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## **FOOD AND DRUG SAFETY ON THE CHEAP: IT CAN'T BE DONE**

Hundreds have been sickened by salmonella-contaminated vegetables – victims of an under-funded Food and Drug Administration that once again has failed to ensure the safety of our food. Those recovering from their illness may be pleased to learn that the FDA is about to receive a long-overdue increase in its funding. But their pleasure will be short-lived when they realize the small size of the increase.

The FDA – hampered for years by a tight budget – is in trouble again, this time not only from the salmonella outbreak, but for its failure to stop the importation of an unsafe drug. A batch of heparin made in China, not inspected by the FDA, was found to be adulterated with a poisonous substance. During the past six months, dozens of patients treated with this batch of heparin died, and hundreds suffered serious medical complications. This is just what the FDA is meant to prevent.

In recent years the FDA has approved the marketing of several risky drugs, including Vioxx, Ketek, Avandia, Accutane, Bextra, and Rezulin. These drugs and others were finally withdrawn from the market or had new restrictions placed on their use, but only after long delays. Vioxx – a multi-billion dollar cash cow for the manufacturer – caused strokes, serious heart attacks, and deaths probably numbering in the tens of thousands before it was taken off the market.

The excessive influence of manufacturers over FDA decisions accounts for some of the agency's failings. But the FDA is also laboring under a handicap over which it has almost no control: a budget that year after year has not kept up with its growing oversight responsibilities. With too few scientists and other skilled employees, the FDA can get its work done in only one way: by moving manufacturers' requests for approval of drugs and medical devices as quickly as possible through the FDA pipeline. This necessarily means lowered standards and weaker oversight. Often the result has been unsafe medical products.

Energized by the salmonella outbreak and the heparin incident, Congress now seems intent on strengthening the oversight power of the FDA. A supplemental bill just passed by Congress will add \$150 million to the FDA budget. But this is only a small increase over the total of \$1.5 billion already appropriated for FDA salaries and expenses for fiscal 2008.

Under the present system at the FDA, there are winners and losers:

- o The FDA, overwhelmed by its responsibilities, wins in a narrow sense: it stays within its budget for the approval of new drugs and medical devices, keeps up with its huge workload, and meets deadlines.

- o Manufacturers are winners: they get their products on the market without much interference from the FDA.

o The public loses: unsafe foods, drugs, and devices continue to be marketed. Some unlucky individuals lose heavily, paying with their health and sometimes with their lives.

The work of the FDA won't improve much as long the agency is kept on a miserly budget or one with only modest increases.

In a November 2007 report, *FDA Science and Mission at Risk*, a panel of experts described the crushing demands on the FDA's limited resources. The panel recommended an almost unprecedented increase in the FDA budget – at least a doubling by 2012, from \$1.5 billion in 2008 to \$3.2 billion in 2012. Even this amount, which is much more than Congress seems ready to authorize, may be too small.

Adequate funding of the FDA may prove to be an unattainable goal as long as the U.S. budget is dominated by war, national debt, and rising deficits. But if that is so, we should face the consequences squarely. Incidents like those caused by salmonella, heparin, and Vioxx will happen again. The FDA's perennial shortcomings will continue to claim human victims.

***Dr. Ned Feder, Staff Scientist***

*Before joining POGO in September 2006, Ned Feder was a scientist at the National Institutes of Health. He came to the NIH in 1967 as the head of the Section on Biophysical Histology, conducting basic research in cell biology. In the mid-1980s he and an NIH colleague began to study professional misconduct among biomedical researchers and found that violations of ethical standards seemed common. Published reports on their controversial observations drew attention in academia, in the press, and on Capitol Hill. As a result of hearings by a subcommittee of the House Energy and Commerce Committee, the NIH and the Department of Health and Human Services were compelled to create the Office of Research Integrity. In 1993, senior NIH officials directed Dr. Feder and his colleague to stop their ongoing studies of misconduct in medical research, and they were reassigned to administrative jobs unconnected with the examination of scientific misconduct. Over the years, Dr. Feder has published articles in the scientific and lay press on a wide range of topics including histochemistry, cell biology, mycology, scientific misconduct, and conflicts of interest. He received an M.D. degree from Harvard Medical School in 1953 and was a faculty member of the Harvard Biology Department from 1961 to 1967.*

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