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Introductory Remarks to the Biotechnology Applications in Biomaterials Workshop*

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Good morning, I'm here to welcome you on behalf of the Food and Drug Administration (FDA). I'm pleased to be here and pleased that this workshop could be developed as a joint effort of FDA and the Society for Biomaterials, and the other cosponsors: the National Science Foundation (NSF); the National Institute of Standards and Technology (NIST); and the Industrial Biotechnology Association (IBA).

Welcoming you gives me the opportunity to say a few things as well. I have a passing familiarity with biotechnology from my years at the Center for Biologics Evaluation and Research, but I came here to learn. I congratulate the organizers on a very promising program.

This workshop grew out of the federal government's biotechnology and materials crosscutting efforts, an initiative of the Office of Science and Technology in the White House. Scientists from across the FDA met with scientists form other federal agencies to develop national policy for biotechnology and materials science. A number of reports have resulted from this initiative.

The use of biotechnology approaches in the development of biomaterials represents an exciting emerging technology. As Dr. Coury has noted in the preceding address, it holds many possibilities for medical use. It is clear that the human body presents a hard environment for traditional materials. Biomaterials offer the promise of meeting these challenges.

Biotechnology as applied to biomaterials has a special importance to FDA, as these biomaterials will be used in a myriad of medical devices.

We are interested in fostering communication on all aspects of this issue—research, regulation, and commercial applications. I want to emphasize that we want to work together. We are particularly interested in working with industry while their products are in the early stages. This field is changing so rapidly that we must cooperate if we are to accomplish anything efficiently.

Device sponsors are responsible for the design, manufacture, quality control (Good Manufacturing Practices), testing and clinical development of their products. But working with Center for Devices and Radiological Health staff early in the process can help address problematic issues in a timely way. Given our unique overview of the field and high volume of reviews, we can provide a broad perspective in assessing your program and making suggestions. Our materials and biotech/life sciences staff bring a special expertise and value to these development discussions with sponsors. Our scientists are the heart of our review programs.

The unique qualities of biomaterials derived from biotechnology will present special public health challenges and important questions, such as (1) do these biomaterials present special risks?, (2) do they work in unexpected ways?, and (3) what are the most effective regulatory means for ensuring that the devices made from these biomaterials are safe and effective?

Jurisdictional issues must also be considered. Which Center will handle a product is determined by such parameters as concurrent use of other products, and use in combination products. In addition, our new jurisdiction procedures assign a lead center for single entity products.

FDA currently divides up the work according to Center expertise. At the Center for Biologics Evaluation and Research, the staff is expert in issues about risks of cells carrying adventitious agents. They have many gene jockeys and immunologists who work on biotech products. At the

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Center for Drugs Evaluation and Research, the focus is on clinical development and pharmaceutical toxicology. And at the Center for Devices and Radiological Health, engineers, physicists and medical specialists are working on biotechnology.

FDA is using the strengths of each center to forge the agency's program, which is coordinated by the Office of the Commissioner.

Already we are seeing applications to study biotech devices and to put them on the market. One example is interactive wound and burn dressings—in effect, artificial skin developed through tissue engineering techniques. Examples of other products in the developmental stage include endothelial cells put on vascular grafts to reduce thrombus formation in the wall of an organ and encapsulated cell implants that consist of cells secreting hormones, enzymes or neurotransmitters, enclosed within a polymer capsule and implanted into a targeted site within the body. Implants include islets of Langerhans in diabetic patients and dopamine-secreting cells in patients with Parkinson's disease. I am certain that the creativity of our scientists and medical practitioners will in turn derive many more uses.

In the meantime, FDA must determine what types of regulatory systems are appropriate for these products. As we do this, we want to promote sound technological development. But first and foremost, we are a public health agency. As we evaluate new biotechnology devices, we must assure their safety and effectiveness. We must look at these products in the context of benefit versus risk. To promote sound public policy, this must be based on good science and a realistic approach to obtaining and sharing information.

We welcome the suggestions and advice of industry, both today and in the future. We are hoping that this workshop will aid the development of our regulatory approach. Our questions include (1) does the use of biotechnology materials in a product always create new questions of safety and effectiveness and hence mean that a Premarket Approval Application is needed?, (2) what sort of toxicology approach is appropriate for biotech-produced materials?, and (3) as one moves from traditional materials to biotech materials for comparable uses, to what extent are clinical trails needed to show safety and effectiveness?

A note to industry. You can objectively discuss the characteristics of your biotechnology products, but don't pre-sell them—advertising and promotion before a product is cleared is prohibited. And as you prepare your pre-market submissions, feel free to use our staff as a resource to ensure you are meeting all requirements.

The Center intends to develop guidance documents for biotechnology products as we have for other products. Already, we have developed a draft guidance document for interactive wound and burn dressings. As technology develops, we must determine what type of information is needed for guidance for other products, and what types of guidance are really helpful to manufacturers as well as our reviewers.

On an international note, as with other aspects of FDA's program, we are interested in harmonization of procedures to evaluate biotechnology products. So far, this looks most interesting with Europe, Canada, and Japan.

In closing, I want to emphasize again: We are interested in working together with you as this exciting technology yields medical products we never thought possible.