

# *Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers*

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## **Introduction**

In recent months, a flurry of media stories has drawn public attention to the seemingly esoteric topic of the Food and Drug Administration's (FDA) attempts to preempt a variety of state tort suits against drug and medical device manufacturers. Under the direction of FDA Chief Counsel Daniel E. Troy, the agency has submitted briefs in multiple lawsuits, each time supporting the manufacturer's argument that federal law preempts state common law claims. Much of the media coverage has focused on the potential conflicts of interest raised by Mr. Troy's previous representation of companies such as those he now invokes FDA's power to protect.

While Mr. Troy's endeavors prior to his appointment by President Bush as FDA Chief Counsel provide context to the agency's recent aggressive push for federal preemption, a much less visible aspect of these activities is the contribution that his substantive legal arguments are making to the Administration's anti-consumer tort reform agenda. Although federal preemption of state common law claims may seem like an obscure issue of little concern to most consumers, Mr. Troy's vigorous assertion of federal preemption claims threatens to deprive countless citizens of their rights under established state law.

Both the legal arguments raised by Mr. Troy on behalf of FDA and the manner in which FDA has come to weigh in on the preemption question represent a significant departure from past agency practice. Acting in his capacity as the agency's Chief Counsel, Mr. Troy has actively sought guidance from pharmaceutical firms concerning lawsuits in which FDA could play a role in promoting preemption. Since he assumed the helm of FDA's legal ship, the agency has submitted briefs in five recent lawsuits involving drugs or medical devices. More often than not, FDA has filed those briefs on its own initiative, without being asked to do so by the court.

Examined in the context of relevant Supreme Court precedent, it becomes clear that FDA's recently articulated position on preemption stretches the doctrine far beyond its appropriate and established bounds. No change in the relevant statute, regulations or case law has taken place to prompt FDA's aggressive new stance on preemption. Rather, it appears that the primary motivating concept behind FDA's pro-preemption briefs is the Bush Administration's tort reform agenda. Already FDA's briefs have prompted some courts to find state tort claims preempted, thereby effecting significant changes in the law that had not occurred prior to Mr. Troy's tenure.

FDA's *amicus* briefs represent part of a larger threat that the Bush Administration poses to the crucial role that private tort suits play in supplementing regulatory programs aimed at protecting health, safety and the environment. Recent questions concerning whether FDA appropriately dealt with studies suggesting a link between antidepressants and suicidal tendencies highlight the crucial importance of the role and availability of tort recovery as a supplement to regulatory oversight.

## ***FDA's Recent Intervention in Private Lawsuits***

The Bush Administration's FDA has garnered considerable media attention, as newspapers have run stories with eye-catching headlines such as: *In a Shift, Bush Moves to Block Medical Suits; FDA Stepping Into Liability Lawsuits on Side of Drug Makers It Regulates*, and *FDA's Chief Lawyer Stands Up for the Big Guys*.<sup>1</sup> These and other articles focus on the actions of Daniel E. Troy, President Bush's appointee to the position of FDA Chief Counsel. Over the past two years, Mr. Troy's FDA has filed "friend of the court" (*amicus curiae*) briefs, or statements of interest, in five private lawsuits involving drugs or medical devices, four of which were product liability suits brought by injured consumers.<sup>2</sup> In the briefs, Mr. Troy brings

FDA's considerable weight to bear in favor of the manufacturers' defense that federal law preempts the consumer plaintiffs' claims.<sup>3</sup>

Federal preemption is a principle of constitutional law derived from the Supremacy Clause, which provides that a federal law can supersede or supplant any inconsistent state law or regulation.<sup>4</sup> In the context of Mr. Troy's recent legal briefs, preemption is the asserted authority of the federal government to override the powers of the states to determine what label warnings (in the case of drugs) or design criteria (in the case of medical devices) may be required by state legislation or held subject to liability in litigation.<sup>5</sup> Put simply, preemption causes "the nullification of state actions that conflict with or supplement FDA decisions."<sup>6</sup> If a court agrees with FDA and the manufacturer that a tort claim is preempted, the court must rule in favor of the defendant.<sup>7</sup> The import of the preemption doctrine, and the reason that Mr. Troy's *amicus* briefs have garnered the attention they have, thus becomes clear – if a product manufacturer can successfully argue that the federal law preempts plaintiff's claim, the lawsuit disappears (and precedent to support future assertions of the preemption defense is established).

The benefit of preemption to potential product liability defendants is obvious: it provides a shield against expensive settlements and/or judgments in favor of plaintiffs. What is less clear is why FDA, the agency charged with regulating to protect the health and safety of consumers, would work so hard to deprive consumers injured by the products it regulates of their only remedy. At a 2002 legal symposium, Mr. Troy and the Bush Administration set forth plans for "FDA Involvement in Product Liability Lawsuits."<sup>8</sup> At the symposium, held by the Food and Drug Law Institute (FDLI), Mr. Troy maintained that because the federal Food, Drug and Cosmetic Act (FDCA) gives FDA broad authority to regulate the content of labeling for all drugs and advertising for prescription drugs, allowing state courts and juries to impose additional requirements in conflict with FDA determinations could require drug firms to choose between state and federal compliance and lead to inconsistency in drug firms' communications to physicians and patients about drugs.<sup>9</sup> Accordingly, Mr. Troy declared that FDA would "participate in product liability lawsuits brought under state law as necessary

to safeguard its considerable expertise in regulating the content of drug labeling and advertising."<sup>10</sup>

### *FDA's New Role Under Dan Troy*

Mr. Troy's articulated rationale for FDA's intervention into private lawsuits represents a significant departure from the views on preemption consistently held by the agency during past Administrations. In 1996, FDA's Clinton-era Chief Counsel, Margaret Jane Porter, spoke at an FDLI seminar.<sup>11</sup> Her opening remarks referred to FDA's "long-standing presumption against preemption" even in the implementation of a section of the FDCA that contains an explicit preemption provision.<sup>12</sup> In sharp contrast to Mr. Troy's stated position that "state courts and juries should not second-guess the agency's scientific determinations,"<sup>13</sup> Ms. Porter explained that "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."<sup>14</sup>

In addition to the Bush Administration's drastic views on the roles of federal regulation, state common law and preemption, the agency has moved in a "radical new direction"<sup>15</sup> with respect to its involvement in private lawsuits. Specifically, Mr. Troy has taken the extraordinary step of seeking out lawsuits in which FDA could intervene on behalf of product liability defendants (*i.e.*, large drug companies) in support of preemption. At a December 2003 conference on drug and medical device litigation for defense lawyers and in-house counsel, Mr. Troy told the audience of several hundred pharmaceutical attorneys to suggest lawsuits into which the agency might intervene.<sup>16</sup> The signed affidavit of a conference participant states that Mr. Troy cautioned that since FDA "can't get involved in every case," interested attorneys should make their particular cases "sound like a Hollywood pitch."<sup>17</sup>

Indeed, even prior to Mr. Troy's appeal at the December 2003 conference, his office had responded to pleas from defense counsel in at least two product liability cases. During the month of July 2002, when Pfizer faced a lawsuit alleging that its antidepressant drug Zoloft caused a patient to commit suicide, one of the company's attorneys "called Dan Troy and informed him of the case."<sup>18</sup> Within a couple of months, FDA had filed a brief before the United States Court of Appeals for the

Ninth Circuit, without being asked (by the court) to do so.<sup>19</sup>

In another case, where a plaintiff sought damages for injuries allegedly sustained from pacemakers manufactured by Pacesetter, Inc.,<sup>20</sup> the Circuit Court of Shelby County, Tennessee denied defendant Pacesetter Inc.'s Motion for Summary Judgment.<sup>21</sup> Soon thereafter, counsel for Pacesetter wrote to the office of FDA Chief Counsel, to remind FDA that motions in the interlocutory appeal of the matter were soon due, and that "accordingly, FDA's Motion to Intervene should likewise be submitted by that time."<sup>22</sup> FDA timely submitted a brief in support of preemption.<sup>23</sup>

Responding to Mr. Troy's unprecedented actions, Representative Maurice D. Hinchey (D-N.Y.) successfully introduced legislation to cut \$500,000 from the office of FDA Chief Counsel's budget.<sup>24</sup> Other veteran observers of FDA confirm Representative Hinchey's assertions that Mr. Troy's active pursuit of, and intervention in, private lawsuits takes the agency in a new direction. Professor James O'Reilly, University of Cincinnati Law Professor and former FDA counsel, noted that, "FDA is now in the business of helping lawsuit defendants" and that the practice is "a dramatic change in what FDA has done in the past."<sup>25</sup> The Public Citizen Litigation Group agrees that FDA "has not supported preemption of personal injury claims prior to this administration."<sup>26</sup>

