Risk Communication for Nanobiotechnology: To Whom, About What, and Why?

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Regulatory oversight and public communication are intimately intertwined. Oversight failures, both actual and perceived, quickly galvanize attention from both the media and the public, as has occasionally happened in all of the historical cases with which this symposium is concerned — gene therapy, workplace chemicals, drugs and devices, and genetically modified organisms (GMOs), especially those used as (or in) foods. Some developments, such as GMOs, seem to have more cultural significance or "cultural resonance" than others and are especially likely to garner public attention. Developments in nanotechnology, on the other hand, do not seem to have captured as much popular attention. However, the accelerating convergence between nanotechnology as material science and biotechnology, health, and medicine could easily change this situation.

In media accounts, advocates for emerging technologies (e.g., industry representatives, academic or medical researchers, and other pro-technology stakeholders) may compete in the media "marketplace of ideas" with both outright opponents and those who advocate for a more precautionary approach (e.g., some non-governmental environmental or consumer organizations). Scientists can belong to, or be enlisted by, either side in debates, sometimes creating media coverage featuring "dueling scientists" that effectively polarizes public opinion, a scenario that especially describes the history of GMOs. While journalism is often criticized for approaching science stories this way, attention to all sides of a debate is a core ethical principle of journalistic practice. Few, if any, journalists — even science specialists — are in a position to make clear distinctions between correct and incorrect science in the absence of a strong scientific consensus. With respect to uncertain risks and other thorny ethical and policy issues, the situation is even more complex.

Yet many policy negotiations and deliberations take place largely in private — not necessarily in secret, but at the federal level "inside the beltway" of Washington, D.C., and without much publicity. Science and technology policy is rarely breaking news outside aca-

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demic and governmental circles. Until something bad happens, it is assumed, with some justification, that the public is largely uninterested in these highly technical decisions.

Regulations sometimes do require that information on risks and uncertainties be included proactively in communication efforts aimed at non-expert consumers outside of the regulatory and policy communities, whether in obtaining informed consent for medical treatments; including risk information on drug labels, in drug advertisements, or on chemicals used in the workplace; providing nutritional and other information on food packages; or opening environmental impact assessments to public comment. However, even this proactively publicized information seems to attract little attention until and unless there is unmistakable evidence of harm. Nutritional labels and warnings are easily ignored; informed consent may be just another form to sign for someone anxious to be treated for a medical condition; and environmental impact proceedings may attract only a small number of participants, disproportionately those who have predefined stakes in the outcome.

In short, risk communication for emerging technologies is often somewhat haphazard. This injects substantial uncertainty into the process of introducing these emerging technologies — a process that sometimes seems to take place while all concerned are waiting for the other shoe to drop (that is, for something bad to happen, whether an unanticipated consequence of the technology itself or the emergence of widespread public concern, justified or not). This is the situation with nanotechnology right now, and it will be even more the situation as nanotechnology and biotechnology continue to converge.

In response, in recent decades more proactive means have been sought in Europe and (increasingly) the United States to garner broad public input with respect to new technologies. This input is commonly sought "upstream" of hard policy decisions in the ultimate hope of gaining legitimacy for those decisions and perhaps increasing their quality, as well as their palatability. An enormous investment on the part of the U.S. government currently supports studies of the societal implications of nanotechnology, including experiments with upstream public engagement. Science centers and science museums have taken up this issue, reexamining their traditional role as educators and trying to create new forums for public discussion.[1] Science cafés, town hall meetings, and other occasions for public deliberation about science and technology policy are becoming increasingly common.

This is not just a matter of transparency being seen as an inherent good in a democratic society. In part, this is also a defensive strategy. When communication fails, oversight may also be seen as failing, and as other papers in this symposium demonstrate, communication transparency is an important component of perceived regulatory "success." Abundant evidence suggests that a perceived lack of transparency erodes trust, and that the erosion of trust increases concern about risks — sometimes to levels perceived as disproportionate to what the best science and engineering might predict, a phenomenon termed "social amplification of risk."[2]

Technology risks may instead be attenuated rather than amplified, and nanotechnology currently appears to be a case in point. Such technologies lack the kind of cultural resonance that would crystallize public concern (as can happen, for example, when technologies appear to work against widely shared cultural values and ethical assumptions), even though in scientific terms these technologies might be considered of equal or greater potential harm.[3] While risk perceptions are inevitably shot through with value judgments and cannot be reduced to a simple formula, regulators and other policy makers have scant resources and must decide which risks most need attention.

