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**Global Research & Development**

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February 4, 2008

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

Dear Dockets Management:

Re: **Request for Comments on the Science and Technology Report**  
[Docket 2007N-0489, 73 *Federal Register*, 869, November 9, 2007]

Pfizer submits these attached comments to the Request for Comments on the Science and Technology Report, 73 *Federal Register*, 869, January 4, 2008.

Pfizer appreciates the opportunity to provide comments on this report and would invite direct dialog with the Agency if you would consider the opportunity valuable.

Sincerely,

William F. Murphy, Ph.D.  
Director, Worldwide Regulatory Policy and Intelligence  
Pfizer Global Research & Development

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## General Comments

Pfizer welcomes the opportunity to comment on the report prepared by the FDA Science Board "FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology" (*Federal Register* January 4, 2008). The report highlights FDA's importance as a critical component of our nation's health care delivery system and how their work is vital to the economic health of the nation, regulating a trillion dollars of products annually. In providing comment on the Report, we would like to take the opportunity to recognize the FDA for their diligence, dedication, and professionalism toward the important work they perform.

Pfizer supports the principle conclusion of the Science Board Report that a critically under funded FDA can not optimally perform its mission because of the impact on scientific capacity and capability. The FDA is a key stakeholder in the efforts to improve the quality and delivery of healthcare in the US. We agree with the Report that a lack of science capacity "compromises not only the public health mission since the Agency can not effectively regulate products built on emerging science, but it also hampers the Agency's ability to support innovation in the industries and markets that it regulates". As noted in the Report, the conclusions reached by the Science Board are supported by numerous other reports from the National Academies of Science, the Government Accountability Office (GAO), the HHS Inspector General, Congressional committees, and other expert groups.

## Specific Comments

1) There is concern that without a comprehensive understanding of the science supporting the products they regulate, the Agency can become unnecessarily risk adverse which will prevent or delay getting innovative medicines to patients. The impact is potentially greatest for new technologies where the regulated Industry needs to work with an FDA that is scientifically current. The Report specifically mentions emerging science and technology areas that are most challenging to FDA and thus most likely impacted (e.g., systems biology including panomics, combination products, medical imaging, regenerative medicine, etc). As one step, FDA should seek to further leverage its partnerships with other Governmental science agencies such as the NIH as a means to ensure currency in science. Inherent in this suggestion is the understanding of the common mission of these agencies to advance the application of innovative science to deliver new medicine.

2) There is also concern that continued inadequate funding of the Agency will manifest itself as inconsistent regulation. As noted in the Report, increased FDA responsibilities and declining resources have led to the loss of key review staff at the Agency, which has further burdened remaining staff. A high rate of reviewer turnover has the potential to affect ongoing drug development programs. Agreements are reached with Agency

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reviewers on the appropriate course of action for a development program. Frequent mid-stream personnel changes can lead to disruptions to agreed upon development paths, potentially leading to a request for additional clinical studies that are time consuming and increase the cost of drug development.

3) As discussed in the Report, FDA must not only catch up with the new knowledge and technology available today, but anticipate and respond to future scientific challenges. One important step in this direction was the launch of the Critical Path Initiative (CPI) in 2004. One particular comment on Critical Path stood out in the Report. The comment, originating from the 21<sup>st</sup> Century FDA Task Force Working Group, referred to Critical Path as a vision that if implemented will "transform the FDA from an organization of rule-based regulators to a public health Agency staffed with 21<sup>st</sup> Century science-based standard setters". We agree the CPI is vital to developing future science at FDA. Presently, funds for the CPI are very limited. Appropriate funding of the CPI would, in our view, quickly translate into tremendous advances in the science capability of the Agency.

4) The Report discusses the need to restructure the Agency and suggests the creation of several new science related positions. Different aspects of Agency restructuring have been suggested in other recent reports (e.g., 2006 Institute of Medicine Report). Specific modifications to the current organizational structure are proposed in the Report, and all have merit. However, we suggest that restructuring proposals not be considered in a piecemeal fashion, but rather consider a broader evaluation of the Agency's current mission and function. To that end, it would be prudent for FDA to seek input on scenarios for organizational restructuring from a knowledgeable external body.

