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DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
001	Memorandum	FDA Preemption of Tort Action [2 PAGES RELEASED IN WHOLE ON PRA RE-REVIEW 09/16/2025 JLS]	2	06/14/2002	
002	Report	FDA Preemption of Tort Action [37 PAGES RELEASED IN WHOLE ON PRA RE-REVIEW 09/16/2025 JLS]	37	06/14/2002	
003	Memorandum	Proposal: Include a Preemption Provision… [2 PAGES RELEASED IN WHOLE ON PRA RE-REVIEW 09/16/2025 JLS]	2	06/14/2002	

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SERIES:
Kavanaugh, Brett - Subject Files

FOLDER TITLE:
FDA Preemption

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RESTRICTION CODES

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P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
001	Memorandum	FDA Preemption of Tort Action	2	06/14/2002	P5;
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FDA PREEMPTION OF TORT ACTIONS CONCERNING FDA-APPROVED LABELING DECISIONS

Executive Summary

FDA implements the most comprehensive drug regulatory program in the world. Yet today judges and juries are routinely second-guessing the Agency's regulatory judgments through damage awards or injunctive relief in personal injury actions which challenge various FDA decisions and actions.

One common example are claims where jurors are invited by tort plaintiffs to declare FDA-approved labeling "inadequate" or "misleading" in some respect. Such lawsuits have always been inappropriate given the pervasive FDA control over such labeling. But they will be especially troublesome to -- and will effectively nullify -- the Agency's current effort to simplify drug labeling so as to better inform doctors, and thereby better protect the lives of their patients.

The preemption of tort actions challenging FDA labeling and related claims based on other alleged deficiencies which purportedly render FDA-approved warnings "inadequate", is thus a reasonable and necessary response to protect FDA's obligations to clearly communicate the risks of benefits of prescription drugs to health care providers.

The need for preemption is clear. There can be no doubt that FDA already exercises plenary control over the content and format of all labeling for prescription drugs. To put the matter simply, FDA mandates every word in such labeling on both the safety and efficacy of the drug.

As much as preemption is justified by the current pervasive FDA control over drug labeling, it will be absolutely essential if the Agency intends to promulgate the pending revision to its rules in the hope of achieving more focused -- and hence safer -- labeling. In its analysis of the proposed rules, the Agency recognized that "product liability" considerations have been one of the reasons labeling has become so complex that important warnings to physicians -- and consequently their patients -- have been diluted. FDA has therefore proposed that labeling be made much more focused through the use of a "Highlights" section and the elimination of data of little use to a practioner such as information on "adverse effects" which are unlikely to have been caused by the drug.

These are significant public policy goals which go to the heart of FDA's core mission of patient safety. But they will not be effected if manufacturers (and the Agency itself) must contend with contrary tort judgments based on the all-too-common view of plaintiff's experts or jurors that "it is always better to put more information into a label."

As an integral part of its current review of its labeling regulations, FDA should therefore preempt tort claims premised on any alleged "failure to warn" where the manufacturer has complied in issuing FDA-approved labeling.

For the same reasons, FDA should not permit tort plaintiffs to undermine its labeling decisions -- especially its insistence on simplified adverse drug event information -- through allegations of insufficient ADE reporting made in conjunction with a challenge to FDA-approved labeling. Again, there can be no doubt that the Agency's existing ADE regulations already pervasively "occupy the field" and hence justify preemption.

In the past, FDA has sometime taken the position that its regulation of prescription drug labels should not be accorded preemptive effect. However, it is well-established that "[a]n agency's view of what is in the public interest may change, either with or without a change in circumstances."

politically

fraud on the FDA

lobbying the FDA to keep labels from warning

FDA failing to warn

preemption on labeling re pregnancy

- complete rewrite on pref

FDA PREEMPTION OF TORT ACTIONS CONCERNING FDA-APPROVED LABELING DECISIONS

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One common example are claims where jurors are invited by tort plaintiffs to declare FDA-approved labeling "inadequate" or "misleading" in some respect. Such lawsuits have always been inappropriate given the pervasive FDA control over such labeling. But they will be especially troublesome to and will effectively nullify -- the Agency's current effort to simplify drug labeling so as to better inform doctors, and thereby better protect the lives of their patients. The preemption of tort actions challenging FDA labeling -- and related claims based on other alleged deficiencies, such as "inadequate" reporting of adverse drug events purportedly make those FDA-approved warnings "inadequate" -- is thus a reasonable, and indeed necessary, response to protect FDA's labeling programs.

I. The Current Disregard for FDA Labeling Decisions in Tort Actions

Although product liability lawsuits once might have been viewed as compatible FDA regulation, today's "mass tort" environment has rendered that view woefully obsolete. Plaintiffs now regularly obtain significant damage awards and injunctive relief inconsistent with FDA's labeling decisions by taking advantage of a system ill-equipped to assess the scientific merits (or lack of merit) of the plaintiffs' claims.

For some time, it has been clear that, left to their own devices, the courts will not defer to the primacy of FDA regulatory actions absent clear Agency preemption. For example, in Wooderson v. Ortho Pharmaceutical Corp., the Supreme Court of Kansas upheld a verdict against a prescription drug manufacturer for actual and punitive damages. The court held that the manufacturer had provided an inadequate warning in FDA-approved labeling notwithstanding clear evidence that the Agency had not only approved the labeling, but in fact had rejected proposals to include the very warning plaintiffs claimed was appropriate.[1]

In Brochu v. Ortho Pharmaceutical Corp., the First Circuit, sitting in diversity, similarly affirmed a verdict against a prescription drug manufacturer and held that labeling provided an inadequate warning even though FDA had not only approved the labeling, but had drafted the particular warning as uniform class labeling. Without appropriate guidance from the Agency, the court simply declared that "approval by the FDA of the language involved is not necessarily conclusive on the question of the adequacy of the warnings."[2]

In just the last few years, there have been many instances where pharmaceutical manufacturers have been forced to pay large judgments, or enter into massive settlements, as a result of "failure to warn" claims challenging labeling FDA has specifically reviewed and approved. To cite but a few:

- Hoffmann-LaRoche has been held liable for an allegedly inadequate warning of birth defects related to its drug Accutane, despite the fact that FDA had

[1] 681 P.2d 1038, 1042, 1057 (Kan. 1984).

[2] 642 F.2d 652, 658 (1st Cir. 1981).

repeatedly reviewed and approved those warnings. One state supreme court, in upholding such a verdict, recognized the importance of creating labeling that "reflect[s] a balance between the need for conciseness and a drug company's temptation to include every potential effect," but nevertheless held that FDA's approval of the specific warning language would not save the company from such tort claims.[3]

- Pfizer has been required to defend tort actions alleging that its labeling for Zoloft should have included a warning about the possible "side effect" of suicide, even though FDA had considered and rejected proposals to include such a warning in the label. Again, the courts simply rejected the defense that such specific FDA action should preempt inconsistent tort claims.[4]

- In a series of cases, Merrell Dow has been required to defend itself against claims that it should have included a warning about birth defects allegedly caused by its drug Bendectin, notwithstanding that FDA has repeatedly reviewed the relevant epidemiological data and concluded that no such warning was appropriate.[5]

- American Home Products has been forced to defend hundreds of lawsuits alleging that the warning for the side effect of primary pulmonary hypertension in the labeling for its drug Redux should have been worded differently and been enclosed in a "black box," despite the fact that the precise text and format of that warning, as well as the decision not to use a "black box" border, was expressly approved by FDA following full review of that issue by the Agency's medical staff and an advisory committee of outside experts employed by FDA for such purposes.

