

WHERE'S THE BEEF? HOW SCIENCE INFORMS GMO REGULATION AND LITIGATION

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I. INTRODUCTION

During the 1984 U.S. presidential primaries, faced with opponent Gary Hart's repeated assertion that he was the candidate of "new ideas," Democratic candidate and former Vice President Walter Mondale famously responded with a slogan from a national hamburger chain's commercial: "Where's the beef?"¹ The phrase thus entered the popular lexicon as a shorthand for skepticism about touted big ideas, and more generally about any proclamations of experts, authorities, and know-it-alls. Science, the focus of this review, inhabits a duality where it is simultaneously the source of an "expert" worldview that has become increasingly dominant, but where it is also one of the most effective tools for debunking convention, myth, and overblown ideas. In short, science is both the bun and the beef. This duality is perhaps nowhere more evident than in the numerous, sometimes conflicting, roles that science and scientists play in the ongoing controversy over the ever-expanding use of genetically engineered crops and other organisms.

Biotechnology has demonstrated its potential in diverse areas including agriculture, aquaculture, biofuel production, bioremediation of environmental pollutants, biological pest control, and even the production of pharmaceuticals. However, biotechnology is not without both real

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1. *Mondale Asks Hart 'Where's the Beef?'*, FLORENCE TIMES DAILY, March 12, 1984, at 2A, available at http://news.google.com/newspapers?nid=1842&dat=19840312&id=_2AeAAAAIBAJ&sjid=mcgEAAAAIBAJ&pg=2796,2401957.

and perceived risks, and thus it continues to be an extremely controversial and often litigious subject. Consumers, some members of the scientific community, public interest groups, organic growers, and other stakeholders have voiced concerns about possible risks of genetically modified (GM or "transgenic") organisms. These risks fall into the general categories of human health effects, environmental harms such as invasiveness, and contamination of non-GM crops. These concerns have resulted in increased pressure for both national and international regulation to ensure that crops and animals generated by biotechnology are safe for the environment, human health, and biological diversity. The future of Idaho agriculture depends, as does the future of agriculture worldwide, on the ability to balance environmental quality and consumer health concerns with the economic needs of producers. This review will consider the sometimes-conflicting roles that science plays, not only in the development of biotechnology and transgenic crops in particular, with an emphasis on some crops that are important to the state of Idaho, but also in developing regulatory guidelines for trade in transgenic crops and their use in agriculture, as well as in the extensive litigation that has sprung up around their deregulation and deployment.

Throughout this discussion runs one common thread: scientific uncertainty. Controversial public policy decisions about agricultural biotechnology, whether made legislatively, administratively, or in the courts, involve evaluation of risks that are primarily understood through scientific processes and institutions.² Scientific uncertainty is a transdisciplinary concept, and different disciplines contribute shades of meaning to it.³ Economists usually mention uncertainty in the context of risk, where risk is a product of the probability of an event occurring and the quantifiable adverse impact of that event if it occurs.⁴ If the probability of the event is neither one nor zero, there is uncertainty. In biology, uncertainty is usually associated with the unexplained processes and mechanisms (e.g., natural variation, errors in measurement, differing methodology, incomplete information) by which variability in observed phenomena arises.⁵ Such uncertainty typically is presented as confidence intervals, standard errors, or posterior probability distributions.⁶ As Dale Jamieson, the Director of Environmental Studies at NYU, noted, "[s]cientific uncertainty is not simply an objective value that can be

2. For a discussion of "risk" versus "uncertainty," see DOUGLAS W. HUBBARD, *THE FAILURE OF RISK MANAGEMENT: WHY IT'S BROKEN AND HOW TO FIX IT* (2009). Hubbard defines risk as a state of uncertainty (i.e., lack of complete certainty, or in other words, the existence of more than one possibility) where some of the possibilities involve a loss, or other undesirable outcome. *Id.* at 8–9.

3. See Christopher L. Jerde & Jonathan M. Bossenbroek, *Uncertain Invasions: A Biological Perspective*, in *BIOECONOMICS OF INVASIVE SPECIES: INTEGRATING ECOLOGY, ECONOMICS, POLICY, AND MANAGEMENT* 126 (Reuben P. Keller et al. eds., 2009).

4. See *id.*

5. Mark L. Taper & Subhash R. Lele, *Dynamical Models as Paths to Evidence in Ecology*, in *THE NATURE OF SCIENTIFIC EVIDENCE: STATISTICAL, PHILOSOPHICAL, AND EMPIRICAL CONSIDERATIONS* 275–97 (Mark L. Taper & Subhash R. Lele eds., 2004).

6. *Id.*

reduced by science alone."⁷ Rather, it is constructed simultaneously by both science and society, in order to serve sometimes conflicting purposes.

Scientists philosophically celebrate uncertainty as a tool for formulation of hypotheses, often to the chagrin of legislators, regulators, and the judiciary. It sometimes seems difficult for a scientist to commit to a factual statement without adding that, on the other hand, another explanation is always a possibility. René Descartes, intellectual giant of the Enlightenment, famously declared "de omnibus dubitandum" ("doubt everything"), and that viewpoint has become the reigning methodology of scientific inquiry. The scientific ethos in which doubt and uncertainty are enthusiastically embraced does not always fit well with the adversarial nature of the decision-making process, or the role that binary decisions play in environmental regulation and litigation. For that reason, science is frequently ineffective at providing solutions even to those problems with important scientific dimensions.⁸ There are so many uncertainties about both the risks and benefits of agricultural biotechnology that, much as Jamieson observed regarding the climate change debate, both biotech "hawks" and "doves" are able to claim science as an ally while simultaneously accusing their opponents of ignoring or misusing it.⁹

Public and scientific concerns about potential negative effects of genetically engineered organisms released into the environment, along with continuing uncertainty about the likelihood of such effects, are now more than a quarter-century old.¹⁰ In April of 1987, those concerns and uncertainties were personified by a young scientist dressed in a white protective suit and face mask, as she sprayed genetically engineered bacteria onto plants in a small strawberry patch in Brentwood, California, while reporters, protesters, and the curious watched from behind a chain-link fence.¹¹ That experiment, the first authorized environmental release of genetically modified organisms (GMOs) in the U.S., was roundly criticized by environmental groups.¹² It had been the focus of a lengthy series of public relations and legal battles. The white "moon suit" worn by the young scientist was more than just a prop for the television cameras; it was also emblematic of uncertainty about the dispersal and safety of the engineered bacteria. The U.S. Environmental Protection Agency (EPA), which monitored the release experiment, had

7. Dale Jamieson, *Scientific Uncertainty and the Political Process*, 545 ANNALS AM. ACAD. POL. & SOC. SCI. 35 (1996), available at <http://www.jstor.org/stable/1047890>.

8. Jamieson, *supra* note 7, at 35.

9. *Id.* at 36.

10. See Mark A. Stein, *Farming Area Residents Calmly Await First Open-Air Test of Altered Bacteria*, L.A. TIMES, April 6, 1987, http://articles.latimes.com/1987-04-06/news/mn-167_1_altered-bacteria.

11. *Id.*

12. See Thomas H. Maugh II, *Altered Bacterium Does Its Job: Frost Failed to Damage Sprayed Test Crop, Company Says*, L.A. TIMES, June 9, 1987, http://articles.latimes.com/1987-06-09/news/mn-6024_1_frost-damage (explaining how the uprooting of nearly 2000 plants by vandals adversely affected data collection).

previously conducted (in conjunction with the University of California, Berkeley) extensive trials with non-engineered bacteria in an attempt to develop some predictive methodology in this novel risk assessment arena.¹³

The courts already were involved in the controversy. Two years earlier, the D.C. Circuit Court of Appeals had affirmed an injunction against the University of California, which prevented the university from performing a similar experiment. In that decision, the court expressed its concern that governmental agencies had not yet given "adequate consideration to broad and important issues relating to its role in approving deliberate release experiments."¹⁴ The appellate court, quoting an environmental impact statement prepared by the National Institute of Health, observed that:

Should organisms containing recombined DNA be dispersed into the environment, they might, depending on their fitness relative to naturally occurring organisms, find a suitable ecological niche for their own reproduction. A potentially dangerous organism might then multiply and spread. Subsequent cessation of experiments would not stop the diffusion of the hazardous agent.¹⁵

Today, while predicted doomsday scenarios surrounding the environmental release of GMOs have not materialized, high levels of controversy, litigation, and scientific uncertainty still persist. Nonetheless, GMOs continue to transform our world. Since the first commercial introduction of transgenic crop plants more than fifteen years ago, genetic engineering has demonstrated its potential in a diversity of areas including agriculture, aquaculture, biofuel production, bioremediation of environmental pollutants, biological pest control, and even the production of pharmaceuticals.

Scientists in both the private and public sectors provide the fundamental conceptual and technological advances that have made the genetic engineering of crop plants possible. Some researchers with a more applied focus, including many in the university system whose work is federally supported by the National Institute of Food and Agriculture (NIFA, formerly known as the Cooperative State Research, Education, and Extension Service, or CSREES), help provide the technology transfer necessary for widespread adoption, production, and marketing of new GM crops.¹⁶

13. Steven Lindow et al., *Aerial Dispersal and Epiphytic Survival of Pseudomonas Syringae During a Pretest for the Release of Genetically Engineered Strains into the Environment*, 54 APPLIED & ENVTL. MICROBIOLOGY 1557 (1988).