In an attempt to defend Mr. Troy's actions, five former FDA Chief Counsels<sup>27</sup> wrote a letter claiming that "there is ample precedent for the actions that Mr. Troy has recently been undertaking," and that his actions are "not radical or even novel."<sup>28</sup> However, as noted in Representative Hinchey's response, the Former Chief Counsels cite inapposite legal precedent.<sup>29</sup> To demonstrate by example that Mr. Troy's active solicitation of lawsuit information from corporate defendants, and unsolicited intervention in private cases is "not radical or even novel,"<sup>30</sup> the Former Chief Counsels cited cases where FDA was either the defendant in the case to begin with<sup>31</sup> or was asked by the court to submit a brief.<sup>32</sup> Moreover, in a newspaper article published prior to Representative Hinchey's proposal to penalize the Chief Counsel's office, Peter Barton Hutt, FDA Chief Counsel in the Nixon Administration, acknowledged that while he supported FDA's legal position, he "probably wouldn't be out there encouraging" lawsuits.<sup>33</sup>

## Dan Troy's Legal Arguments in Context

Mr. Troy's own justification for FDA's aggressive intervention in private lawsuits since his appointment is that the agency "only intervenes in private-party lawsuits when it has a significant, direct stake in the outcome and only files briefs in cases in which the courts have already ruled against the position the FDA supports."<sup>34</sup> His explanation fails to address either why FDA is aggressively seeking out lawsuits in which to intervene or why, in the absence of any intervening change in the governing law, the agency's substantive views on the preemption issue have changed so dramatically from FDA's former "long-standing presumption against preemption."<sup>35</sup>

That presumption (now reversed under the guidance of Mr. Troy) is consistent with the fundamental principles upon which the doctrine of preemption rests. Time and again, the Supreme Court has articulated the basic canons that should guide judicial evaluation of preemption claims. The starting premise is that the States are independent sovereigns in the United States federal system of government.<sup>36</sup> It is a familiar principle of constitutional law that powers not delegated to the federal government are reserved to the States.<sup>37</sup> Among the most basic reserved powers is the police power – the inherent power of a sovereign to make all laws necessary to preserve the public safety, health and welfare.<sup>38</sup> Accordingly, the Court assumes "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>39</sup> Consequently, "[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case."<sup>40</sup> In the case of the FDCA, the "overriding" purpose of the statute is *to protect the public health*, and the Supreme Court has made clear that the Act must be given a liberal construction consistent with that intent.<sup>41</sup>

There are two major classifications of federal preemption, each of which is implicated by Mr. Troy's recent rash of *amicus* briefs. Express preemption occurs when Congress expressly contemplated the role of the States and included a statutory provision that explicitly abrogates state power in a particular area.<sup>42</sup> Even when an explicit preemption provision appears in the statute under consideration, the Supreme Court has found that the presumption against preemption of state police power mandates a narrow interpretation of the scope of the provision, consistent with "both federalism concerns

and the historic primacy of state regulation of matters of health and safety.”<sup>43</sup> In product liability cases involving medical devices, the issue before a court charged with deciding whether plaintiff’s tort claim is preempted is the proper scope of an express preemption provision contained in the statute governing medical devices.

In the absence of express preemption, a court may still find that “a federal statute implicitly overrides state law either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively, or when state law is in actual conflict with federal law.”<sup>44</sup> Since the prescription drug provisions of the FDCA do not contain any preemption provision,<sup>45</sup> FDA’s recent *amicus* briefs in prescription drug litigation rely on the more tenuous doctrine of implied preemption. As explained more fully below, however, the Bush Administration’s assertion of preemption in both medical device and prescription drug cases stretches the doctrine beyond the bounds delineated by the Supreme Court.

### ***Medical Device Litigation: Murphree v. Pacesetter and Horn v. Thoratec***

On September 20, 2000, Gary Murphree filed suit against Pacesetter, Inc. in the Circuit Court of Shelby County, Tennessee.<sup>46</sup> Mr. Murphree alleged that the two pacemakers he had received, both manufactured and later recalled by Pacesetter, left him with third-degree heart block, a failure of the heart’s electrical signals that can lead to cardiac arrest.<sup>47</sup> After receiving a letter from Pacesetter’s counsel following the court’s denial of Pacesetter’s motion for summary judgment,<sup>48</sup> FDA filed a brief arguing that Murphree’s claim was preempted.<sup>49</sup> In the brief, FDA argued that “the prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged FDA with implementing.”<sup>50</sup> Private tort suits, the brief maintained, would create uncertainty and chaos “for both the regulated industry and FDA.”<sup>51</sup>

Though the trial court rejected Pacesetter’s assertion of (and FDA’s support of) the preemption defense, the matter will be re-visited on appeal.<sup>52</sup> Nonetheless, FDA’s brief in *Murphree* has already succeeded in aiding a federal appeals court to rule in favor of a manufacturer and find a plaintiff’s tort claims preempted.<sup>53</sup> The United States Court of Appeals for the Third Circuit recently held that the express preemption clause in the Medical Device Amendments (MDA) to the FDCA preempted Barbara Horn’s state law claim (on behalf of her deceased husband, Daniel Horn) against Thoratec Corporation.<sup>54</sup> After suffering a heart attack, Mr. Horn was implanted with a HeartMate, a pump manufactured by Thoratec that assists blood flow between the heart’s ventricle and aorta in patients with cardiac conditions.<sup>55</sup> Complications ensued, and a disconnection of the HeartMate apparatus allowed an air bubble to travel to Mr. Horn’s brain.<sup>56</sup> He then suffered a hemorrhage that rendered him brain dead.<sup>57</sup> Less than four months after he was implanted with the HeartMate, Mr. Horn was pronounced dead.<sup>58</sup>

Barbara Horn filed her husband’s state law claims against Thoratec in federal court, where she alleged that the HeartMate had been defectively designed and manufactured and that Thoratec had failed to warn of the alleged defects.<sup>59</sup> Thoratec moved for summary judgment on the ground that Horn’s claims were expressly preempted.<sup>60</sup> The court agreed, and Horn appealed.<sup>61</sup> Subsequently, FDA submitted its statement of interest in the *Murphree* case.<sup>62</sup> Early this year, the Third Circuit allowed Thoratec to amend the record on appeal to include FDA’s brief in *Murphree*, and approximately one month later it asked FDA to submit a letter brief in the *Horn v. Thoratec* appeal.<sup>63</sup> The court’s opinion relied substantially on both FDA briefs to reach its conclusion that Horn’s tort claims could not proceed.

In so concluding, the *Horn* court had to distinguish the Supreme Court’s seminal holding in *Medtronic, Inc. v. Lohr*. In that case, the Court held that although Section 360k of the MDA provides for express preemption of certain state law “requirements” governing medical devices, the relevant statutory and regulatory language evidences “an overarching concern that preemption occur

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only where a particular state requirement threatens to interfere with a specific federal interest.”<sup>64</sup> The *Lohr* Court’s extensive analysis concluded that the statutory language itself, the overriding purpose of the MDA (to provide for the safety and effectiveness of medical devices intended for human use)<sup>65</sup> and the FDA regulations all supported the conclusion that the tort claims under review, including use of defective materials and failure to warn,<sup>66</sup> were not of the specific nature required in order to be preempted by the MDA.<sup>67</sup> The Supreme Court reasoned that because the general state common-law requirements were not specifically developed “with respect to” particular medical devices, they were not the kind of requirements that Congress and FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements.<sup>68</sup> Ultimately, the Court stated, “given the critical importance of device specificity in our (and FDA’s) construction of § 360k, it is apparent that few, if any, common-law duties have been preempted by this statute.”<sup>69</sup>

The *Horn* court distinguished *Lohr* first on the basis that the federal requirement in question was of greater specificity than the provision that was before the Supreme Court.<sup>70</sup> Turning next to the more analogous state law requirements at issue, the Third Circuit went to great lengths to diminish the importance of the Supreme Court’s statement that “it is apparent that few, if any, common-law duties have been preempted” by the MDA’s preemption provision.<sup>71</sup> FDA’s *amicus* arguments may have been especially persuasive in this regard. The court noted the agency’s unequivocal statement that “[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices,” because tort relief in the form of damages could pressure manufacturers to add warnings that FDA had not approved.<sup>72</sup> The court further quoted FDA’s prediction that such “individualized redetermination of the benefits and risks of a product” could harm the public health by “resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments.”<sup>73</sup> The *Murphree* court similarly quoted FDA’s professed concern that “such uncertainty as to the status of medical devices would create chaos for both the regulated industry and FDA.”<sup>74</sup>

### *Prescription Drug Litigation*

Beyond pushing the law in a new direction in the medical device arena, the current FDA is also pressing

courts to preempt state tort claims involving prescription drugs. FDA’s actions in this regard are especially remarkable, because (as noted above) the prescription drug portions of the FDCA do not contain a preemption provision.<sup>75</sup> Indeed, since the statute’s enactment, no reported decision ever has held that the FDCA preempts common law claims for damages caused by drugs.<sup>76</sup> Moreover, in 1933, Congress rejected a suggested provision in a draft of the original FDCA providing a federal cause of action for damages because “a common law right of action (already) exists.”<sup>77</sup> Keeping in mind the maxim that “[t]he purpose of Congress is the ultimate touchstone’ in every pre-emption case,”<sup>78</sup> and the Supreme Court’s admonition that the historic police powers of the States should not be found to be preempted “unless that was the clear and manifest purpose of Congress,”<sup>79</sup> it becomes apparent that FDA’s arguments in favor of preemption in the prescription drug cases are extraordinary.

