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ARTICLES

The "Revolving Door" between Regulatory Agencies and Industry: A Problem That Requires Reconceptualizing Objectivity

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Abstract There is a "revolving door" between federal agencies and the industries regulated by them. Often, at the end of their industry tenure, key industry personnel seek employment in government regulatory entities and vice versa. The flow of workers between the two sectors could bring about good. Industry veterans might have specialized knowledge that could be useful to regulatory bodies and former government employees could help businesses become and remain compliant with regulations. But the "revolving door" also poses at least three ethical and policy challenges that have to do with public trust and fair representation. First, the presence of former key industry personnel on review boards could adversely impact the public's confidence in regulatory decisions about new technology products, including agrifood biotechnologies. Second, the ''revolving door'' may result in policy decisions about technologies that are biased in favor of industry interests. And third, the ''revolving door'' virtually guarantees industry a voice in the policy-making process, even though other stakeholders have no assurance that their concerns will be addressed by regulatory agencies. We believe these three problems indicate a failure of regulatory review for new technologies. The review process lacks credibility because, at the very least, it is procedurally biased in favor of industry interests. We argue that prohibiting the flow of personnel between regulatory agencies and industry would not be a satisfactory solution to the three problems of public trust and just representation. To address them, regulatory entities must reject the traditional notion of objectivity. Instead they should adopt the conception of objectivity developed by Sandra Harding and re-configure their

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regulatory review on the basis of it. That will ensure that a heterogeneous group of stakeholders is at the decision-making table. The fair representation of interests of different constituencies in the review process could do much to inspire warranted public confidence in regulatory protocols and decisions.

Keywords Ethics · Conflict of interest · Genetically modified (GM) organisms · Objectivity · Policy · Regulatory agencies · Revolving door · Risk assessment

Introduction

Several reports have documented the back and forth flow of key personnel between the United States (US) government regulatory agencies and industry, or, in other words, the "revolving door" phenomenon (Mattera 2004; RDWG 2005).[1] Often, the movement of personnel between the two sectors occurs during time periods such that persons who were involved in the development of certain products as industry employees, upon finding work at a federal agency, participate in the government regulatory review of those very technologies. There are potential benefits to the revolving door. Industry veterans might have specialized knowledge that could be useful to regulatory bodies and vice versa. However, the revolving door between the two sectors raises at least three ethical and policy issues that have to do with public trust and democratic representation of interests in the regulatory process. In this paper, we argue that addressing those problems requires that regulatory agencies like the US' Food and Drug Administration eschew their commitment to the traditional conception of objectivity. We hold that they should base their regulatory review practices on an alternative notion of objectivity, specifically, "strong objectivity" (Harding 1998, 2004).

In the first section, we review evidence and examples of the revolving door between US regulatory agencies and industry over a number of years. We also consider US policies aimed at addressing the conflicts of interest resulting from the revolving door. Then, in the second section, we analyze three ethical issues and policy problems concerning public trust and democratic decision-making that arise because of the revolving door phenomenon. They are as follows:

1. Policy decisions about new technologies might be biased in favor of industry.[2]
2. The existence of the revolving door could adversely impact the public's confidence in new technological products, review protocols, regulatory decisions about them, and the government in general.

[1] Due to space constraints, we consider the phenomenon of the revolving door in the US only.

[2] We recognize that not all businesses that form a particular industry will necessarily have the same interests in every regards. For instance, in certain respects the interests of small scale farms that produce organic vegetables are very different from those of the companies that engage in large scale farming using pesticides. We are also aware that trade groups and associations with considerable lobbying clout tend to represent the concerns of the powerful members of industries. In the fourth section of the paper, we address the conflicts of interests that might exist between different subgroups comprising a particular industry and we offer a way of addressing them.

3. The revolving door phenomenon virtually guarantees industry a seat at the policy-making table even though other stakeholders have no assurance that their concerns will be addressed by government regulatory bodies.

We argue that these three problems signal a "public failure" (Bozeman and Sarewitz 2005) of regulatory review of new technologies. In a democracy, one of the ways in which the review process may be a public failure is if it is procedurally or substantively biased in favor of a particular group such that it creates or reinforces unjust power relations between different constituencies. We contend that prohibiting the flow of personnel from industry to government regulatory agencies is not the solution to the three problems of public trust and fair representation. Instead, the remedy lies in regulatory agencies reconsidering their commitment to the standard conception of objectivity.

In the third section of the paper, we make the case that US regulatory agencies' risk assessments and the resulting policy decisions are based on the traditional conception of objectivity. That notion presumes that knowledge claims and epistemic agents can be value neutral. We argue that that notion of objectivity is flawed because normative considerations influence knowers and the knowledge claims they produce.

The fourth part of the paper begins with a discussion of a hypothetical case of the risk assessment of a genetically engineered (GE)[3] fish. We argue that regulatory agencies like the US' Food and Drug Administration (FDA) should reject the traditional conception of objectivity, adopting instead an alternative notion of objectivity, specifically, "strong objectivity" (Harding 1998, 2004). Reconfiguring the regulatory review process so that it is strongly objective will mean that regulatory agencies will have to commit themselves to identifying and rigorously interrogating the normative concerns shaping regulatory decision-making (including risk assessments) of new technologies. To that end, agencies like the FDA, for instance, will have to make place at the risk evaluation table for a diverse group of stakeholders, affording them voice in the regulatory process. That approach will be a crucial step in the democratization of the decision-making protocol for new technologies, including agrifood biotechnologies. In doing that, the regulatory review would control for industry bias; a heterogeneous group of stakeholders would be guaranteed say in the process. Thus, regulatory review and policies would inspire warranted public confidence.

Regulatory Decision-Making and Evidence of the Revolving Door

In the US, regulatory agencies, such as the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), have the responsibility to review pre-market safety data and information and decide upon the approval of new technologies, such as agrifood

[3] We use the terms "genetically engineered" and "genetically modified" interchangeably to denote the process of manipulating a gene using recombinant DNA methods. That method allows for the insertion of a gene or a gene sequence in the DNA of the new host, generating a targeted result.

biotechnology, for market release (OSTP 1986). Multiple laws and regulations guide the scope of their regulatory decision-making, including determining the types of data that are required for specific classes of products. At all agencies, the Administrative Procedures Act governs the process. It requires that prior to final promulgation of regulations, agencies publish draft regulations in the *Federal Register* for public review and comment (reviewed in Kerwin 2003). Agency staff and managers are responsible for taking the public's comments into consideration before making the final decisions about product approval.

Currently, in the US, there is a close relationship between government decision makers at regulatory agencies and the industry. The tight bond, in part, can be attributed to the revolving door between industry and regulatory agencies. That close relationship raises the question whether federal agencies are predisposed to make decisions that favor product approval, and thus, economic gain of the commercial sector at the expense of other concerns, such as human health or environmental safety. This is a matter of particular concern in the case of agencies, such as the USDA, the FDA, and the EPA, that regulate consumer, medical, agricultural, and industrial products. Those organizations' decisions significantly affect the well-being of individuals, communities, non-human animals, and the environment.

