



Food & Water Watch - 1616 P Street, NW Suite 300 Washington, DC 20036

www.foodandwaterwatch.org

0129 8 FEB -4 P4:55

February 4, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2007N-0489 (FDA Report on Science and Technology)

Submitted electronically

Dear Sir or Madam:

On behalf of the non-profit consumer group Food & Water Watch, I welcome this opportunity to submit these comments on the report prepared by the Subcommittee on Science and Technology of the FDA Science Board entitled, "FDA Science and Mission at Risk."

We would like to commend the FDA Science Board for undertaking this effort. While FDA Commissioner Andrew von Eschenbach requested this report, we were disappointed to learn that the members of the subcommittee charged with the evaluation had to argue with the Commissioner to permit them to identify the resource deficiencies that have plagued the agency for decades. Without that analysis, this report would have been less than useful or realistic. We applaud the courage shown by the subcommittee to stand up to the Commissioner.

We were especially impressed with the candor of the subcommittee on several points.

First, the subcommittee members concluded that relying on industry user fees to support certain areas of FDA's regulatory work has had a corrosive effect on the agency. The subcommittee noted that this approach to funding FDA's activities has contributed to a decline in FDA's public credibility and has caused a distortion in funding of FDA's various functions. User fees were intended to augment annual congressional appropriations for FDA's activities; instead, revenues generated by user fees have replaced congressional appropriations leaving those functions within FDA that rely solely on taxpayer support starving for resources.¹

Two of the major casualties within FDA have been the Center for Food Safety and Applied Nutrition (CFSAN) that is responsible for regulating the safety of nearly four-fifths of the nation's food supply and the Office of Regulatory Affairs (ORA) that is responsible for allocating FDA's inspection workforce across the country and abroad. Because of the resource

¹FDA Science Board. "FDA Science and Mission at Risk," November 2007, pp. B-14,15.

deficiencies plaguing these two entities within FDA, the number of domestic food inspections has dropped by 78 percent since 1973 and it is virtually non-existent for imported foods.²

While there are proposals being discussed in the 110th Congress to fund some of FDA's food regulatory functions through user fees, we agree with the subcommittee's conclusions that both President Bush and the Congress should return to providing personnel and funds to FDA by appropriations and not by user fees. We believe that subcommittee member Peter Barton Hutt's call to increase the number of FDA employees by fifty percent and to double FDA appropriations over the next two years³ deserves serious consideration by both the Administration and Congress, but must be accompanied by management and business plans that are transparent and developed with input from the Congress and stakeholders.

Second, the call by the subcommittee for a major infusion of resources to improve the agency's information technology infrastructure must be a priority for this Administration and Congress. The subcommittee enumerated the current deficiencies at the agency. We have experienced first-hand the information technology shortcomings at FDA. When Food & Water Watch researched the level of inspection for certain imported seafood products, we filed a Freedom of Information Act request with FDA for certain information. It took over sixteen months for that information to be transmitted to us. When we received it, we found that some of the data did not correlate with other data in the database we received, so we were forced to clean up FDA's own data.⁴ We were also shocked to learn that during the height of the massive nationwide spinach recall in 2006, the e-mail system at CFSAN collapsed and there was no efficient way to communicate and to transmit data efficiently during that critical time.⁵

Third, we agree with the subcommittee's assertion that there is insufficient capacity at the agency in modeling, risk assessment and analysis. The recent risk assessment issued by the agency on the safety of products from cloned animals is a perfect example of FDA's inability to conduct adequate risk assessments. Of the 968 pages in the FDA analysis, few pages actually analyze the studies on safety of foods from clones and their offspring. Most of the peer-reviewed papers in the assessment are on problems with the cloning process, not the safety of meat and milk from clones. The FDA admits, "It is not possible to draw any conclusions regarding the longevity of livestock clones or possible long-term health consequences associated with cloning due to the relatively short time that the technology has existed." The study that the FDA used to conclude that milk from cloned cows did not cause allergic reactions fed the milk of cloned cows to only 10 rats. Only one study used conventional toxicological methods to assess

² *Ibid.* pp. B-20, 21.

³ House Subcommittee on Oversight and Investigations, Energy and Commerce Committee. Testimony by Peter Barton Hutt, January 29, 2008.

⁴ Food & Water Watch. "Import Alert," July 2007, (see http://www.foodandwaterwatch.org/food/copy_of_pubs/reports/import-alert, p. 7)

⁵ House Subcommittee on Oversight and Investigations, Energy and Commerce Committee. Testimony by Dr. Dale Nordenberg, January 29, 2008.

the effects of feeding animals meat and milk from cloned animals and this study used only 10 male and 10 female rats in its design. We need better studies and more long-term studies. But despite having no data on meat or milk from cloned goats, the FDA concluded that they were safe to eat.

Fourth, while not in the report itself, we were heartened to hear several members of the subcommittee call for a thorough review of ORA at the January 29, 2008 hearing conducted by the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee. ORA is the heart and soul of FDA because it is the entity that is responsible for enforcing the various laws FDA administers. While it seems that it has borne the brunt of the financial difficulties experienced by the agency over the past three decades, especially on the food side, it operates under a cloak of secrecy.

The recent attempts to reorganize field operations within the agency seem to have been concocted by very few people based in agency headquarters in Rockville with very little input by agency field personnel, stakeholders, and Congress. As a result, there was a public backlash against the plans once they became public and the agency was forced to back down. On August 3, 2007, we filed a Freedom of Information Act request to access copies of the Work Plans used by ORA over the past several years so that we could understand the deficiencies in the inspection resources within the agency. We were denied access to that information and were told that it was for security reasons. We have since appealed that decision and we plan to litigate if that appeal is denied. Food & Water Watch has been able to access information about the inspection personnel shortages within USDA's Food Safety and Inspection Service.

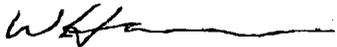
The agency sometimes is its own worst enemy. It is prone to bureaucratic arrogance. The situation I just described is a perfect example because we would like to assist the agency with addressing its problems, but if it is unwilling to share the most basic of information, it makes the situation difficult for us to justify our support. We will not advocate any additional funding for this agency until we clearly understand what the current situation is and we are assured that the agency management is held accountable for its actions. There are members Congress who feel the same because they have been stonewalled by this agency on a whole host of issues. We were especially troubled by the testimony given by Linda Shames of the Government Accountability Office (GAO) at the January 29, 2008 Oversight and Investigations Subcommittee hearing on the GAO's assessment of the FDA's "Food Protection Plan" when she observed:

"FDA officials told us that they have internal plans for implementing the 'Food Protection Plan' that detail timelines, staff actions, and specific deliverables. While FDA officials told us they do not intend to make the plans public, they do plan to keep the public informed of their progress. Without a clear description of resources and strategies, it will be difficult

for Congress to assess the likelihood of the plan's success in achieving its intended results."⁶

Again, the Subcommittee on Science and Technology should be congratulated for issuing such a thorough report. We realize that the proposed budget for FDA that President Bush is proposing for FY 2009 is far short of what is really needed to address all of the problems identified by the subcommittee. It will require political will, a change in management attitude at FDA, and an open and transparent discussion of the crisis at hand before we will see any significant movement to fix all that ails FDA.

Sincerely,



Wenonah Hauter
Executive Director

⁶Government Accountability Office. "Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical" Statement of Lisa Shames, Director Natural Resources and Environment," January 29, 2008, p.11.