Congress of the United States
Washington, DC 20515

February 23, 2006

Honorable Michael O. Leavitt
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue
Washington, D.C. 20201

Dear Mr. Secretary:

We strongly object to the FDA's recent announcement of its view that the FDA-approved drug label preempts a sweeping range of traditional state actions related to drug labeling and advertising, including state product liability and medical malpractice cases. The Bush Administration's preemption claim reverses a long-standing FDA policy of permitting complementary State activities intended to protect consumers from unsafe drugs. Although this policy reversal will substantially undermine the States' ability to protect their citizens, neither affected state and local entities, nor the general public were given an opportunity to comment.

A reversal of long-standing agency policy against pre-emption should have been narrowly drawn to protect principles of federalism and the safety of the drug supply, with strong legal support in statutory language, legislative history, and caselaw. Instead, the list of preempted claims is so broad as to sweep in a range of state actions that would be entirely consistent with FDA decisions, as well as actions on issues that FDA has never even considered. For legal support, the preamble relies on misleading characterizations of the governing statute and irrelevant cases, while ignoring contrary legislative history. It also fails to disclose that, to date, courts have overwhelmingly rejected the Administration's attempts to assert its preemption theory.

The FDA's preemption announcement is particularly troubling at a time when FDA's own ability to protect Americans from unsafe drugs has been called into question by a series of cases in which the FDA was slow to warn consumers of significant drug risks. This is not the time to prevent the States from filling in the gaps in the federal safety net. The announcement provides unfortunate evidence that the Bush Administration is more committed to protecting drug industry profits than to building a sound system for ensuring drug safety.

Because the FDA announcement is so misleading in its justification for the preemption claim, and provided no opportunity for dissenting views to be heard, we are setting forth in more detail its critical omissions and misstatements.

1. The announcement simply ignores clear evidence that the Bush Administration's preemption claim is inconsistent with Congress' intent.

The Supreme Court has made clear that the validity of any preemption claim by a federal agency turns on whether Congress intended to preempt the state law(s) in question. *See, e.g., Bates v. Dow,* 125 S. Ct. 1788, 1801 (2005) ("In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest'"); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case"). In its announcement, however, the FDA simply ignores clear evidence that Congress did not intend the drug label to preempt state law except in very narrow circumstances.

The principle purpose of the FDA's announcement appears to be to preempt state court products liability actions. The legislative history of the Federal Food, Drug, and Cosmetic Act (FFDCA) establishes, however, that, far from intending to preempt state court products liability actions, Congress relied on their existence. When Congress enacted the Food, Drug, and Cosmetic Act in 1938, it specifically rejected a proposal to include a private right of action for damages caused by faulty or unsafe products regulated under the Act on the ground that such a right of action already existed under state common law.[1]

From 1938 until 2001, state court liability actions for injuries resulting from approved drugs proceeded uninterrupted by FDA or Congress. As the Supreme Court stated only last year in a case rejecting a claim that the federal pesticide label broadly preempted state law:

> The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.

Bates v. Dow, 125 S. Ct. at 1792 .

Congress has never acted to preempt state product liability cases involving drug labeling or advertising. To the contrary, when Congress passed the landmark 1962 Drug Amendments to the FFDCA, it said, in section 202, that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a *direct and positive conflict* between such amendments and such provision of State law." [Emphasis added.] We note that this is much narrower preemptive language than, for example, the preemptive

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[1] *See, e.g.*, Hearings Before Subcomm. of Comm. On Commerce on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933); Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. 895, 924 &n. 130 (1995) ("Congress rejected a provision in a draft of the original FD&C providing a federal cause of action for damages because 'a common law right of action [already] exists'") (quoting legislative history).

language of the Federal Insecticides and Rodenticides Act (FIFRA), which provides that States "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. §136v(b).[2] Nothing in the FFDCA preempts requirements that are "different or in addition to" those required by federal law, unless they are in "direct and positive conflict" with federal law.

Until the Bush Administration, the FDA has, in fact, always interpreted this "direct and positive conflict" preemption authority narrowly. It was never interpreted to preempt state products liability cases or additional, but non-conflicting, labeling requirements. In the announcement, the Bush Administration was able to cite only three prior cases of preemption based on the drug label, each limited to preempting state laws that contradict a particular label statement established by regulation on an over-the-counter drug. In contrast, the January announcement purports to preempt not only state laws that contradict specific FDA requirements, but a sweeping range of laws and court actions having even indirect bearing on drug labeling or advertising.

2. The announcement falsely states that the Bush Administration preemption claim reflects longstanding FDA policy.

The announcement states that it has been the government's "longstanding" position that the wide range of state actions listed in the preamble is preempted. The announcement further claims that this "longstanding" position is based on the agency's view that the drug label represents "both a ceiling and a floor," i.e., that the label is so comprehensive that no other information can or should be provided to physicians or patients. To the contrary, until the Bush Administration, the FDA's consistent position was that the drug label did not preempt state laws except in very narrow circumstances, precisely because the drug label does not always reflect advances in knowledge about drugs once they are marketed.