The US does have policies designed to manage conflicts of interest (COI) faced by federal employees. It also has rules requiring disclosure of those COI. For example, 18 §USC Section 208 prevents federal employees from handling matters in which they or their relatives have a financial interest and senior officials in the government must disclose those COIs on forms that are available to the public upon request (RDWG 2005). However, there are no laws preventing persons who work for regulated industries from seeking employment with the federal government at the end of their industry tenure (RDWG 2005). While the Standards of Ethical Conduct for Employees of the Executive Branch indicates that a federal employee must avoid "an appearance of a loss of impartiality in the performance of his official duties" (CFR Title 5, Chapter XVI, Part 2635), which includes the handling of a matter for a company for whom he/she served as employee, contractor, agent, consultant, director, officer, or trustee within the last year, regulatory approval of new technological products usually takes several years, and history tells us that federal employees have indeed made key decisions about products from industries within which they used to work.

Recent reports document that key positions in regulatory agencies are often staffed with former high ranking corporate personnel. For instance, David Hoffman, a recent director of the Biotechnology Regulatory Services (BRS) division at USDA's Animal and Plant Health Inspection Service, was a researcher at Paradigm Genetics Inc., a biotech firm, directly before his service at BRS (Mattera 2004, 28). BRS is the body that makes key decisions about approval of genetically engineering organisms (GEOs) in agriculture for field trials or market release (interstate commerce or de-regulation). Also, David Hegwood, the Counsel to the Secretary of Agriculture, was formerly employed at a Washington DC law firm; his duties entailed advising the company's industry clients about international biotechnology trade issues (Mattera 2004, 28). Nancy Bryson, USDA's general counsel, was previously a partner at a Washington DC law firm that advised industry clients on

"biotechnology product approval and regulations" and she served as the co-chair of the firm's biotechnology practices (Mattera 2004, 28). The Secretary of Agriculture, Ann Veneman, had served on the board of Calgene, a biotech company that submitted the Flavr Savr tomato, a GE food product, for market approval to the FDA in 1994 (RDWG 2005). These are not anomalous instances. When key decisions were being made about GE crops and their regulatory approval, over a dozen other high ranking USDA officials had ties to the GEOs or agricultural biotechnology industry (RDWG 2005, 20).

The revolving door phenomenon, specifically, the flow of high ranking industry personnel into the government regulatory sector is not limited to the USDA. Linda Fisher, a former Deputy Administrator of EPA, was an executive at Monsanto Corporation before she joined the EPA (RDWG 2005, 22). She became an employee of the agency at a time when it was making the crucial decision whether it should exert its authority under the Federal Insecticide Rodenticide and Fungicide Act for the regulation of GE plants with genes that act like pesticides (NRC 2000; Reuters 2001). The FDA's Deputy Commissioner for policy, Michael Taylor, who helped draft the policy on recombinant Bovine Growth Hormone, had been a lawyer for Monsanto before his term at FDA (Newell 2003, 62).

To our knowledge, these and other such officials at the USDA, the EPA, and the FDA did not recuse themselves from decisions about the regulation of agrifood biotechnologies products. It is worth considering that even if they had, the implementation of policies by lower-ranking managers might have been influenced by their knowledge of their superiors' employment history in industry.

The door between industry and government also swings the other way. High ranking ex-government workers often secure employment either in the very industries they used to regulate or at firms that provide lobbying or legal services for those businesses (Eggan and Kindy 2010). For example, after leaving his post as the USDA Secretary, Dan Glickman joined a law firm where his job was to advise the company's clients on issues such as biotechnology (Mattera 2004, 28). Similarly, the Assistant Secretary at USDA, joined the Government Affairs Practice Group of Downs Rachlin Martin PLLC where he worked on biotechnology and other issues (Mattera 2004, 28). When the revolving door leads out of government into the industry, the possibility exists that former high ranking federal officials continue to have influence on policy by virtue of their close relationships with career agency staffers serving on government regulatory bodies.

We have argued that the revolving door exists and that the law does not bar the practice. Below, we make the case that the revolving door is responsible for at least three ethical and policy problems.

Public Trust and Democratic Representation in the Regulatory Process *and* the Revolving Door: Ethical and Policy Issues

We hold that, first, policy decision-making (including risk assessments) should be based on the ethical principles that the public subscribes to, and second, laws ought to be a reflection of the intended execution of policies (Beauchamp and Walters

1999). Thus, in this section, we simultaneously discuss three ethical and policy problems caused by the revolving door. Given space constraints, we limit our engagement to only those three issues of public trust and democratic representation in regulatory decision-making.

Justification for the Revolving Door

In a democracy, generally, individuals have the freedom to seek employment where they please. Prima facie, the fact that they used to work for the government cannot be used to prohibit them from working in the private sector. The reverse also holds true. Respect for individuals' autonomy means that no democracy may issue a blanket prohibition against former industry employees seeking work in the government sector. Aside from the issue of individuals' freedom to seek employment, there are epistemic and pragmatic grounds for allowing the free flow of employees between government and industry. Ex-industry personnel could bring their knowledge and experience of industry to regulatory bodies, facilitating the ability of agencies like the FDA, the EPA, and the USDA to serve the public good. Similarly, individuals previously employed by regulatory agencies but now working in the private sector could help businesses become and remain compliant with government rules, policies, and protocols.

While the phenomenon of the revolving door can bring about good, it also has the potential to cause at least three serious problems that have to do with public trust and just representation of interests in policy decision-making. We term them the "Biased Policies Problem," the "Appearance of Bias Problem," and the "Narrow Representation of Interest Problem" and discuss them below.

Biased Policies Problem

The concerns about the flow of employees between the private sector and government regulatory bodies are based on the premise that the primary role of regulatory agencies is to safeguard the interest and well-being of the citizenry (see FDA's mission statement at www.fda.gov). In a democracy like the US, that responsibility has been placed on the government by the people. To fulfill that duty, the state has created agencies such as the USDA, the EPA, and the FDA. The problem that could be occasioned by the movement of personnel from industry to regulatory agencies is that government agencies might privilege the interests of the industry over that of the public. That is not to say that the concerns and interests of the public and the industry can never align; they may do so. Rather, the problem arises when their interests are at odds. Mattera (2004), for instance, contends that the employee exchange between the USDA and the industry has put the public at risk. Given that high ranking positions in the USDA are populated by ex-industry personnel and the industry has managed to secure the lobbying and legal services of firms that employ former high ranking agency officials, Mattera argues that "… US consumers (have been) … turned into a vast pool of unwitting test subjects for the biotech industry's questionable agenda for transforming agriculture" (2004, 28). That concern becomes even more compelling when it is taken into account that risk

experts' evaluations are not value-neutral; rather, they are the product of particular normative considerations (Kuzma and Besley 2008; Meghani 2009). If industry personnel infiltrate high level government positions, their assessment of risks from new technologies and the policies they formulate about them *might* be biased in favor of technology promotion and market success of industry products. Similarly, when the door swings the other way with former key government employees finding work in the very industries they used to regulate (or at lobbying or legal firms that serve those industries), the worrisome possibility exists that they might use their connections within regulatory agencies to encourage officials to favor industry at the cost of, for instance, the public's health or the environment.

