Transgenic Crops in the Age of Human Rights: Moral Uncertainty and Rational Risk Policy

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INTRODUCTION

History has proven it is characteristically human to modify the environment for some perceived benefit. Since the domestication of plants and animals more than 10,000 years ago, humankind has manipulated plants to improve yields and provide more food. This process evolved from breeding to crossbreeding and now to genetic engineering. In 1996, the first genetically modified crop available for commercial use reached the market.[1] In the ten years since, the use of genetically engineered or transgenic crops has proliferated at impressive rates despite an ongoing debate about the ethical implications and possible consequences of genetically altered food. Between 2003 and 2004, the use of transgenic crops worldwide increased by 20% to a total of 200 million acres.[2] In 2004, 8.25 million farmers in 17 countries planted genetically altered crops, thereby joining a $4.7 billion market.[3] The rate at which transgenic crops are overtaking traditional varieties is even more surprising. Between 1997 and 2002, the percentage of soybeans that were Roundup Ready® soybeans, a transgenic variety, increased from 1.9% to 74% and transgenic cotton increased from just 4% in 1997 to 70% in 2002.[4] In addition to the proliferation of existing plants, scientists are developing and testing new varieties with traits ranging from pest and drought resistance to improved nutrition and taste.[5]

Despite this growth, or perhaps because of it, the argument over transgenic crops has only intensified over the past ten years. At the same time, transgenic crops are often absent from broader discussions of the ethical propriety of genetic engineering. The genetic alteration of plants shares many of the foundational issues that make ethical discussions of genetic engineering of humans and other animals so difficult. Nevertheless, some substantial differences and the unique history of transgenic crops provide a

1 CLIVE JAMES, PREVIEW: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2004, at viii (ISAAA Briefs No. 32-2004), *available at* http://www.isaaa.org/Resources/publications/briefs/32/download/isaaa-brief-32-2004.pdf.

2 *Id.* at iii.

3 *Id.* at iii, vii.

4 Michele C. Marra et al., *The Payoffs to Transgenic Field Crops: An Assessment of the Evidence*, 5 AGBIOFORUM 43, 43 (2002), *available at* http://www.agbioforum.org/v5n2/v5n2a02-marra.pdf.

5 *See* John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 810 (2001).

unique opportunity to learn how to address the issues underlying the biotechnology debate. The importance of food has the public engaged—but substantially fewer moral and religious objections to genetically altered food remove some of the blinding passion that accompanies the idea of genetically altered animals and humans. The clear goals of using transgenic crops to abate world hunger and the existing regulatory structure also provide a framework for discussing issues related to genetic engineering that is absent when applying gene technology to animals or humans. As such, the development of transgenic foods and the subsequent debate provide a unique learning opportunity for effectively structuring the debate of these difficult issues. Mistakes by advocates and opponents of transgenic crops early in the discussion have polarized the arguments, obfuscated the public's understanding of the issues, and foreclosed a productive discourse about transgenic plants. By appreciating mistakes made in handling an issue that is less complex than those on the horizon, we can avoid the temptation to engage in empty rhetoric and properly weigh the benefits and risks of genetic engineering.

DEVELOPMENT OF GENETIC ENGINEERING

At a point near the end of the last European Ice Age, humans began domesticating and exploiting plants and animals.[6] Throughout the past ten to fifteen thousand years, humanity has used the limits of available technology to manipulate plants to improve both the yield and the variety of the food supply.[7] This activity took a great step forward in 1865 when Gregor Mendel, a Moravian monk who had been experimenting with peas, published "Versuche über Pflanzen-Hybriden" ("Experiments with Plant Hybrids").[8] By exposing the basic laws of heredity, Mendel's work formed the foundation for modern genetics. For over a hundred years, scientists, farmers, and even hobbyists applied Mendel's lessons through traditional breeding techniques to transfer genes between the same or closely related species of plants and animals.[9] Then, in the mid-1970s, scientists discovered a process known as recombinant DNA technology, whereby scientists remove discrete sections of a DNA molecule and replace them with others.[10] The emergence of this technology immediately touched off ethical discussions in the scientific community.[11]

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6 PETER J. UCKO & G.W. DIMBLEBY, THE DOMESTICATION AND EXPLOITATION OF PLANTS AND ANIMALS, at xvii (Aldine Publishing Co. 1968).

7 *See id.* at xvii–xx.

8 GREGOR MENDEL, EXPERIMENTS IN PLANT HYBRIDISATION (Harv. Univ. Press 1965) (1866); *See also* PETER PRINGLE, FOOD INC.: MENDEL TO MONSANTO—THE PROMISES AND PERILS OF THE BIOTECH HARVEST 9 (Simon & Schuster 2003).

9 *See* Karen Charman, *"Biotechnology Will Feed the World" and Other Myths*, 6 PR WATCH NEWSLETTER (Ctr. for Media & Democracy, Madison, WI), Oct.–Dec. 1999, at 8, *available at* http://www.prwatch.org/prwv6n4.pdf.

10 THOMAS A. SHANNON, MADE IN WHOSE IMAGE? GENETIC ENGINEERING AND CHRISTIAN ETHICS 4 (Humanity Books 2000).

11 *See* LISA YOUNT, BIOTECHNOLOGY AND GENETIC ENGINEERING 10 (Facts on File rev. ed. 2004).

Though part of an ongoing scientific debate, genetic engineering took a significant legal turn in 1980 in the seminal case of *Diamond v. Chakrabarty*.[12] In *Chakrabarty*, the United States Supreme Court observed that the "laws of nature, physical phenomena, and abstract ideas" were not patentable under 35 U.S.C. § 101[13] because new plants and minerals are "manifestations of . . . nature, free to all men and reserved exclusively to none."[14] However, in a 5-4 decision, the Court determined a human-made, genetically engineered bacterium was patentable as a new and useful "manufacture or composition of matter."[15] The Court stated Congress intended the statute to "include anything under the sun that is made by man."[16] In reaching its decision, the Court rejected arguments made in an *amicus* brief filed by scientists and ethicists suggesting a "parade of horribles," including the potential for pollution and disease as well as the loss of biological diversity.[17] The Court reasoned any action it might take would have little effect deterring the scientific mind and that such determinations of policy were for the legislative process.[18]

HUNGER AND HUMAN RIGHTS

As the Court noted, the decision in *Chakrabarty* did not spawn genetic engineering, but it did dramatically affect the debate. Proponents of genetically modified organisms, which now included agribusiness interests, began to tout the potential for transgenic crops to end world hunger. The political environment was also ripe for transgenic crops. As part of a global human rights movement, the United Nations declared in 1974, "[e]very man, woman, and child has the inalienable right to be free from hunger and malnutrition in order to develop fully and maintain his physical and mental faculties."[19] Ethicists concerned about human rights also targeted American foreign policy. Author Henry Shue argued that certain things were "basic rights"—those goods that are necessary for the enjoyment of any other rights.[20] Control of these goods, food being among the most obvious, creates a duty not to deprive and a duty to aid the hungry.[21] Despite the focus on human rights, improvements in agriculture, and changes in the world economy, the number of malnourished people around the world has been consistently more than 800 million for decades.[22] Dramatic growth in

12 447 U.S. 303 (1980).
13 *Id*. at 309.
14 *Id.* (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).
15 *Id.*
16 *Id.* (quoting S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)).
17 *Id.* at 316.
18 *Id.* at 317.
19 2 ENCYCLOPEDIA OF BIOETHICS 869 (Warren T. Reich et al. eds., Simon & Schuster MacMillan rev. ed. 1995) [hereinafter BIOETHICS].
20 HENRY SHUE, BASIC RIGHTS: SUBSISTENCE, AFFLUENCE, AND U.S. FOREIGN POLICY 22–29 (Princeton Univ. Press 2d ed. 1996).
21 *Id.* at 55–60.
22 *See, e.g.*, 2 BIOETHICS, *supra* note 19, at 869; FOOD & AGRIC. ORG. OF THE U.N., THE STATE OF FOOD INSECURITY IN THE WORLD 2004, at 5 graph (2004), *available at*

the world's population and the depletion of natural resources raise serious questions about the carrying capacity of the earth as we begin the twenty-first century.[23] Biotechnology offers transgenic crops as a key component in solving both the agricultural and environmental crises.

BENEFITS OF TRANSGENIC CROPS

The dire situation regarding world hunger and population growth provides proponents of biotechnology with their strongest argument. From the beginning, transgenic crops have benefited from the clear goal of reducing world hunger. Many scientists who have devoted their lives to improving food and food production around the world argue that genetic engineering is essential "to improve the quantity, quality, and availability of food."[24] Proponents of biotechnology see agricultural improvements as indispensable to the ability to feed the 8.3 billion people anticipated in the next quarter century.[25] Transgenic crops offer increased yields, dependability, and nutritional quality to food producers around the world.[26] Improvements in food production could have beneficial effects on the environment as well. Replacing traditional crops with transgenic varieties could allow farmers to bring less land under cultivation, which would protect natural habitat and actually preserve biodiversity.[27] Transgenic crops also offer the potential to conserve environmental resources by reducing pesticide and herbicide use as well as creating foods more fit to the local environment.[28] In this way, transgenic crops become a win-win proposition—crops that produce higher yields with less harm to the environment. In theory, and more recently in practice, scientists are able to tailor crops to a particular growing environment or the nutritional needs of a particular population. Scientists around the world have developed plants that "resist insects, disease, drought, salt, and herbicides."[29] The Third World is already benefiting from the technology. Small-scale farmers in Africa, who desperately need agricultural technology to improve food production in some of the most acidic soil in the world,[30] benefit from transgenic seeds and crop protection technologies targeted to local growing conditions and practices.[31] Given

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ftp://ftp.fao.org/docrep/fao/007/y5650e/y5650e00.pdf.