As part of a larger project organized by the University of Minnesota, this paper reviews the communication dynamics associated with the broad range of historical cases of regulated technology with which this symposium is concerned: genetically engineered organisms (GEOs) in the food supply, pharmaceuticals and medical devices, chemicals in the workplace, and gene transfer research or "gene therapy." Each of these technologies is analogous in a different way to various emerging nanobiotechnologies.[4]

First, however, some further attention to the purposes and motives behind "risk communication" and "upstream engagement" of citizens is in order. Note that this paper is primarily concerned with *public* communication processes — that is, forms of communication directed at, or participated in by, members of the public who are not necessarily experts (scientific, medical, engineering, or regulatory specialists), rather than communication among different regulatory bodies, or between scientists and regulators.

What Is the Goal of Communication?

Risk communication has many distinct forms that serve distinct goals. Informed consent is based on widely recognized ethical principles that call for the recipients of medical treatments and participants in research to be made aware of the risks as well as the potential benefits. This is communication that takes place primarily between a patient or research participant (and, especially for minors, the individual's family

or guardian) and a health care provider or researcher. Warning labels on pharmaceuticals, ingredient lists and nutritional information on food products, and warning labels on chemicals are other examples of communication that is legally required but that is aimed primarily at individual consumers of a product, in contrast to citizens engaged in a collective process of policy development or similar decision making.

In the United States, public hearings on federal Food and Drug Administration (FDA) or Environmental Protection Agency (EPA) policies engage a range of individuals, but often, in practice, this means organized stakeholders with particular interests in the outcome. Environmental impact statement (EIS) processes at the federal, state, or local level may reach out to a different class of stakeholders, residents of a particular geographic area where construction or similar activity is being proposed. In principle, organized opposition may persuade an industry or other organization to go elsewhere. For existing facilities, community "right to know" legislation requires industry to make risk information available to local residents. But a new emphasis on broad public engagement of ordinary citizens as a necessary part of the process of introducing new technology is a different, much less familiar, idea.

What exactly is the goal of public communication surrounding regulatory policy for technology (that is, communication that reaches the public sphere, often taking place via the mass media)? What is the goal of communication with particular publics regarding public policy decisions surrounding science and technology issues (that is, communication involving a broad range of ordinary citizens, in addition to stakeholder groups)? Finally, why should we need to communicate "upstream" of making specific policy decisions (rather than afterward)?

Some commentators feel that public communication will increase broad public engagement in the decision-making process and is therefore an inherent good that is consistent with democratic values. Others may be more interested in upstream communication as a sort of early warning system, effectively a form of market research that alerts technology's shepherds (in industry, academia, and government) to potential public objections. Still others, perhaps yet more cynically, may view communication primarily as a strategic option, a means of enlisting (or one might better say "co-opting") public or stakeholder opinion. In principle, the idealistic use of upstream engagement to improve democracy seems quite different from its use as either market research or pro-technology propaganda. But in practice, it can be hard to tell the difference.

The strategic use of risk communication is ethically problematic to the extent that it may be organized for the purpose of causing individuals, stakeholders, or other "publics" to accept a technology that they might otherwise reject. It would be equally problematic if it were organized to persuade people to reject a technology they might otherwise accept. In this context, communication — whether "upstream" or not — is distinguishable only with difficulty from advertising or political propaganda. Yet most people are likely to remain uninformed and largely apathetic about new technology of which they are largely unaware.

The strategic use of risk communication is ethically problematic to the extent that it may be organized for the purpose of causing individuals, stakeholders, or other "publics" (groups of individuals united by a common worldview or common interests, but perhaps not formally organized as stakeholders) to accept a technology that they might otherwise reject. It would be equally problematic if it were organized to persuade people to reject a technology they might otherwise accept. In this context, communication — whether "upstream" or not — is distinguishable only with difficulty from advertising or political propaganda. Yet most people are likely to remain uninformed and largely apathetic about new technology of which they are largely unaware.

If considering citizens' views is an ethical good, somehow we need to encourage citizen opinion formation. This may be done in a way that mimicks the process through which opinions would naturally form, if people's attention were not "used up" by the myriad

other issues of everyday life. Social psychologists use the terms "heuristic" versus "systematic" processing to describe the difference between superficial exposure to information, requiring reliance on simple cues like the identities and perceived character of spokespeople, and deeper thought. The goal of public engagement activities is largely to encourage deeper thought about issues that might otherwise be ignored.