### *In re Paxil*

Presently, a class action lawsuit is pending before a California federal court, in which dozens of plaintiffs contend that Glaxo SmithKline (GSK) has engaged in false advertising by promoting its drug Paxil as “non-habit forming.” Paxil is an antidepressant in the class of medicines known as SSRIs, or selective serotonin reuptake inhibitors.<sup>80</sup> SSRIs treat depression by normalizing levels of the brain chemical serotonin.<sup>81</sup> However, SSRIs also have effects on numerous other parts of the brain’s cellular system.<sup>82</sup>

In August 2002, the court granted plaintiffs’ request for a preliminary injunction barring GSK from continuing to air television commercials claiming that Paxil was “non-habit forming.”<sup>83</sup> GSK motioned the court to reconsider its ruling, and, after asking FDA to file a brief and considering all arguments, the court lifted the preliminary injunction.<sup>84</sup> In its brief, FDA asserted, among other things, that Paxil does not cause withdrawal symptoms but merely causes a “discontinuation syndrome,”<sup>85</sup> and that in any event, plaintiffs’ claim was preempted. Although the court ultimately lifted the preliminary injunction on other grounds,<sup>86</sup> it soundly rejected the preemption argument.

FDA (and GSK) argued for implied preemption on the ground that the comprehensive nature of the FDCA,

when taken together with FDA's expertise, evidences a Congressional intent to preempt state law.<sup>87</sup> The court found the argument that FDA has exclusive domain over control and regulation of prescription drug advertisements to be unpersuasive.<sup>88</sup> The court noted that neither FDA nor GSK had cited any case holding that the FDCA preempts state law, and noted that "if anything, FDA's and GSK's arguments ran contrary to the grain of other decisions."<sup>89</sup> Judge Marianna Pfaelzer elaborated:

FDA's and GSK's position vitiates, rather than advances, the FDCA's purpose of protecting the public. That is, FDA and GSK invite the 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, and the Court declines the invitation.<sup>90</sup>

Despite the court's outright rebuff of FDA's theory, Mr. Troy plans to continue his "fight for the FDA's supremacy."<sup>91</sup> He has indicated that he intends to raise the argument again before Judge Pfaelzer in the ongoing Paxil litigation.<sup>92</sup>

### ***Motus v. Pfizer***

Five days after filing its brief in the Paxil litigation, FDA submitted an *amicus curiae* brief to the United States Court of Appeals for the Ninth Circuit<sup>93</sup> in a case involving another SSRI drug, Zoloft.<sup>94</sup> Flora Motus initially brought the case in state court on behalf of her husband Victor, who committed suicide approximately one week after commencing to take Zoloft for his depression.<sup>95</sup> Ms. Motus alleged that Pfizer failed to adequately warn of the dangers, contraindications and side-effects of Zoloft.<sup>96</sup> After successfully removing the case to federal court, Pfizer moved for summary judgment on the ground that the inadequate warning claims were preempted.<sup>97</sup>

Specifically, Pfizer argued that FDA had instructed it to use certain verbatim text in its labeling that did not link suicide to the drug but rather warned that the possibility of suicide is inherent in depression.<sup>98</sup> Additionally, before and during FDA's consideration of the Zoloft application, the agency considered claims that

other SSRIs (such as Prozac) cause suicide and determined on each occasion that the scientific evidence was insufficient to compel a warning linking Prozac to suicidal behavior.<sup>99</sup> Pfizer therefore argued that "plaintiff's attempt to use state tort law to require warnings that Zoloft causes suicide" conflicted with FDA's determinations concerning SSRI warnings.<sup>100</sup>

The district court rejected the preemption defense, instead finding on a variety of grounds that Pfizer had failed to demonstrate that it would be impossible to comply both with FDA requirements and with a state law or decision requiring a stronger warning.<sup>101</sup> In a separate proceeding, the court granted summary judgment to Pfizer on the ground that Ms. Motus was unable to present any evidence to establish that her husband's doctor would have acted differently had Pfizer included a warning about an association between Zoloft and suicidal behavior.<sup>102</sup>

Ms. Motus appealed the court's judgment to the Ninth Circuit, and Pfizer cross-appealed the earlier ruling on its preemption argument.<sup>103</sup> FDA filed an *amicus curiae* brief without being asked to do so by the court, and it did so within months of Mr. Troy's receipt of a phone call from one of Pfizer's attorneys, requesting that the government file a brief in support of preemption.<sup>104</sup> FDA's involvement in the case was especially alarming to plaintiff's counsel, because before being appointed to the position of FDA Chief Counsel, Mr. Troy had represented Pfizer for pay as a private attorney.<sup>105</sup> According to Mr. Troy, since the mandatory recusal period had elapsed at the end of May, he "didn't see any problem" with filing a brief that supported Pfizer's defense less than four months later.<sup>106</sup>

In the brief, Mr. Troy and FDA argued that the claims were preempted because:

when Zoloft was prescribed for Victor Motus, *any* warning, no matter how worded, that could reasonably have been read as describing or alluding to [a causal relation to suicide] 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. This is not just because FDA had rejected any link between Zoloft and suicide when . . . the agency approved the drug as a

treatment for depression. Subsequently, in response to petitions making similar allegations as to the related drug Prozac, FDA found *no* link between *antidepressants* and suicide.<sup>107</sup>

In addition to arguing for implied preemption on the basis of actual conflict, FDA raised the over-deterrence argument that it has also advanced in the *Murphree* and *Horn* cases<sup>108</sup> involving medical device claims:

Under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment, could well frustrate the purpose of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects.<sup>109</sup>

In the end, the Ninth Circuit affirmed the lower court's ruling that Mrs. Motus had failed to establish proof that stronger warnings could have altered her husband's medical treatment or averted his suicide, and it therefore did not address the preemption issue.<sup>110</sup> But the story of FDA's brief in the case doesn't end there. Though FDA may not have succeeded in establishing precedent in the Ninth Circuit, its *amicus* brief has been convincing lower courts to preempt similar tort claims in other jurisdictions. Two federal district courts in Texas have found failure to warn claims against Pfizer preempted, resting their holdings in large part on FDA's views as expressed in its *Motus* brief.<sup>111</sup>

### ***FDA's Shift in Position: A Manifestation of the Bush Tort Reform Agenda***

FDA's legal briefs in *Murphree*, *Horn*, *In re Paxil* and *Motus* represent a 180-degree shift from the agency's prior position on the preemption issue. After the Supreme Court's landmark decision in *Medtronic, Inc. v. Lohr*, former FDA Chief Counsel Margaret Porter stated that the Court's refusal to find the plaintiff's claims preempted was consistent with FDA's "long-standing presumption against preemption."<sup>112</sup> Porter further elaborated, stating that:

[g]iven the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe

that Congress intended to effect so sweeping a change without even a comment. Rather, the agency believes that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a state, and did not intend to preempt state tort remedies for injury to individual consumers.<sup>113</sup>

The pre-Bush Administration FDA's view on the interplay between state tort claims and federal regulation was expressed formally in a brief submitted to an Illinois court in 1996,<sup>114</sup> when FDA asserted that because the federal approval process represents FDA's endorsement of a minimum standard, federal approval should not displace state common law that may provide additional protection to consumers.<sup>115</sup>

What has caused the agency's views to shift so drastically? The Supreme Court has not decided any case that reverses either its reading of the MDA's preemption provision or its mandates on the presumptions that inform any preemption decision (express or implied). Congress has not passed any legislation altering the language of the MDA's preemption provision or adding a preemption provision to the FDCA's prescription drug sections. FDA has not gone through formal administrative procedures to promulgate a new regulation that interprets the MDA and/or the FDCA in such a way as to preempt state tort claims. Stated simply, there has been no intervening change in the law of preemption to justify such a drastic reversal by FDA.