Most telling, of course, is that the preamble to the proposed rule, issued in 1999, specifically stated that the rule did not preempt state actions. It is also clear, however, that the position stated in the preamble reflected a continuous and longstanding agency position against preemption. For example, in promulgating the predecessor regulation on drug labeling in 1979, the agency said: "drug labeling does not always contain the most current information and opinion available to physicians about a drug because advances in medical knowledge inevitably precede formal submission of proposed new labeling by the manufacturer and approval by FDA," that "[c]ommunication of significant medical information should be encouraged, not restricted," and that "the addition to labeling and advertising of additional warnings ... is not prohibited by

[2] Even with FIFRA's broader language, the Supreme Court has refused to hold that FIFRA preempts state liability actions that are based on "parallel" state requirements. *Bates v. Dow*, 125 S. Ct. 1788 (2005).

[FDA's] regulations."[3] The notice cited with approval a state court case holding that a company may have a common law duty to revise its warnings earlier than obtaining FDA approval.

Much more recently, in 1996, FDA's Chief Counsel said in a speech that FDA had a "longstanding presumption against preemption" and 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."[4]

The assertion on pages 46-47 that medical malpractice actions are also preempted is particularly suspect. The FDA has never, in its entire history, claimed that the drug label preempts actions against health care practitioners for failure to warn patients of drug risks.

Whether the FDA's new view of preemption in fact represents a "longstanding" position, or is a reversal of a longstanding position is highly significant to its legal strength. The Supreme Court has repeatedly held that an agency assertion of preemption that reverses prior longstanding agency policy is entitled to little or no weight by the courts. *Bates v. Dow*, 125 S. Ct. at 1801 ("The notion that FIFRA contains a nonambiguous command to pre-empt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."); *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000).

3. The announcement mischaracterizes the FDA's authority to ensure that the drug label contains up-to-date warnings of drug risks.

To justify its sweeping preemption argument, the agency makes a number of assertions about the comprehensive nature of FDA's review of safety and effectiveness information and the adequacy of the disclosure of risks and benefits on the drug label. Several of these assertions are seriously misleading. Perhaps the most significant and troubling misrepresentation of FDA's regulation of the drug label is the claim that, after approval, the approved drug label continues to provide, on a timely basis, comprehensive information about the risks and benefits of the drug. The preamble also strongly implies that FDA can immediately require the inclusion of new information in a drug label whenever the agency thinks disclosure of such information is warranted.[5] While both of these claims appear to be essential to the agency's policy justification for preempting all state action, neither is true.

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[3] FDA, *Specific Requirements on Content and Format of Labeling for Human Prescription Drugs*, 44 Fed. Reg. 37,434, 37,435 et seq. (June 26, 1979).

[4] Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, (1997).

[5] *See, e.g.*, p. 39: "FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA

FDA approves drugs based on small clinical trials in which the participants are carefully screened. At the time of approval, the drug label contains only the information that could be definitively established by the small trials. These trials cannot produce reliable evidence about low-frequency side effects, nor do they always provide adequate information about the benefits and risks of using the drug in a much broader population.[6]

Unfortunately, important information about how to use the drug safely and effectively that is developed after approval is not always added to the drug's label in a timely way. This is primarily because, despite the preamble's implication to the contrary, FDA has very limited authority to require the collection of that information or to require its timely inclusion in the label. Although the agency can and does monitor reports of adverse events after approval, it is well-recognized that such reports rarely provide definitive evidence of risks. Frequently, additional studies are needed to confirm and define risks that are signaled by adverse event reports. After approval, however, FDA cannot, except in narrow cases, require a drug company to study further benefits and risks. When such studies are conducted voluntarily, they may take many years to complete.

More importantly, the label is owned by the manufacturer, not by FDA, and FDA cannot require a company to change the label, short of winning a lengthy court proceeding, completing a rulemaking, or withdrawing the drug from the market. None of these options can be accomplished in less than a matter of months or years. In practice, this inability to require immediate changes in the label leaves the agency having to negotiate changes in the drug label with drug manufacturer. There are many examples, including the recent Vioxx case, in which the manufacturer refused FDA's request to add important new risk information to the label for many months, and even then watered down the language requested by FDA.[7] According to FDA testimony, there was a gap of 7 months between FDA's request that Merck add new information about cardiac risks of the drug and the date Merck actually added the information.[8] There are

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continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate."

[6] FDA, Managing the Risks from Medical Product Use, at pp. 7-8 (1999), accessed online at http://www.fda.gov/oc/tfrm/riskmanagement.pdf.

[7] Senate Committee on Health, Education, Labor, and Pensions, Testimony of Sandra Kweder, FDA, *FDA's Drug Approval Process: Up to the Challenge?,* 109th Congress (March 1, 2005).

