Statement of

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At

Public Meeting on Nanotechnology Materials in FDA-Regulated Products

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I appreciate the opportunity to participate in this public meeting, and I applaud the Food and Drug Administration for convening it.

I also want to thank the Project on Emerging Nanotechnologies[2] for commissioning me to prepare a recent report analyzing FDA's tools for regulating the products of nanotechnology. My comments today will be based largely on the analysis and conclusions in that report.

Today's meeting is important because nanotechnology and FDA's role in regulating it are important, to public health *and* to the nation's economy. The amazing powers of nanotechnology have beneficial application to virtually every product category under FDA's jurisdiction, including medical devices and drugs that can make a dramatic difference in the health of millions of people. The successful development and introduction of such products are thus a matter of great public interest.

The success of nanotechnology will depend to an important extent, however, on how FDA plays its oversight role. Our society expects a lot of FDA. It expects the agency to *protect public health* by keeping unsafe products off the market and to *promote public health* by ensuring safe and effective new products reach the market promptly. And industry and consumers alike expect FDA, by doing its job well, to *provide the basis for public confidence* in nanotechnology and in the vast array of products it will generate.

This is a tall order. And it comes at a tough time for FDA. As many are beginning to realize, FDA simply does not have the resources it needs to do what people expect. FDA's current budget would have to be almost 50% greater than it is today just to enable

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[2] The Project on Emerging Nanotechnologies is funded by the Pew Charitable Trusts and based at the Woodrow International Center for Scholars. The full text of the report is available on line at http://www.wilsoncenter.org/index.cfm?topic_id=166192&fuseaction=topics.event_summary&event_id=202902

FDA to do what it did in 1996 and fulfill the new mandates imposed by Congress and the administration since then. And this does not take into account the fact that, as technology and globalization advance and new public health challenges emerge, FDA's job gets harder every year.

One grave manifestation of this resource crisis is the recent decline in public confidence in FDA. A Harris poll last spring showed that, between 2004 and 2006, the share of the American population holding a positive view of FDA's efforts to ensure the safety of new prescription drugs dropped from 56% to 37%.

Loss of public confidence in FDA is a matter of real public health concern. In the case of drugs, obtaining the benefits of innovative medicines depends on sound prescribing practices and good compliance by patients, both of which depend on confidence that the risks of the products are well understood and being properly managed. This, of course, requires FDA being fully on top of information about the risks of products not only pre-market but also after products are marketed, and that requires resources, to obtain and analyze the information needed to make good and timely public health decisions.

The fact is, however, that going back many years, over successive administrations, FDA's funding to perform such core public health functions as overseeing drug safety has been inadequate. And this is the context within which FDA is now expected to oversee the wave of new products that will flow from the application of nanotechnology.

In addition to post-market oversight, my report identifies other ways in which the lack of resources impedes FDA's ability to prepare for nanotechnology and play its regulatory role. These include severe constraints on safety-related research and on investment to develop tools for the pre-market safety evaluation of nanotechnology products, as well as constraints on providing developers of new products with the testing and regulatory guidance they need so that innovation will not be slowed.

Ironically, FDA's resource problem may have its most immediate and visible impact on nanotechnology in an area often considered less central to FDA's public health mission, namely cosmetics. The consumer product inventory compiled by the project on Emerging Nanotechnologies lists several dozen cosmetic products, already on the market, that claim to incorporate nanomaterials or otherwise be based on nanotechnology.

FDA has no pre-market legal authority over cosmetics and thus no built-in mechanism for gaining knowledge about new products or evaluating their safety prior to the products entering the market. FDA and the industry have compensated for this by collaborating on a set of voluntary, industry self-regulatory mechanisms that generally work well for conventional cosmetic ingredients. These include the FDA regulation that says cosmetic companies should either develop adequate substantiation for the safety of their products or state on the product label that safety has not been substantiated.

But what constitutes adequate substantiation of safety for a cosmetic product containing engineered nanomaterials? Even more basic, what is the exact composition and function

of the nanomaterials being used in cosmetics today? What information do manufacturers have about their safety?

These are questions it seems to me FDA should be able to answer when the public turns to the agency for assurance that nanotech cosmetics are safe. But how will FDA do this? Where will it get the resources to develop scientific guidance on safety substantiation? How will it mount the effort to get detailed knowledge about products being marketed and in the pipeline, especially in the absence of legal tools for obtaining such information?

Let me be clear about one important thing. I do not pose these questions to raise an alarm about the safety of nanotech cosmetics or to claim that other categories of nanotechnology-derived products entering the market are unsafe. What we do know about nanomaterials, however, is that the safety of nano-scale materials cannot be assumed based solely on knowledge about the safety of larger-scale versions of the same material.

So, what we know about the safety of any particular application of nanotechnology is that we just don't know, unless and until we have the data and analysis that reasonably answers the safety question.

And this brings me to the bit of advice that I hope will guide the way FDA and the industries it regulates work together in coming months and years to ensure proper oversight of nanotechnology. ***FDA must find ways to obtain the information it needs to provide the oversight people expect both before and after nanotechnology enters the market place.***

In the near term, the worst thing that could happen for the credibility of FDA and for public acceptance of nanotechnology is for FDA to be in the dark if a safety problem arises with a marketed cosmetic product or food application or when the public simply asks, are these products safe?

In the longer term, lack of the knowledge and information required for prompt pre-market decisions and sound post-market oversight about drugs or devices will similarly undermine FDA's credibility and get in the way of beneficial innovation.

My report contains a number of recommendations for meeting FDA's information needs, some of which FDA could pursue under current law and some of which require congressional action, but all of which require resources FDA does not have. I hope that the administration, Congress and the large stakeholder community concerned about the success of nanotechnology will come together to give FDA the tools it needs to do its job.

Realistically, of course, FDA's resource picture will not change overnight, and Congress is at best slow to act in giving FDA new legal tools, which makes near-term collaboration and sharing of information between FDA and the regulated industry vitally important.

Particularly for cosmetic, dietary supplement, and food applications, which are not subject to the comprehensive product-specific pre-market reviews applicable to drugs and devices, FDA and the industry must immediately find ways to provide FDA detailed information about the specific applications of nanotechnology that are in the pipeline or emerging in the marketplace. This can and should be done in ways that protect legitimately confidential business information from public release while meeting FDA's information needs.

FDA also has an obligation to provide near-term guidance to these industries. FDA can contribute some certainty and order to the marketplace by answering such questions as:

- What is the regulatory status of nano-scale versions of food substances and packaging materials that are currently listed, in their conventional form, in FDA's food additive and generally recognized as safe (GRAS) regulations?

- Is additional safety testing needed for these new versions? Does FDA expect developers to come to FDA prior to marketing?

- Does FDA consider nano-scale versions of dietary supplement ingredients to be "new dietary ingredients" and subject to the pre-market notification requirement of the Dietary Supplement Health and Education Act?

- What if any bearing does a Cosmetic Ingredient Review evaluation of a conventional-scale ingredient have on the safety substantiation of the nanoscale version?

These are not easy questions, and any answer FDA gives today may properly be considered preliminary, but, if it does not provide its best guidance on these questions soon, FDA risks becoming a bystander as nanotechnology enters the consumer product marketplace.

I again thank FDA for convening this meeting and for the effort it is making to prepare for oversight of nanotechnology. I have great faith in the commitment of FDA's staff to the agency's public health mission. I hope this meeting is the first step in a broad collaborative effort to give FDA the tools it needs to do its job.

I will be pleased to answer your questions.

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