23 2 BIOETHICS, *supra* note 19, at 870–71.

24 *See* Norman Borlaug, Letter to the Editor, *Open Letter to the Editor*, INDEPENDENT (London), Apr. 20, 2000, *reprinted in* THE ETHICS OF FOOD: A READER FOR THE TWENTY-FIRST CENTURY 74, 77 (Gregory E. Pence ed., 2002) [hereinafter ETHICS OF FOOD].

25 *See id.* at 78.

26 *Id.* at 79.

27 Kurt Buechle, Note, *The Great, Global Promise of Genetically Modified Organisms: Overcoming Fear, Misconceptions, and the Cartagena Protocol on Biosafety*, 9 IND. J. GLOBAL LEGAL STUD. 283, 290 (2001).

28 SHANNON, *supra* note 10, at 13.

29 YOUNT, *supra* note 11, at 13.

30 Cornell University News Service, *Crop Engineered to Grow in Poisonous Soil*, SCIENCE DAILY, Aug. 29, 2007, http://www.sciencedaily.com/releases/2007/08/070827153025.htm.

31 *See* Florence Wambugu, *Why Africa Needs Agricultural Biotech*, *in* GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY 304, 305 (Michael Ruse & David Castle eds., 2002) [hereinafter GENETICALLY MODIFIED FOODS].

the disparities of world food distribution, it is disingenuous for privileged societies to take an excessively cautious approach to genetically engineered foods when the vast majority of humankind cannot afford that luxury.[32]

To proponents, society reaps these benefits at little cost. Characterizing the process as an extension of traditional breeding practices, genetic engineers find no moral objection to manipulating nature to develop transgenic crops.[33] In fact, some see genetic engineering as preferable because it is more precise than traditional breeding methods.[34] While traditional breeding transfers genes between organisms, genetic modification involves moving only a single gene.[35] Thus, the ability arises to make beneficial combinations that were impossible by traditional breeding. Genetic scientists then use these combinations to engineer products suited to the planting conditions or nutritional needs of a certain area, thereby increasing food production and nutrition in ways not possible without biotechnology.[36] While science must be respectful of natural processes and wary of hubris, the reality of human expansion demands the increased production and nutrition biotechnology can provide.

OPPOSITION TO TRANSGENIC CROPS

Despite the admirable goals and potential benefits of transgenic crops, biotechnology faces persistent opposition. The arguments against biotechnology generally take two forms: 1) moral or ethical objections to tampering with nature, and 2) a fear of unintended consequences, which tends to focus on human health and the environment. For many reasons, the preliminary development of biotechnology did not involve a significant debate about the wisdom of genetic engineering itself. First, there was little organized opposition to confront the rapidly developing technology.[37] Those who held views that science should not meddle with nature were isolated and were not organized. Next, as demonstrated by the *Chakrabarty* Court's treatment of ethical concerns, opponents had difficulty finding an audience for vague moral arguments urging restraint. In contrast to the proponents of genetic engineering who express clear goals of ending hunger, moral objections prove difficult to articulate.[38] The relation of genetic engineering of crops and animals to traditional breeding and natural evolution also muted many of the concerns that the public eventually developed in relation to genetic modification of human beings. At the time the first generation of modified crops were entering development, there was very little

32 Borlaug, *supra* note 24, at 77–78.

33 *See* J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105, 106 (2000).

34 C. of Food, Agric., & Envtl. Sci., Ohio St. Univ., GMO: FAQ (Frequently Asked Questions), http://web.archive.org/web/20020403135603/http://ohioline.osu.edu/gmo/faq.html (last visited Sept. 1, 2007) [hereinafter OSU GMO FAQ].

35 *Id.*

36 *See* SHANNON, *supra* note 10, at 13.

37 *See* Kunich, *supra* note 5, at 813–14.

38 *See* 2 BIOETHICS, *supra* note 19, at 932.

emphasis on wrongness because there was, and continues to be, no general concern for plant welfare.[39] Moreover, since humans had been breeding plants and animals for much of history, opponents had the burden of showing how the use of the new technology was ethically suspect.[40] In time, opponents have attempted to articulate a fundamental difference between traditional breeding and the splicing of traits between species, but this distinction has not really appeared to take root with the public.[41]

MORAL CONSIDERATIONS AND THE LACK OF RELIGIOUS OBJECTION

A dearth of religious objection to genetic engineering compounds the difficulty of articulating a moral objection to genetically altered foods. In fact, most religions find genetically modified organisms compatible with their doctrine—even supporting biotechnology if used properly.[42] The issue then becomes not a question of *if* but a question of *how*. Much of the religious acceptance of interventions in nature proceeds from the Bible. In Genesis, God commands humanity to take dominion over the earth: "[F]ill the earth and subdue it; and have dominion over the fish of the sea and over the birds of the air."[43] Starting from this premise, the Catholic view of genetic engineering has evolved but has remained consistently supportive. In fact, the Second Vatican Council ("Vatican II") determined mastery over nature was part of God's will.[44] Rather than being deterred from building up the world, man is compelled to do so.[45] The view of many who contributed to Vatican II is that man is a co-creator with God.[46] However, Vatican II did recognize limitations on man's role as a creator, stating, "[A]ll things are endowed with their own stability, truth, goodness, proper laws, and order. Man must respect these as he isolates them by the appropriate methods of the individual science or arts."[47] This approach recognizes the legitimacy of altering nature and the autonomy of science as long as the creator is given proper reverence.

Pope John Paul II modified the approach taken by Vatican II, but did not reject it. In his view, since the order of nature, though not fixed, had its origin in God, man's guide must be in harmony with the law of nature.[48] At the Jubilee of the Agricultural World, November 11, 2000, Pope John Paul II noted the concerns of the scientific community about the sustainability of the present agricultural system.[49] Specifically addressing the ge-

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39 *Id.* at 936.
40 *Id.* at 933.
41 *See* Kunich, *supra* note 5, at 812-13.
42 2 BIOETHICS, *supra* note 19, at 932.
43 *Genesis* 1:28.
44 SHANNON, *supra* note 10, at 36.
45 *Id.*
46 *Id.* at 38.
47 *Id.* at 42.
48 *Id.* at 36.
49 Pope John Paul II, Address at Jubilee of the Agricultural World (Nov. 11, 2000), *reprinted in* GENETICALLY MODIFIED FOODS, *supra* note 31, at 111, 111–14.

netically engineered food, he expressed the need for the utmost care in the assessment and valuation of the consequences of modification.[50] The Pope cautioned, "[Biotechnologies] must be submitted beforehand to rigorous scientific and ethical examination, to prevent them from becoming disastrous for human health and the future of the earth."[51] Though the Catholic position is rooted in natural law, there is no morally absolute objection to genetic engineering based on that natural law. In the absence of a complete prohibition, the focus becomes one of personal responsibility and stewardship to prevent exploitation and unintended consequences.[52]

Though also cognizant of the biblical text, the Protestant approach is slightly different. However, it too stops well short of a prohibition of genetic modification. Taking a more holistic approach, Protestants tend to locate the debate within an ecological setting.[53] One view finds this difference possibly rooted in the Reformation, which emphasized sin and its destructive effects on humanity.[54] In contrast to the Catholic view, the Protestant position derives more from a concept of stewardship than one of natural law.[55] For example, Methodists see God as the creator, man as his stewards, and technology in service to both humanity and God.[56] Similarly, the Orthodox Church sees humanity as "both a given and a potential."[57] Again, the emphasis is on the use and consequences of genetics rather than prohibition based on any moral argument.

Although the issue is very complex under Jewish law and the doctrine is still evolving—there is no outright objection to genetically modified foods.[58] Judaism takes the view that God created the universe but left it in an incomplete state.[59] God created Adam as a partner who is charged with completing the creation by finding the cure for disease and producing enough food for the hungry.[60] Technology should work toward the benefit of humanity without violating divine rules.[61] This approach defers the determination of morality to the assessment of the consequences. The benefits must outweigh the risks, but if they do, genetically engineered foods have a place in society.

Similar to the scriptural approach taken by other religions, Islam adopts a worldview rooted in revelation.[62] Religious leaders conduct a

50 *Id.* at 112.

51 *Id.*

52 SHANNON, *supra* note 10, at 55.

53 *Id.* at 78.

54 *Id.*

55 *Id.* at 79.

56 *Id.* at 61.

57 *Id.* at 62.

