NIH: Moving Research from the Bench to the Bedside

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Good morning, I am Dr. Anna Barker, Deputy Director for Strategic Scientific Initiatives for the National Cancer Institute (NCI) of the National Institutes of Health within the Department of Health and Human Services, and Co-chair of the NCI/FDA Oncology Task Force.

Thank you, Mr. Chairman and distinguished members of the Subcommittee, for the opportunity to be with you this morning to discuss the National Cancer Institute's recent announcement of the formation of joint Task Force with the Food and Drug Administration (FDA). The mission of the Task Force is to work together to explore areas of mutual interest and responsibility that could better inform and optimize the development and review processes for new cancer drugs and technologies. The scope of this Task Force includes several areas of common interest including the extension of current collaborations and the development of: 1) a formal interagency agreement; 2) bioinformatics platforms; 3) joint programs to further optimize each agency's research and regulatory processes; 4) science-based models for endpoints to assess clinical benefit in patients; and 5) joint training programs and appointments for staff. NCI is committed to meeting the challenge of eliminating suffering and death due to cancer by 2015; and we anticipate that this collaboration with the FDA will help to achieve that goal by providing safe, more efficacious cancer drugs to patients sooner.

With over 1.4 million Americans diagnosed with cancer each year, NCI recognizes the need for a closer collaboration with the FDA in order to best serve patients' needs. NCI's goal, in furthering all of its collaborations with the FDA, is to work jointly to improve communication and outcomes in key areas of cancer drugs, especially targeted agents and diagnostics development. This alliance with the FDA will focus on the development of a seamless continuum between discovery, development, and delivery of new cancer drugs and devices.

Exponential growth in biomedical research and the explosion of enabling technologies have resulted in a "new science" of oncology. Since there is still a great deal that we must learn about cancer, we must continue to support the biomedical research that drives this engine of discovery. In parallel, it is critical that we translate our understanding of cancer beyond the cell into the individual and into specific populations. The sequencing of the

human genome and our sustained investment in all areas of biomedical research have led to an ever-increasing fundamental understanding of cancer as a disease process. This foundation of knowledge now provides us with multiple opportunities to intervene at various steps of this process through the development of new drugs and technologies to detect, prevent, and treat cancer. We must capitalize on this 21st century "inflection point" in cancer research, accelerate the translation of knowledge into new interventions for cancer patients, and ensure that they are delivered to all who are in need.

The collaboration between the NCI and the FDA will be formalized through an interagency agreement. Interagency agreements between government agencies allow and facilitate the exchange of services, supplies, advice, counsel, and funds. NCI has several successful Interagency Agreements already in place with the FDA, including the Cooperative Center for Biologics Evaluation and Review-NCI Microarray Program for the Quality Assurance of Cancer Therapies and other Biological Products, and the FDA-NCI Clinical Proteomics Program. The clinical proteomics initiative has allowed our agencies to jointly provide the foundation for the development of proteomics-based diagnostics technology.

Proteomics is the study of the proteins that are produced by cells to carry out the specific tasks that underlie most of our life processes. New technologies that were developed through the Clinical Proteomics Program have generated protein fingerprints that may provide early warnings of cancer and offer new ways to measure drug side effects. This collaboration has yielded the identification of more than 130 proteins in cancers of the breast, ovary, and esophagus that change in types and amounts as the cells in these tissues grow abnormally. The assessment of these patterns may provide new means of diagnosing and treating cancers earlier. Most recently, this collaboration has produced a new technique that may allow physicians to monitor patients' responses to molecularly targeted drugs. In one study, researchers successfully identified specific proteins that may be useful in monitoring patients treated for breast and ovarian cancer. This approach could assist physicians in monitoring patients on therapy to determine if a particular drug is working effectively. The NCI-FDA proteomics team has developed new tools for visualizing and analyzing protein patterns that reduces the risk of error, increases productivity, and provides an efficient method to analyze large sets of protein data. NCI and FDA staff will continue to develop this clinical proteomics collaboration and use it as a foundation to build initiatives in other areas, such as diagnostic imaging and molecular targeting.

The FDA-NCI Task Force will also explore opportunities to facilitate the sharing of information technologies and tools that may further optimize the drug and device development process. To this end, the Task Force has established a working subgroup to examine the potential of creating an overarching and inclusive bioinformatics structure that is capable of capturing and integrating data from preclinical, pre-approval, and post-approval research across all the sectors involved in the cancer drug development and delivery process. Bioinformatics is a key linkage across the discovery, development, and delivery continuum - and common data platforms for communication will be key to future progress. A new NCI initiative, the NCI Cancer Bioinformatics Grid (CaBIG),

which will be piloted in a selected number of NCI cancer centers and programs this year, will provide tools and expertise to support the achievement of this goal.

Common bioinformatics platforms will serve to facilitate the performance and reporting of clinical trials - a key step in evaluating the safety and efficacy of new drugs and technologies in patient populations. The Task Force also plans to identify opportunities to optimize other interfaces that occur across the continuum of drug and device development and delivery. An additional focus of the group's efforts to optimize the work of all sectors is the further development of biomarkers; which have the potential to optimize and accelerate both the discovery and development of new targeted cancer drugs for treatment - and to improve diagnostics for early detection of cancer.

The group will mutually examine science-based strategies that could enable the development of standard approaches for evaluating potential biomarkers of clinical benefit. Some of these biomarkers and technologies may someday serve as surrogate endpoints for the conventional measures of clinical benefit currently being used to assess new agents and technologies. NCI and FDA will explore ways to develop the science required for the development of evidence-based standards and approaches to evaluate these endpoints. A portion of this effort will also be dedicated to further study of standards and processes that could facilitate the development of safe agents for cancer prevention, especially chemoprevention.

Finally, all of these initiatives will benefit from staff training and joint appointments of staff and fellows, who will have training rotations at both agencies. The Task Force is currently assessing existing programs that offer opportunities for joint training and appointments as well as determining opportunities for new efforts in areas such as new technologies. In conclusion, the goal of this Task Force is to ensure that the NCI and FDA work together more effectively than ever before - for the benefit of cancer patients and their families. We have a tremendous opportunity to optimize and hopefully to accelerate the development process for new cancer drugs and diagnostics. Bridging the gaps between research and regulatory processes benefits everyone involved, especially cancer patients. Building on past collaborative efforts with FDA, and working toward the development of a seamless continuum between the discovery, development and delivery of safe and effective drugs, will help the NCI achieve its goal of eliminating suffering and death due to cancer by 2015.

Thank you again for this opportunity to discuss NCI's new collaboration with FDA to optimize and accelerate the development of safe and more effective drugs and technologies to detect, prevent, and treat cancer. I will be happy to answer any questions that the Subcommittee may have.