with public health.<sup>29</sup> The Supreme Court in 1985 held that where . . . the field that Congress is said to have preempted has been traditionally occupied by the States we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.<sup>30</sup> The regulation of prescription drugs is a matter of public health that has been traditionally occupied by the States.<sup>31</sup>

Clearly, it was Congress intent that the FDCA only preempt state law actions where there is a direct and positive conflict with state law. The FDA, in the preamble to its Final Rule, asserts that such a conflict exists whenever the FDA has approved a drug's label and a plaintiff challenges the sufficiency of that label. However, this claim does not stand up to scrutiny.

The FDA has identified no direct and positive conflict. Conflict preemption applies in one of two instances: 1) Where it is impossible for a private party to comply with both state and federal law, and 2) Where the state law stands as

an obstacle to the accomplishment and execution of the full purposes and objective of Congress. *Crosby v. Nat'l Foreign Trade Counsel*, 530 U.S. 363, 372-73 (2000) (citing *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) and *Hines v. Davidowitz*, 312 U.S. 52, 66-67 (1941)). Hypothetical conflicts or the possibility of future conflicts between federal and state law cannot qualify as actual conflicts for the purposes of the conflict preemption doctrine. See, e.g., *Favel v. American Renovation and Const. Co.*, 2002 MT 266, 312 Mont. 285, 59 P.3d 412, 425 (Mont. 2002), *Solorzano v. Superior Court*, 10 Cal.App.4th 1135, 13 Cal.Rptr.2d 161 (Cal.Ct.App.,1992) ( Mere speculation about hypothetical conflict between federal and state law is not enough to establish federal preemption. ); *Seigel v. American Sav. & Loan Assn.*, 210 Cal.App.3d 953, 258 Cal.Rptr. 746, 752 (Cal.App. 1989) ( In determining whether a state law conflicts with federal statutes or regulations, the federal-state conflict must be actual and unavoidable, not merely possible. ). According to the Supreme Court, a court should not find pre-emption too readily in the absence of clear evidence of a conflict. *Witczak v. Pfizer, Inc.*, 377 F.Supp.2d 726, 728 (D. Minn. 2005) (quoting *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 885 (2000)). Rather, a court should presume that the historic police powers of the States were not to be superceded by the Federal Act unless that was the clear and manifest purpose of Congress. *Witczak*, supra, 377 F.Supp.2d at 728-29 (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)).

Adopting FDA's theory of conflict preemption would, in one fell swoop give the FDA's informal actions the force and effect of law; allow the FDA to avoid the notice and comment provisions of the APA; immunize the FDA's actions from judicial review; and allow drug companies to obtain complete tort immunity for their drugs simply by exerting their influence on FDA officials. Long enduring principles of constitutional and administrative law have, for good reason, survived to prevent such encroachments upon our system of checks and balances. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 123 S.Ct. 518, 527,(2002). See also *INS v. Cardoza-Fonseca*, 480 U.S. 421, 447-48, 107 S.Ct. 1207, 1221, (1987) (quoting *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n. 9 (1984) for its holding that: The judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent. ) (emphasis added).

The FDA's historic position on this is backed up by sound policy. As the court in *Mazur v. Merck & Co., Inc.*, 742 F.Supp. 239 (E.D. Penn. 1990), pointed out:

Federal regulation serves a very different purpose than state tort law. Essentially, federal regulation serves deterrent purpose by limiting the manufacture of inherently dangerous products to those applicants who meet certain stringent safety standards, while state tort law serves the equally important purpose of compensating individuals injured by those very same products. Since compliance with FDA regulations will not ensure that a manufacturer's products will not cause injury, compliance will not necessarily exempt a manufacturer from liability. When those products do cause injuries, the state tort system provides a means of compensation. State tort law is intended to supplement federal regulation by providing a vehicle for compensation of vaccine-related injuries . . . .

I accept, for the sake of argument, Merck's contention that the purpose behind FDA regulation of vaccine labeling is uniformity. But if a state jury determines that Merck should have disclosed more information regarding the causal link between SSPE and MMR II, if in fact there is one, see *infra* at 263, Merck can petition the FDA to allow it to change its package insert. 21 C.F.R. [601.12. Thus, Merck could meet both federal and state law requirements. Moreover, it makes sense from a policy standpoint to permit civil judgments to supplement federal regulations.