Appearance of Bias Problem

Trust is a crucial determinant of laypersons' perception of risk and acceptance of new technologies. According to Siegrist et al. (2007), trust influences affect or feelings, which shapes perception of risks and benefits and, ultimately, public acceptance. Even though trust in institutions does not fully eliminate the sense of risk, it is a valuable instrument for abating the perception of risk (Lang and Hallman 2005). Meijboom et al. (2006) argue that building consumer trust in agrifood systems involves more than providing information to the public about risk; it is about trustworthiness. Trustworthiness in institutions is fostered not only by clarity and availability of information but also transparency about the values underlying the decision-making.

It is improbable that the revolving door phenomenon will increase the trustworthiness of regulatory bodies, the review process, or regulations. The revolving door is likely to result in regulatory reviews wherein the values governing decision-making are the product of the attitudes and relationships between industry and the government, and those values will not be made explicit to the public.

The public seems to consider least trustful those who stand to benefit financially from GE products. Lang and Hallman (2005) have found that the federal government, grocers and grocery stores, industry, and the media are not well trusted by the public. In contrast, universities, consumer advocacy organizations, medical professionals, scientists, and farmers are considered fairly credible (Lang and Hallman 2005). A 2006 poll revealed that biotechnology companies and the news media were the two least trusted groups, while scientists and academics were near the top of the poll (PIFB 2006a). However, until recently, because of a dearth of independent, expert advisory committees (comprising of academic scientific experts), the members of academia played a limited role in GEOs oversight, including environmental release of GE crops and food safety of GE crops (NRC 2002).

The close connections between government and industry, due in part to the revolving door, could exacerbate the public's feelings of mistrust. The presence of former key industry personnel on government regulatory boards creates a semblance of impropriety. It could cause the public to regard with suspicion the federal government's policies, even if the risk regulations are not biased toward business. If the citizenry believes regulatory agencies are biased, and thus, unreliable, it could ignore public health warnings and safety reports issued by them. For instance, if the populace believes that the FDA is biased towards vaccine makers and a particular

vaccine is held by the public to be responsible for a specific illness (even though there is not any compelling evidence in support of that claim), parents might decide to not get their children inoculated. That could result in a public health crisis. Moreover, reservations that the citizenry might have about the neutrality of regulatory agencies may translate into a lack of political support for government agencies, possibly resulting in diminished funding for them, compromising their ability to protect public health. It is also worth considering that doubts about the credibility of regulatory agencies might evolve into a general distrust of the integrity and reliability of the government sector in its entirety.

Narrow Representation of Interest Problem

By virtue of the revolving door between the business world and regulatory agencies, veterans of the commercial sector (who understand its interests and concerns) are able to participate in the policy decision-making, including risk assessment. In contrast, other interest groups, such as environmental and consumer organizations, are afforded few such opportunities. Typically, all they can do is voice their concerns when a regulatory agency invites comments on its draft reports. It is at the discretion of the regulatory entity to engage with them or not. For instance, the FDA refused to address the ethical concerns raised by various citizen groups, including environmental and animal rights organizations, in response to the agency's draft report regarding the safety of food products derived from cloned livestock (Meghani and de Melo-Martín 2009). The agency claimed that non-science based concerns involving "moral, religious, or ethical issues associated with animal cloning for agricultural purposes, the economic impact of products being released in commerce, or other social issues (were) unrelated to FDA's public health mission" (US FDA 2008). This is the purity approach to risk assessment that assumes that "it is possible to resolve concerns about food safety or environment without simultaneously doing anything about social consequences" (Thompson 2007, 299). It presupposes that the causal mechanisms for food safety risks are purely biochemical, while those for environmental risks are ecological (Thompson 2007, 299). It also assumes that "social consequences (of risks) are economic or sociological, with relatively little biological base" (Thompson 2007, 299). Presumably, on the basis of its commitment to this purity approach to risk, the FDA considers itself justified in refusing to address ethical or other social concerns voiced by the public. However, the agency's stance that it is not part of its responsibility to address such issues makes no sense given its mission. The FDA's goal of protecting public health is a normative one (Meghani and de Melo-Martín 2009).

As we illustrated in the previous sections, by virtue of the revolving door, key former industry employees, who know of the industry's concerns and interests, are often at the regulatory decision-making table (Mattera 2004; RDWG 2005). Typically, access to regulatory decision-making "space" is limited to experts from industry and regulatory agencies (e.g., NRC 2002). Fischer (2004) notes that experts "prove not to be the neutral, objective participants that they would have us believe. All too often they have served—wittingly or unwittingly—to legitimate decisions made elsewhere by political elites" (22). He argues that U.S. democracy leaves much to be desired and citizen participation is low.

In a purely procedural sense, the current regulatory system is undemocratic. It is biased in favor of the industry. That is unacceptable because democracies are premised on the principle that everyone matters and matters as much as anyone else (Nielsen 1985). When government regulatory agencies privilege the concerns of the industry over that of the polity, they institute a de facto "tyranny of a minority faction" (Fung 2007, 453). The resulting policies, practices, and decisions pander to a small group, whose will and interests might be at odds with that of the rest of the populace. Tyrannies may take different forms, such as the tyranny of the rich (Cohen and Rogers 1983) or the tyranny of the expert (Dahl 1989). But they share in common a tendency to undermine the efforts of the people to be autonomous. Thus, the revolving door phenomenon has the potential to subvert a very basic principle of democracy. Procedures should be established so that all stakeholder groups have a voice in policy-making, including risk assessment. That requirement is unlikely to be simple to implement but commitment to democracy may entail taking the onerous and complicated route (more on this later).