[8] House Committee on Government Reform, Testimony of Steven Galson, FDA, *Full Committee Hearing on Ensuring the Safety of FDA-Approved Drugs*, 109th Congress (May 5, 2005) (testimony attachment, accessed online at: http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4090B1_04_E-FDA-TAB-C.htm).

many other examples in which FDA issues a "public health advisory" or other public warning about a newly identified drug risk that is not in the drug label

Finally, the label carries little or no information about either the risks or the benefits of new uses of a drug that are discovered after approval, unless the manufacturer chooses to seek approval of those "off-label" uses. FDA's preemption announcement fails to acknowledge any of these common delays in adding important information to the drug label.

4. The claimed preemption sweeps in many state actions that are not even arguably in conflict with FDA's oversight of drug labeling and advertising.

The announcement lists several types of state actions that FDA claims would be preempted. Although the announcement claims that it is only preempting state actions that are in conflict with federal regulation, these categories are so broadly worded that they would sweep in many state actions that are completely consistent with FDA's regulation of drug labeling and advertising. In some cases, they would sweep in state actions on issues that FDA has never even considered. The agency appears to believe that it has authority to prevent states from requiring disclosure of information about drug risks, or providing damages for failure to disclose such risks, even if the information is truthful and not in conflict with the approved label or with FDA's view of the risks and benefits of the drug.

A partial list of examples follows. These examples undercut the FDA's argument that the claimed preemption is necessary to prevent conflicts with federal regulation. They also appear to violate Executive Order 13132, which provides in section 4(c) that "[a]ny regulatory preemption of State law shall be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated."

a. The announcement provides no exclusion from preemption in the situation that occurred in the Vioxx case, i.e., where FDA has requested a change in the drug label based on new information, and the manufacturer fails to make the change for a prolonged period, during which injuries occur. According to FDA, if a State issued a warning identical to that proposed by FDA, or a citizen brought a claim for an injury that occurred during the period that the drug company failed to provide the warning requested by FDA,[9] those actions would be pre-empted.

b. The agency's broad language would also appear to preempt any state actions concerning risks that have been disseminated by FDA through means other than the drug label, but which the manufacturer has not yet agreed to put in the label. Because there is a frequent lag between the discovery of risk information and its incorporation in the drug label, FDA (and

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[9] According to the announcement, such actions would be preempted unless FDA had "required" the change at the time of the state action. (p. 46). As described earlier, FDA has no authority to "require" a change in labeling except through time-consuming rulemakings or court or administrative adjudications, none of which would permit prompt warnings of newly discovered risks.

manufacturers) use a variety of methods to disseminate risk information to physicians and patients, including letters, bulletins in medical journals, news releases, and the FDA website. For example, the FDA issued a "public health advisory" in March of 2005 warning of a possible association between two eczema drugs and cancer. The manufacturer did not update its label to include this risk until 11 months later. The FDA apparently intends to prevent states from taking actions that are completely consistent with such non-label warnings. For example, a state court action against a health care practitioner for failure to provide a warning to a patient about a risk disseminated by FDA through any means other than the label would apparently be preempted.

c. The agency contends that the approved drug label preempts not only claims related to label warnings but claims related to advertising. The announcement states that an action against an ad for "making statements that FDA approved for inclusion in the drug's label" would be preempted. As FDA is well-aware, it is unfortunately very common for manufacturers to disseminate ads that include positive statements from the drug's label but omit important negative information from the label. It is apparently the agency's intention to preempt a state court action based on an ad that included positive statements from the drug's label and omitted negative information.

d. The announcement claims, without explanation of any kind, that the drug label preempts state malpractice actions against health care providers "for claims related to dissemination of risk information to patients beyond what is included in the labeling." [page 47.] The unqualified language of this statement would appear to preempt cases against physicians for failure to warn a patient of risks associated with an off-label (unapproved) use, since, by definition, such risks rarely appear in the approved drug label. Yet, the FDA rarely conducts any review of the data on off-label uses, and makes no claim that the approved drug label represents a comprehensive source of data on such uses.

5. The announcement fails to admit that the Bush Administration's attempts to assert this kind of preemption in the courts have been overwhelmingly rejected.

The preamble states that the Bush DOJ has filed amicus briefs in state court actions on behalf of the FDA arguing that the state court actions were preempted by the FDA drug label. It is our understanding that the defendant in one of these cases, Pfizer, has also filed copies of the FDA amicus brief in several other state court actions around the country. It is further our understanding that the FDA's argument has been rejected by the courts in the majority of the cases where it has been considered.

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Such a significant reversal of FDA's long-standing practice of permitting complementary State consumer protection efforts should not be based upon a litany of mischaracterizations and omissions of law and FDA policy. It is time that the Bush Administration turn its efforts toward protecting American consumers instead of the interests of the pharmaceutical industry. If you have any questions regarding this letter, please contact Rachel Sher, of Congressman Waxman's staff at (202) 225-3976.

Sincerely,

Henry A. Waxman
Ranking Member
Committee on Government Reform

John D. Dingell
Ranking Member
Committee on Energy and Commerce

Sherrod Brown
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce