1st Annual Conference on Nanotechnology Law, Regulation and Policy

Food and Drug Law Institute and the Project on Emerging Nanotechnologies

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Keynote Address

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Good morning. First, I'd like to thank the Food and Drug Law Institute and the Woodrow Wilson Center's Project on Emerging Nanotechnologies for giving me this opportunity to speak with you.

I also applaud both organizations, as well as their partners Arizona State University and the Burdock Group, for taking the initiative to organize this first annual conference on nanotechnology law, regulation and policy. Nanotechnology is a topic – and a challenge – that will be on the front burner at the Food and Drug Administration (FDA), and in many other settings, for years to come. And I'm sure the second, third, and fourth annual conferences, and many beyond, will provide valued opportunities for the community to address nanotech issues.

The great thing about conferences like this is that they are all about looking ahead, anticipating issues, and hopefully laying a foundation that will help ensure the future works out the way we would like. I have to confess, though, that I get a certain amount of pleasure thinking about topics like nanotechnology in their historical context.

In my first stint at FDA beginning in 1976, to date myself, the big technology shift happened when the secretaries in the Office of Chief Counsel traded in their IBM Selectrics for Lanier Mag Card machines. FedEx was the hot new way to get documents from one place to another in a hurry. And among FDA's highest profile regulatory issues were the saccharin ban, Red Dye No. 2, and PCBs in fish – all efforts to address safety issues spawned by advances in chemical technology.

In my second stint, in the early 90's, I was, believe it or not, still able to function without access to e-mail, but plant biotechnology and the Calgene tomato were front and center as regulatory challenges for FDA, and genomics was emerging as a platform for drug development and innovation promising great health benefits.

Today, it's nanotechnology. And, just as our Blackberries have zoomed us to our present state of instant connectivity, nanotechnology promises to be at least as transformative as

any new technology that has ever come along, if not more so – and to be at least as challenging for FDA.

As everyone in this audience is well aware, nanotechnology can make possible striking and highly beneficial innovation in virtually every category of products regulated by FDA – super-strong materials for implantable devices, breakthrough drug delivery systems that take therapeutic agents precisely to the point of action, and active food packaging materials that can detect harmful bacteria in food – just to name a few.

The potential benefits for patients and consumers are great, and the economic potential for industry is large as well, with sales of nano-enabled therapeutic and food products expected to reach $35 billion within three years and grow rapidly from there.

The questions that I know are on everyone's mind at this conference are these: How can we be sure these potential benefits of nanotechnology are realized? And, in particular, what is FDA's role, and is FDA ready to play it?

In my few minutes here today, I'll share a few perspectives on FDA and its readiness to oversee nanotechnology. And my message is simple. While I have considerable faith in the resilience of FDA's staff, the public's expectations are high, and we simply cannot take for granted that FDA is equipped to meet them. It's a cautionary message, but one I hope serves as a call to action for those with a stake in the success of nanotechnology.

First, a word about the public's expectations. Experience has taught that the American public wants it both ways when it comes to FDA oversight of innovative technology, and as well they should. They want FDA to foster prompt availability of beneficial new products, and they want FDA to ensure that risks are well understood and managed, both before and after products enter the market.

In our democratic system, it should come as no surprise that this high expectation is built into many features of the regulatory statutes FDA implements. On the one hand, FDA has strong pre-market regulatory authority to ensure the safety and effectiveness of drugs and medical devices, but, on the other hand, Congress and FDA have tailored pre-market approval requirements in many ways to help ensure that pre-market reviews do not unduly delay market entry. And they have established user fee programs to fund prompt reviews.

The public's high expectations are often revealed with particular force regarding issues that arise <u>after</u> products enter the market. And we saw last fall in the case of drug safety that these expectations have a lot of political weight, as evidenced by the significant new post-market regulatory powers Congress gave FDA in the user fee reauthorization legislation.

So, the public wants speed and safety. With regard to nanotechnology, however, I see three things going on that will make it difficult to deliver what the public wants. The first is the novelty of the scientific issues raised by nanotechnology. The second is the current

gap in information and scientific tools to address those issues. And the third is FDA's dire resource situation.

On the first point, the novel feature of nanotech materials is the entirely new properties potentially associated with materials at the nanoscale. In my lay terms, nanoscale materials have the potential to go places in the body and do things when they get there that conventional scale particles cannot do. These features have obvious benefits in drug and medical device design, but also the potential for unanticipated adverse effects.

If you'd like a more scientific synopsis of the new issues posed by nanoscale materials, as they affect FDA oversight, I can recommend no better source than the July 2007 report of FDA's own Nanotechnology Task Force. As the Task Force points out, the toxicity of nanomaterials may vary not just with mass but also with surface area, reactivity and electrical charge.

This does not mean that nanoscale particles are necessarily unsafe, but it does mean that we cannot assume their safety based on what we know about the conventional scale version of the material. At least for now, *de novo*, case-by-case safety assessment is required.

The difficulty, however, as the FDA Task Force recognizes, is that we do not at present have the information and tools we need to make such assessments. Not surprisingly, considering their recent arrival on the scene, we simply do not have the same body of what the Task Force calls "generalizable knowledge" about the potential interaction of nanomaterials with biological systems that we have on conventional materials.

This is the basic knowledge that is needed to both ask the right safety questions and devise the testing approaches needed to answer them. Until that knowledge is built up and testing approaches are reasonably validated, FDA is likely to be very cautious in making safety decisions about nanoparticles. And rightly so.