14. Found. on Econ. Trends v. Heckler, 756 F.2d 143, 160 (D.C. Cir. 1985).

15. *Id.* at 148-49 (quoting NAT'L INST. OF HEALTH, ENVIRONMENTAL IMPACT STATEMENT ACCOMPANYING THE GUIDELINES FOR RESEARCH ON RECOMBINANT DNA MOLECULES (1976)).

16. Press Release, U.S. Dep't of Agric., USDA Grants Invest in Specialty Crop Research and Education Activities (Oct. 25, 2010), available at <http://www.csrees.usda.gov/news>

Scientific input also provides one basis for the development of regulations for the use of GM crops. A predictive framework that incorporates up-to-date scientific and technical knowledge is essential for informed planning and decision-making with respect to the agricultural deployment of GM crops, and also to shape the design of detailed regulatory controls and procedures. Regulatory authorities need accurate information to evaluate permit applications, and to determine, for example, set-back distances for GM crops relative to organic crops and wildlands, as well as to allocate resources for necessary monitoring.

Regulatory policies in the United States are intended to be based on scientific understanding of the nature of biotechnology products and optimal practices for their safe use. In 1986, the Coordinated Framework for the Regulation of Biotechnology was established for federal oversight of GMOs.¹⁷ In order to address uncertainties about these issues and other emerging products of biotechnology, the White House Office of Science and Technology Policy and the Council for Environmental Quality undertook a review of the relevant agencies and statutes for regulating biotechnology products in May of 2000.¹⁸ This review, along with a number of federal and state laws, covers oversight of GMOs today.¹⁹ Currently, oversight for GMOs and related products is shared among three federal agencies. USDA's Animal and Plant Health Inspection Service (APHIS) implements rules for engineered organisms that pose risks to plant health, oversees field testing of biotechnology-derived plants, and grants or denies the petitions for nonregulated status, which is required to grow or sell any GM crop.²⁰ The EPA has regulatory authority for GM crops with pesticidal properties, and also regulates recombinant microorganisms under the Toxic Substances Control Act.²¹ Using the same regulatory framework as it does to safeguard general food products, the FDA regulates biotechnology food products by focusing on safety and nutritional characteristics instead of the production methods.²²

While these three agencies perform most GM crop regulatory work, other federal agencies, including the U.S. Fish and Wildlife Service (FWS), the Bureau of Land Management, and the National Marine Fisheries Service, may regulate GM crops under federal legislation such

room/news/2010news/10252_scri_awards.html (announcing twenty-eight grants made through the USDA's NIFA to universities around the United States).

17. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

18. OFFICE OF SCI. & TECH. POLICY, CEQ/OSTP ASSESSMENT: CASE STUDIES OF ENVIRONMENTAL REGULATION FOR BIOTECHNOLOGY (2001), <http://www.whitehouse.gov/administration/eop/ostp/library/archives> (each section of the report is listed by part, under the heading "2001").

19. *Id.*

20. *See About Aphis*, U.S. DEPT OF AGRIC. ANIMAL & PLANT HEALTH INSPECTION SERV., http://www.aphis.usda.gov/about_aphis/ (last visited May 29, 2012).

21. *See* 15 U.S.C. §§ 2602, 2605 (2006).

22. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

as the Endangered Species Act and the National Invasive Species Act.²³ These other agencies typically only have regulatory power when GMOs have a potentially adverse impact on environment.²⁴ In addition, state regulatory authorities may add another layer of oversight by regulating the release of aquatic GMOs into their wildlife and fishery resources.²⁵

Similarly, legal measures that potentially affect interstate or international trade must have a scientific basis to comply with any applicable trade regulations.²⁶ High-quality information is also needed to support education and public awareness initiatives, in particular when it comes to potentially controversial policies such as the widespread use of agricultural GMOs. And, science informs litigation based on environmental or product liability issues surrounding these products. Courts rely on sound scientific data and interpretation for both efficacy and fairness.

Thus, science plays many roles in the development, deployment, assessment, and regulation of transgenic crops. And, while the relevance of scientific input to these often controversial issues is mostly unquestioned, there is no end to arguments about what constitutes "good" science in this arena, who should be conducting the science, and who should be paying for it. Science, like all human endeavors, reflects the institutional and disciplinary biases of its practitioners. Politics and science become so intertwined that it can be impossible to separate the scientific questions from the political questions. With sometimes evangelical fervor, the parties on both sides of the issues surrounding GM crops consistently proclaim: "Science is on our side." Thus, science has taken on a role similar to that historically occupied by God in internecine religious wars. And, as in those religious struggles, the face of science may look quite different to those on opposite sides of the conflict.

II. GM CROPS IN IDAHO AND WORLDWIDE

The agricultural sector dominates Idaho's economy.²⁷ Famous for potatoes, of which it is the nation's largest producer,²⁸ Idaho also is a major supplier, both nationally and worldwide, of wheat and barley,²⁹

23. Guy R. Knudsen, *Impacts of Agricultural GMOs on Wildlands: A New Frontier of Biotech Litigation*, 26 NAT. RESOURCES & ENV'T 13, 15 (2011).

24. *Id.*

25. See, e.g., MINN. STAT. § 18F.07 (2010) (prohibiting the release of a GMO without first obtaining a permit from the state).

26. Daniel A. Sumner, *World Trade Rules Affect Horticultural Biotechnology*, 58 CAL. AGRIC. 77, 78 (2004), available at <http://californiaagriculture.ucanr.org/landingpage.cfm?article=ca.v058n02p77&fulltext=yes>.

27. See Idaho Dep't of Labor, *Idaho Gross Domestic Product*, <http://labor.idaho.gov/publications/IdahoGDP.pdf> (last visited Nov. 2, 2011) (Idaho's agriculture, forest, fishing, and hunting industries combined to form five-and-a-half percent of the 2008 Idaho GDP).

28. U.S. DEP'T OF AGRIC., NAT'L AGRIC. STATISTICS SERV., POTATOES: 2010 SUMMARY (2011), <http://usda01.library.cornell.edu/usda/current/Pota/Pota-09-29-2011.pdf>.

29. Mykel Taylor et al., *Barley Profile*, AGRIC. MARKETING RESOURCE CENTER, http://www.agmrc.org/commodities_products/grains_oilseeds/barley_profile.cfm (last updated May 2011).

alfalfa, sugar beets,³⁰ and other crops. Southern Idaho's desert climate greatly reduces the disease pressure exerted on plants compared to more humid environments,³¹ so that Idaho is the largest producer of seed for beans and other field crops,³² which are then planted in other states. Northern Idaho is home to some of the most intensive turfgrass seed production in the world.³³ Idaho's crop production has also created a food processing industry; for example, the state is the nation's largest producer not just of potatoes, but also of processed potato products, the majority of which are sold in international markets.³⁴ As in the rest of the country, the proportion of Idaho's agricultural sector that relies on GM crops is likely to increase dramatically in the foreseeable future, both as the result of increased planting of currently available GM varieties, along with deregulation of new GM crops.

The total global area planted with GM crops increases annually.³⁵ It was ninety-million hectares (ha) in 2005, with five countries (USA, Argentina, Brazil, Canada, and China) accounting for approximately ninety-five percent of the total area devoted to GM crops.³⁶ Soybean is the GM crop occupying the greatest acreage globally, followed by corn, cotton, and canola.³⁷ For each of these crops, the most common engineered trait is herbicide tolerance; e.g., Monsanto's numerous glyphosate-resistant (Roundup Ready) crop varieties.³⁸ Corn and cotton have also been engineered to express the insecticidal toxin derived from the bacterium *Bacillus thuringiensis* (Bt).³⁹ A variety of other food crops have been commercialized on a smaller scale, although not all have been market successes. Other types of engineered traits in commercialized GM crops include resistance to various plant pathogens including fungi, bacteria, viruses, and nematodes. Golden rice, a variety engineered to biosynthesize beta-carotene, was developed as a fortified food to be used

30. Sara Schumacher et al., *Sugarbeet Profile*, AGRIC. MARKETING RESOURCE CENTER, http://www.agmrc.org/commodities_products/grains_oilseeds/sugarbeet_profile.cf m (last updated Sept. 2011).

31. Samuel J. Fuchs et al., University of Idaho, *Dry Beans*, IDAHO CROP PROFILES 1 (2003), <http://www.cals.uidaho.edu/edcomm/pdf/CIS/CIS1092.pdf>.

32. See U.S. Dep't of Agric., *A Look at Idaho Agriculture*, AGCLASSROOM.ORG, <http://www.agclassroom.org/kids/stats/idaho.pdf> (last updated July 2010) ("Idaho is known for its seed industry producing 80-85% of the sweet corn seed produced in the world; also a leading supplier for alfalfa, field and garden beans; Kentucky Bluegrass seed; and carrot, onion, turnip, [and] lettuce seeds.").

33. David Wong, *Forage, Turf and Legume Seed Production in the U.S.A.*, ALBERTA AGRIC., FOOD & RURAL DEV., [http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/sis9103/\\$file/turf.pdf?OpenElement](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/sis9103/$file/turf.pdf?OpenElement) (last updated Sept. 20, 2004).