*Id.* at 247-48.

Accepting the FDA's arguments would effectively give the FDA the ipse dixit authority to shield the subject matter of its regulatory actions, or lack thereof, from any form of judicial scrutiny. Our constitutional system of checks and balances does not permit the FDA to grant drug companies immunity from civil or criminal liability; nor does it permit the FDA to keep from state citizens the very information necessary to protect their own health and safety. See *Grundberg v. Upjohn Co.*, 813 P.2d 89, 100-04 (Utah 1991) (Howe, J. dissenting) ( Numerous congressional investigations have demonstrated that the FDA has often approved drugs in complete ignorance of critical information relating to the hazards of such drugs which was contained either in its own files or in the published medical literature, or both. Emphasis added.)

Courts have long recognized that there are policy problems with the argument that state tort lawsuits involving prescription drug labeling are preempted. First and foremost, given the presumption against preemption, courts recognize that the FDA is a consumer-protection agency.<sup>32</sup> As one court articulated, the FDA's argument that state tort lawsuits involving prescription drug labeling are preempted vitiates, rather than advances, the FDA's purpose of protecting the public. The argument would require a court to find that in enacting the FDCA for the purposes of

protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state claims. This position contravenes common sense . . . . 33

FDA admittedly does not have the resources or manpower to achieve a perfect record, nor does it provide remedies to the victims when it fails; state product liability laws provide remedies and an invaluable safeguard.

#### VI. FDA's Actual Long-Standing Views Regarding Preemption For Prescription Drugs

In the preamble to these new regulations, the FDA asserts that its pro-preemption argument represents the government's long standing views on preemption. 34 In actual fact, however, the government's involvement in private state tort lawsuits involving prescription drugs is relatively new as is the FDA's asserted basis for preemption. Prior to the government's 2002 amicus brief in the *Motus v. Pfizer, Inc.* case,<sup>35</sup> the government rarely, if ever, intervened in FDA state-tort lawsuits on behalf of either manufacturers or consumers.<sup>36</sup> Tracking the path the FDA took to its current preemption stance reveals that, in fact, FDA's position is motivated less by concern for protection of consumers and more by the current administration's bent towards tort reform.

Various FDA commissioners through the years have recognized that the FDCA and its associated regulations do not preempt state tort lawsuits in prescription drug cases. In 1978, the commissioner recognized that the boundaries of civil tort liability for failure to warn are controlled by applicable state law. 37 The next year, in discussing the effects of what is now 21 C.F.R. [314.70(c)(6)(iii)(A)], the commissioner noted that manufacturers, not simply the FDA, have the power to warn consumers of problems with drugs without FDA approval.<sup>38</sup>

In 1994, the FDA sought to enact a regulation which would have the effect of preempting state and local laws regarding the disclosure of the identity of patients and reporters in adverse event reports which were submitted to the FDA.<sup>39</sup> Although the agency was enacting a regulation which could have had the effect of limiting information private litigants could receive in products liability suits against manufacturers, the agency was careful to limit the scope of its action so as not to affect products liability suits generally.<sup>40</sup> A deputy FDA commissioner stated:

FDA recognizes the sophistication and complexity of private tort litigation in the United States and the proposed preemption action is not intended to frustrate or impede tort litigation in this area. Indeed, FDA recognizes that product liability plays an important role in consumer protection.<sup>41</sup>

Two years later, the Justice Department submitted an amicus brief to the U.S. Supreme Court in support of the plaintiff and against the manufacturer's preemption claim in *Medtronic v. Lohr*, 518 U.S. 470 (1996).<sup>42</sup> That case involved the express preemption provisions of the Medical Device Amendments to the FDCA. In declaring the government's statement of interest, the brief stated that the FDA's administration of the FDCA is affected by the extent to which state-law remedies for defective medical devices are available. 43 In discussing the role of the jury to the device's label, the government stated that:

The federal labeling provisions do not, standing alone, preempt failure-to-warn claims. The success of those claims depends on a jury determination, under instructions consistent with the federal labeling requirements, that the labeling of the defendant's device was inadequate . . . . It is possible that the FDA, applying the federal labeling provisions, could likewise determine that the labeling of the defendant's device was inadequate.<sup>44</sup>

FDA's last official preemption statement regarding prescription drugs, prior to 2001, was in 1998 regarding the FDA's decision to implement new regulations regarding medication guides that were to be given to consumers at the point of sale.<sup>45</sup> In its Final Rule publication, the agency responded to comments by manufacturers that the new medication guides would adversely affect the legal liability of manufacturers . . . . 46 The manufacturers suggested that FDA provide for federal preemption of State regulation with respect to civil tort liability claims and other labeling requirements. 47 The agency's response was clear and unequivocal.

