If peanut butter can kill us, just how safe are we?

By HOWARD LEVINSON

The Food and Drug Administration (FDA), part of the U.S. Department of Health and Human Services, is requesting nearly $2.4 billion to protect and promote public health as part of the president's fiscal year (FY) 2009 budget - a 5.7 percent increase over the budget that the FDA received for the current fiscal year. One wonders whether we will get our monies worth.

The Centers for Disease Control and Prevention (CDC) estimates that food-borne diseases cause approximately 76 million illnesses, 325,000 hospitalizations and 5,000 deaths in the United States each year. These could be conservative figures, as many food-borne illnesses may go unreported or mistaken as the flu. The estimated cost of food-borne illness is $10 to $83 billion annually. (source: fda.gov/oc/oms/ofm/budget/2008/Detail/2A-FoodsPerformance.htm)

The most recent salmonella outbreak from contaminated peanut butter that Georgia-based Peanut Corporation of America (PCA) processed brings to the forefront the importance of a functional FDA.

Michael Rogers, FDA spokesman, reported that salmonella had been identified at the PCA processing plant in 2007 and 2008. In fact, there were no records to indicate that the line producing the salmonella-contaminated peanut product in January 2008 was ever cleaned. The company used a private laboratory to retest after allegedly correcting processing problems. The subsequent tests were negative for salmonella.

The problem lies in the sampling process. The samples from one lot of peanut paste tested negative. The company distributed paste manufactured after January 25, 2008. The firm continued to manufacture peanut paste in this system." (source: fda.gov/ora/frequent/483s/r_ATL-DO_PCA_Blakely_GA_Form_FDA_483_dtd_Jan_09-27_2009.pdf)

Companies are allowed to use private laboratories for testing. Clearly, the tests did nothing to correct the contamination. One can only wonder whether the private labs are functioning according to the laws and regulations the FDA sets forth and if this system is sufficiently objective. There have been discussions over the years at the FDA in support of a private laboratory accreditation concept. Some participants suggested that FDA or other scientific entities should establish an accreditation process that complies with a number of different laboratory accreditation organizations.

Questions and concerns about private labs and food safety emerged in June 2008 after lawmakers subpoenaed nine companies responsible for analyzing the most dangerous food entering the country as part of an investigation that gained more urgency with an outbreak of salmonella from tomatoes. A House Energy and Commerce subcommittee investigated the possible circumvention of government import alerts.

Foods posing a potential danger should only be allowed into the marketplace after a laboratory has determined that they are safe, according to FDA rules. But investigators have been told that it is a routine practice for private labs to test food until a clean result is obtained, sounding suspiciously similar to the PCA practice.

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"This repeated testing is done without FDA knowledge that potentially dangerous food has been imported into this country and has entered commerce," said Rep. Bart Stupak (D-Mich.), chairman of the House subcommittee that authorized the subpoenas. (source: boston.com/business/articles/2008/06/13/lawmakers_approve_subpoenas_over_food_testing)

Several nationwide recalls have occurred over the past couple of years, which remind us how devastating food-borne illness can be. Contaminated peanut butter led to illnesses in more than 300 people and at least 50 hospitalizations in 2006. Contaminated spinach resulted in more than 200 illnesses, three deaths and more than 100 hospitalizations. Reports of kidney failure and deaths in cats and dogs prompted a recall of more than 100 brands of pet food. In each of these instances, the FDA intervened and acted in the public's interest after notification.

However, there seems to be continuing problems at the agency, not merely limited to food safety.

The FDA oversees more than one-fourth of the U.S. economy, including prescription and over-the-counter (OTC) drugs, packaged food, animal drugs and food, biological products and blood banks. It is responsible for ensuring the safety of a wide range of devices, from cell phones to pacemakers, airport X-ray scanners and the medical equipment in many hospitals and doctors' offices. Drugs and medical devices must be approved before they can be sold. The FDA can order manufacturers to change labels, add warnings or pull the product off the market, but often after it is too late.

The FDA cannot be expected to catch all side effects before approving new drugs or devices, but Americans should expect them to do a better job. Historically, the FDA has been admonished for a number of controversies, such as failing to warn of the risk adverse effects.

FDA rules require clinical-trial sponsors to turn over financial disclosure information on their investigators when they submit product marketing applications. However, the FDA does not do a good job of following up on incomplete disclosure information, the report said. A recent Department of Health and Human Services, Office of the Inspector General (OIG) report revealed that of the clinical investigators listed on the required disclosure forms, only 1 percent disclosed a financial interest with the potentially marketed drug or product, despite estimates in the "Journal of the American Medical Association" that "between 23 percent and 28 percent of academic researchers had financial interests in medical companies." To further complicate that minimal figure, the report acknowledged that the FDA did not even have a complete list of clinical investigators.

The OIG report indicated that 42 percent of FDA-approved marketing applications the OIG reviewed were missing the required financial disclosure information. (source: oig.hhs.gov/oei/reports/oei-05-07-00730.pdf)

The FDA recently was added to a list of "high-risk" areas of the federal government because it may not be able to adequately do its job, according to the Government Accountability Office (GAO). The GAO said the FDA was being hampered by globalization, more complex products and laws that have made it more difficult for it to ensure the safety of pharmaceuticals, biologic drugs and medical devices. (source: reuters.com/article/healthNews/idUSTRE50L64V20090122)

Hopefully, the new administration in Washington and the expanded budget for the FDA will foster safer foods and drugs.