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**MEMBERS OF CONGRESS QUESTION FDA PROPOSAL DESIGNED
TO CREATE LIABILITY SHIELD FOR DRUG AND DEVICE COMPANIES**

WASHINGTON, DC — Today Representatives Henry A. Waxman, John D. Dingell, Frank Pallone, Jr., Rosa L. DeLauro, and Edward Markey, and Senators Edward M. Kennedy, Patrick J. Leahy, and Christopher J. Dodd, questioned the basis for a new Food and Drug Administration (FDA) proposal that was apparently designed to shield pharmaceutical and device companies from liability for injuries sustained by American consumers as a result of unsafe products.

“We are concerned that the intent of this proposal is to protect companies in the pharmaceutical and device industry from being held liable for marketing products they know are unsafe,” said the members in a letter to FDA Commissioner von Eschenbach. “Such a policy change comes at the expense of consumers and violates the mission of the FDA.”

FDA’s proposed rule would amend the regulations that permit companies to promptly update their drug and device labels with new safety information without waiting for FDA approval. These regulations serve the vitally important public health function of ensuring that patients and healthcare providers are made aware of safety risks associated with their medical products at the earliest possible moment.

Given that FDA failed to identify a public health basis for why this lengthy proposal was necessary at this point in time, the letter’s authors ask FDA to answer questions justifying the expenditure of the agency’s limited resources on this effort.

The complete text of the letter follows:

Dear Dr. von Eschenbach:

We are writing to express our profound regret about FDA’s proposed rule to amend the regulations that permit companies to promptly update their drug and device labels with new safety information.^[1] FDA has failed to provide any justification for expending its very limited resources on issuing this 26 page proposal that will serve only to deprive American consumers of critically important and timely information about the safety of their drugs and medical devices. We are concerned that the intent of this proposal is to protect companies in the pharmaceutical and device industry from being held liable for marketing products they know are unsafe. Such a policy change comes at the expense of consumers and violates the mission of the FDA. The issuance of the proposed CBE rule is not an isolated case, but part of a pattern of actions in the Bush

Administration's final months to permanently insulate the drug and device industry from liability.^[iii]

FDA's current regulations permit manufacturers to change their labels to add or strengthen a contraindication, warning, precaution, or adverse reaction without waiting for approval by the agency of such a change.^[iii] These regulations, also known as the "changes being effected (CBE) supplements" regulations, serve the vitally important public health function of ensuring that patients and healthcare providers are made aware of safety risks associated with their medical products at the earliest possible moment.

Prior to the implementation of these regulations over 20 years ago, manufacturers were forced to seek FDA approval before making virtually all changes to FDA-approved products.^[iv] Industry found this policy burdensome and requested that the agency change it — they contended that "this requirement is unnecessary, takes FDA reviewers away from more important work, and causes costly delays for applicants who must defer making changes in approved products until the supplement is approved."^[v]

FDA itself also recognized that a policy that would permit companies to make certain changes without first seeking FDA approval "would help concentrate the agency's limited resources more on applications for marketing, and would also permit pharmaceutical manufacturers to institute certain postmarketing changes sooner."^[vi] Thus, in 1982, the agency and industry agreed that: (1) FDA, with its very limited resources, could not be expected to approve every possible change to the ever-increasing number of regulated medical products; and (2) permitting manufacturers to add certain safety information to labels before FDA approval would assure that the American public was warned about risks associated with their products in a timely way.

Since 1982, FDA's funding situation has taken a dramatic turn for the worse. Today, FDA is an agency that is all but starved of resources. Experts from every affected sector agree that this desperate funding situation has rendered FDA unable to protect the American public from even the most basic threats, including contaminated food, tainted and dangerous drugs, and faulty medical devices. According to FDA's own Science Board, FDA's ability to carry out its mission is so compromised by loss of resources that American lives are now at risk.^[vii]

In the face of this public health crisis, the Bush Administration has turned its back on American consumers. At a time when the FDA lacks the resources to adequately protect Americans from unsafe drugs and devices, it is astonishing that the Bush Administration has opted to dedicate FDA's strained resources to protecting the drug and device industry from liability for marketing dangerous products. The 26 page CBE proposal has no purpose other than to shore up the industry's legal arguments for avoiding liability. Indeed, the proposed rule fails to identify a single problem associated with these regulations that would warrant a modification, much less a public health threat of such magnitude as to put issuing the proposal at the top of FDA's priority list. We note, however, that the proposal was immediately cited by the Solicitor General in a letter

to the United States Supreme Court in support of the industry's argument that FDA approval preempts individual product liability cases.^[viii]

We are further concerned about FDA's characterization of the proposed rule as an effort to merely "codify the agency's longstanding view on when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency's review of such change."^[ix] To the contrary, the proposed changes would instead drastically limit the situations in which a manufacturer is permitted to make add or strengthen a contraindication, warning, precaution, or adverse reaction without waiting for FDA to approve such a change. Under FDA's proposal, a manufacturer would now be prohibited from adding or strengthening a contraindication, warning, precaution, or adverse reaction in the absence of FDA approval unless there is "evidence of a causal association."^[x]

This proposed rule sets forth a much higher standard than was previously applied in FDA's regulations and will inevitably result in fewer company-initiated warnings. Further, it is apparently designed to bolster the argument by companies defending against lawsuits that the regulations precluded them from adding contraindications, warnings, precautions, and adverse reactions in the absence of FDA approval, whereas under FDA's current regulations, it is clear they would have been free to do so.