FDA began by stating that tort liability can not be a major consideration for FDA which must be guided by the basic principles and requirements of the act in its regulatory activities. 48 The agency noted that Federal preemption could unduly interfere with the goals and objectives of existing State programs . . . . 49 And the agency recognized that state tort law is not at odds with the objectives of the FDA:

FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations. FDA's regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements. States may authorize additional labeling but they cannot reduce, alter, or eliminate FDA-required labeling.<sup>50</sup>

For years the FDA, through its own statements, believed that state tort law and its regulations regarding prescription drugs could, and should, coexist. Thus, the FDA's new preemption arguments do not represent the government's long standing views on preemption, but rather have been created out of whole cloth to aid manufacturers who are subjected to tort liability for failing to adequately disclose the known or reasonably knowable risks associated with their drugs.

## VII. FDA's Incursion Into Private Tort Lawsuits

Until his resignation in late 2004, FDA Chief Counsel, Daniel Troy was the pharmaceutical industry's inside man, filing legal briefs on behalf of former clients such as Pfizer Inc. (the maker of Zoloft) and soliciting defense attorneys to submit their cases for government amicus brief consideration.<sup>51</sup> Although the newly appointed Chief Counsel, Sheldon Bradshaw, lacks the blatant pharmaceutical industry ties that Troy had, he was not selected to his position because of a sudden change-of-heart in the political leadership or direction of the FDA. In fact, following in his predecessor's footsteps, Bradshaw submitted a legal brief in support of Pfizer's federal preemption arguments in the case *Kallas v. Pfizer*, Case No. 04-CV-0998 PGC, (D. Utah, 2005), discussed more fully below.<sup>52</sup>

### A. FDA's Amicus Brief In *Motus v. Pfizer*

The FDA filed its first brief in favor of a manufacturer of antidepressants in September 2002 in a California case pending in the Ninth Circuit U.S. Court of Appeals. *Motus v. Pfizer* Nos. 02-55372 & 02-55498 (9th Cir.) Daniel Troy, who was FDA's Chief Counsel at the time, was contacted by Pfizer's litigation defense counsel in the summer of 2002 requesting that the government get involved in this private lawsuit to help Pfizer with its preemption argument related to Zoloft-induced suicidality.<sup>53</sup> Troy argued in the brief that, even though Pfizer never sought to strengthen Zoloft's warning label concerning suicidality, any warning, no matter how worded, suggesting a link between Zoloft and suicidality would have been false and misleading, would have misbranded the drug, and the FDA would have rejected any effort by Pfizer to use such a warning.<sup>54</sup> The Ninth Circuit never decided the preemption issue, instead ruling on another appellate issue, concluding the case on unrelated grounds.<sup>55</sup>

In the *Motus* amicus brief, the government made many of the same assertions contained in the preamble to these new regulations. Specifically, the brief stated that Pfizer would have been liable for publishing a label that was false and misleading if it had issued the warning advocated by the plaintiff in that case.<sup>56</sup> The FDA's support for this assertion was the fact that the FDA, prior to the plaintiff's decedent's death, had approved Zoloft's label as safe and effective without a suicidality warning.<sup>57</sup> Although not fully developed until its later brief, the government's argument depended on the implication that unless and until the FDA believes there is scientific evidence sufficient to support a warning, any such inclusion by the manufacturer would render the drug misbranded. The government rejected the notion that prescription drug regulations are minimum standards and, instead, asserted that the presumption against preemption does not apply to the FDA.<sup>58</sup>

