Quaestio Iuris

vol. 09, nº. 04, Rio de Janeiro, 2016. pp. 2166-2206
DOI: 10.12957/rqi.2016.25675

THE PROBLEM OF THE IMPROBABLE DISRUPTORS: FOUR VIEWS ON THE ROLE OF SCIENCE IN POLICY-MAKING

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Abstract

This is an essay on a pressing issue that is crucial to societal decision-making on an wide range of policy issues, from climate change to the war against terrorism: the politicization of science. It deals with the relation between science and policy-making in science-based regulation of chemical risk, but its purport is much broader. Specifically, I use a hypothetical case of a category of potentially hazardous chemical substances, called the Improbable Disruptors, to illustrate the various ways in which science can be influenced by special interests and explained to politicians, and how the metaphysical rules of science and the presentation of scientific information can be used to influence government policies and regulatory decisions.

In the case presented here, the government of a hypothetical nation, Demonata, is faced with a decision on how to manage the potential hazards of the Improbable Disruptors. To ensure its decision is well informed, it seeks counsel from four scientific advisers, who present diverging opinions on the science relevant to the decision the Demonata government faces, and on the course of action the government should adopt.

The conduct of science (and of scientists) and the translation of scientific information for policy-making may reflect deeper philosophical, social, and political beliefs or convictions. This essay shows how these beliefs and convictions may color science and the advice provided by scientists on a specific policy issue. It is intended to demonstrate how the content of both science and scientific advice may vary as a function of beliefs; it does not present fledged analysis of the issue of 'politicization' of science, and does not attempt to fully evaluate the four scientific opinions provided to the Demonata government. Rather, this essay is intended to reinvigorate the debate on politics' role in science and science's role in policy-making by demonstrating how the practice is evolving. Throughout this essay, the reader is invited to identify and reflect on the actions of the various players, the key issues arising the science-policy interface, the differences between the opinions discussed, and the origins and reasons for these differences. Based on his/her own analysis, the reader is asked to answer the key question posed at the end of the essay: if you were the government of Demonata, what would you do, and why would you do so?

Keywords: Politicization of science; science and policy-making; presentation of scientific information; government policies; regulatory decisions.

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In the case presented here, the government of a hypothetical nation, *Demonata*, is faced with a decision on how to manage the potential hazards of the *Improbable Disruptors*. To ensure its decision is well informed, it seeks counsel from four scientific advisers, who present diverging opinions on the science relevant to the decision the *Demonata* government faces, and on the course of action the government should adopt. These opinions can be viewed as "Idealtypes" of commonly held ideals, beliefs, and attitudes about science and its role in policy-making. If it is not clear from the outset what exactly the issue are, and why these issue are important, in the course of this essay, it will become clear.

The use of a hypothetical case enables us to move beyond a discussion of the facts, and engage the issues relating to the relevance and meaning of the facts. I should note, however, that the case presented here is realistic. Although the facts described in this essay are, in some cases, out of place or even made up, the case has been intentionally designed to resemble key aspects of actual cases that have arisen in the real world; it thus is realistic, in the sense that all of its key features correspond to, or have been inspired by, some aspect of an actual case. This essay's case presents an artificially inflated concentration of such features, so as to capture much of the academic and political debate on the relevant issues associated with science-based risk regulation in a modern society. To bring some of the policy choices in sharper focus, the situation in *Demonata* is contrasted with the circumstances in *Demodeka*, another large nation and *Demonata*'s largest trading partner. *Demonata* and *Demodeka* are nations like the United States and European Union, but the issues raised are relevant to any nation that meets this essay's accounts of either *Demonata* or *Demodeka*.

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THE AFFLUENT SOCIETY AND ITS CHARACTERISTICS

Demonata is an affluent republic on the Western hemisphere. The last significant war on this continent ended 70 years ago, and its people have become accustomed to peace. It is a sophisticated, multi-cultural, and tolerant society. Hunger is no longer an issue for *Demonata*'s people, but obesity is becoming a problem. As a result of substantial investments in science, technology, and innovation, the people of *Demonata* enjoy clean drinking water and sanitation, good and safe food, decent housing, cars with very low air emissions, energy-efficient color television with large screens, smart phones, internet, and social media.

The people of *Demonata* are collectivistic and individualistic at the same time. They rely on the government for many necessities of life and for their protection, but they also insist on their own identity and their ability to choose for themselves; they assert their identity by making personal choices from a wide range of branded consumer products, such as clothes and shoes, and adopting often strong opinions on the issues of the day, week, or month served up by the public media. Almost as large as the market economy, the public sector continues to increase gradually. The government manages the economy, regulates firms and industrial and commercial activities, and provides education, health care, a wide range of subsidies, and other social benefits. Average life expectancy continues to increase, and the incidence of many diseases has dropped substantially.

THE LEGAL AND POLITICAL SYSTEM

Demonata is a capitalist, market-based democracy in a globalizing world, and, from time to time, struggles with the tension between the two. Based on the idea that every human being is an end in itself, the people of *Demonata* have established a constitutional democracy that allocates much power to government to engage in collective action, but also grants a large number of individual fundamental rights. These rights include political rights, classical rights to liberty, security, and physical integrity, freedom of speech, religion, and assembly, equality and non-discrimination, and novel social rights establishing entitlements to social goods such as human dignity, work, housing, education, and health care. There is a fundamental human right for almost everything, including the protection of individual data, access to a free placement service, and asylum.

Governed by an extensive set of policy principles, the republic of *Demonata* strives for sustainable development, environmental protection, protection of human health and safety, and social justice for all. Its ambitions are tempered only by scarcity of resources and a proportionality principle that requires balancing of the policy means with the policy objectives. On a regular basis, it reaffirms its commitment to the protection of the environment and human health by solemnly declaring that these rights take precedence over economic interests. Legality, legal certainty, and the rule of law do not necessarily prevent the government from doing what is right, although the courts might be willing to grant relief against serious infractions of these principles if private parties

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have standing to bring legal actions.

SCIENCE AND TECHNOLOGY IN THE AFFLUENT SOCIETY

As noted, science, technology and innovation have brought the people of *Demonata* prosperity. Science has made them smarter, and better equipped to understand the world. But science was also held responsible for some of worst atrocities that ever happened. During the last war, a totalitarian system had used science in the name of a troubling ideology and in deeply unethical ways. But the evils of science and technology were not limited to military applications, war-time or totalitarian regimes. Even the peaceful civil application of nuclear power had proved to be unsafe, leading to regular accidents causing many deaths and injuries, extensive property damage, and the imposition of cancer risks on large groups, including people living far away from the place where the disaster happened. More and more, the people of *Demonata* began to see and experience the adverse effects of the most visible consequence of science and technology, industrialization: environmental pollution, human diseases caused by synthetic chemicals, loss of nature and biodiversity, etc.

In response to these developments, the government of *Demonata* took measures to tame the "Golem" of science and technology. It prohibited the use of scientific information obtained in an illegal or unethical manner. It imposed restrictions on human subjects research to ensure compliance with ethical requirements. It implemented a funding policy to ensure that science and technology are politically accountable and respond to social needs. It democratized the governance of universities and research institutions and gave students, academics, politicians, and other stakeholders a voice in decision-making. All of its efforts represented an infringement of academic freedom to some, and did not go far enough to others. As noted above, *Demonata* also took measures to limit industry's effects on the environment and human health.

In a related development, social scientists, inspired by a reinvogarated, slef-conscious emphasis on understanding ("*Verstehen*"), as opposed to explaining ("*Erklären*") challenged the emphasis of natural science on methodology and empirics, as well as its reductionist approach, which was deemed unsuitable to investigate complex systems involving numerous loop-back mechanisms, such as the human body and the earth's climate. It was also pointed out that scientific studies often involve important, but hidden subjective value judgments (including about the "significance" of findings), may ignore critical aspects such as irreversibility and incommensurability, and may make unproven assumptions that are doubtful, such as that an animal model accurately represents effects in human beings, and that there is a level of exposure below which no adverse effects will occur. The most radical social theorists went even further, and saw science as an instrument of power in the hands of the dominant elite.

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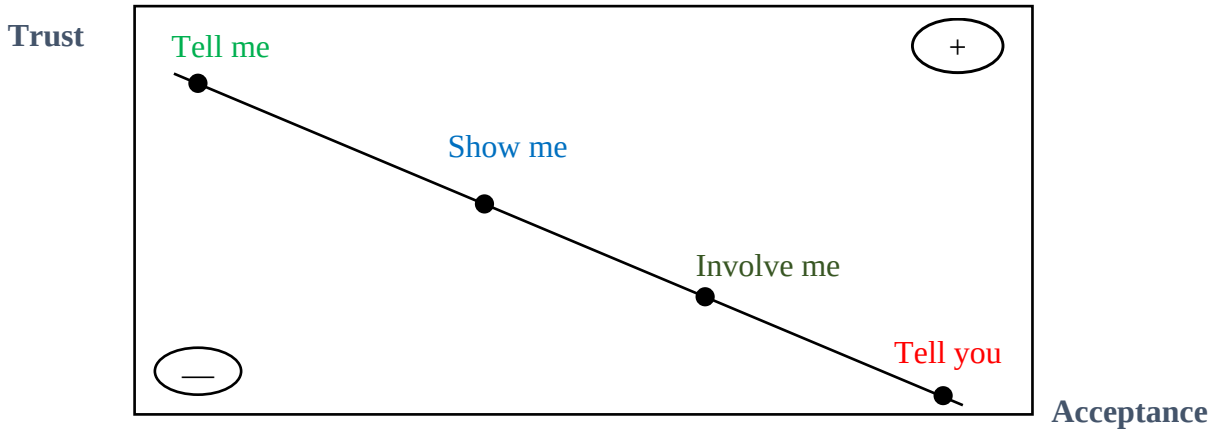
THE ISSUE OF RISKS

Despite their ever increasing living standards, not everybody is happy, however. Some people worry about the inequality in income, and would rather have less if all others have the same. Other people worry about threats to the environment and public health and safety. As surveys have confirmed, a substantial portion of *Demonata*'s population is concerned about various natural and man-made risks, including chemical risks.

There is a lack of trust in firms to supply accurate information on the risks associated with their activities and products, and to manage such risks adequately. The level of trust in government is only slightly higher. After mismanagement of several food contamination scandals and incidents involving hazardous chemicals in toys and cosmetics, surveys suggest that the public is not confident that the government has the ability to identify and regulate emerging risks to the environment and human health and safety. Social scientists argue about the issue whether a lack of trust in government is good or bad. Some social theorists have argued that a critical distrust of government is healthy for a society and will enable citizens over time to become capable of independent judgment.

A leading treatise on the relation between public trust, involvement, and acceptance of risk posits that as trust decreases, the level of public involvement in decision-making must increase to obtain the public's acceptance of the risk. If trust drops to a very low level, risk will be accepted only if the public gets to make the decision on the risk concerned. To illustrate this point, the following graph appears in the book:

Figure 1. The Relation Between Trust, Level of Involvement, and Acceptance[2]



1. In the (+) area, actual or alleged perceived risk is low, and the skepticism of NGOs, media, and the engaged public can be effectively addressed.
2. In the (—) section, actual or alleged perceived risk is high, and communication and dialogue tend not to reduce resistance of NGOs, media, and the engaged public.

[2] *Credits*: Modified from a presentation by Dr. Urban Jacobson at The Conference Board Council on the Environment & Product Stewardship, Milan, January 16-17, 2008, as modified by Michael J. Penman in 2014 in Brussels. The theory behind this graph is loosely based on Ragnar E. Lofstedt. Risk Management in Post-Trust Societies. New York: Earthscan, 2008.

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Although most immediate and substantial risks in *Demonata* are effectively controlled, science has identified many remote, small, and often invisible risks. These risks exist only because scientists have been able to identify them. They often relate to chronic exposure, "long tail" harms, small increases in naturally occurring diseases, or poorly understood changes in biological and ecological systems. Scientists have become more and more specialized, and developed highly sensitive instruments and models to measure even the smallest possible effects as well as small effects that occur only in long term, such as those due to climate change. They identify the risks that the body politic subsequently regulates. On this ground, science and other knowledge systems have been characterized as a form of power. As power, science and knowledge would be subject to same partisan influences as other political issues. In the mind o some theorists and politicians, science and power thus became joined.

A particularly important dictate addressed the limits of science and scientific uncertainty. As science began to pursue ever more remote and smaller risks, the knowledge it generated became less certain, more tentative. Scientists do not always agree on what the science demonstrates. But uncertain knowledge or a minority scientific opinion may still be a valid basis for policy decisions. Science, it was suggested, should therefore explicitly address the uncertainties inherent in its methods, measurements, and conclusions, and also give room to minority opinions. To prevent undue delays in taking adequate risks management measures, a lack of scientific certainty should not be used as a justification for not regulating a risk. To codify this mandate, *Demonata* even adopted a formal policy principle, the precautionary principle, which also allows policy makers to reverse the burden of proof and require that companies provide evidence of the absence of risks before they launch new products or activities.

In addition, another new branch of social science started to study risk from a psychological perspective. It tried to determine how risks affect people psychologically, and how people perceive risks. Psychometric research on risk perception has shown that laypersons perceive risks differently than experts. There often is a big gap between "actual" risk as determined by science and "perceived" risk as experienced by laypersons. It has been suggested that laypersons apply "richer" frameworks to evaluate risks, which include factors such as novelty and voluntariness of a risk. On this basis, arguments are made that laypersons' perceptions of risk, like those of experts, represent important, though possibly partial and selective, views of the situations that threaten society. For purposes of policy-making, risks should therefore be evaluated not only by scientists, but also by laypersons, and, thus, be socially constructed in deliberative or discursive processes. Both politicians, who depend on votes, and consumer goods companies, who depend on purchases, agree that risk perception is critically important, because perceived risks drive citizen and consumer preferences. Their preferences are relevant, independent of their correspondence to reality or truth. In other words, voters and consumers, by definition, are never wrong.

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THE SPELL OF *DEMODEKA*

Another large republic, *Demodek*a, has been established by people who left *Demonata* because they were expelled or prosecuted, or left out of impatience with Demonata's social and government structure. *Demodeka* is larger, wealthier, and more powerful than *Demonata*. Since the last war on *Demonata*'s continent, *Demodeka* has been providing military security in the region. *Demodeka* is known for its emphasis on liberty and the opportunities it offers to those who are willing to work hard or take risks.

Demodeka is *Demonata*'s largest trading partner. The economies of the two nations are strongly linked, there is substantial trade in goods and services, as well as substantial cross-border investment. Although these two nations have much in common politically and economically, the people of *Demonata* have ambivalent feelings towards *Demodeka*; while some elites emphasize the lack of culture (in particular, good food), its superficiality, moralism, materialism, and imperialism, others praise its mature political system, its efficiency, dynamism, and innovative industry, and its excellence in science and education.

While Demonata has been called a law state ("Rechtstat"), Demodeka is known as a science state ("Wirtschaftstat"), although this characterization is quickly becoming blurred. Unlike *Demonata,* the new republic of *Demodeka* has established science-based risk regulatory programs. It has set rules to ensure that the data used in policy-making is representative, relevant, and reliable, has been developed in accordance with sound scientific methods, and peer-reviewed. *Demodeka* also operates structured programs for risk regulation, which require not only scientific risk assessment but also cost-benefit analysis of proposed risk management measures. A central agency oversees this process and can hold policy-makers accountable. Any proposed regulations must be published and all citizens have an opportunity to submit comments on such proposals, which the regulators must consider. Citizens also have a right to seek judicial review of regulations that they regard as unlawful or unconstitutional.

Demonata's regime has been inspired by these programs, but is generally a looser, and often non-binding version of it. Some groups in *Demonata* believe that the basic tenets of *Demodeka*'s programs should also be introduced in *Demonata*, while other groups in *Demodeka* would rather see these programs scaled down. The two nations have already entered into several bi-lateral agreements, but are currently negotiating a comprehensive free trade agreement that would also grant each nation some level of protection against non-science-based or disproportionate trade-distortive regulations and a right to participate in the other nation's regulatory procedures.

THE STATE OF POLITICS ON THE *IMPROBABLE DISRUPTORS*

Endocrine-related diseases and disorders are increasing around the globe. Scientific understanding of whether and, if so, how chemicals, in particular at low levels, can interfere with normal hormone function is still

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limited, but growing. In both *Demonata* and *Demodeka*, a policy issue has arisen with respect to a category of chemicals known as "plasticizers" that are widely used in a range of products made of polymerized plastics, including consumer products. Evidence from animal models and human studies has given rise to the suspicion that exposure to *Improbable Disruptors* during developmentally critical times plays a role in the rise of endocrine-related cancers and reproductive malformations; a whole series of other diseases, including behavioral and learning problems, obesity, and diabetes, have also been associated with *Improbable Disruptors*, but the evidence is weak. Calls have been made for more research to understand the effects and health implications of these substances for humans and wildlife. Due to their potential, but unlikely, endocrine-disrupting effects, these chemicals are called the *Improbable Disruptors*.

The *Improbable Disruptors* increase the "plasticity" or fluidity of polymers, which makes the plastic more flexible, less brittle, less crackable and breakable, and thus increases its strength and durability, enhancing user convenience and safety. Some of the products in which they are used, are intended for the vulnerable, i.e. pregnant women, children, the elderly, and the sick. It is suspected that these chemicals may disrupt their endocrine system, and could potentially cause adverse health effects, including carcinogenic and repro-toxic effects. In addition, they might adversely affect animals and wildlife. The need for a better understanding of the *Improbable Disruptors* has been recognized.

As the government of *Demonata* became concerned that political pressure might built up to the point where they had to take measures against the *Improbable Disruptors*, it decided to make subsidies available for the development of "green" alternatives. A consortium including several universities and two small green chemistry companies were awarded funding to develop a biodegradable substitute for the *Improbable Disruptors*. After several years of intense research and development, the consortium came up with a substitute called "*GreenFlex*." *GreenFlex* is less effective as a plasticizer, and, thus, causes a higher risk of cracking and breaking, which could result in injury or death, but it has been designed not to include the chemical group that is suspected to be responsible for the *Invisible Dsirupters'* adverse effects. There is no long term toxicity data available on *GreenFlex*, however. Moreover, its costs about twice as much as the cheapest *Invisible Disrupter*, and the production capacity is currently limited (approximately 2.5% of the total production capacity of *Improbable Disruptors*).

A cost-benefit analysis financed by the government has estimated that the complete replacement of all *Improbable Disruptors* with *GreenFlex* would take 5 years and involve a direct cost of USD 5 billion per year (EUR 5.5 billion). The authors of the report could not estimate the health and environmental impact of the substitution, because no reliable, validated data was available on either the *Improbable Disruptors* or *GreenFlex*. In addition, they observed that no data on the impact of *GreenFlex*'s reduced performance (e.g. cracking of breakage of infusion bags or tubing with potential adverse effects for patients) was yet available. They concluded that, once there is clear, quantitative evidence of the health and environmental of both compounds, a full estimate

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of the costs and benefits of substitution could be made.

The GreenState Campaign

In the early 2000s, reports were published by a "green" local government's environmental agency about the *Improbable Disruptors* leaching from children's teething rings. Emboldened by these reports, an environmental NGO by the name of *GreenState* launched a campaign under the name "*Play It Safe"* against those *Improbable Disruptors* that are used in plastics for children's products, calling them "gender benders," as part of wider campaign against certain plastics. *GreenState* used slogans such as "our children must be kept safe from '*gender benders"* and "do you want to play Russian roulette with your children" to reinforce its message that the *Improbable Disruptors* are unsafe for children. It also included photographs of children suffering from cancer in its informational materials, under the heading "how do you explain your choices to your children."

Another part of the campaign focused on the "ruthlessness" of capitalist industry and employed slogans such as "capitalism used to destroy only democracy, but it now also destroys our future." To further bolster its plea for a ban on the *Improbable Disruptors*, *GreenState* also initiated a survey and psychometric research which established that the majority of subjects believe that these compounds are dangerous and cause cancer and repro-toxic effects at very low doses, and that their fear is based on the novelty and uncontrollability of these risks, and the dread and irreversibility of the effects. In addition, *GreenState* had levels of the most common *Improbable Disruptors* measured in household dust, including in children's bed rooms, as well as in the blood of pregnant women, cancer patients, persons with fertility problems, and sick children; levels far above detection levels were found for some compounds. It also "repackaged" scientific research conducted by academic institutions to emphasize the disastrous effects of *Improbable Disruptors*, which prompted the researchers to comment that *GreenState* incorrectly presented their hypotheses as conclusions.

The same message, in different forms, backed up by different pieces of "evidence," and always with dramatic visual material, was repeatedly disseminated through multiple media outlets to increases both the message's impact and credibility. *GreenState* attempted to launch a similar campaign in *Demodeka*, but at the request of a group of chemical companies, a court enjoined the campaign on the ground that it was libelous and not based on evidence. Following this injunction, public concern in *Demodeka* abated substantially.

Chemical Justice Campaign

The issues of the *Improbable Disruptors* had also drawn the attention of a group called "*Chemical Justice*," which fights for social justice and equality in relation to exposure to chemical risks. This group was concerned about the risks for vulnerable populations, such as infants and pregnant women, but also wanted to

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know whether there could be disproportionate exposure for some minority groups. Chemical Justice worked with an academic group sympathetic to its cause to conduct a large scale study to determine whether defined minority groups were more exposed to the risks of the *Improbable Disruptors* than the average population.

To their surprise, they found that due to more frequent and more intense use of consumer products containing *Improbable Disruptors*, the relative risk for the poor, for immigrants, and homosexuals was 1.10, i.e. a 10% increase over the background risk. Their study was criticized for simply assuming, without proof, that *Improbable Disruptors* pose risks, and that all of them pose equal risks, and not reflecting the background risk associated with exposure to chemicals potentially posing similar risks. Nevertheless, in the popular press, it made headlines, such as "the first victims of *Improbable Disruptors* will be poor immigrants," "chemical risks spare the rich and straight," and "is the chemical industry homophobe."

Chemical Justice, which is funded solely by private donations, also prepared a paper for politicians to alert them to their exposure to *Improbable Disruptors* in sex toys. The paper asked whether "it is worth the risk," and included photographs of ex-politicians that died of cancer. The message was that putting *Improbable Disruptors* in sex toys is "entirely another matter" given how close and intimate users get with them, and suggested that politicians should support legislation to keep *Improbable Disruptors* out of sex toys. After this low profile campaign, which was deliberately kept out of the public media, a parliamentary committee commented that consumers must be protected when it comes to sexual health." Embarrassment or false taboos should not prevent a thorough investigation from being conducted. If there is uncertainty, appropriate action should be taken." Capitalizing on the opportunity created by the publicity, a sex toys producer changed the labels on its *Improbable Disrupter*-free product line to read: "Contains No risky *Improbable Disruptors*, only *GreenFlex*." It also launched an advertising campaign based on the slogan "it is just like buying your organic groceries, read the labels to make sure that your toys are *Improbable Disrupter*-free."

The Berakini Affaire

Further, Elic Berakini, a professor of biology at a leading university in *Demonata* and the president of the scientific advisory board of the *Institute for Independent Research on Hazardous Chemicals*, which is known for being opposed to *Improbable Disruptors*, conducted long term studies involving the feeding of several *Improbable Disruptors* in high doses to rats. According to Berakini, the study represented the first detailed documentation of long-term deleterious effects, including malign tumors and fetal malformations, arising from the *Improbable Disruptors*. The study report was published in the scientific journal Chemical Toxicology. Although the study was not designed to detect risks of cancer or repro-toxicity, in a tightly orchestrated media offensive that included the release of a book and a film, Berakini promoted the cancer results and malformations as the study's

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major findings. The ethics committee of the Centre for Scientific Research decried these media activities as inappropriate for a high-quality and objective scientific debate.

In addition, the *Demonata* Chemical Safety Authority found that the conclusions of Berakini were not supported by the data presented. The study's main shortcomings involved the high p-value of 0.50 (i.e., if the results are not true, the probability of obtaining the observed sample results, or "more extreme" results, by chance is 50%), and the low statistical power (i.e., the probability of rejecting the null hypothesis when it is not correct) due to small number of observations, as well as the use of a rat species that shows a high incidence of spontaneous malign tumors and congenital malformations after their third month of life. Following serious scientific criticism of the study, the journal announced that it had decided to retract the paper, after the authors had refused to do so, based on the inconclusiveness of the results. However, the article was republished in a popular journal called *Environmental Sciences*, this time with lots of photographs showing rats with massive tumors and deformed rat fetuses. Berakini also launched another popular website on his studies, and linked it to the leading anti-*Improbable Disruptor* site managed by a NGO.

THE STATE OF THE SCIENCE ON THE IMPROBABLE DISRUPTORS

The Endocrine System

The endocrine system plays a fundamental role in the physiological response to changes in the environment in order to keep an organism's response within the homeostatic space. It is generally recognized that chemical substances, like natural hormones, may interact with the endocrine system in a way that does not cause any harm and is entirely normal. The endocrine system is intended to respond to environmental fluctuations. Such homeostatic responses are normal adaptations, and are transient, reversible, and within the normal range. The difficulty lies in distinguishing between those hormonal responses that do not lead to "disruption" or harm, and those that should be called "disrupting" and harmful. Only some hormonally active substances, at some level of exposure in some individuals, will damage the function of the hormonal system, and should be regulated on that basis. Thus, the distinction between harmless and harmful interactions is critical in this area of science.

In addition, the endocrine system plays a programming role, however, during the development of an organism from the embryonic to the fetal stage and during childhood and adolescence. Serious disturbance of these programming functions (e.g. the suppression of androgen activity by estrogens) could result in malformations. Further, the endocrine system may be implicated in the etiology of hormonally-induced malign tumors, such as breast cancer and prostate cancer. Accordingly, the *Improbable Disruptors* may have teratogenic and carcinogenic effects, and be implicated in other pathological processes and hormonally-induced diseases.

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The Category of Improbable Disruptors

Because the term "*Improbable Disruptor*" is typically used loosely to include also hormonally active substances that do not cause adverse effects, the category of *Improbable Disruptors* may have to be sub-divided into several classes. Such a division could be made on the basis of theory or empirical evidence, or a combination of the two. Each of these methods has been advocated by some scientists. In reality, of course, science is always driven and informed by an iterative, inter-related cycle between observations and theory: hypotheses and theory help to identify the relevant observations, and the observations help to confirm or reject hypotheses and shape theory. An additional complication is that scientific data from several areas and many studies (such as toxicological data, including dose-dependence, exposure data, etc.) need to be integrated to assess whether and where adverse effects of *Improbable Disruptors* are likely to arise.

Methodology of Assessing the State of Science

In *Demonata*, the state of science is determined in accordance with certain concepts and rules. In accordance with these concepts, an assessment of the state of the science requires several decisions. First, one should determine the precise question that needs to be answered, and, on that basis, the relevant science should be identified in accordance with a set of rules. In other words, a state of the science assessment should have a defined scope and employ a structured approach to the collection and review of data. If the question is whether the *Improbable Disruptors* cause cancer or repro-toxic effects, the science that studies this causal relation is relevant; the science that relates to other chemicals may be relevant, but the science regarding the public's perception of the risks posed by the *Improbable Disruptors* is irrelevant. Second, the quality of the relevant studies and data must be assessed, and only the data that meets minimum quality standards should be included in further analysis. Such standards include study design, study design, implementation and conduct of the study, recordkeeping, and interpretation. Third, a standard and methodology for data assessment, interpretation, and integration should be set.

In accordance with established standards of toxicology, assessment of endocrine disrupting properties should be based on a strength of the evidence approach, which gives more weight to studies that have superior design (e.g., controlled studies, rather than retrospective studies), greater quality, and greater power (e.g., greater study size). Data interpretation and integration requires an analysis of the consistency of study results, any bias or confounding variables that may influence the findings, and any data gaps. Causal mechanisms and pathways should be understood, so that data relating to various steps in a causal chain can be analyzed and compared to construct the complete causal evidence. In doing so, mere association (or correlation) should be distinguished

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from real causal relations. In the case of the *Improbable Disruptors,* a key aspect of data analysis is how dose–responses observed in experimental animal models relate to the potential and actual exposure of human beings and wildlife. In the interpretation of the data, strengths and weaknesses of the findings, as well as other possible explanations of the results, and controversies on the key issues, should be considered.

The Toxicological Approach

Toxicologists and most regulators agree that *Improbable Disruptors* should be identified as endocrine disrupters based on robust scientific evidence for three specific criteria: (1) the substance must act through an endocrine mechanism of action that alters the function of the endocrine system; (2) it must cause an adverse health effect; and (3) this adverse effect must be caused by the altered endocrine function. Thus, the consensus holds that factors to be considered in this regard are dose, dose–response, potency, and adversity. A substance's potency is its power to produce an effect, in this case, an endocrine disrupting effect, which is a function of its receptor site affinity, i.e. a substance's ability to bind to a receptor site, and its efficacy, i.e. a substance's ability to activate the receptor, resulting in a hormonal response. Generally, endogenous hormones have both strong affinity for their receptor sites and high efficacy for activation of these receptors, and are therefore highly potent for endocrine modulators. On the other hand, exogenous chemical substances are rarely as potent as hormones, due to reduced affinity, low efficacy, or both.

According to toxicologists and most regulators, the identification of endocrine disruptive substances of regulatory concern should be based on established toxicological principles and toxicologically sound studies; if, for instance, potency is ignored, many synthetic substances could be regulated that are no more potent than substances in common foodstuffs, such as grains and fruits. For each *Improbable Disruptor* that meets the criteria for an endocrine disrupting effect, a "threshold of adversity," i.e. an exposure concentration below which an adverse endocrine effect is not observed or expected to occur, should be established. Such a threshold is based on the generally accepted concept that toxicologically relevant responses occur only when the extent of endocrine modulation elicited by a substance exceeds the counteractive capability of the homeostatic mechanism. If actual or realistic potential exposures to the substance at issue, are a concern, regulatory intervention should be considered. On the basis of the biological threshold, a regulatory threshold can be established by applying a safety factor (e.g. a factor of 5) to create a margin of safety. Exposure below this threshold is deemed safe for human health and/or the environment; accordingly, regulators and industry should take risk management measures to ensure that exposure to the substance is below the safe threshold.

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The Endocrine Biology Approach

Environmental scientists, endocrine biologists, and a few regulators, however, have challenged the rigorous application of the conventional criteria. Claiming that the toxicologists mix science and policy and apply a "collection of prejudices," they believe that a more holistic and flexible framework for identifying substances with endocrine properties of concern, should be developed. Such a framework should not stick to "old school" reductionism and examine chemicals in depth one by one, but take full advantage of modern achievements in biomedical research that would allow new understanding of the synergistic effects of classes of toxic substances in complex biological systems. It should explicitly recognize scientific uncertainty, and be based on both quantitative and qualitative information, including possible exposure scenarios, and cumulative effects of multiple hormonally active chemicals.

Further, due account should be taken of the tremendous complexity, sensitivity, and susceptibility of the hormonal system, the possibility of irreversibility, ambiguity, and deep scientific uncertainty, including model uncertainty, and the inability of science to exclude adverse effects. Non-linear, non-monotonic relations between dose and response, and incoherence between model, methods, and findings, are to be expected in the highly complex endocrine system, which is characterized by multiple inter-related loop-back mechanisms. Alarming signs of declining male fertility and serious abnormalities in fish, for instance, should not be ignored on the grounds that the science is not yet certain. In the interest of environmental and social justice, special recognition should be given to possible exposure of vulnerable populations, such as embryos and fetuses, infants, children, and the sick, related "windows of vulnerability," and disproportionate impacts on the poor and minorities, such as homosexuals. Economic interests and the costs of substitution, these scientists argue, may not be used as an excuse for scientists to adopt stringent methodological or causation requirements in order to deny the existence of the hazards and risks associated with the *Improbable Disruptors*.

Further, in assessing the science, the public's perception of the risks posed by these substances, as well as the utility of the activities and products causing such risks, should be taken into account. If there are alternatives to potential endocrine disruptors, scientific, causal and evidentiary requirements, should be further relaxed. The existence of naturally occurring substances with similar endocrine effects should not prevent the restriction of synthetic endocrine disruptors, which tend to pose higher risk. In all cases, the science should reflect multi-causality, the multiple perspectives and opinions on the issues, and the urgent need to act decisively, these scientists assert.

Current Methodological Issues

The current debate on the scientific methodological issues centers on the following issues. First, which

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studies and data are to be included in the assessment of the potential hazards or risks associated with the *Improbable Disruptors*? Specifically, should epidemiological studies, retrospective studies, *in silico* and *in vitro* studies be included? Should studies that suffer from deficiencies be excluded from analysis, or should they be included but, maybe, given less weight? This is an important issue, because there are many such studies relevant to the *Improbable Disruptors*. Common deficiencies include lack of representativeness, weak study design, insufficient study size, methodological problems, implementation issues, investigator bias, selection bias, and a host of confounding variables. A minimum level of scientific robustness is required to secure data integrity, but what is that minimum? Second, is it justified to require that the results of a study be statistically significance (p-value) at the 0.05 level, as is typically done? Studies above this level may still have value, and several such studies are potentially relevant to the assessment of the *Improbable Disruptors*. But is it justifiable to set a p-value on a case-by-case basis? Similar questions can be asked about statistical power.

Third, how much weight should studies showing mere correlation have? Correlation is not causation, but may be indicative of a causal link. Much of the evidence on the potential endocrine disrupting effects of *Improbable Disruptors* establishes weak correlations, not causation. Fourth, may an *Improbable Disruptor* be presumed to have an endocrine disruptive effect based solely on exposure and a potential or putative causal mechanism, despite a lack of empirical evidence showing that that the substance is causally linked to endocrine disruption? The same question arises where causation is inferred from of a series of possibly or partially related, or even entirely unrelated, facts or findings, which collectively are taken to suggest a causal link. For instance, may an increase in the incidence or prevalence of endocrine-mediated diseases be taken as evidence of possible endocrine disrupting effects of the *Improbable Disruptors,* even if no increased exposure to these substances has been demonstrated? Fifth, in the absence of persuasive causal evidence, how much attention should be paid to possible alternative explanations, including known causes or risk factors, for increases in endocrine-mediated disease rates? In the absence of a thorough evaluation of alternative causal explanations, is it justified to implicate the *Improbable Disruptors* as causal factors?

Non-Monotonic Dose-Response Curves

The most controversial topic of all, however, is the alleged non-monotonic dose-response relation between the dose of or exposure to an *Improbable Disruptor* and the hormonal response. The graphs below show two such possible non-monotonic relations.

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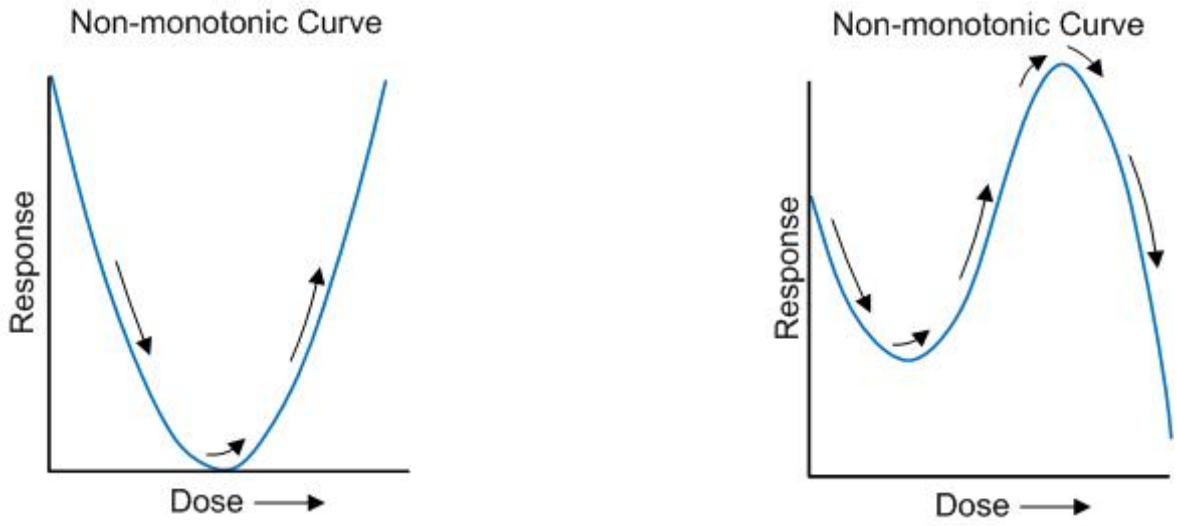

Source: US Environmental Protection Agency, Endocrine Disruption: State of the Science Non-Monotonic Dose Response Paper, available at http://epa.gov/ncct/edr/non-monotonic.html (accessed 28 April 2015)

Note that as the dose approaches zero, the graphs do not move toward (0,0), which means that the investigated substance's effect is also caused by other substances or processes, such as natural hormones or other chemicals; thus, the graphs show super-imposition of two or more dose-response curves, which might be taken to reveal an incomplete understanding of the underlying mechanisms. If such non-monotonic relations indeed exist, the implications could potentially be quite drastic. As the argument goes, it might not be possible to establish any safe threshold for the *Improbable Disruptors* concerned; they would be non-threshold substances, and any exposure to them would be problematic. Thus, very low doses of such *Improbable Disruptors* could cause potentially serious effects, and prohibition or substitution of all such substances might well be the preferred regulatory measure. More generally, it would call into question the adequacy of the current testing strategies for chemical substances.

As toxicologists and regulators have pointed out, however, without more, it is not clear what the "response" in these graphs denotes; "endocrine disruption" is not a toxicological endpoint, but a mechanism, a mode of action, that may cause an adverse effect. Even if a non-monotonic relation has been scientifically established, a substance-specific risk assessment approach integrating exposure and adverse effects, would be required to determine any endocrine disrupting effect caused by that substance. As discussed, such an assessment is to be based on toxicological data for the specific substance concerned, derived information on potency, and other relevant evidence.

Recently, a regulatory authority of *Demodeka* released a detailed opinion on non-monotonic dose-response relations. It concluded that such relations do occur in estrogen, androgen, and thyroid systems in ecological and mammalian studies *in vitro*, they are not commonly identified *in vivo,* and are rarely seen in apical

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endpoints after low-dose and/or long-term exposure. Any such relations should be evaluated in context with the totality of the available scientific data, including epidemiologic and human studies. Further, the *Demodeka* authority concluded that there is currently no *reproducible* evidence that the early key events involved in the expression of non-monotonic dose-response relations that are identified at low dose are predictive of adverse outcomes that may be seen in humans or wildlife populations for estrogen, androgen or thyroid endpoints. Therefore, it confirmed that current testing strategies are unlikely to mischaracterize, due to such relations, a chemical that has the potential for adverse perturbations of the estrogen, androgen or thyroid pathways.

Safety Thresholds

It has been suggested that the issue of the existence of a threshold for *Improbable Disrupters* remains under debate. Of course, the issue of thresholds is closely related to the issue of low dose effects. The philosophical argument supporting the "no threshold" hypothesis is that the existence of dose thresholds cannot be definitively proven or ruled out by experimental approaches, because all methods for measuring effects have their detection limits which obscure any thresholds, if they exist. Additional complicating factors are biological variation and the limited power available with the dose groups' sizes typically used in toxicity testing. The scientific argument for the "no threshold" hypothesis is the "additivity-to-background" argument, which has also been made to support a "no threshold" approach for genotoxic carcinogens: *Improbable Disruptors* act by the same mechanism as endogenous factors, such as hormones, and therefore merely add to (or detract from) the actions of these factors and increase (or decrease) the response of already ongoing biological processes. At a group or population level, thresholds may be "masked" by, or be irrelevant due to, individual variation, if the threshold-dose varies to such a degree that the threshold cannot be detected.

The arguments made in support of the existence of thresholds for the *Improbable Disruptors* include the observations that the healthy homeostasis of an organism results from an orchestrated network of myriad thresholds for every component substance, and that the mode-of-action concept implies the necessary existence of a threshold. The complexity of a biological system makes non-threshold dose-response curves unlikely for many "higher" endpoints, such as behavior, reproduction, organ weights, and growth. From an empirical perspective, the weight of evidence demonstrates the presence of thresholds for the *Improbable Disruptors*. Further, a threshold can be expected if there is no corresponding endogenous hormone, if the endogenous hormone induces no adverse effect, or if there is effective homeostatic control. Accordingly, whether a threshold exist, may depend on the endpoint under investigation and the substance's mechanism of action. It follows that the "threshold/no threshold" debate is related to the question of "adversity," i.e. what types of effects should be considered "adverse;" adverse effects, of course, can be observed in adequately designed and performed toxicity

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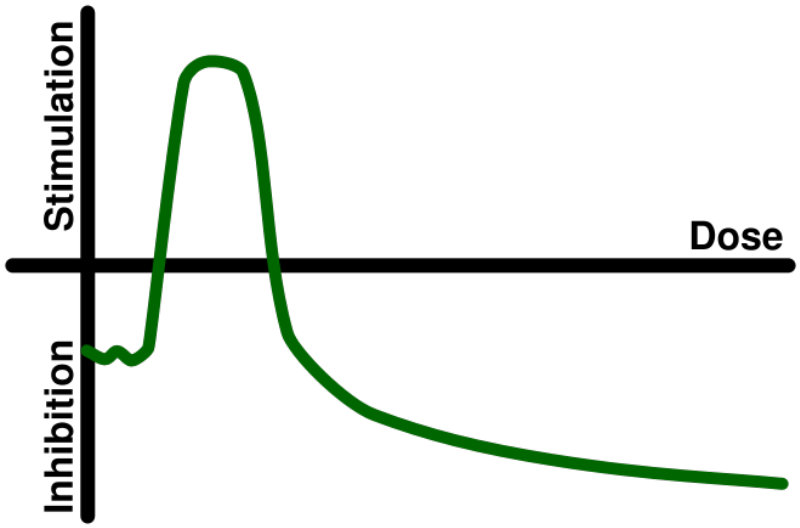
studies. Consequently, if any effect is regarded as a problem, thresholds may not exist; if, on the other hand, only adverse effects are considered, thresholds are likely to exist.

In short, without much stronger evidence to the contrary, there is no reason to believe that it is *a priori* impossible to define a practically relevant safe threshold for the *Improbable Disruptors*. As this debate is linked to the debate about non-threshold genotoxic substances, it should be noted that the default assumption for carcinogens that exposure to even very small amounts of a chemical may result in additional risk, is being reexamined. At a certain, low dose, a gentoxic substance may no longer increase the spontaneous mutation rates. Of course, a scientifically defendable threshold could ground a non-observable-effect-level (NOEL) and an exposure limit for *Improbable Disruptors*.

Finally, inconsistent with the "low dose adverse effects" hypothesis, toxicologists have argued that low dose exposure to chemical substances may be beneficial. The theory known as "hormesis" posits a biphasic response to increasing dose of or exposure to a substance. It suggests that beneficial or stimulatory effects may be caused by very low doses of toxic chemicals that are harmful or inhibitory at higher doses. There now is substantial empirical evidence for this theory for a range of chemicals. The dose-response curve of chemicals with a hormetic effect looks like this:



Source: Wikepedia, http://en.wikipedia.org/wiki/Hormesis

With respect to the *Improbable Disruptors*, it is not clear whether hormesis could apply. Since all chemicals can induce toxicity, depending on the dose, and hormesis may occur as an overcompensation to a disruption in homeostasis, hormesis might be expected to occur for all agents. On the other hand, this is not likely to be the case for agents that induce hormesis via direct stimulation since these agents are typically going to occur via a receptor-mediated pathway activation process. There is evidence, however, to suggest that once an organism has been exposed to one form of hormone-affecting chemical, it effectively acts as a blocker to other such chemicals that the

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organism may be exposed to.

FOUR SCIENTIFIC ADVISERS

The government of *Demonata* is considering the science and politics relevant to the *Improbable Disruptors*. Thus far, the government has not taken a position on any regulatory measures, but, as noted under [xx], above, it has decided to fund scientific research on the *Improbable Disruptors*. Due to press reports about a suspected relation between fetal malformations and the *Improbable Disruptors*, the political pressure to take action is building up.

Demonata has recently established a position of Chief Scientific Adviser, whose job it is to advise the government on the state of science relevant to policy issues. The biologist who serves as Chief Scientific Advisor has a known bias against the *Improbable Disruptors*. For that reason, the *Demonata* government has decided to ask four scientists from across the spectrum of scientific opinions to provide advice. The four scientists selected by the government represent the traditional, rational, post-normal, and post-modern scientific perspectives. These scientists have been selected on the basis of their education, experience, publications, standing, and reputation within their specialism. All are knowledgeable on the issues the government of *Demonata* faces. The government intends to use this advice to design and implement a comprehensive policy on the *Improbable Disruptors,* including any appropriate regulatory measures and other action. In addition, it may use the advice received to revisit and reform its science policies and the procedures it employs in regulatory decision-making.

In order to assess and compare the various opinions, *Demonata*'s Minister of Logic has prepared a questionnaire for the scientific advisers. The questionnaire asks the scientists to recommend a course of action based on the state of scientific knowledge. It provides background information, the government's objectives, and a series of instructions, including to keep the answers brief. Further, the instructions enquire about prior involvement and conflicts of interest. None of the scientists have declared a conflict, and all feel that their opinions are unbiased. Parts 1 through 5 of this essay are attached to the questionnaire as a background paper and the advisers are asked to consider the information stated in this paper in formulating their opinion.

The two key questions posed to the advisers are whether science shows that the *Improbable Disruptors* cause any suspected adverse effects, and whether the government, on the basis of the state of the science, should take any measures with respect to the *Improbable Disruptors*. These are the 15 specific questions posed to the advisers:

1. Please state briefly your views on science's role in society. Address the process of science, the relation between science and values, and the relation between science and politics.

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2. Which evidence do you deem relevant to answering the question whether the *Improbable Disruptors* cause adverse effects, specifically, cancer and repro-toxic effects? Please state the reasons, and address specifically *in silico*, *in vitro* and animal models, studies showing correlation, and risk perception studies?
3. What prerequisites should any evidence on the *Improbable Disruptors*' adverse effects meet? Should the studies done by *GreenState*, *Chemical Justice*, and *Berakini* be considered? Which evidence should be excluded? Are quantified results necessary? Is statistical significance required, and, if so, at what level? Is a minimum statistical power be required? How should bias and confounding be addressed?
4. What standard should govern the evaluation of the evidence on the *Improbable Disruptors*' adverse effects? Is empirical causal evidence a prerequisite for finding a causal link between the *Improbable Disruptors* and cancer or repro-toxic effects? How should the strength of the evidence be assessed, and what role should alternative explanations play?
5. How do you recommend we deal with scientific uncertainty, system complexity, irreversibility, and cumulative effects? What role does the precautionary principle have to play in science (e.g. in relation to types of permissible proof, minimum levels of proof, burden of proof, etc.)? Do you think that the science should take the *worst case* scenario into account?
6. What criteria should govern the identification of *Improbable Disruptors* that should be deemed to have the capability to cause adverse effects? How is it relevant that the *Improbable Disruptors* are not classified as hazardous under *Demonata*'s current legislation on classification?
7. With respect to the *Improbable Disruptors*, do you think there is scientific evidence for the "non-monotonic dose-response," "no-threshold," and "low-dose adverse effects" hypotheses? What weight do you give to the conclusion reached by the *Demodeka* authority that the evidence does not suggest that the *Improbable Disruptors* cause adverse effects?
8. In your opinion, do the *Improbable* Disruptors pose hazards, risks, or both? Can you quantify any risks? How can any risks be reduced?
9. How does the availability of alternatives such as *GreenFlex*, influence the scientific analysis of the evidence on the *Improbable Disruptors*' adverse effects? If safer alternatives are available, should the scientific threshold for finding adverse effects be lowered?
10. On the basis of all evidence that you believe should be included in the analysis, do you believe that the *Improbable Disruptors* cause cancer and repro-toxic effects? Please briefly state the main grounds for your opinion.
11. Do you believe that *GreenFlex* is likely to be safer? What do you see as the relative costs and benefits of *GreenFlex* versus the *Improbable Disruptors?* Should *GreenFlex* replace the *Improbable Disruptors*?

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12. Do you think that NGOs, industry, and civil society should be involved in making any of these decisions? Please distinguish between scientific decisions and other decisions. Should the scientific and regulatory process be open and transparent?
13. On the basis of the available scientific evidence, should the government of *Demonata* take any regulatory or other measures in relation to the *Improbable Disruptors*? If so, which ones?
14. *Demonata* is committed to a high level of environmental and health protection, and prioritizes health and the environment over economic interests and costs. It is also committed to taking precautionary action, and implementing proportional measures to achieve its objectives. In light of these commitment, what regulatory or other measures do you recommend that the government take in relation to the *Improbable Disruptors*? Please specify the measures you recommend (generally binding restrictions, labeling, etc.).
15. Based on your experience with science-based regulatory decision-making in the case of the *Improbable Disruptors*, do you recommend that *Demonata* make changes to its process, procedures, or substantive standards?