Ordinary opinion polling, especially for highly technical issues, may not be informative without thoughtful consideration on the part of whoever is answering the poll questions. Alternative "consultation" models such as the consensus conference, the citizen jury, and the deliberative poll are all designed to gain some understanding of what people might think, if only they had the opportunity to think more carefully, about the prospects and perils of particular new technologies. However, "upstream" engagement necessarily takes place with only a limited knowledge of the risks and uncertainties under discussion.

Pro-technology advocates, persuaded that public engagement will make people more accepting of technological change, and pro-engagement communication specialists pursuing public engagement to improve democratic practice have shared interests in making engagement activities happen. At present, opponents of particular forms of technology seem less likely to participate in these activities, which they may even see as co-opting their positions; organizers and sponsors of public engagement activities also may not be comfortable enlisting the organized opposition as participants.

While anti-technology advocates sometimes seem to get the lion's share of press attention, pro-technology propaganda on behalf of scientific and technological developments is common as well. Most people in our society expect benefits as well as risks to come from technological developments. While there are often strong public objections to technologies that turn out to be riskier (or less well regulated) than anticipated, this in itself may be analyzed as a reflection of an underlying technological optimism characteristic of U.S. culture. Violating assumptions of technological beneficence and regulatory adequacy thus produces strong reactions, precisely because it is unexpected.[5] This outcome is not helpful, of course, to technology's promoters. There are strategic, as well as ethical, reasons not to overplay the propaganda card: it often backfires.

Another ethically problematic use of risk communication involves its use to pass on at least partial responsibility for a risk to the audience for the communication. Thus hearings associated with environmental impact statements may make local community residents co-responsible for decisions involving whether to permit and where to locate risky activities (manufacturing processes involving toxic chemicals, power plants, railroad lines used for transporting risky materials, and so on). Getting informed consent for a medical treatment makes the patient co-responsible for the decision to undergo the treatment. Yet the community resident is not as knowledgeable about the pollution risk as the expert advisor, and the patient is not as knowledgeable about the treatment risk as the physician providing the information. Further, both decisions are implicitly coerced or constrained: the community member wants a job (and perhaps higher property values due to an economic stimulus, although at some risk of lower property values if pollution occurs) and the patient wants a cure.

Somewhat similarly, the provision of nutritional information makes the food consumer co-responsible for his or her unhealthy diet, although this case is different because nutritional labeling is part of a steady stream of background information that many consumers simply ignore, whereas EIS activities and informed consent are less routine. Further, since people have to eat and additional background understanding of human nutrition and physiology are required to make complete sense of this information, nutritional labels may have little impact absent media campaigns highlighting known risks (e.g., the recently visible concern over the transfat content of some processed foods).

Warning information included in package labels as well as advertising for over-the-counter and prescription drugs remains controversial, with increasing numbers of physicians under pressure from patients to prescribe something those patients have seen advertised and physicians themselves being the target of advertising and marketing. As for nutritional information, much of the information about drugs that is publicly communicated requires additional context to be fully understood, including fine distinctions between conditions that are defined as "normal" (e.g., personality characteristics such as shyness, minor aches and pains) and conditions defined as "disease."

A guiding ethical principle across all of these risk communication circumstances might be recognizing the difference between using risk communication to empower people to participate in making decisions that reflect their own values rather than (necessarily) the values of the technology's promoters or detractors, and using it to abrogate responsibility for risk-oriented decisions to other, often less knowledgeable and less powerful, constituencies. Further, the accurate transfer of expert knowledge — what science studies scholars call the "deficit" approach — does not elimi-

nate the role of individual and social values in making decisions about risky technologies. But again, in practice, these different uses of risk communication may be difficult to distinguish.

So what exactly constitutes "responsible" risk communication for emerging technologies? Is it even possible? Why do it? The preceding analysis has suggested why asking the public (or "publics") to consider risk prospectively has some substantial ethical (and even strategic) disadvantages. Since these are not trivial, what are the arguments for doing risk communication at all? What makes "upstream" engagement about risk worth its own risks?