34.

35. *Pocket K No. 16: Global Status of Commercialized Biotech/GM Crops in 2010*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS (Apr. 2011), <http://www.isaaa.org/resources/publications/pocketk/16/default.asp>.

36. *Id.*

37. *Id.*

38. FOOD & WATER WATCH, GENETICALLY ENGINEERED FOOD: AN OVERVIEW 1, 3 (2011), <http://documents.foodandwaterwatch.org/doc/GeneticallyEngineeredFood.pdf>.

39. *Id.* at 3.

in regions of the world where there is a shortage of dietary vitamin A.⁴⁰ A number of companies are also working to engineer plants that produce pharmaceuticals.⁴¹

The first genetically modified commercial food item, Calgene's slow-ripening FlavrSavr tomato, received FDA approval in 1992 but soon disappeared from the marketplace following an unenthusiastic reception by consumers.⁴² By 1995, Monsanto had developed and registered a transgenic version of Idaho's most famous agricultural product: the Russet Burbank potato.⁴³ Monsanto's NewLeaf potato incorporates the Bt toxin gene to provide protection from the Colorado potato beetle.⁴⁴ Several other variants of the NewLeaf product, which provided additional resistance to potato leafroll virus and potato virus Y, were also registered in the U.S. and Canada.⁴⁵ Monsanto suspended sales and marketing of the NewLeaf potato varieties in 2001 to, in the company's words, "focus . . . on four key row crops: corn, soy, wheat and cotton,"⁴⁶ but perhaps also in part due to consumer resistance to GM produce.

Monsanto's NewLeaf potato varieties remain fully approved in the U.S. and Canada, and as the company itself notes, potatoes are an important crop and the day may come when, depending on market demand and other factors, Monsanto will re-enter the GM potato business.⁴⁷ If that day comes, the company is likely to avoid the strategic mistake of widely advertising the GM nature of its product. The reluctance of consumers to knowingly purchase and eat transgenic foods presents an ongoing challenge to the agricultural biotech industry,⁴⁸ which has devoted considerable resources to defeating efforts to require labeling of GM food products. Controversy over GM food labeling has frequently been presented as an "expert-lay divide,"⁴⁹ with the implicit assumption that scientifically unsophisticated consumers are incapable of making informed choices.

40. *Id.* at 3–4.

41. *See id.*

42. *Id.* at 4.

43. Monsanto Co., *The NewLeaf Potato*, <http://www.monsanto.com/newsviews/Pages/new-leaf-potato.aspx> (last visited Nov. 2, 2011); *see also* Elliot A. Toevs et al., *An Industry Perspective of All-native and Transgenic Potatoes*, 14 *AGBIOFORUM* 14, 14 (2011) (discussing the Monsanto NewLeaf potato).

44. *Id.*

45. *Id.*

46. Monsanto Co., *supra* note 42.

47. *Id.*

48. *See* Melissa L. Finucane, *Mad Cows, Mad Corn and Mad Communities: The Role of Socio-Cultural Factors in the Perceived Risk of Genetically-Modified Food*, 61 *PROC. NUTRITION SOC'Y* 31, 32 (2002). Finucane breaks down consumer concerns about GM food into categories including "unknown risk" (e.g., the science is new and scientists do not yet know enough about potential dangers of GM foods) and "dread risk" (the risk is involuntary, inequitable, or has potentially catastrophic consequences; e.g., consumers may be unaware of what they're eating, the benefits of GM foods accrue to producers while consumers bear the risks, and the ubiquity of GM foods could globally amplify any ill effects). *See id.*

49. *Id.* at 31.

Opponents of labeling have attempted to portray the biotech industry's anti-labeling stance as a consumer protection issue. For example, the American Enterprise Institute has published a widely publicized book, which claims that GM food labeling laws in other countries have "no scientific justification . . . [and] have succeeded in stigmatizing and limiting the availability and benefits of GM foods."⁵⁰ As so often happens in biotech versus anti-biotech skirmishes, the side that most convincingly allies itself with science acquires a potent public relations weapon.

The biotech industry and some governmental organizations, both national and international, routinely make the claim that a history of safely using GM foods can be upheld.⁵¹ However, the suggestion has been made that biotechnology companies would enhance the credibility of such claims if they routinely published results of their studies on the safety of GM foods in international peer-reviewed journals.⁵² As Jose Domingo remarked in a letter to the journal *Science*, "[t]he general population and the scientific community cannot be expected to take it on faith that the results of such studies are favorable. Informed decisions are made on the basis of experimental data, not faith."⁵³ Critics have noted that there is a paucity of long-term human or animal epidemiological studies to support claims of GMO safety due in part to the lack of labeling and traceability in GMO-producing countries.⁵⁴ Indeed, the vast majority (ninety-seven percent by some estimates) of edible GM crops (soy, corn, oilseed rape, canola, excluding cotton) are grown in South and North America, where GMOs are not labeled.⁵⁵

III. TRANSGENIC ALFALFA: A CONTINUING SAGA OF REGULATION AND LITIGATION

In 2005, Monsanto's Roundup Ready alfalfa was approved by the U.S. Department of Agriculture (USDA) and went on the market.⁵⁶ Conventional (non-organic) alfalfa growers in Idaho and elsewhere hailed

50. GARY E. MARCHANT, ET AL., *THWARTING CONSUMER CHOICE: THE CASE AGAINST MANDATORY LABELING FOR GENETICALLY MODIFIED FOODS* 3 (2010). Marchant et al. argue that GM foods are safe, abundant and inexpensive, and provide vast benefits including less pesticide use and fewer burdens on the environment. Since mandatory labeling would deter investment in the burgeoning biotechnology industry and deprive the public of important innovations, the authors believe that GM labeling laws are antithetical to the idea of consumer choice. *See id.*

51. *See, e.g., Biotechnology Safety and Advantages*, MONSANTO CO., <http://www.monsanto.com/newsviews/Pages/biotech-safety-gmo-advantages.aspx> (last visited Nov. 2, 2011); *20 Questions on Genetically Modified Foods*, WORLD HEALTH ORG., <http://www.who.int/foodsafety/publications/biotech/20questions/en> (last visited Nov. 2, 2011).

52. Jose L. Domingo, Letter, *Health Risks of GM Foods: Many Opinions but Few Data*, 288 SCI. 1748 (2000).

53. *Id.*

54. Joël Spiroux de Vendômois et al., *Debate on GMOs Health Risks After Statistical Findings in Regulatory Tests*, 6 INT'L. J. BIOLOGICAL SCI. 590, 590 (2010).

55. Clive James, *Global Status of Commercialized Biotech/GM Crops: 2009*, 41 ISAAA BRIEF 1, 13–14 (2009).

56. *Roundup Ready Alfalfa*, MONSANTO CO., <http://www.monsanto.com/newsviews/Pages/roundup-ready-alfalfa-supreme-court.aspx> (last visited Nov. 2, 2011).

the new weed control that was now available to them. Six years later, transgenic alfalfa continues to be a poster child for the ongoing scientific, regulatory, and legal battles between pro- and anti-biotech groups. The GM alfalfa story is illustrative of the ambiguous role that science plays in the development of federal regulations, in legal struggles between the opposing forces, and in the court of public opinion.

Idaho ranks third nationally for production of alfalfa hay.⁵⁷ The state also ranks seventh nationally in total cropland acres that are certified organic (as of 2005), with most of that land being planted with organic hay.⁵⁸ Organic hay is a lucrative and rapidly growing market in Idaho, where a continuing increase in the number of certified organic dairy cows has led to an equally large surge in organic feed.⁵⁹ By some estimates, Idaho leads the nation in production of organic hay.⁶⁰ Organic alfalfa growers nationwide were alarmed by the potential for organic alfalfa seed to be contaminated with GM material.⁶¹ The position of groups such as the Organic Seed Alliance is that the "USDA Organic" label indicates that a product is free of transgenic material; thus, potential contamination with transgenic material reduces the integrity of organic products and inhibits the growth of the industry.⁶² Organic growers contend that the potential for GM material contamination in alfalfa, a perennial field crop, is greater than many other crops.⁶³ Bees and other pollinators potentially can transfer transgenic pollen miles from its source.⁶⁴ However, others note that since a seed generation is required for gene flow and seeds are rarely formed in hay production fields, there may be relatively little opportunity for genes to flow between alfalfa fields.⁶⁵

In early 2006, a suit was filed by the Center for Food Safety and a consortium of additional plaintiffs (Geertson Seed Farms, Trask Family Seeds, CFS, Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, and Western Organization of Resource Councils) in the U.S. District Court for the Northern District of California.⁶⁶ Plaintiffs cited the USDA's failure to prepare an Environmental Impact Statement (EIS), which constituted a

57. IDAHO STATE DEP'T OF AGRIC., IDAHO AGRIC. FACTS (2011), [http://www.agri.idaho.gov/Categories/Marketing/Documents/English/Final 2011 - for emailing.pdf](http://www.agri.idaho.gov/Categories/Marketing/Documents/English/Final%202011%20-%20for%20emailing.pdf).