We have argued that the revolving door phenomenon results in the "biased policies problem," the "appearance of bias problem," and the "narrow representation of interest problem." We believe these three problems indicate a "public failure" (Bozeman and Sarewitz 2005) of regulatory review. Bozeman and Sarewitz (2005) note that the US' current science and technology policy treats market success (read: market permeation and corporate profits) as the primary standard for measuring the success of a technology. They find that approach unacceptable because it may entail disenfranchisement of non-industry stakeholders and the public in general. Bozeman and Sarewitz propose that science policy and technologies should not be assessed solely on the basis of their market success; they also ought to be evaluated to determine whether they are "public failures" (Bozeman and Sarewitz 2005, 122). Public failure of policy and technology occurs when neither the public nor the market sector provide goods and services that realize public values (Bozeman and Sarewitz 2005). The public values of a society are those that embody the privileges, norms, social supports, rights, and procedural guarantees that that nation aims to provide to all its members (Bozeman and Sarewitz 2005, 122). In a democracy, for instance, two key public values are fair representation of interests and transparency in governance. Borrowing Bozeman and Sarewitz's rubric for assessing policy, we contend that the current regulatory review process qualifies as a public failure because it is undemocratic. As we argued earlier, it is opaque (the values governing policy decisions are not always disclosed to the public) and it is procedurally biased towards the industry. By favoring industry interests, it re-inforces the pre-existing unjust power imbalance between the public *and* industry as well as the unfair power differential between advocacy groups working for consumers or the environment *and* industry. As a result, industry interests are catered to at a significant cost to the public in general, non-industry groups, and the environment. Thus, the current regulatory review protocol poses a significant threat to the public good and to the US as a democracy.

It is arguable whether the US government has recognized this flaw in the current regulatory review process. The lack of appropriate attention to the problem may be attributable, at least in part, to the neoliberal commitment of the various US

administrations since the 1980s. Neoliberalism is premised on the assumption that the most efficient way to enhance the well-being of individuals is for the government to foster private enterprise. Thus, it advocates little or no regulation of businesses or the creation of policies that serve commercial interests. The 1980s were a period during which US political leaders became concerned about "the decline in US competitiveness (in the global market)" and the role of excessive regulations in that change (Prakash and Kollman 2003, 620). Those worries motivated the government to re-conceptualize the role of regulatory agencies, including entities that oversaw biotechnology.[4] Until then, the FDA had functioned as the guardian of public's health (Karwaki 1996; Ferrara 1998). As the protector of the populace's health, the FDA's relationship, for instance, with the pharmaceutical industry had been adversarial (Abraham and Davis 2007). Moreover, the agency had been risk averse (Abraham and Davis 2007). With the rise of neoliberalism as the dominant ideology in the US and the surge of nationalist concern about fostering American global dominance in the pharmaceutical arenas, the government re-configured the FDA's relationship with industry. Since then the agency has become a facilitator for industry, assisting it in its goal of expediently introducing products in the domestic and global markets (Prakash and Kollman 2003, 620; Ferrara 1998).

The neoliberal orientation of the regulatory agency, arguably, has served well commercial interests.[5] For instance, with the passage of the 1992 Prescription Drug Users Fee Act and 1997 FDA Modernization Act in the United States, the FDA's regulatory duties have been re-defined such that they favor the pharmaceutical industry, possibly at the cost of the public's health in the following ways (Wiktorowicz 2003; Abraham and Davis 2007):

1. The regulatory review process has been accelerated.
2. The agency increasingly consults and cooperates with the pharmaceutical industry.
3. The regulatory expectations of pre-market data requirements have been lowered such that drug approvals are now based on one clinical trial rather than two.
4. The agency increasingly relies on risk assessments based on post-marketing surveillance, marking a significant shift in its requirements about safety data.

While the above mentioned regulatory shift has to do with pharmaceutical products, it can be considered indicative of a larger cultural change within the agency, which, along with the revolving door, fosters the interests of the industry.

So far we have argued that the revolving door phenomenon has the potential to undermine the US as a democracy. It is also capable of compromising the public's health and its trust in government.[6] However, we do not believe that industry

[4] At that time, biotechnology had been identified as a promising new scientific and trade frontier.

[5] Ceccoli has argued that the Prescription Drug Users Fee Act marked a change in the FDA's understanding of consumer protection to take into account the "perils of delay in approving new drugs" and it was an attempt on the part of the agency to align its regulatory process with that of various other Western, industrialized nations (2004, 16).

[6] Unfortunately, the latter possibility has not received much attention. We acknowledge, however, that with the recent change in administration and the banking and mortgage crises (that many feel were precipitated from a lack of regulation (Calmes 2008)) this orientation might be shifting.

veterans should be prohibited from seeking employment in regulatory agencies. They bring knowledge of industry that could be useful. In the next section, we argue that the remedy for the three problems of public trust and fair representation in the regulatory review process requires that agencies like the FDA reject the traditional conception of objectivity. Instead, they should subscribe to the concept of "strong objectivity" (Harding 1998, 2004) and reform their regulatory decision-making process on the basis of it.

Reconceptualizing Objectivity

Regulatory Policy Decisions about Genetically Engineered Products

As mandated by presidential executive orders and various statutes (EPA 1983; White House 1993, 2007), regulatory agencies assess the impact on human health, environment, and the economic risks and benefits of new technologies in utilitarian terms (EPA 1983; OSTP 2000). The criteria used by the federal government are primarily limited to human and animal safety, environmental risks, and costs and benefits (EPA 1983; White House 1993, 2007; Kuzma and Meghani 2009).[7] Genetically engineered organisms (GEOs) are no exception, and the initial Coordinated Framework for Regulation of Biotechnology[8] was established on the premises that it was the product not the process that mattered, the risks from GEOs were "the same in kind" as conventionally bred organisms, and therefore, no new laws were needed to regulate GEOs (OSTP 1986; NRC 2000). These arguments were seen by the regulatory and expert bodies as "science-based," or based upon data and information examined by experts in the natural sciences.

The three federal regulatory agencies, the FDA, the EPA, and the USDA, involved in the review of GE organisms and their products still rely on the assumption that their risk assessments are "science-based" (i.e., objective, untainted by social concerns).[9] But that supposition is not justified. Lewenstein has argued that "we should be wary of the attempt to draw boundaries between (social) issues and technical ones" (2005, 17). We submit that risk assessments are not purely

[7] At the time of writing this paper, the new Obama Administration posted a notice in the *Federal Register* for comments on formulating a new Executive Order on Federal Regulatory Review, calling for recommendations on: disclosure and transparency; encouraging public participation in agency regulatory processes; the role of cost-benefit analysis; the role of distributional considerations, fairness, and concern for the interests of future generations; methods of ensuring that regulatory review does not produce undue delay; the role of the behavioral sciences in formulating regulatory policy; and the best tools for achieving public goals through the regulatory process (OMB 2009). There seems to be a shift in the willingness on the part of the administration to consider, along with science-based risk assessment and cost-benefit analysis, other normative factors in formulation of regulations, and the arguments in this paper would support such revisions to federal regulatory review.

[8] In 1986, the Coordinated Framework established as a formal policy by the federal government. It describes "the federal system for evaluating products developed using modern biotechnology" (United States Regulatory Agencies Unified Biotechnology Website).

[9] The notion of science as a value neutral activity is flawed for a number of reasons (see, for instance, Grundmann and Stehr (2003) and Jasanoff and Wynne (1998)).

scientific endeavors, rather they are shaped by normative (i.e., cultural, economic, ethical, or political) considerations, and thus, the regulatory decisions based on them are not value neutral either (more on this later).