We do know something about what "successful" communication policy for emerging technology would *not* look like. First, the goal of persuading people to accept expert views without thoughtful consideration is *not* a likely goal for a successful policy. At a minimum, this propagandistic approach runs the risk of backfiring, as it did in the "mad cow" case in the U.K., which in turn opened the door to public rejection of expert views on the alleged link between autism and measles vaccine — *not* a good outcome. World War II era propaganda research firmly established that two-sided messages are likely to be more persuasive than one-sided messages with most audiences, especially those likely to be exposed to the other side later on.[6]

Second, the goal of providing people with all of the technical information they need to fully understanding particular technologies before they choose to accept or reject them is both impractical and based on a faulty assumption. The statistical link between knowledge about and attitudes toward a particular technology is a very weak one across a range of new technologies.[7] People are unlikely to be persuaded to agree with the scientific, engineering, or medical communities on the basis of technical information alone; not only is some degree of heuristic processing inevitable, but values as well as knowledge are important to such decisions. In addition, even expert opinion can be divided, as is true today for issues ranging from GMOs to nuclear power.

Finally, both knowledge and values need to be broadly defined in this context. "Knowledge" can include what is sometimes called "local knowledge" or folk wisdom, not just the scientific, engineering, or medical knowledge of experts. Folk knowledge can be based on past experiences, resulting (for example) in the emergence of particular patterns of trust with respect to scientific experts or regulatory agencies. It can also be based on direct observations of local ecology and climate, farmers' handed-down knowledge of natural cycles, and so on. And the concept of "values" extends beyond those directly connected to the benefits or risks of the technologies themselves to the valuing of a stable and thriving economy and the fabric of social life in which those technologies are embedded.

Thoughtful, technology-oriented scholarship recognizes that choosing to adopt particular technologies (or not) is a values-based decision that inevitably affects the future form and direction of society, as well as individual choices made within that structure.

Increasing the popular awareness of the risks, benefits, and uncertainties of specific technologies for the purpose of empowering people to contribute to decision making about the adoption of these technologies (or not) requires upstream *engagement*, that is, thoughtful consideration. Each of us has many issues — from the demanding, concrete, immediate issues of daily life (paying bills, negotiating traffic, holding down a job, raising children) to issues more removed from our immediate vision (foreign policy, climate change, safety from invisible contaminants, wise use of science and technology). We all perform a kind of cognitive "triage" to decide which issues demand our attention at a given moment. As a result, issues that are further removed — such as policy for technologies whose risks and benefits are as yet uncertain — will get shunted aside.

Many contemporary strategies for upstream risk communication are attempts to get beyond "heuristic" (or superficial and cue-driven) processing of risk information to the point of "systematic" (or thoughtful) consideration[8] of how these elements (risks, benefits, uncertainties) interact with our own values, in order to suggest wise policy. Perhaps we would rather accept a risky treatment than forego it, knowing there was something we could have tried. Perhaps not. Perhaps we would rather accept a risky — or simply unsavory — industrial facility in our backyard if it means our family will have jobs. Perhaps not. The calculus of such decisions involves values, as well as facts. Physicians, scientists, and engineers cannot — should not — make these decisions for us. Their appropriate role is to empower us to make our own decisions, based in part on the best expert knowledge.[9]

From a utilitarian perspective, risk communication based on these ideas may improve societal decision making (not just meet the strategic goals of technology's promoters). From a rights-based perspective, democratic theory suggests that citizens have an inherent or inalienable right to choose society's future form and direction, as well as make their individual decisions about individual technologies from as knowledgeable a vantage point as possible. Thoughtful, technology-oriented scholarship recognizes that choosing to adopt particular technologies (or not) is a values-based decision that inevitably affects the future form and direction of society, as well as individual choices made within that structure.[10]

At present, nanotechnology and nanobiotechnology appear to involve *attenuated* risks rather than *amplified* ones. Nothing terribly bad has happened, and no one seems to care very much. Few want to "rain on the parade" of emerging nanotechnology products (over 800 at last count[11]) unnecessarily by pointing out that carbon nanotubes and other nanoparticles may cause lung disease, that nanoparticles of heavy metals may enter cells and cross the blood-brain barrier with unknown effects, that manufactured nanoparticles released into the environment will ultimately enter aquatic and other ecosystems, also with unknown effects, and that almost nothing is really known so far about the long-term effects of worker (or researcher, or ecosystem) exposure to these materials.

Other challenges face attempts at upstream public engagement in the United States (as elsewhere) for both nanotechnology and nanobiotechnology. Not only are the risks very poorly understood, there is no solid national consensus on what kind of regulatory policy principles we should follow, whether an approach that discounts unproven risks or a "precautionary" approach that seeks proactive proof of harmlessness. Further, American citizens respond strongly to the risks of technologies that seem to oppose their ethical and value systems or threaten their economic or social well-being. We have no mechanisms in place for understanding these non-physical risks on a systematic basis. And only a small percentage of the public is ever likely to "engage" in time-consuming discussions and other "upstream" activities, meaning that media coverage will remain a primary source of most technology-related information for many.