Instead, the Bush Administration's FDA now argues that the agency's former view (that federal approval should not displace state common law that may provide additional protection to consumers) fails to "take sufficient account of the state-of-the-art risk management principles that FDA currently follows."<sup>116</sup> FDA declared that "[t]he Government now believes" that the better implementation of the statutory scheme is to focus "not only on identifying the risk minimization appropriate for the device, but also on ensuring that the measures selected do not present their own public health disadvantages."<sup>117</sup> Thus, with no more than a bare assertion that common law tort claims might cause drug and medical device manufacturers to take actions that actually increase risk to consumers, the Bush Administration has concluded that consumers are better off without private legal

recourse. For an administration that purports to respect the authority of states, this conclusion has a derisive implicit premise: State court judgments, according to the Bush Administration, are likely to be so erratic and unfounded as to harm the very people they intend to protect.

Such a speculative, condescending assertion cannot by itself explain the Administration's actions. Consumers are not the constituency that will be made better off by eliminating private legal recourse for injuries sustained by drugs and/or medical devices. Instead, Mr. Troy's legal arguments in favor of preemption are consistent with, and are a means of promoting, the Bush Administration's position on tort reform. President Bush often attacks trial lawyers, claiming that tort suits drive up health care costs and impose a huge burden on the economy.<sup>118</sup> After declaring tort reform an "emergency" upon assuming office as Governor of Texas, Mr. Bush helped to ensure enactment of seven tort reform bills, including measures that reduced punitive damage liability and raised the burden of proof for plaintiffs seeking such damages.<sup>119</sup> Business groups, many of which were among Mr. Bush's largest gubernatorial campaign contributors, had laid the groundwork for the measures.<sup>120</sup>

Mr. Troy has helped to advance George W. Bush's pro-business, pro-tort reform tradition by establishing an "open-door policy" for industry, thereby earning for himself a reputation for being as receptive to industry as any FDA Chief Counsel.<sup>121</sup> It is no coincidence that FDA's top legal voice is so closely aligned with the Administration's political agenda. In the summer of 2001, the Bush Administration had settled on Michael J. Astrue as its choice for FDA Commissioner.<sup>122</sup> Senator Edward M. Kennedy, chair of the Senate Committee on Health, Education, Labor and Pensions, opposed Astrue's candidacy on the ground that the then Senior Vice-President and General Counsel of Transkaryotic Therapies, Inc. (a biopharmaceutical company) was too closely tied to industry.<sup>123</sup> President Bush's appointment of Mr. Troy to the position of FDA Chief Counsel, which

did not require the advice and consent of the Senate, was seen as a reaction to Senator Kennedy's protest.<sup>124</sup> A medical device industry publication voiced the Administration's hope: "Until Bush is able to place someone in the commissioner's office who will meet Kennedy's approval, perhaps Mr. Troy can bring about more regulatory circumspection at the agency."<sup>125</sup>

Indeed, Mr. Troy's background is rife with themes of "regulatory circumspection." After attending Columbia University School of Law, he clerked for outspoken conservative Judge Robert Bork of the United States Court of Appeals for the D.C. Circuit.<sup>126</sup> In private practice, Mr. Troy repeatedly sued FDA on behalf of the Washington Legal Foundation, arguing that the agency had only limited ability to regulate

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drug companies.<sup>127</sup> As an associate scholar of legal studies at the American Enterprise Institute, he argued that companies that dumped toxics before it was illegal to do so should not be held liable for the cleanup of such waste.<sup>128</sup> Mr. Troy's greatest anti-regulatory achievement may be his successful argument before the Supreme Court on behalf of Brown & Williamson Tobacco Corporation that FDA has no authority to regulate tobacco.<sup>129</sup>

Mr. Troy's philosophy as FDA Chief Counsel is, in large part, consistent with his conservative views: agencies should limit their actions to what the law explicitly authorizes them to do.<sup>130</sup> Yet in the area of preemption, Mr. Troy argues consistently for FDA authority well in excess of what the relevant statutes stipulate, what the Supreme Court has delineated, and what FDA has historically asserted. In fact, in that area, he has managed to change the entire nature of the Chief Counsel's office, converting it from a legal office to an activist policy office.<sup>131</sup>

Mr. Troy's enthusiastic endorsements of broad FDA authority in the realm of preemption are best understood as a manifestation of George W. Bush's continued attempts to promote tort reform. The Chief Counsel has specifically stated that FDA "is deeply immersed in tort reform issues."<sup>132</sup> Jay P. Lefkowitz, former director

of President Bush's Domestic Policy Council stated that FDA's litigation strategy embodies "good health policy and good tort reform."<sup>133</sup>

In short, FDA's 180-degree shift from the agency's prior position on the preemption issue represents neither a response to some intervening change in the law, nor a reflection of drastically different "state-of-the-art risk management principles."<sup>134</sup> The current FDA's arguments – diametrically opposed to the views consistently held by previous FDAs – represent a concerted effort to advance the Bush Administration's activist tort reform policy agenda. It is precisely for this reason that courts should regard FDA's pro-preemption *amicus* briefs with great circumspection. Although an agency's construction of its own regulations is normally entitled to substantial deference by the courts, the fact that FDA's complete about-face has taken place in the absence of any credible change in legal or factual circumstances significantly undercuts its arguments.<sup>135</sup>

### ***What's at Stake: Regulation, Tort Law and SSRI Warnings***

The Bush Administration's FDA has vociferously argued that allowing state tort claims against the manufacturers of drugs or medical devices that FDA has approved would undermine FDA's review and approval of product labeling. In particular, state tort suits could result in "scientifically unsubstantiated warnings" by manufacturers that could, in turn, result in the underutilization of beneficial treatments, to the detriment of consumers.<sup>136</sup> This simplistic and speculative argument, however, fails to address the ramifications of eliminating tort remedies and implicitly rests on the assumption that FDA's "centralized expert evaluation"<sup>137</sup> is based on all relevant data and studies.

Aside from the harsh consequences to consumers who would be left without any means of obtaining compensation for injuries caused by defective prescription drugs or medical devices, preemption of tort claims would destroy the vital role that state common-law remedies play in supplementing and augmenting federal health and safety regulations.<sup>138</sup> Specifically, the tort system is often able to get to the truth in ways that are largely unavailable to regulatory agencies.<sup>139</sup> The tort system allows trial lawyers, so often vilified by President Bush, to spend the resources needed to obtain and review

documents from unwilling defendant manufacturers, question company representatives during depositions and thereby uncover evidence of fraud and misrepresentation.<sup>140</sup> For example, court-ordered discovery allowed counsel for the plaintiffs in the Paxil litigation to see raw data on the drug's safety and efficacy, while FDA saw only the completed write-ups.<sup>141</sup> Also obtained in discovery but never seen by FDA were the manufacturer's internal communications about how to approach the agency.<sup>142</sup>

Past examples of tort litigation uncovering information that FDA failed to find demonstrate just how crucial the role of civil discovery through tort suits can be. It was a trial lawyer, not FDA that discovered that one of the published clinical studies of thalidomide (the drug prescribed for morning sickness that caused severe birth defects) had been ghost written by an employee of the drug's manufacturer.<sup>143</sup> In the state tobacco litigation, private attorneys for the states discovered and made available for public inspection documents establishing facts that the industry had denied to FDA (and Congress) for decades.<sup>144</sup>

Recent revelations about data demonstrating a link between SSRI drugs and suicidal behavior underscore the very real need to protect the role of tort litigation in supplementing FDA's regulatory efforts. In June 2003, less than a year after FDA asserted to the United States Court of Appeals for the Ninth Circuit in the *Motus* case that its internal review of SSRI data disclosed that "there is no difference in the risk of suicide between those on SSRI's and those on placebo,"<sup>145</sup> the agency issued a statement recommending that Paxil not be used in children and adolescents for the treatment of depression.<sup>146</sup> The recommendation was based on "reports of a possible increased risk of suicidal thinking and suicide attempts" in children under the age of 18 treated with Paxil.<sup>147</sup>