The Traditional Scientist

1. Science is concerned with the real, objective world, and attempts to discover the laws of nature; its business is causation. It should be conducted separately from politics, and has no place for values, beliefs, and authority. Indeed, it is value-free, except insofar that it stands for rigorous enquiry to find the truth. Science is a world in itself, governed by rigorous methodology, and principles of reproducibility and scientific integrity. Scientists should therefore be independent, and search for the truth in a disinterested and objective way.
2. Science should be sound. All scientific evidence that is both (i) relevant to the issue as to whether the *Improbable Disruptors* cause cancer or teratogenic effects, and (ii) produced in accordance with principles of sound methodology, is relevant. This includes empirical studies and *in vitro* studies on point; *in silico* studies may or may not be relevant. Animal models may be relevant. Studies showing only correlation should, in principle, not be deemed relevant, unless the correlation is strong and there is biological plausibility for the suggested causal link. Risk perception studies are not relevant, because they deal with an entirely different question and are unreliable to begin with; as a popular saying goes, "everybody is entitled to his own opinions, but not his own facts." More generally, insofar as any social science actually is science, it is not relevant to the issue at hand.

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3. All scientific evidence should be assessed to confirm that it meets fundamental scientific standards to ensure reproducibility and sound methodology and to reduce bias and confounding. Theoretical, qualitative studies should be considered, but if they are to have evidentiary value to the question, they should be confirmed by empirical evidence. The studies done by *GreenState*, *Chemical Justice*, and *Berakini* do not meet scientific standards, since they are biased. If causal relations are not binary, quantified results are necessary to sort out the strength of the effect. Any study showing correlation must meet the threshold for statistical significance with a p-value of 0.05, i.e., a confidence interval of 95%. A minimum statistical power is required, but is a function of the strength of the effect and sample size.
4. Sound science meets two standards: minimum data quality and strength of the evidence. If studies do not meet the minimum standards, they should be excluded. If they meet such standards, they should be assessed and ranked for their strength on a particular issue. If there are two or more studies on point available, the strongest study should govern; supporting studies are relevant as well. It is unavoidable that empirical causal evidence is a prerequisite for finding a causal link between the *Improbable Disruptors* and cancer or repro-toxic effects. How else could we know that there is a causal link at all? Alternative explanations should always be considered to understand the strength of the causal link.
5. There is nothing special about scientific uncertainty, system complexity, irreversibility, and cumulative effects. Scientists deal with these issue regularly, and they are manageable; if they are not, you do not know what you looking at, you do not understand the problem, and there is nothing else to be said. Uncertainty is our business, and we are trying to turn it into certainty. The precautionary principle has nothing to do with science, and does not define or affect any scientific standards. It is not even clear what it might mean, it is incoherent, a silly attempt to sneak politics into science. Likewise, *worst case* scenarios are not scientific at all; science concentrates on what is probable, not on what is possible in theory.
6. There should be a complete causal theory. It seems that a sound toxicological theory based on potency, adversity, and a causal link between the two, could potentially establish a complete causal theory, but we need empirical evidence. Given that the *Improbable Disruptors* are not classified as hazardous under *Demonata*'s current legislation on classification, we should be skeptical of claims that these substances causes any adverse effect; if there is a new class of hazardous substances, it should be defined carefully and we need evidence that the *Improbable Disruptors* meet the definitional criteria.
7. There is no hard scientific evidence for the "non-monotonic dose-response," "no-threshold," and "low-dose adverse effects" hypotheses for the *Improbable Disruptors*. There are some loose indications, and other "soft" suggestive material, but it does not amount to evidence, because there is no corroboration. The available models are not robust, not validated, nor verified, and they are not presentative of realistic

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exposure scenarios. This is also the conclusion reached by the *Demodeka*'s authority. Any such relations would go against the generally accepted paradigm that the "dose makes the poison" and stronger effects at higher doses. This paradigm has served us well for a long time; speculation should not cause us to abandon it.

8. Based on the available scientific evidence, the *Improbable* Disruptors pose neither hazards, nor risks. There are indications for and against hazards, so no conclusion can be drawn. But even if one finds a potential hazard, there still is no risk, because there is no evidence of any relevant realistic exposure to the hazard that can give rise to a risk.
9. The availability of alternatives such as *GreenFlex*, is completely irrelevant to the scientific analysis of the evidence on the *Improbable Disruptors*' adverse effects. The scientific threshold for finding adverse effects has simply nothing to do with allegedly safer alternatives. These are distinct issues that should be kept strictly separate.
10. On the basis of the strength of all relevant and scientifically sound evidence, the *Improbable Disruptors* do not cause cancer or teratogenic effects. There is some theory suggesting as much, and there is much speculation based on correlation, but there simply is no empirical evidence whatsoever.
11. There are no data on *GreenFlex*, so how could any scientist express an opinion on its safety. There is data on the *Improbable Disruptors* and that data is not a cause for concern. I have no idea of the relative costs and benefits of *GreenFlex* versus the *Improbable Disruptors*, and I do not think anybody else can express an opinion on this issue.
12. NGOs, industry, and civil society should not be involved in making any scientific decisions, because they lack the requisite expertise. If they believe they have relevant information, let them submit it to the scientists for review. Likewise, given the expertise required for regulatory decision-making, they should not be involved in those decisions either. Parts of the regulatory process, but not the scientific process, could possibly be opened to the public, although it is unlikely to be helpful at all. Whether any such "democratization" should proceed, is not a scientific issue.
13. On the basis of the available scientific evidence, there is no justification for the government of *Demonata* to take any regulatory or other measures in relation to the *Improbable Disruptors*. There is no evidence that these substances cause any harm. Regulation requires proof of harm; in the absence of proof of harm, no regulation may be imposed.
14. The fact that *Demonata* is committed to a high level of environmental and health protection, or places health and the environment above economic interests and costs, and likes to take precautionary action, does not change the fact that there is no evidence of any harm being caused by the *Improbable Disruptors*. A political desire to protect does not justify arbitrary regulatory measures.

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15. The experience with science-based regulatory decision-making in the case of the *Improbable Disruptors* shows that *Demonata* should protect science against manipulation by politicians and activists. Independent, value-free, and disinterested enquiry should be guaranteed, and the government should not create opportunities for the production of value-based, interested, or politically relevant or convenient science, also known as propaganda. The government does not have to regulate the process, procedures, and substantive standards of science; it should just stay out! What we are asking for is simply unquestioning deference toward science. I hope we are not asking too much.

The Rational Scientist

1. Over the last several decades, there has been much debate about science's role in society. This debate, however, has not altered our understanding of the fundamentals of the scientific enterprise, at least in the natural sciences. Science is aimed at producing useful, reliable knowledge of a particular kind, i.e. generalizable knowledge that helps society understand, predict, and prevent risks, or take advantage of opportunities. A scientific endeavor is an iterative process involving a cycle of observation and theory, deduction and induction, aimed at enhancing understanding. Models are useful, indeed inevitable in many cases, but need to be validated. Science is not value-free, and society does not want value-free science. As a general rule, however, values are treated as external constraints imposed on the scientific process; otherwise, scientists should strive to keep illegitimate values, and like external influences, out of the process. Of course, decisions have to be made about what is being investigated, and how it can be investigated ethically, and values may play a role there. Measurements, however, should be governed by accuracy and relevancy, free of moral values. But in addition to measuring and recording, scientists assess, infer, and prioritize, i.e. they interpret. Interpretation of results may involve some values, such as at which specific point one decides that there is correlation or causation; inasmuch as science is a continuing process, these decision points are regularly revisited. Laypersons' values are unhelpful in making these decisions, however, as they are not based on expertise or authority. In order to ensure that science is able to produce reliable, unbiased knowledge of use to society, it is important to keep politics out of the scientific process and debate. Politics serves a different purpose, and is unhelpful to findings facts and truth.
2. The issue of relevancy of evidence is critical, and it is also relatively straightforward. If one is trying to answer the question whether the *Improbable Disruptors* cause adverse effects, specifically, cancer and repro-toxic effects, one needs evidence that is relevant to the causal link between these compounds and the effects. What is relevant, of course, is a function of causal mechanisms and pathways. One looks for

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reliable evidence relevant to each link in the causal chain, both corroborating evidence confirming suspected causal links and contradictory evidence denying putative causal relations. *In silico* and *in vitro* studies have some relevancy, depending on the causal theory. Generally, empirical evidence is much more helpful, however. *In vivo*, animal models, for instance, can provide strong evidence of causation, because they can be conducted under controlled, *ceteris paribus* conditions. Note, however, that animal models need to be validated in terms of their predictive power for effects on human beings, in particular in the area of endocrinology. Studies showing correlation are not causative, but can support causal theories. Public risk perception studies, on the other hand, are not relevant, because they address a different question, namely, how does the public perceive risks, assuming they exist; biological science examines this assumption, and it is this assumption that is the issue. A claim that the body politic does not have to accept scientific facts, and could find its own "facts," is problematic, since science, if it functions properly, has superior and much less biased fact-finding capability. Likewise, evidence relating to the effects as such, is also irrelevant; for instance, studies on the consequences of fetal malformations are irrelevant to the question of the causal link between the *Improbable Disruptors* and fetal malformation.

3. In selecting evidence for evaluation, minimum data quality requirements serve to ensure that the record is not contaminated with unreliable or irrelevant data; we could call it "sound science," but this term has been discredited by NGOs based on alleged past abuses by industry. The selection process requires scientific integrity, i.e. the absence of bias in a particular direction, and should be done by a team of the best scientists on the issue. In the case of the *Improbable Disruptors*, any evidence on the *Improbable Disruptors*' adverse effects should meet a set of requirements to ensure relevancy, reliability, and reproducibility including data quality requirements, sound methodology, sound execution, sound record-keeping, etc. The studies done by *GreenState*, *Chemical Justice*, and *Berakini* do not appear to meet these requirements, i.e. they are either not relevant or unreliable or unreproducible, but there is no need to prejudge this question now; they can be assessed in due course in the context of study and evidence assessment. All evidence that does not meet the conditions I specified above, should be excluded. In assessing dose-response relations, quantified findings and results tend to have higher evidentiary value than qualitative results, but qualitative analysis, including causal analysis, of course, is relevant and can be reliable; entirely qualitative, scenario-based risk assessments, on the other hand, generally lack scientific grounding and are speculative. A statistical significance threshold should be applied to correlation studies, because correlations are of little use if they are weak. The level traditionally used is 0.05; if we change that level, we should change it generically, after due consideration, not on an *ad-hoc* basis, only for the *Improbable Disruptors*, for instance. The same reasoning applies to minimum

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statistical power. Bias and confounding are addressed in the evaluation of studies; investigator bias is a particularly problematic issue in the context of the *Improbable Disruptors,* as much science is being conducted by scientists that have a strong inclination against these compounds, which may affect their observations and data evaluations.