58 *See* Carl Feit, *Genetically Modified Food and Jewish Law (Halakhah)*, *in* GENETICALLY MODIFIED FOODS, *supra* note 31, at 123, 124.

59 *Id.*

60 *Id.*

61 *Id.* at 124.

62 Mohammad Fadel, *Islam and the New Genetics*, 13 ST. THOMAS L. REV. 901, 901 (2001).

case-by-case analysis of emerging technologies based on four sources: the Qur'an; God's word as revealed to Mohammed; the sunna, the normative practice of the Prophet Muhammad here on earth; and community standards.[63] If none of these is available, the leaders adopt a utilitarian approach.[64] In practice, the assessment of a new technology or situation depends on reason by analogy—a practice that seems similar to common law jurisprudence in the United States and England. Under the Islamic approach, human intervention in nature is permissible so long as the purpose for the intervention is for the benefit of human beings.[65] Man does not violate any prohibition against changing God's creation if he promotes welfare by reducing need or treating a disease.[66] However, those leaders in the Islamic community who are more conservative do favor complete prohibition. As evidence of the impropriety of tampering with nature, these leaders rely on the passage of the Qur'an which provides: "And He created everything, and determined [each thing] precisely."[67] If God created each thing precisely, man has no authority to tamper with God's creation. Another well-established principle in Muslim ethics may also have a practical effect on whether transgenic crops are morally acceptable. Muslims believe that the removal of existing harm deserves greater precedence than achieving new benefits.[68] Even if it is not always conceptually easy to distinguish the difference, this precept may suggest a different approach on a case-by-case basis.[69] Although no general prohibition exists, Islamic ethics may require a specific assessment of goals before adopting genetically modified foods as the solution.

This brief examination of religious views on genetic engineering demonstrates the absence of a *per se* prohibition on genetic enhancement of the world's food supply based on religion. Moreover, the judiciary has also foreclosed any personal religious objection by finding that the United States' regulatory scheme, which allows transgenic crops to be sold without labeling, does not violate the free exercise of religion by persons who object to transgenic crops.[70] Absent any religious objection, the analysis of the morality of transgenic crops largely lends itself to an assessment of the risks and rewards. The focus becomes eliminating unintended consequences and assuring that the intended consequences are just. The analysis is utilitarian in nature, deciding how to best use the technology for the benefit of humankind, rather than based in moral absolutes. As such, opponents have struggled to articulate an argument against genetically altered crops based on morality.

63 *Id.* at 901–02.
64 *Id.* at 902.
65 *Id.* at 903.
66 *Id.*
67 *Id.* at 904 n.6 (*quoting al-Furqan* 25:2 (THE QUR'AN)).
68 *Id.* at 909–10.
69 *Id.* at 910.
70 *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179–80 (D.D.C. 2000).

LOST OPPORTUNITY

This difficulty of articulating moral opposition to transgenic crops and genetic engineers' reaction to it represents a primary failing in the discussion regarding the exploration of biotechnology. Proponents did not find anything intrinsically wrong from a theological point of view nor any well-framed argument against genetic engineering. As such, they assumed their desired ends were just and forged ahead without engaging the community in a meaningful dialogue that could have ameliorated many of the public's misgivings about biotechnology. Whether borne of arrogance, a drive for profits, or a single-minded devotion to discovery, some scientists and agribusiness executives failed to understand that, for many people around the world, there is still an ethical issue to balance with the laudable goal of feeding the hungry.

Science is an institution that deserves great respect, but that respect results from the efforts of those visionaries who have explained to the public how a scientific discovery could benefit humankind. In the laboratory, the scientific method operates independently of social pressures, but to realize its potential, science must interact with the outside world. Science has the ability to create new technology, but the proper use of that technology is often a matter of values. Science must inform traditional beliefs, but also proceed with an understanding of the anxiety caused by the displacement of existing values. Further complicating the issue, science is not fully operating in its normal fashion in the development of many transgenic plants. Collegial competition and peer review yield to market competition, the threat of negative publicity, and the jealous protection of patents. These factors foster an atmosphere of secrecy that engenders societal skepticism.

EVOLVING OPPOSITION

Critics of transgenic crops also accuse proponents of portraying the skeptical public as misinformed or uneducated.[71] For example, Leon Kass, currently Chairman of the President's Council on Bioethics (the "Council"), suggests that scientists cast the issue as beneficial knowledge versus ignorant and superstitious anxiety.[72] Given the larger issues involved, Kass believes the public is right to be ambivalent about genetic engineering.[73] He believes people's worries are in touch with the deepest matters of human dignity, and we ignore them at our peril.[74]

Despite the expansion of transgenic crops and the difficulty of expressing moral opposition without a religious objection, opponents of transgenic crops continue to press arguments for limiting genetic engineer-

71 Matthew Rich, Note, *The Debate Over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 900–01 (2004).

72 LEON R. KASS, LIFE, LIBERTY, AND THE DEFENSE OF DIGNITY: THE CHALLENGE FOR BIOETHICS 120 (2002).

73 *Id.*

74 *Id.*

ing itself. Groups opposed to genetically altered crops argue that the persistent resistance in Europe, the United States, and around the world demonstrates public resistance to genetically engineered food independent of possible consequences.[75] Notwithstanding the acceptance of genetic engineering by the world's organized religions, many opponents of biotechnology still build their arguments for prohibition or restraint on a basis of vague spirituality. A useful device in the debate about genetically altered food has been to focus any discussion of morality on the genetic alteration of humans and then project the public's uncertainty or apprehension back to genetic alteration in any form, including the alteration of plants.[76] The idea is to gain support for categorical prohibition against any type of intervention in nature based on morality and driven by fear of chimeras or loss of humanity. Though some objections to genetic alteration are real, such arguments when made by interested groups appear to be designed to capitalize on the resurgence of piety and sanctimonious environmental activism currently en vogue in American culture.

More constructively, ethicists struggle to find real limitations on science and self-interest in an age when technology and the rate of advancement can quickly surpass our ability to understand the personal, social, and cultural implications of a new discovery. Representative of this effort, the Council reflects the struggle between progress and the amorphous apprehension many people still hold about genetic engineering. The Council sees biotechnology as a form of human empowerment, but the techniques of the technology do not define its purposes.[77] Therefore, society's focus must be on the abilities and goals of biotechnology, rather than the process itself.[78] By adopting this view, the Council concedes the validity of genetic engineering and aligns itself with the position held by the majority of the world's religions. As such, the issue again becomes a matter of degree or balance rather than a complete prohibition.

The Council seems to suggest a limitation on genetic engineering based on a vague religiosity and a form of natural law affected by modern environmentalism.[79] Wary of "upsetting eons of gradual and exacting evolution," the Council is concerned with the problem of hubris.[80] The Council also notes the precautionary principle and its conservative approach to interventions into the natural world with some deference, but never actually adopts the principle's heavy burden on new technology.[81] Instead, the

75 Gregory E. Kaebnick, *On Genetic Engineering and the Idea of the Sacred: A Secular Argument*, 13 ST. THOMAS L. REV. 863, 863–64 (2001).

76 *Id.*

77 *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS 2 (2003), *available at* http://www.bioethics.gov/reports/beyondtherapy/beyond_therapy_final_webcorrected.pdf [hereinafter COUNCIL ON BIOETHICS].

78 *Id.* at 2–3.

79 *Id.* at 287.

80 *Id.*

81 *See id.* The precautionary principle is an environmental idea that posits, "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken

Council proposes that "[m]odesty born of gratitude for the world's 'givenness' may enable us to recognize that not everything in the world is open to any use we may desire or devise . . . ."[82] Noting man's Promethean aspiration to remake nature to serve our purposes and satisfy our desires, the Council states that this approach is erroneous because it risks unintended consequences and reveals an improper disposition to the naturally given world.[83] The Council's observations are of little help in determining any practical limitation on science and the role of the law or government in deciding or moderating complex moral issues. It is difficult to translate an academic argument about the proper disposition toward nature into an understanding of what *ought* to be and how the law can effectuate that desired result. Although the impact on the environment and the resulting effects on humanity are central to the discussion of genetic engineering, the absence of ethical directives about what ought to be done leaves us with limitations designed to avoid unintended consequences.[84]

The Council also observes that part of the trouble with genetic engineering is that the uncertainty of the goals that should ensure man's interventions are not just representations of will or ends in themselves.[85] However, this potential criticism does not readily apply in the field of transgenic crops. Putting any profit motive aside, everyone would agree that providing the means for the world's population to feed itself is an admirable goal. Accordingly, transgenic crops should be an easier issue on which to reach consensus than genetic engineering of animals or humans. Focusing on the specific issue of transgenic crops would elevate the debate about the prudence of genetic engineering. Scientists and the public could then work together to determine whether transgenic crops are proper tools to increase food production and, if so, the ways in which society can acceptably use these tools.

