This endnote section from *Altered Genes, Twisted Truth* is posted here so that people reading a physical version of the book can print it or store it on their computer, tablet, or e-reader – which will facilitate transition between the main text and the endnotes.

Notes

Introduction

1 The FDA acknowledges that it has been operating under a policy "to foster" the US biotechnology industry. See, e.g., "Genetically Engineered Foods," *FDA Consumer* (Jan. - Feb., 1993), 14.

2 Keller, Evelyn F. *The Century of the Gene*. (Cambridge: Harvard University Press, 2002), 142-43.

3 Ibid. 143.

4 Ibid. 144.

5 Ibid. 148.

1. The Politicization of Science

1 Among the Harvard professors who regarded Mayr as the greatest 20th century biologist were E.O.Wilson and Stephen Jay Gould. See Meyer, A., "On the importance of being Ernst Mayr," *PLoS Biol* 3(5):e152 (2005): 0100.

2 When used in this way, the term "gene-splicing" refers to manipulations of biotechnicians. As will be discussed in subsequent chapters, although segments of DNA are also spliced into DNA molecules through natural processes, the details of these processes significantly differ from those of recombinant DNA technology.

3 Regal recorded these words in a set of recollections about his endeavors to set the genetic engineering venture on a more scientific track – recollections that he sent to me for use in this book. The statements from him that follow in this and other chapters are largely drawn from these recollections and from my extensive conversations and email correspondence with him. Accordingly, except for quotes excerpted from his published articles, I will not provide specific references for his various statements.

4 Crichton completed the first draft of *The Andromeda Strain* in 1967.

5 Morrow, J.F., Cohen, S.N., Chang, A.C.Y., Boyer, H.W., Goodman, H.M., Helling, R.B., "Replication and transcription of eukaryotic DNA in Escherichia coli," *Proceedings of the National Academy of Sciences* 71 (1974): 1743- 47. Prior to that accomplishment, other researchers had learned how to join two pieces of DNA together. The initial fusion was achieved by a team in Paul Berg's lab at Stanford University; and Berg subsequently received a Nobel Prize in recognition of this and other groundbreaking research in recombinant DNA technology. Jackson, D. A., Symons, R. H., and Berg, P., "Biochemical methods for inserting new genetic information into DNA of Simian Virus 40: Circular SV40 DNA molecules containing lambda phage genes and the galactose operon of Escherichia coli," *Proceedings of the National Academy of Sciences* [PNAS] 69 (1972): 2904.

6 As discussed in the previous note, Berg had been able to create some recombinant DNA even before scientists had discovered how to isolate individual genes from one species, copy them, and then splice them into the DNA of other species. But his technique was relatively complicated and could not be widely employed. The tumor-inducing virus that he planned to work with is referred to as SV40.

7 For a discussion of this incident see the preface to the 2013 paperback edition of: Pollack, R., *The Faith of Biology and the Biology of Faith* (New York: Columbia University Press, 2013).

8 Berg, P., "A Stanford Professor's Career in Biochemistry, Science Politics, and the Biotechnology Industry," an oral history conducted in 1997 by Sally Smith Hughes, Regional Oral History Office, The Bancroft Library, University of California, Berkeley (2000), 92; http://texts.cdlib.org/view?docId=kt1c6001df&doc.view=entire_text.

9 Ibid., 93.

10 Singer, Maxine and Soll, Dieter, "Guidelines for DNA Hybrid Molecules," *Science* 181 (September 21, 1973): 1114.

11 Wright, Susan, *Molecular Politics: Developing American and British Policy for Genetic Engineering 1972-1982* (Chicago: University of Chicago Press, 1994), 136.

12 Ibid.

13 Berg, Paul et al., "Potential Biohazards of Recombinant DNA Molecules," *Science* 185 (July 26, 1974): 303.

14 Ibid.

15 Barinaga, Marcia, "Asilomar Revisited: Lessons for Today?" *Science* 28, no. 5458 (March 3, 2000): 1584–85.

16 Watson, J. and Tooze, J., *The DNA Story* (San Francisco: W.H. Freeman, 1981), 49.

17 Wright (1994), op. cit. note 11, 135.

18 Ibid., 26.

19 Cited in Goodell, Rae, "How to Kill a Controversy: The Case of Recombinant DNA" in *Scientists and Journalists: Reporting Science as News*, Friedman, S.M., Dunwoody, S. and Rogers, C., eds. (New York: The Free Press/Macmillan, 1986), 172.