58. *Organic Farmland Acres Growing Rapidly*, IDAHO FARM BUREAU (Sept. 12, 2007), <http://www.idahofb.org/index.php?action=news.story&rowid=170>.

59. *Id.*

60. *Id.*

61. *Twelve Reasons Why GE Alfalfa Threatens Organic*, ORGANIC SEED ALLIANCE, <http://www.seedalliance.org/ge-alfalfa-talking-points-2/> (last visited Nov. 2, 2011).

62. *Id.*

63. *Id.*

64. *Id.*

65. DANIEL H. PUTNAM, METHODS TO ENABLE COEXISTENCE OF DIVERSE PRODUCTION SYSTEMS INVOLVING GENETICALLY ENGINEERED ALFALFA, UNIV. OF CAL. DIV. OF AGRIC. & NATURAL RESOURCES PUB. NO. 8193, at 4 (2006), available at <http://anrcatalog.ucdavis.edu/pdf/8193.pdf>.

66. *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 U.S. Dist. LEXIS 14533 (N.D. Cal. Feb. 13, 2007).

violation of the National Environmental Policy Act (NEPA).⁶⁷ In 2007, the district court enjoined the sale and planting of transgenic alfalfa seed until the APHIS could complete an EIS to evaluate potential environmental effects of deregulating the product.⁶⁸ In September 2008, the U.S. Court of Appeals for the Ninth Circuit upheld the injunction on all planting of Roundup Ready alfalfa seed.⁶⁹ In affirming the lower court's decision, the Ninth Circuit determined that the district court appropriately applied a traditional balancing test in formulating the injunction.⁷⁰ It further held that an evidentiary proceeding would be redundant with APHIS's obligation to prepare an EIS.⁷¹

Had the Ninth Circuit remanded the case in *Geertson* for a full evidentiary hearing, would the outcome have been different? Perhaps not, but the plaintiffs may have been fortunate that the Ninth Circuit's decision preceded the U.S. Supreme Court's ruling in *Winter v. NRDC*, which was issued only a few months later.⁷² *Winter* had national defense implications, and perhaps in part for that reason, the Court felt obligated to emphasize a standard that requires injunctive relief in environmental protection cases to be based on hard evidence that irreparable environmental or economic injury is likely, rather than merely "possible," regardless of the strengths of a plaintiff's arguments on the merits.⁷³ In her dissenting opinion in *Winter*, Justice Ginsburg noted that courts "do not insist that litigants uniformly show a particular, predetermined quantum of probable success or injury before awarding equitable relief."⁷⁴ In Ginsburg's view, in the context of environmental claims, flexibility is important in the face of uncertain future harm. At least one observer noted at the time that the *Winter* decision might have the effect of significantly raising the bar for injunction-seeking, anti-biotech plaintiffs.⁷⁵

In 2010, the U.S. Supreme Court reversed the Ninth Circuit's injunction against planting Roundup Ready alfalfa seed, and remanded the case back to the district court, and then to the USDA for a determination of interim measures to be implemented, pending the agency's completion of the EIS.⁷⁶ APHIS subsequently completed the EIS in December 2010 and, in January 2011, authorized the resumption of sale and planting of Roundup Ready alfalfa.⁷⁷

67. *Id.* at *10.

68. *Id.* at *38–39.

69. *Geertson Seed Farms v. Johanns*, 541 F.3d 938, 947–48 (9th Cir. 2008).

70. *Id.* at 946.

71. *Id.* at 947–48.

72. *Winter v. NRDC, Inc.*, 555 U.S. 7 (2008).

73. *Id.* at 21–22.

74. *Id.* at 51 (Ginsburg, J., dissenting).

75. Guy R. Knudsen, *Biotech Crop Litigation Update*, AGRIC. MGMT. COMM. NEWSL. (A.B.A Section of Env't Energy and Res., Chicago, IL), Aug. 2009, at 7 [hereinafter *Litigation Update*].

76. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010).

77. Anti-GMO groups were appalled that barely a week after the decision to deregulate transgenic alfalfa, APHIS announced that, as an interim measure, it would continue to

The Court's decision was welcomed by a coalition of agricultural industry organizations that had filed a joint friend-of-the-court brief in support of the petitioners in *Monsanto v. Geertson*.⁷⁸ These included the American Farm Bureau Federation, Biotechnology Industry Organization, American Seed Trade Association, American Soybean Association, National Alfalfa and Forage Alliance, National Association of Wheat Growers, National Cotton Council, and National Potato Council.⁷⁹ A recent article in *Nature Biotechnology* summarized the biotech industry viewpoint: while hailing the USDA decision to authorize the planting and sale of Roundup Ready alfalfa, the industry remains "concerned that the agency will begin making non-science-based concessions to the organic community at the expense of biotech crop developers and growers."⁸⁰ It is unclear just what kinds of "non-science-based concessions" were being referred to, since—in the case of Roundup Ready alfalfa—many observers were surprised that APHIS did just the opposite of making concessions, instead approving unrestricted planting of the genetically modified crop. Agriculture Secretary Tom Vilsack was quoted as saying that "[a]fter conducting a thorough and transparent examination . . . APHIS has determined that Roundup Ready alfalfa is as safe as traditionally bred alfalfa."⁸¹

The scientific high ground was simultaneously being claimed by both sides in the transgenic alfalfa controversy. The agency's choice not to impose any restrictions at all on transgenic alfalfa was surprising in light of a major study published in 2008 by the Council for Agricultural Science and Technology (CAST), which provided a comprehensive overview of gene flow in alfalfa as well as procedures to mitigate gene flow.⁸² Recommended measures included maintenance of appropriate isolation or setoff distances between organic and GM alfalfa fields and collection of science-based, pollinator-specific pollen mediated gene flow data to optimize setoff distances for protecting organic production.⁸³ Ironically, the National Alfalfa & Forage Alliance (NAFA) had previously been one of the more proactive industry groups in promoting a "coexistence strat-

allow planting of Roundup Ready sugar beets despite a court order to complete a final EIS before making a final decision on deregulation for that crop. Press Release, Organic Trade Association, OTA Deplores USDA Action to Proceed with Genetically Engineered Sugar Beets Despite Court Order (Feb. 7, 2011), *available at* http://www.organicnewsroom.com/2011/02/ota_deplores_usda_action_to_pr.html.

78. News Release, Idaho Farm Bureau Federation, Ag Groups Applaud Supreme Court Ruling on Biotech Alfalfa (June 21, 2010), *available at* <http://www.idahofb.org/index.php?action=news.article&rowid=53>.

79. *Id.*

80. Emily Waltz, *Industry Exhales as USDA Okays Glyphosate-Resistant Alfalfa*, 29 NATURE BIOTECHNOLOGY 179, 179 (2011).

81. Carey Gillam & Christopher Doering, *UPDATE 3-U.S. Farmers Get Approval to Plant GMO Alfalfa*, REUTERS, Jan. 27, 2011, *available at* <http://www.reuters.com/article/2011/01/27/gmo-alfalfa-usda-idUSN2727513020110127>.

82. ALLEN E. VAN DEYNZE ET. AL., COUNCIL FOR AGRIC. SCI. & TECH., GENE FLOW IN ALFALFA: BIOLOGY, MITIGATION, AND POTENTIAL IMPACT ON PRODUCTION (2008), [http://sbc.ucdavis.edu/files/CAST Alfalfa Gene Flow157.pdf](http://sbc.ucdavis.edu/files/CAST%20Alfalfa%20Gene%20Flow157.pdf).

83. *Id.* at 2, 23.

egy" for the different types of growers, and had produced a series of documents addressing coexistence issues relevant to organic alfalfa seed and hay producers, as well as alfalfa seed and hay exporters.⁸⁴

Other reports support the likelihood of transgene escape from Roundup Ready alfalfa fields. Novel genetic material can move into environments or organisms beyond the intended host, such as through the dispersal of seeds or pollen of a genetically modified plant by wind, animals, or insects. Novel genes (transgenes) engineered into crops could be introduced into the genomes of their non-GM counterparts or wild relatives.⁸⁵ In addition to the potential for contamination of non-GM crops, some scientists are concerned that hybridization between GM crops and their wild relatives may result in the evolution of increased weediness in the wild plants (so-called "superweeds") because of their resistance to current control strategies. An escaped crop plant may itself be a weed, which is simply any plant growing where it is unwanted, as has happened in Canada with genetically modified, herbicide-tolerant canola.⁸⁶ Also, wild plant relatives might suffer an increased risk of extinction due to hybridization with GM crops.

A study on potential within-field and long-distance dispersal of alfalfa pollen confirmed the possibility of long-range dispersal of genes from alfalfa hay production fields by pollen,⁸⁷ and concluded that "complete containment of transgenes within alfalfa seed or hay production fields would be highly unlikely using current production practices."⁸⁸ Similarly, a study of feral alfalfa plants collected from sites along roadsides and abandoned fields within two miles of Roundup Ready alfalfa seed fields found glyphosate-resistance traits at 83 percent of the twenty-three collection sites, out to a distance of almost two miles from the pollen source.⁸⁹

Whether APHIS considered this scientific information and decided it was unimportant, or perhaps largely ignored it, is unclear. Only days before APHIS granted deregulated status to Monsanto's GM alfalfa, the Center for Food Safety (CFS), a major player in the U.S. anti-biotech movement, sent a strongly worded letter to Secretary Vilsack claiming that the final EIS "fails to meet the high standards of scientific integrity

84. Mark H. McCaslin & Allen E. Van Deynze, Nat'l Alfalfa & Forage Alliance, *Coexistence for Organic Alfalfa Seed and Hay Markets* (2008), available at <http://alfalfa.ucdavis.edu/+producing/files/biotech/csorganic.pdf>.