Judges across the nation have been rejecting the preemption argument, as well as the FDA briefs themselves. One state court judge in California ordered the FDA's brief in *Motus* stricken from the record, calling it hearsay and irrelevant. <sup>59</sup> In another case in Illinois, the judge pointed out that the brief contains nothing more than legal argument by FDA counsel. <sup>60</sup> In a Minnesota case, the judge rejected Pfizer's arguments, stating that it declines to treat statements from a single FDA legal brief as declarations afforded the preemptive force of law. <sup>61</sup> The judge also called Pfizer's arguments perverse and a public policy argument gone awry. *Id.* A federal judge in Texas pointed out that the law allows, even encourages, manufacturers to be proactive when learning of new safety information related to their drug. <sup>62</sup> Manufacturers, not the FDA, are tasked with the responsibility of taking proactive steps once a manufacturer learns of reasonable evidence of an association of a serious hazard with a drug, the court stated.

### B. FDA's Amicus Brief In *Kallas v. Pfizer*

The FDA submitted its latest brief in *Kallas v. Pfizer* at the request of U.S. District Court Judge Paul G. Cassell. The case involved a 15-year-old Utah girl, Shyra Kallas, who committed suicide while taking Zoloft. According to the brief, it is for FDA alone to judge whether there is reasonable evidence of an association between a particular risk and a drug that triggers a drug manufacturer's duty to warn under the law. Contrary to FDA's misstatement of the law, it is the drug manufacturer's judgment that triggers both the duty to warn and the duty to bring the information to the FDA's attention. As discussed above, if it was actually the law that a drug manufacturer's duty is not triggered before the FDA sees the risk, then all drug companies could escape liability by doing less or nothing, counting on the FDA to miss the signals. Clearly, this is not the message the FDA should be sending to drug companies.

In essence, the government's position in *Kallas* was that because the FDA did not recognize an increased risk of suicidality at the time of Shyra Kallas' death in November 2002 (while acknowledging that the risk was found shortly thereafter in studies it had in its hands at the time of Ms. Kallas' death), her parent's lawsuit against Pfizer should be dismissed without any determination on the merits of the case. In other words, because Shyra Kallas died before the FDA got around to analyzing the data, which ultimately resulted in black box warnings, a lawsuit to determine whether Pfizer is liable for her death cannot be brought.

The FDA's preemption position is particularly egregious in the wake of recent FDA failures to protect the public health (in particular related to antidepressants)<sup>63</sup> and later *Vioxx*. Indeed, editors of prestigious medical journals have recognized that the story of research into SSRI antidepressant use in childhood depression is one of confusion, manipulation, and institutional failure and these failings are a disaster. The editors urged that changes are required at every level of the global health-care infrastructure.<sup>64</sup> The brief also stands in contrast to statements by FDA whistleblowers, one of whom has warned that the FDA, as currently configured is broken and incapable of protecting Americans from dangerous drugs.<sup>65</sup>

One of the most dramatic and articulate criticisms of FDA's ability to protect the consuming public came from FDA scientist, Dr. David Graham who testified during Congressional hearings that, not only is the FDA broken, but Americans are virtually defenseless as a result of FDA's current operating scheme. His testimony illustrates why FDA approval and subsequent post-marketing acquiescence should have no preemptive effect. For instance, he testified that, when a serious safety issue arises post-marketing, CDER's immediate reaction is almost always one of denial, rejection and heat . . . . There is an inherent conflict of interest.<sup>66</sup>

Dr. Graham testified that the Center for Drug Evaluation and Research culture views the pharmaceutical industry it is supposed to regulate as its client, over-values the benefits of the drugs it approves and seriously under-values, disregards and disrespects drug safety. Dr. Graham highlighted the problems with the FDA's reliance on a 95% paradigm. In other words, according to Dr. Graham, a drug is considered safe until you can show with 95% or greater certainty that it is not safe. He explained: It's the equivalent of beyond a shadow of a doubt . . . . In order to demonstrate a safety problem with 95% certainty, extremely large studies are often needed. And guess what. Those large studies can't be done. Dr. Graham used two analogies to prove his point. He stated that, if a weather man reports that there is an 80% likelihood of rain, most people would bring an umbrella. His second analogy: Imagine for a moment that you have a pistol with a barrel having 100 chambers. Now, randomly place 95 bullets into those chambers. The gun represents a drug and the bullets represent a serious safety problem. Using CDER's standard, only when you have 95 bullets or more in the gun will you agree that the gun is loaded and a safety problem exists. Let's remove 5 bullets at random. We now have 90 bullets distributed across 100 chambers. Because there is only a 90% chance that a bullet will fire when I pull the trigger, CDER would conclude that the gun is not loaded and that the drug is safe.<sup>67</sup>