4. As the question we are trying to answer is whether the *Improbable Disruptors* cause adverse effect in the real world, we need empirical causal evidence showing that such a causal chain exists. This evidence can be supported by other, non-empirical or non-causal evidence corroborating the putative causal relation. The strength of the evidence is a function of how much information it provides on the existence of the causal chain; contradictory evidence and alternative scientific explanations play a role at every turn, and part of the evidence's explanatory power is its ability to disprove alternative explanations. This standard should govern the evaluation of the evidence on the *Improbable Disruptors*' adverse effects.
5. There is no such thing as scientific certainty, the concept is unhelpful; certainty/uncertainty is not a binary function, but a continuous scale, a matter of degree. Scientific uncertainty may be produced by system complexity; indeed, the more complex a system is, the harder it will likely be to discover causal relations in the system. Cumulative effects are just one element of complexity. To non-scientists, complexity may be overwhelming, but to scientists, complexity is a common element of analysis. Irreversibility, on the other hand, is a troubling concept in science, as it is ill-defined: whether an effect is considered irreversible is subjective, in some, non-trivial sense, every event is irreversible. Moreover, irreversibility is not necessarily undesirable. Science has no use for the precautionary principle, because it is an undefined, political concept or slogan. Scientists that use the precautionary principle, as scientists, are dishonest and trying to rig the rules of the science game. It has been suggested that "responsible science operates on the precautionary principle," but the opposite is true. The precautionary principle is typically used by scientists to change the rules governing the types of permissible scientific proof, the minimum levels of proof required, and the burden of proof, but these changes are all made on the basis of non-scientific or political considerations. Of course, at some level, the choices about evidence reflect values, such as the importance of a reliable body of scientific knowledge, but *ad-hoc* opportunistic fiddling with the rules is invariably to the detriment of the scientific enterprise. Likewise, science is not concerned with *worst case* scenarios; such scenarios are unscientific, they reflect the investigator's imaginative capabilities, fears, and hopes, but not science. Further, with worst case piled upon worst case, scientific statements become extremely improbable by the end of the procedure.
6. The definition and criteria governing the identification of *Improbable Disruptors* that should be deemed to have the capability to cause adverse effects, should be entirely causal; in other words, they should cover the inherent capability to cause the adverse effect (not just any effect), the exposure routes and scenarios

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(which should be proven), and the actual causation of the effect in the real world (empirical evidence). Proxies for causality, such as potency, are second best, but possibly the only way we can currently operationalize the definition. The fact the *Improbable Disruptors* are not classified as hazardous under *Demonata*'s current legislation on classification, could be taken to demonstrate one of two things: these compounds have no adverse effects and the classification system works, or they have adverse effects and the system requires adjustment. It, of course, is possible, that science discovers new adverse effects not covered by a classification system, but we should not jump to that conclusion.

7. At the current state of the science relevant to the *Improbable Disruptors*, the "non-monotonic dose-response," "no-threshold," and "low-dose adverse effects" hypotheses, are just that: hypotheses. Hypotheses should not be treated as conclusions. Some limited evidence for these hypotheses is available, but the strength and weight of the evidence do not suggest that we can confidently say that the *Improbable Disruptors* cause any adverse effect. To be sure, there is evidence of effects, but there is no credible, persuasive evidence that these effects are adverse. A further complication, the "hormesis" hypothesis contradicts these hypotheses, and suggests that low dose effects may be beneficial, rather than adverse. I reviewed the conclusion reached by the *Demodeka* authority that the available scientific evidence does not suggest that the *Improbable Disruptors* cause adverse effects, and have found that their reasoning is evidence-based and accurately reflects the current state of the science. We need to assess new theories against the paradigm that the "dose makes the poison" and that stronger effects occur at higher doses. For now, the dominant paradigm is much more consistent with the data than the alternative hypotheses. We need much stronger evidence to the contrary to overcome the current paradigm.
8. In my opinion, there is no credible evidence that the *Improbable Disruptors* pose any hazard or risk. There is no "sound science," if I may use that term, to support any such conclusion. That being the case, risks can be quantified at zero, non-existent. It is true that "absence of evidence" is not the same as "evidence of absence," but, absence of evidence is the only evidence we can hope to obtain if there are no effects. Changing the default assumption so that hazard and risk are assumed, and their absence is to be proven, does not work from a scientific perspective, because it is impossible to prove the absence, the non-existence of anything. In this respect, sound science, if that is what you want to call it, is asymmetric.
9. The availability of alternatives such as *GreenFlex* does not influence the scientific analysis of the evidence on the *Improbable Disruptors*' adverse effects. This finding is simply irrelevant to the causality question. Whether or not safer alternatives are available, the scientific threshold for finding adverse effects remains what it is. Of course, substitutes are relevant to a comparative cost-benefit analysis of the *Improbable Disruptors* and any alternatives, but that is not the question you asked.

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10. On the basis of all evidence that I believe should be included in the analysis, I find no persuasive evidence that the *Improbable Disruptors* cause cancer and repro-toxic effects, because the evidence does not provide a complete and empirical account of the causal chain and mechanisms that would be involved in such causation. There is not yet even a credible theory of how the *Improbable Disruptors* could cause adverse effects. There is some ambiguous, correlative, and non-causal evidence, but there is also evidence to the contrary. Thus, no causal link can be found.
11. No data is available on *GreenFlex*, so it is not possible to reach any conclusion on its safety. The proposition that *GreenFlex* is safer than the *Improbable Disruptors* assumes that what is to be proven: on the basis of a substantial body of evidence, the *Improbable Disruptors* have not been found to present risks, but we have no data on *GreenFlex*. Under these circumstances, you need to rephrase your question. Likewise, the relative costs and benefits of *GreenFlex* versus the *Improbable Disruptors* presents a very incomplete picture; we do know that *GreenFlex* is more expensive and less performant, which would seem to suggest that it should not replace the *Improbable Disruptors*.
12. In scientific debate, non-experts do not have a useful role to play. Scientific debate thrives through the experienced and considered judgments of scientists. Their judgments should not be relegated to being just a sectional interest; doing otherwise would frustrate science's very aim, and denigrate scientists. Allowing non-experts to exercise influence both patronizes the public and panders to the conceit of those who claim to represent its "values." On the other hand, experts employed by NGOs, industry, and civil society, probably upon invitation, could be involved in science evaluations and debates, but, as all scientists, they should conduct the debate on the basis of scientifically meritorious arguments, and refrain from attempting to insert politics. In my experience, the problem with activists often is that their opinions are colored by the pre-defined objectives of their organizations, such as getting rid of all *Improbable Disruptors*. The scientific process is open and transparent to everybody, but to understand it one needs to invest. The government should be careful to deny invitations, outside of the scientific process, to take account of non-peer reviewed and anecdotal evidence in order to "keep ahead of public anxiety;" there is no such need. NGOs, industry, and civil society could be consulted in connection with regulatory decision-making, and they may have information relevant to the decisions. This process should also be open and transparent.
13. On the basis of the available scientific evidence, the government of *Demonata* has no grounds for taking any regulatory measures in relation to the *Improbable Disruptors*? There is no reason to require labeling, because no risk has been identified. In relation to other measures, the government could decide to fund further research, although it may consider other priorities, given that a lot of resources have already been spent on this issue and little progress has been made. How long does *Demonata* want to invest in

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research on what might turn out to be a phantom risk, in particular given all other pressing needs? If the government supports monitoring or further research, it should provide for oversight to ensure sound science and methodology.

14. *Demonata*'s commitments to offering a high level of environmental and health protection, placing health and the environment above economic interests and costs, taking precautionary action, and promoting proportionality, are political commitments that have no relevance to science. They do not affect the scientific evaluation, although they may well play a role in the policy debate on any proposed regulatory or other measures in relation to the *Improbable Disruptors*. In the regulatory debate, proportionality would seem to suggest that less restrictive measures, such as labeling, have preference over more restrictive measures, such as generally binding concentration limits, if the risks are proven to be small.
15. Based on my experience with science-based regulatory decision-making in the case of the *Improbable Disruptors*, *Demonata* should consider ways to reduce political interference with science. One way in which politics enters science is through activist science, as the *Berakini* affaire shows. There should be a mechanism to hold such scientists accountable so that scientific integrity can be restored. Further, *Demonata* should not provide a procedure that enables lay knowledge and values to be expressed in scientific decision-making. The scientific process has no mechanism to accommodate and account for lay and local knowledge, and wider social interests and values, which may be (and probably often are) no more than disguised subjective opinions; these interest require political deliberation, not scientific debate. Science is likewise not able to help regulators act more swiftly and proceed on the basis of activist outcries. It would be unwise for *Demonata* to suggest that science can be used for direct democracy purposes, because it cannot meet these expectations. Science can inform democratic decision-making, but is not in itself a democratic process. Put simply, science cannot go comfortably beyond the available scientific evidence, and the legitimacy of some scientific finding cannot be determined by a committee of laypersons or opinion poll.

The Post-Normal Scientist

1. Much has been said about the environmental crisis, far-reaching technological changes, and the inadequacy of modern institutions, including science. Science is one of several ways to understand society and the natural world, and it is relative to a society and culture. We have to be extremely skeptical of self-serving claims of "sound science" or objective scientific knowledge and the "one truth" paradigm, as power relations and elitist discourse are never far away. Experience has taught us that the values of scientific inquiry often conflict with other fundamental social values. Our ability to innovate runs

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unacceptably ahead of our ability to control. Novel technologies may increase inequality, threaten cultures, and harm our health and the environment. We have to restore trust in science as a protective system and in politics to act on science for, not against, the people. Mono-causal explanations must make way for richer, multi-causal, multi-factorial understandings of risk. Fortunately, we are now beginning to understand the democratic possibilities of science and how we can reconstruct political deliberation. Further, in the past, an unjustifiable distinction was made between society and nature; our contemporary understanding is one based on a social understanding of nature. This implies that all knowledge and science is socially constructed; exactly what that means is still being debated, but the principle is clear. Social values, therefore, are an integral part of the scientific process, also in the natural sciences; we have seen the evils to which science without values leads. The rightful place of science is politics; science cannot fulfil its promise unless it is part of society's broader political process. This is all the more important in the case of the *Improbable Disruptors* and similar situations, because we live in an era of increasing connectivity and bewildering complexity characterized by non-linearity, which has transformed (or metamorphosed) our society. Policy-makers thus need a new set of "technologies of humility" for systematically assessing the unknown and the uncertain, so as to be able to make socially acceptable decisions.

2. All evidence is relevant to answering the question whether the *Improbable Disruptors* cause cancer and repro-toxic effects. Only if the process is inclusive and opens the door to all people, all perspectives, and all forms of expert knowledge, as well as lay knowledge, can truly informed scientific decisions be made. Thus, in addition to *in silico*, *in vitro* and animal models, and studies showing correlation, risk perception studies, lay knowledge, including multi-cultural experiences, and any information about what the risks concerned mean to real people in their daily lives, and how these risks affect their expectations, hopes, and dreams, is essential to an understanding of what science tells us about the *Improbable Disruptors'* terrible effects.
3. Strict prerequisites applying to scientific evidence have in the past been abused to exclude other perspectives, alternative knowledge, and minority opinions from consideration and debate. This "sound science" rhetoric is unacceptable, because science should not be allowed to force its "facts" on democracy and the people. We all have our own ideals, beliefs and attitudes towards finding the truth, and there are vastly different opinions on what science or knowledge is relevant. Exclusion of knowledge based on a single perspective is a very bad solution, which has led to all the travesties we have seen in the past, including the Chernobyl nuclear disaster and the depletion of the ozone layer. The knowledge and studies done by *GreenState*, *Chemical Justice*, and *Berakini* are as much part of the body of knowledge as a controlled *in vivo* study. Quantified results are not necessary; qualitative information can be just as, or

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even more, important. Minimum statistical significance or power are exclusionary means and should be avoided. Bias and confounding are issues, but they are issues as much in conventional science as in post-normal science.

4. No objective, single standard can govern the evaluation of the evidence on the *Improbable Disruptors*' adverse effects. Empirical causal evidence should be supplemented with other sources of knowledge; no single piece of evidence is a prerequisite for finding a causal link between the *Improbable Disruptors* and cancer or repro-toxic effects. This decision is so important that society needs to be as inclusive as possible with respect to opening a dialogue and harvesting information and opinion. The strength of the evidence should be assessed in a deliberative, multi-stakeholder discourse, in which alternative explanations, risk perceptions, and feelings have a role to play.
5. As I attempted to describe above, the problem we urgently face is how to live democratically and at peace with the knowledge that our societies are inevitably 'at risk'. Critically important questions of risk management cannot be addressed by technical experts with conventional tools of prediction. Post-normal science is designed precisely to address the pervasive issues of scientific uncertainty, system complexity, irreversibility, and cumulative effects. It is the best way to implement the precautionary principle and democracy in scientific discourse. Multi-stakeholder groups can serve as an extended peer review communities and deliberate on the types of proof, the minimum levels of proof, the burden of proof, and other issues relevant to the risks under consideration. It is essential that science take the *worst case* scenario into account, because, as history has proved over and over again, in our capitalist industrialized societies the worst case is often the outcome that materializes. We tend to be overly optimistic, and scientific information tends to be biased in favor of safety; basing decisions on worst case scenarios will protect us against at least some of these mishaps.
6. Likewise, the identification of *Improbable Disruptors* that have the capability to cause adverse effects, should take place within extended peer review communities or similar inclusive democratic discourse. In this process, the issue is not that the *Improbable Disruptors* are not classified as hazardous under *Demonata*'s outdated and self-serving legislation on classification. The multi-stakeholder discourse I recommend should examine perspectives not only on the *Improbable Disruptors*' effects, but also on their aims: do we need these "products" to begin with? If we do not need them, the risk discourse takes on a different dimension, and begins to look like a subterfuge. People's expectations and feelings matter as much as some rationalistic concept of risk; and they matter more where issues are complex, science is uncertain, and risks involve irreversibility and the threat of catastrophe.
7. Whether the *Improbable Disruptors'* effects should be understood with reference to the "non-monotonic dose-response," "no-threshold," and "low-dose adverse effects" hypotheses, is to be

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deliberated and decided in the communities of interest. Only they can legitimately make these decisions, because only they participate in the process in which all evidence is deliberated. The conclusion of the *Demodeka* authority that the *Improbable Disruptors* cause no adverse effects, is wholly incredible, because it was made in accordance with an outdated elitist technocratic process controlled by the prevailing powers. In a democratic, extended community, the viewpoints and stories of victims should be heard; for instance, I can imagine that the testimony of a mother of a child suffering malformations, can be very powerful in this process.