Another serious problem with the current regulatory review protocol is that regulatory agencies' decisions about approval of GE products occur largely outside of the public's view (NRC 2002), making it difficult for the citizenry to participate in the decision-making process about which ethical, economic, cultural, or political considerations should shape regulations. Although the process has become somewhat more transparent than it used to be because of better websites on decision-making within the Coordinated Framework (see "US Federal Agencies Unified Biotechnology Website" http://usbiotechreg.nbii.gov/), the companies sponsoring GEOs can limit the public's access to relevant risk information on the grounds that it would require disclosure of confidential business information (NRC 2000, 2002; PIFB 2006b).

Our previous work using stakeholder elicitation and interviews to rate the performance of GEOs oversight in the US suggests that there are numerous conflicts of interest in the system, transparency is low, public input in decision-making is minimal, and more stakeholder engagement is needed in the risk analysis process (Kuzma et al. 2009). One industry representative in this study called for "early and broad stakeholder engagement" and that "stakeholder should be defined very broadly meaning: public, NGOs, federal regulators, industry, academia, etc."[10] (Kuzma et al. 2009). A former government representative noted that the scientific community is wholly mistrusted and that the "science community should not decide how much regulation it should be subject to. Sooner or later you are going to have stakeholders involved, so it might as well be sooner. Can't make good regulatory system without broad input from stakeholders and other "independent" people. You need to get outside of influence. When your friends are doing stuff you trust them, and that is a problem with oversight. You need people that are regular people and environmental risk experts" (Kuzma et al. 2009). An academic interviewed noted that the "development of system should be more inclusive. Coordinated Framework [for GEOs oversight] was a closed door process. Need to involve public, not just industry. No people who were thoughtfully critical were at the table" (Kuzma et al. 2009).

Next, we discuss these issues from the standpoint of public policy and ethics.

Policy Decisions Based on the Traditional Conception of Objectivity

The FDA is a key player in the review of GE products, especially those relating to human food, animal feed, and now, GE animals (US FDA 2008). One of the FDA's key goals is to help "… the public get the *accurate, science-based information* they need to use medicines and foods to improve their health (our italics)" (US FDA, *FDA's Mission Statement*). In making that claim the agency seems to subscribe to a naïve form of positivism that rests on the assumption that it is possible to do science

[10] The comments from experts and stakeholders were gathered anonymously and cannot be attributed to individuals, according to Institutional Review Board protocol.

that is untainted by political, ethical, economic, or cultural values (Meghani and de Melo-Martín 2009). In other words, the FDA appears to hold that scientific activities and epistemic agents can be objective, i.e., value neutral (Gaskell et al. 2001, 101).

Traditionally, the term "objective" when applied to claims tends to imply at least two things about those propositions. First, they are produced by objective knowers, i.e., epistemic agents who have detached themselves from all of their normative commitments as they participate in knowledge-building activities. Second, objective propositions are generated from theories that are unsullied by normative considerations. The standard conception of objectivity assumes that the value neutrality of epistemic agents and propositions (i.e., the transcendence of knowers and knowledge claims from the local, historical, and contingent), ensures their epistemic credibility (Harding 2004, 136–137).

The Concept of Strong Objectivity Vs. the Traditional Conception of Objectivity

We contend that the traditional conception of objectivity, both with regards to knowledge claims and epistemic agents, is flawed. Human knowers cannot divest themselves of all of their normative values, beliefs, goals, and concerns as they participate in epistemic projects. Given human psychology and physiology, they can only function as knowers by virtue of their membership in epistemic communities (Nelson 1990 and 1993). Those communities help their members make sense of the world by creating frameworks for understanding and interacting with the biological and social world. (Languages and theories qualify as such frameworks.) Such communities also shape the interests, beliefs, desires, and projects of their members. These epistemic communities may be formal organizations or informal ones, with loose membership criteria. Humans generally belong to multiple epistemic communities simultaneously (Meghani 2008). Thus, the knowledge building projects that we participate in reflect the concerns, values, and beliefs of the multiple epistemic communities of which we are members (Meghani 2008). This is not to say that knowers cannot choose which epistemic communities they belong to or the values they subscribe to; they may do so, to varying degrees. Depending on social norms about sex, race, ethnicity, etc., and their particular economic and political circumstances, including nationality, persons have greater or lesser freedom to join or leave certain epistemic communities as well as engage in world traveling such that they experience different forms of life. The point here is that humans as knowers cannot divorce themselves of all of their normative commitments as they participate in epistemic projects. Membership in at least some epistemic communities (with a concomitant adoption of at least some of their values) is a necessary pre-condition for functioning as a knower. It is for that reason that it is a mistake to assume that the members of the committee appointed by the FDA to conduct the risk assessment of a new GEO are objective epistemic agents. They invariably bring some normative commitments to the risk evaluation table.

The application of the traditional conception of objectivity to knowledge claims is problematic too. Theories and the knowledge claims derived from them are not always value free. Longino (1990) has argued that between the hypotheses and data of any theory, there is not a necessary, unique, and immediate relation. Rather there

is a gap, which can be bridged by different background assumptions. Longino makes the case that depending on one's background assumptions, one could read differently the same state of affairs, i.e., evidence (1990[11], 2002).

Some of the background assumptions that mediate the relationship between hypotheses and evidence may carry normative commitments.[12] Given that the relationship between hypotheses and data is mediated by background assumptions that might be normatively loaded, it should not be assumed that the theories of risk assessment that the FDA uses to make its policies are value neutral. The agency's risk assessments are not necessarily value free.

There is also another reason for questioning the objectivity of FDA's risk assessments. All risk assessments have normative dimensions (Kuzma and Besley 2008; Meghani 2009; Lewenstein 2005). They are at work in each of the stages of risk assessment: hazard identification (or problem formulation for ecological risk assessment (ERA)), dose–response modeling (or characterization of effects for ERA), exposure assessment, and risk characterization (NRC 1983; EPA 1998). During problem formulation or hazard identification, the decision has to be made which factors will be designated risks that will be investigated. After all it is impossible to examine the risk potential of any and all factors. The parties

[11] To demonstrate that background assumptions mediate the relationship between hypotheses and data, Longino uses an example from neuroscience. Behavioral endocrinologists Ehrhardt and Meyer-Bahlburg (1981) have theorized that differences in gender role behavior are significantly determined by fetuses' exposure to sex hormones (Longino 1990, 119). This theory is anchored in their research on girls with Congenital Adrenocortical Hyperplasis (CAH). CAH is a condition marked by higher than statistically normal production of androgen during female fetal development (Longino 1990, 114). Ehrhardt and Meyer-Bahlburg hypothesized that greater than normal exposure to androgen as fetuses causes these females to exhibit "tomboyish" behavior. As evidence they cited the correlation between girls with CAH and "tomboyish" behavior. On the basis of their research on CAH girls and drawing on cases in other mammalian species, for examples, rats, where behavior is hormonally determined, Erhardt and Meyer-Bahlburg theorize that prenatal exposure to sex hormones "importantly influences" gender role behavior in the human species (Longino 1990, 119).