- Indeed, attorneys have become so adept at using advertising and the Internet to solicit plaintiffs that virtually any pharmaceutical is at risk for similar "failure to warn" attacks. For example, a recent visit to the website "ClassActionAmerica.com" maintained by one group of plaintiff attorneys reveals class actions that are either pending or allegedly in the process of "being filed" against the following drugs:

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3 Wagner v. Roche Laboratories, No. 95-1209 (Ohio 1996).

4 Motus v. Pfizer, Inc., No. 00-00298, (C.D. Cal. 2000).

5 See, e.g., Blum v. Merrell Dow Pharmaceuticals, No. 1, E.D. (Pa. 2001).

Accutane	Lotronex	Relenza
Albuterol	LYMErix	Rezulin
Avandia	Paxil	Serone
Baycol	Posicor	Sporanox
Cardura	PPA Products	Stadol
Celebrex	Propulsid	Trovan
Duract	Prozac	Vioxx
Lamisil	Raplon	Zithromax
Lipitor	Raxar	Zoloft

The website -- whose slogan is "Justice is Now a Click Away" -- invites potential plaintiffs to submit information on the drugs they have used, with promises of extensive remuneration.

The Agency thus needs to exercise its inherent authority to preempt inconsistent tort lawsuits to ensure that its regulatory decisions, especially in the critical area of drug labeling, are not effectively nullified. FDA's prior statements in this area do not foreclose such a measured response. Given the large damage awards and unwarranted injunctive relief becoming all too common in tort cases involving prescription drugs, the Agency would be more than justified in preempting such actions because they interfere with FDA's regulatory goals. Moreover, insofar as any "change" in policy is required to uphold the integrity of Agency labeling decisions, FDA may move away from its prior interpretations so long as it provides a reasoned explanation for its action.[6] As discussed in detail below, the current rule-making -- in which FDA has invited and received comments on the appropriateness of preemption as part of its comprehensive revision of its labeling regulations -- provides such an opportunity.

[6] Chevron U.S.A. Inc. v. Natural Resources Def. Council, Inc., 467 U.S. 837-38 (1984); Rust v. Sullivan, 500 U.S. 173 (1991).

II. FDA Preemption of Certain Tort Actions Would Be Consistent With General Principles of Federalism

There are three methods of preempting state and local regulation inconsistent with some federal regulatory program. In some instances, Congress specifically includes express language in the governing statute -- express preemption.[7] In other situations, where Congress has not included such express statutory language, preemption will still be implied where federal regulation occupies the field.[8] Finally, as the Supreme Court confirmed last year, state or local laws must also be preempted where they would otherwise "prevent or frustrate the accomplishment of a federal objective."[9]

It is well-settled that judicial injunctions and damage verdicts are "state action" for such preemption purposes: "Regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is, designed to be a potent method of governing conduct and controlling policy."[10]

In 1992, the Supreme Court applied this principle in the specific context of a product liability lawsuit. As the Court held, the "phrase 'state law' . . . include[s] common law as well as statutes and regulations" for preemption purposes.[11]

Since the Federal Food, Drug and Cosmetic Act does not expressly preempt tort actions as to pharmaceutical products, FDA's expression of its regulatory intent will be

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7 Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517 (1992).

8 Fid. Fed. Sav. & Loan Ass'n v. De la Cuesta, 458 U.S. 141, 152-53 (1982).

9 Geier v. Am. Honda Motor Co., 529 U.S. 861, 873-74 (2000).

10 Animal Legal Def. Fund Boston, Inc. v. Provimi Veal Corp., 626 F. Supp. 278, 282 (D. Mass. 1986) citing S.D. Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959).

11 Cipollone, 505 U.S. at 522.

the cornerstone of any preemption analysis. In assessing that intent, the courts will consider all types of Agency statements.[12]

As outlined below, given the pervasive manner in which FDA regulates the labeling of prescription drugs, the Agency would be more than justified in preempting tort lawsuits which are producing damage awards and injunctions contrary to FDA's best medical judgment. The rationale for such preemption is especially compelling today given the Agency's goal of comprehensively revising its regulations to achieve even more uniform, streamlined, and scientifically-supported labeling for physicians and patients alike -- a goal which will be frustrated by the insistence of tort plaintiffs that judges and juries condemn the very labeling FDA has reviewed and approved.

III. Prior FDA Statements on Preemptive Intent

Over the past twenty years, FDA has exercised its authority to preempt state or local regulation of drugs on a number of occasions, but thus far the Agency has not extended the same logic and policy considerations to preempt, in a more comprehensive manner, inconsistent tort judgments by judges or juries rejecting FDA-approved and mandated labeling. The current rule-making in which FDA is revising its regulations to require manufacturers to employ simplified labeling, which will omit unnecessary information and "highlight" significant data, will undoubtedly produce more clashes between such FDA policies and contrary tort lawsuits – with manufacturers caught in the cross-fire. For that reason alone, the Agency should include appropriate preemptive language in its adoption of those new regulations.

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[12] Hillsborough County Fla. v. Automated Med. Labs., Inc. 471 U.S. 707, 718 (1985).

In reviewing FDA's articulated positions regarding preemption, it is important to recognize that, for most of the years that FDA has regulated prescription drugs, it had not reached the level of pervasive control over drugs and drug labeling manifest today. As FDA has increasingly regulated drug production and labeling, however, it has also increasingly found preemption appropriate to achieve and protect its regulatory objectives.

The Food, Drug, and Cosmetic Act of 1938 required that manufacturers of marketed drugs demonstrate only that their products were safe for human use. Any labeling that accompanied these drugs, therefore, was largely promotional, and indications made therein did not need to be supportable.

The Drug Amendments of 1962, however, required manufacturers to demonstrate additionally that their products were effective for the treatments indicated on the labeling.[13] FDA was thus charged with the responsibility for reviewing and approving the labeling for every "new drug," including its package insert, to ensure that it was not false or misleading in any particular and that it did not omit any information necessary to the safe and effective prescribing of the drug by a physician. Manufacturers of all drugs cleared for marketing prior to the effective date of the 1962 amendments were required to submit efficacy data to expert panels of the Drug Efficacy Study Group, which was established by the FDA, in cooperation with the National Academy of Sciences and National Research Council, to review such information. The Group's review focused

[13] The Amendments also required good manufacturing practices, imposed recordkeeping requirements, broadened inspection authority, regulated prescription drug advertising, required drug establishment registration, and required reporting of adverse drug reactions, among other actions.

particularly on whether the efficacy information submitted by manufacturers supported the claims and indications made in their products' labeling. The FDA then published Drug Efficacy Study Implementation ("DESI") notices for each drug, which declared the efficacy rating for the drug with respect to each of its indications. Depending on the rating, a manufacturer might have been required to submit additional data in support of its claim or else amend the labeling to include only supportable claims.

The DESI review, was thus the first real FDA review of drug labeling; and it took a number of years to complete. The review established the critical importance of drug labeling: Of more than 16,500 claims made in labeling prior to 1962, only 19% were found to be supported by efficacy data, leading the FDA to conclude that "most package inserts fail in their primary purpose of providing the physician and the pharmacist with authoritative and objective guides to prescribing or dispensing" drugs.[14]

Not surprisingly, following the DESI review FDA proposed in June of 1975 its first set of regulations designating a required format for prescription drug labeling.[15] The rule, finalized in 1979,[16] specified the headings that should appear in drug labeling and the information that should be included under each heading.

The formal regulations governing the labeling of prescription drugs have remained largely unchanged since the promulgation of the 1979 rules. The FDA's approach to the manner in which these regulations should be implemented, however, has

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[14] "Conditions for Marketing Human Prescription Drugs," 40 Fed. Reg. 26142, 26144 (June 20, 1975).

[15] See "Labeling for Prescription Drugs Used in Man," 40 Fed. Reg. 15392 (Apr. 7, 1975).