20 Bennett, William and Gurin, Joel, "Science that Frightens Scientists: The debate over DNA," *The Atlantic Monthly* 239 (February, 1977): 43-62.

21 Lewin, Roger, "The Asilomar Conference: Was the Asilomar Conference a Justified Response to the Advent of Recombinant DNA Technology, and Should It Serve as a Model for Whistle-Blowing in the Future?" in *Bioscience Society; Report of Schering Workshop*, Roy, D.J. et al., eds., (Chichester, New York: John Wiley & Sons, 1991), 206.

22 Ibid.

23 Wright, Susan, "Molecular Biology or Molecular Politics? The Production of Scientific Consensus on the Hazards of Recombinant DNA Technology," *Social Studies of Science* 16, no. 4 (Nov. 1986): 593-620, 595.

24 Ibid.

25 Watson, James D., "An Imaginary Monster," *Bulletin of the Atomic Scientists* 33 (May 1977): 12.

26 Watson expressed his regret in a speech quoted in McAuliffe, Sharon and McAuliffe, Kathleen, *Life For Sale* (New York: Coward, McCann & Geoghegan, 1981), 176.

27 Kay, Lily, *The Molecular Vision of Life: Caltech, The Rockefeller Foundation, and the Rise of the New Biology* (New York: Oxford University Press, 1993); Pnina Abir-Am, "The biotheoretical gathering, transdisciplinary authority and the incipient legitimation of molecular biology in the 1930s: new perspectives on the historical sociology of science," *Hist Sci* 25 (1987):1-70.

28 Weaver, Warren, *Scene of Change: A Lifetime in American Science*, (New York: Scribner's, 1970), 56.

29 Ibid., 57.

30 Regal, Phil, "Metaphysics in Genetic Engineering: Cryptic Philosophy and Ideology in the 'Science' of Risk Assessment." In *Coping with Deliberate Release: The Limits of Risk Assessment,* Van Dommelen, Ad, (ed.), International Centre for Human and Public Affairs, Tilburg/Buenos Aires (1996).

31 Weaver, op. cit. note 28, 183.

32 Regal, "Metaphysics in Genetic Engineering," op. cit. note 30.

33 Alibek, Ken, *Biohazard: The Chilling True Story of the Largest Covert Biological Weapons Program in the World – Told from Inside by the Man who Ran It* (New York: Random House, 1999), xi.

34 Chargaff, Erwin, "On the Dangers of Genetic Meddling," *Science* 192 (1976), 940.

35 Ibid., 938.

36 King, Jonathan, quoted in McAuliffe and McAuliffe, op. cit. note 26, 174; See also Bennett and Gurin, op. cit. note 20, 56-57.

37 Wald, George, "The Case Against Genetic Engineering," in *The Recombinant DNA Debate*, Jackson, D. and Stich, S., Eds. (Prentice-Hall, 1979), 127-28.

38 Ibid.

39 Wald, George, speaking at a press conference in Washington, D.C. March 1977. Quoted in Kimbrell, A., *The Human Body Shop: The Engineering and Marketing of Life,* (New York: Harper Collins, 1994), 159. Although Wald's statement that genetic engineering is the "biggest break in nature" occurred at a press conference, I think it's appropriate to include it along with statements he wrote in an earlier article because doing so does not in any way misrepresent his thinking – and enables it to be expressed in a compact manner.