## VIII. Conclusion

State tort law encourages manufacturers to be proactive about risks associated with their drugs and to act quickly when safety risks emerge, not wait for FDA to take action. Preemption would close off one of the few avenues by which we learn of safety and efficacy information that pharmaceutical companies do not publish and sometimes even hide from the FDA. Civil lawsuits uncover internal company documents to which not even FDA is privy. The tort system provides an important check on the conduct of the drug industry. Moreover, the FDA's argument, if successful, would take away the sole means by which consumers obtain compensation for drug-induced injuries. Shielding manufacturers from liability for the harm their products cause while treating the FDA as infallible is a far greater threat to the public health than product liability litigation.

## Endnotes

1. See Dept. of Health and Human Serv., Docket No. 2000N-1269, Requirement of Content and Format of Labeling for Human Prescription Drug and Biological Products, p. 38 (Jan. 18, 2006) (hereinafter Preemption Preamble).

2. *Ibid.*

3. *Id.* at 43.

4. *Id.* at 41-42.

5. Preemption Preamble, *supra*, n.1 at 42.

6. 21 C.F.R. 201.57(e).
7. In October 2004, Merck, the manufacturer of Vioxx, withdrew Vioxx from the market following an analysis conducted by FDA scientist Dr. David Graham in which he discovered a significant increased risk of heart attacks in those taking Vioxx.
8. Committee on Health, Education, Labor, and Pensions, FDA's Drug Approval Process: Up to The Challenge? March 1, 2005.
9. *Id.* at 23.
10. *Id.* at 24.
11. SSRI manufacturers took advantage of this lack of authority when they successfully negotiated with the FDA to remove language from the new black-box warnings required for antidepressants. The FDA-proposed language included the statement that causality has been established between the risk of suicidality and SSRIs, but this language was removed from the final version. Indeed, the FDA's panel of scientists voted overwhelmingly in September 2004 that the drugs caused an increased risk of suicidality in children and adolescents.
12. Of course, a plaintiff cannot bring an action under 21 U.S.C. [352, however, a state-law cause of action is, essentially, that the manufacturer failed to include within the drug's label necessary information.
13. The government's statements in the *Motus Amicus* brief regarding section 314.70 and misbranding are absurd and hypothetical. The government attempts to assert that it would be misbranding if a manufacturer over-warned regarding a risk associated with its drug. However, the statute to which the government cites in support of its argument only requires adequate warnings to avoid a charge of misbranding. 21 U.S.C. 352(f). By only requiring that warnings be adequate, Congress clearly contemplated liability for misbranding only when a manufacturer provided inadequate warnings.
14. Ray and Stein, Reform of Drug Regulation Beyond an Independent Drug-Safety Board, *N Engl J. Med.* 354:2, January 12, 2006.
15. See *Consumer Magazine*, Why Drugs Get Pulled Off The Market (January-February 2002), [http://www.fda.gov/fdac/features/2002/102\\_drug.html](http://www.fda.gov/fdac/features/2002/102_drug.html); Robert Temple, Commentary on The Architecture of Government Regulation of Medical Products 82 *Va. L. Rev.* 1877, 1885-1887 (Nov. 1996) ( It is . . . relatively unusual for drugs to be rejected on safety grounds. *Id.* at 1885); Clinical Therapeutics and the Recognition of Drug-Induced Disease, stating, Clinical trials are effective tools primarily designed for assessing efficacy and risk-benefit ratio, but in most cases they are neither large enough nor long enough to provide all information of a drug's safety. ).
16. Fergusson et al., Association between suicide attempts and selective serotoninreuptake inhibitors; systematic review of randomised controlled trials, *British Medical Journal*, (19 February 2005), Volume 330.
17. Urgent Message from Professor G. Duff, Chairman of the Committee on Safety of Medicines: Selective Serotonin Reuptake Inhibitors Use in Children and Adolescents with Major Depressive Disorder, December 10, 2003, [http://medicines.mhra.gov.uk/ourwork/monitorsafeequalmed/safetymessages/cemssri\\_101203.pdf](http://medicines.mhra.gov.uk/ourwork/monitorsafeequalmed/safetymessages/cemssri_101203.pdf).
18. FDA, CDER, Summary Minutes of the CDER Psychopharmacologic Drugs Advisory Committee and the FDA Pediatric Advisory Committee, September 13-14, 2004, [http://www.fda.gov/ohrms/dockets/ac/04/minutes/2004\\_4065M1\\_Final.htm](http://www.fda.gov/ohrms/dockets/ac/04/minutes/2004_4065M1_Final.htm).
19. See *Hill v. Searle Laboratories, Inc.*, 884 F.2d 1064, 1068 (8th Cir. 1989) ( FDA regulations are generally minimum standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area. ); *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F.Supp.2d 1018, 1033 (S.D. Ill. 2001); *Cartwright v. Pfizer, Inc.*, 369 F.Supp.2d 876, 882 (E.D. Tex. 2005). But see *Dusek v. Pfizer, Inc.*, Case No. A. H 02 3559, 2004 U.S. Dist. LEXIS 28056 (S.D.Tex. 2004) (rejecting argument that FDA's regulations are minimum standards) and *Needleman v. Pfizer, Inc.*, Case No. A. 3:03 CV 3074 N, 2004 U.S. Dist. LEXIS 15495 (N.D. Tex. 2004).
20. *Norfolk Southern Railway Co. v. Shanklin*, 529 U.S. 344, 359 (2000) (J. Breyer, concurring).
21. 21 C.F.R. [201.57(e) (2005).
22. *Ibid.*
23. 21 C.F.R. [314.70(c)(6)(iii)(A) (2005).