In July 2003, FDA asked manufacturers for information about pediatric studies of other depression drugs, including several SSRIs.<sup>148</sup> After reviewing the data, FDA issued a Public Health Advisory to health care professionals, stating that it had not "been able to rule out an increased risk of suicidality" for any of the drugs.<sup>149</sup> FDA further stated that additional data and analysis, as well as a public discussion of available data were needed.<sup>150</sup> The public discussion recommended

by the Advisory was convened on February 2, 2004, for the purpose of addressing concerns and gathering information from a variety of sources and perspectives about the relationship between suicidal behavior and SSRI drugs.<sup>151</sup> Prior to the meeting, FDA scientists met to discuss the agenda. Dr. Andrew Mosholder, an FDA drug-safety analyst who studied clinical trials of antidepressants, stated that he planned to present his conclusion: young people who took antidepressants were far more likely to show suicidal tendencies than those who took placebo pills.<sup>152</sup>

High-ranking officials at FDA, however, decided that Dr. Mosholder would not be permitted to speak about his findings.<sup>153</sup> Though Dr. Mosholder would attend the meeting to make another presentation, upper level decisionmakers decided that another FDA official would describe the antidepressant drug data Mosholder had analyzed without offering any conclusion.<sup>154</sup> Concerned about the reliability of Dr. Mosholder's conclusions, FDA hired researchers at Columbia University to re-analyze the same data.<sup>155</sup> The Columbia study, completed after the February meeting, reached conclusions nearly identical to Mosholder's.<sup>156</sup>

In September 2004, after an advisory committee meeting held as a follow-up to the February 2 meeting, Dr. Robert Temple, director of FDA's office of medical policy, stated that "we now all believe that there is an increase in suicidal thinking and action that is consistent across all the drugs."<sup>157</sup> Dr. Temple was one of the officials who decided to prevent Dr. Mosholder from presenting the same conclusion in February.<sup>158</sup> According to Temple, the data demonstrating the consistent link between antidepressants and suicidal behavior were contained in 15 clinical trials, some of which had been hidden for years from the public by the drug companies that sponsored them.<sup>159</sup>

This timely example of the ability of regulated entities to hide data concerning the very dangers that FDA seeks to protect the public against underscores the necessity of preserving the tort remedies that the Bush Administration is trying so hard to eliminate. Common law claims hold companies liable for poorly designed and manufactured products, and they can indirectly influence corporate conduct. A company is not as likely

to disregard studies that indicate that its product causes death or injury if it knows that it may be held liable for damages caused by that product in the future, and it will not be tempted to hide those studies if it knows that a jury may award punitive damages when the cover-up is later uncovered. A complete shield from liability based on an existing FDA label deprives consumers of the additional incentive that the threat of tort recovery provides to manufacturers. Without the possibility of damaging information ever being revealed through litigation, manufacturers of drug and medical devices would have every incentive to withhold even more such information from FDA.

In its *Motus* brief, FDA rested its preemption argument in large part on the fact that FDA had rejected a link between Zoloft and suicide, and it explicitly argued that the agency "found *no* link between *antidepressants* and suicide."<sup>160</sup> Consumers would be harmed, the agency asserted, by over-warning about a link between SSRI drugs and suicidal behavior.<sup>161</sup> Two courts relied on FDA's arguments to find a plaintiff's claims preempted, thus preventing them from using discovery tools to explore the merits of their assertions.<sup>162</sup> Despite recent developments, Mr. Troy has stated that FDA has "not rethought [its] legal views on preemption merely because the facts [on SSRIs] change."<sup>163</sup> In the face of a flagrant failure of the regulatory system, the Bush Administration continues to believe that whether FDA is right or wrong in its conclusions about the dangers of products it regulates, consumers are better off without a legal remedy.

## Conclusion

Mr. Troy's successes in urging courts to adopt a radically aggressive preemption policy illustrate "how a White House can use its administrative and legal powers to change the regulatory terrain without taking the often arduous course of asking Congress to change the law."<sup>164</sup> The Bush Administration has pursued its tort reform agenda through arcane legal vehicles that are largely hidden from public view, and it has enlisted the industry to alert it to chances to do so. Courts should be reluctant to accept the flawed and unprecedented statements of this administration's FDA, and consumers should be outraged at these clandestine attempts to erode their legal protections.

## End Notes

\* Policy Analyst, Center for Progressive Regulation (CPR), B.A., J.D., University of Maryland. This White Paper is the first in a series of efforts by CPR to highlight the Bush Administration's pervasive attempts to consolidate federal power in the area of state tort law. The author is grateful for the invaluable input and guidance of the following CPR Scholars: Thomas O. McGarity, who holds the W. James Kronzer Chair at the University of Texas School of Law and is the President of CPR; David C. Vladeck, Associate Professor of Law and Co-Director of the Institute for Public Representation at Georgetown University Law Center (and former Director of the Public Citizen Litigation Group); and Douglas A. Kysar, Assistant Professor of Law at Cornell Law School.

<sup>1</sup> Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004; Robert Cohen, *FDA Stepping Into Liability Lawsuits on Side of Drug Makers It Regulates*, THE SEATTLE TIMES, May 11, 2004, at A2; and Patrick McGann, *FDA's Chief Lawyer Stands Up for the Big Guys*, LEWISTON MORNING TRIBUNE, July 31, 2004, at 10A. See also, e.g., Anne C. Mulkern, *Watchdogs or Lap Dogs? When Advocates Become Regulators*, THE DENVER POST, May 23, 2004, at A-01; Gary Young, *FDA Strategy Would Pre-empt Tort Suits; Does it Close Off Vital Drug Data?*, NATIONAL LAW JOURNAL, March 1, 2004, at 1; Jeff Swiatek, *FDA Gets Involved in Court Disputes*, INDIANAPOLIS STAR, October 20, 2002, at E01.

<sup>2</sup> *Horn v. Thoratec*, 376 F.3d 163 (3<sup>rd</sup> Cir. 2004); *Motus v. Pfizer*, 358 F.3d 659 (9<sup>th</sup> Cir. 2004); *Dowhal v. SmithKline Beecham Consumer*, 88 P.3d 1 (Cal. 2004); *In re Paxil Litigation*, 2002 WL 31375497 (C.D. Cal. 2002); and *Murphree v. Pacesetter, Inc. et al*, No. 005429-00-3 (Tenn. Circuit Ct.), *appeal docketed*, No. W2004-01432 (Tenn. Ct. App.).

<sup>3</sup> See, e.g., Letter Brief of *Amicus Curiae* United States, 2004 WL 1143720, *Horn v. Thoratec*, 376 F.3d 163; Brief of *Amicus Curiae* United States, 2002 WL 32303084, *Motus v. Pfizer*, 358 F.3d 659; and Brief of *Amicus Curiae* United States, 2003 WL 23527781, *Dowhal v. SmithKline Beecham*, 88 P.3d 1.

<sup>4</sup> BLACK'S LAW DICTIONARY 1197 (7<sup>th</sup> ed. 1999). See, e.g., *Rose v. Arkansas State Police*, 479 U.S. 1, 3 (1986) ("[T]he Supremacy Clause invalidates all state laws that conflict or interfere with an Act of Congress (citing *Hayfield Northern R. Co. v. Chicago & North Western Transp. Co.*, 467 U.S. 622, 627, and n. 4 (1984); *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824)))).

<sup>5</sup> See James T. O'Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 FOOD & DRUG L.J. 287, 288 (2003).

<sup>6</sup> See Young, *supra*, n. 1.

<sup>7</sup> See, e.g., *Needleman v. Pfizer, Inc.*, 2004 WL 1773697, \*6 (N.D. Tex. Aug. 6, 2004) (slip op.) (finding plaintiff's failure to warn claim preempted and granting summary judgment to Pfizer).

<sup>8</sup> See Pear, *supra*, n. 1.

<sup>9</sup> Daniel E. Troy, *FDA Involvement in Product Liability Lawsuits*, UPDATE, Jan.-Feb. 2003, at 4, 7. This article, which appeared in The Food

and Drug Law Institute's (FDLI) bi-monthly magazine, "was adapted from remarks originally delivered at FDLI's annual Advertising and Promotion Conference, September 11-12, 2002." *Id.* at 4.

<sup>10</sup> *Id.* at 7-8.