40 Wald, George, "The Case Against Genetic Engineering," op. cit. note 39.

41 Lewin, Roger, (1991), op. cit. note 21, 206.

42 Wright (1986), op. cit. note 23, 593.

43 Ibid., 601.

44 Ibid., 600.

45 Ibid., 600-01.
46 Ibid., 601.
47 Ibid.
48 Ibid.
49 Ibid., 602.
50 Thomas, Gavin; http://www.microbiologyonline.org.uk/ecoli.htm.
51 Wright (1986), op. cit. note 23, 603.
52 Ibid., 602, no. 20.
53 Ibid., 604.
54 Ibid.
55 Ibid., 604-5
56 Ibid., 605.
57 Ibid., *emphasis in original.*
58 Ibid., 606. The full quote that appears on p. 45 of the transcript of the meeting is: "I think that is what you have to deal with. It may not mean a thing, but that is very easy to do. Its molecular politics, not molecular biology and I think we have to consider both, because a lot of science is at stake." In an email to me (in answer to my questions) Wright explained that from the prior discussion, it is clear the word "that" refers to the problem of convincing the public. Accordingly, in her article, Wright renders the first sentence as: "I think (the problem of convincing the public) is what you have to deal with."
59 Ibid.
60 Ibid., 600. In an email to me, Wright confirmed that the media were not invited to any of the conferences or even informed of them – and so were not present.
61 Ibid., 607.
62 Quoted in Wright (1986), op. cit. note 23, 607.
63 Ibid., 608.
64 Ibid.
65 Quoted in Dutton, Barbara, *Worse than the Disease: Pitfalls of Medical Progress* (New York: Cambridge University Press, 1992), 193.
66 Ibid.
67 Ibid.
68 Wright (1986), op. cit. note 23, 613.
69 Ibid.
70 Ibid.
71 Wright (1994), op. cit. note 11, 275. The Academy's misrepresentation appeared in a report issued by its Assembly of Life Sciences.
72 Ibid., 269.
73 Dutton, op. cit. note 65, 193.
74 Ibid.
75 Ibid., 193-94.
76 Wright (1994), op. cit. note 11, 269.

77 Ibid., 270.

78 Ibid., 271.

79 Edward M. Kennedy, speech to the Association of Medical Writers, September 27, 1977, New York, quoted in Wright (1994), 272.

80 Wright (1994), op. cit. note 11, 272.

81 Ibid., 245.

82 Chang, Shing and Cohen, Stanley N., "*In Vivo* Site-Specific Genetic Recombination Promoted by Eco RI Restriction Endonuclease," *Proceedings of the National Academy of Sciences* 74 (November 1977): 4811-15. The fragments of mouse DNA were not integrated within the central area of the bacterial DNA (its *chromosome*) but within a small ring of DNA outside of it (called a *plasmid*). Chromosomes and plasmids will be discussed in Chapter 4, which will also more thoroughly examine Cohen's experiment and the deceptive claims that were made about it.

83 Stanley Cohen quoted in Wright (1994), op. cit. note 11, 272.

84 Stanley Cohen to Donald Fredrickson, September 6, 1977, ORDAR, quoted in Wright (1994), op. cit. note 11, 246.

85 Dutton, op. cit. note 65, 194.

86 Wright (1994), op. cit. note 11, 272. Wright says Kennedy used Cohen's claim as an "escape hatch."

87 Roy Curtiss to Donald Fredrickson, April 12, 1977, *ORDAR* 8, quoted in Wright (1994), op. cit. note 11, 244. I learned of the conflict between the letters through Wright's observations.

88 Wright (1994), op. cit. note 11, 246.

89 Ibid., 291.

90 In light of the extensive information I've read, it seems reasonable to assume that most legislators, including Kennedy, were never adequately informed about the illegitimacy of Cohen's claim. However, I have seen no explicit evidence to that effect. Further, although several legislators were sent copies of the Curtiss letter in April 1977, it seems that when Cohen's claim was issued six months later, they did not realize that it was undercut by the earlier document. For one thing, Cohen's letter did not mention the unusual conditions under which the research was performed; and the fact that he'd employed them was not well-publicized.

91 Wright (1986), op. cit. note 23, 609.

92 Ibid., 610.

93 Transcript quoted in Wright (1986), op. cit. note 23, 611.

94 Ibid., 612.

95 Ibid.

96 Ibid.

97 Ibid.

98 Ibid., 615 and Wright, op. cit. note 11, (1994), 513, n. 56. Wright obtained the quote in an interview she conducted.

99 Wright (1994), 256.

100 Wright (1986), op. cit. note 23, 614.

101 Ibid.

102 Ibid., 596, 615

103 Wright (1994), op. cit. note 11, 351.

104 Newmark, Peter, "WHO Looks for Benefits from Genetic Engineering," *Nature* 272 (20 April 1978): 663-64, quoted in Wright (1986), op. cit. note 23, 614.

105 Wright (1994), op. cit. note 11, 366.

106 Wright, Susan, email communication.

107 Ibid.

108 Wright (1994), op. cit. note 11, 64. The molecular biologist who proposed a dangerous experiment was Sydney Brenner, of the University of Cambridge.

