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September 22, 2004

Dr. Lester Crawford
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Crawford:

As you know, I have been following closely the Food and Drug Administration's unsolicited intervention into private state lawsuits on behalf of drug companies and medical device manufacturers being sued by individuals harmed by their products. I believe these activities undermine FDA's primary mission of protecting the public health and must stop. During the course of my research into this issue, however, I have come across a related matter that reaffirms my belief that FDA is not fulfilling its mandate.

On March 22, 2004, the Food and Drug Administration issued a Public Health Advisory asking the manufacturers of ten anti-depressants to add a new warning to their labels regarding worsening depression and suicidality in patients being treated with antidepressant medications. This was considered to be a critically important step by many medical experts who have long been calling on FDA to warn doctors and patients about such a link. That is why I was deeply troubled to find that the final label FDA subsequently approved was significantly weaker and effectively undermined the primary purpose of the March advisory.

One of the most important points in the March advisory was the following sentence:

Although FDA has not concluded that these drugs cause worsening depression or suicidality, health care providers should be aware that worsening of symptoms could be due to the underlying disease or might be a result of drug therapy.

The need for doctors and patients to be aware of a possible linkage between drug therapy and worsening depression or suicide was at the heart of the recommendations by FDA's advisory committees and a key part of the March advisory. I was therefore disturbed to see that in the final FDA-approved drug labels there is not a single reference to anti-depressants and their possible causation of worsening depression or suicidality. Instead, the labels go to considerable length to say without equivocation that a causal link between the drugs and worsening depression or suicidality has not been established.

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Another very disturbing issue is the omission of a critical word in the "Information for Patients" section of the label, which is also the section that patients and their families are most likely to read. The March advisory made clear that if patients experience certain adverse symptoms they should "report such symptoms *immediately* to their health care provider." The final label, however, omits the word "immediately," thereby reducing the sense of urgency the March advisory intended to instill.

These changes from FDA's public health advisory along with a number of other changes that further undermine the sense of urgency conveyed in the March advisory are disturbing. I am very concerned about how FDA came to agree with the drug makers on this weaker label.

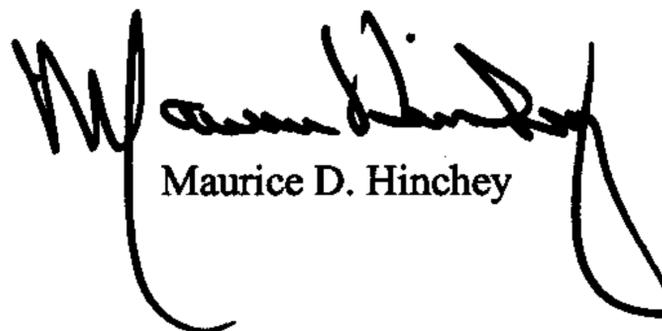
In order to review the process that led to these changes being made, I request that you provide me with the following materials by October 8, 2004:

- All documents, memoranda, letters, phone logs, e-mails and meeting materials prepared by, or sent or received by, anyone at FDA concerning the drafting or implementation by the ten specified manufacturers of the March 22, 2004, Public Health Advisory; and
- A list of all meetings between FDA personnel and any representative of the ten manufacturers, concerning the new labels, and the names of all attendees.

Unfortunately, this appears to be the latest episode in FDA's recent pattern of siding with the drug industry rather than carrying out its responsibility to protect the public health. It is well known now that your Chief Counsel, an attorney who formerly represented a major drug company, has filed unsolicited briefs in support of drug manufacturers being sued by people harmed by anti-depressants. Now we learn that FDA has weakened the new warning label that is currently on anti-depressants. It is important that we determine why this label was weakened to ensure that this does not occur again. This is particularly true in light of the fact that new, stronger warnings concerning a causal link between anti-depressants and suicide are expected to be issued by FDA as a result of the most recent recommendations from its advisory committees. All efforts should be taken to make certain these new warnings are not weakened as well.

Thank you for your attention to this matter. I look forward to your response.

Sincerely,



Maurice D. Hinchey