<sup>11</sup> Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, n a1 (1997) (noting that article is an updated version of speech presented at FDLI's seminar "After the Lohr Decision: What You Can Learn to Help Reduce Your Organization's Exposure to Product Liability," Washington, D.C. (Oct. 8, 1996)). Significantly, Ms. Porter opened her remarks at the seminar by noting that "earlier versions of the program were billed as an opportunity to learn how to help reduce manufacturers' product liability exposure. FDA was not interested in providing such advice, the program was revised to offer an opportunity to understand product liability exposure." *Id.* at 7 (emphasis added). Mr. Troy's markedly different view of the role for FDA can be seen in the way his appearance at a 2003 conference for in-house counsel and trial attorneys was billed:

This roundtable of top defense attorneys and in-house counsel will provide an insightful update on the preemption doctrine and defense techniques for ensuring the best use of it. Dan Troy, Chief Counsel of the FDA, will kick off the discussion by giving his valuable insight into why the FDA chooses to file amicus briefs on certain cases . . . and what we're likely to see next. This dynamic session is sure to be a highlight of the conference!

Full Agenda for the 8<sup>th</sup> Annual Conference for In-House and Trial Attorneys: *Drug and Medical Device Litigation*, December 14, 15 & 16, 2003, <[http://www.americanconference.com/drug/agenda\\_full.cfm](http://www.americanconference.com/drug/agenda_full.cfm)> (site visited 12/9/2003) (on file with author) (emphasis added).

<sup>12</sup> See Porter, *supra*, n. 11, at 7 (referring specifically to FDCA § 521, part of the Medical Device Amendments (MDA) to the FDCA).

<sup>13</sup> See Troy, *supra*, n. 9, at 7.

<sup>14</sup> See Porter, *supra*, n. 11, at 11.

<sup>15</sup> 150 CONG. REC. H5581-04 (daily ed. July 13, 2004) (statement of Rep. Hinchey).

<sup>16</sup> See Mulkern, *supra*, n. 1.

<sup>17</sup> See <<http://www.house.gov/hinchey/issues/fda.shtml>> (site visited September 2, 2004), quoting from Affidavit of Jessica R. Dart, ¶15, *Dusek v. Pfizer, Inc.*, No. H-02-3559 (S.D. Tex. Feb. 20, 2004).

<sup>18</sup> Michael Kranish, *FDA Counsel's Rise Embodies U.S. Shift*, THE BOSTON GLOBE, December 22, 2002 (quoting Pfizer attorney Malcolm Wheeler).

<sup>19</sup> Brief of *Amicus Curiae* United States, *Motus v. Pfizer*, see *supra*, n. 3.

<sup>20</sup> Kathleen Kerr, *Can FDA Seal Be Broken?*, NEWSDAY.COM, August 11, 2004.

<sup>21</sup> Letter from Michael J. Weber (Feldman Gale & Weber, P.A.) to Paige Taylor (Assoc. Chief Counsel, FDA) (November 25, 2003),

available at: < <http://www.house.gov/hinchey/issues/fda10.pdf>> (site visited 9/21/2004).

<sup>22</sup> *Id.*

<sup>23</sup> Statement of Interest of the United States of America, *Murphree v. Pacesetter, Inc. et al.*, No. 005429-00-3 (Tenn. Circuit Ct. Dec. 12, 2003), cited and quoted in *Horn v. Thoratec Corp.*, 376 F.3d 163, 171 n.13, 178 (3<sup>rd</sup> Cir. 2004).

<sup>24</sup> See 150 CONG. REC. H5581-04, *supra*, n. 15.

<sup>25</sup> See Mulkern, *supra*, n. 1.

<sup>26</sup> See Cohen, *supra*, n. 1.

<sup>27</sup> Each of the five former Chief Counsels are now in private practice, working for firms that represent clients in the fields of drug and medical device law:

Peter Barton Hutt is a partner at Covington and Burling in Washington, D.C. See <[http://www.martindale.com/xp/Martindale/Lawyer\\_Locator/Search\\_Lawyer\\_Locator/lawyer\\_search.xml](http://www.martindale.com/xp/Martindale/Lawyer_Locator/Search_Lawyer_Locator/lawyer_search.xml)> (site visited 9/21/2004).

Richard A. Merrill also works for Covington & Burling, as of counsel. *Id.* Covington and Burling's representative clients include, among others, Eli Lilly, GlaxoSmithKline, Johnson & Johnson and Merck. See <<http://www.chambersandpartners.com/us/default.asp?action=rf&rf=fprofile&fid=3826>>, (site visited 9/2/2004).

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Nancy L. Buc is a Resident Partner at Buc & Beardsley, a boutique firm that specializes in Food, Durg, Medical Device, Biologics and Cosmetic Law. See <[http://www.martindale.com/xp/Martindale/Lawyer\\_Locator/Search\\_Lawyer\\_Locator/lawyer\\_search.xml](http://www.martindale.com/xp/Martindale/Lawyer_Locator/Search_Lawyer_Locator/lawyer_search.xml)> (site visited 9/2/2004).

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<sup>28</sup> Letter from Peter Barton Hutt, Richard A. Merrill, Richard M. Cooper, Nancy L. Buc and Thomas Scarlett to Hon. Henry Bonilla (July 15, 2004), 150 CONG. REC. E1505-03 (daily ed. July 22, 2004) (letter submitted into record by Rep. Barton) (the

"Former Chief Counsels' Letter").

<sup>29</sup> Letter from Hon. Maurice D. Hinchey to Hon. Henry Bonilla, 2 (August 5, 2004), available at <[http://www.house.gov/apps/list/press/ny22\\_hinchey/morenews/080504fda\\_bonilla.html](http://www.house.gov/apps/list/press/ny22_hinchey/morenews/080504fda_bonilla.html)> (site visited 9/21/2004).

<sup>30</sup> See Former Chief Counsels' Letter, *supra*, n. 21.

<sup>31</sup> See *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973), cited by Former Chief Counsels' Letter, *supra*, n. 21.

<sup>32</sup> See *Bernhardt v. Pfizer*, 2000 WL 1738645, \*1, n.3 (S.D.N.Y. 2000) (noting that "[a]t the Court's request, the United States has submitted a Statement of Interest"); and *Jones v. Rath Packing Co.*, 425 U.S. 933 (1977) (inviting the Solicitor General to file brief expressing the views of the United States), opinion at 430 U.S. 519 (1977), cited by Former Chief Counsels' Letter, *supra*, n. 21. The court's opinion in the final case cited by the Former Chief Counsels does not reveal what, if any, involvement FDA had in the case. See *Eli Lilly & Co. v. Marshall*, 850 S.W.2d 164 (Tex. 1993), cited by Former Chief Counsels' Letter, *supra*, n. 21.

<sup>33</sup> See Mulkern, *supra*, n. 1.

<sup>34</sup> *Troy: Untitled Enforcement Letters Are Strong Enough to Support Enforcement Acts*, 10 FDA ADVERTISING & PROMOTION MANUAL, MONTHLY BULLETIN, 1, 3 (November 2002).

<sup>35</sup> See Porter, *supra*, n. 11, at 7 (referring specifically to FDCA § 521, part of the Medical Device Amendments (MDA) to the FDCA).

<sup>36</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

<sup>37</sup> See U.S.C.A. Const. Amend. X.

<sup>38</sup> See BLACK'S LAW DICTIONARY, *supra*, n. 4, 1178.

<sup>39</sup> *Lohr*, 518 U.S. at 485, (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715-16 (1985)).

<sup>40</sup> *Id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Gade v. Nat'l Solid Wastes Management Ass'n.*, 505 U.S. 88, 96 (1992); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)).

<sup>41</sup> *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (emphasis added).

<sup>42</sup> See O'Reilly, *supra*, n. 5, 288.

<sup>43</sup> *Lohr*, 518 U.S. 470 at 485.

<sup>44</sup> *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (internal citations omitted) (quoting *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990)).

<sup>45</sup> 21 U.S.C. §§ 351 *et seq.*

<sup>46</sup> *Murphree v. Pacesetter, Inc. et al*, No. 005429-00-3 (Tenn. Circuit Ct.), *appeal docketed*, No. W2004-01432 (Tenn. Ct. App.).

<sup>47</sup> Kerr, *supra*, n. 20.

<sup>48</sup> Letter from Weber to Taylor, *supra*, n. 21.

<sup>49</sup> Statement of Interest of the United States of America, *Murphree v. Pacesetter*, *supra*, n. 23.

<sup>50</sup> *Id.*, 7-9.

<sup>51</sup> *Id.*

<sup>52</sup> *Murphree v. Pacesetter, Inc.*, No. W2004-01432 (Tenn Ct. App.).

<sup>53</sup> *Horn v. Thoratec Corp.*, 376 F.3d 163, 171 n. 13, 178 (3<sup>rd</sup> Cir. 2004).

<sup>54</sup> *Id.* at 180.

<sup>55</sup> *Id.* at 164-65.

<sup>56</sup> *Id.* at 165.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> Statement of Interest of the United States of America, *Murphree v. Pacesetter*, *supra*, n. 23.

