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October 14, 2009
To Margaret.Hamburg@fda.hhs.gov
and by fax to 301-847-3531

Margaret H. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hamburg:

Thank you for your thoughtful response to our letter of June 6. We have carefully considered the plans you described in your letter of September 25 for dealing with the issues we raised. Because we believe these plans are inadequate, we are writing today to urge a specific alternative.

When we wrote to you in June, we cited the case of AM2PAT, a small company that manufactured and sold syringes. The syringes were contaminated by bacteria that caused deaths and serious illnesses in December 2007. Soon afterwards the company was shut down. However, long before the calamity and the shutdown, the FDA had ignored clear warnings of safety violations requiring strong intervention. In our letter we asked that you request an investigation of this case by the Inspector General of DHHS – in particular, an investigation of the FDA's role as an enabler of wrongdoing by AM2PAT.

A "never before" event

Our decision to write today's letter is tied to a remarkable event of great promise that took place three weeks ago at the FDA.

We refer to the FDA's September 2009 preliminary report on the Menaflex knee device (31 pages plus appendices). Even two experienced reporters of the *New York Times* were impressed by the report: "The agency has never before publicly questioned the process behind one of its approvals, never admitted that a regulatory decision was influenced by politics, and never accused a former commissioner of questionable conduct" (article by Gardiner Harris and David M. Halbfinger of the *Times* on September 24).

The September report on the Menaflex did not appear out of nowhere. It was clearly inspired by a March 6, 2009, article on the Menaflex, "Political Lobbying Drove FDA Process," by Alicia Mundy in the *Wall Street Journal*. The report and the article both describe the same troubled history of the Menaflex during its review and final approval for marketing. Both documents identify the four members of Congress whose pressure on the agency influenced the review of the Menaflex.

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Although the FDA report is the longer and more detailed of the two accounts, the story told by the writers of the report is not much different from the story published by the *Wall Street Journal.*

There is, however, a profound difference between the two documents. The FDA report was prepared by three officials at the highest levels of the agency. Thus, unlike the article in the *Wall Street Journal*, the report bears the FDA's stamp of approval, so to speak. Clearly implied are two ideas: that the FDA considers the original account of wrongdoing to be accurate, and that the FDA will take appropriate corrective action on various internal problems spotlighted by the example of the Menaflex. It is the first time in many years that the FDA has acted so decisively, and it is presumably why the *Times* reporters were agog.

On the other hand . . . .

Now we turn to the AM2PAT case. The FDA stamp of approval is lacking in all full accounts of this case. As noted in our letter of June 6, the case has been covered thoroughly in the press. But now, more than a year after the main facts were reported by journalists, the FDA has yet to take official notice of this case as it did of the Menaflex case. We think it's fair to say that the FDA leadership, by ignoring the AM2PAT case, is turning a blind eye to a notorious example of FDA deficiencies that contributed to several deaths and hundreds of injuries, some of them permanently disabling.

The AM2PAT syringes did vastly more harm than the Menaflex. As far as we know, the Menaflex has not caused any deaths or serious injuries or perhaps any injuries at all. Indeed, the Menaflex remains on the market, still with the FDA's approval. Despite the procedural and regulatory violations that are the main subject of the FDA report, the agency has indicated that it has no basis to question the safety of the Menaflex.

Returning to the AM2PAT case: it's in a class by itself. We are not aware of any other case in recent years in which the deficiencies of the FDA and the resulting serious harm to patients are more obvious. For this reason we believe that the AM2PAT case, if subjected to careful, public examination, would be of unusual value to the FDA. Such an examination would provide detailed evidence of shortcomings in the agency's handling of this particular case and, by extension, its handling of other past and future cases as well. A report on the AM2PAT case would provide a virtual roadmap to some of the sweeping reforms that the FDA needs and that you want.

New laws or regulations were not needed

When the FDA report on the Menaflex was prepared, the mere act of investigating and publishing the report, with its recommendations, had instant benefits.

As a result, we doubt that agency regulations will be disregarded in the future as they were during the Menaflex review; that members of Congress will again brazenly pressure the Commissioner to give special treatment to a medical product under review by the agency; or that written records of nonstandard procedures by agency personnel will be kept as poorly in the future as they were for the Menaflex. These specific, real benefits were achieved without any new laws or regulations. An investigation and public report did the trick. It's likely that similar and possibly greater benefits, though in different areas of FDA regulation, would accrue to the agency simply through the act of investigating and reporting the AM2PAT case.

There is also the question of the financial resources that the FDA needs to meet its regulatory responsibilities. This issue was not discussed in the Menaflex report, but writers of any report on the AM2PAT case should be directed to discuss the question of numbers of staff available for review and inspection of devices, their training, and related matters – not only to inform the public, but for the enlightenment of those responsible for setting the FDA budget.

Like the *Times* reporters, we too are impressed by the quality of the FDA's report on the Menaflex. We therefore believe that the AM2PAT case could be examined either by the OIG, as we originally suggested, or by the FDA itself.

We urge you to reconsider your decision to defer action on the AM2PAT case. In your letter of September 25 you wrote that the "OIG is already conducting a study to evaluate FDA's adverse event reporting system for medical devices," and you add, "I plan to wait for the final OIG study and the outcome of Dr. Shuren's evaluation of CDRH's approach to regulating medical devices before determining whether any additional evaluation is warranted." We see no reason why an examination and public report on the AM2PAT case cannot proceed in parallel with the two studies you identify in your letter. Indeed a study by the FDA focusing in detail on the agency's shortcomings in the AM2PAT case is likely to be helpful to the OIG in its study of the adverse event reporting system.

The trouble with the plan in your September 25 letter is that it takes too long. Major reforms lie in the distant future, with a time scale in years. Meanwhile, because of deficiencies in regulation by the FDA, there will almost certainly be medical products that receive FDA approval and remain on the market until it becomes obvious they are unsafe. This has happened in the past – clearly for the AM2PAT syringes, less clearly for other devices – and it is bound to happen again, not only for medical devices but for drugs, biologicals, and foods. Certain reforms require multi-year planning, rule-making, and legislation. Others, however, can begin quickly, and for these, an examination of the AM2PAT case can point the way.

The AM2PAT case contains valuable lessons for the FDA. It will be a black mark against the agency if it fails to examine this case promptly and publicly. An unhampered examination and candid report would speak not only to the public but to the FDA, the White House, and the Congress. That is why we hope you will decide to arrange promptly for an examination and report on the AM2PAT case.

We would welcome the opportunity to meet with you or Dr. Sharfstein to discuss these matters.

Sincerely,

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cc: Joshua Sharfstein