109 Wright (1994), op. cit. note 11, 250.

110 Ibid., 248-50.

111 Ibid., 249, 463.

112 Rowe quoted in Wright (1994), op. cit. note 11, 372.

113 The study was published as: Israel, M.A., Chan, H.W., Hourihan, S.L., Rowe, W.P. and Martin, M.A., "Biological activity of polyoma viral DNA in mice and hamsters," *J. Virol* 29 (1979): 990–96. The specific type of polyoma virus that was employed is referred to as PY. It's in the same viral group as the tumor-producing SV40 that Paul Berg had, several years previously, intended to insert within an E. coli-infecting virus – which roused the concern of Robert Pollack and ultimately spurred the development of the precautionary measures that the Rowe-Martin experiment was intended to relax.

114 Israel, Mark A. et al., "Interrupting the Early Region of Polyoma Virus DNA Enhances Tumorigenicity," *Proceedings of the National Academy of Sciences* 76 (August 1979): 3714.

115 Wright (1994), op. cit. note 11, 373. For a discussion of the various results, see 368-74.

116 Ibid., 368.

117 Ibid., 366-67.

118 Ibid., 375-66. At an RAC meeting in May 1979, Jonathan King of MIT noted that an experiment confined to *E. coli* (such as Rowe-Martin) could not confirm the safety of rDNA research with other organisms.

119 On November 10, 2010, I accessed the false claim at: http://www.niaid.nih.gov/labsandresources/labs/aboutlabs/lmm/viralpathogenesisvaccinesection/Pages/martin.aspx.

In January 2014, I discovered that this URL is no longer functional and that Martin's current biographical information omits the misrepresentation that was present in 2010 – and had presumably been posted for many years. In fact, the current page does not specifically mention the Rowe-Martin experiment at all. The new URL is: http://www.niaid.nih.gov/LabsAndResources/labs/aboutlabs/lmm/viralPathogenesisVaccineSection/Pages/martin.aspx#niaid_inlineNav_Anchor.

It's quite plausible that the falsehood was removed as a result of being exposed by information I circulated describing it. A supporter of the bioengineering venture may well have read it and alerted Dr. Martin about the need for revision.

120 Wright (1986), op. cit. note 23, 616.

2. Expansion of the Biotech Agenda

1 Because commercialization of a GE food was still more than a decade away, attention at that time was primarily focused on whether a gene-altered crop could damage the environment during field testing, not on whether it might eventually bring new risks to the dinner table. Food safety did not become a salient issue until much later – and it will be discussed in subsequent chapters.

2 Interview with Arnold Foudin, Ph.D., Deputy Director, Biotechnology Permits, PPQ, APHIS, USDA, Washington, DC (October 6, 1997), cited in Jones, Mary Ellen, "Politically Corrected Science: The Early Negotiation of U.S. Agricultural Biotechnology Policy," a Doctoral Dissertation in Science and Technology Studies at Virginia Polytechnic Institute (1999), 63.

3 Ibid., 88.

4 Interview with David MacKenzie cited in Jones, (1999), op. cit. note 2, p. 89, n. 231. The word "disbelief" is the term that Jones uses in describing his reaction as related to her.

5 Ibid., 101.

6 Ibid.

7 Ibid., 105-06.

8 Ibid., 108.

9 Ibid.

10 Berg, Paul et al., "Potential Biohazards of Recombinant DNA Molecules," *Science* 185 (July 26, 1974): 303.

11 At the April 22, 1981 meeting of an RAC working group, concern was raised that risk assessment data was still limited to *E. Coli* K-12; and I have seen no indication that by December of that year the situation had changed. *See* Minutes of Large-Scale Review Working Group of the RAC, April 22, 1981, in US Department of Health and Human Services, (1982); Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules," November 1980-August 1982, Office of Recombinant DNA Activities, NIH Publication No. 83-2604, 78.

12 Jones (1999), op. cit. note 2, 109. Jones reports that Jonathan King (of MIT) and Ruth Hubbard and George Wald (both of Harvard) "reproached" Baltimore ". . . for conflict of interest, accusing him of promoting the deregulation of an industry in which he had a considerable economic interest." In referencing their allegations (in footnote 287), she cites documents they filed with the NIH in 1982 as: Documents relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules" November 1980-August 1982, Office of Recombinant DNA Activities, NIH Publication No. 83-2604; Hubbard (p.717), Jonathan King (p.

719), and George Wald (p.701). These documents are no longer available on the NIH website.