<sup>63</sup> *Third Circuit Asks FDA to Submit Brief in Pending Medical Preemption Case*, BNA PRODUCT LIABILITY DAILY, March 10, 2004. The court allowed Thoratec to amend the record on appeal by including FDA's filing in *Murphree* on January 24, 2004 and requested FDA to submit a letter brief on February 27, 2004. *Id.*

<sup>64</sup> *Medtronic*, 518 U.S. at 500. The MDA preemption section provides:

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

<sup>65</sup> *Lohr*, 51 U.S. at 486-90.

<sup>66</sup> *Id.* at 481.

<sup>67</sup> *Id.* at 499-500.

<sup>68</sup> *Id.* at 501.

<sup>69</sup> *Id.* at 502.

<sup>70</sup> *Horn*, 376 F.3d at 169-73. Thoratec's HeartMate had been through FDA's Pre-Market Approval (PMA) process, pursuant to 21 U.S.C.

§ 360(e)(c). *Id.* at 164-65. The device at issue in *Lohr* had received FDA approval through the "substantial equivalence" process set forth in 21 U.S.C. § 510(k). *Lohr*, 518 U.S. at 480. The *Lohr* Court found that the generality of the federal requirements imposed under the "substantial equivalence" process made the claim

quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

*Id.* at 501. The *Horn* court read this language to suggest that "the analysis would have been significantly different if the device at issue in *Lohr* had weathered a more exacting federal investigation, such as the PMA process." *Horn*, 376 F.3d at 169 (citing *Medtronic*, 518 U.S. at 501).

<sup>71</sup> *Id.* at 174-76. The Third Circuit reasoned that because Justice Breyer wrote separately to emphasize that he was "not convinced that future incidents of MDA preemption of common-law claims will be 'few' or 'rare,'" *Lohr*, 518 U.S. at 508 (Breyer, J., concurring in part), the appropriate reading of the *Lohr* decision was not the broad pronouncement made by Justice Stevens that few, if any, common-law duties had been preempted. Rather, the Third Circuit read *Lohr* to advise that "a court should carefully examine the state common law claim in order to determine whether that claim would impose a substantive requirement that conflicts with, or adds a greater burden to, a specific federal requirement." *Horn*, 376 F.3d at 174. The court concluded that "Horn's general state law claims would impose substantive requirements on [Thoratec] that would conflict with, or add to, the requirements imposed by FDA involved in the design, manufacturing, fabrication and labeling of the HeartMate." *Id.* at 176.

<sup>72</sup> *Id.* at 177-78 (quoting Letter Brief of *Amicus Curiae* United States, at 25-26).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 178 (quoting Statement of Interest of the United States of America, *Murphree v. Pacesetter*, 7-9).

<sup>75</sup> 21 U.S.C. §§ 351 *et seq.*

<sup>76</sup> Brief of *Amicus Curiae* Public Citizen, 2003 WL 22716063, \*13, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9<sup>th</sup> Cir. 2004).

<sup>77</sup> See Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895 (1994) (citing H.R. 6110, 73d Cong., 1st Sess. Section 25 (1933); S. 1944, 73d Cong., 2d Sess. S24 (1933); Hearings Before a Subcommittee of the Committee on Commerce of the United States Senate on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933)).

<sup>78</sup> *Id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Gade v. Nat'l Solid Wastes Management Ass'n.*, 505 U.S. 88, 96 (1992); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)).

<sup>79</sup> *Medtronic v. Lohr*, 518 U.S. at 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715-16 (1985)).

<sup>80</sup> See, e.g., Jamie Talan, Paxil Subject of Suit; AG, in First Action of its Kind, Accuses GlaxoSmithKline of Concealing Details About Drug's Risks, *NEWSDAY*, June 3, 2004, p. A06.

<sup>81</sup> See *id.*

<sup>82</sup> *Id.*

<sup>83</sup> *In re Paxil Litigation*, 2002 WL 31375497, \*1 (C.D. Cal. 2002).

<sup>84</sup> *Id.* at \*1-\*2.

<sup>85</sup> Kranish, *supra*, n. 18.

<sup>86</sup> The court lifted the preliminary injunction based largely on FDA's explanation of its own consideration of whether the advertisements were misleading. FDA's "extensive fact finding process engaged in by FDA with regard to Paxil and its approval of Paxil's advertisements" changed the court's "evaluation of Plaintiffs' likelihood of success on the merits to a degree dictating that the preliminary injunction should be denied." *In re Paxil*, 2002 WL 31375497 at \*2.

<sup>87</sup> *Id.* at \*1.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.* at \*1 (internal citation omitted).

<sup>91</sup> See Kranish, *supra*, n. 18.

<sup>92</sup> Matt Fleischer-Black, *Cosmetic Advocacy*, *THE AMERICAN LAWYER* (August, 2003).

<sup>93</sup> FDA's brief in the Paxil litigation was filed on September 5, 2002. *In re Paxil*, *supra*, n. 86 at \*1. Its *amicus* brief before the Ninth Circuit was filed on September 10, 2002. Brief of *Amicus Curiae* United States, *Motus v. Pfizer*, 358 F.3d 659, *supra*, n. 3.

<sup>94</sup> *Motus v. Pfizer*, 358 F.3d 659 (9<sup>th</sup> Cir. 2004) (*Motus III*). Zoloft is the registered trademark and brand name in the United States for sertraline hydrochloride, an SSRI. *Motus v. Pfizer*, 127 F. Supp.2d 1085, 1088 (C.D. Cal. 2000) ("*Motus I*").

<sup>95</sup> *Motus I*, 127 F. Supp.2d at 1086.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 1087.

<sup>98</sup> The text of the warning FDA instructed Pfizer to include was:

*Suicide*—The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Zoloft (sertraline) should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

*Id.* at 1088.

<sup>99</sup> *Id.* at 1089-90.

<sup>100</sup> *Id.* at 1092.

<sup>101</sup> *Id.* at 1096. The court summarized its findings:

[S]everal other courts have determined that FDA requirements are minimum standards and that FDA approval is not a shield to liability; 21 CFR § 314.70(c)(2)(1) permits manufacturers to strengthen warning labels without prior FDA approval; Pfizer has not limited its attack to any specific warnings; and finally the FDA has not made any statement that Pfizer could not include a strengthened suicide warning. In light of these factors, the Court finds that Pfizer has not established that it would be impossible to comply simultaneously with FDA requirements and with a state law or decision requiring a strengthened warning.

*Id.*

<sup>102</sup> *Motus v. Pfizer Inc.*, 196 F.Supp.2d 984, 999 (C.D. Cal. 2001) (*Motus II*).

<sup>103</sup> See *Motus III*, 358 F.3d at 660.

<sup>104</sup> See Kranish, *supra*, n. 18.

<sup>105</sup> Letter from Karen A. Barth (counsel for Flora Motus) to Daniel Troy, Esq., (January 3, 2003) (on file with author); see also Kranish, *supra*, n. 18.

<sup>106</sup> Kranish, *supra*, n. 18.

<sup>107</sup> Brief of *Amicus Curiae* United States, *supra*, n. 3, \*21 - \*22, *Motus III* (emphasis in original).

<sup>108</sup> FDA's argument that excessively strong warnings could result in under-utilization of a treatment were successful in the limited context presented by the case of *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004). In *Dowhal*, a citizen of California filed suit against SmithKline, seeking to force the company to include a warning required by the California Health and Safety Code in its labeling of nicotine replacement therapy (NRT) products. *Id.* at 917-19. The warning required by the California law would have warned that NRT products "contain[] a chemical known to the State of California to cause birth defects or other reproductive harm." *Id.* at 918. FDA did not permit SmithKline to use the stronger warning, however, instead requiring a label that warned that the "medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known." *Id.* at 919. FDA filed an *amicus* brief in support of preemption. Brief of *Amicus Curiae* United States, 2003 WL 23527781, *Dowhal*, 88 P.3d 1.

The court concluded that it had no reason to question FDA's expert determination that "the risk of harm may be so remote that it is outweighed by the greater risk that a warning will scare consumers into foregoing use of a product that in most cases will be to their benefit." *Id.* at 934. However, the court rejected the broader arguments raised in FDA's brief, noting that in most cases FDA

warnings and the California state warnings would “serve the same purpose — informing the consumer of the risks involved in use of the product — and differences in wording would not call for federal preemption.” *Id.* In the specific case of NRT use by pregnant women, however, the court reasoned that:

[T]he FDA warning serves a nuanced goal — to inform pregnant women of the risks of NRT products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking. This creates a conflict with the state’s more single-minded goal of informing the consumer of the risks. That policy justifies federal preemption here.