While the Council represents a view of genetic engineering that reflects a cautionary approach based in a vague, contemporary religiosity, others have attempted secular explanations for a reluctance to tamper with nature. Philosopher Gregory E. Kaebnick argues that terms like "Frankenfood," a term commonly used by critics to describe genetically modified plants, reveal that part of the public's concern is with meddling *per se*.[86] In addition to concern about unintended consequences, the terminology suggests concern about tampering with something intrinsically valuable to humanity. Kaebnick argues the apprehension about biotechnology is not reli-

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even if some cause-and-effect relationships are not fully established scientifically." Science and Environmental Health Network, Wingspread Statement on the Precautionary Principle, (1998), http://www.sehn.org/state.html#w [hereinafter Wingspread Statement].

82 COUNCIL ON BIOETHICS, *supra* note 77, at 289.

83 *Id.* at 287–89.

84 MICHAEL J. REISS & ROGER STRAUGHAN, IMPROVING NATURE?: THE SCIENCE AND ETHICS OF GENETIC ENGINEERING 63 (1996).

85 COUNCIL ON BIOETHICS, *supra* note 77, at 289.

86 Kaebnick, *supra* note 75, at 864.

gious, but instead is a secular version of the sacred.[87] Employing Ronald Dworkin's view of the sacred, Kaebnick notes: "[t]he most compelling example of a secular notion of the sacred is the widespread view that the environment ought to be treated with respect."[88] Perhaps rooted in Henry David Thoreau's *Walden*, in which the author chronicled his life in the woods, the modern environmental movement urges ethical limitations on humanity's interactions with the natural world.[89] Humanity's exploitation of the environment for its own ends at the expense of other species violates something sacred.[90]

Conceptually, it is easy to support the idea of man living harmoniously with nature. To an extent, humanity's unique ability to alter the natural order imposes a duty of stewardship. Most people agree it is in humanity's interest for nature to thrive in diversity. However, taken too far, this idea of harmony denies the reality of limited resources and the brutality of nature itself. Throughout history, men and women have battled other men and women as well as other species for the resources needed for survival. The only remedy for this ongoing struggle is to increase the supply of resources, or to lower the demand for existing resources. Recognition of this reality is essential to an informed debate about humankind's relationship with nature.

Furthermore, as we have seen, the difficulty with an appeal to the sacred is that it seems "vague, inarticulable, and emotional, particularly when compared to the central concepts of Kantian or utilitarian thought."[91] As such, moral discussions of the sacred are difficult to criticize or defend.[92] This ambiguity makes it particularly difficult to engage in a productive discussion of limits, especially when proponents of biotechnology are entrepreneurs and intrepid scientists, both of whom deal in concrete, analytical terms. Further, desire compels scientists and entrepreneurs to remove limitations even when they seem insurmountable. This compulsion is hardly conducive to a dialogue with opponents espousing vague notions of the sacred, no matter how widely held.

In attempting to define a means by which we can argue about the sacred, Kaebnick roots the concept in the philosophical tradition based on deeper values or virtues.[93] Traditionally, virtue ethics includes respect for "thicker values" like kindness, honor, integrity, responsibility, loyalty, humility, and conscientiousness, as opposed to "thinner" values like autonomy and utility.[94] The sacred reincorporates moral beliefs about humanity's relationship with nature in contrast to popular notions of maximizing hap-

87 *Id.*
88 *Id.* at 865.
89 HENRY DAVID THOREAU, WALDEN (1910).
90 *Id.*
91 *Id.*
92 *Id.*
93 *Id.* at 866.
94 *Id.*

piness or eliminating deprivations of some feature of rationality that offer little help with defining the proper relationship.[95] To this end, Kaebnick suggests adopting a deontological counterpart to the consequentialist "cautionary principle," which he describes as holding that a novel project or endeavor that realistically might cause harm to the environment or public health may not be undertaken until there is reasonable evidence that harm can be avoided.[96] In the same way, the sacred view treats the world with restraint, shifting the burden of proof to those proposing a new type of intervention.[97] Any discussions of proposed interactions with nature must begin with recognition of the value in leaving nature as it is regardless of consequences.[98] An absolute ban is not necessary under a secular approach, but a reasoned public debate requires acknowledging deep-seated convictions about our relationship with the natural world.

AGRIBUSINESS RESPONDS

Although moral objections are difficult to articulate, the corporations developing transgenic crops have become more responsive to ethical concerns. Similar to the virtue ethics underpinning a secular notion of the sacred, some companies that develop transgenic seeds have adopted a stewardship model much like that espoused by several of the leading religions. For example, DuPont, a leading manufacturer of transgenic seeds, adopted guiding principles based on ensuring food safety, protecting the environment, conserving biodiversity, and engaging stakeholders, as well as working to improve food, nutrition and the quality of life.[99] Seed companies like DuPont see themselves as respectful of the wishes of society and protecting the environment with caution and care while balancing those interests with the need for increased productivity. Keeping in mind the obvious influence of a well-compensated public relations department, DuPont's statement and similar pledges by others in the biotechnology industry, represents an attempt to re-engage the public in a discussion of difficult issues. While skepticism is reasonably appropriate, the shared language of stewardship and responsibility should serve as a starting point for a dialogue about basic moral issues and the benefits and risks that are the heart of debate over genetic engineering.

PRACTICAL LIMITATIONS AND THE RISK OF UNINTENDED CONSEQUENCES

In addition to the persistent, though amorphous, moral objection some individuals have to transgenic crops, much of the public and many in the scientific community share concerns about the risks posed by such crops and whether the purported benefits outweigh the risks to health and the en-

95 *Id.* at 871–72.
96 *Id.* at 872–73.
97 *Id.* at 872–73, 876.
98 *Id.* at 872–73.
99 DuPont, Bioethics Guiding Principles, http://www.dupont.com/biotech/difference/principles.html (last visited Sept. 5, 2007).

vironment.[100] Although the rhetoric frequently suggests absolute moral limitations, the details of the debate essentially boil down to scientific arguments or assessments of risk.[101] However, that reality does not eliminate a values-based discussion of transgenic crops, but merely alters the form of the discussion. Risk-based cost-benefit analysis inherently involves balancing different practical and ethical interests to reach a consensus that enables action.

In the cost-benefit area, opponents of genetic engineering employ scientific and socio-cultural arguments that are more tractable than those made for prohibition of genetic engineering based on moral absolutes. Though initially unprepared for the explosion of biotechnology in the 1990s, critics now express tangible concerns about safety and the environment that frequently resonate with the public.[102] As time has passed, opponents of transgenic crops have more information to support their arguments and an effective support network to publish their views.

EROSION OF THE MORAL HIGH GROUND

To start, opponents have tried to remove some of the moral high ground from those who claim transgenic crops will be able to feed the world. Acknowledging the dire state of nutrition in the world, opponents argue that starvation is not a result of insufficient production, but is in fact a distribution problem.[103] The United Nations World Food Program notes that there is currently more than enough food produced, but the problem is one of access.[104] Failures in the distribution system and political pressures prevent adequate supplies of food from reaching those in need. In addition, critics argue that many farmers cannot afford to grow modern crops and consumers cannot afford to buy them—a fact not helped by increased corporate control over food resources.[105] Further, many opponents believe the purported benefits of transgenic crops are not suited to ecological, small-scale agriculture practiced by the majority of farmers around the world.[106] The high costs of research and development prompted many researchers to focus on seed varieties that would have the widest application worldwide.[107] Arguably, this broad approach has prevented many areas most in need of increased production from benefiting from the technology.

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100 Marc A. Saner, *Real and Metaphorical Moral Limits in the Biotech Debate*, 19 NATURE BIOTECHNOLOGY 609 (July 2001), *reprinted in* GENETICALLY MODIFIED FOODS, *supra* note 31, at 78–79.

101 *Id.* at 78.

102 YOUNT, *supra* note 11, at 15.

103 *Id.* at 18.

104 Charman, *supra* note 9, at 9.

105 *Id.*

106 VANDANA SHIVA, *Genetic Engineering and Food Security in* STOLEN HARVEST, (South End Publisher 2000), *reprinted in* ETHICS OF FOOD, *supra* note 24, at 130, 132.

107 Matthew Feldman, et al., *Why So Much Controversy Over Genetically Modified Organisms? Answers to 10 Frequently Asked Questions about GMOS*, CIMMYT, Feb. 7, 2000, http://www.cimmyt.org/abc/10-faqaboutgmos/htm/10-faqaboutgmos.htm

The agribusiness corporations producing the majority of the modified crops have amplified the fear of a monopoly over the world's food supply by aggressively protecting their research. Following *Chakrabarty* and related legislation, breakthroughs in genetic engineering are patentable as intellectual property. Owners of those patents vigorously protect their proprietary interests in significant ways. Contrary to typical farming practices, farmers who purchase transgenic seeds cannot save and replant seeds.[108] This is a particular concern in developing countries where farmers have reused seeds for centuries to try to improve yields.[109] Under a typical licensing agreement, farmers purchase seeds sold for a single season.[110] The following planting season farmers must either re-license or purchase new seeds.[111] Farmers accused of violating such agreements have found themselves defending lawsuits.[112] In fact, one of the leading manufacturers of transgenic seeds, Monsanto, claims ownership for genes and plants containing its patented material regardless of where they are or how they got there.[113] Further alarming farmers and many governments, Monsanto and the United States government hold a patent on so-called "terminator technology" that makes seeds sterile and of no value beyond a single planting.[114] The dominant concern is that a few multinational corporations could control the entire food supply. In response to a public outcry, there is an international moratorium on use of the seeds, but recent efforts to test the seeds in field trials have renewed concern about the technology.[115] While expressing legitimate concern, these arguments reveal that much of the apprehension surrounding genetic engineering is less about science or morality than it is about the economic influence of large multi-national corporations.

