Commentary: Public Outreach by the FDA: Evaluating Oversight of Human Drugs and Medical Devices

Mark S. Frankel

It is abundantly clear that the Food and Drug Administration (FDA) is under fire from a number of quarters. Yet, ironically, many of those same critics have been supporters of increasing the FDA's mandate over the past few decades in the face of rapidly advancing science. It appears that society has decided that it cannot live without the FDA, but is not satisfied with the one it has. Society's relationship with the FDA is about to be tested once more as nanotechnology emerges as an important public policy issue.

The authors of the case study on oversight of drugs and devices rightly observe that oversight by the FDA of nanotech drugs, devices, and biologics — i.e., nanobiotechnology — is a matter of great social importance.[1] The ability of nanotechnology to contribute to public health is potentially enormous, but, as the authors note, so are the risks. Although there will be other government agencies involved in the oversight of nanotechnology, the FDA will be front-and-center in the nation's effort to balance the promise of this exciting area of research with its dangers, many of which are likely not yet known.

As part of their approach to examining the oversight challenges facing the FDA with the emergence of nanotechnology, the authors' surveyed a group of experts for their views on 28 criteria, including such items as public input, capacity, and health and safety (see Figure 2 in the case study for a list of criteria). Ultimately, they were able to use results from 15 experts, a sample size that they readily acknowledge has serious limitations in adding to our knowledge base.

In principle, I have no problems with using experts as a source of opinion and knowledge on the matters we are discussing. But that begs the question of what millions of Americans think about the issues. At several points in the essay, the authors note the importance of public input into developing an effective and transparent oversight process for nanotechnology. That public input, and the challenges it poses for FDA oversight of nanotechnology, is the focus of the remainder of this commentary.

Why Public Input?

It would be easy to answer the question of "why public input?" with the simple refrain that we live in a democracy, a "government by the people, for the people, and of the people," in Abraham Lincoln's words. It would also fall far short of what we need to know in order to understand the connection between public

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input and public policy. In the context of the issue that occupies us here — FDA oversight of nanotechnology, with its very real consequences for people's lives — the need for public input is grounded in some very critical, practical considerations. Among them are the following: (1) the public wants, and deserves, assurances that its tax dollars are being used effectively within the law; (2) the success of FDA oversight will depend, to some extent, on the willingness of citizens to report adverse effects from products involving nanotechnology; (3) securing the promised benefits of nanotechnology depends, in large part, on the public's acceptance and use of its products; and (4) no government oversight system can succeed in the absence of public confidence and trust in both the people who run it and the way it is administered. Public input is not simply window dressing. If done well, it should foster public confidence that the views of citizens are being heard and considered in designing and operating the oversight system.

The Challenges of Public Input

Securing useful public input into complex decisions about highly sophisticated technologies presents many challenges to public policy, and nanotechnology will be particularly thorny. The challenges are threefold. First, low public confidence in the FDA will foster skepticism among the public, causing them to doubt the seriousness of any outreach by the agency, and to consider absenting themselves from any public deliberations. Second, the general lack of knowledge about nanotechnology among ordinary Americans raises concerns about the quality of their input. And third, the way in which the "average" citizen obtains and evaluates knowledge about a public policy issue tends to favor emotion over facts. I now turn to each of those challenges.

The Public's View of FDA

During the last few years alone, the public has been exposed to numerous reports of troubling performance by the FDA. This bad news, whether referring to FDA's lax enforcement of drug or food safety regulations (which may have led to serious illness or even deaths), its cozy relationship with industry (that some argue biases the expert advice it receives, leading to premature approval of products), or its torturous review process (delaying public access to potentially life-saving medicines), has taken a heavy toll on public opinion.