To my knowledge, there were no allegations that Paul Berg had any conflict of interest; and the evidence indicates that he endeavored to avoid such conflicts – and to maintain proper boundaries between academia and industry.

13 Jones, op. cit. note 2, 113.

14 Ibid., 113-14. Due to these lacks, the director of NIH deferred action pending receipt of more information about containment – information that was not provided until the following year. Eventually, the proposal was given final approval on August 7, 1981.

15 Ibid., 146-47.

16 Ibid.

17 Ibid., 156.

18 As noted in Chapter 1, because the various statements from Regal in this book are largely drawn from his written recollections and from my extensive conversations and email correspondence with him, except for quotes excerpted from his published articles, I will not provide specific references for his various statements.

19 The generic arguments did exclude at least one class of GMO: those derived from organisms known to be pathogenic.

20 Regal, Philip, "Models of Genetically Engineered Organisms and Their Ecological Impact," in *Ecology of Biological Invasions of North America and Hawaii* , Mooney, H. and J. Drake., eds. (New York: Springer-Verlag, 1986), 117.

21 Cited in Ibid., 118.

22 Ibid. (emphasis in original).

23 Because the wrinkle-inducing allele is recessive, it doesn't get expressed in as many peas as does the allele that confers smoothness, which is dominant. So the majority of peas are smooth.

24 Regal further notes the illegitimacy of the claim that gene-splicing is akin to crossing two distantly related (yet inter-breedable) species – a process that generally reduces the fitness of the resultant organisms. He points out that this infirmity results because the offspring of sexual reproduction receive one set of chromosomes from each parent, and that when the parents are distantly related, these sets are not *co-adapted*. He contrasts this with genetic engineering, where a few foreign genes are added to a *stable* genome in which the sets of chromosomes *are* co-adapted.

Moreover, Regal points out another significant respect in which genetic engineering radically differs from traditional breeding: it can alter parts of the genome that the latter cannot touch. In his words:

"Traditional breeding is limited to rearranging only a fraction of the DNA molecule – the fraction that varies within a population. Yet much of the DNA molecule does not vary among individuals in a population. For example, dogs have only two eyes. Even though eyes are under genetic control, they do not vary in number and thus we cannot select for dogs with three or more eyes.

This part of their DNA code is 'locked up' in various ways beyond the reach of natural or artificial selection. Mutagenesis can induce random changes in parts of the code that are locked up, but mutagenesis cannot systematically rewrite this part of the code in a biologically coherent way. With rDNA techniques one can, in principle, go into the DNA code books that are 'locked up' and rewrite them."

25 Raven's current views on GMOs are discussed in endnote 8 of Chapter 14.

26 A member of Reagan's White House staff recounts: "We wanted it to be an American technology," Jones (1999), op. cit. note 2, 231.

27 For instance, this was the view of Warren Weaver and Max Mason, two of molecular biology's prime promoters. See: Schwartz, J. "The Soul of Soulless Conditions? Accounting for genetic fundamentalism," *Radical Philosophy* 86 (November/December 1997): 4.

28 The NAS website devotes many pages to its building; and over several years, the main page has displayed the prominent heading: "The NAS Building . . . a Temple of Science." (The heading was present when I first visited that web page in 2007, and as of January 2014, it's still in use. Further, it's reasonable to presume that it was there long before I first accessed the page.) http://www.nasonline.org/about-nas/visiting-nas/nas-building/

29 Einstein was elected a foreign associate of the Academy in 1922 and became a member in 1942, two years after he became a naturalized citizen.

30 Jones (1999), op. cit. note 2, 231.

31 Ibid., 227-28.

32 Ibid., 164.

33 Ibid., 69, 217, 239.

34 Ibid., 217.

35 Ibid., ii.

36 Ibid., 330.

37 National Academy of Sciences, "Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues" (1987): 6.

38 Ibid., 22.

39 Ibid., 20.

40 Marchant, Gary, "Modified Rules for Modified Bugs," *Harvard Journal of Law and Technology* 1 (Spring and Summer, 1988): 165.

41 Krimsky, S. and R. Wrubel, *Agricultural Biotechnology and the Environment: Science, Policy, and Social Issues* (Champaign, IL: University of Illinois Press, 1996), 219.

42 Dumanoski, "Academy Report Challenged," *Boston Globe*, August 24, 1987, 44 (Cited in Marchant, G., op. cit. note 40, 166.)

