

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2004S-0233]

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Certifier R. LEDESMA

Solicitation of Comments on Stimulating Innovation in Medical Technologies

AGENCY: Department of Health and Human Services.

ACTION: Notice.

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**SUMMARY:** The Department of Health and Human Services (HHS) is seeking public comment on how HHS and its agencies can work together to facilitate the development and approval of new medical technologies.

**DATES:** Submit written or electronic comments by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments concerning this document to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

**FOR FURTHER INFORMATION CONTACT:**

*For general questions about this document:* Lisa Rovin, Office of the Commissioner (HFP-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1443.

*For information about the seven specific questions listed in the SUPPLEMENTARY INFORMATION section of this document:* Tom Kuchenberg, Office of the Secretary, Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201, 202-205-8644.

**SUPPLEMENTARY INFORMATION:**

## I. Background

HHS is seeking comment on how to stimulate innovation in medical technologies, such as drug and biological products and medical devices. We are interested in hearing about ways HHS and its agencies (e.g., National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), and Centers for Disease Control and Prevention (CDC), can work together to facilitate the development and approval of new medical technologies.

Recent advances in basic sciences, such as genomics, proteomics, and bioinformatics, have created the potential for the development of innovative medical technologies that can provide new hope and better quality of life for many Americans. At the same time, more funds are being invested in biomedical science in America than ever before. NIH, which is just completing a 5-year doubling of its budget to \$27 billion (Ref. 1), has launched its Roadmap initiative (Ref. 2). The Roadmap initiative aims to transform the nation's medical research enterprise and help speed the movement of research discoveries from the laboratory to the patient.

During the past decade, pharmaceutical firms have increased their research and development investments to more than \$30 billion (Ref. 3). Considering the many other organizations involved in medical research in this country (e.g., Department of Defense, Department of Energy, Department of Veteran's Affairs, academic organizations, and foundations), the total amount spent each year in the development of medical technology in the United States could conceivably approach \$100 billion.

With an aging population it is worth noting that in 2002 Medicare expenditures for new drugs and devices were approximately \$4 to 6 billion.

To help speed access to these new technologies, CMS is working on novel ways to better coordinate coverage, payment, and coding for a more timely reimbursement process.

Nonetheless, there is concern that new discoveries in basic sciences are not rapidly translating into new medical products for patients. In a recent report announcing its Critical Path initiative<sup>1</sup> (Ref. 4), FDA noted that the numbers of new drug and biologic applications being submitted to FDA are decreasing despite the dramatic increase in research and development spending over the past decade.<sup>2</sup> Current estimates suggest that it takes 10 to 15 years and \$800 million in investment for a new drug to make it from the laboratory bench to a patient's bedside (Ref. 5). On April 22, 2004, FDA published a notice in the **Federal Register** (69 FR 21839) asking for input on the scientific and technical hurdles that cause delays and other problems during the product development process. That notice focused exclusively on FDA. In this notice we are requesting that all constituents comment on what HHS agencies can do together to stimulate innovation in medical technologies.

HHS, through its operating agencies (e.g., NIH, FDA, CMS, and CDC), is an important part of the nation's medical technology infrastructure. To help HHS understand what it can do to facilitate the development of innovative medical technologies, we are asking the following questions:

1. What strategies and approaches could HHS implement to accelerate the development and application of new medical technologies?

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<sup>1</sup> The report lays out FDA plans to help make the critical path more predictable and efficient. If products that are likely to fail can be identified earlier in the development process, more research and development resources can be devoted to developing those products that are likely to succeed.

<sup>2</sup> Only one in five products that reach the clinical testing stage ever makes it to marketing.

2. How can HHS help its agencies (e.g., NIH (and its grantees), FDA, CDC, and CMS) to work together more effectively to eliminate obstacles to development of medical technologies?

3. How can the HHS scientific and regulatory agencies work more effectively with CMS to eliminate obstacles to development?

4. What forums should HHS use to survey constituents about obstacles to innovation (e.g., public meetings, contract research, focus groups)?

5. How can the portability of information between HHS agencies be optimized?

6. Which HHS policies and programs effectively spur innovation? Which policies and programs at NIH (and its grantees), CMS, FDA, and CDC should be expanded to help spur innovation? Do any policies and programs pose obstacles to innovation?

7. What role should be played by nongovernmental partners in assisting the Federal Government in this process?

## **II. Comments**

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## **III. References**

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Elias A. Zerhouni, "Statement of the Director to the House Subcommittee on Labor-HHS-Education Appropriations on the FY 2004 President's Budget Request," April 2, 2003.

2. National Institutes of Health, Roadmap Overview, September 2003.

3. Tufts Center for the Study of Drug Development, U.S. Pharmaceutical Industry Inflation-Adjusted R&R Expenditures and NCE Approvals, 1963-2002.

4. FDA, "Innovation or Stagnation, Challenge and Opportunity on the Critical Path to New Medical Products," March 2004.

5. Tufts Center for the Study of Drug Development, "Background: How New Drugs Move Through the Development and Approval Process," November 2001.



Dated: 5/18/04  
May 18, 2004.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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