A 2006 *Wall Street Journal* Online/Harris Interactive Health-Care Poll found that "most adults say they are concerned about the FDA's ability to make independent decisions that will ensure that patients have access to safe and effective medicines (80%),...[and] that 82% of adults feel the FDA's decisions are influenced by politics rather than medical science."[2] In a similar poll conducted in 2008, 62% of those polled gave the FDA a negative rating on "[e]nsuring the safety of prescription drugs that are manufactured outside the United States."[3] Furthermore, during the past two years there has been a flurry of congressional hearings at which Members of Congress have pointedly questioned the FDA's ability to protect the public.[4] Of course, the recent deadly salmonella outbreak due to contaminated peanut butter has further tainted the FDA in the public eye,[5] prompting President Obama to call for a "comprehensive review" of the agency.[6]

The Public and Nanotechnology

The FDA's challenge to develop effective and acceptable oversight for nanobiotechnology in the face of low public confidence is compounded by a public that knows very little about nanotechnology. If it is true that "[t]he future of nanotechnology will be determined in large measure by the public's assessment of its potential benefits and risks,"[7] then the FDA, if not society at large, has much cause for worry. A 2008 nationwide survey of over 1,000 adults by Hart Research Associates found that "[t]he large majority of Americans have little or no awareness of nanotechnology," with 75% saying that they have heard "nothing at all" or "just a little" about nanotechnology.[8] The authors of the survey write that "[n]early half of adults are too unsure about nanotechnology to make an initial assessment on the tradeoffs between risks and benefits."[9]

This lack of knowledge on the part of the public is problematic for the FDA and any others challenged to develop public policy for nanotechnology. In the absence of basic knowledge about nanotechnology

and its potential impacts, people are in no position to evaluate risks and benefits rationally, and policy makers cannot craft sound oversight proposals that will satisfy the public. Complicating this low level of knowledge is the way that people obtain and evaluate information on complex matters.

In complex matters, people are generally too far removed from the situation to truly understand the potential consequences and have very little time in their busy lives to devote to wrapping their minds around a complicated issue. People respond and interpret based on perception and appearance, more than they do on "facts." This certainly has implications for nanotechnology, where so few people have even basic knowledge. With little attention to facts, rhetoric and emotion become powerful cues for influencing public opinion. This often means that entrenched stakeholder groups with very specific agendas will attempt to sway public opinion in their favor by emphasizing rhetoric and emotion over facts. The public will be ill-equipped to judge such appeals.

In formulating public policy, it is critical to understand this interplay of perception and reality. Reality is often so complex and unverifiable at the moment that the "truth" of any claim is not as important as how the situation is perceived. This does not mean that facts are unimportant. But when they are difficult to know and understand, the readiness of people to perceive a situation as a problem and to take some action is shaped to a greater extent by their values and experience and by their comfort with the messages they receive from other players in the policy arena. This has important ramifications for engaging the public on emerging issues in science and technology.

Reaching Out: Challenges for the FDA

So I end where I started, with the paper by Paradise et al., and the point they make toward the end of their paper that "[t]here needs to be [a] transparent process as FDA examines its options for treatment of nanotechnology in drugs and medical devices." What, exactly, does a "transparent process" require? Let me propose the following attributes.

The process should involve two-way communication, in which the FDA listens as much as it talks. Rather than simply waiting for the public to engage the existing administrative process for developing policy (for example, by responding to notices in the *Federal Register*, by submitting a Freedom of Information Act [FOIA] request, or by offering testimony at public meetings), the FDA should develop more aggressive strategies for reaching out to the public. A good example is the agency's collaboration with WebMD to expand their existing consumer web presence and increase their visibility as a source of information useful to the public.[10]

In reaching out to the public, the FDA must realize that there is no single "public." There is a range of publics, each having its own informational needs, and they "react very differently to information, and — most importantly — are looking for answers to questions that often have very little to do with the scientific issues surrounding emerging technologies."[11] The Hart Research Associates survey of public awareness of nanotechnology cited earlier notes that "[a]wareness is lowest among women, especially age 50 and over… adults who have acquired a high school degree or less education…those whose annual household income is less than $30,000…and African Americans."[12] Other research has documented that "[m]any traditional outreach efforts…often fail to reach minority populations and citizens of lower socioeconomic status,"[13] and that a person's ethnic background can "influence such factors as how much weight is accorded some facts, how a problem is configured, what aspects of a problem are noticed,…."[14] The lesson here is that the FDA must pay attention to not only what its says, but also to who is listening and how the message is being perceived. In other words, the straightforward delivery of sound information — "the facts" — will not be sufficient if the agency is serious about engaging the public in a meaningful way.

The drugs and devices case study underscores the importance of public input into the development of oversight for nanobiotechnology, but stops short of describing what that means and how it should happen. In a limited way, this essay tries to fill that gap in order to understand more fully what is involved when the policy process meets the public.

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