85. See Norman C. Ellstrand, *When Transgenes Wander, Should We Worry?*, 125 PLANT PHYSIOLOGY 1543 (2001).

86. See S. I. Warwick, A. Légère, M.-J. Simard & T. James, *Do Escaped Transgenes Persist in Nature? The Case of an Herbicide Resistance Transgene in a Weedy Brassica Rapa Population*, 17 MOLECULAR ECOLOGY 1387 (2008).

87. P.C. St. Amand, D.Z. Skinner & R.N. Peaden, *Risk of Alfalfa Transgene Dissemination and Scale-Dependent Effects*, 101 THEORETICAL & APPLIED GENETICS 107, 111 (2000).

88. *Id.* at 113.

89. Bob Hammon, Carrie Rinderle & Melissa Franklin, *Pollen Movement from Alfalfa Seed Production Fields* (2006), <http://wci.colostate.edu/Assets/pdf/Hammon.RRpollenflow.pdf>.

demand by the President and his Office of Science and Technology Policy."⁹⁰ The CFS letter represents a common anti-GMO perspective, namely that the USDA relies too heavily on corporate science and fails to obtain adequate, independent, peer-reviewed data regarding the claims of the biotech companies in support of their products.

To some observers, the Supreme Court's *Monsanto v. Geertson* decision also revived a formerly prevailing regulatory assumption (which had been weakened by the Ninth Circuit's *Geertson v. Monsanto* decision): organic and conventional producers must bear the burden of segregating their crops from biotech crops grown nearby, if contamination with transgenic material is of concern, e.g., because of a risk of pollen drift. One biotech industry interpretation of this apparent shift is that *Monsanto v. Geertson* protects "the rights of farmers who choose to grow biotech crops, and who want access to the benefits that biotechnology can provide."⁹¹

Technological advances in molecular biology have made it a generally straightforward matter to detect contamination of conventional crops with transgenic material.⁹² Variants of this technology have played a role in some of the most significant biotechnology litigation to date. In *StarLink Corn*, farmers sued Aventis Crop Science after traces of the genetically engineered corn variety StarLink, which was intended for animal feed, were found in food products meant for human consumption.⁹³ Test kits, based on enzyme-linked immunosorbent assay methods, are readily available for the recombinant protein construct in StarLink corn.⁹⁴ The plaintiffs in *StarLink Corn*, which was eventually settled out of court for \$110 million, alleged that the manufacturer was strictly liable because the product was defective as designed, and could not be safely used for its intended animal feed purpose, since it would inevitably become commingled with the human food supply.⁹⁵ The plaintiffs also alleged that the defendants were negligent in their monitoring of farmers using the product and in their enforcement of the measures

90. Open letter from Andrew Kimbrell, Esq. and Bill Freese, Ctr. for Food Safety, to Sec. Tom Vilsack, Dep't of Agric., <http://www.centerforfoodsafety.org/wp-content/uploads/2011/01/Open-Letter-CFS-to-Vilsack-FINAL-1-24-10-with-CC-list.pdf>; Press Release, Ctr. for Food Safety, CFS Urges USDA to Get the Science Right, Prioritize Farmers, On Roundup Ready Alfalfa (Jan. 25, 2011), <http://www.centerforfoodsafety.org/2011/01/25/cfs-urges-usda-to-get-the-science-right-prioritize-farmers-on-roundup-ready-alfalfa> (announcing open letter to Secretary Vilsack regarding genetically engineered Roundup Ready alfalfa).

91. News Release, Idaho Farm Bureau Fed'n, Ag Groups Applaud Supreme Court Ruling on Biotech Alfalfa, (June 21, 2010), <http://www.idahofb.org/index.php?action=news.article&rowid=53>.

92. See DIANA L. BRANDNER, *PCR-Based Detection of Genetically Modified Foods*, in 23 TESTED STUDIES FOR LABORATORY TEACHING 69 (M.A. O'Donnell ed., 2002), available at http://ucbiotech.org/resources/methods/GMO_detection.pdf.

93. *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d 828, 834–35 (N.D. Ill. 2002).

94. Mary W. Trucksess, *Determination of Cry9C Protein in Corn-Based Foods by Enzyme-Linked Immunosorbent Assay: Interlaboratory Study*, 84 J. OF AOAC INT'L 1891 (2001).

95. *StarLink Corn*, 212 F. Supp. 2d at 837.

required to ensure that GM corn remained segregated from non-GM corn.⁹⁶

Molecular biology techniques allow detection of unique inserted gene sequences in plants. This allows biotech companies to identify the progeny of GM seeds that they sell and which contain genetic material they enforce patent rights. Lewontin and Levins described this development as "a combination of legal and biological weapons in the hands of the breeders,"⁹⁷ those weapons being "legal rights granted to breeders by the Plant Variety Protection Act and subsequent court decisions, in combination with the use of standard DNA 'fingerprinting' that allows an unambiguous determination of the source of farm products."⁹⁸ Thus, in *Monsanto Canada Inc. v. Schmeiser*, such technology enabled Monsanto to successfully sue Percy Schmeiser, a Canadian canola breeder and grower, for patent infringement, after he allegedly harvested and saved seed from glyphosate-resistant canola plants patented by Monsanto, and then sold the subsequent harvest for feed.⁹⁹ Monsanto also successfully sued farmers Mitchell and Eddie Scruggs for infringing patents relating to genetically modified Roundup Ready soybean seeds and Bollgard-containing cotton seeds.¹⁰⁰ In *Monsanto v. Scruggs*, the defendants unsuccessfully argued that Monsanto's test results should be disregarded for not complying with accepted scientific standards, like failing to use a negative control.¹⁰¹

IV. PHILOSOPHICAL DIFFERENCES ON THE INTERNATIONAL FRONT: THE PRECAUTIONARY PRINCIPLE VS. SO-CALLED "SCIENCE-BASED" RISK EVALUATION OF GMOS

International concerns about the transnational movement of the products of biotechnology, and possible adverse effects on biodiversity, were first addressed, although briefly, in the context of the Convention of Biological Diversity (CBD), adopted in Rio de Janeiro in 1992.¹⁰² The CBD requires Parties to "[e]stablish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology," which pose the threat of adverse environmental impacts that could affect biological diversity or present risks to human health (the term "living modified organism" (LMO) is essentially synonymous with "GMO," except that GMO is sometimes used to refer to nonliving bulk commodities of recombinant origin.¹⁰³ Here, the two terms will be used interchangeably and restrict-

96. *Id.* at 835.

97. RICHARD LEWONTIN & RICHARD LEVINS, BIOLOGY UNDER THE INFLUENCE: DIALECTICAL ESSAYS ON ECOLOGY, AGRICULTURE, AND HEALTH 336 (2007).

98. *Id.*

99. *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 (Can.).

100. *Monsanto Co. v. Scruggs*, 459 F.3d 1328 (Fed. Cir. 2006).

101. *Id.* at 1335.

102. United Nations Conference on Environment and Development: Convention on Biological Diversity, *opened for signature* June 5, 1992, 31 I.L.M. 818.

103. *Id.* at art. 8(g).

ed to living organisms that are released into the environment and which are potentially capable of growth and reproduction).¹⁰⁴ The CBD also requires that Parties consider the need and appropriate form of “protocol setting out appropriate procedures, including advance informed agreement, in the field of the safe transfer, handling, and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.”¹⁰⁵

Thus, in the biodiversity protection context, the CBD distinguishes LMOs from other organisms on the basis of their origin in recombinant DNA technology, rather than on any potentially invasive or otherwise harmful characteristics of the organisms themselves. This focus on the recombinant nature of organisms, rather than more generally on their potential for invasiveness or other biodiversity-harmful traits, was carried forward into the Cartagena Protocol, which took effect on September 11, 2003.¹⁰⁶ The United States has signed, but not ratified the Convention on Biological Diversity, and thus is not a party to the Cartagena Protocol. Nonetheless, the United States played a significant role as an initial advocate of the latter instrument. The Cartagena Protocol's objective is to facilitate the safe importation and use of LMOs. Organisms that the Cartagena Protocol covers include genetically engineered plants, animals, and microorganisms that cross international borders.¹⁰⁷

The primary goal of the Cartagena Protocol is to minimize adverse effects on biodiversity, including possible risks to human health, without unnecessarily disrupting world food trade.¹⁰⁸ The Protocol imposes different levels of stringency depending on the intended use of a particular LMO. For those that will be directly used as food or feed or for processing, only a relatively simple information procedure is required.¹⁰⁹ For LMOs intended for introduction into the environment of the importing state, the Protocol requires an Advanced Informed Agreement (AIA) prior to the first transboundary movement of the organism. Components of the AIA include notification and an exchange of information between the exporting and importing countries.¹¹⁰

The Cartagena Protocol adheres to the precautionary principle or “precautionary approach” first delineated in the Rio Declaration on Environment and Development.¹¹¹ The most commonly expressed version of the precautionary principle is: “Where there are threats of serious or

104. *Id.*

105. *Id.* at art. 19(3).

106. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *adopted on Jan. 29, 2000*, 39 I.L.M. 1027 (entered into force Sept. 11, 2003), <http://bch.cbd.int/protocol/text/>.

107. *Id.*

108. *See generally id.* at arts. 1, 2.

109. *Id.* at 1031–32.

110. *Id.* at 1030–33.

111. United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 3–14, 1992, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26 (Vol. I), Annex I, Principle 15 (Aug. 12, 1992).

irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”¹¹² As applicable to the Cartagena Protocol, the precautionary principle provides that lack of scientific certainty about the extent of potential adverse effects shall not prevent a party, typically the importing State, from deciding not to allow LMO imports. Proponents of this approach included a number of developing nations who expressed fears that “a major loss of biodiversity” could result “from a replacement of traditional farming methods by genetically engineered crops.”¹¹³ Their views were echoed by environmental non-governmental organizations present at Cartagena including Greenpeace and the Worldwide Fund for Nature.¹¹⁴

The decision to follow the precautionary approach was contentious.¹¹⁵ During the development of the Cartagena Protocol, the U.S., although initially a state sponsor of the process, lobbied unsuccessfully for adoption of a less restrictive “scientific evidence standard,” alternatively known as the “sound scientific knowledge” basis.¹¹⁶ The scientific evidence standard is consistent with that found in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures; the latter is relevant to alien species characterized as pests or pathogens, to the extent that measures to manage these species affect international trade.¹¹⁷ WTO member states may adopt national measures to protect human, animal, or plant health / life from risks arising from the entry, establishment or spread of pests, diseases, or disease-causing organisms and to “prevent or limit other damage” within its territory from these causes.¹¹⁸

The scientific evidence standard essentially requires that confirmed scientific evidence of harm be present prior to banning the import of a LMO. In this effort, the U.S. was joined by a number of other countries (the so-called “Miami Group,” whose other members were Argentina, Australia, Canada, Chile, China, and Uruguay), and was bolstered by support from the U.S. biotech industry. The motivation for the U.S. to first champion, but then abandon, the Cartagena Protocol has been debated. Keleman and Vogel pointed out that governments are more likely

112. *Id.*

113. See Lavanya Rajamani, *The Cartagena Protocol—A Battle Over Trade or Biosafety?*, THIRD WORLD NETWORK, <http://www.twinside.org.sg/title/lavanya-cn.htm>. (last visited on Nov. 3, 2011).

114. *Id.*

115. See ROSIE COONEY, THE PRECAUTIONARY PRINCIPLE IN BIODIVERSITY CONSERVATION AND NATURAL RESOURCE MANAGEMENT, INT’L UNION FOR CONSERVATION OF NATURE, POLICY AND GLOBAL CHANGE SERIES NO. 2, at 13 (2004), <http://data.iucn.org/dbtw-wpd/edocs/PGC-002.pdf>.

116. See Rafe Pomerance, *The Biosafety Protocol: Cartagena and Beyond*, 8 N.Y.U. ENVTL. L. J. 614, 618–20 (2000).

117. *The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)*, WORLD TRADE ORG., Article 2(2), http://www.wto.org/english/tra-top_e/sps_e/spsagr_e.htm (last visited Oct. 25, 2011); *id.* at Annex A.

118. *Id.* at Annex A.

to support international environmental agreements when those agreements provide advantages to domestic producers in international competition, and tend to oppose such agreements when the costs of compliance put domestic firms at a competitive disadvantage.¹¹⁹ From this perspective, early U.S. enthusiasm for a biotechnology protocol might be viewed as a preemptive attempt to occupy the regulatory field, in which a weak protocol would effectively codify a more laissez-faire approach to international regulation of biotechnology, to the advantage of U.S. producers. However, as a major biotech-exporting country with anti-biotech litigation an ongoing feature in its courts,¹²⁰ the United States apparently was concerned that inclusion of the precautionary principle as a fundamental tenet of the Cartagena Protocol could have a chilling effect on exports. Some observers believed that the Miami Group's strategy was to maintain exports of GMO commodities without the hindrance of information, documentation, or a chance for informed decision-making by importing countries.¹²¹ Allegedly, "frustrated delegates from the developing world" were heard to complain that "the negotiations at Cartagena were on 'Biotrade' not Biosafety."¹²²

Arguably, the term "scientific evidence standard" is misleading, since both the precautionary principle and the scientific evidence standard involve risk management approaches in the face of uncertainty, and neither is fundamentally more "scientific" than the other. In one sense, the conflict involves differing approaches to the rate of technological transfer: the position of the United States favors a "rapid rate of technological transfer," while Europe generally advocates a "slow[er] and [more] cautious rate."¹²³ These conflicting approaches may also be analyzed in the context of the burdens of proof that they require. The precautionary principle places the burden of proving that GM products do not pose a threat to human health or the environment on the developers of the products,¹²⁴ whereas the so-called scientific evidence standard places the burden of proving that the GM product presents a significant and quantifiable risk to health or the environment on those opposing the product's introduction.

Ahteensuu observed that in quantitative risk assessment, which he considered "the prevailing institutionalized risk governance methodology," conclusive scientific proof has generally been used as the "prerequisite for taking preventative measures."¹²⁵ However, in numerous in-

119. R. Daniel Kelemen & David Vogel, *Trading Places: The Role of the United States and the European Union in International Environmental Politics*, 43 COMP. POL. STUD. 427, 444-50 (2009).

120. See Knudsen, *supra* note 69, at 5.

121. Rajamani, *supra* note 107.

122. *Id.*

123. See Dane Scott, *Perspectives on Precaution: The Role of Policymakers in Dealing with the Uncertainties of Agricultural Biotechnology*, 5 INT'L J. OF GLOBAL ENVTL. ISSUES 10 (2005).

124. *Id.* at 12, 23-25.

125. Marko Ahteensuu, *Defending the Precautionary Principle Against Three Criticisms*, 11 TRAMES 366, 378 (2007).

stances there have been early indications of environmental damage before it materialized or fulfilled the strict criteria for scientific acceptance, so that taking no precaution in the state of uncertainty resulted in serious adverse consequences.¹²⁶ Conversely, the scientific evidence standard places the burden of proof on those who would oppose the introduction or deployment of GM crops or other GM organisms. Cranor notes that the scientific tradition (e.g., the use of statistical confidence limits) "strongly and asymmetrically" protects against false positive errors; for example, inferential procedures that show health or environmental risks when there are none.¹²⁷ This standard contrasts with that used in tort law, where the prevailing view is that "*legal* false positives (i.e., mistakenly deciding for plaintiffs) should be approximately equal to *legal* false negatives (i.e., mistakenly deciding for defendants)."¹²⁸

Thus, a cultural gap arises between science and law concerning the standards of proof required within each culture. Uncertainty raises "a substantial barrier for the party with the burden of proof,"¹²⁹ so that it's hardly surprising that proponents and opponents of GM crops each lobby for a different evaluation regime. The culture of science is not necessarily helpful at resolving these differences. As Cranor notes, science is open-ended, with even comparatively settled conclusions being open to revision, so that "scientists ordinarily assert their views with considerable uncertainty even [when] their personal beliefs may be stronger."¹³⁰

In its opposition to enshrining the precautionary principle as a fundamental component of the Cartagena Protocol, the United States' position was consistent with its domestic stance: Biotechnology products in the United States are not considered "special," but are, in principle at least, regulated under the same laws that govern the "safety, efficacy, and environmental impacts of similar products derived by more traditional methods."¹³¹ The Coordinated Framework is based on the assumption that the "process" of genetic engineering itself poses no unique risks; rather, the regulatory emphasis is on the "product" that results.¹³² Thus, for example, the FDA regulates biotechnology food products with the same requirements that are used to safeguard all foods in the marketplace, such as safety and nutritional characteristics. This approach, known as "substantial equivalence," was first proposed by the Food and Agriculture Organization (FAO) and World Health Organization (WHO)

126. EUR. ENV'T AGENCY, LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896–2000 (Poul Harremoës et al. eds., 2001).

127. Carl F. Cranor, *Daubert and the Acceptability of Legal Decisions*, 5 J. PHIL., SCI., & LAW 1, 2, May 2005, <http://www6.miami.edu/ethics/jpsl/archives/all/cranor.pdf>.

128. *Id.* (italics in original).

129. *Id.*

130. *Id.* at 2–3.

131. Pew Initiative on Food and Biotechnology, *Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products*, PEW TRUSTS, http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf (last visited June 2, 2012).