Because Section 314.70 currently permits manufacturers to warn consumers of potential risks at the earliest moment, FDA's proposal will also result in a delay in getting consumers important information about the safety of their drugs and medical devices, while FDA takes the time it needs to review and approve those warnings.

The preamble to FDA's January 16 proposed rule refers to the new labeling change authority set forth in the recently enacted Food and Drug Administration Amendments Act of 2007 (FDAAA) and asserts that this legislation "confirm[s] that Congress intends FDA to carefully regulate the content of labeling for approved products."^[xi] It is indeed true that, in FDAAA, Congress intended to give FDA, for the first time, the clear authority to require certain changes in drug labeling. Vioxx is a painful illustration of what had previously been a serious gap in FDA's authority. In that instance, FDA haggled with the company about the content of the labeling change for over 14 months while consumers continued to take the drug, completely unaware of the serious health risks associated with it. Thus, FDAAA provides FDA with the ability to avoid this kind of protracted negotiation so that the agency can ensure that the important safety information it believes should be in the label is promptly added.

The preamble, however, makes a glaring omission in its description of congressional intent with respect to FDAAA's labeling change authority. FDA failed to cite the "Rule of Construction" which clearly demonstrates Congress' equally important goal: to preserve the responsibility of drug companies to promptly update their own product labels to reflect the most current safety information available. That section states:

(I) Rule of Construction.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).^[xii]

Congress was well aware of FDA's CBE supplement regulations. The rule of construction was intended to clarify Congress' intent to preserve the fundamental premises of the CBE regulations: that drug companies are much better positioned to know the risks associated with their own products, that the public should be promptly warned about those risks, and that we cannot rely upon a very over-burdened and under-funded FDA to promptly review and approve such warnings before they are added to product labels.

Given that FDA has failed to provide any evidence or rationale for its proposal, we would like to request the following information:

1. Please provide data on the number of CBE supplements the agency has received each year from 1982 to the present;
2. Please describe any cases in which a manufacturer used the CBE procedure to add or strengthen a contraindication, warning, precaution, or adverse reactions in a manner that harmed the public health, including the dates of such cases, and explain why the agency believes that modifying the regulations has become a high public health priority at this time;
3. Please provide any documents demonstrating concern on the part of the Center for Drug Evaluation and Research or the Center for Devices and Radiological Health about misuse of the CBE regulations, or about public health risks arising from its current language; and
4. Please provide the number of FTEs used to issue this proposed rule and a timeline for when work began on this effort.

Please provide a response to this request by no later than February 13, 2008.

FDA is one of the nation's preeminent public health agencies. Every day, Americans count on the FDA to protect them from unsafe foods, drugs, and medical devices. In stark contrast to this vitally important public health mission, the agency's proposed rule protects the profits of the pharmaceutical and medical device companies rather than the health and safety of American consumers. We urge you to reconsider this action.

Sincerely,

Henry A. Waxman
Chairman
House Committee on Oversight
and Government Reform

Edward M. Kennedy
Chairman
Senate Committee on Health, Education,
Labor, and Pensions

John D. Dingell
Chairman
House Committee on Energy and
Commerce

Patrick J. Leahy
Chairman
Senate Committee on the Judiciary

Edward J. Markey
Chairman
Subcommittee on Telecommunications
Housing,
and the Internet
House Committee on Energy and
Commerce

Christopher J. Dodd
Chairman
Senate Committee on Banking,
and Urban Affairs

Frank Pallone, Jr.
Chairman
Subcommittee on Health
Rural
House Committee on Energy and
Commerce
Agencies

Rosa L. DeLauro
Chairwoman
Subcommittee on Agriculture,
Development, Food and Drug
Administration, and Related
House Committee on Appropriations

[i] Food and Drug Administration, *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 Fed. Reg. 2848 (Jan. 16, 2008) (proposed rule) (hereinafter “Proposed Rule”).

[ii] It was recently revealed that the Bush Administration is similarly diverting FDA resources to developing and issuing a document whose apparent purpose is to protect drug and device manufacturers from prosecution for illegal marketing. Letter from Chairman Henry A. Waxman to FDA Commissioner Andrew C. von Eschenbach, M.D. (Jan. 22, 2008) (online at www.oversight.house.gov/story.asp?ID=1696).

[iii] 21 CFR 314.70, 21 CFR 601.12, and 21 CFR 814.39.

[iv] Food and Drug Administration, *New Drug and Antibiotic Regulations*, 47 Fed. Reg. 46622, 46634 (Oct. 19, 1982) (proposed rule).

[v] *Id.*

[vi] *Id.* at 46635.

[vii] *FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology*, 3 (Nov. 2007) (online at www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf).

[viii] Letter from Solicitor General Paul D. Clement to Honorable William K. Suter, Clerk, Supreme Court of the United States (Jan. 16, 2008).

[ix] Proposed Rule, *supra* note 1, 2848.

[x] Proposed Rule, *supra* note 1, 2853.

[xi] Proposed Rule, *supra* note 1, 2850.

[xiii] 21 U.S.C. 355(o)(4)(I).