Meanwhile, there is still no huge public outcry for action on nanotechnology; most members of the public appear unconcerned, as do many experts, while a handful of advocates (including some industry representatives) push for some sort of stronger oversight, if only because this will chart a clearer path forward. Some experts fear that the public will overreact if uncertain but substantial risks are discussed openly. Gradually, regulators are becoming more concerned about nanotechnology oversight, partly as a result of advocacy activities, and industry representatives are as well, if only out of self-interest. Extending this discussion beyond nanotechnology-as-material-science to nanobiotechnology, more popular awareness of risks is likely. How can we engage the public in this dialogue about what to do, in order to address nanobiotechnology's risks as well its substantial promises in a responsible way? There is no crystal ball that will resolve these questions. However, a closer look at the communication dynamics of our historical comparison cases may offer further insights.

Distinguishing Audiences and Using New Channels

One additional analytical step is necessary to think clearly about risk communication for nanobiotechnology. Up to now this discussion has referred to "the public," or in some cases specific "publics," without much focus on what these terms might actually imply. Most modern societies are strongly — and increasingly — pluralistic. People living and working in these societies come from different ethnic, racial, and language groups; they embrace different religious traditions, some people strongly, and others weakly or not at all; and although many immigrants are attracted to the shores of America for "the good life," visions about exactly what this might constitute are hardly uniform. Indeed, one broadly shared element of our own political culture is that it specifically allows for religious and political variation, that is, freedom. Further, the rapid evolution of communication technology has resulted in an unprecedented explosion of information and messages that literally reach around the globe, making national boundaries largely irrelevant. Messages sent in North America may reach audiences anywhere, and vice versa.

Different audiences and publics have different values. Arguably, there is no such thing as a "general public." Rather, many publics with different belief systems and different concerns co-exist. These may form distinct "interpretive communities" whose understanding of information, messages, and situations is more broadly shared within the group than outside of it. People with very particular stakes in an issue — those with a specific disease, or who live in a particular geographic neighborhood, or who belong to a particular political group or other advocacy organization — form specialized audiences with a predetermined stake in the types of issues that specially affect them. In modern times, risk communication is not a "one size fits

all" proposition. Even broadly distributed media messages are subject to radically different interpretations.

Communication also takes place within human society at many different levels. Historically, communication scholarship has distinguished between interpersonal, organizational and small group, and mass communication, but these distinctions are breaking down. Is an individual standing in a discount store aisle and reading the usage warning information on a mass-marketed, mass-distributed cleaning product engaged in "mass" communication, or something more individual? Is the cell phone a medium for interpersonal communication like a land-line telephone, or a mass communication device that can also send and receive text messages, including everything from product advertisements to weather warnings that are sent to many people at once? An automated voice message from my pharmacy reminds me that I may have a prescription that can be refilled; is this interpersonal or mass communication? And what about the Internet — when everyone can choose his own news, what has happened to the concept of "mass" communication?

All of these considerations involving, on the one hand, the existence of distinctive audiences, interpretive communities, or "publics" and, on the other hand, rapidly evolving communication media providing vastly enhanced personal choice among information sources, are parts of the contemporary communication "landscape" in which risk communication now takes place. Communication is also globalized, due to both technological and economic globalization processes, which adds an additional layer of complexity. Standards for acceptable risk clearly vary around the world based on a broad range of value-laden concerns and priorities.

Six distinct models are especially useful for thinking about public communication of the risks of nanobiotechnologies (or, for that matter, other new technologies). Five of these have been introduced at various points in the preceding discussion: the "informed consent" model that privileges individual choice in medical and other research settings and that is primarily a matter of interpersonal communication; the "community sovereignty" model that privileges self-determination by local communities and is the foundation of EIS procedures; the "occupational safety" model through which workers in particular locations and occupations are (by federal mandate) given information on specific risks associated with their work; the "marketing communication model" in which individuals are treated primarily as product consumers and target audiences for both advertisements and product-specific risk information; and the "marketplace of ideas" model in which it is hoped that individuals acting as citizens of a democratic society will recognize and embrace true ideas if given full information and complete freedom of choice. A sixth model, the typical FDA-style public hearing on a new drug or policy, takes place at a national level, but the format is designed on the EIS or community sovereignty model in which the primary voices likely to be heard are those of organized stakeholder groups, in part because the logistics and costs of attendance may be barriers to others.