Longino criticizes Erhardt and Meyer-Bahlburg for using loaded language (such as "tomboyish") in their study and for not taking into account that their evidence (i.e., the reports about the "tomboyish" behavior of CAH girls by the girls themselves and their parents and teachers) might be problematically influenced by the observers' expectations. She also contends that the relationship between their hypothesis (about CAH girls) and the evidence that they cite in support of it is mediated by a background assumption of which Ehrhardt and Meyer-Bahlburg appear to be unaware. The crucial bridging background assumption in question is a model of the brain that assumes that there is an uni-directional, causal relationship between brain structure and chemistry and behavior. Longino argues that if Erhardt and Meyer-Bahlburg had worked with an alternative model of the brain that recognized both agent intentionality and interaction between agents and their environment (along with brain structure and physiology) as determinants of human behavior, it is unlikely that they would draw as strong a causal connection between prenatal exposure to sex hormones and gender role behavior as they have done (This account is taken from Meghani's unpublished dissertation, *Can Medical Theories Be Objective?* (2006)).

[12] For instance, the two models of the brain rely on different "metaphysical assumptions about causality and human action," which have different attendant social, ethical, and political commitments and entailments (Longino 1990, 161). The model that draws a strong uni-directional relationship between brain structure and physiology is committed to a form of biological determinism. Such a model does not recognize the possibility of agency, including intentionality, thus, it limits our sense of ourselves as autonomous entities. Alternatively, the model that allows for agency, interaction between agents and their environment, and biology as determinates of behaviors confirms our sense of ourselves as capable of acting autonomously (Meghani's unpublished dissertation (2006)).

responsible for deciding what should be considered a risk make a non-epistemic, normative decision about the matter. If they decide to study the impact of a new GE plant on human health but not the environment because studying the latter phenomenon might delay market introduction of the GE plant, they make a judgment that reflects a particular ranking of normative commitments. Alternatively, the decision to study the affect of the new GE plant on humans *and* the environment, even if it means putting off the entry of the product into the marketplace, mirrors a different ordering of values.

Risk characterization and risk management also may be influenced by non-epistemic considerations. Policymakers, in conjunction with psychologists, economists, and health physicists attempt to determine the kind and level of risk that the public would consider acceptable (Schrader-Frechette 1991, 55). Risk-cost-benefit analysis (RCBA) is one of the ways in which risks are characterized for decision making (Schrader-Frechette 1991, 61). RCBA requires that risk experts convert risk, benefits, and costs of particular endeavors and products into monetary terms and weigh whether costs outweigh benefits. In doing that evaluators inevitably make normative judgments; they decide if the monetary value placed on costs, risks, and benefits appropriately represent the real cost, benefit, or risks at issue. A common cost is put in terms of detriments to human life (or the health of an ecological species) and the number of lives debilitated or lost by the risk. Risk experts make normative assumptions (i.e., they make suppositions that are shaped by cultural, ethical, economic, or political considerations) when they assign a monetary value on human or other life, such as whether to treat the young or the elderly as the same, the importance of considering susceptible populations in the risk distribution for cost-benefit analysis, and how non-fatal illnesses should be considered (e.g., Arnesen and Nord 1999). In determining whether the magnitude of risks, costs, or benefits should outweigh the distribution of those factors amongst different populations, non-epistemic value judgments are made by those assessing the risks (Schrader-Frechette 1991, 61).

We have argued that the traditional conception of objectivity is flawed because it assumes that it is possible for human knowers *and* propositions to transcend local, contingent, and historical values and interests. The methods that have been developed on the basis of that notion of objectivity to ensure the value neutrality of epistemic agents, theories, and observation claims have not been successful. Various philosophers of science and epistemologists have demonstrated that those approaches have failed to ensure the value neutrality of propositions and epistemic agents (Longino 1990; Harding 2004). The inability of those methods to identify the normative concerns shaping knowledge claims can be attributed to limited diversity within the epistemic community responsible for vetting knowledge claims. That narrowness of vision has resulted in knowers failing to recognize the contextual, historical, and contingent factors shaping scientific practice (Harding 1998; 2004, 128–129). It is because the values and interests shaping knowledge claims are shared by the members of the epistemic community that they do not stand out for those knowers. They are neutral background for them; they do not "see" them (Harding 2004, 128–129).

In the interest of identifying the values shaping risk assessments and policy, we propose the adoption of the "strong objectivity" standard. The concept of strong objectivity was devised by Sandra Harding as an alternative to the standard conception of objectivity. She has argued that the traditional conception of objectivity is flawed and lacks rigor (Harding 1998, 2004). Harding contends that the standard conception of objectivity is only *weakly* objective because of its limited focus. It is solely concerned with identifying individual scientists' biases at work in the context of justification (Harding 1998, 132; 2004, 137). It assumes that the neutrality of scientific activity is assured by the process of peer review. It does not attempt to identify and interrogate the non-epistemic values, concerns, and beliefs that influence the decision of scientists to undertake a particular project as opposed to some other one or to adopt a specific research methodology rather than another one (Harding 2004). Those normative elements importantly shape scientific projects and the failure to identify and scrutinize them means that their influence goes unexamined and unchallenged. Moreover, the possibility of other lines of scientific inquiry based on different starting assumptions, values, and beliefs remain unexplored and unfulfilled. In the interest of investigating those other possible paths of scientific investigation and developments *and* for the sake of subjecting to scrutiny the values, concerns, and beliefs that shape choice of scientific projects, methodology, and hypotheses, Harding espoused adoption of the "strong objectivity" standard. Besides subjecting scientific inquiry to peer review, the strong objectivity approach requires that the choice of research question, design, and methodology be rigorously examined (Harding 2004). The ethical, economic, cultural, and political elements shaping scientific projects be identified and interrogated. However, as key normative commitments might be shared by the members of the scientific community, for all intents and purposes, they might not be able to "see" them, and thus, they would not be able to subject them to rigorous interrogation (Harding 2004). For the sake of identifying and questioning the values, beliefs, and concerns that shape their inquiry but which are invisible to them, Harding argued, scientists ought to engage with social groups who do not share their worldview. In particular, she advocated that scientific communities enter into dialogue with socially marginalized groups that are critical of the dominant norms (Harding 2004). By virtue of their outsider status, those groups are better positioned to identify and question the culturally pervasive beliefs, values, and concerns than the socially dominant groups. The analyses developed by marginalized groups[13] are the product of a *struggle* to see through and beyond the account of social reality constructed by the culturally dominant paradigms (Hartsock 1998, 37).[14] Harding should not be read as advocating the unquestioning acceptance of the criticism of the dominant world view constructed by marginalized groups. She holds that the analyses developed by the socially marginalized should be considered valuable *starting points* for discussions about the values, norms, and goals that ought to shape scientific inquiry (Harding 2004, 131). Of course, values, beliefs, and worldviews that fail to respect the moral equality and human rights of all persons would not be endorsed.