132. *Id.*

in the early 1990s.¹³³ Substantial equivalence is consistent with the scientific evidence standard in providing the assumption that GM foods do not have particular adverse properties (e.g. toxicity or allergenicity) until those properties have been established by scientific research.¹³⁴

Some critics, however, question the validity of the substantial equivalence dogma. De Vendômois et al. summarized points of international debate on health risk studies for the major commercialized edible GM crops: soy, maize, and oilseed rape.¹³⁵ These crops were engineered to be herbicide-tolerant (primarily glyphosate) or to produce Bt toxin variants.¹³⁶ Chronic health risks under debate include unpredictable insertional mutagenesis effects, metabolic effects, or novel pesticide residues,¹³⁷ as well as potential allergenicity or gene transfer events (to cells of the body or to bacteria in the gastrointestinal tract). Often, it is difficult to demonstrate adverse effects for substances whose activities have long latency periods, or cause effects common to other agents, or whose effects are subtle. If long periods of time are involved, it would be difficult for persons exposed to toxicants to discover that their ailments are the result of exposure.¹³⁸

V. THE EVOLVING CULTURE OF SCIENCE: OBJECTIVITY, REDUCTIONISM, AND CORPORATIZATION

On the one hand, science is the generic development of human knowledge over the millenia, but on the other it is the increasingly commodified specific product of a capitalist knowledge industry.

—Lewontin & Levins¹³⁹

Pay no attention to that man behind the curtain!

—The Great Oz, in THE WIZARD OF OZ¹⁴⁰

The nature and scope of scientific responsibility for biotechnology, and the research agenda that drives them, comprise one of three major areas in which criticisms or concerns about agricultural biotechnology arise, the others being human health and environmental impacts, and

133. Joint FAO & WHO Expert Consultation, May 29–June 2, 2000, Safety Aspects of Genetically Modified Foods of Plant Origin 1 (June 2011).

134. *Id.* at 3–4.

135. Joël Spiroux de Vendômois et al., *Debate on GMOs Health Risks After Statistical Findings in Regulatory Tests*, 6 INT'L J. OF BIOLOGICAL SCI. 590 (2010), <http://www.biolsci.org/v06p0590.pdf>.

136. *Id.* at 590–91.

137. *Id.* at 591.

138. See Clayton P. Gillette & James E. Krier, *Risk, Courts, and Agencies*, 138 U. OF PA. L. REV. 1027, 1039 (1990) (“Many public risks are latent in their materialization.”).

139. RICHARD LEWONTIN & RICHARD LEVINS, *BIOLOGY UNDER THE INFLUENCE: DIALECTICAL ESSAYS ON ECOLOGY, AGRICULTURE, AND HEALTH* (2007).

140. THE WIZARD OF OZ (Metro-Goldwyn-Mayer 1939).

socioeconomic consequences.¹⁴¹ Several factors may have profound effects on the motivations and actions of scientists. These include the sometimes illusory quest for objectivity, the tension between objectivity and advocacy, the influence of societal forces including professional recognition and advancement, and scientists' need to fund their research. Scientific responsibility is also put to the test in the courts when scientists are called upon to provide testimony in areas of their expertise.

Partho Sarathi Ray observed that for practicing scientists, the "aura of objectivity of science" ("objectivism") allows scientists to feel that they are in the "pursuit of understanding material reality as it is, independent of the subjective conditions around [them]."¹⁴² To the layperson, this may have the effect of "[making] science appear to be infallible and all-powerful, representative of ultimate truths."¹⁴³ The objectivist mindset of many scientists bolsters the viewpoint that science deals exclusively with objective properties of matter, and that these transcend the subjective conditions inherent in human activity, even while science itself is essentially a human activity.¹⁴⁴

The dominance of objectivism in science reflects the continuing influence of reductionist thought, in which biological systems are dissected into their constituent parts, the properties of which are thought to solely influence the material reality of the whole. Reductionism has had at least two significant influences on the scientific components of the GMO debate. First, it permeates scientific perspectives on the role of genes in biological systems, and thus, implicitly, the extent to which the tools of molecular biology are sufficient to effectively understand and manipulate biological systems.¹⁴⁵ The "one gene-one enzyme hypothesis," as first elaborated by Beadle and Tatum in 1941, proposes that genes act through the production of enzymes, and that each gene is responsible for producing a single enzyme that in turn affects a single step in a metabolic pathway.¹⁴⁶ Edward Tatum, who won the 1958 Nobel Prize in Medicine for his work, stated that "all biochemical processes in all organisms are under [genetic] control . . . [and] are resolvable into a series of individual stepwise reactions . . . [each] controlled in a primary fashion by a single gene."¹⁴⁷ As Francis Crick, a senior statesman of DNA research,

141. JEFFREY BURKHARDT, *Biotechnology, Ethics, and the Structure of Agriculture*, in *ETHICS AND AGRICULTURE* 317, 317 (Charles V. Blatz ed., 1991).

142. Partho Sarathi Ray, *Dialectics of Science - Science is its Own Era Reflected in Thought*, RADICAL NOTES (Oct. 6, 2008), <http://radicalnotes.com/content/view/72/39>.

143. *Id.*

144. *Id.*

145. See Marc H. V. Van Regenmortel, *Reductionism and Complexity in Molecular Biology*, 5 EUROPEAN MOLECULAR BIOLOGY ORGANIZATION REPS. 1016 (2004), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1299179/pdf/5-7400284.pdf>.

146. George W. Beadle & Edward L. Tatum, *Genetic Control of Biochemical Reactions in Neurospora*, 27 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 499 (1941).

147. Edward L. Tatum, Nobel Lecture: A Case History in Biological Research (Dec. 11, 1958) (transcript available at http://nobelprize.org/nobel_prizes/medicine/laureates/1958/tatum-lecture.html).

famously claimed: "The ultimate aim of the modern movement in biology is to explain *all* biology in terms of physics and chemistry."¹⁴⁸ Implicit in reductionism, at least in its most extreme manifestation, is the ability to predict all the consequences of our genetic manipulation of organisms, a perspective that not only is favorable to commercial biotechnology, but which also lends it the aura of scientific authority. Reductionist rhetoric frequently shows up in biotech industry contentions that recombinant DNA technology is essentially little more than an improved variation on traditional plant or animal breeding (i.e., they both are just means of moving genes around).¹⁴⁹ But, as Regal noted, rhetoric is not the same thing as a professional, scientific comparison between the genetic mechanisms of traditional breeding and those of genetic engineering.¹⁵⁰

Reductionism, along with the sheer volume of expanding scientific knowledge, has led to the ever-increasing fractionation of science into innumerable specialized areas. Specialization serves an important social purpose for scientists, in that it promotes publication, advancement, and tenure for those in academia. Proponents of specialization argue that groups of specialists working as teams can solve problems related to the subdivision of knowledge within a field. However, specialization can also prevent researchers from seeing the bigger picture, due to the narrowness of their training and the "ideology of expertise."¹⁵¹ Lewontin and Levins contend that the training of specialists rather than the education of scientists encourages the "combination of micro-creativity and docility that permits scientists to work on the most monstrous of projects without attention to their consequences."¹⁵² The trend towards scientific specialization fosters beliefs about the transcendence of science, exacerbates the expert-lay divide, and fails to consider that science, and our understanding of it, results from a mutual formative process, or dialectical relationship, between humans and society.¹⁵³

The trend towards reductionism as a dominant paradigm of science parallels what has been called the increasing corporatization of science. Susan Wright has argued that the rapidly evolving association between science and industry in the field of biotechnology radically transformed research practices and standards, such that "a turn from traditional scientific norms and practices toward a corporate standard took place. The dawn of synthetic biology coincided with the emergence of a new ethos,

148. FRANCIS H. C. CRICK, *OF MOLECULES AND MEN* 10 (1966).

149. For example, Monsanto's statement on their website that "[b]iotechnology is a more direct approach than breeding since it allows you to incorporate genetic material directly into the germplasm" is not a false statement, but rather an example of reductionist simplification of a complex question. *Do GM Crops Increase Yield?*, MONSTANO, <http://www.monsanto.com/newsviews/Pages/do-gm-crops-increase-yield.aspx> (last updated Nov. 21, 2009).

150. P.J. Regal, *Scientific Principles for Ecologically Based Risk Assessment of Transgenic Organisms*, 3 *MOLECULAR ECOLOGY* 5 (1994), available at <http://www.psrastr.org/pjrisk.htm>.

