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Request for Comments on the Science and Technology Report

The American Society for Microbiology (ASM) concurs with the highly disturbing conclusions of the Food and Drug Administration (FDA)¹ Science Board Report to assess whether FDA science and technology can support current and future regulatory needs. For years, ASM and other scientific and health organizations have been warning of deteriorating scientific research, infrastructure, and personnel resources for the FDA which is responsible for regulating approximately \$1 trillion in consumer products annually.² In just the past year, publicized discoveries of contaminated products from toys to pet food have reminded us of the FDA's critical role in safeguarding public health. As the study report emphatically states, the nation is at risk if FDA science is at risk.³

Concern about the FDA science and technology base has been increasing as federal mandates for FDA oversight have multiplied. The Science and Technology Subcommittee, which includes prominent members and advisors from industry, academia and government, concluded in November 2007 in its 300-page report that FDA science is in dire need of resources and up-to-date information processing.

The Science Advisory Board report, *FDA Science and Mission At Risk*, found science at the agency "in a precarious position" and clearly inadequate to meet broad FDA responsibilities, which include the safety and efficacy of human and veterinary drugs, biological products, medical devices, most of our nation's food supply, cosmetics, and more.⁴ The report describes twenty years of fiscal neglect, during which 125 additional statutes have been enacted increasing the FDA's already heavy workload. The ASM commends the FDA Commissioner for requesting the report on science preparedness at FDA and has high regard for the FDA staff.

The ASM has repeatedly urged the Administration and Congress to recognize and support the crucial need for strong FDA science and technology. The ASM believes that excellent science must be the foundation upon which FDA effectively fulfills its

regulatory mission. Expert staff resources and modern communication technology to support regulation are imperative. The FDA must make a sustained commitment to rebuild its science base and to assure additional resources are used for this purpose and for science-based approaches to regulation. The ASM recommends that the FDA prepare a plan as soon as possible that specifically focuses on rebuilding science and scientific expertise and technology at the agency.

The consequences of ignoring the FDA's science base are evident. Notable public safety challenges are cited in the Subcommittee's report. The ASM agrees that key oversight efforts are suffering from shortages in essential personnel, financial resources, and appropriate data processing. Areas that are dependent on good science include food safety, assessment of diagnostic tests, evaluation of imported goods, approval review of medical devices that use state-of-the-art technologies, and rapid response investigation of contaminated products. New diagnostic tests based on cutting edge molecular technology are being delayed.

Some FDA safety reviews, like those of thousands of OTC drugs, have languished undone for decades. In the decade from 1996 to 2006, adverse event reports on prescription drugs submitted annually to the FDA by health care practitioners increased 146 percent to nearly 472,000, yet there was no increase in personnel to address these reports.⁵ About 80 percent of the active ingredients used in prescription drugs are imported, but FDA personnel shortages have resulted in steady declines of on-site inspections at foreign manufacturers, despite the fact that imported drugs and active ingredients were valued at more than \$42 billion in 2006. That year, FDA inspectors made only 32 field inspections in India and 15 in China, the two largest exporters of these products to the United States.⁶

Import issues, inspections, and the need for cutting-edge laboratory capabilities affect the safety of our national food supply. The subcommittee report concluded that "disintegration of the FDA food regulation function has continued unabated over the past quarter century."⁷ Addition of new large-scale responsibilities for the FDA Center for Food Safety and Applied Nutrition (CFSAN), enacted by Congress, coincided with a 15 percent reduction in center staff from 1992 to 2007.⁸ Only fourteen FDA personnel are responsible for regulating cosmetics, an industry with more than \$60 billion in annual sales.⁹

Information gathered during the Subcommittee's year-long study of FDA science points to the serious potential for ongoing threats. Since 1973, there has been a 78 percent reduction in the number of FDA field inspections of foreign and domestic food establishments.¹⁰ FDA estimates that its understaffed Field Force routinely inspects food manufacturers once every ten years at most.¹¹ We now import more than 15 percent of our food supply, with food products accounting for the majority of FDA-regulated imports flooding into this country. From 1990 to 2005, imports under FDA purview increased from 2 million to over 8 million per year, with minimal concomitant increases in FDA resources.¹² Much of the enhanced inspection funding allocated following September 11, 2001, has since vanished from annual budgets. In 2002, the agency

designed a new science based import inspection program, but appropriation requests were denied. Constrained by shortages, the FDA currently conducts a quick visual check of less than one percent of imports and an actual physical examination of less than one-tenth percent.¹³ There are few scientific investigations that trace back product contamination and research prevention strategies.