8. Again, the process we employ to decide whether the *Improbable* Disruptors pose hazards, risks, or both, is critical. To make truly informed, and socially acceptable decisions, it is imperative that we understand the social foundations of vulnerability. Quantification of risks is not the solution. Risk calculations tend to subordinate individual experiences of risk to aggregate numerical calculations, which alienates and excludes those that are most vulnerable to these risks. Vulnerability analysis recognizes the importance of socio-economic factors. In these assessments, individuals, not populations, are the unit of analysis, as we need acknowledge differences within groups, and not reduce individuals to statistical representations. A calculus of vulnerability includes factors such as individual history, place, and social connectedness, which jointly determine human resilience. Through direct participation in the analysis of their vulnerability, ordinary citizens may regain their identity as subjects, rather than remain undifferentiated objects in yet another expert discourse. It is this kind of process and analysis that we need to apply in the case of the *Improbable Disruptors*.
9. If public participation is not part of the deliberative structures, it may occur too late to identify alternatives to dominant or default options. In the multi-stakeholder process I recommend the availability of alternatives such as *GreenFlex*, should be considered as part of broad social scientific analysis of the evidence on the *Improbable Disruptors*' adverse effects, as well the aims and any benefits, if any, of these compounds. Safer alternatives, of course, may influence the scientific threshold for finding adverse effects.
10. The process I recommend is able to review all relevant information and evidence and to make a decision on the key question as to whether the *Improbable Disruptors* cause cancer and repro-toxic effects. In my opinion, there is little doubt that they do have some dreadful effects, and there is also little doubt that their utility is limited to sustaining the plastic disposables economy and our consumer society. There is both theory and other evidence to support these findings. The main argument against is that there is not enough evidence, but "absence of evidence" is not the same "evidence of absence."
11. With respect to the questions as to whether *GreenFlex* is likely to be safer, I can give the same answer as in response to your question under 10. The relative costs and benefits, assuming these terms include

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people's experiences and hopes, of *GreenFlex* versus the *Improbable Disruptors* must be deliberated in the community of interest if it considers it useful. But they may well reach a conclusion that *GreenFlex* should replace the *Improbable Disruptors* without cost-benefit analysis. I should note also that cost-benefit analyses, as conventionally conducted, are deeply flawed, because it is easy to put numbers on the cost of regulation, but very hard to quantify the benefits to society of not having diseases and deaths caused by products such as the *Improbable Disruptors*.

12. As I explained, NGOs, civil society, and industry should be involved in the decision-making process to restrict the *Improbable Disruptors*. This applies to both scientific decisions and other decisions. Indeed, the scientific and regulatory process should be opened up, and made both transparent and deliberative. With respect to industry, the process has to be structured so that its influence is duly counter-acted. In the past, industrial interests have consistently made it hard for regulators to reach conclusions by producing shoddy critiques of scientific reports to "manufacture doubt." Society needs to protect itself against these "merchants of doubt," and remove the thin layer of scientific veneer that perfects their political blackmail.
13. There is no question that the government of *Demonata* should ban *Improbable Disruptors*. The alternative, i.e. setting some threshold value, is too risky, because, in particular for vulnerable populations, there is no evidence of the absence of effects below the threshold; potency-based cut-off values are therefore arbitrary and not based on scientific evidence. The specifics of the regulatory ban of the *Improbable Disruptors* are to be determined in multi-stakeholder deliberative discourse. This process provides an avenue through which society can collectively reflect on the ambiguity of its experiences with the *Improbable Disruptors*. Such civic deliberation should also be aimed at learning, rather than just decision-making.
14. *Demonata*'s commitments to offering a high level of environmental and health protection, placing health and the environment above economic interests and costs, and taking precautionary action will guide the inclusive, deliberative process. These important commitments should crystallize in appropriate regulatory and other measures in relation to the *Improbable Disruptors*. Given the available evidence, a ban is the only legitimate measure. Since science is at the heart of the political decisions to be made in relation to the *Improbable Disruptors,* it has been the target of partisan influences in the corridors of democracy. It is time *Demonata* takes science and politics back.
15. In the answers to the foregoing questions, I outlined how *Demonata* should conceive of and structure science-based regulatory decision-making in the case of the *Improbable Disruptors*. Substantial changes are required to process, procedures, and substantive standards. To create inclusive, deliberative, and reflexive communities, the *Improbable Disruptors* have created contradictions for institutions of risk

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governance, and demonstrate society's demand for more complete and multivalent evaluations of costs and benefits of chemical technology. Broad multi-stakeholder participation and interactive knowledge-making improve legitimacy and accountability and produce more credible and sustainable assessments of products such as the *Improbable Disruptors*. This inclusive mode of knowledge production makes science more socially embedded and more closely tied to contexts of application, and is able to break with the artificial separation of science from values. We cannot continue to emphasize prediction and control at the expense of reflection and social learning. The process I recommend should be treated as a standard operating procedure of democracy. It draws in all those whose knowledge and values are essential to making progressive policies, based on normative discourse and inclusive, albeit possibly tough, deliberations, so that we do not repeat past mistakes. Social "technologies of humility" can help society make decisions in cases such as the *Improbable Disruptors*. In the science-based multi-stakeholder process designed to address the *Improbable Disruptors,* the "can do" orientation of science and engineering is integrated with the "should do" questions of ethical and political analysis, so that the human subject is engaged as an active, imaginative agent, as well as a source of knowledge, insight, and memory. If we do so, we can also rid the process of the partisan influences on science exercised by industrial interests, and put science and policy-making in the service of protecting the people.

The Post-Modern Scientist

1. Like all knowledge, science is power. If one possesses knowledge, one is able to control other people. Thus, those that seek power, seek science and knowledge. Unlike politics, science operates under a veil of a disinterested search for truth. But that is just appearance, it is thin veneer to hide the interests that drive this search. There are so many choices to be made in science; one can make these choices in a way that guarantees the results one is looking for. Anybody who denies this and claims that science is an objective, disinterested search for truth, is a liar and should be distrusted. Science inherently is an instrument of power and domination. Science and technology can be used as tools for the consolidation of power, but also as a means to challenge vested interests, tradition and power. Science and technology can be, but by no means are guaranteed to be, enablers for achieving social change. They can be forces for human emancipation and liberation, and for saving humanity and the planet.
2. Any "evidence" that helps to support the desired answer or outcome is relevant; there is no objective way to determine relevancy of evidence. If one wants to show that the *Improbable Disruptors* cause cancer and repro-toxic effects, the evidence one needs to generate and provide is cancer and repro-toxic effects; if one wants to show the opposite, one needs non-cancer and non-repro-toxic effect. Anything goes, *in*

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silico, *in vitro* and animal models, studies showing correlation, and risk perception studies can all be used, as necessary to achieve the objective. Perceived risk and actual risk are one and the same, and neither politics nor the economy gives an iota whether it is one or the other.

3. There are no prerequisites that evidence on the *Improbable Disruptors*' adverse effects should meet. Science cannot claim universal validity; it is relative. The studies done by *GreenState*, *Chemical Justice*, and *Berakini* have just as much validity, or invalidity, as any other studies. Whether evidence will be excluded, is a matter of power politics, not merit. Quantified results and qualitative studies can both be useful. Statistical significance is a concept that is typically employed by the powers-that-be to keep the floodgates closed. The same applies to minimum statistical power; if one can get away with it, why not try? Bias and confounding are everywhere; the only question is whose bias and confounders prevail.
4. Everything is politics, and politics is everything, although the individual may like it differently. The standard that governs the evaluation of the evidence on the *Improbable Disruptors*' adverse effects, is the prevailing standard imposed by the dominant elites. Traditionally, governments have insisted on empirical causal evidence as a prerequisite for finding a causal link, because that way they are able to exercise monopolistic control over evidence. You should ask whether you want to find a causal link between the *Improbable Disruptors* and cancer or repro-toxic effects. Then you know how you should assess the strength of the evidence, and how you can account for alternative explanations. If you want to break industry's hold on society, you should ask what course of action will have an emancipatory and liberating effect? In light of the people's perception of risk and injustice, it looks like getting rid of the *Improbable Disruptors* is possible and, thus, legitimate.
5. Based on the narrative on this issue, the people of *Demonata* will be better off without the *Improbable Disruptors*. Scientific uncertainty, system complexity, irreversibility, and cumulative effects are all ways to address the contradictions of the capitalist system that allows the *Improbable Disruptors* to be produced. Likewise, the precautionary principle can be applied in science to counter-act the alienation that has plagued it; it is time people take science back. Let them decide what proof they want, what types of proof are permissible, what minimum levels of proof, burdens of proof, etc. Let them decide whether the *worst case* scenario is the really the worst case.
6. Science is becoming an intolerable power. It is not only monopolistic and exclusive, but also addictive. Science has become the opium for the powerful elites, just as religion is the opium for the masses. But is this science any different than religion? The criteria that should govern the identification of *Improbable Disruptors* that should be deemed to have the capability to cause adverse effects, are as much religion as they are science. The fact that the *Improbable Disruptors* are not classified as hazardous under

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Demonata's current legislation on classification, is no more than an indication of exploitation, of prevailing power relations. Emancipation requires a revolution in science.

7. The *Improbable Disruptors* are not the cause, but the symptom of an underlying disease. Science has been misappropriated by an deeply skewed and unfair capitalist industrialism. The productive system itself is sick, and produces a host of side effects, some of which even have a boomerang effect on those who created these effects. Of course, there is scientific evidence for the "non-monotonic dose-response," "no-threshold," and "low-dose adverse effects" hypotheses; the question is when *Demonata*'s government will acquire the courage to recognize these adverse effects. Needless to say, the conclusion reached by the *Demodeka* authority that the evidence does not suggest that the *Improbable Disruptors* cause adverse effects, is what it is: a futile attempt to consolidate its capitalist domination over the people.
8. The hazards and risk imposed on the people and the environment by the *Improbable Disruptors* are beginning to rise to the level of total catastrophe. We are not talking about small things, but about humanity's continued existence, its ability to propagate, and about its right to be free from malformation and cancer. Do we really need to quantify these hazards and risks in order to justify action? How much longer can we wait?
9. Anything is better than the *Improbable Disruptors*. For one, *GreenFlex* is a huge improvement, and this confirms that the diagnosis of the *Improbable Disruptors*' adverse effects is scientifically justified. Of course, whenever safer alternatives are available, they should be preferred; any adaptation of the scientific threshold for finding adverse effects is a negligible sacrifice on the altar of the survival of humanity and planet earth.
10. On the basis of all evidence, there is no question that the *Improbable Disruptors* cause cancer and reprotoxic effects. Despite all of the onerous causation requirements, methodological barriers, and other obstructions, still a lot of evidence has accumulated. Imagine what the evidence would look like if a non-selective inclusive perspective were adopted?
11. There is more than a possibility that *GreenFlex* is safer, maybe not so much because it is totally free of risk, but because the *Improbable Disruptors* are so risk-laden. If we need to decide based on the relative costs and benefits of *GreenFlex* versus the *Improbable Disruptors*, it should not be hard to justify that *GreenFlex* replace the *Improbable Disruptors*.
12. There is no justification for monopolizing science and excluding the people from the process of science. Inasmuch as science is an instrument of domination, the only way for the people to govern themselves is to govern science. NGOs and civil society should take control of science and decision-making, and make industry work to their benefit, rather than exploitation. As a first step, the scientific and regulatory process

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DOI: 10.12957/rqi.2016.25675

should be opened up and made transparent to the people, and then the rest will follow. After much suffering, the people have had enough of science in the service of socially unjust capitalism.