[16] See "Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs," 44 Fed. Reg. 37434 (June 26, 1979).

not remained stagnant. Through the issuance of guidelines and its role as the approver of both the initial drug labeling as part of a New Drug Application ("NDA") and any proposed changes to the labeling post-marketing, the FDA has continuously asserted more and more control over the labeling.

In December 2000, the FDA proposed extensive revisions of its prescription drug labeling regulations. FDA's stated motivation behind this action is its concern that labeling has become overly complicated and is therefore no longer a useful tool for prescribing physicians. Based upon the findings of surveys and focus groups, the FDA has proposed, among other things, that drug labeling be divided into three sections: a section highlighting the prescribing information, an index to the comprehensive prescribing information, and the comprehensive prescribing information itself. The proposed rule thus represents another step in FDA's increasing control over prescription drug labeling.

As discussed above, the FDA did not begin aggressively regulating the format or substance of drug labeling until the mid- to late-1970s. It is not surprising, therefore, that, prior to that time, the Agency rarely addressed the issue of preemption of state laws relating to labeling. However, as FDA regulation of labeling format and substance has evolved and become increasingly specific, the FDA has repeatedly provided for the preemption of state regulation where it concludes such regulation would hinder federal regulation objectives in both labeling and related areas:

Reye's Syndrome Warnings. In 1986, FDA promulgated regulations to require that the labels of OTC aspirin products include a warning that they should not be used to treat chicken pox or flu symptoms in children without consulting a doctor about the risk

of Reye's Syndrome. In the preamble to its final rule, FDA noted that the voluntary public education and labeling efforts of the industry had produced considerable variances in the messages conveyed.[17] To increase consumer awareness, avoid public confusion, and achieve consistency in the marketplace, FDA therefore issued a uniform labeling requirement.

In the preamble of the regulation, FDA stated that it was "preempt[ing] State and local packaging requirements that are not identical to it with respect to oral and rectal OTC aspirin-containing drug products for human use."[18] Although acknowledging that state and local requirements might be appropriate in some circumstances, the Agency determined that any product label that differed from those established by its rule would undermine FDA's objectives of consistency and uniformity. And while the text of the final regulation itself did not contain express preemption language, FDA nevertheless relied on its statement of intent in the preamble to establish its preemptive effect.

Confidentiality of Adverse Event Reporters/Patients. In 1994, FDA became concerned that, although the Agency's own regulations prohibited the release of confidential information on doctors and patients involved in adverse drug event (ADE) reports -- a mainstay of the Agency's labeling information -- manufacturers might be compelled to disclose such information by state laws or rules permitting discovery in tort or other litigation.[19] To encourage health care providers to report such ADEs fully and

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17 51 Fed. Reg. 8180 (March 7, 1986).

18 51 Fed. Reg. at 8181.

19 59 Fed. Reg. 3944 (Jan. 27, 1994).

accurately, FDA therefore amended its regulations to preempt any such discovery in the courts.

FDA grounded this preemption on its belief that such discovery rules could conflict with its own ADE regulations:

> Although Congress did not expressly preempt State law in this area, the agency finds Federal preemption to be appropriate because such State or local laws, rules, regulations, or other requirements would impede FDA's ability to monitor product safety after approval to ensure that human drug products, biologics, and medical devices are safe and effective for their intended uses.[20]

Expressly preempting state tort discovery, the final regulation provides that

> No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report except as provided in this section.[21]

Tamper-Resistant Packaging for OTC Drugs. In response to the Tylenol poisoning cases in 1982, FDA promulgated regulations requiring tamper-resistant packaging for OTC drugs. In the preamble to its final rule, FDA once again preempted any state or local requirements that "were not identical to . . . [the FDA rule] in all respects."[22] It is noteworthy that, in this instance, the FDA rule established only general standards for tamper-resistant packaging (e.g., the packaging must have "an indicator or barrier to entry that would provide the consumer with visible evidence that the package

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[20] 60 Fed. Reg. 16962, 16963 (Apr. 3, 1995).

[21] 21 C.F.R. § 20.63(f)(2).

[22] 47 Fed. Reg. 50442, 50447 (Nov. 5, 1982).

had been tampered with or opened"), and thus left manufacturers with significant flexibility in choosing among various systems capable of satisfying that standard.[23] Nevertheless, the Agency concluded that any contrary state requirements must be preempted.

Again, although FDA cited its general "authority and responsibility . . . to establish a uniform national requirement for tamper-resistant packaging of OTC drug products," the text of the regulation did not contain express preemptive language.[24] As in the Reye's Syndrome case, FDA simply relied on its statement of intent in the preamble to the rule to establish preemption.

In an analysis that could equally be applied to tort actions questioning the appropriateness of FDA-approved labeling, the Agency recited a litany of situations in which state requirements could interfere with FDA's objectives -- e.g., forcing manufacturers to adopt a particular state's standard for products marketed throughout the country which would effectively negate the FDA regulations; compelling manufacturers to use certain packaging systems with no assurance that they were in fact the best to prevent tampering; forcing manufacturers to adopt separate requirements for each jurisdiction; and permitting differences in interpretation, such that a product meeting the federal requirement would nevertheless be deemed inadequate at the state level.[25]

Bernhardt v. Pfizer. Most recently, in November 2000, the Justice Department officially took the position that FDA labeling regulations preclude a court from ordering

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[23] Id. at 50444.

[24] Id. at 50449-52.

[25] Id. at 50448.

changes to approved prescription drug labeling in tort litigation. The plaintiffs in Bernhardt had sought a court-ordered "emergency notice" and "revised drug warnings" for users of the prescription drug Cardura and to require "revised warnings on Cardura labels and packaging."[26] The federal district court, sua sponte, asked the Government to submit its views on whether FDA's labeling regulations preempted the plaintiffs' claims. The Government, with FDA's concurrence, responded in Statement of Interest that

> Congress has assigned to the Food and Drug Administration . . . the exclusive responsibility to regulate and enforce the laws with respect to prescription drugs sold in the United States. Because the FDA's mission to protect the public health rests on its ability to maintain exclusive control over approved prescription drug labeling, the injunctive relief sought by plaintiffs -- both modifications to approved product labeling and the issuance of labeling in the form of warning letters -- intrudes upon the FDA's role and is preempted. In other words, to ensure that the public receives uniform, consistent information with respect to prescription drugs, and that this information is based on highly developed expertise, any request to order changes related to the approved drug labeling must be addressed directly and exclusively to FDA.[27]

In support of its conclusion that Congress intended FDA's regulation of drug labeling to be "exclusive," the Government described FDA's comprehensive program for the review and approval of product labeling and warnings. Given that pervasive regulatory regime, the Government recognized that it would frustrate FDA's ability to regulate prescription drug labeling if a court (much less a jury) could substitute its

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[26] Statement of Interest of the United States, at 3.

[27] Id. at 1-2. Ultimately, the Court in Bernhardt avoided the preemption issue, relying instead on the doctrine of primary jurisdiction to require the plaintiffs first to submit their request to FDA in the form of a citizen petition. Bernhardt v. Pfizer, 2000 WL 1738645, at *1 (S.D.N.Y. Nov. 22, 2000).

judgment for that of FDA.[28] (The Government declined to take a position regarding preemption of the plaintiffs' claims for monetary damages, although it acknowledged that "in certain circumstances" common law tort actions for inadequate warnings "may" not be preempted.)[29]

Unfortunately, the procedure that the court adopted in Bernhardt was highly unusual. As described below, most courts called upon to decide whether FDA regulations preempt common law tort actions do not solicit the views of the federal government – but rather simply allow a jury to substitute its views for those of FDA. The approach that the court followed in Bernhardt thus does not provide manufacturers or FDA with meaningful protection against tort interference with federal drug regulation.