*Id.* at 935.

<sup>109</sup> *Id.* at \*23.

<sup>110</sup> *Motus III*, 358 F.3d at 661.

<sup>111</sup> *Needleman v. Pfizer Inc.*, 2004 WL 1773697, \*4 (N.D. Tex. Aug. 6, 2004) (slip op.) (“[T]he Court places weight on FDA’s unambiguous statement [in the *Motus* brief] that it would view any statement describing a relationship between Zolofit use and suicide as “false and misleading” and it would deem any state warning requirement preempted”); *Dusek v. Pfizer, Inc.*, No. H-02-3559, 12-13 (S.D. Tex. Feb. 20, 2004) (slip op.) (“The Court concludes that the FDA’s position as stated in the [*Motus*] amicus brief that any label suggesting that Zolofit can cause suicide would be false or misleading provides support for preemption”).

<sup>112</sup> Porter, *supra*, n. 11, 7.

<sup>113</sup> *Id.* at 9.

<sup>114</sup> *Kernats v. Smith Indus. Med. Sys., Inc.*, 669 N.E.2d 1300 (Ill. App. 1996).

<sup>115</sup> Letter Brief of *Amicus Curiae* United States, *Horn*, *supra*, n. 3, 29.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at 29-30.

<sup>118</sup> Pear, *supra*, n. 1.

<sup>119</sup> Richard A. Oppel, Jr. and Jim Yardley, *The 2000 Campaign: the Texas Governor, Bush Calls Himself Reformer; the Record Shows the Label May Be a Stretch*, THE NEW YORK TIMES, March 20, 2000, at A16.

<sup>120</sup> *Id.*

<sup>121</sup> See Stacey Shultz, *Mr. Outside Moves Inside*, U.S. NEWS & WORLD REPORT, March 24, 2003 (quoting Wayne Pines, former FDA official and current president of regulatory services and healthcare at APCO, a Washington, D.C. communications consulting firm.)

<sup>122</sup> John Carey, *Just What the Doctor Ordered for FDA?*, BUSINESS WEEK, August 5, 2002.

<sup>123</sup> *Id.*

<sup>124</sup> James G. Dickinson, *Bush Taming FDA? Some Think Not*, MEDICAL DEVICE & DIAGNOSTIC INDUSTRY, October 2001.

<sup>125</sup> *Id.* The position of FDA Commissioner remained vacant from January 19, 2001 through November 14, 2002, when Mark B. McClellan was sworn in as Commissioner. <<http://www.fda.gov/oc/commissioners/mccllellan.html>> (site visited 09/28/2004). In the 14-month period between his own appointment and that of Commissioner McClellan, Mr. Troy held at least 50 meetings with representatives of the industries FDA regulates, none of which were memorialized in any way. See Shultz, *supra*, n. 121.

Dr. Lester M. Crawford Jr., who was appointed deputy commissioner in February 2002 and headed the agency until McClellan’s appointment, was named to lead FDA as acting commissioner as of March 27, 2004, following Dr. McClellan’s departure. <<http://www.fda.gov/oc/commissioners/mccllellan.html>>.

<sup>126</sup> See Fleischer-Black, *supra*, n. 92.

<sup>127</sup> See Mulkern, *supra*, n. 1.

<sup>128</sup> See Kranish, *supra*, n. 18. Troy’s book, *Retroactive Legislation*, was published under the auspices of the American Enterprise Institute in 1998. See <[http://www.aei.org/publications/bookID.223/book\\_detail.asp](http://www.aei.org/publications/bookID.223/book_detail.asp)> (site visited 09/28/2004).

<sup>129</sup> See Kranish, *supra*, n. 18.

<sup>130</sup> See Carey, *supra*, n. 122.

<sup>131</sup> See Shultz, *supra*, n. 121.

<sup>132</sup> See <<http://www.house.gov/hinchey/issues/fda.shtml>> (site visited September 2, 2004), quoting from Affidavit of Jessica R. Dart, ¶6, *Dusek v. Pfizer, Inc.*, No. H-02-3559 (S.D. Tex. Feb. 20, 2004).

<sup>133</sup> Pear, *supra*, n. 1.

<sup>134</sup> See Letter Brief of *Amicus Curiae* United States, *Horn*, *supra*, n. 3, 29.

<sup>135</sup> See, e.g., Letter Brief of Public Citizen, Counsel for Appellant, at 3-4, *Horn v. Thoratec*, 376 F.3d 163, available at <<http://www.citizen.org/documents/HornSurreply4.601.pdf>>; see *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference due to government depends on, among other things, consistency and formality of government’s position).

<sup>136</sup> See Letter Brief of *Amicus Curiae* United States, *Horn*, *supra*, n. 3, \*25-\*26; Brief of *Amicus Curiae* United States, *Motus III*, *supra*, n. 3, \*23.

<sup>137</sup> See Letter Brief of *Amicus Curiae* United States, *Horn*, *supra*, n. 3, \*25.

<sup>138</sup> See Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 Washburn L.J. 549, 570 (2002).

<sup>139</sup> *Id.* at 571.

<sup>140</sup> *Id.*

<sup>141</sup> Young, *supra*, n. 1. Karen Barth Menzies of the Los Angeles law firm Baum Hedlund represents the plaintiffs in *In re Paxil*.

<sup>142</sup> *Id.*

<sup>143</sup> McGarity, *supra*, n. 138, at 571 (citing Michael D. Green, *Bendectin and Birth Defects*, 78 (1996)).

<sup>144</sup> *Id.*

<sup>145</sup> Brief of *Amicus Curiae* United States, *Motus III*, *supra*, n. 3, \*22. The brief was submitted on September 10, 2002. *Id.* at \*i.

<sup>146</sup> *FDA Statement Regarding the Anti-Depressant Paxil for the Pediatric Population*, June 19, 2003, available at <<http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01230.html>> (site visited 09/02/2004).

<sup>147</sup> *Id.* The statement also included a large block warning in its statement advising that “[d]espite the new possible concerns about the use of Paxil in children, it is essential that patients taking Paxil do not suddenly discontinue use of the drug.” *Id.* Nine months earlier, FDA’s brief in the Paxil litigation had asserted that the drug did not cause withdrawal symptoms but merely a “discontinuation syndrome.” See Kranish, *supra*, n. 18. FDA’s brief in the Paxil litigation was filed on September 5, 2002. *In re Paxil*, *supra*, n. 86 at \*1.

<sup>148</sup> Anna Wilde Mathews, *Mood Disorder: In Debate Over Antidepressants, FDA Weighed Risk of False Alarm*, THE WALL STREET JOURNAL, May 25, 2004, at A1. FDA sought the information for Prozac, Zoloft, Luvox, Celexa, Wellbutrin, Effexor, Serzone and Remeron. *Id.*

<sup>149</sup> FDA Public Health Advisory, *Reports of Suicidality in Pediatric Patients Being Treated with Antidepressant Medications for Major Depressive Disorder (MDD)*, October 27, 2003, available at <<http://www.fda.gov/cder/drug/advisory/mdd.htm>> (site visited 09/02/2004).

<sup>150</sup> *Id.*

<sup>151</sup> Transcript of the February 2, 2004 meeting of the Psychopharmacologic Drugs Advisory Committee with the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee, 12-13, available at: <<http://www.fda.gov/ohrms/dockets/ac/04/transcripts/4006T1.pdf>> (site visited 09/30/2004).

<sup>152</sup> Mathews, *supra*, n. 148.

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> Gardiner Harris, *FDA Links Drugs to Being Suicidal*, THE NEW YORK TIMES, September 13, 2004 at A1.

<sup>156</sup> *See id.*

<sup>157</sup> *Id.*

<sup>158</sup> Mathews, *supra*, n. 148.

<sup>159</sup> *Id.*

<sup>160</sup> Brief of *Amicus Curiae* United States, *supra*, n. 3, \*21 - \*22, *Motus III* (emphasis in original).

<sup>161</sup> *Id.* at 23.

<sup>162</sup> *Needleman v. Pfizer Inc.*, 2004 WL 1773697, \*4 (N.D. Tex. Aug. 6, 2004) (slip op.); *Dusek v. Pfizer, Inc.*, No. H-02-3559, 12-13 (S.D. Tex. Feb. 20, 2004) (slip op.), *supra*, n. 111.

<sup>163</sup> Young, *supra*, n. 1.

<sup>164</sup> Kranish, *supra*, n. 18.

### *About the Center for Progressive Regulation*

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