

The FDA Is in Trouble

And So Are We, Part 2

In Part 1, I covered how FDA had proposed dramatically reorganizing its field force. Due to Congressional opposition in both houses, FDA senior management has temporarily suspended some plans, but they are apparently still pursuing reorganization (1-3). Here we provide an analysis of why the plan is doomed to failure. As currently proposed, the FDA reorganization would put Americans at risk.

POOR LEADERSHIP AND LESS ENFORCEMENT

In law enforcement, a typical “span of control” in managing investigators is to have no more than 5-7 direct reports (4). The larger the geographic area, or the more specialties managed, the harder it is. Currently, FDA regional directors manage four districts and meet regularly with their inspectors and compliance staff, reassign personnel quickly in an emergency, and follow up on enforcement cases that may be delayed in headquarters. Under the proposed reorganization, each headquarter director would manage six to seven districts — a huge geographic area to cover. With less direct contact with field staff and more time spent traveling, the quality of field management and enforcement would suffer.

In an emergency, commands would have had to go through two brand new structures: one through the inspection directorate and the other through the laboratory directorate. The proposed reorganization would reverse 93 years of close collaboration between inspectors and the laboratories by separating their reporting structures and reverse 40 years of operating with strategic regional hubs (5).

Inexperienced Leadership: The head of FDA’s field force, the associate commissioner for regulatory affairs (ACRA), had not worked as an FDA investigator, compliance officer, or field manager before being appointed to lead the field force. She had worked for USDA with the Food Safety and Inspection Service (FSIS), where she simultaneously reorganized its field force (sound familiar?) and implemented hazards analysis and critical control points (HACCP), a food safety program.

The current FDA commissioner has been at the agency for approximately two years. He has said that the reorganization would allow the FDA to automate its laboratories with robotic equipment, citing the USDA’s consolidation to three laboratories. However, USDA tests only meat, making it relatively easy to automate testing compared with the FDA’s much broader product testing scope.

FLAWED PREMISE

The premise for the reorganization seems to have been that FDA already has all the money it is ever going to have, that it has been losing staff, and it must consolidate. So rather than asking for sufficient funding for his people, the FDA commissioner was planning to cut field offices nearly in half.

Congress has been actively investigating food and drug safety for several months. The House recently issued a draft bill (the Food and Drug Safety Import Bill of 2007) prohibiting the closure of FDA laboratories and district offices and requiring that the Secretary of Health and Human Services consult with affected employees in developing a written reorganization plan. In a recent hearing, FDA’s associate commissioner for regulatory affairs said that lab consolidation and closures are no longer being considered (3). She stated that field staffing is now 3,200 (3). This means that 800 field staff have resigned or retired since FY 2003, including at least four experienced field executives, or a 20% drop in field staffing in four to five years (6).

Poor Planning: Fully 30% of the agency’s staff are currently eligible for retirement, and it takes about three years for a new hire to become a fully trained FDA investigator.

Games: During the recent hearings, it became clear that FDA leadership has withheld requested information from Congress, including the cost to do the field reorganization, specifics on its reorganization plan, and a documented justification for the plan (3). FDA investigators are trained to uncover the truth, so why would agency leaders not thoroughly research and justify any proposed major changes? Why would FDA leaders not consult with their experienced staff and freely


communicate information on the proposed reorganization with their employees?

NO MORE FDA?

To regulated industry, the field force *is* the FDA. If the reorganization is implemented as planned, industry may spend more time “training” junior investigators during inspections. Industry may also have to travel to the FDA headquarters in Rockville, MD, to discuss inspection-related issues.

The FDA must have sufficient resources, be well-led at all levels, and must be allowed to make independent science-based decisions that will be backed by its administration. If we do not take action now, we may have to rebuild the agency from the ground floor up. Maybe this is the level of food and drug safety that we deserve because we have been unwilling to adequately fund the agency and ensure that its leaders are committed to protecting the American people.

REFERENCES

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