* * *

FDA's increasing use of preemption parallels a similar expansion of use preemption doctrine by the courts. This trend in preemption jurisprudence was evident by at least the early 1990's. For example, as noted above in 1992 the Supreme Court decided Cipollone v. Liggett Group, Inc. holding that the Public Health Cigarette Smoking Act of 1969 preempted state tort law "failure to warn" claims stemming from the advertising or promotion of cigarettes notwithstanding that the statute did not explicitly preempt common law damages actions.[30]

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[28] Statement of Interest, at 7.

[29] Id. at 11, n.3.

[30] The statute referred only generally to "requirement[s] or prohibition[s]" imposed under state law. 505 U.S. at 515.

The expansion of preemption doctrine continued two years ago in Geier v. American Honda Motor Co.[31] In Geier, the Court held that a state law tort claim based on an automobile manufacturer's failure to equip a vehicle with a passive restraint device was preempted because it would constitute an obstacle to important federal objectives. Even though the relevant statute included a "saving" clause stating that compliance with a federal safety standard would not exempt any person from any liability under common law, the Court applied ordinary preemption principles and found a conflict between the state law suit and federal regulations. Specifically, the Department of Transportation had promulgated regulations regarding passive restraint devices that attempted to balance a number of competing policy considerations, including costs, safety risks, public acceptance, and comparative effectiveness. Under those regulations, automobile manufacturers had to equip some but not all of their vehicles with passive restraints. The Court recognized that plaintiffs' tort action rested on an alleged duty for manufacturers to equip all its cars with airbags, which duty "would have stood as an obstacle to the accomplishment and execution of the important ... federal objectives" embodied in the regulations.[32] Geier thus demonstrates the Supreme Court's increasing reluctance to allow state tort actions "where doing so would upset the careful regulatory scheme established by federal law,"[33] even when there is an express saving clause in the relevant federal statute.

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31 529 U.S. 861 (2000).

32 Id. at 881-882 (quotations omitted).

33 Id. at 870 (quotations omitted).

Following Geier, the Court last year examined preemption in the specific context of the Federal Food, Drug and Cosmetic Act in Buckman Co. v. Plaintiffs' Legal Committee.[34] In Buckman, the plaintiffs had alleged that a consultant to the manufacturer of orthopedic bone screws used by the plaintiffs made fraudulent representations to FDA regarding the intended use of the devices.[35] The Court held that the plaintiffs' claims conflicted with and were, therefore, impliedly preempted by the Federal Food, Drug & Cosmetic Act.[36] The decision rested on the Court's observations that in the area of medical device regulation the FDA has established a "detailed regulatory regime" and pursues "difficult (and often competing) objectives."[37] To allow state law fraud-on-the-FDA claims in such a setting would result in conflicts with carefully considered FDA policies and the Agency's responsibility to police fraud consistently with its judgment and objectives.[38] For example, such claims, arising from 50 states' tort regimes and exposing manufacturers to unpredictable civil liability, could discourage manufacturers from seeking approval of medical devices with potentially beneficial off-label uses despite FDA's general acceptance of off-label uses.[39] The Court additionally noted that such claims could also result in applicants overburdening the FDA

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34 531 U.S. 341 (2001).

35 Id. at 343.

36 Id. at 348.

37 Id. at 349-350.

38 Id. at 350-351.

39 Id.

with "a deluge of information that the [FDA] neither wants nor needs," compromising the Agency's ability to achieve its regulatory objectives.[40]

These decisions of the Supreme Court demonstrate that it will uphold decisions by federal agencies to preempt tort lawsuits founded on theories which conflict with federal objectives in areas even less pervasively regulated by agency action.

IV. The Justification for Preemption in FDA's Current Regulation Of Labeling

The Agency thus needs to exercise its inherent authority to preempt inconsistent tort lawsuits to ensure that its regulatory decisions, especially in the critical area of drug labeling, are not effectively nullified. FDA's prior statements in this area do not foreclose such a measured response. Given the large damage awards and unwarranted injunctive relief becoming all too common in tort cases involving prescription drugs, the Agency would be more than justified in preempting such actions because they interfere with FDA's regulatory goals. Moreover, insofar as any "change" in policy is required to uphold the integrity of Agency labeling decisions, FDA may move away from its prior interpretations so long as it provides a reasoned explanation for its action.[41] The current rule-making -- in which FDA has invited and received comments on the appropriateness of preemption as part of its comprehensive revision of its labeling regulations -- provides such an opportunity.

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[40] Id.

[41] Chevron U.S.A. Inc. v. Natural Resources Def. Council, Inc., 467 U.S. 837-38 (1984); Rust v. Sullivan, 500 U.S. 173 (1991).

That case for preemption is hardly difficult to make. There can be no doubt that FDA already exercises plenary control over the content and format of all labeling for prescription drugs. To put the matter simply, the Agency must review and approve every word in such labeling, insuring that it fairly and accurately describes the benefits and risks of the product. Although manufacturers may influence the labeling through discussions with FDA, the Agency is the ultimate arbiter of what is said. It is thus grossly unfair for judges or juries in uncoordinated tort cases to declare the very warnings FDA has approved to be "inadequate."

Although well-known to those who practice food and drug law, the comprehensive elements of FDA's labeling regulations merit brief review as the predicate for such preemption. Specifically, no drug may be marketed until FDA has approved a new drug application ("NDA") demonstrating that it is safe and effective for its intended uses.[42] As part of that NDA process, a manufacturer must submit the "proposed text of the labeling" for the drug, together with "annotations to the information in the summary and technical sections of the application that support the inclusion of each statement in the labeling."[43] Those data must include "all information about the safety of the drug product," including pertinent animal data, demonstrated or potential adverse effects, clinically significant drug/drug interactions, epidemiological studies on related drugs, and safety information presented by gender, age and racial subgroups.[44]

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[42] 21 U.S.C. § 355(a) (1994 ed).

[43] 21 C.F.R. § 314.50(c)(2)(i) (2000).

[44] 21 C.F.R. § 314.50(d)(5)(vi)(a).

FDA, in turn, may not approve an NDA until it is satisfied that the drug's labeling appropriately describes its indications, dosages, routes, methods, frequency and duration of administration; and any relevant hazards, contraindications, side effects, or precautions -- as well as conforms in all other respects to the Agency's rules governing the content and format of labeling.[45] Those regulations mandate all aspects of the drug's labeling including the type size and layout; the precise order and required contents of each section in the labeling; and whether certain types of warnings should be included in a "black box."[46] Of special importance here, the regulations expressly prohibit statements of differences of opinion with respect to warnings required in that labeling.[47]

FDA maintains this close control over prescription drug labeling even after approval. Most notably, a manufacturer may not amend such labeling without FDA approval, except for purely editorial or typographical changes, which must be reported to FDA in an annual report.[48] Generally, FDA approval is required before a labeling change can be made, although a manufacturer is permitted to amend its labeling to add or strengthen a contraindication, warning, precaution or adverse reaction, or to add or strengthen an instruction about dosage and administration for safety reasons, prior to receiving FDA approval of the change.[49] But, even in those instances, such changes must be submitted to the Agency for its ultimate review.

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45 21 C.F.R. §§ 201.100(c)(1); 314.125(b)(6),(8).

46 21 C.F.R. Part 201, Subparts A, B, D.

47 21 C.F.R. § 1.21(c)(1).

48 21 C.F.R. § 314.70.

49 21 C.F.R. § 314.70(c)(2) (2000).