Finally, these new scientific challenges are coming along at a time of dire resource constraints at FDA. And this gets to the heart of the question of whether FDA is equipped to do what the public expects it to do.

The FDA scientists and regulatory experts who made up the Nanotechnology Task Force not only identified the knowledge gaps but recommended steps to fill them. These include:

- Promoting and collaborating on research to understand the basic safety science of nanoscale materials;
- Building in-house scientific expertise and infrastructure to make good use of the emerging body of knowledge;
- Evaluating current safety testing approaches; and
- Developing new approaches as needed to properly test nanoscale materials.

This is not a pie-in-the-sky agency wish list. It is rather a simple accounting of the basic scientific foundation that must exist at FDA if it is to do its job on nanotechnology.

Unfortunately, this need is coming along at a time when FDA simply does not have the resources to meet it – a fact that, fortunately, is becoming increasingly well known.

Late last year, a subcommittee of FDA's Science Board, comprised of outside experts and stakeholders, issued a scathing report on the state of science at FDA. The subcommittee cited the combination of rapidly growing demands on the agency and lack of investment in the agency's basic scientific infrastructure, and it concluded that "FDA cannot fulfill its mission" because its science base has eroded, its staff lacks the needed scientific capacity and capability, and its information technology infrastructure is inadequate.

The subcommittee specifically included nanotechnology among a group of emerging technologies it doubts FDA can adequately regulate for lack of science capability and capacity.

Strong words. And very disturbing words. And a real challenge to FDA and the communities surrounding it.

It's a difficult challenge because the solution to FDA's resource problem will not come cheaply or easily. Just this week, the Science Board subcommittee, in response to a request from Chairmen Dingell and Waxman, issued an estimate of what it would cost to address the science deficiencies at FDA. They recommend more than doubling FDA's appropriated budget over the next five years. For comparison, the FY 2009 budget President Bush proposed for FDA last month does not even keep pace with regular increases in the cost of doing business. It is, in real capacity terms, a budget cut.

So, increasing FDA's budget is an uphill battle, but it's a battle that must be won.

I said earlier that I have confidence in the resilience of FDA's career staff, in part because I know that what they are going through on nanotechnology is simply the recurrence of a familiar pattern. New challenges come along, whether in the form of new congressional mandates, new administration initiatives, or from the labs of the nation's inventors. But new resources almost never follow.

Today, nanotechnology is just one of many such new challenges, some of which are, frankly, of much more immediate public health concern. Congress, for example, just gave FDA new tools to regulate drug safety, which will require substantial management attention and resources to implement. And FDA is under great pressure to overhaul its approach to food safety. FDA and the White House recently announced new strategies for both domestic and imported foods, but without any real increase in resources to implement them. As long as FDA's year-to-year budget allocations remain essentially a zero sum game, these initiatives, not nanotechnology, will rightly get the bulk of any discretionary resources.

So, what does a resilient and creative FDA staff do? On nanotechnology, the staff took the right first step in issuing the Task Force report candidly outlining the issues and what needs to be done. It has also shifted around modest resources to fund in-house studies on issues like dermal absorption of nanoparticles, just to help ensure that some of the cosmetic and consumer products already on the market without FDA review don't pose significant hazards.

And, where FDA has pre-market oversight authority and the sponsor bears the burden of proof, as with drugs, medical devices, and food additives, FDA will be cautious in granting approval until the needed data are in hand.

Commendable as these steps are, they are not, in my view, enough to meet the public's dual desire for speed in access to beneficial new products and a high assurance that the products are safe.

A pre-market approval process that bogs down for lack of the scientific knowledge and tools to ask and answer the right questions about safety and effectiveness is in no one's interest. Safety may be served by blocking market entry, but we all lose from lack of access to beneficial innovation.

From a safety standpoint, the greater concern is for cosmetics and dietary supplements, products that seem to be leading the way to the marketplace but are generally not subject to an FDA pre-market safety review. If a safety issue should arise about a marketed nanotech product, the impact on consumer confidence and acceptance of the technology would go well beyond the particular product involved.

So, what should developers of nanotechnology products and other stakeholders be doing to help ensure FDA can properly play its oversight role? I have three suggestions.

First, be a partner with FDA in developing the scientific knowledge and tools to evaluate nanotechnology. For companies, this might include investing directly in the needed data collection and methods research. It might include lobbying the White House-run National Nanotechnology Initiative to give higher priority to safety-related research and to fund work that directly addresses FDA's needs.

Second, whether a product is subject to FDA pre-market review or not, companies should be open with FDA in providing information on products under development and how the companies are addressing safety evaluation, so that there can be mutual learning as applications of nanotech progress.

Finally, anyone who cares about FDA's success on nanotechnology should join the political effort to solve the agency's resource problem. The Alliance for a Stronger FDA is a new and potentially potent vehicle for this effort. The companies, trade associations, patient and consumer groups that have come together under the Alliance banner have already done important work educating Congress and the public. They have laid the

foundation for what will have to be a sustained, long-term effort to meet FDA's resource needs. And, with very tough budget years ahead, they will need all the help they can get.

It has not been my purpose to kick off this conference with a dose of doom and gloom. From where I sit, excitement and optimism about the promise of nanotechnology are quite in order. But the success of the technology, which rests in part on FDA's capacity to oversee it, cannot be taken for granted. It rests in your hands.

Thanks again for this opportunity to be with you.