Note that the "public engagement" movement rests on the "marketplace of ideas" assumption that collective wisdom will generally prevail. The other five models all provide, at least potentially, some elements of disempowerment and coercion. In some cases the communicator has an implicit or explicit outcome goal. This is true not only in the "marketing communication model" (which applies to both food products and pharmaceuticals), but also in the "informed consent model" in which the communicator is, or represents, someone who is (in effect) recommending a course of action, most commonly a form of medical treatment. In other words, these communicators have an implicit stake in the outcome. In addition, in the "informed consent model," they are communicating with someone who is potentially vulnerable to coercion due to the desire to get well. The "community sovereignty" or EIS model is much like the "marketplace of ideas" model but at a local level. However, this too is a coerced or constrained model to the extent that rejecting a development means rejecting its economic benefits. The national hearings model is arguably the least coerced or constrained but generally even more focused on stakeholder views, since potential speakers generally have to plan in advance and have funds available for transportation and participation. The "occupational safety" model may require workers to process complex information about conditions that relate to their employment; the fact that full recognition of a significant risk could mean that the employment itself is too risky creates a strong psychological disincentive for accepting the risk information. This, therefore, is also a potentially coerced or constrained form of communication.

A key and nearly unique component of the "marketplace of ideas" model is that the recipient of the communication is acting as a citizen member of a collective body, not an isolated consumer. This also applies to the "community sovereignty model," for example, in EIS deliberations, with two important caveats: community-oriented deliberations about risk often have an element of coercion or constraint as described above, and they are often conceptualized as involving primarily stakeholder perspectives since neutral citizens are least likely to attend. The EIS tradition

itself is closely associated with situations of environmental controversy; these activities are not very far "upstream," in other words.

Unfortunately public engagement activities at the national level based on a "marketplace of ideas" concept are quite rarely implemented and may, as a practical matter, be almost impossible. Scholars continue to experiment with alternatives, but not only is it difficult and expensive to get a sufficient number of people to participate, but mechanisms for injecting the outcomes of such activities (i.e., summaries of what people think, on reflection and after discussion) into policy determinations are weak to nonexistent. With rare exceptions, this model remains an ideal rather than a reality. Figure 1 summarizes distinctions among our most common models for public communication about risks; note that FDA hearings are described as also having a "process" goal, meaning the public comment process is required, but its effect on policy decisions may not always be obvious or direct.

Communication via the news media (as opposed to advertising, which is a big part of the "marketing communications model") does not appear in this figure because such communication has too many variations to be summarized effectively in this way. Media can be consumed individually or in a group setting, for example. However, there are no actual "participants" other than journalists, because the communication is one-way, and the applications are extremely diverse. All types of risks have become the subject of news stories. The goal is most often, ostensibly, providing information to citizens, but the news media have been accused of being influenced by both sources and advertisers to such an extent that their own freedom to communicate is compromised. They have also been accused of letting their own business interests (i.e., sales of copies or audience share) dictate what news they cover and how.

Figure 1

Characteristics of Common Risk-Communication Models (Other Than Mass Media News Reports) Used in the United States and Elsewhere in the Developed World

Model	Typical application	Typical participants	Coercion vs. free choice	Communicator motivation	Individual vs. group setting	Voluntary vs. mandatory
Informed Consent	Drug trials; experimental medicine	Patient/provider	Coercion potential	Goal-driven (treatment); compliance	Individual	Mandatory
Marketing Communication	Product sales (including food products, chemicals, drugs)	Consumer/ marketer	Coercion potential (varies)*	Goal-driven (sales)	Individual (via labeling, ads)	Risk information generally mandatory
Occupational	Workplace warnings	Worker/ employee	Coercion potential	Regulatory compliance	Individual (mostly)	Mandatory
Community Sovereignty	EIS+ hearings (local enviro. controversy)	Stakeholder/ regulator or planner	Coercion potential	Goal-driven (consensus, acceptance)	Group discussion	Mandatory process
National	FDA policy, hearings, national EPA policy	Stakeholder/ regulator	Free choice but limited participation	Regulatory compliance	Individual speakers	Mandatory process
Marketplace of Ideas	Public engagement activities	Citizen (expert^)	Free choice as ideal	Goal-driven (mixed goals)	Group discussion	Voluntary

* All marketing communication has sales as a goal, and risk information is generally provided only in response to legal requirements. However, for the consumer, the level of motivating perceived need for the product may vary widely, the communication is not face-to-face (which can increase coercion), and the individual is usually free to decline without penalty or embarrassment.