The holder of an approved NDA similarly is subject to substantial reporting requirements after the drug is approved, such that FDA is kept abreast of any emerging information about a drug. The required post-approval reports include expedited and periodic reports of all foreign and domestic adverse drug experiences,[50] as well as annual reports of all new information that might affect the safety, effectiveness or labeling of the drug.[51] If FDA believes that any such information merits a change in the drug's labeling, it can request that the company make the change voluntarily.[52] If the manufacturer refuses to do so, the Agency has a broad range of enforcement options, up to and including withdrawal of the NDA and criminal penalties.[53]

Finally, FDA may require a manufacturer to disseminate "Dear Doctor" letters or other explanatory information regarding a prescription drug.[54] In such cases, FDA regulations mandate the content and format of the communications, down to the type of envelope that must be used, the size and style of the typeface, and the color of the border that must be included on the outside envelope.[55]

Given this pervasive FDA control over prescription drug labeling, it is patently unfair for tort plaintiffs to pursue "failure to warn" claims predicated on the alleged inadequacy of the very labeling FDA has mandated. Allowing such actions is poor public policy as well. Judges and juries hardly have the medical expertise needed to

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50 21 C.F.R. § 314.80.

51 21 C.F.R. § 314.81(b)(2).

52 21 U.S.C. § 393(b)(4).

53 21 U.S.C. §§ 355(e), 333.

54 21 U.S.C. § 375(b).

55 21 C.F.R. § 200.5 (2000).

determine whether a particular warning should have been added to the labeling for a prescription drug. Neither the Agency nor manufacturers should any longer be forced to modify their best medical judgments out of fear of such uninformed and often Draconian second-guessing.

V. Preemption Is Essential If The Agency's Desire for More Informative, And Hence Safer, Labeling Is to Be Realized

As much as preemption is justified by the current pervasive FDA control over drug labeling, it will be absolutely essential if the Agency intends to promulgate the pending revision to its rules in the hope of achieving more focused -- and hence safer -- labeling. In its analysis of the proposed rules, the Agency recognized that "product liability" considerations have been one of the reasons labeling has become so complex that important warnings to physicians -- and consequently their patients -- have been diluted. FDA has therefore proposed that labeling be made much more focused through the use of a "Highlights" section and the elimination of certain information on "adverse effects" which are unlikely to have been caused by the drug and similar data of little use to a practitioner.

The Agency began its explanation of these proposed changes by finding that

> [a]lthough the format and content requirements for prescription drug labeling in §§ 201.56 and 201.57 have enabled health care practitioners to prescribe drugs more safely and effectively, the requirements, together with various developments in recent years, have contributed to an increase in the amount, detail, and complexity of labeling information. This has made it harder for health care practitioners to find specific information and to discern the most critical information in product labeling.[56]

[56] Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics, 65 Fed. Reg. 81082, 81083 (Dec. 22, 2000).

The Agency further acknowledged that one reason for such prolix, and therefore less effective, labeling has been the specter of product liability litigation:

> The use of labeling in product liability and medical malpractice lawsuits, together with increasing litigation costs, has caused manufacturers to become more cautious and include virtually all known adverse event information, regardless of its importance or its plausible relationship to the drug.[57]

Although expressing some uncertainty on the extent of the problem -- and therefore calling for further comment -- the Agency noted that its new approach of reducing the amount of information included in labeling, and "highlighting" only the most important, could create additional problems for manufacturers in product liability cases:

> Other comments expressed concern about the inclusion of a highlights section because of its potential effect on product liability. The comments stated that including a highlights section would force manufacturers to pick and choose only certain parts of the warning information listed in the comprehensive information. One comment stated that this "would allow an expert witness testifying on behalf of a patient who suffered an adverse reaction that was listed in the full prescribing information to argue that a manufacturer's warning was inadequate or buried because that specific adverse reaction was not also highlighted in the Summary."
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> The agency recognizes that prescription drug labeling may be used as evidence in product liability cases and other types of civil actions to determine, among other things, whether a manufacturer has adequately disclosed information about risks associated with its drug. However, the agency believes that it is highly speculative to assert

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[57] Id.

> that, because certain risk information has been summarized in or omitted from the highlights section of prescription drug labeling (but included in its entirety in the comprehensive prescribing information), a manufacturer may be found liable in a product liability action based on a theory that the warning is "buried."
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> The agency is seeking comment on whether the inclusion of a highlights section would have a significant effect on manufacturers' product liability concerns and, if so, whether this concern has been adequately addressed in this proposal. If it is believed that product liability concerns have not been adequately addressed, the agency seeks comment on whether it could take different or additional measures to alleviate product liability concerns without eliminating the highlights section altogether, or lengthening it to an extent that it would no longer serve its intended purpose.[58]

In response to this request for comments, PhRMA explained that the Agency could achieve its goals of simplified, and hence more effective, labeling by preempting tort actions in which "experts" hired by plaintiffs invite jurors to second-guess the decisions of FDA and manufacturers to put certain information in one section of the labeling rather than in the "Highlights" -- or, indeed, to omit such information entirely in accordance with the Agency's new regulatory approach. Such preemption is, in fact, essential if FDA is to adopt a "Highlights" approach and to focus on adverse events that are more realistically related to the drug.

This last feature of the proposed regulations deserves some additional comment. FDA has long had recognized that its current labeling regulations, which call for the inclusion of all ADE reports "reasonably associated" with the subject drug, are producing

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[58] 65 Fed. Reg. 81087-88.

prolix "laundry lists" of such adverse events with little or no meaning for practitioners. As the Agency noted with regard to its proposal to adopt the more thoughtful standard endorsed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, adverse events should be included in labeling only where "a causal relationship between a medical product and an adverse event is at least a reasonable possibility. . . ."[59] Once again, the Agency has proposed this change not to assist manufacturers, but rather to make labeling more effective for physicians -- and hence enhance patient safety:

> The agency is proposing this change in terminology because the "reasonably associated" language in the current definition can be, and in many cases has been, interpreted as meaning that a reaction should be included merely if there is a temporal association, rather than a reasonable causal association, between a response and a drug. This has resulted in the inclusion of information in the "Adverse Reactions" section of labeling that is not meaningful to prescribers and which dilutes the usefulness of the clinically meaningful information.[60]

The Agency has concluded that such streamlining of labeling will both reduce medical costs and save lives. As to the former goal, the Agency explained that overly-inclusive labeling wastes precious physician time:

> The proposed new format for prescription drug labeling (i.e., package inserts or professional labeling) would reduce the time physicians, pharmacists, and other health professionals must spend reading prescription drug labeling by highlighting frequently used information, by including an indexing system to direct readers to more detailed material in other sections of the labeling, and by reordering

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[59] 65 Fed. Reg. 81003.

[60] 65 Fed. Reg. 81094.

> and reorganizing the detailed material to facilitate access to information deemed to be most important to prescribers.[61]
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> [T]he annual value of physician time save . . . over 10 years equals approximately $62.8 million.[62]

Even more importantly, the Agency found that such simplified labeling should improve physician decisions as to when and how to prescribe a drug:

> Under the proposed rule, the highlights section would emphasize the drug information that physicians report is the most important for decisionmaking. . . . *Moreover, certain information will be removed from existing professional labeling because the rule only allows inclusion of data that are pertinent to the clinical uses specified in the indications section. Consequently, this proposed rule would improve the ability of physicians to select the most safe and effective pharmaceutical treatments for their patients and to administer those treatments in the most safe and effective manner. In addition, the proposal may enhance the likelihood that physicians will communicate important information to patients, which could improve patient understanding and compliance with treatment.* FDA is unable to quantify the magnitude of these expected improvements in treatment effectiveness and health outcomes, but the agency believes they could be significant.[63]

Last, but by no means least, the Agency expressed its belief that such simplified labeling would avoid some debilitating -- sometimes fatal -- adverse drug events:

> *Because it will highlight important information about dosage, side effects, and contraindications, the proposed new prescription drug labeling format would decrease the number of adverse drug events (ADE's) caused by incorrect product use.* Many ADE's result from poor or incorrectly applied information (e.g., prescribing too high a

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61 65 Fed. Reg. 81104.

