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The FDA Is in Trouble

And So Are We

As you may have heard, the United States Food and Drug Administration (FDA) had proposed dramatically reorganizing its field force, including closing nearly half of its field offices and laboratories. Due to Congressional opposition in both houses, agency leaders at least temporarily suspended their plan (**1, 2**). The following is a postmortem analysis of why the plan was flawed. Let's hope that wiser minds prevail, and FDA leaders do not continue to push for a reorganization that would dramatically decrease agency efficiency and the safety of the US food and drug supply.

It is hard to watch something that protects all of us be destroyed. FDA commissioner Andrew von Eschenbach and the head of the field force, associate commissioner for regulatory affairs Margaret Glavin, had proposed closing seven of 13 FDA laboratories, reducing the number of district offices from 20 to 16 (including closing district offices in the industry hubs of New Jersey and Puerto Rico), and closing all five regional offices, that serve as command and control posts at strategic locations across the country. They had also proposed reducing the number of compliance officers to 10 — less than one per district (**3**). Before the recent Congressional opposition, the reorganization was to have gone into effect on 1 October 2007, and the labs were to close in fiscal years (FY) 2008 and 2009.

Office of regulatory affairs (ORA) employees are the "eyes and ears" of the agency — FDA's inspection and enforcement arm. ORA employees conduct inspections, collect and analyze samples, initiate investigations, oversee recalls, take enforcement actions, and monitor the entry of regulated products at US borders (**4**). Laboratories scheduled to close included the one closest to the Salinas Valley, "America's salad bowl," and the source of the recent *E. coli* contamination case in fresh spinach; one of the two labs that developed the method to test for melamine in pet food; and the only FDA lab capable of testing both radiological contamination of food and also complex medical devices. With the recent serious cases of melamine in pet food, antifreeze in tooth paste, lead paint in toys, salmonella in peanut butter, and *E. coli* in spinach, and the earlier loss of half of the nation's flu vaccine supply due to microbial contamination — this proposal is senseless.

The FDA Commissioner had said that the reorganization was about doing the right thing in the right way, and that it would allow the FDA to modernize its equipment, have state-of-the-art labs, and bring its lab infrastructure into the 21st century (**4**).

Washington State Representative Jay Inslee said in a recent hearing, "Who needs Al Qaeda when you have *E. coli*? Who needs Al Qaeda when you've got melamine? . . . If Osama bin Laden [were] responsible for the *E. coli* poisonings of Americans taking place, and the melamine, and the other contaminants that have come from foreign manufacturers, this country would act. We would actually do something. We wouldn't close half of FDA's offices in response to that threat" (**4**).

Field Staffing

FDA's field staffing has fallen from 4,004 in 2003 to an estimated 3,460 or fewer today (**5, 6**). Lab staffing alone fell 24% from 2003 to 2007 (**7**). The proposed reorganization would have eliminated 37% more laboratory positions. FDA regulates products that account for $0.25 of every dollar spent by Americans, with a budget of $2 billion and approximately 9,000 employees. The Fairfax, VA, school district has a budget equal to FDA's budget (**8**).

Proposed Structure

In the proposed reorganization, FDA management would have been further centralized, essentially establishing a three-district structure in headquarters to replace the five regional offices in the field (**3**). FDA initiated a three-district structure in 1914 and implemented its regional offices in 1968 (**9**).

FDA district staff have testified that the field was not given information on how the new structure was determined, and they observe that it appears the agency is getting top-heavy at the expense of field forces that do the core functions of the agency. Experienced field managers believe the planned reduction in compliance officers will further reduce enforcement (**10**).

I believe the reorganization plans are being driven by a desire to reduce enforcement. FDA senior management does not seem to wish to protect the American people, to regulate the industry, or to enforce the law. In Part 2, we'll discuss additional reasons why the reorganization plan was seriously flawed.

References

1. *H.R. 3161: Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2008.*

2. *S. 1859, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2008.*

3. Dykstra G. Transformation of ORA. *GMP Conference,* University of Georgia, Athens, GA, 13 March 2007.

4. "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply," 17 July 2007; www.fda.gov/ola/2007/foodsafety071707.html, and http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.071707.FoodSafety.Part2.shtml.

5. Immel BK. Downregulating the FDA: Part 1, Inspections. *Immel Report*, September/October 2005; www.immel.com.

6. ORA, FDA. Field Activities, in *FY 08 Budget*; www.fda.gov/oc/oms/ofm/budget/2008/8-FieldNarrative.pdf.

7. House Committee on Energy and Commerce. *Letter to Andrew von Eschenbach*, 15 June 2007; http://energycommerce.house.gov/Press_110/110-ltr.061507.FDA.Lab Closures.pdf.

8. Hubbard W. Wrongly Blaming the FDA. *Washington Post*, 8 May 2006.

9. Brannon M. Organizing and Reorganizing FDA. 75th Anniversary Commemorative Volume of the *Food and Drug Law*: Food and Drug Law Institute, Washington, D.C., 1984; 135–173.

10. Heppe CA. *Testimony to House Energy and Commerce Committee*, 17 July 2007; http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.071707.Heppe-testimony.pdf.

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