24. See O Reilly, James T., *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warnings?*, 58 *Food & Drug L.J.* 287, 290, 293 (2003). Prof. O Reilly states that in 1995, a bill was introduced in the House of Representatives that would have preempted laws on prescription drug labels but it was never passed. See H.R. 2071, 104th Cong., 1st Sess. (1995).

25. See *Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908, 912-913 (5th Cir. 1987); *Witczak*, 377 F.Supp.2d, 726, 729 (D. Minn. 2005); *Cartwright*, supra, 369 F.Supp.2d at 882-83; *Zikis v. Pfizer, Inc.*, 2005 U.S. Dist. LEXIS 9591 (N.D. Ill. 2005); *Caraker*, supra, 172 F. Supp. 2d at 1033-34; *In re Tetracycline Cases*, 747 F. Supp. 543, 549-50 (W.D. Mo. 1989).

26. Drug Amendments of 1962, S. 1552, 87th Cong. (1962) (Public Law 87-781, Oct. 10, 1962); see also Merrill, Richard A., *The Architecture of Government Regulation of Medical Products*, 82 *Va. L. Rev.* 1753, 1764 (Nov. 1996). Mr. Merrill states that the 1962 amendments launched the modern U.S. drug regulatory system.

27. *Id.* at [202 (emphasis added)].

28. See *Witczak v. Pfizer, Inc.*, 377 F.Supp.2d 726, 732 (D. Minn. 2005) ( If Congress intends to create a class of protected businesses, it has the means and ability to do so. ); *Cartwright v. Pfizer, Inc.*, 369 F.Supp.2d 876, 884-85 (E.D. Tex. 2005) (noting that the absence of a preemption provision for prescription drugs signals an intent by Congress not to preempt prescription drug cases).

29. See *Hillsborough County v. Automated Med. Labs.*, 471 U.S. 707, 715 (1985). See also *Witczak*, supra, 377 F.Supp.2d at 729.

30. *Hillsborough*, supra, 471 U.S. at 715.

31. See O Reilly, supra, n. 24, at 291 ( FDA came late to the regulation of this field, and was catching up with existing regulatory activities of state pharmacy boards. )

32. *Witczak*, supra, 377 F.Supp.2d at 731 ( Congress certainly did not intend to bar drug companies from protecting the public when enacting the FDCA; its goal was to protect the public. )

33. *In re Paxil Lit.*, 2002 U.S. Dist. LEXIS 24621 (C.D. Cal. 2002).

