



1201 Maryland Avenue SW, Suite 900, Washington, DC 20024
202-962-9200, www.bio.org

February 4, 2008

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2007N-0489, Request for Comments on the Report of the FDA Science Board Subcommittee on Science and Technology - "FDA Science and Mission at Risk"

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) is pleased to provide the following comments on the Report of the Food and Drug Administration (FDA) Science Board Subcommittee on Science and Technology entitled *FDA Science and Mission at Risk* (the report). BIO applauds the courage of FDA leadership in requesting an independent evaluation of the Agency's scientific programs with the goal of enhancing the agency's scientific infrastructure and capabilities and the overall societal value of FDA operations. Further, BIO recognizes and appreciates the strong professional commitment of FDA staff to promoting and protecting the public health. However, BIO must also concur with the sobering conclusions of the Subcommittee that chronic lack of federal funding in an era of increasing FDA responsibility has undermined the agency's scientific base and jeopardized the agency's ability to accomplish its core public health mission. BIO supports a fully funded, science-driven FDA that has the resources it needs to keep pace with rapidly evolving biomedical science and make sound regulatory decisions in a timely and efficient manner.

BIO represents more than 1,150 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology

technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhance agriculture, and a cleaner and safer environment.

Biotechnology researchers are at the forefront of the revolution in genomic, proteomics, and bioinformatics. To date, biotechnology researchers and companies have created, tested, and brought to the market more than 200 new therapies and vaccines, including products to treat cancer, diabetes, autoimmune disorders such as arthritis, and HIV/AIDS. BIO member companies recognize that a reliable, science-driven regulatory environment can help to drive innovation, promote economic competitiveness, and maintain high patient confidence in the integrity of their medicines. Indeed, FDA's scientific knowledge and expertise is essential for evaluating the safety and efficacy of medical products. However, FDA's core mission is undermined if the Agency lacks the resources to keep pace with the latest advances in biomedical science. As stated in the report,

FDA's inability to keep up with scientific advances means that American lives are at risk. While the world of drug discovery and development has undergone revolutionary change — shifting from cellular to molecular and gene-based approaches — FDA's evaluation methods have remained largely unchanged over the last half century. Likewise, evaluation methods have not kept pace with major advances in medical devices and use of products in combination. (p. 3)

A particular strength of the report is its assessment not only of the deficiencies in program areas ranging from food safety to medical product development, but in its recommendations regarding improvements to the infrastructure that is required to support these activities and build a strong scientific foundation at FDA.

FDA Funding:

The vision of a 21st Century FDA will not be realized in the absence of substantial increases to the FDA's base appropriations. Along with its responsibilities from additional statutory mandates and the pressures of regulating an increasingly globalized economy, the FDA has faced an appropriated budget that remains flat, and federally funded staffing levels that have actually diminished. For example, in 2005 appropriations funded 150 fewer medical reviewers in the human drug review program compared to 1992. BIO firmly agrees with the report's assessment that

... adequate resources — human and financial — alone will not be sufficient to repair the deteriorating state of science at FDA, which is why we also recommend significant restructuring. But without a substantial increase in resources, the Agency is powerless to improve its performance, will fall further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public. (p. 8)

BIO notes that user fees play an important role in supplementing federal funding for certain targeted FDA activities, such as human drug and biologic review, but PDUFA fees were never intended to supplant a sound base of appropriations for FDA's core

activities. BIO is concerned that FDA has become over-reliant on these user fees to meet the core mission of the human drug program. This over-reliance on industry fees has created an unseemly misperception that FDA is beholden to the industry it regulates. In the long-term, this perception is not in the best interest of patients, biopharmaceutical innovators, or FDA. Therefore a substantial increase in FDA's base appropriations is essential if the agency is going to be able to fulfill its public health mission.