62 Id.

63 65 Fed. Reg. 81105 (emphasis added).

> dose for a patient with poor kidney function, or prescribing a drug to a patient with known contraindications) and are potentially preventable.
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> [A] study found that a majority of preventable ADE's (about 1 ADE per 100 hospital admissions) were related to errors or miscalculations in physician ordering, the stage most likely to be affected by improved prescription drug labeling information. Given the approximately 35 million hospitalizations annually in the United States, *these data suggest that about 350,000 ADE's among hospitalized patients are potentially preventable with better labeling for health professionals.*
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> The actual proportion of the ADE costs that would be prevented under the proposed rule cannot be predicted with certainty. If these costs were reduced by even 1 percent, however, the proposed rule would reduce hospitalization costs by $38.4 million per year. Over 10 years, the present value of these benefits would total $233.8 million. Furthermore, if additional averted costs (e.g., physician visits, additional outpatient costs, patient time, lost productivity) were included, the savings from the ADE's avoided would be substantially higher.[64]

These are all significant public policy goals which go to the heart of FDA's mission. But they will not be effected -- indeed, they are likely to be subverted -- if manufacturers (and the Agency itself) must contend with contrary tort judgments based on the all-too-common view of plaintiff's experts or jurors that "it is always better to put more information into a label."

In sum, it would hardly be fair for the Agency to prohibit drug manufacturers from including unnecessary safety information in drug labeling, while simultaneously

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[64] Id. (emphasis added).

refusing to acknowledge that such omissions will increase the manufacturers' exposure to unwarranted product liability claims. And such a policy would further undermine FDA's regulatory authority as well.

As an integral part of its current review of its labeling regulations, FDA should therefore announce its intent to preempt tort claims premised on any alleged "failure to warn" in FDA-approved labeling. As noted above -- and consistent with the Supreme Court's recognition that preemption need only be announced by an agency in its regulatory decisions -- FDA should include in its final rule a clear statement recognizing that such tort actions, demeaning the very labeling the Agency has approved, conflict with its comprehensive authority in this critical area.

VI. Preemption of "Failure to Warn" Cases Predicated On Alleged Inadequate Adverse Event Reporting

For the same reasons, FDA should not permit tort plaintiffs to undermine its labeling decisions -- especially its insistence on simplified ADE information -- through claims based on allegations of insufficient ADE reporting typically made in conjunction with a challenge to the adequacy of FDA-approved labeling. Again, from a preemption perspective, there can be no doubt that the Agency's existing ADE regulations already pervasively "occupy the field" -- and, as noted above, FDA has previously preempted certain aspects of tort litigation such as discovery requirements -- to preserve its control in this sensative area.

The comprehensive FDA rules on ADEs require manufacturers to establish effective procedures for worldwide surveillance of safety information relating to their drugs, expedited reporting of serious and unexpected ADEs whether occurring in the U.S.

or abroad, and periodic reporting of other nonserious or expected ADEs. FDA, in turn, routinely inspects manufacturers to assure that they comply with these demanding regulations. If the Agency identifies any failure to submit required reports, untimely reporting, misclassification of events, inadequate surveillance systems, or other deficiencies, it will issue a "Notice of Inspectional Observation" detailing the alleged violations. If the FDA is not satisfied that the manufacturer has an adequate plan to respond to such observations, it may issue a "Warning Letter" informing the company that the Agency considers it to be in violation of its regulations. FDA may impose significant administrative and criminal penalties if it determines that a company has failed to comply with its ADE regulations -- and the Agency has not been reluctant to do so.[65]

Despite this pervasive regulation of ADE reporting, plaintiffs' lawyers are often successful in convincing juries that a manufacturer is liable for some "failure to warn" based on purported violations of the ADE regulations, even absent any FDA determination that any violation has occurred. Yet, like the "fraud on the FDA" claims the Supreme Court recently held to be preempted in Buckman, whether a manufacturer has violated the ADE reporting regulations is a question that bears directly on the relationship between FDA and the entities it regulates -- and, as such, is inherently a matter for the Agency, not a civil tort court.[66]

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[65] 21 C.F.R. §314.80.

[66] Buckman Co. v. Plaintiffs' Legal Comm., 212 S.Ct. 1012 (2001).

In Buckman, an allegedly injured plaintiff contended that a manufacturer had evaded FDA's "thorough review" of certain medical devices by fraudulently filing a petition under what is known as the "510(k)" "grandfathering" process, and that but for the alleged fraud the device would not have been approved for use. The Supreme Court, however, held that such claims "conflict with, and are therefore impliedly

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Again, the vice here is not just unfairness to manufacturers; such contrary tort lawsuits undermine FDA policies as well. Specifically, if FDA were to "overregulate" ADE reporting -- as juries do when they assume every adverse event should be reported in every conceivable way -- manufacturers would flood the Agency with unwanted, useless information. As the pending proposal on labeling makes plain, FDA specifically wants to avoid that dangerous situation. The ADE regulations likewise evidence the Agency's desire to limit the amount and timing of information that is submitted; and the determinations regarding what is "serious," "nonserious," "expected," and so forth require considerable medical judgment. Allowing juries to force companies to flood FDA with useless information will thus inevitably undercut the Agency's regulatory objectives. As a necessary part of its proposals to develop simplified, focused labeling with respect to ADE information, FDA should therefore announce its intent to preempt "failure to warn" claims based on alleged violations of ADE reporting regulations.

VII. The Announcement of Preemption of Such Tort Theories in the Final Rule Would Be Consistent with Established Principles of Administrative Law

In light of this extensive and compelling record, the Agency will be more than justified in making preemption part of the final rule under its new labeling initiative. Such an action is also consistent with general administrative law principles.

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preempted by federal law." Id. at 1017. The Court reasoned that "[t]he FDA . . . has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Agency," and "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the Act. Id. at 1018 n.4.

A. Such a "Change" in Agency Position Can be Made

As noted above, in the past, FDA has sometime taken the position that its regulation of prescription drug labels should not be accorded preemptive effect.[67] However, there are no impediments to reconsidering this issue and reaching the opposite conclusion at this time. It is well-established that "[a]n agency's view of what is in the public interest may change, either with or without a change in circumstances."[68] In its landmark Chevron decision, the Supreme Court reaffirmed this principle:

> An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis.[69]

Similarly, in a case involving regulations promulgated by the Interstate Commerce Commission, the Court explained:

> [T]he Commission, faced with new developments or in light of reconsideration of the relevant facts and its mandate, may alter its past interpretation and overturn past administrative rulings and practice. . . . [T]his kind of flexibility and adaptability to changing needs and patterns . . . is an essential part of the office of a regulatory agency. Regulatory agencies do not establish rules of conduct to last forever; they are supposed, within the limits of the law and of fair and prudent administration, to adapt their rules and practices to the Nation's needs in a volatile, changing economy.[70]

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[67] But see Statement of the Interest of the United States in Bernhardt v. Pfizer, No. 00-Civ.-4042 LMM (S.D.N.Y.) (arguing that FDA labeling regulations preclude a court from ordering changes to approved prescription drug labeling in tort litigation).

[68] Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 57 (1983) (quoting Greater Boston Television Corp. v. FCC, 444 F.2d 841, 852 (D.C. Cir.), cert. denied, 403 U.S. 923 (1971)).

[69] Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837, 863-64 (1984).

[70] American Trucking Ass'n v. Atchison, Topeka, and Santa Fe Ry. Co., 387 U.S. 397, 416 (1967).