The concentration of biotechnology and the potential for abuse is also a central concern of religious leaders who approve of genetic engineering in theory. The Catholic Church has expressed concern that excessive intellectual property rights to widely used crops could have a devastating impact on developing nations.[116] Pope John Paul II observed, "All too often, the fruits of scientific progress, rather than being placed at the service of the entire human community, are distributed in such a way that unjust inequalities are actually increased or even rendered permanent."[117] Noting

108 Rich, *supra* note 71, at 898.
109 *See id.*
110 *Id.*
111 *Id.*
112 Asgrow Seed Co. v. Winterborer, 513 U.S. 179 (1995).
113 Rich, *supra* note 71, at 912.
114 Stephen Leahy, *Ban Endures on Terminator Seeds*, INTER PRESS SERVICE NEWS AGENCY, Feb. 11, 2005, http://www.ipsnews.net/interna.asp?idnews=27410
115 *Id.*
116 Archbishop Agostino Marchetto, Address to the Convention Organized by the Catholic University of the Sacred Heart on the Theme of "New Frontiers for Bioethics: The Biotechnologies" (Nov. 18, 2000), *available at* http://www.vatican.va/roman_curia/secretariat_state/documents/rc_seg-st_doc_20001118_marchetto-univ-sacred-heart_en.html.
117 Pope John Paul II, Message of the Holy Father to the Group "Jubilee 2000 Debt Cam-

the "social mortgage" on all private property, he counseled, "The law of profit alone cannot be applied to that which is essential for the fight against hunger, disease and poverty."[118] Similarly, the World Council of Churches stated that, "justice is denied if 'biotechnology is used to increase the control of the rich nations and groups over the biological resources of creation . . . .'"[119] Islam also focuses on distributive justice, noting that "benefits should not be priced to exclude the poor and underprivileged from benefiting from the advances of science."[120] Clearly, discussions of the proper allocation of the benefits of transgenic crops should be a part of the public debate, but the risk of exploitation does not necessitate a prohibition on genetic engineering.

Unfortunately, even if all the questions about distribution are satisfactorily answered, the disagreement about the safety of genetically modified foods has undermined the ability for transgenic crops to help end world hunger. Resistance to transgenic crops in Europe has spread to some of those who stand to benefit the most from the promises of new biotechnology. To the dismay of biotechnology supporters, several countries in dire need of food have refused donations that contained genetically altered grain.[121] In August of 2002, the African nations of Zambia, Zimbabwe, Mozambique, and Malawi rejected U.S. corn from the United Nations Food Programme, citing fear of health risks or the loss of European markets for their own products.[122] Whether economically or socially based, the criticisms of biotechnology and the companies that own the patents have dramatically slowed the pace of implementation around the world.

EVALUATING REAL RISK TO HUMAN HEALTH AND THE ENVIRONMENT

In addition to questioning the purported benefits, opponents also express genuine concern for potential risks to individual health and the environment. Critics contend that proper risk assessment requires more than we know.[123] In contrast to traditional breeding, which enabled breeders to observe any untoward effects developed over time, rapid changes facilitated by genetic engineering could create wide-scale unintended consequences.[124] Most of the concerns focus on two areas: food safety and the effect on the environment.[125] Opponents of transgenic crops express concern about both the means and the ends of genetic engineering. For example, many see the introduction of genetically altered products into the food

paign,"(Sept. 23, 1999), *available at* , http://www.vatican.va/holy_father/john_paul_ii/speeches/1999/september/documents/hf_jp-ii_mes_23091999_jubilee-2000-debt-campaign_en.html.

118 *Id.*

119 SHANNON, *supra* note 10, at 65 (citations omitted).

120 Fadel, *supra* note 62, at 909 (citations omitted).

121 YOUNT, *supra* note 11, at 17–18.

122 *Id.* at 17–18.

123 2 BIOETHICS, *supra* note 22, at 933.

124 *Id.*

125 David Magnus & Arthur Caplan, *Food for Thought: The Primacy of the Moral in the GMO Debate*, *in* GENETICALLY MODIFIED FOODS *supra* note 31, at 80, 81.

supply as an experiment on unwilling subjects without following the scientific method.[126] Critics contend that testing has been inadequate at every stage of the process. Moreover, scientists are splicing genes into food products from species that do not interbreed in nature and often have no history of food use.[127] One of the primary health concerns is that allergens unknown to consumers could pose risk of illness or death. For example, one variety of soybeans genetically altered with a protein from a Brazil nut had to be abandoned after millions of dollars of development when researchers discovered people who were allergic to Brazil nuts were also allergic to soybeans with the spliced protein.[128]

Proponents counter that there is a consensus in the scientific community that there is nothing inherently unsafe about splicing genes from one organism to another and that any disagreement about the process concerns specific classes and uses.[129] They reiterate that safety depends on the food's properties and have nothing to do with the process by which it is produced.[130] Even though transgenic crops receive more testing than any other food item, critics argue that transgenic crops receive no extensive laboratory testing, leaving the effects of long-term exposure to transgenic crops largely unknown.[131] The difficulty with this long-term exposure argument is that the same can be said for almost any scientific advancement relating to human beings, including everything from inoculations to electricity. While uncertainty suggests caution, it certainly does not justify paralysis.

A second area of concern is the potential impact of genetically altered plants on the environment. Some scientists note the dangers of releasing new organisms into existing ecosystems.[132] In particular, concern centers on the difficulty of estimating the effects of genetic drift from modified plants to native populations, which could threaten the environment. Such drift could reduce biodiversity as genetically enhanced plants take over and push out natural competitors.[133] The threat of genetic drift is not only theoretical, as gene flow may already be occurring. Many in the scientific community were alarmed when genetically modified corn contaminated the national treasury of corn at Capulalpan, Mexico, despite the Mexican government's prohibition on genetically modified corn—a program specifically designed to protect the native gene pool.[134] This type of unintended drift

126 KATHLEEN HART, EATING IN THE DARK 4–8 (2002).

127 Mae-Wan Ho, *The Unholy Alliance*, 27 THE ECOLOGIST 152 (July-Aug. 1997), *reprinted in* ETHICS OF FOOD, *supra* note 24, at 80, 84. *See, e.g.*, HART, *supra* note 126, at 33 (listing genes with no history of food use being inserted into food products).

128 YOUNT, *supra* note 11, at 15; *see also* OSU GMO FAQ, *supra* note 34.

129 OSU GMO FAQ, *supra* note 34.

130 *Id.*

131 Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J. L. REFORM 403, 417 & n.84 (2002).

132 Rich, *supra* note 71, at 895–97.

133 *Id.* at 895–96.

134 *Id.* at 896–97.

could lead to a loss of biodiversity and a tendency toward uniformity that makes crops more vulnerable to pests and pathogens that will co-evolve.[135]

Moreover, there is a risk that the genes could pass to wild relatives, creating what critics describe as "superweeds."[136] Wild plants that acquire genes that make them more resistant to herbicides would require stronger herbicides that in turn could do more damage to the environment or endanger natural plants and animals that depend on those plants for food. Similarly, scientists are concerned about resistance to pesticides. Corn with a gene from the bacterium *Bacillus thuringensis (Bt)* that is toxic to many insects is one of the most widely planted transgenic crops.[137] Critics worry that as insects build immunities to *Bt* toxins, new pesticides may have to be developed.[138] In addition, the loss of *Bt* as a pesticide would be devastating to organic farming, which relies heavily on the natural pesticide.[139]

Proponents admit that science does not yet know all of the effects of biotechnology. Nevertheless, they suggest the risks are unlikely to materialize and that users can substantially reduce the risks by proper measures, such as planting refuges around fields of transgenic crops to sustain populations of insects susceptible to the toxins.[140] Proponents also argue that transgenic crops have a less drastic effect on the environment than existing means.[141] Even though many opponents of genetic engineering attempt to paint a picture of transgenic crops forced on the small, family farmer who wishes only to grow a few vegetables for sale at the local market, the reality is that industrial farms using large amounts of chemicals grow the majority of the world's food.[142] Any change caused by genetic engineering must be seen in this context and not compared to an idyllic view of the American farmer that may have never existed, and certainly would not be able to respond to the expanding agricultural needs of the world today.

Opponents of transgenic crops agree that appropriate precautionary means can reduce the risks to health and the environment.[143] Correspondingly, proponents of genetically altered crops concede that the potential risks associated with some technologies outweigh the benefits.[144] One nat-

135 MARC LAPPE & BRITT BAILEY, AGAINST THE GRAIN: BIOTECHNOLOGY AND THE CORPORATE TAKEOVER OF YOUR FOOD (Common Courage Press 1998), *reprinted in* ETHICS OF FOOD, *supra* note 23, at 156, 158–63.

