ACS Presidential Symposium: "Nanotechnology: Delivering on the Promise -- Opportunities and Challenges for Health, Safety, and the Environment"

The Regulatory Void?

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Good morning ladies and gentlemen. It is a pleasure to be here. I would like to thank President Schmidt for the invitation to present, and for her leadership in convening this Symposium.

My topic this morning is *The Regulatory Void?* I modified the title by adding a question mark. It is, after all, questionable what exactly is a regulatory void, and whether we have one.

What is a "void"? The word itself conjures up images and impressions that are unflattering. As an adjective, void means, among other things, not valid or legally binding as in "to void a contract." When used as a noun, it means "a completely empty space," uninhabited, or unoccupied.

With regard to the regulation of nanotechnology, none of these terms feels right to me. Yet the reverse seems equally ill-fitting. Upon reflection, my view is we are getting there, the space is not a void, but there are "voids" that need to be filled, and our challenge as a community of stakeholders is to determine how best to do so. Our success will be measured by how quickly and ably we fill these voids.

As a relatively new technology, nanotechnology tests us at many levels. Scientists know that nanotechnology, as any new technology, tests us at the scientific level with regard to understanding nanoscale materials' chemical and biological properties and exposure pathways. Commercially, any new technology tests even the most gifted entrepreneur. Most importantly for me

as a lawyer, it tests the core integrity of existing governance tools -- laws, regulations, guidance, and everything else along the governance spectrum -- to regulate, as appropriate, without stifling nanotechnology so as to prevent it from offering the promise of a better tomorrow. This is not easy, as we all know.

As stewards of this technology, even a basic sense of history compels us to be mindful of prior mistakes, and to do things differently from another big "it" -- biotechnology. Debates to this day vascillate between images of a utopian world heralding a better tomorrow and a dystopian collapse of human civilization as we know it. This experience is very instructive as to what to do differently.

On the governance side, we have adapted the rubber-suit approach -- the stretching/contorting/adapting of existing tools to address nano issues. The very speed of innovation leaves us no choice. Existing legal authorizations have bestowed upon federal agencies laws, the implementation of which must "adapt" to manage the potential risks occasioned by nanotechnology and nanoscale materials. I believe our legal infrastructure is sufficiently robust for this purpose; my Section of the American Bar Association so concluded ten years ago. When I chaired the ABA Environment, Energy, and Resources Section, I lead an effort to prepare a series of legal briefs on exactly this topic. Over 100 lawyers contributed to the effort and carefully reviewed existing environmental statutes and concluded they were sufficiently robust to manage risks from nanotechnology. Plainly, however, gaps, or "voids," exist as to the effective and comprehensive deployment of resources to implement the authority agencies possess. These voids exist at many levels -- lack of resources, lack of data, lack of participation from industry and other stakeholders for whatever reason to contribute information, among other gaps. Our challenge is to fill these voids as quickly as possible.

Similarly, new technologies test political will. One of our biggest challenges as a community, certainly for me as a lawyer, is navigating changes in Administrations, in career staff leadership positions, in agency priorities and policies, in diminishing resources and an exodus of

senior and very experienced agency staffers, and in differing levels of technical understanding of nanotechnology among Members of Congress and their staffs. These changes similarly create voids and pose formidable challenges in aligning program goals within and among agencies and expressing those goals coherently and consistently through the federal family of agency actions.

With regard to the regulation on nanotechnology, there is no dirth of federal regulatory activity. Many agencies represented in the NNI are actively engaged in regulatory measures -- FDA, CPSC, EPA, and NIOSH most especially. NIOSH is listed not because it regulates, but because its contributions to industry and other nano stakeholders with regard to the development of safe handling practices and related areas are so significant. I never pass on an opportunity to thank John Howard's leadership and Chuck Geraci's and his colleagues' epic contributions to the field. Yes, there are gaps or voids in these regulatory efforts, but certainly the space is by no means empty.

I would like to focus now on EPA activities, as that is where I spend most of my time. There are voids in EPA's understanding of the toxicological and exposure characteristics of nanomaterials. This is because there is limited information on these materials. EPA, industry, and others are working to fill these gaps. It is important to do so as we must have a better understanding of the toxicological profile and exposure implications of nanoscale materials to ensure we protect human health and the environment. As a legal matter, some nanoscale chemical substances are considered "new" under TSCA and require notification to EPA as a predicate to marketing the nanoscale chemical. EPA's authority under TSCA is an important tool to add to our knowledge of nanoscale materials and to ensure the commercialization of these materials pose no unreasonable risk.

There is no such notification requirement for existing chemical nanoscale materials. This is becuase EPA's Inventory Policy, issued in 2008, provides that nanoscale versions of chemicals listed on the TSCA Inventory are themselves considered existing if the nano version shares the same molecular identity as its conventional counterpart.

Over the past decade, EPA has received some 160 PMNs for new nanoscale substances. Most have been allowed into commerce but with restrictions. One hundred percent undergo detailed review, which takes 6-24 months, not the 90 days under TSCA.

Now, I mentioned that there are gaps or voids in EPA's understanding of nanoscale chemical substances. The PMN process enables EPA to obtain information regarding new nanoscale chemical substances. EPA similarly lacks information on nanoscale versions of "existing" chemical substances. Well, some of these gaps could be filled in the foreseeable future as EPA is poised to propose a TSCA rule that would compel the submission of infomation to EPA under TSCA Section 8(a). The proposal has been many years in the making and illustrates a lack of alignment of priorities, common goals, and regulatory objectives between EPA and OMB, and other federal agencies privy to the proposal. The rulemaking, when issued in final, will be an important tool to help fill some large information voids.

Moving quickly to EPA's pesticide office, OPP issued a proposed policy on nanoscale materials in pesticides in 2011. OPP proposed obtaining information on such materials by using either its "adverse effects" reporting mechanism, or its data call-in authority under FIFRA. Unsurprisingly, the adverse effects approach met with significant push-back. That policy was issued four years ago and is still in a state of suspended animation. This has created a directional void and is overdue for clarification. Importantly, EPA has registered a nanopesticide -- nanosilver (biocide) in textile applications -- and was sued almost immediately for it. There are clear gaps in OPP's knowledge and practice in registering nanopesticides. This is one area where industry needs to step up, and where OPP needs to step up and reformulate its outdated and largely "voided**"** position from 2011.

EPA's Water Office has recently entered the nano space. Last September, the Water Office announced its decision to collect information on wastewater discharge hazards associated with

nanomaterials manufacturing and processing. This information will assist in addressing voids in the Water Office's understanding of nanoscale water discharges.

EPA is engaged in many different levels in the governance of nano, including at the international level. Its long engagement with the OECD and the Working Party on Manufactured Nanomaterials has yielded significant contributions to our knowledge and understanding of the properties and risks of nanoscale materials. EPA's work with Canada under the RCC is equally beneficial. Of course, EPA's development of test methods and data to address hazards and exposures throughout the OECD, EPA's own ORD, and collaborations with federal partners continues to fill important knowledge voids. That, collectively, will better integrate data into risk assessment and risk management decision-making.

This brings me to my concluding thoughts. Federal policy is and has been supportive on delivering the promise of nanotechnology. The federal government's approach to delivering on that promise through an integrated, coherent, efficient, and effective regulatory approach across federal agencies is a work in progress. Voids plainly exist and need to be filled to diminish incoherence, inconsistency, and directional uncertainty, all of which frustrate commercial development and invite disarray in business. Significant private sector support is needed; enhanced communication and collaboration among stakeholders is needed to leverage effort; and strong federal leadership is needed to ensure alignment on core policy objectives and goals.

Thank you.