****Letters Included****

**FOR IMMEDIATE RELEASE** **CONTACT:** Laura Capps/Melissa Wagoner
February 23, 2006 (202) 224-2633

**KENNEDY, DODD, WAXMAN, DINGELL, AND BROWN CALL ON BUSH ADMINISTRATION TO STOP FDA PROVISION THAT UNDERCUTS STATE LAWS THAT PROTECT PATIENTS**

Washington, DC: Today Senator Kennedy and Senator Dodd sent a letter to Secretary of Health and Human Services Leavitt urging him to stop a provision in the FDA drug labeling regulation that would undermine State consumer protection laws, including product liability laws. The Senators ask Secretary Leavitt to explain the justification behind shielding the drug industry from lawsuits. Representatives Dingell, Waxman, and Brown also sent a letter to Secretary Leavitt questioning the basis for the FDA's claim that State lawsuits related to prescription drugs should be barred by FDA regulation of prescription drugs.

Below are the texts of the letters. PDFs of the letters with signatures are available upon request.

February 23, 2006

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Leavitt:

We are writing to express our concern about the final rule published on January 18, 2006 in the Federal Register amending 21 CFR parts 201, 314, and 601. The rule modifies drug labeling requirements in order to give information to physicians in a more concise and appropriate manner. We certainly support such an initiative, and believe it will help physicians provide better care to their patients.

However, the preamble to the final rule asserts broad and vague federal preemption of state drug labeling, advertising, and product liability laws. Such an assertion is inconsistent with long-standing Food and Drug Administration practice and Congressional intent. In fact, the preamble to the proposed rule, published in the Federal Register on December 22, 2000, explicitly stated that "this proposed rule does not preempt state law." At the very least, such a drastic reversal of policy with such far-reaching implications should be subject to public consideration and an opportunity for comment on whether the agency has the legal authority to preempt state requirements.

We strongly believe that states have an important role to play in protecting consumers and patients from unsafe drugs, and question the notion that the FDA alone can provide this protection. As a former Governor, you understand that important advances in public health and safety have been achieved at the state level. This new FDA claim of preemption would undermine state laws, even in cases where those laws address an area where FDA has not acted, and would smother the ability of states to take reasonable steps to protect public health and the safety of their citizens. Given recent questions about FDA's ability to ensure the safety of prescription drugs, it is a particularly inopportune time to remove the safety net that state consumer protection laws provide.

We are somewhat comforted by reports that Scott Gottlieb, Deputy Commissioner for Medical and

Scientific Affairs at the FDA, has stated that the preamble assertion that State product liability claims are preempted by FDA regulation of prescription drug labeling is not legally binding. This statement is consistent with the agency's regulations, which state that a preamble statement is an advisory opinion under 21 CFR 10.85(d)(1) that "may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement," as provided under 21 CFR 10.85(j). However, Dr. Gottlieb's statement notwithstanding, further clarification of the Administration's intent is necessary. We respectfully request that you provide answers to the following questions no later than March 31, 2006.

1. When Congress enacted the Federal 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. *See, e.g.*, Hearings before Subcommittee of Committee 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).

In section 202 of the Drug Amendments of 1962, Congress stated 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." Since 1938, Congress has never chosen to preempt State product liability actions through amendments to the Act.

Given these unambiguous statements of Congressional intent, please explain—
(a) Why the agency completely ignores the clear legislative history that Congress intended State product liability actions to survive under the federal law, and
(b) why a statutory statement that state law is preempted only in cases of "direct and positive conflict" does not control the agency's contrary interpretation of the law.

1. In the December 2000 proposed rule, the agency stated that the regulation would <u>not</u> preempt state law. In the preamble of the final rule, on pages 43 and 44, the agency cited only three specific FDA regulatory requirements – all with respect to over-the-counter products – that FDA has described in preambles from before 2000 as preempting State law. These examples suggest that FDA has pursued preemption only narrowly in the past. Yet the final preamble asserts that it has been the government's "longstanding" position that state actions related to drug labeling and advertising, and even medical malpractice, are preempted. Please explain this dubious assertion and provide all agency statements before 2001 with respect to this issue.

1. Under Executive Order 13132, issued by President Reagan and reissued by President Clinton, a federal agency such as FDA must consult with State and local authorities about, and examine, the effects on States and localities of each regulation it issues. In the proposed rule, FDA indicated that the regulation would not preempt State law. We understand that, relying on this representation and their own analyses of the proposed rule, the States did not comment on it. Please describe what the agency did to consult with State and local governments about this regulation.

1. FDA justifies its sweeping preemption argument by making a number of seriously misleading assertions about the comprehensive nature of the agency's review of safety and effectiveness information and the adequacy of the disclosure of risks and benefits on the drug label. 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 at page 39 also strongly implies that FDA can immediately require the inclusion of new information in a drug label whenever the agency decides disclosure of such information is warranted. Neither of these assertions is true, however.

Important information about how to use a drug safely and effectively that is developed after approval is not always added to the drug's label in a timely way, because FDA has very limited authority to require the collection of such information or require its timely inclusion in the label. Although the agency monitors reports of adverse events after approval, such reports rarely provide definitive evidence of risks, and additional studies are often needed to confirm and define any 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 often take years to complete, if they are completed at all.

More importantly, the label is owned by the manufacturer, and FDA cannot require a company to change the label, short of initiating a lengthy court proceeding or withdrawing the drug from the market. Both of these options take months or even years. In practice, this inability to require immediate changes in the label means the agency must negotiate changes in the drug label with the drug manufacturer. As a result, manufacturers can delay for months before adding important new risk information to a drug's label, and can water down the language requested by FDA. For example, it took more than 18 months for Merck to add new information about cardiac risks to the label of Vioxx.

Is the agency now claiming that it has the authority to require manufacturers to conduct post-approval studies to assess newly discovered risks, or that it has authority to require immediate label changes? If not, what is the basis for FDA's argument that the drug label always contains up-to-date information on newly discovered risks? Is it FDA's position that the Vioxx label at all times contained information that correctly described FDA's view of the risks of that drug? Would claims be preempted that Merck failed to warn patients who used Vioxx?

* * *

If you have any questions about this request, please do not hesitate to let us know, or have you staff contact Ben Berwick with Senator Dodd (224-5484) or David Bowen with Senator Kennedy (224-7675). Thank you for considering this important request on drug labeling, and we look forward to your reply.

With respect and appreciation,

Edward M. Kennedy
United States Senator

Christopher J. Dodd
United States Senator

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] <#_ftn1>

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 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] <#_ftn2> 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 <u>not</u> 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 <u>against</u> 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 [FDA's] regulations."[3] <#_ftn3> 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] <#_ftn4>

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] <#_ftn5> While both of these claims appear to be essential to the agency's policy justification for preempting all state action, neither is true.

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] <#_ftn6>

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] <#_ftn7> 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] <#_ftn8> There are 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] <#_ftn9> 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 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,

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Henry A. Waxman
Ranking Member
Committee on Government Reform

John D. Dingell
Ranking Member
Committee on Energy and Commerce

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

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