136 YOUNT, *supra* note 11, at 14; Rich, *supra* note 71, at 895.

137 YOUNT, *supra* note 11, at 14.

138 Rich, *supra* note 71, at 895.

139 CHARLES M. BENBROOK ET AL., PEST MANAGEMENT AT THE CROSSROADS 221 (1996); YOUNT, *supra* note 11, at 14.

140 OSU GMO FAQ, *supra* note 34.

141 *See id.*

142 *See* WENDELL BERRY, *The Unsettling of America*, *in* THE UNSETTLING OF AMERICA: CULTURE AND AGRICULTURE (1977), *reprinted in* ETHICS OF FOOD, *supra* note 24, at 5, 17–25; Skip Spitzer, *Industrial Agriculture and Corporate Power*, GLOBAL PESTICIDE CAMPAIGNER Aug. 2003, at 1.

143 *See* RICHARD A. POSNER, CATASTROPHE: RISK AND RESPONSE 38 (2004) (discussing the process of bioconfinement as a method of reducing the dangers of transgenic crops) ; OSU GMO FAQ, *supra* note 32 (discussing the requirements of plant refuges to sustain nearby insect populations).

144 Magnus & Caplan, *supra* note 125, at 83.

ural philosophical framework for assessing the appropriate choices and means is utilitarianism. Under this view, stakeholders must weigh the risks and benefits and determine which outcome maximizes utility as measured by the net benefit to society.[145] As demonstrated by the abandonment of the soybean with the Brazil nut gene, some products may be too dangerous to develop in relation to the anticipated benefit while others are worthwhile. Conceptually, a utilitarian view seems appropriate, but as applied, it proves very difficult given the range of values worldwide.

RATIONAL RISK POLICY: ALLOCATING COSTS AND BENEFITS

One issue that inevitably arises is who will bear the costs and who will reap the benefits.[146] This issue has particular poignancy with respect to transgenic crops because private corporations in large industrialized countries primarily own the technology, whereas the targets are often the poorest countries of the third world.[147] Moreover, the public is wary of the technology and assumes that the risks it perceives are motivated by the profit margins of privately held corporations. Potential evidence of a skewed utility analysis is that most of the first generation crops appear to be suited to wide distribution and corporate profit motives, such as selling herbicides in conjunction with the seeds, rather than improving yields in difficult third world climates or improving nutrition or taste for consumers.

VARIATIONS IN RISK TOLERANCE

Another disabling feature is that individuals have vastly different levels of tolerance for risk depending on their situation. Rational people frequently disagree about how much risk is acceptable given possible outcomes—witness the stock market, the insurance industry, and Las Vegas. Different people look at the same information and reach different conclusions. For example, Judge Richard A. Posner argues that proponents of transgenic crops, like Indur Goklany, underestimate the danger that the process might get out of hand and that a genetically modified plant or animal will out-compete and destroy native species.[148] In contrast, Goklany looks at the same evidence and believes the benefits clearly outweigh the costs.[149] Goklany argues that opponents of genetically modified crops ignore the potential downside of not using the technology because they deem the crops too risky.[150] He observes that "[f]ew actions are either unmitigated disasters or generate unadulterated benefits."[151] Therefore, in a situa-

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145 *Id.*

146 CASS R. SUNSTEIN, RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT 124–25 (2002).

147 GENETICALLY MODIFIED FOODS, *supra* note 31, at 299.

148 POSNER, *supra* note 143, at 38–39 (2004).

149 *Id.*; INDUR M. GOKLANY, CTR. FOR THE STUDY OF AM. BUS. POLICY STUDY 157: APPLYING THE PRECAUTIONARY PRINCIPLE TO GENETICALLY MODIFIED CROPS, (Aug. 2000), *reprinted in* GENETICALLY MODIFIED FOODS, *supra* note 31, at 265, 266.

150 *Id.* at 265.

151 *Id.* at 266.

tion in which the outcome is ambiguous because both the costs and benefits are uncertain, you must compare all of the consequences and then determine which action is preferable.[152] In certain situations, inaction could be the riskier behavior.[153] This analysis demonstrates the difficulty in deciding whether adopting transgenic crops or banning them entails more risk, especially given the degree of uncertainty and people's varying levels of tolerance for risk. Frequently, people are quick to assert their view as the correct one, but it is difficult to find "right" answers to matters so affected by personal values. The number of variables and the lack of good information on which to base effective risk assessments demonstrate the need for a sustained public dialogue on this issue rather than sensationalist headlines and visceral reactions.

FLAWED RISK ANALYSIS

The frequency with which risk decisions are flawed further complicates any assessment of risk. Research demonstrates that individuals overestimate the small risks they face and underestimate the more substantial ones.[154] Moreover, when assessing risks, individuals tend to pay a great deal of attention to risks perceived as new or novel, but very little to those to which they have become accustomed.[155] For example, a new food additive is more likely to get attention than risks posed by improper diet and lack of exercise.[156] There is even dissonance within the food context. Many people reluctant to accept foods developed by what they see as an unnatural process have no problem eating foods with labels full of artificial ingredients and preservatives. This tendency to be overly attentive to novel risks could cause the public to overestimate small risks associated with emerging biotechnologies, prompting consumers to make inefficient decisions.

Furthermore, modes of thinking and mental shortcuts that facilitate normal decision-making are often ineffective or even problematic in the risk context.[157] Without cognitive shortcuts, individuals could not function when confronted by the astronomical number of choices modern society presents. However, the shortcuts necessitated by everyday life are frequently inadequate for rational risk assessment. Risk ambiguity in a situation can generate irrational responses.[158] In fact, three common fallacies apply with considerable force to the issue of transgenic crops. These fallacies affect decision making about risk and associated cost-benefit analysis regarding potential environmental and health risks.[159] First, people tend to

152 *Id.* at 265–66.
153 *Id.* at 266.
154 W. KIP VISCUSI, RATIONAL RISK POLICY 6 (1998).
155 *Id.* at 17.
156 *Id.*
157 SUNSTEIN, *supra* note 146, at 84.
158 VISCUSI, *supra* note 154, at 18.
159 SUNSTEIN, *supra* note 146, at 36.

believe that "risk is an all or nothing" proposition.[160] An activity or product must be either dangerous or safe. Second, people are generally "committed to a belief in the benevolence of nature," so people always see human activities as being more dangerous than natural ones.[161] This belief in the benevolence of nature could cause opposition to transgenic crops without understanding the harsh effects nature often has on agriculture in many parts of the world. For some, a proper reverence for nature unrealistically forecloses tampering with nature in any way. Finally, many people have a "zero-risk" mentality.[162] Undoubtedly due in part to the significant scientific advancements in the twentieth century, the public believes it is possible to remove all, or nearly all, of the risk from an activity.[163] This belief creates unrealistic expectations and acts as a bar to potentially beneficial products such as transgenic crops. For a technology to satisfy such a low level of acceptable risk, any benefit must be unrealistically large to counterbalance even the smallest risk of harm. Such standards could deny society considerable benefits without an understanding of the corresponding costs.

COMPOUNDED DIFFICULTY

The divergence of expert scientific opinion regarding the safety of transgenic crops compounds the difficulties the public has assessing risk. When there are divergences in judgment regarding the degree of risk, people tend to place a greater weight on the worst-case scenario.[164] Substantial disagreement in the scientific community is likely to cause not only confusion but also alarmist responses.[165] The strong resistance to transgenic crops in Europe and the growing resistance in the United States, despite any evidence of an adverse health effect, arguably demonstrate such a response. Adding to the difficulty of accurately assessing risk, "self-interested private groups are entirely willing to exploit the underlying forces" to promote a particular point of view.[166] For example, the manufacturers of transgenic crops exploit concerns about population growth and public compassion for the world's hungry for financial gain under a thin auspice of altruism.[167] Similarly, "European companies have tried to play up fears of genetically engineered food as a way of fending off competition from American farmers."[168] Politicians and environmental groups have also exploited uncertainty about genetic engineering to promote their own interests.[169]

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160 *Id.*
161 *Id.*
162 *Id.*
163 *Id.*
164 VISCUSI, *supra* note 154, at 21.
165 *Id.*
166 SUNSTEIN, *supra* note 146, at 91
167 *See* SHIVA, *supra* note 106, at 131.
168 SUNSTEIN, *supra* note 146, at 92.
169 *Id.* at 91–93; THOMAS BERNAUER, GENES, TRADE, AND REGULATION: THE SEEDS OF

Instead of improving the assessment process, political and social forces exacerbate the cognitive limitations confronting risk assessments. As discussed above, opponents tend to minimize or even ignore risks presented by alternatives to biotechnology. Often risk analysis requires assessment of risk-risk tradeoffs.[170] There may be competing risks arising from an alternative policy or behavioral responses to it, but activists tend to downplay or ignore the alternative risks.[171] For example, if genetically modified crops allow better yields under lower tillage, the preservation of natural habitat may present a net benefit in biodiversity and environmental protection. Similarly, if transgenic crops in fact require fewer herbicides, the environment may benefit overall as compared to conventional practices. On the other hand, if proponents are unable to convince the intended beneficiaries of relief that transgenic crops represent a safe alternative, as was the case with the rejected food relief in Africa in 2002,[172] the purported benefit does not materialize and may not justify the risk. In contrast to the currently polarized positions in the debate over transgenic crops, effective risk analysis will require a collaborative effort to overcome the problems people have assessing risk.