34. See Dept. of Health and Human Serv., Docket No. 2000N-1269, *Requirement of Content and Format of Labeling for Human Prescription Drug and Biological Products*, at 38 (Jan. 18, 2006) (hereinafter *Preemption Preamble*).

35. The Justice Department first submitted a brief in support of Pfizer's preemption argument in the Ninth Circuit in a case entitled *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004). The Ninth Circuit never reached the preemption question and, instead, affirmed the district court's order on different grounds. The government's brief from the *Motus* case is available at 2002 WL 32303084. Just recently, the government submitted a similar brief in support of Pfizer's preemption argument in the district of Utah in a case entitled *Kallas v. Pfizer, Inc.*, Case No. 2:04 CV 998 PGC (D. Utah) (brief filed September 15, 2005) (no electronic citation available).

36. See O Reilly, supra, n. 24 at 288 ( Until DHHS asserted prescription drug preemption in a brief to the Ninth Circuit in late 2002, FDA had remained aloof from preemption arguments that often had been made by prescription drug manufacturers in defense of individual products liability lawsuits. )

37. See *MacDonald v. Ortho Pharmaceuticals Corp.*, 475 N.E.2d 65, 70 (Mass. 1985) (citing 43 Fed. Reg. 4214 (1978)).

38. 44 Fed. Reg. 37447 (1979). See also *Witczak*, supra, noting that when the original Changes Being Effected regulation was enacted in 1965, the agency noted that the regulation was promulgated precisely to allow drug makers to quickly strengthen label warnings when evidence of new side effects are discovered. 377 F.Supp.2d at 729 (citing 30 Fed. Reg. 993 (1965)). See also 50 Fed. Reg. 7452, 7470 (1985) ( . . . important safety information . . . should be immediately conveyed to the user. )

39. 59 Fed. Reg. 3944 (1994).

40. *Id.* at 3947-48.

41. *Id.* at 3948.

42. 518 U.S. 470 (1996). The government's Amicus Brief is available at 1996 WL 118035 hereinafter Medtronic Amicus Brief.

43. Medtronic Amicus Brief, at \*2.

44. *Id.* at \*28.

45. 63 Fed. Reg. 66378 (1998).

46. *Id.* at 66383.

47. *Ibid.*

48. *Ibid.*

49. *Ibid.*

50. *Ibid.* Additionally, the FDA noted that providing patients with more information about the drugs they are prescribed could reduce potential liability by improving patient compliance and patient monitoring of serious adverse events, thus decreasing drug-induced injuries and hospitalizations. Written information could also represent a clear opportunity for patients to be made aware that certain risks accompany drug therapies, and that not all serious adverse events are caused by deficiencies in the drug product or actions by the health professional. Clearly, the FDA, in 1998, was in favor of providing patients with as much information as possible regarding the risks of drugs with serious and significant concern.

51. Karen Barth Menzies, *The Fox in the Chicken Coop*, ATLA Continuing Education, 2003, [http://baumhedlundlaw.com/AttorneyArticles/kb\\_ssrilitigation/FDA\\_Intervention.pdf](http://baumhedlundlaw.com/AttorneyArticles/kb_ssrilitigation/FDA_Intervention.pdf); See also Michael Kranish, *FDA Counsel's Rise Embodies US Shift*, Boston Globe, December 22, 2002, [http://www.baumhedlundlaw.com/media/ssri/paxil/boston\\_globe\\_fda.htm](http://www.baumhedlundlaw.com/media/ssri/paxil/boston_globe_fda.htm); Stacey Schultz, *Mr. Inside Moves Outside*, US News and World Reports, March 24, 2003, [http://courses.che.umn.edu/02fscn11021s/general\\_food\\_safety/Ephedra/web%20pages/USNew3\\_03DanielTroy.html](http://courses.che.umn.edu/02fscn11021s/general_food_safety/Ephedra/web%20pages/USNew3_03DanielTroy.html); Gary Young, *FDA Strategy Would Preempt Tort Suits*, National Law Journal, March 1, 2004, <http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1076428430132>.

52. Lily Henning, *Is FDA's New Chief Counsel a Change in Name Only? New Counsel Keeps Industry Friendly Policies Put in Place by His Predecessor*, Legal Times, Sept. 20, 2005.