As plans for a large scale restructuring of the Agency may take years, we suggest two near term changes. The first is to institute a recommendation made in the 2006 IOM report (topic 3.1), that the FD&C Act be amended to appoint the FDA Commissioner to a 6 year term of office. This step alone will act to lend stability to the beleaguered Agency. The second suggestion is to consider dividing the two major FDA functions into two separate agencies, one responsible for ensuring the safety of our nation's food supply and the other for regulating medicines and medical devices. Splitting these functions could also serve as an important step toward a unified national food safety system, elements of which are currently covered by 15 federal agencies.

5) Several sections of the Report discuss deficiencies in FDA's current Information Technology (IT) capabilities. FDA's IT systems were described as lacking the information science capability and infrastructure to fulfill its regulatory mandate (Section 3.3.2.), insufficient information infrastructure support to regulate products based on new science (Section 3.3.3.), an IT infrastructure that is obsolete and unstable (Section 3.3.4.), and their IT workforce being insufficient and suboptimally organized (section 3.3.5). All these deficiencies are related to chronic under funding, but even significantly improved funding may not be enough to correct their IT structure. Again, in place of piecemeal

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fixes to current systems, FDA should consider developing a cohesive Agency IT strategy, presumably guided by knowledgeable external information technology experts.

The following provides suggestions to consider on specific issues as the Agency considers the future structure of their IT systems.

- Open standards and antiquated business processes ... the report states that "Standards activities are in process with strong external collaboration and FDA is providing important leadership among standards-setting bodies." FDA benefits from working within open standards forums to help establish interoperability across their data warehouses and systems. FDA should participate within the open standards community as one among many participants rather than mandating outcomes. Otherwise, poor practices and antiquated paper processes will be perpetuated and true interoperability will be inhibited.
- Ensure a computer literate workforce that embraces the use of technology ... All the technology in the world will be useless unless the FDA can institute effective implementation plans that influence the internal environment to embrace the use of these technologies. Many reviewers remain in a paper-based mindset that is incapable of utilizing new technology. FDA must promote computer literacy and as it recruits additional resources, it must similarly seek a computer literate workforce.
- Establish a well defined and documented information architecture ... the report states that "Strong collaborations with external partners in other areas, including data modeling, are also taking place." Information architecture sciences must be employed to optimize results. Without this architecture, the chances of achieving economies or best practices across the Agency are diminished.
- Leverage shared services ... the recommendation related to Finding 3.3.2 states that "FDA IT must develop the intramural capability to support all regulatory science activities and should catalyze the development of multi-sectoral shared health information exchanges to support industry innovation and fulfillment of regulatory responsibilities." This is a basic endorsement of the model for CRIX International. We agree that FDA would benefit strongly from standards-based shared services.
- Advocate global standards that speed data acquisition while eliminating regulatory burden ... the Subcommittee recommended that "FDA develop the capacity to do advanced data mining and use analytical methodologies and tool development for large databases, as well as the development of new statistical methods and trial designs." This will not be possible without development of globally harmonized data standards and terminologies that enable electronic submissions. Furthermore, these standards must enable expedient data acquisition to conduct necessary scientific review while alleviating regulatory burden.
- Partner for the development of standards ... FDA should partner with stakeholders on the development and adoption of IT standards. The Subcommittee recommended that "FDA needs to work closely with the legislative branch to develop the mandates to drive adoption of data sharing standards." We hope this mandate is not taken as supporting FDA current paper based processes. Development of new standards will

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necessitate cooperation across the stakeholder community to understand the flow of the works process, and recognizing all parties have requirements to enable decisions based on "best information possible". FDA should not see itself as a standards development organization, but rather work within the open standards community with other constituents.