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Fax

To: Dockets Open for Comment **From:** Suanna Bruinooge

Fax: 301-827-6870 **Pages:** 3

Phone: 301-827-6860 **Date:** February 4, 2008

Re: Docket No. 2007N-0489
 FDA Report on Science and Technology' **cc:**

Urgent For Review Please Comment Please Reply Please Recycle

• **Comments:**

I am submitting these comments on behalf of the American Society of Clinical Oncology. If you have any questions, please contact me at 703-299-1050.

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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

RE: Docket No. 2007N-0489, "FDA Report on Science and Technology"

Dear Sir or Madam:

The American Society of Clinical Oncology (ASCO) is the leading medical society for physicians involved in cancer treatment and research. As such, ASCO has a substantial interest in the efficiency and effectiveness of the Food and Drug Administration (FDA) in its regulation of new therapies for cancer, as well as for cancer prevention agents and cancer diagnostics. We wholeheartedly agree with the conclusions of the FDA Science Board that the science mission of FDA needs to be recognized, sustained and enhanced for the future. There are a few things not directly discussed in the report that we want to suggest, such as collaborations with professional societies.

We agree with the report's recommendation that collaboration with scientists external to the agency can help address some of the scientific needs. We encourage FDA to consider the potential for collaboration with professional organizations in order to achieve this goal. Support from scientific organizations, such as ASCO, would provide valuable expertise without the requirement of substantial fiscal investment by the federal government. ASCO has already done this by working with FDA to facilitate meetings with groups of experts on clinical trial endpoints and alternative trial designs, as well as opportunities for educational interactions through our annual meeting, thematic meetings, and workshops on trials methodology and drug development. We urge you to consider these as models and expand these types of opportunities for facilitating and maintaining scientific knowledge among FDA staff.

Another means for FDA to collaborate with external scientists is through strengthening and encouraging relationships among federal agencies that devote significant resources to cultivating scientific expertise, such as the National Institutes of Health. It is very important in this time of constrained funding to leverage our nation's investment in scientific knowledge throughout the federal government. Such collaboration will also ensure that agencies are implementing policies that are consistent with scientific knowledge and other agency activities.

The report focuses on an overarching agency structure devoted to scientific knowledge. As the agency considers how to prioritize its funding it should ensure that scientific competency is *completely integrated* into all the review and oversight responsibilities of the agency, not simply within the office of the Chief Scientific Officer. Cancer treatment is trending towards the use of more complex and rapidly evolving biologics and targeted therapies. It is critical that the agency make sure that its medical and scientific reviewers stay abreast of the science and are therefore competent to carry out the mission of ensuring safe and effective drugs and biologics.

2008 Annual Meeting
May 30-June 3, 2008
Chicago, Illinois

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FDA staff should also be well-versed in cutting-edge scientific and regulatory advances so that they are afforded the opportunity to lead regulatory discussions, workshops and panels, and proactively develop educational guidance. This can only be accomplished with acceptable retention practices and professional development plans.

We are aware of the funding challenges confronting FDA. Ideally, appropriated funds would be adequate to cover agency activities without the need for user fees, which create an impression of undue industry influence. We appreciate, though, the near term likelihood that appropriations will not reduce the need for such fees. We will encourage Congress to support funding levels that permit the FDA to accomplish the full range of activities essential to assuring safe and effective drugs and biologics. At the same time, we encourage the agency to use this report as a catalyst for exploring improvements that will strengthen this vital link between scientific discovery and delivery of more effective cancer treatments to the American consumer.

Sincerely,



Joseph S. Bailes, MD
Chair, ASCO Government Relations Council

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