Critical Path:

BIO has strongly supported the Critical Path Initiative since its inception. We appreciate FDA's recognition of the need for a serious assessment and discussion of existing barriers and possible solutions to an increasingly costly and slow drug development process. However, BIO is concerned about FDA's ability to keep up with emerging scientific advances, such as genomics and bioinformatics, and how that may slow the development on new medicines to treat disease. The report rightly cites FDA's Critical Path Initiative as a promising area where the Agency has been striving to modernize drug development science so that innovative scientific tools are available to regulate the next generation of medical products. The report further states that

The Initiative has been limited by a significant lack of resources for maintaining operations, let alone adding the trained professionals necessary to bring the Critical Path strategy to tactical reality. (p. 25)

For the Critical Path Initiative to be successful and meaningful, FDA's Critical Path programs must receive the resources they need for reviewer training and implementation. BIO supports the subcommittee's recommendation that the Agency establish new organizational mechanisms and target additional resources to implement the Critical Path Initiative fully, and that the Critical Path initiative be expanded to include all regulated products and their associated life cycles.

Recruitment and Retention:

BIO believes that FDA's greatest strength is its people, and shares the Science Board's concerns regarding the agency's ability to sufficiently recruit and retain top scientific and medical staff. As the Science Board report states,

FDA's failure to retain and motivate its workforce puts FDA's mission at risk. Inadequately trained scientists are generally risk-averse, and tend to give no decision, a slow decision or, even worse, the wrong decision on regulatory approval or disapproval. (p. 5)

BIO member companies highly value FDA regulatory guidance during pre-clinical and clinical development of new biotechnology medicines. However, if there is excessive staff turnover or if the continuity of communications between the Agency and our

members is interrupted due to the FDA's failure to retain well-qualified scientists, our members' product development programs will be severely disrupted and there will be a very negative impact on the allocation R&D resources.

Further, BIO is concerned about current Department of Health and Human Services (HHS) Human Resource (HR) procedures that may cause significant delays in the hiring process. During the months in which their applications are under review, many candidates may accept other job offers. Given the importance of recruiting the best scientific and policy staff so that FDA can improve its performance and meet the Food and Drug Administration Amendments Act (FDAAA) implementation goals, we strongly recommend that FDA and HHS work together to streamline HHS' HR processes so that the significant number of new staff required by FDA can be hired in a timely manner.

BIO supports competitive salaries for FDA staff and opportunities for continued education, such as external fellowships, to keep pace with advancements in biomedical and regulatory science. The report also calls for a number of new or significantly enlarged programs, such as an Incubator for Innovation in Regulatory and Information Science (IIRIS), an enhanced governance structure for managing science and specific new positions to manage the science programs both at the level of the Office of the Commissioner and within the Centers. While this proposal may have merit, we note that there are other existing initiatives that may overlap with IIRIS, and it is important that all of these activities move forward in a coherent and harmonized fashion.

Information Technology (IT):

Recent advances in biomedical science have been driven in part by critical improvements in informatics and computer science, but funding shortages at FDA have prevented the agency from similarly leveraging modern informatics. The FDA's mission depends on timely access to accurate information to assure drug, food and device safety. BIO is supportive of recent FDA IT management initiatives, such as the development of the Bioinformatics Board and the development a five-year IT plan. However, FDA continues to operate in a hybrid world of both paper and electronic media. Critical FDA data remains in inaccessible paper warehouses, computers and network servers are obsolete and unreliable, and FDA lacks the resources to conduct business process analysis needed to more efficiently automate agency regulatory operations and drive international standards development. The lack of funding for new IT systems has resulted in slow adoption of critical technology, and data and information standards, throughout the medical product, food, and cosmetic industries.

Conclusion:

Along with many other stakeholders, BIO is calling for a renewed public commitment to FDA and its unique role in protecting American consumers and patients (we are members of The Alliance for a Stronger FDA, a broad and diverse coalition that brings together

over 170 patient groups, nonprofit organizations, consumer advocates, public health organizations and innovative companies to work together to increase federal funding for the FDA). We believe that *FDA Science and Mission at Risk* is a thoughtful, candid assessment of the FDA's scientific capacity, workload, and resources, and that its content provides significant support for a renewed public commitment to the FDA.

BIO appreciates the opportunity to comment on this report of the FDA Science Board Subcommittee on Science and Technology and we would be pleased to provide further input or clarification of our comments, as needed.

/s/

Sara Radcliffe
Vice President, Science and Regulatory Affairs
Biotechnology Industry Organization