\+ EIS stands for Environmental Impact Statement.

^ Role of expert varies depending on model; generally, the goal is to reduce power differential in communication between experts and others.

However, the news media are ubiquitous in our society and generally considered essential to democratic processes, even if flawed. Further, the impact of the other six models of public risk communication depends in many ways on mass communication via the news media. Few people are likely to participate in most public meetings, whether local or national. Many more get some sense of vicarious participation or at least awareness of issues and controversies through news coverage. Even in the case of the informed consent model, which is the only model in which communication is directed at specific individuals, other people hear about experimental interventions primarily when they hit the news.

Entertainment programming (from docudramas to soap operas) is also an important source of some kinds of risk information, notably health risks. Films are as well (fiction and documentary) and even novels. Most people do not make clear cognitive distinctions between what they learn from entertainment sources and what they learn from the news.

Nanobiotechnology Predecessor Cases and a Look into the "Crystal Ball"

Having described these various risk communication models and the circumstances in which they tend to be used, we are now in a better position to analyze how communication has worked in the case studies on which this symposium focuses. This discussion will look at each case of technology oversight with an eye to identifying weak points in the communication models used.

Gene Therapy

While the oversight process for novel research interventions such as gene therapy is complex, the way in which the risks are communicated to individual research participants is through the informed consent process. Individual cases of negative outcomes, such as the unexpected death of 18-year-old Jesse Gelsinger in 1999, have occupied the forefront of media communication. The Gelsinger case was followed by media reports that many previous "adverse events" had gone unreported to oversight authorities, and that participants were not adequately informed of the risks. Ultimately, tighter supervision of gene therapy trials resulted.

Since nanoparticles are likely to prove useful as delivery systems for introduced genes in future gene therapy research, gene therapy is itself evolving into a form of nanobiotechnology. The potential risks (as well as the potential benefits) of gene therapy are still under investigation. In addition, there is considerable uncertainty about the fate of various forms of nanoparticles in the human body. The very characteristics that make nanoparticles interesting candidates for gene delivery into cells — their ability to enter the cells and otherwise migrate throughout the human body, including crossing the blood-brain barrier — may mean that the ultimate fate in the body of some of these particles will continue to be difficult to predict.

We are almost certain to continue to rely on the informed consent model for communicating risks to individual research participants. However, this is clearly a case in which broader public discussion of the risks and potential benefits involved might be critically needed to help raise our collective awareness of the trade-offs and may have an important role to play in informing policy. In the future, the cases we hear about are likely to involve genetic enhancements, not just treatments of recognized genetic diseases, and these cases are likely to raise significant ethical issues beyond those we currently face.

As gene therapy and other highly technical, highly experimental interventions involving nanotechnology and nanobiotechnology continue to evolve, it seems inevitable that additional "adverse events," possibly including additional deaths, will occur. Yet when this happens, media discussion is likely to focus on the specific events in relative isolation. The technical complexity of the biology and medicine involved almost precludes adequate attention from the media absent a new tragedy. In other words, it may take another serious "adverse event" in the news to again call public attention to the risks.

Drugs and Devices

The FDA regulates drugs and devices, including gene therapy interventions. As with gene therapy, media and other public attention tends to surround cases of oversight failure rather than instances of regulatory success, with coverage rapidly rising in the event of failure then swiftly falling off in a classic "issue attention cycle" pattern.[12] Yet public opinion polls continue to show that the American public generally trusts the FDA.[13]

One important difference between communication surrounding still-experimental procedures like gene therapy and that involved with other drugs and devices is that companies can market FDA-approved drugs and devices directly to consumers (DTC) through ordinary advertisements. This fairly recent development has been controversial. Hundreds of drugs and devices already on the market involve nanobiotechnology.[14] FDA-approved products follow a DTC advertising (or "marketing communication"), as well as an informed consent, model. But it probably will not take many failures of nanobiotechnology

oversight to suggest to consumers that all nanobiotech is suspect.

FDA advisory committees have been accused of including members with conflicts of interest, even though those who are most knowledgeable about a drug or device are often those who have been somehow involved in its development. So far, such criticisms seem largely confined to a vocal minority, but this is subject to change. At the same time physician-to-patient communication is not going to be the only way that potential future patients find out about nanobiotechnology. The future predicted in the "crystal ball" is murky.