[13] It is worth noting that this, like other knowledge building enterprises, is a communal endeavor.

[14] Thus, it would be a mistake to assume that all members of marginalized group will *automatically* have this kind of critical understanding of the culturally dominant worldview.

By calling for the identification and interrogation of the normative concerns shaping scientific inquiry, Harding was not espousing the elimination of any and all ethical, economic, cultural, or political values, beliefs, and concerns identified through this engagement process (Harding 2004). Rather, she was arguing for scientific practice that, first, is aware of the particular values, beliefs, and concerns that shape its projects, and second, recognizes that a different set of normative commitments and worldview would open up a different line of scientific inquiry.

As the strong objectivity approach is more likely than the traditional (read: weak) objectivity one to identify and question the ethical, economic, cultural, or political values, beliefs, and concerns that shape scientific inquiry, we believe it should be used by regulatory agencies. Implementation of the strong objectivity standard by agencies such as the FDA would mean that the multiple stakeholders would have to be involved in regulatory decision-making about new technologies. Risk assessments, for instance, would no longer be conducted unilaterally by government experts (including industry veterans). Rather, stakeholders representing diverse interest groups would be part of the evaluation process. Joint decisions would have to be made about which normative concerns should determine risk evaluations. The deliberations amongst those at the regulatory decision-making table would not occur behind closed doors. They would have to take place in public. That transparency would do much to ensure public confidence in the regulatory review process. In addition, it is because the policy dialogue would be public that those who represent or belong to the socially dominant groups might be more likely to treat with respect those who speak for or belong to marginalized populations than they might otherwise.

Our proposal builds upon the ideas of scholars who have promoted deliberative democratic approaches to decision-making (e.g., Habermas). The National Research Council (NRC) describes one such approach that is most relevant to risk analysis, termed the analytical-deliberative process (NRC 1996). In this process, interested and affected parties are consulted at the beginning, end, and at all stages of risk analysis, and their viewpoints are to be taken into account in the regulatory decision making process. Their non-scientific specialized knowledge is to inform the risk analysis process. Thus, not only scientific but also cultural, economic, political, and ethical issues are to be considered. Our approach differs from the one advocated by the NRC in that we propose a more formalized method for inclusion of diverse stakeholders in the risk assessment process. In addition, we identify the shortcomings in the current regulatory process *and* we provide a rigorous epistemological theory in support of our stance. Other approaches like corporate moral responsibility (Brom et al. 2006) and the specific inclusion of ethical principles in deliberation (Mepham 1996) are worth noting, but also differ from our approach in that they do not focus on risk analysis in regulatory decision-making.

In the next section, we use a hypothetical case involving a GE fish to demonstrate the implementation of the strong objectivity method during the risk assessment process. The FDA has decided to consider GE animals as "New Animal Drug," requiring the company manufacturing the genetically engineered organisms to provide risk and safety data about them (US FDA 2008 and 2009; Pollack 2010). There are at least two problems with that classification decision. First, it is unclear

how the drug regulatory guidelines will be interpreted to establish ecological risk assessment criteria for GE animals (and their offspring). Second, the application process for new drugs is confidential to protect the proprietary interests of pharmaceutical companies, and the piecemeal adoption of that protocol with regards to GE animals makes it unlikely that the public will have an opportunity to evaluate the risk assessments provided by the companies creating GE animals prior to the FDA's regulatory decision (Pollack 2007). For instance, the agency's review of the AquAdvantage Salmon, a fish genetically engineered to grow much faster than its conventional counterpart, was conducted behind closed doors because it was classified as a new veterinary drug, and whose developer, AquaBounty, claiming proprietary interest did not permit the FDA to make public the research and other supporting data it had provided to it (Layton 2010). Siobhan DeLancey, an FDA spokeswoman, defended the lack of transparency on the grounds that the agency had "... obligations under the regulations to protect company confidential information" (Layton 2010).

The Strongly Objective Approach to GE Product Risk Assessment

Hypothetical Case of GE Fish

A genetically engineered *Oreochromis niloticus* (commonly known as tilapia) developed by Nutritious Fish Corporation is up for review at the FDA. The fish grows faster and is better able to resist certain bacterial infections than its non-genetically engineered counterpart. That translates into higher profits for fish farms; they can sell their stocks sooner and spend less (than they might otherwise) on treating infections resulting from or exacerbated by the conditions under which the fish are kept in the holding pens. While studies show that such fish tend to develop excessively large deformed heads and jaws and these traits are passed along to their offspring, including those that are the result of mating between it and non-GE fish, Nutritious Fish Corporation contends they are safe for human consumption. As evidence, the sponsoring company has submitted studies that show that in chemical terms the GE fish are substantially equivalent to their non-genetically engineered counterpart.

Ecologists, on the other hand, argue that if the GE tilapia were to escape into the wild, it might lead to the extinction of non-GE tilapia. They claim that the introduction of even a small number of GE fish, with a mating advantage due to size and a reduced likelihood of survival, would result in the eventual extinction of the local GE and non-GE tilapia population.[15]

Implementation of the Strong Objectivity Approach during the FDA's Risk Assessment of the Hypothetical GE Fish

Adoption of the strong objectivity approach in the risk assessment of the hypothetical GE fish would require that place be made for multiple stakeholders

[15] This claim is based on research by Muir and Howard (1999).

at the FDA's risk assessment table. As argued earlier, the values and concerns shaping the evaluation are more likely to be identified and rigorously interrogated if the review process is structured to allow a diverse set of stakeholders to participate in the process than if it is limited to government experts (some of whom are former industry employees). The heterogeneous stakeholder group would jointly deliberate and decided upon which normative considerations should guide the risk evaluations of the new biotechnology. In addition, a well-balanced advisory committee, with the majority of members free from any conflict of interest would serve as consultants (US GAO 2004).

Participation in the process would not be limited to government (and former industry) experts. Not only marginalized environmental and animal rights groups would have to be seated at the table, various other constituencies would also have to be given a place, including representatives of fishermen opposed to fish farms. During the risk assessment process, the epistemic merits of the studies (such as adequacy of the sample size and the length of the studies) submitted by Nutritious Fish Corporation to the FDA would be scrutinized by scientific and risk experts (i.e., experts who were not affiliated with the industry or other stakeholders on the regulatory board) in the presence of the stakeholders. Special care would need to be taken to avoid noted problems with stakeholder engagement, such as "group think" (Tait 2009). Also, citizens would need to understand experts' reasoning processes and experts would have to learn more about "practical modes of reason that inform the citizen's world" (Fischer 2004, 24).

