

NTEU

The National Treasury Employees Union

July 11, 2011

VIA E-MAIL AND FACSIMILE

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
White Oak Building
10903 New Hampshire Avenue, Room 2217
Silver Spring, MD 20993

Dear Dr. Hamburg:

I was distressed to receive reports about comments made by an FDA management official at last Thursday's hearing before the House Energy and Commerce Subcommittee on Health which seemed to blame NTEU for the lack of inspections at drug production plants overseas.

I was not at the hearing, and we have been told the video will not be available until later, but my understanding is that in response to a question from a member of the subcommittee regarding the frequency of inspections of foreign drug plants, Dr. Janet Woodcock claimed there were difficulties making inspections because FDA has a union and that travel by employees was restricted. She named NTEU, and had an exchange with a member of Congress about problems associated with fewer foreign inspections, essentially blaming NTEU. I find the implication that NTEU shares responsibility for fewer inspections, false and offensive.

Dr. Hamburg, as I am sure you know, the employees at FDA are among the most dedicated and professional of any in public service. NTEU has a negotiated agreement with HHS/FDA that addresses the matter of how employees are selected for a foreign inspection, not if employees can be sent on these trips. Under the Memorandum of Understanding (MOU), FDA first selects from a dedicated cadre of foreign inspection experts, these being experienced professionals who have volunteered to serve on the cadre and to whom the agency has wisely provided some modest incentives. If members of this cadre are not available, the MOU requires that FDA first solicit volunteers before assigning others to this work. Nothing in any union agreement prevents FDA from assigning employees to perform as many foreign inspections as FDA management wishes.

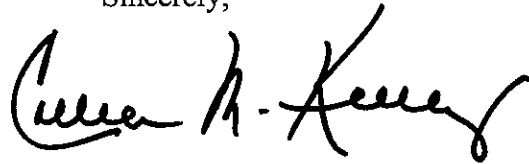
I believe NTEU and the administration have a shared understanding that the real issue here is not the fact that FDA employees have a union but that the agency does not have the resources it needs to perform the needed number and frequency of overseas inspections. That is

Dr. Margaret A. Hamburg
July 11, 2011
Page Two

why NTEU has been one of the strongest voices for increased funding for FDA. On June 16, the House passed its Agriculture/FDA appropriations bill for FY 2012 which reduced discretionary funding by \$285 million, representing 11.6 percent of the discretionary budget. That reduction was opposed by NTEU, and we will fight for additional funding for resources when the Senate takes up the bill.

It is a very serious matter to us if, as part of a congressional hearing, Dr. Woodcock has in any way misrepresented or misspoke about NTEU's impact on the ability of FDA to best fulfill its mission. I urge you to correct the record with the subcommittee. I would be happy to discuss this matter further with you, if you would like. And I look forward to hearing from you on this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Colleen M. Kelley". The signature is written in a cursive, flowing style with a large initial "C".

Colleen M. Kelley
National President