Qualified science personnel are leaving FDA and replacements often are difficult to attract even if FTEs are funded. Adequate review of new drugs, vaccines, and biologics requires scientists with a working knowledge of the science underlying these products and this often requires that FDA staff be active scientists themselves. Support for investigation by FDA scientists has substantially eroded. FDA will not be able to recruit and retain higher quality people if scientific investigation by staff is not encouraged and supported.

Deficiencies cut across FDA programs, despite agency efforts to prioritize resources and work more efficiently. Too many FDA activities have become reactive to crises, often armed with outmoded tools, rather than proactive efforts solidly based on cutting-edge science. Years of neglect or denial over the state of FDA science also have eroded public perception of FDA. FDA was highly regarded three decades ago, with a public confidence rating of about 80 percent. Today, the rating sinks to 30-40 percent.¹⁴

To the detriment of public health, not only has FDA funding slowed considerably, it has lost ground. From 1988 to 2007, despite burgeoning responsibilities, the agency gained an increase of only 12 percent in personnel and lost more than \$300 million to inflation.¹⁵ Previous studies, like the 2006 NAS report *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, have likewise warned of downward trends in FDA capabilities without robust infusions of financial support.¹⁶

Reversing the trend towards an ineffectual FDA will be difficult in the current economic climate. Along with other stakeholders, ASM acknowledges the significant scale of overdue funding needed to fully restore FDA science.¹⁷ To rebuild overloaded FDA programs, the Subcommittee report recommends a restructuring of the agency, as well as a doubling of FDA appropriations and a 50 percent increase in personnel over a two-year period.¹⁸ While ASM supports such measures, it is important to point out that rebuilding the scientific infrastructure at FDA is a long term, not a short-term, endeavor. Any funding and personnel increases must be sustained to have a significant impact on the quality of the scientific enterprise at FDA and on the effectiveness of regulatory activities.

We urge the FDA, the Administration and Congress to take the Subcommittee recommendations seriously and address each recommendation in the report. We strongly recommend that FDA prepare a plan within a specified time period to assess how to rebuild FDA science and technology and what specific resources will be needed. The plan should take into consideration how resources, both current and requested, could be more effectively and efficiently utilized by focusing on highest priority tasks and risks. For example, the current regulatory approach to approval of diagnostic tests could be

more effective if it focused on high risk assays instead of those at relatively low risk. The plan should also address how FDA could build partnerships with academia, state agencies, and other federal agencies to bolster its scientific capacity, and with other regulatory agencies to more efficiently discharge its regulatory responsibilities. This is especially important over the short term until improved funding and additional staff are available to the agency. The rebuilding of FDA science will be a long-term effort in the current budgetary situation; therefore, additional resources must be targeted and wisely used based on a clear plan and strategy for addressing priority gaps. Failure to take appropriate action now will further affect the FDA's ability to safeguard public health.

Thank you for the opportunity to submit comments on this important report.

Sincerely,


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President, ASM


Ruth L. Berkelman, M.D.
Chair, Public and Scientific
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¹ *FDA Science and Mission At Risk: Report of the Subcommittee on Science and Technology*, November 2007 http://www.fda.gov/ohrtms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf

² See ASM archives of FDA Budget Statements: <http://www.asm.org:80/Policy/index.asp?bid=4445>

³ *FDA Science and Mission At Risk*, p. 2

⁴ *Ibid.*

⁵ *FDA Science and Mission At Risk*, p. B-16

⁶ *FDA Science and Mission At Risk*, p. B-22

⁷ *FDA Science and Mission At Risk*, p. B-18

⁸ *Ibid.*

⁹ *Ibid.*

¹⁰ *FDA Science and Mission At Risk*, p. B-20

¹¹ *Ibid.*

¹² *FDA Science and Mission At Risk*, p. B-21

¹³ *FDA Science and Mission At Risk*, p. B-21

¹⁴ *Ibid.*

¹⁵ *FDA Science and Mission At Risk*, p. B-7

¹⁶ *FDA Science and Mission At Risk*, p. B-12

¹⁷ <http://www.iom.edu/?id=37339>

¹⁸ See funding suggested by various groups, pp. 7-8, 55-56

¹⁹ *FDA Science and Mission At Risk*, pp. 8, B-1, B-2, B-12, B-13 (for estimates from FDA)