13. It is clear that on the basis of the available scientific evidence, the government of *Demonata* should prohibit the *Improbable Disruptors*. The environment and the people do not need invisible demons that deform their children, give them cancer, and render them infertile.
14. A complete prohibition is the logical consequence of *Demonata*'s commitments to a high level of environmental and health protection, placing health and the environment above economic interests and costs, and taking precautionary action. Any weaker regulatory measures would not be effective, given the resistance of industrialism and capitalism to change and its ability to manipulate and circumvent the system.
15. The experience with the *Improbable Disruptors* shows that *Demonata* should transform its process, procedures, and substantive standards to give power to the people and break capitalism's hold on industry and science. Only then is there any hope that we can control the forces arising from the tension between science, democracy and capitalism.

THE BIRD IS IN YOUR HANDS

You have heard the opinions of four scientific advisers. They reflect diverging views on the role of science, the possibility of objective science, and the relation between science and politics. They show also that science no longer is (if it has ever been) a standardized uniform, apolitical exercise in finding objective truth conducted by independent, well-educated experts who have no interest other than finding that truth; to the contrary, science has become politicized, and at least some scientists, as scientists, are openly political, and they can be openly political because they endorse accepted political ideals, such as striving for high levels of protection of human health and the environment. Under the umbrella of the precautionary principle, scientists are constantly invited to venture beyond the limits of their knowledge and speculate about possible hazards, so that they can be nipped in the bud before they become risks that cause harm. This politicization also enables scientists to begin to redefine the metaphysical rules of science. It is important to note that this politicization did not occur because society concluded that there is no objective truth, or that there is no objective way or method to find truth. Rather, it seems to have occurred due to the logic of the "science is power" movement. It is typically justified by two types of argument against objective value-free science.

The first argument against the ideal of objective science is this: given that science is not "value-free," society must make sure science uses the "right" values, which implies political or non-expert mingling with science.

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The second argument is that, given that science is to be used in policy-making, politics should play a role in the scientific enterprise to ensure that it is "politically" and "socially" relevant. But are either of these arguments right? And could the prescribed remedy be worse than the disease? With the third wave in science studies, maybe we are now beginning to see a turn away from these dogmas. The counter-arguments are being calibrated, but will likely converge around the following main strands: Even though science is not (and, to be sure, should not be) value-free, there are ways to control for the values applied in science in a way that allows it to retain its objective character. And although politics may legitimately control public spending on science, it should not introduce bias into science's search for truth. These arguments may well become the counter-weights that can help save science from total politicization. Or do you think that politicized science is more valuable to society than depoliticized science?

Much of what has happened to science in *Demonata* has resulted from the incentives of the key decision-makers and their inability to lead. In *Demonata*, some brand of realism appears to govern. Politicians want votes, and firms want customers, and they believe that the cost of changing voters' and customers' risk perceptions and opinions is simply too high. If politicians want to stay in power and firms want to thrive, they have to cater to their voters' and consumers' desires to be protected from perceived risks (note, however, that, in reality, they can cater only to their perceptions of risk perceptions and preferences). Science is not a foundation, but merely an instrument in this endeavor. In this constellation, the precautionary principle is able to reinforce the idea that opinions matter more than facts, or maybe more accurately, that opinions are facts and facts are opinions. Because we all have opinions, we all should have a say. The precautionary principle break's scientists' hold on the risk policy process, demonopolizes knowledge, and extends an open invitation to those without evidence, expertise or authority, to shape risk policies. Values (or alleged values) and health and environmental protection principles have been incorporated into both the scientific process and risk policy-making. You may find this troubling or enriching, and your inclinations may determine whether you like a particular scientific adviser's opinion.

In evaluating the various opinions, ask yourself what the main similarities and differences are. Review what is covered by each opinion, and ask what has been left out. How do each of the advisers see science, its relation with the natural world, its relation with values, and its role in policy-making? How do their views and arguments stack up against the arguments of the other advisers? How do their views on science's social role affect their opinions on the *Improbable Disruptors*, what they emphasize, and what they leave out? Why does uncertainty and complexity feature prominently in some opinions, and not in others? Is it useful to focus on uncertainty, or, indeed, does uncertainty make an issue special? Can't uncertainty be scientifically or socially constructed in each and every case? In short, which of the four advisers do you find most credible? But then relate this analysis to the evidence presented in parts 1 through 6 of this essay. How does each opinion square with the

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evidence? What science is relevant to the decisions to be made, as well as sound by itself? How does each adviser account for causation? Is it justified to assume a causal relation between terrible harms (fetal malformations, cancer, etc.) and the *Improbable Disruptors*, and, if so, on the basis of which facts and findings is that justified? How important is it to you that risk policies are evidence- and science-based? Do you think that public risk perception should play a role? Do you think NGOs and other stakeholders can help to convey public risk perceptions? And who decides?

If you know the answers to those questions, those are your opinions. But if you were the government of *Demonata*, what would you do? Would you follow your own opinions, or would you set those aside in favor of the dictates of the public interest? Which of the four advisers would you follow? Why? And why would you not endorse the opinions of the other three? How would you respond to critics that endorse the advice of one of the three you did not pick? Can uncertainty, irreversibility, and complexity be sound justifications for making assumptions and resorting to swift action, or could they be means to evade the debate or guises for political choices or ignorance? In modern, uncertain society, is it still true that "the stupid are cocksure, while the intelligent are full of doubt"? Who should set the metaphysical rules of science? What kind of scientists do you think *Demonata* needs: scientists that are full of passion and responsive to the immediate social needs, or those that are detached, careful, diligent, and interested in reality? Does it need humble people trembling at the sight of mother Nature's tremendous complexity, or bold innovators who are intellectually prepared for discovery and adventure, or both in some proportion? Is it useful for scientists to display humility and emphasize the uncertainty of scientific knowledge; how would this help to regain society's trust? How do you see science's role in questioning, challenging, and investigating popularly held beliefs and prejudices, and the humble scientist's ability to join in this effort? How can society make sure its scientists, including specifically, social scientists, are reliable and do not conduct politics in the name of science? In short, should science be a merit-based discipline of intellectual scrutiny in which only the educated can participate usefully, and that therefore is shielded from democratic militancy and political rhetoric? Or should it be a deliberative, democratic, multi-cultural exercise in identifying those scientific projects that will be socially relevant, not offend anyone, and protect everyone? If you are inclined to answer "a little bit of both," ask yourself whether it is possible to have both at the same time, and what the socially acceptable science would accomplish.

More generally, should the process and procedure of science and policy advice be changed? How important do you think the decision making *process* or *procedure* is? Should civil society or NGOs be consulted on the scientific opinions, or on the proposed decision, or on both? Why, what is their role? Can they really ensure that science is value-based and value-driven? Can they help to restore society's trust in science, if that trust need restoring? If so, how can we be sure that, under the guise of values, they do not inject their own opinions and subjective preferences into science? It would seem to be a smart strategy to label opinions as values, so that they

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acquire a status that requires no justification and places them beyond debate. And how can values be cleared of taboos, prejudices, superstition, fears, feelings, and emotions, all of which are incompatible with the pursuit of objective science? But even if values do reflect the greatest common denominator in public sentiments, don't they also reflect contemporary delusions and "political correctness"? How can scientists pass critical judgment on purported knowledge, including the knowledge produced by their peers, which is their core competency, if they are restrained by values?

Risk regulation is science-based, but also involves policy and possibly political decisions. That does not necessarily mean, however, that the issues are fewer. Indeed, many of the same issues of accountability, legitimacy, and legality arise. Does it make sense to posit that health and environmental protection always take precedence over economic interests? Should NGOs and civil be consulted? Why? Should they have decision-making power? If so, how can their representativeness and accountability be ensured? Given its interest in the outcome, should the government of *Demodeka,* or any of its industry associations, NGOs or citizens, be consulted? If so, why? If not, why not? When it comes to regulatory decision-making, where and how do alternatives and cost-benefit analysis come in? Is procedure as important as the substantive outcome, or more or less important? Why? Do you think that the process can render any outcome legitimate? If so, why? More generally, do you a tension between science and democracy? If so, how do you think society can manage or reduce that tension? Do you see a tension between democracy and the capitalist system? If so, in what sense? Is there a tension between all three, science, democracy and capitalism? If you were the government of *Demonata*, would you improve your system of risk governance? If so, how? How would you prevent a tyranny of an activist minority? In this essay, the chemical substances have been called the *Improbable Disruptors*, but do you see other disruptors? If so, who or what are they and what do they disrupt?

Independent of your answers to all of these questions, you are likely to agree that there is something wrong with science and policy-making. Although all of us agree that there is "something" wrong, we may not achieve consensus on the diagnosis, prognosis, and therapy. But to improve upon the current system, we only have to acknowledge that the notion of science as power is false and unproductive, and should be abandoned. We only have to agree that it makes sense to require that scientists do not behave as activists, and commit to scientific integrity, rather than scientific rhetoric. We only have to accept that scientific expertise represents a special, privileged kind of knowledge, because it can claim generalizability, some level of general applicability. We should decide only that scientific enquiry regarding questions of fact should be conducted in space that, although governed by some values, is free from politics. If we keep scientific fact-finding and theory-building separate from policy-making and politics, both science and democracy will be better off, because we, once again, will be able to make that important distinction between what the science says, and what the policy requires.

A million questions, but they all boil down to one: is the bird alive? The bird is in your hands. The case of

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DOI: 10.12957/rqi.2016.25675

the *Improbable Disruptors* shows that the world of science is not impervious to politics, but does politics belong there? The decision is yours.

O PROBLEMA DOS DISRUPTORES IMPROVÁVEIS: QUATRO PONTOS DE VISTA SOBRE O PAPEL DA CIÊNCIA NA FORMULAÇÃO DE POLÍTICAS

Resumo

Este é um ensaio sobre uma questão premente que é crucial para a tomada de decisão da sociedade sobre uma ampla gama de questões políticas, desde a mudança climática à guerra contra o terrorismo: a politização da ciência. Trata-se da relação entre a ciência e a formulação de políticas na regulação do risco químico baseada na ciência, mas seu propósito é muito mais amplo. Especificamente, eu uso um caso hipotético de uma categoria de substâncias químicas potencialmente perigosas, chamados Disruptores Improváveis se, para ilustrar as várias maneiras pelas quais a ciência pode ser influenciada por interesses especiais e explicada aos políticos e como as regras metafísicas da ciência e a apresentação da informação científica pode ser usada para influenciar as políticas governamentais e as decisões regulatórias. No caso apresentado aqui, o governo de uma nação hipotética, Demonata, é confrontado com uma decisão sobre como gerenciar os perigos potenciais dos Improbable Disruptors. Para garantir que a sua decisão esteja bem informada, busca conselhos de quatro conselheiros científicos, que apresentam opiniões divergentes sobre a ciência relevante para a decisão que o governo Demonata enfrenta e sobre o curso de ação que o governo deve adotar. A conduta da ciência (e dos cientistas) e a tradução de informações científicas para a formulação de políticas podem refletir convicções filosóficas, sociais e políticas mais profundas. Este ensaio mostra como essas crenças e convicções podem colorir a ciência e os conselhos fornecidos pelos cientistas sobre uma questão política específica. Pretende-se demonstrar como o conteúdo da ciência e do parecer científico pode variar em função das crenças; Não apresenta uma análise aprofundada da questão da "politização" da ciência e não tenta avaliar completamente os quatro pareceres científicos fornecidos ao governo Demonata. Em vez disso, este ensaio pretende revigorar o debate sobre o papel da política no papel da ciência e da ciência na formulação de políticas, demonstrando como a prática está evoluindo. Ao longo deste ensaio, o leitor é convidado a identificar e refletir sobre as ações dos diversos atores, as questões-chave que surgem na interface ciência-política, as diferenças entre as opiniões discutidas e as origens e razões dessas diferenças. Com base na sua própria análise, o leitor é solicitado a responder à pergunta-chave colocada no final do ensaio: se você fosse o governo de Demonata, o que você faria, e por que você faria isso?

Palavras chave: Politização da ciência; Ciência e formulação de políticas; Apresentação de informações científicas; Políticas governamentais; Decisões regulamentares.

Trabalho enviado em 20 de setembro de 2016.
Aceito em 22 de outubro de 2016.