151. See LEWONTIN & LEVINS, *supra* note 89, at 125.

152. *Id.*

153. RICHARD LEVINS & RICHARD C. LEWONTIN, *THE DIALECTICAL BIOLOGIST* (Harvard Univ. Press 1985).

one radically shaped by commerce."¹⁵⁴ Critics of a so-called "second academic revolution" contend that the integration of a mission for economic development has transformed the traditional teaching and research university into what some (including numerous enthusiastic university administrators) call the "entrepreneurial university."¹⁵⁵ The concept of the entrepreneurial university is in part an institutional reaction to ever-decreasing support for public higher education, but some observers worry that when professors in effect become entrepreneurs, whatever academic freedom and scientific authority they possess will be tarnished.¹⁵⁶

As an expression of neoliberalism, i.e. a market-driven approach to social and economic policy-making, the intrusion of corporate culture into the academy has the potential effect of favoring commercialization and deregulation over civic discourse and scientific integrity.¹⁵⁷ The Federal Bayh-Dole Act of 1980, which permits universities and other non-profit institutions to pursue ownership of inventions derived from publicly-funded research, has been criticized for privatizing the fruits of research that should be owned by the public, as partially evidenced by the enormous increase in university patenting and licensing activities since its enactment.¹⁵⁸ To the extent that a university's interests overlap with corporate economic interests, conflicts of interest may arise that compromise the university's independence to engage in academic research without regard to its commercial potential.¹⁵⁹ This situation may damage both the quality of the research, as well as public confidence in its legitimacy.¹⁶⁰

In the United States, the 106 publicly funded land-grant colleges and universities, many of which have a mission to focus on agricultural research and extension, are especially vulnerable to the corrosive effects of corporatization. Most university research is extramurally funded, and research faculty are under considerable pressure to bring in grant dollars to maintain their research programs. Both federal and industry

154. SUSAN WRIGHT, *MOLECULAR POLITICS* 107 (Univ. of Chicago Press 1994).

155. Henry Etzkowitz, *The Evolution of the Entrepreneurial University*, 1 INT'L J. TECH. & GLOBALISATION 64 (2004).

156. See MARTIN KENNEY, *BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX* (1986). While acknowledging that a primary motivation of the entrepreneurial university is the need for diversified funding and enhanced university-corporate collaboration, proponents of the entrepreneurial university concept also emphasize other values that ideally would be enhanced in the entrepreneurial university setting. These include expansion of higher education to poorly served segments of society, distance education, increased use of instructional technology, and lifelong learning. See John E. Neal, *Quality Assurance in the Entrepreneurial University*, 1998 NEW DIRECTIONS FOR INSTITUTIONAL RES., Dec. 10, 2002, at 69–85, <http://onlinelibrary.wiley.com/doi/10.1002/ir.9906/pdf>.

157. See Henry A. Giroux, *Neoliberalism, Corporate Culture, and the Promise of Higher Education: The University as a Democratic Public Sphere*, 72 HARV. EDUC. REV. 425 (2002).

158. Risa L. Lieberwitz, *The Corporatization of Academic Research: Whose Interests Are Served?*, 38 AKRON L. REV. 759, 764–67 (2005).

159. *Id.* at 766–67.

160. *Id.* at 767.

funding support biotechnology research, either at the fundamental or applied level. Agricultural commodity growers' groups contribute large amounts of money to university research, and some faculty are almost entirely dependent on commodity support for their programs. With few exceptions (e.g., organic growers' groups, which contribute relatively small amounts to university research), commodity groups tend to be pro-biotechnology. The impression that university agricultural research is "bought and paid for" has become pervasive, and sometimes universities seem slow to recognize the problem. For example, Penn State University, the only land-grant university in Pennsylvania, maintains an extensive Penn State Extension web presence, with the prominent heading "Trusted, Science-Based Information."¹⁶¹ A letter on this site is entitled "Protect Farmers' Choice to Plant Biotech Crops . . . AND HELP BRING BACK ROUNDUP READY ALFALFA."¹⁶² This implicitly "Penn State-approved" letter solicits readers to submit pro-deregulation comments to the USDA, and is authored by biotech industry executives Mark McCaslin and Steve Welker of Forage Genetics International and Monsanto Company, respectively.¹⁶³ It is hardly surprising that the research university system is sometimes seen as being in collusion with the commercial biotechnology industry, whose primary purpose, in one view, is to "extend the control of capital over agricultural production."¹⁶⁴

Although objectivity is venerated by most scientists, subjective judgment also emerges as a form of uncertainty throughout the scientific process, from choosing a methodology and evaluating the quality of data, to interpretation of results and making decisions based on those interpretations.¹⁶⁵ When scientists provide input to legislation and policy, or appear as witnesses in litigation, the distinction between objective and subjective testimony can become tenuous. For example, it has been suggested that "[t]he tendency of [WTO dispute settlement] panels to seek scientific advice, even when the evidence is clear and none of the parties to the dispute has requested scientific input, may imply" a need to bolster "the legitimacy of [the panel's] findings rather than . . . a real need to solve the scientific issues underlying the legal dispute."¹⁶⁶ The difficulty of how to incorporate scientific uncertainty into environmental policy debate is not unique to questions surrounding GM crops. For example, the inability or unwillingness of scientists to assign specific

161. PENN STATE EXTENSION, <http://extension.psu.edu> (last visited Nov. 3, 2011).

162. Open letter from Mark McCaslin, President, Forage Genetics International, and Steve Welker, Alfalfa Lead, Monsanto Company, *Protect Farmers' Choice to Plant Biotech Crops . . . And Help Bring Back Roundup Ready Alfalfa*, PENN STATE EXTENSION, <http://extension.psu.edu/field-crop-news/documents/mpc-rr-alfalfa.pdf> (capitalization in original).

163. *Id.*

164. LEWONTIN & LEVINS, *supra* note 89.

165. John Harwood & Kevin Stokes, *Coping with Uncertainty in Ecological Advice: Lessons from Fisheries*, 18 *TRENDS ECOLOGY & EVOLUTION* 617 (2003).

166. Theofanis Christoforou, *Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty*, 8 *N.Y.U. ENVTL. L.J.* 622, 642 (2000).

probabilities to catastrophic environmental effects has been cited as a major factor inhibiting effective action to control global warming.¹⁶⁷

In the courtroom, judges and juries for the most part are not scientifically trained, but nonetheless "are often required to make judgments in cases where they lack specific knowledge pertaining to the facts at issue."¹⁶⁸ When fact-finders lack knowledge "regarding the significance or probative weight of the evidence" before them, they "must often rely on the knowledge of others ("experts") in reaching their decisions."¹⁶⁹ Although the legal profession generally agrees on the need for criteria to ensure the reliability of scientific evidence, there is no uniform and coherent conceptual framework for determining the validity of scientific knowledge in court.¹⁷⁰ Federal Rule of Evidence 702,¹⁷¹ the standard that evolved from *Daubert*,¹⁷² is used in federal courts and many states and assigns the trial judge the task of assuring that scientific expert testimony is truly a product of scientific knowledge. Criteria available for the judge's use include availability of sufficient facts or data, whether the scientist's testimony has been subjected to peer review and publication, existence of appropriate standards and controls, and the degree to which the theory or technique has been generally accepted by the scientific community.¹⁷³

Cranor and Eastmond argue that in implementing *Daubert*, some judges increase the burden on plaintiffs by imposing more stringent requirements on scientific evidence than the scientists themselves would have, such as by requiring evidence or levels of confidence that scientists would not require.¹⁷⁴ Another problem arises when litigants search carefully for published studies that favor their own position, or mislead the public or the courts about what the scientific evidence shows.¹⁷⁵ Additionally, it is often possible to design scientific studies so as "to find a desired outcome," so that the "[scientific] literature is at some risk from misleading studies created for admissibility reviews."¹⁷⁶ In this way, the

167. Jim Giles, *Scientific Uncertainty: When Doubt is a Sure Thing*, 418 NATURE 476, 476 (2002).

168. David M. Godden & Douglas Walton, *Argument from Expert Opinion as Legal Evidence: Critical Questions and Admissibility Criteria of Expert Testimony in the American Legal System*, 19 RATIO JURIS 261, 264 (2006).

169. *Id.* (alteration added).

170. See Bert Black et al., *Science and the Law in the Wake of Daubert: A New Search For Scientific Knowledge*, 72 TEX. L. REV. 715, 717 (1994).

171. FED. R. EVID. 702.

172. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993); see Black, *supra* note 158, at 746–47 (discussing how the Supreme Court examined Federal Rule of Evidence 702 in *Daubert*).

173. *Daubert*, 509 U.S. at 590–94.

174. See Carl F. Cranor & David A. Eastmond, *Scientific Ignorance and Reliable Patterns of Evidence in Toxic Tort Causation: Is There a Need for Liability Reform?*, 64 LAW & CONTEMP. PROBS. 5, 15 (2001).

175. See GERALD MARKOWITZ & DAVID ROSNER, DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION 214–15, 222–24 (2002).

176. Cranor, *supra* note 115, at 10.

use of *Daubert* by judges may indirectly act to distort the scientific literature.

VI. CONCLUSION

Twenty-seven years after the original airing of the Wendy's hamburger chain's "Where's the beef?" slogan, that company is once again asking the familiar question in a new advertising campaign.¹⁷⁷ Much as with the ongoing debate about genetic engineering and its place in agriculture, the observer is tempted to note that "plus ça change, plus c'est la même chose." Critics of the role that science and scientists have played in the GMO discussion are still likely to ask where the beef is, since many of the questions and controversies that surrounded the first release of GMOs have not been satisfactorily resolved. If that resolution is equated with the removal of uncertainty, the issues probably never will be resolved to the satisfaction of all parties. Nonetheless, the use of biotechnology to modify attributes of agricultural crops is almost certain to increase, as is the number of GM crops available to growers and the total acreage planted to those crops. Science and scientists will continue to play a critical role in the inevitable worldwide expansion of GM crops, as scientific input informs legislation, regulation, and the settling of legal disputes. Important ongoing challenges for the scientific community will include maintaining both the appearance and the reality of fairness and objectivity, and helping the public understand and accommodate uncertainty as a basic component of environmental decision-making and regulation.

177. Stuart Elliott, *After 27 Years, an Answer to the Question, 'Where's the Beef?'*, N.Y. TIMES, Sept. 25, 2011, at B4, available at http://www.nytimes.com/2011/09/26/business/media/after-27-years-an-answer-to-the-question-wheres-the-beef.html?_r=2.