Occupational Safety

Occupational safety looms as a major weak point for nanotechnology/nanobiotechnology communication. At present, protections for university-based nanotechnology researchers (e.g., graduate assistants) are not universally mandated. Actual data on workplace exposures and risks are limited. Mechanisms for increasing Occupational Safety and Health Administration (OSHA) attention to nano-related risks remain unclear.

This represents significant potential liability for nano interests, as well as significant public relations risks. As communities and workers become aware of exposure to nanoagrichemicals, an important class of nanobiotechnology applications, this is likely to become a highly contentious area because communication roles are uncertain. Who is responsible for alerting workers to potential risks? In the United States, exactly what triggers nano regulation through OSHA? And how effective will that regulation be?

Nanoagrichemicals raise substantial issues of environmental justice as well. Migrant U.S. workers who may not speak English, foreign graduate assistants at U.S. universities experimenting with nanobiotechnology, and other disadvantaged workers will be differentially exposed to these risks. This is a significant challenge for the industry, as such concerns will not be easily dismissed.

Genetically Modified Organisms (GMOs)

This is a crucially important model for nanobiotechnology, especially the use of nanobio in agriculture. Much of the attention to upstream public engagement for nanotechnology's introduction can be attributed to concern about the divided public opinion that accompanied the introduction of genetically modified foods, most notably in Europe but also in the United States, Canada, and elsewhere.

U.S. federal regulation of GMOs was the product of extensive discussion and negotiation. Much debated was whether the technology should be overseen by the USDA, FDA, or EPA. In the end, roles were carved out for all three agencies, but this took time. Meanwhile, reports that GMO corn genes had spread throughout Mexico[15] and that modified corn intended only for animal consumption had reached U.S. consumer markets in error[16] proliferated. Industry representatives became concerned that this bad publicity would undermine consumer faith in the food supply. While this controversy has died down, rumors persist that new GMO products are being withheld from the market for fear that the public reaction will not be favorable.

From a public communication perspective, the introduction of GMOs into the food supply was accompanied by an industry-driven emphasis primarily on the marketing communication model. Some of the advertisements used (e.g., in the U.K.) made blatantly propagandistic claims; many messages blamed public ignorance for the rejection of GMOs, a significant public relations mistake.[17] Anti-GMO organizations responded in kind. Public opinion in the United States about GMOs remains divided to this day. Whether this could have been avoided had the proliferation of marketing (and anti-marketing) messages been avoided is itself uncertain. However, it seems quite likely that extreme messages on both sides contributed to the persistent polarization.

Conclusion

With respect to public communication, the case study analyses sketched here suggest that worker safety could emerge as a significant environmental justice concern. Disadvantaged workers, ranging from university-based graduate assistants to migrant agricultural workers, will be differentially affected by any investment in nanobiotechnology that presents exposure risks. The GEOs case in particular suggests that past public relations strategies are inadequate. Blaming public ignorance for negative reactions has proven to be a weak approach.

Public faith in the FDA seems to remain strong, albeit with increasing questions being asked about its effectiveness. Public optimism remains about the emerging medical applications of nanotechnology. Yet this social capital is easily wasted if repeated publicity of too many "adverse events" is forthcoming. Informed consent is necessary, but perhaps not sufficient, insurance against such an outcome.

Nanotechnology as material science does not elicit initial public rejection, but nanobiotechnology could easily meet a different fate due to the increased cultural resonance of the "bio" component. The research and development communities would be well served by efforts to anticipate and mitigate public reactions

to the use of nanobio in both medicine and agriculture. At the same time, public engagement has at least the potential to empower non-experts to participate in two-way dialogue about choosing the best path forward, facilitating the marriage of local and expert knowledge.

Acknowledgement

This material is based upon work supported by the National Science Foundation under grant no. 0758195 to the University of Nevada, Las Vegas and grant no. 0608791 to the University of Minnesota. Any opinions, findings, and conclusions or recommendations expressed in this article are those of the author and do not necessarily reflect the views of the National Science Foundation.

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2. See, e.g., R. Kasperson and J. Kasperson, "The Social Amplification and Attenuation of Risk," *Annals of the American Academy of Political and Social Science* 545, no. 1 (1996): 95-105.
3. It is not the purpose of this paper to argue that scientific analyses are necessarily superior to (e.g., more accurate than) culture-based predilections or aversions; however, the two often support contradictory conclusions.
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