

NCI and FDA Announce Joint Program to Streamline Cancer Drug Development

Under an agreement between the Food and Drug Administration (FDA) and the National Cancer Institute (NCI), which is part of the National Institutes of Health (NIH), the two agencies will share knowledge and resources to facilitate the development of new cancer drugs and speed their delivery to patients.

FDA Commissioner Mark McClellan, M.D., Ph.D., and NCI Director Andrew von Eschenbach, M.D., said today that they will establish a multi-part Interagency Agreement to enhance the efficiency of clinical research and the scientific evaluation of new cancer medications. The planned agreement, to be announced formally at this week's meeting of the American Society of Clinical Oncology in Chicago, will enhance existing programs and add new joint programs to the existing close cooperative relationship between NCI and FDA, both of which are part of the Department of Health and Human Services (HHS).

"This new collaboration between two key HHS agencies means that federal researchers and regulators will be working together more effectively than ever before," said HHS Secretary Tommy Thompson. "The result will be a more unified, integrated, and efficient approach to the technology development and approval process at a critical time for a disease that affects too many lives," Secretary Thompson said.

The agreement offers potential benefits for the more than one million Americans who are diagnosed with cancer each year. "The FDA is committed to finding better ways to get safe and effective treatments to patients with life-threatening diseases as quickly as possible," said McClellan. "At a time when the opportunities to reduce the burden of cancer are greater than ever, sharing tools and resources with our colleagues at the National Cancer Institute will help us fulfill that mission," he said.

"The effort between NCI and FDA in cancer therapies is a prototype that should inform and eventually be applied across all areas of research," said NIH Director Elias A. Zerhouni, M.D. "Dr. McClellan and I are committed to NIH and FDA working closely to find innovative ways to more rapidly make the fruits of our discoveries available to the public."

"The collaboration will help the two agencies take full advantage of their combined knowledge base at a time when many new kinds of anti-cancer agents are in the pipeline," said von Eschenbach. "Molecularly targeted drugs and other novel agents offer great promise, but they also present new challenges that require more collaboration between those involved in their discovery and development," he said.

An NCI/FDA Oncology Task Force, which involves senior staff from both agencies, will oversee implementation of the specific components of the agreement. Areas of collaboration announced today include the following:

- Developing markers of clinical benefit (biomarkers) for evaluating new cancer medicines. The two agencies will work to develop a standard approach for evaluating biomarkers that demonstrate a drug's clinical effectiveness and that can potentially serve in clinical trials as surrogate endpoints, which are substitutes for more conventional measures, such as survival time or mortality. Better defined surrogate endpoints could help speed the development of new drugs.
- Creating a cancer bioinformatics infrastructure to improve data collection, integration, and analysis for preclinical, preapproval, and post-approval research across all of the sectors involved in the development and delivery of cancer therapies.
- Addressing joint technology development issues. NCI and FDA staff will continue their current collaboration on clinical proteomics (involving the discovery of protein markers in the blood that can be used to detect and monitor disease course and drug response) as a possible model for initiatives in areas such as diagnostic imaging and molecular targeting.
- Advancing the development and evaluation process for cancer chemoprevention agents, including the development of clinically meaningful endpoints.
- Conducting a systematic review of current policies to identify other ways in which FDA-NCI collaborations can enhance the development and regulatory process for cancer technologies.
- Improving consumer awareness of the consequences of their choices about diet and nutrition for cancer prevention.
- Enhancing staff capabilities through collaborative training, joint rotations, and joint appointments.

"This is truly a unique opportunity to improve the development process for new cancer drugs and diagnostics," said Anna Barker, Ph.D., NCI's deputy director for strategic scientific initiatives, and co-chair of the NCI/FDA task force. "Whether you're in academia or industry or government, bridging the gaps between research and regulatory processes will benefit everyone involved, especially cancer patients."

Theresa Mullin, Ph.D., FDA's assistant commissioner for planning, who co-chairs the task force for the FDA, added that the group will also explore how to create representation on each other's advisory boards. "Direct clinical input from outside experts can be very important in accelerating development and establishing the right standards, especially at early stages in the process," she said.

The new partnership is an important step toward NCI's challenge goal to eliminate suffering and death due to cancer by 2015, as well as toward FDA's

goals of improving the availability and use of safe and effective treatments for cancer. "The bottom line is that this collaboration holds great promise for getting better cancer drugs to patients sooner," von Eschenbach said. "Our job is to translate the promise of this unique collaboration into real benefit for patients as soon as possible."

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For more information about this collaboration, go to a Q & A on the topic at <http://www.cancer.gov/newscenter/pressreleases/NciFdaQandA>. For more information about FDA's activities to improve the development and use of cancer therapies, and to improve consumer information about steps to prevent cancer, visit FDA's Web site at <http://www.fda.gov>.