If people do not have accurate risk perceptions, providing information can remedy the market failure.[173] Information can play an important role in fostering better risk decisions.[174] The disagreement about the risks associated with transgenic crops and the cognitive limitations affecting the assessment of those risks suggest both the importance and the difficulty of designing an appropriate regulatory regime. Effective risk analysis is both necessary for regulation and potentially aided or impeded by it. Information generated by the regulatory process can assist individuals in making individual risk assessments. In the nature of a feedback loop, the public discourse, which includes actions by government agencies, shapes individual risk judgments that then feed back into the public discourse.[175] In this way, the risk assessment process compounds the effect of inaccurate information. As such, only a system that provides accurate information to the public can foster an environment in which the public can reach a consensus on the difficult issue of genetic engineering.

REGULATION OF TRANSGENIC CROPS

Opponents of the current regulatory framework for transgenic crops in the United States criticize it as too deferential to business interests.[176] The

CONFLICT IN FOOD BIOTECHNOLOGY 68–70 (2003).

170 VISCUSI, *supra* note 154, at 169–70.

171 *Id.*

172 YOUNT, *supra* note 11, at 17–18.

173 VISCUSI, *supra* note 154, at 26.

174 *Id.* at 43.

175 SUNSTEIN, *supra* note 146, at 92–93.

176 *E.g.*, Kurt Eichenwald et. al, *Biotechnology Food: From the Lab to a Debacle*, N.Y. TIMES, Jan. 25, 2001, *reprinted in* GENETICALLY MODIFIED FOODS, *supra* note 31, at 31–40.

process by which the government implemented the current regulatory system fostered these criticisms and resulted in another failure of proponents of transgenic crops to effectively engage the public. In an atypical move, executives from Monsanto met with Vice President George Bush at the White House in 1986 and requested regulation of genetically altered food designed to reassure the public that the underlying science was safe.[177] Rather than engage the public in a rational dialogue about the risks and benefits of genetic engineering to ensure public acceptance, Monsanto purportedly adopted a strategy of manipulating market perceptions. Initially, the biotechnology industry traded political capital to get favored regulations, while gradually trying to win support from the public and environmental groups.[178] In time, however, Monsanto's strategy changed to one designed to erase regulatory barriers and ignore the complaints of critics on the way to rushing the new technology to market.[179] The strategy and resulting regulatory scheme galvanized opposition and undermined any meaningful debate.[180]

The regulatory framework for transgenic crops involves the coordination of three federal agencies.[181] The Food and Drug Administration ("FDA") is responsible for regulating genetically modified food and feeds.[182] The United States Department of Agriculture's ("USDA") Animal and Plant Health Inspection Service ("APHIS") regulates importation and interstate movement of genetically modified crops, as well as oversees the introduction of transgenic crops into the environment.[183] Finally, the Environmental Protection Agency ("EPA") is responsible for regulating plants that produce pesticides.[184]

Opponents of transgenic crops have been the most critical of the FDA's policies. The thrust of the FDA's regulatory approach is to assess the risk posed by the product itself without regard to the process by which it was developed.[185] Oversight is only appropriate when the risk is unreasonable and when the benefits of oversight are greater than the related costs.[186] Under the provisions of the Federal Food Drug and Cosmetic Act ("FFDCA"), the FDA is responsible for regulating new foods and food additives.[187] The FFDCA gives the agency the power to regulate food labe-

177 *Id.* at 31–32.

178 *Id.* at 32–33.

179 *Id.* at 33, 39.

180 *Id.* at 33.

181 Coordinated Framework for Regulation of Biotechnology: Announcement of Policy; Notice for Public Comment, 51 Fed. Reg. 23,302, 23,304 (June 26, 1986).

182 *Id.*

183 *Id.*

184 *Id.*

185 Statement of Policy: Foods Derived from New Plant Varieties; 57 Fed. Reg. 22,984 (May 29, 1992) [hereinafter Statement of Policy].

186 Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 741 (2003).

187 21 U.S.C. §§ 301–399 (2000).

ling and approve all food additives.[188] New substances added to foods must get approval in advance unless the FDA determines the substance is "generally recognized as safe" ("GRAS").[189] In 1992, the FDA announced a narrow view of its regulatory role with regard to genetically altered plants in its "Statement of Policy: Foods Derived from New Plant Varieties" ("Statement of Policy").[190] The FDA decided to apply existing regulations rather than generate new regulations for genetically modified varieties.[191] In its Statement of Policy, the FDA announced that genetically modified crops are the "substantial equivalent" of crops developed through conventional breeding.[192] As such, crops produced by the process of gene splicing are GRAS and therefore not subject to regulation as a food additive.[193] Based on this determination, the FDA completes no pre-market review of the products and requires no special labeling.[194] Moreover, the producer rather than the FDA makes the determination as to whether a product qualifies as GRAS.[195] However, even without pre-market regulation, producers face strong incentives to market safe products, including the threat of FDA seizure, bad publicity, tort liability, and even criminal liability.[196]

JUDICIAL DEFERENCE

Despite the apparent inconsistency presented by allowing a patent for a product that qualifies as a "distinct and new variety"[197] of plant and the determination that the plant is the "substantial equivalent"[198] to existing varieties and therefore not subject to approval or labeling, the FDA's position has been vindicated by the courts. In *Alliance for Bio-Integrity v. Shalala*,[199] a coalition of opponents of genetic engineering contested the FDA's policy on genetically modified foods on several grounds.[200] The District Court for the District of Columbia determined the FDA did not violate various procedural requirements when it developed its policy on transgenic crops.[201] The court rejected the substantive challenges to the agency's policy and deferred to the FDA's presumption that transgenic crops are GRAS.[202] The court was also deferential to the FDA's position that no "material change" had occurred in the foods in question, obviating any

188 *Id.*

189 21 U.S.C. § 321(s) (2000).

190 *See* Statement of Policy, *supra* note 185.

191 *Id.* at 22,984.

192 Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons From the StarLink Corn Fiasco*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 607 (2003).

193 *See* Statement of Policy, *supra* note 185, at 22,990.

194 Bratspies, *supra* note 192, at 607.

195 *Id.* at 609.

196 *Id.*

197 PlantPatent.com, Frequently Asked Questions, http://www.plantplanet.com/faq.html#faq006 (last visited Nov. 11, 2007).

198 Bratspies, *supra* note 192, at 607.

199 116 F. Supp.2d 166 (D.D.C. 2000).

200 *Id.* at 166, 170.

201 *Id.* at 173.

202 *Id.* at 178.

need for the agency to impose a labeling requirement.[203] In fact, the court noted the FDA's limited power to consider consumer demand when making labeling decisions.[204] The decision made it clear that a legal challenge would not be a very productive means of changing regulatory policy regarding transgenic crops. However, the discovery process did uncover some disagreement among scientists at the FDA regarding the agency's policy, which critics have used to cast further doubt on the wisdom of, and motivation for, the FDA's policy on risk assessment.[205] The trial also heightened public awareness of biotechnology and fueled the perception that the government was not sufficiently overseeing the development and marketing of transgenic products.[206]

COST-BENEFIT REGULATION

Though criticized as overly deferential to the interests of the biotechnology industry,[207] the current regulatory scheme is consistent with the trend toward cost-benefit regulation. Under the cost-benefit approach, an agency assesses the magnitude of a problem, attempts to assess tradeoffs, and uses effective and inexpensive tools to promote desired outcomes.[208] Proponents of this method argue that it is necessary, given the limited resources available.[209] Furthermore, proponents suggest the goal is not to let companies save money or to scale back regulation, but to ensure that regulation is undertaken with a firm sense of its consequences.[210]

The cost-benefit approach to regulation recognizes that the overestimation of highly publicized risks creates pressure on governmental behavior, especially when risks are novel and generate an exaggerated public response.[211] As a result of strategic errors early on, the response to genetic alteration of food represents just such a reaction, resulting in many groups calling for a total ban.[212] However, every regulation entails opportunity costs, and well-intentioned but ineffective risk regulations should not be viewed as morally or ethically superior.[213] Regulation can lead to two types of errors: 1) rejecting something that is safe and effective or 2) approving something that is not safe and effective.[214] Due to the cognitive difficulties people have assessing risk, current regulatory policies often

203 *Id.* at 178–79.

204 *Id.* at 179.

205 *Id.* at 177 & n.7. *See also* Alliance for Bio-Integrity, http://www.biointegrity.org (last visited Oct. 29, 2007).

206 Marden, *supra* 186, at 756.

207 Genetically Engineered Food, Center for Food Safety, http://www.centerforfoodsafety.org/geneticall7.cfm (last visited Oct. 29, 2007).

208 SUNSTEIN, *supra* note 146, at 4–5.

209 *See id.* at 6.