Indeed, less than two years ago, in the case overturning FDA's assertion of jurisdiction over tobacco products, all of the Justices of the Supreme Court indicated their agreement with this important principle. The four dissenting Justices argued, citing Supreme Court precedent, that FDA was allowed to change its mind about whether it had jurisdiction over tobacco.[71] The five Justices in the majority, who ultimately held based on a different rationale that FDA lacked jurisdiction because of contrary congressional enactments, emphasized that they did not disagree with the FDA's general ability to reverse a previous position: "[O]ur conclusion does not rely on the fact that the FDA's assertion of jurisdiction represents a sharp break with its prior interpretation of the FDCA. Certainly, an agency's initial interpretation of a statute that it is charged with administering is not 'carved in stone.'"[72]

There are other examples: In a 1996 opinion addressing the Comptroller of the Currency's regulatory authority, the Court held that "antiquity" of an agency's pronouncement is not a "condition of [its] validity" and that "the mere fact that an agency interpretation contradicts a prior agency position is not fatal."[73] And in a 1990 case involving the validity of Department of Health and Human Services regulations implementing statutes barring use of federal funds for abortion-related activities, the Court emphasized that it "has rejected the argument that an agency's interpretation is not entitled to deference because it represents a sharp break with prior interpretations of the statute in question."[74]

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71 FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 186 (2000) (Breyer, J., dissenting).

72 Id. at 156 (O'Connor, J.).

73 Smiley v. Citibank (South Dakota), N.A., 517 U.S. 735, 740, 742 (1996).

74 *Rust v. Sullivan*, 500 U.S. 173, 186 (1990).

In light of these authorities, there can be no doubt that the Agency may now move away from its prior position that its labeling regulations do not generally preempt inconsistent State requirements -- just as it has on a number of specific occasions as discussed above.[75]

B. The Public Has Been More Than Sufficiently Notified Such Provision Might Be Adopted

Those who have a vested interest in maintaining state court injunctions and damages awards that undermine the proposed changes to the federal drug labeling regulatory program can be expected to object to any FDA preemption in the final rule. They may even argue they did not receive sufficient notice that FDA was contemplating that issue, and lacked an opportunity to comment on it. However, any such contention would lack merit; and there is no reason to delay release of the final rule to accommodate such specious arguments.

The Administrative Procedure Act, which governs FDA rulemaking, requires only that the Agency publish a "[g]eneral notice of proposed rulemaking," including "either the terms or substance of the proposed rule or a description of the subjects and issues

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[75] It should be noted that the courts have said that an agency changing a longstanding position should supply a "reasoned analysis" justifying the change. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 57 (1983). In particular, an agency must "indicat[e] that prior policies and standards are being deliberately changed, not casually ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute." Greater Boston Television Corp. v. FCC, 444 F.2d 841, 852 (D.C. Cir. 1970), cert. denied, 403 U.S. 923 (1971). Of course, FDA is already required to incorporate in the final rules a "general statement of their basis and purpose." 5 U.S.C. § 553(c). FDA could likewise satisfy the "reasoned analysis" requirement by simply providing, in the release accompanying the Final Rule, an explanation that product liability lawsuits based on failure-to-warn claims are inconsistent with sound FDA regulation of labeling, and recognition of the increasingly pervasive character of FDA labeling regulations.

involved," in the Federal Register.[76] Of course, FDA has already complied with this requirement by publishing its notice of proposed rulemaking in this matter in December 2000.[77]

The fact that the proposed rule, as published in December 2000, did not contain the preemption provision now under consideration does not bar the Agency from including such a provision in its final rule. As the U.S. Court of Appeals for the D.C. Circuit has commented, "[t]he requirement of a submission of a proposed rule for comment does not automatically generate a new opportunity for comment merely because the rule promulgated by the agency differs from the rule it proposed, partly at least in response to submissions."[78] "A contrary rule would lead to the absurdity that in rule-making under the APA the agency can learn from the comments on its proposals only at the peril of starting a new procedural round of commentary."[79] Or, as the First Circuit has similarly held, since "in shaping the final rule [the agency] may and should draw on the comments tendered," opponents of a revised rule "have no right to insist that [the] rule remain frozen in its vestigal form."[80]

The determinative test is whether the new rule is a "logical outgrowth" of the proposed rule[81] or, as one court put it, "if at least the 'germ' of the outcome is found in

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76 5 U.S.C. § 553(b)(3).

77 65 Fed. Reg. 81081 (Dec. 22, 2000).

78 International Harvester Co. v. Ruckelshaus, 478 F.2d 615, 632 (D.C. Cir. 1973).

79 Id. at 632 n.51.

80 South Terminal Corp. v. EPA, 504 F.2d 646, 659 (1st Cir. 1974).

81 Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 547 (D.C. Cir. 1983).

the original proposal."[82] One representative case involved EPA rules changing the definition of "small refinery," a term affording certain companies more lenient treatment under anti-pollution laws.[83] In the notice of proposed rulemaking, EPA proposed to redefine "small refineries," for the first time, in terms of current production rather than capacity maximums.[84] However, the agency invited comments identifying and proposing ways to close any unintended loopholes in the redefinition that might allow companies to circumvent the rule and ultimately increase pollution.[85] In its final rule, in response to comments suggesting concern that refiners could manipulate the definition by cutting production just barely enough to qualify, EPA made the test more stringent by adding another prerequisite: not only must the "small refinery's" current production not exceed the maximum, but so also must its past production.[86]

On judicial review the D.C. Circuit held that the new definition was validly promulgated, and that the agency was not obligated to give new notice when it added the past production component. Despite the fact that the initial notice "did not list specific 'loopholes' that EPA might try to close," the Court ruled that the challenging party "was on adequate notice of the past production requirement" because (1) it "was aware generally that EPA was seeking to identify and close as-yet-undefined loopholes," and

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82 Natural Resources Defense Council v. Thomas, 838 F.2d 1224, 1242 (D.C. Cir.), cert. denied, 488 U.S. 888 (1988).

83 Small Refiner, 705 F.2d 506.

84 Id. at 546.

85 Id. at 546-47.

86 Id. at 546-48.

(2) it should have been aware from the comments of others that the past production requirement was being considered.[87]

Similarly, when OSHA promulgated in a final rule a lead exposure standard that differed from the proposed standard by an "obviously substantial" margin, the court nevertheless deemed the notice adequate because, even though the notice of proposed rulemaking did not mention the standard ultimately adopted, it asked for comment on "whether [the originally proposed] level incorporates an appropriate margin of safety."[88]

As described in greater detail above, in this case, the notice of proposed rulemaking FDA published in December 2000 clearly put into play the issue of the revised labeling rules' effect on product liability and whether preemptive effect should be accorded.

- Describing the unacceptable status quo, in which the pressures wrought by products liability lawsuits are at war with the ideal of meaningful labels, the FDA stated that "the use of labeling in product liability and medical malpractice lawsuits, together with increasing litigation costs, has caused manufacturers to become more cautious and include virtually all known adverse event information, regardless of its importance or its plausible relationship to the drug."[89]

- The Agency noted that some commenters were concerned that the inclusion of a highlights section might exacerbate products liability risks. In particular, the notice quoted the text of one comment regarding the possibility of plaintiffs' expert witnesses manipulating the highlights section to their strategic advantage in a failure-to-warn case.[90]

- The Agency specifically requested comment as follows (and repeated this request in the notice where it collected and set forth in one place all of the various requests for comment):

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87 Id. at 548.

88 United Steelworkers of America, AFL-CIO v. Marshall, 647 F.2d 1189, 1221 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981).

89 65 Fed. Reg. at 81083.