Following that, the risk assessment submitted by Nutritious Fish Corporation would be analyzed to identify the normative concerns underlying and shaping them. As the company evaluated the safety of the GE fish by conducting physicochemical comparison between it and its conventional counterpart, the stakeholders, along with scientific experts, would have the opportunity to identify the normative commitments motivating the sponsoring company's decision to use substantive equivalence as the criterion for risk assessment instead of, say, animal feed toxicity, allergenicity, or immunological studies. That discussion might focus on the fact that the use of substantive equivalence as an indicator of genetically engineered food's safety has been contested. The promotion of that concept as a marker of GE food's safety can be traced to the 1993 *Safety Evaluation of Foods Derived by Modern Biotechnology* report of the Organization for Economic Cooperation and Development (OECD). The report "facilitated the transatlantic policy agenda of regulatory harmonization and trade liberalization" by implying substantive equivalence in terms of physicochemical between GM (GE) food and its non-GM (GE) counterpart was indicative of the safety of the latter (Levidow et al. 2007, 34). Physicochemical comparison tests were favored by the OECD because the comparison tests could be readily implemented and conducted by various countries, setting the stage for global trade in GEOs (Levidow et al. 2007). Critics of the substantive equivalence standard have argued that the criterion reflects the interests of industry rather than that of the public. It did not provide adequate safety information because comparative data on conventional counterparts of GM food are not available (Levidow et al. 2007, 33 and 42). They also hold that more studies on the nutritional, toxicological, and immunological

differences and similarities between GM food and their conventional counterparts are needed (Levidow et al. 2007, 33 and 42).

In the discussion about the appropriateness of using substantial equivalence as the marker of safety, the various constituencies at the risk assessment table would have to consider the question whether national and global commercial interests should be privileged over a more careful, intensive, and thus, slower approach to ascertaining safety of the GE fish. Such a dialogue is crucial because risk assessment has normative dimensions, and, in a democracy, ethical, social, or political questions should be decided by the populace and not by scientific (and former industry) experts acting unilaterally. Furthermore, the resulting regulatory decision would have to take into account cost-benefit analyses for multiple stakeholders, including marginalized stakeholders, such as small scale organic fish producers who, if the GE fish were approved, would have to bear the cost of labeling for "non-GMO" fish products under the current voluntary labeling policies of the US's FDA (Kuzma and Besley 2008).

In the interest of transparency and accountability, the discussion at the risk evaluation table about the new GEO would have to be public. Closed door dialogues would be strongly discouraged, and permitted only if the advisory committee members were present and if absolutely necessary to protect the economic interests of the industry. However, it is worth considering that given that the fundamental principle of democracy is that the citizenry be able to engage in self-definition, the privileging of industry's economic interest over that value by not allowing the public access to information about risk assessment of a new GE product constitutes a violation of that principle.[16] Moreover, if a particular constituency raised an ethical concern about the GE fish, say in terms of its impact on the fishing community, government experts at the risk assessment table would no longer have the right to refuse to engage with that concern. They would not be able to claim that they were not charged with the responsibility of addressing such issues. The stakeholders at the table would have to engage in a dialogue about whether the use of the GE fish was justified given that it would be sold at a lower price than the non-GE tilapia and given that the possibility exists that it could escape into the wild, decimating the population of wild tilapia, thus compromising the livelihood of the fishing community that relied on its conventional counterpart. Health and ecological benefits of the GE tilapia would have to be considered by all "interested and affected" (NRC 1996) stakeholder groups and the scientific advisory committee.

The risk assessment of the GE fish based on the strong objectivity approach recognizes that such evaluations are normatively charged. A heterogeneous group of stakeholders must work together to identify the values shaping risk assessments and determine which normative concerns ought to underlie such evaluations. That process significantly differs from the FDA's current risk assessment protocol, which is based on the traditional conception of objectivity. It assumes that risk evaluations

[16] This issue deserves extended treatment. However, given the limited scope of this paper, we are only able to acknowledge it. Achieving a balance between transparency and democracy which relies on it *and* allowing businesses to recoup investment on technology development through intellectual property protection might be difficult. But it must be done as the current practice of privileging business interests undermines citizen autonomy.

are purely scientific endeavors that are value neutral. Decisions about whether the risks or benefits of new GEOs are acceptable are made unilaterally by government experts, some of whom are former industry experts. It does not guarantee non-industry stakeholders voice in the process. We have argued that the risk assessment based on the standard notion of objectivity is flawed because it relies on the unwarranted epistemological assumption that knowers can detach themselves from all normative commitments as they participate in epistemic projects and that theories and the knowledge claims derived from those theoretical frameworks can be value neutral.

We contend that the FDA and other government agencies should commit to the strong objectivity approach to scientific inquiry (including risk assessment) because it recognizes that normative commitments shape human epistemic endeavors. A regulatory protocol based on that method would require that a diverse set of stakeholders be part of the process of evaluating new technologies. They would work together to identify and deliberate about the normative concerns that should shape regulatory decisions about new GEOs and other technologies. That public and transparent process would do much to inspire justified public trust in the regulatory process, regulations, and the government. Moreover, it would be democratic both in form (because multiple stakeholders would have a voice instead of just the industry) and substance.

Conclusion

We have argued that the current situation and lack of control over the revolving door between industry and regulatory agencies occasions at least three ethical and policy problems that have to do with public trust and fair representation. They indicate a public failure of the regulatory review process. Although we find the revolving door practice fundamentally problematic, we do not believe that the flow of personnel from industry to regulatory agencies and vice versa should be barred. Instead, we make the case, regulatory agencies, such as the FDA, ought to publicly acknowledge that policy decisions about new technologies (grounded on risk assessments of those entities) are not based solely on epistemic grounds, rather they are influenced by normative considerations. We also argue that regulatory agencies should re-configure the policy-making process so that it is strongly objective. They should involve multiple stakeholders in the regulatory review of new technologies, including agrifood biotechnologies. Given that democracies are committed to the idea that citizens have the right to decide which values they live by, the public should have say about the normative concerns that guide regulatory review and approval of new technologies. We hold that this system-wide change in the current approaches to regulation of new technologies is needed to control for industry bias. Democratic participatory mechanisms and transparency are essential for inspiring warranted public confidence in the government as the guardian of the citizenry's interest. The public should be able to decide which risks posed by new technological products are acceptable to it (Schrader-Frechette 1991; Rollin 1995; Kunreuther and Slovic 1996) by means of a democratic process (Rollin 1995;

Meghani 2009). Even the National Research Council, the operating arm of the US's premier scientific organization, has recommended analytical-deliberative approaches to risk analysis (NRC 1996) and the need to improve public participation in environmental decision-making (NRC 2008). The next step is to identify the political hurdles in implementing that approach and to devise strategies for overcoming them.

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