210 *Id.*

211 VISCUSI, *supra* note 154, at 24–25.

212 *See, e.g.*, Genetically Modified Foods & Islam, http://www.muzammal.clara.net (last visited Oct. 29, 2007).

213 VISCUSI, *supra* note 154, at 128.

214 *Id.* at 85.

place excessive weight on the second type of error.[215] The public is much more sensitive to errors of commission, which involve identifiable victims, than to errors of omission, where the loss of life or harm is statistical.[216] This tendency causes the public to favor overly-cautious regulation. For example, many opponents of transgenic crops favor adopting the precautionary principle, which posits, "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[217] This idea shifts the scientific burden of proof to those proposing a new activity.

While proponents of cost-benefit regulation acknowledge some truth in the precautionary principle, they believe the concept goes too far. For example, Cass Sunstein states, "Taken literally, the precautionary principle would lead to indefensibly huge expenditures, exhausting our budget well before the menu of options could be thoroughly consulted."[218] Public interest groups and politicians tend to foster the view that the public can have it all. To serve their own interests, these groups tend to exploit the public's tendency to overreact to visible victims and to require undue caution in hindsight. For example, one person harmed by a revolutionary drug on the evening news, has every public official clamoring to place blame for allowing the product to reach the public.[219] However, at the same time, those same politicians and the public bemoan regulatory processes that prevent drugs imported from other countries due to concerns about safety.[220]

LABELING AND THE RIGHT TO KNOW

Despite the judicial affirmation of the FDA's decision not to require mandatory labeling of transgenic foods, labeling continues to be one of the primary focuses of the debate. In contrast to the nebulous moral arguments in opposition to genetic alteration itself, arguments for labeling find support in other areas of the law. Advocates of labeling point out that consumer demand for labeling of genetically altered food remains consistently high. In 1999, a *Time* magazine poll found 81% of those polled wanted genetically engineered foods labeled, while the FDA received 50,000 written comments largely supportive of labeling.[221] In particular, the concerns about labeling include a desire to safeguard food, prevent allergic reactions, and

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215 *Id.*

216 *Id.* at 85–86.

217 Wingspread Statement, *supra* note 81.

218 SUNSTEIN, *supra* note 146, at 103.

219 *See, e.g.*, *Merck Announces Global Withdrawal of Vioxx After Study Shows Risks*, LIFE EXTENSION, Sept. 30, 2004, http://www.lef.org/news/LefDailyNews.htm?NewsID=1126&section=DISEASE.

220 *See, e.g.*, Marv Shepherd, *Drug Importation and Safety from Drugs Obtained from Canada*, ANNALS OF PSYCHOTHERAPY, June 19, 2007 http://www.theannals.com/cgi/content/abstract/41/7/1288 (last visited Nov. 11, 2007).

221 Marden, *supra* note 186, at 760–61.

avoid interference with moral or religious practice.[222] Consumer groups argue that without a label, consumers are unable to choose what they eat and cannot make informed decisions in the marketplace.[223]

Furthermore, advocates of labeling note that, absent a label, people do not know they are placing themselves at risk, which is the opposite of the way agencies handle drugs and medical devices.[224] The difference in handling also suggests the public's expectations about what government agencies are doing to ensure the safety of transgenic food is greater than what regulators are actually doing. This criticism about the public's right to know proceeds from the idea of autonomy and finds traction in many of the same arguments that support informed consent. Autonomy proceeds from the assumption that a competent adult should be able to make her own decisions about what she wants to do with her own body. Since customers lack valuable information, they are unable to make intelligent choices about the foods they buy and the risks they assume.

In response, proponents of transgenic crops and the FDA maintain there is no difference between transgenic foods and those produced by traditional processes, thus labels are unnecessary.[225] Supporters further note that there is no evidence of adverse health effects associated with transgenic crops.[226] This lack of evidence causes supporters to question what information there is a duty to disclose. In addition, like informed consent, a question arises as to the standard that should determine what information the individual would want to know. It would be unrealistic to provide consumers with all the information available about all the components of each individual product, especially given the physical limitations of labeling. As such, a labeling program would be very limited in the meaningful information it provides consumers about safety and nutrition.

Moreover, consumers may perceive mandatory labeling as a negative signal or voluntary labeling as implying superiority.[227] Scientists and the food industry worry that a label would stigmatize transgenic crops, despite scientific evidence of their safety. Finally, critics of labeling note that excessive labeling can be counterproductive by providing unnecessary information.[228] Any information strategy is subject to the same cognitive limitations the public has making risk assessments, including that the costs may outweigh the benefit.[229] Paradoxically, too much labeling presents a se-

222 *Id.* at 761.

223 Colin A. Carter & Guillaume P. Gruere, 6 AGBIOFORUM 43, 43 (2003), *available at* http://www.agbioforum.org/v6n12/v6n12a13-carter.pdf.

224 Sara Butcher, *Fraud-on-the-FDA and Genetically Modified Foods: Will the Action Stand?*, 22 REV. LITIG. 669, 704 (2003).

225 *See* SUNSTEIN, *supra* note 146, at 261.

226 Emily Robertson, *Finding a Compromise in the Debate Over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 169 (2003).

227 *See* Rich, *supra* note 71, at 908.

228 SUNSTEIN, *supra* note 146, at 260–61.

229 *Id.*

rious risk of information overload, depriving consumers of any realistic opportunity to get valuable information about the products they consume.

COMPROMISE AND COMMON GROUND

Despite these potential difficulties, regulators have responded to public pressure for labels. Adopting a strong individual rights approach, Congress has twice attempted to pass the Genetically Engineered Food Right-to-Know Act, which would have created a labeling scheme independent of the FDA's determination.[230] Neither bill passed, but the growing pressure prompted the FDA to publish "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering."[231] While maintaining its position that transgenic crops are safe, the FDA acknowledged that the diverging views on transgenic crops supported allowing manufacturers to voluntarily include some information regarding the development process as long as it was "truthful and not misleading."[232]

Although there are still objections on both sides of the issue, voluntary labeling appears to offer a reasonable compromise. As we have seen, some effective labeling would help counteract the cognitive difficulty consumers have assessing risks. In this way, the law merely assists economic actors in forming a well-informed contract. If people do not have accurate risk perceptions, their interactions will be inefficient. Some form of labeling takes advantage of the understanding that a well-designed information effort can play a constructive role in sounder risk decisions.[233] Moreover, regulation designed to provide information to the market can remedy the risk that dangerous products that are cheaper to produce will drive safer products out of the market when the consumer lacks pertinent information.[234] To be effective, labeling should be only one part of an overall information campaign to improve public understanding of transgenic crops and raise the level of the debate. Only accurate information can restore a reasoned discussion of the legitimate benefits and risks of transgenic crops.

CONCLUSION

As with most bioethical issues, it is unlikely that any single solution could satisfy all of the interested parties in the debate over genetically engineered foods. The failure of proponents of transgenic crops to effectively engage the public early in the process has polarized opinions on the issue and forestalled any meaningful discussion. Upon closer examination, how-

230 Robertson, *supra* note 226, at 170–71 (citing H.R. 3377, 106th Cong. (1999); S. 2080 106th Cong. (2000)).

231 Marden, *supra* note 186, at 761.

232 *Id.*

233 VISCUSI *supra* note 154, at 45.

234 SUNSTEIN, *supra* note 146, at 255. Despite advocating for information generally, Sunstein opposes labeling of genetically altered foods because he believes the risks of confusion outweigh any benefit. *Id.* at 260–61.

ever, it is clear that transgenic foods still represent an opportunity to open a dialogue that will help facilitate a consensus on this issue. Once open, that dialogue can help create a framework for deciding the more difficult genetic engineering issues on the horizon. The importance of food has the public engaged, and the lack of any religious objection to transgenic crops removes some of the passion that can cloud the discussion of bioethical issues. Without any significant fracture between the religious and the political, discussions of the propriety of transgenic crops should involve less tension than other biotechnology issues. In addition, the clear goals of transgenic crops provide a sound base on which to discuss the risks and benefits of transgenic crops.

Accurate information is central to an effective dialogue about transgenic crops. A regulatory environment focused on allowing the voluntary exchange of information lets those who want to share information do so, while facilitating an atmosphere of education that will enable the public to work toward a consensus on very difficult issues. The law is not particularly good at creating consensus, but instead works best when it allows for choice within limits and leaves a place for personal morality. A comprehensive information campaign can help do that. The free exchange of information and an educated dialogue also minimize the cognitive limitations that lead to irrational behavior.

Political leaders in the United States and around the world must take a more active role in promoting a productive dialogue about genetic engineering. In addition to voluntary labeling, the federal government should create an informational infrastructure to facilitate the exchange of information between manufacturers and the public. Government agencies, manufacturers, and opponents already provide a considerable amount of information on the Internet, but there is no single place a consumer can go to get information and compare the arguments. Part of an effective regulatory scheme should include an information clearinghouse for the most current information on biotechnology. With a better understanding of the real risks and benefits associated with genetic engineering, an engaged and educated public can work with the scientific community to determine what technologies are appropriate and how they can best be used to reach shared goals of meeting the agricultural needs of a growing population.