90 Id. at 81087.

> The agency is seeking comment on whether the inclusion of a highlights section would have a significant effect on manufacturers' product liability concerns and, if so, whether this concern has been adequately addressed in this proposal. If it believed that product liability concerns have not been adequately addressed, the agency seeks comment on whether it could take different or additional measures to alleviate product liability concerns without eliminating the highlights section altogether, or lengthening it to an extent that it would no longer serve its intended purpose.[91]

These references were more than sufficient to alert any observer that "additional measures to alleviate products liability concerns" – namely, preemption of state law claims that could subject a drug manufacturer to debilitating damages awards as a direct and foreseeable result of complying with the new labeling rules and implementing FDA-mandated labels – were one possible "logical outgrowth" of the rulemaking. The D.C. Circuit engaged in similar reasoning in recently upholding Department of Health and Human Services regulations that, for the first time in the final rule, required hospitals to evaluate a patient in a face-to-face assessment within one hour after placing him in restraints or seclusion.[92] Although the opponents of the regulations argued that "a generalized reference to face-to-face assessment in the preamble of the NPRM is insufficient," the Court of Appeals rejected this argument because, among other things, the notice of proposed rulemaking "stated that it was an open question as to whether further, more stringent requirements should be adopted" than those specifically prescribed in the proposed rule.[93] This rationale is directly analogous to FDA's

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91 Id. at 81088; see also id. at 81086 (emphasis added).

92 Nat'l Ass'n of Psych. Health Sys. v. Shalala, 120 F. Supp. 2d 33 (D.D.C. 2000).

93 Id. at 40.

solicitation of comments here on whether additional measures were necessary to alleviate products liability concerns.

Indeed, various parties submitted comments recommending that the agency consider giving the new regulations preemptive effect.[94] These comments underscore the adequacy of notice in two distinct respects: First, they demonstrate that several parties did in fact perceive that the issue of preemption was put into play by the notice of rulemaking, because they saw fit to submit comments on that issue. Second, the comments themselves, which FDA makes publicly available and could have been accessed by preemption opponents, should have removed any doubt that preemption was "on the table" and prompted any reasonable opponent of preemption to articulate its rebuttal.[95]

In sum, the Agency would be well within its discretion to add a preemption provision and issue the final rule without the formality of a new round of notice and comment and the delay and obstruction attendant to that process.[96]

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[94] See Comments of Pharmaceutical Research and Manufacturers of America dated June 14, 2001.

[95] See Small Refiner, 705 F.2d at 548 (challenging party "was closely involved in the entire rulemaking" and "was monitoring the docket"); Action for Children's Television v. FCC, 564 F.2d 458, 470 (D.C. Cir. 1977) (holding that opponents of rule incorporating self-regulation were adequately apprised, in part, because "the industry urged from the outset of these proceedings, in public comments available to [petitioners], that self-regulation was the only appropriate avenue for corrective action").

[96] If the Agency has any reservations about the appropriateness of new notice in these circumstances, there is a possible intermediate approach that can put to rest such doubts, without sacrificing the important policy concerns at stake and the necessity for immediate action. The Agency could proceed to issue the final rule, including the preemption provision, but state that it continues to consider preemption and invite interested parties to submit any comments on a post-promulgation basis. This approach has been specifically endorsed by the D.C. Circuit. District of Columbia v. Train, 521 F.2d 971, 997 (D.C. Cir. 1975) ("the EPA afforded the interested parties an opportunity to submit comments after the regulations were promulgated"), vacated on other grounds sub nom. EPA v. Brown, 431 U.S. 99 (1977).

The following outlines a comprehensive plan for implementing federal preemption of State laws and tort claims with respect to prescription drug labeling regulated by the FDA. Together with the development of an alternative compensation system, preemption would rationalize drug labeling for physicians, while enhancing protections for patients. Thus, the preemption initiative discussed here would be an essential element in transforming a tort system marked by pronounced uncertainties and high transaction costs for litigants into a far more predictable, efficient, and administratively rational system for prescription drug regulation. Such preemption is also independently necessary to ensure that FDA's labeling decisions – especially its current effort to simplify labels so as to make them more effective – are not undermined by the inconsistent judgments of lay judges and juries.

The anchor of the proposed plan is the promulgation of a final FDA labeling regulation that expressly preempts state-law tort failure-to-warn and other related claims. A final rule on the preemptive effect of FDA labeling is the best way to ensure that an FDA preemption policy is accorded binding legal effect in courts throughout the country. We also identify several actions that the agency could take, which are complementary to, but not substitutes for, the preemption regulation.

Proposal: Include A Preemption Provision In The Pending FDA Labeling Regulation

The FDA is currently considering a general revision to its labeling regulations for which it already has received comments. The preemption issue was noted in the NPRM, and some comments supporting broad preemption were submitted in response to the Agency's request for comments. In its comments, PhRMA expressed its opposition to the streamlined approach to labeling set forth in the proposed labeling regulation, noting in particular that the addition of a "Highlights" section to approved prescription drug labeling would "raise significant product liability issues" unless the regulation included a broad preemption provision. We propose that, in the final rule (and preamble thereto), the Agency include a provision declaring the broad preemption of state labeling laws and common law tort claims predicated upon allegations that any FDA-approved label (issued under either the old regulations or the new regulations) fails to supply adequate warnings.

The benefits of this proposal are:

- Formulating this regulation in the context of the existing rulemaking will allow the regulation to be implemented much more rapidly than a freestanding rulemaking addressing only preemption.

- Preemption is consistent with the broad rationales of the proposed labeling rule, which is designed, in part, to streamline labeling requirements in order to reduce the confusion created, in part, by product liability concerns.

- This final regulation would be accorded deference by courts, especially if the preemptive language in the regulation is accompanied by a strong, well-reasoned explanation of why the Agency decided to opt for broad preemption. The need to avoid confusion and to rationalize drug labeling are more than sufficient to justify what may be viewed as a change in the Agency's position on preemption.

Because an effective preemption provision would necessarily be broader than the scope of the currently proposed labeling regulation – which primarily regulates new labels and labels on prescription drugs approved in the five years prior to its final promulgation – FDA may provide a second notice-and-comment period in order to issue a final labeling rule that includes a broad preemption provision. (Such additional notice would preclude a court from overturning the rule on the ground that the FDA provided insufficient notice of its preemption regulation.)

Supportive FDA actions:

1) **Issue a "Guidance Document" on Preemption.**

The FDA frequently issues "guidance documents," and has formalized the procedures to do so. The FDA could issue such a guidance document to explain that the availability of state tort law remedies frustrates the agency's control over the approval of labeling for prescription drugs, and more generally undermines the agency's ability to control the drug review process.

Even though FDAMA requires that they be subject to limited notice-and-comment review, guidance documents do not have the force of law. A well-reasoned guidance document, however, may be accorded some deference in courts to the extent the court regards the reasoning as persuasive.

2) **File amicus briefs in product liability cases; issue formal letters or make other formal pronouncements expressing the FDA's view that its labeling regime has preemptive effect.**

The FDA (in collaboration with the Department of Justice) could target key preemption cases to file *amicus* briefs that argue in a strong and systematic way for preemption under the specific circumstances of the respective cases, and at the same time support the new comprehensive labeling preemption policy. The agency also could prepare letters on preemption in a variety of contexts. A policy supporting preemption could be advanced by letters prepared by the FDA Office of Chief Counsel that support the preemption of state failure-to-warn claims or labeling laws.

Amicus briefs may be persuasive to courts that have an open mind about preemption arguments. A concerted *amicus* effort by the Agency would be aimed at leveling a playing field that has been skewed by the inconsistent positions on preemption taken by the Agency in the past in the labeling context.

The Agency also could issue letters expanding on its reasoning regarding preemption. While letters would be very easy to prepare and issue, their legal effect is probably marginal. Neither *amicus* briefs nor letters would be subject to any form of pre-publication public review.