53. Michael Kranish, *FDA Counsel's Rise Embodies US Shift*, Boston Globe, December 22, 2002, [http://www.baumhedlundlaw.com/media/ssri/paxil/boston\\_globe\\_fda.htm](http://www.baumhedlundlaw.com/media/ssri/paxil/boston_globe_fda.htm); Thomas Frank, *Friends on the Inside*, Newsday.com, October 11, 2004. Despite the fact that Pfizer had been one of Troy's clients and his firm was paid over \$350,000 for work he had conducted for Pfizer in the year before he was appointed FDA Chief Counsel, Troy agreed to file an amicus brief on behalf of FDA. He later justified his action by arguing that he did not become involved until after the required 1-year period in which government employees may not participate in official activities involving former clients. New York Congressman, Maurice Hinchey's website: *FDA is Placing Corporations Above Public*: <http://www.house.gov/hinchey/issues/fda.shtml>. From public accounts, it appears that the 1-year grace period elapsed less than a month before Troy agreed to help his former client.

54. *Motus v. Pfizer*, 02-55372, 02-55498, *supra*, n. 35.

55. *Motus v. Pfizer*, 358 F.3d 659, C.A. 9 (Cal.) 2004, Feb. 9, 2004.

56. 2002 WL 32303084 at \*17.

57. *Id.* at \*21 ( Thus, in 1998, when Zolof was prescribed for Victor Motus, any warning, no matter how worded, that could reasonably have been read as describing or alluding to such a relation between Zolof and suicidality would have been false or misleading, and therefore in conflict with federal law because there was no (and still is not) scientific support for such a warning. )

58. *Id.* at \*19, n.9.

59. *Sybinski v. Pfizer*, (Sup. Ct. Cal., LA July 12, 2005) No. YC047439; see also *Pfizer v. Superior Court of Los Angeles County* No. B184888, Slip Op. Nov. 20, 2005.

60. *Zikis v. Pfizer* (N.D. Illinois, Eastern Div. May 9, 2005) No. 4 C 8104, *supra* n. 25; see also *Zikis v. Pfizer* (N.D. Illinois, Eastern Div. November 8, 2005), Slip Op. 2005 U.S. Dist. LEXIS 27253.

## Mealey's Emerging Drugs &amp; Devices February 16, 2006

61. *Witczak v. Pfizer*, supra, (D. Minn. July 20, 2005) No. 04 CV 2819 JMR/FLN; see also *Witczak v. Pfizer Slip Op.*, Sept. 23, 2005.

62. *Cartwright v. Pfizer*, supra (E.D. Texas, Tyler Div. March 31, 2005) No. 6:04cv292; see also *Miles v. Pfizer*, (M.D. Louisiana, March 30, 2005), No. 03-731-C, no memo of opinion available.

63. Press Release, Grassley Questions FDA's Handling of Research on Antidepressants, Suicide and Letter to Secretary of the Dept. Of Health and Human Services, Tommy Thompson, March 25, 2004, <http://finance.senate.gov/press/Gpress/2004/prg032504b.pdf>; Letter to FDA from the Committee on Energy and Commerce seeking information on antidepressants, March 24, 2004, [http://energycommerce.house.gov/108/Letters/03242004\\_1242.htm](http://energycommerce.house.gov/108/Letters/03242004_1242.htm); Committee on Energy and Commerce hearing: Publication and Disclosure Issues in Anti-Depressant Pediatric Clinical Trials, September 9, 2004, <http://energycommerce.house.gov/108/Hearings/09092004hearing1351/hearing.htm>; Committee on Energy and Commerce hearing: FDA's Role in Protecting the Public Health: Examining FDA's Review of Safety and Efficacy Concerns in Anti-depressant Use in Children, September 23, 2004, <http://energycommerce.house.gov/108/Hearings/09232004hearing1353/hearing.htm#Webcast>.

64. Editorial: Depressing Research, *The Lancet*, Vol. 363, No. 9418, April 24, 2004.

65. David Graham, M.D., M.P.H., Testimony of David Graham, M.D., M.P.H., (November 18, 2004), <http://finance.senate.gov/hearings/testimony/2004test/111804dgtest.pdf>.

66. *Ibid.*

67. *Ibid.*

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