43 Krimsky and Wrubel (1996), op. cit. note 41, 219.

44 Regal relates that after the task force carefully drafted a set of regulations, the state's department of agriculture (which was boosting biotech) managed to

gain control and fashioned so many loopholes that the regulations were rendered virtually meaningless.

45 *Reporters' Guide: Genetic Engineering in Agriculture* (Washington, D.C.: Environmental Media Service, 2000), 29.

46 Ecological Society of America, "The Planned Release of Genetically Engineered Organisms: Ecological Considerations and Recommendations," *Ecology* 70, no. 2 (April 1989).

47 http://www.ourdocuments.gov/doc.php?flash=true&doc=90&page=transcript

48 Ibid.

3. Disappearing a Disaster

1 Janet O'Brien, National EMS Network Newsletter, Fall 1997.

2 Story on Harry Schulte, WCPO-TV, 11 PM News, Cincinnati, Ohio, February 26, 1998.

3 Personal Communication from Betty Hoffing to Jeffrey Smith as reported in Smith, J., *Seeds of Deception: Exposing Industry and Government Lies About the Safety of the Genetically Engineered Foods You're Eating* (Fairfield, IA: Yes! Books, 2003), 107.

4 Personal communication from Gerald Gleich, M.D.

5 The website of a medical doctor who is an authority on tryptophan states that the 2% figure came from the *New England Journal of Medicine*: http://craighudsonmd.com/tryptophan.html (accessed 1-2-12).

6 Hertzman, P. et al., "The Eosinophilia-Myalgia Syndrome: The Los Alamos Conference," *Journal of Rheumatology* 18, no. 6 (1991): 867-73.

7 The CDC's final estimate (which was made almost two decades ago) put the number of deaths at between 80 and 100. The figure of 1,500 permanent disabilities is from Wikipedia.

8 Although the causal link between Showa Denko's LT and the epidemic has been questioned by some researchers (e.g., Shapiro, S., "Epidemiologic studies of the association of L-tryptophan with the eosinophilia-myalgia syndrome: a critique," *J Rheumatol Suppl* [Oct. 1996]: 44-59), the link has been firmly established by published research conducted not only at the Center for Disease Control (CDC), but at the Mayo clinic and other respected institutions. The strength of the connection is attested by CDC scientists who have written: "These studies constitute overwhelming evidence that the cause of the EMS epidemic was ingestion of L-tryptophan produced by Showa Denko," (emphasis added), *The Lancet* 343 (April 23, 1994): 1037.

9 Philen, R.M. et al., "3-(Phenylamino)alanine—a Link Between Eosinophilia-Myalgia Syndrome and Toxic Oil Syndrome?," *Mayo Clinic Proceedings* 68 (1993): 197-200.

10 Ibid.

11 Slutsker, L. et al., *Journal of the American Medical Association* 264, no. 2 (July 11, 1990): 213-17.

12 Garrett L., "Genetic engineering flaw blamed for toxic deaths," *Newsday*, August 14, 1990: C-1.

13 Roberts, Leslie, "L-tryptophan puzzle takes new twist," *Science* 249 (August 31, 1990): 988.

14 Ibid.

15 Ibid.

16 Belongia, E.A. et al., "An Investigation of the Cause of the Eosinophilia-Myalgia Syndrome Associated with Tryptophan Use," *New England Journal of Medicine* 323, no. 6 (August 9, 1990): 357-65.

17 Scientists also sometimes referred to it as "Peak E." Subsequent to the initial publication discussing its structure, a more precise determination was made by a group at the Mayo Clinic, Mayeno, A.N., et al., Characterization of "peak E," a novel amino acid associated with eosinophilia-myalgia syndrome, *Science* 21 (December 1990) 250, no. 4988: 1707-08.

18 Belongia et al., (1990), op. cit. note 16.

19 Charles, Dan, *Lords of the Harvest: Biotech, Big Money, and the Future of Food* (Cambridge: Perseus, 2002), 224.

20 Raphals, P., "Does medical mystery threaten biotech?," *Science* 249, no. 619 (1990).

21 Unpublished study by the FDA and Showa Denko K.K., cited in Toyoda, M. et al., "Formation of a 3-(Phenylamino)alanine Contaminant in EMS-associated L-Tryptophan," *Bioscience, Biotechnology, Biochemistry* 58 (1994): 1318.

22 Ibid., 1318-1320.

23 Belongia et al., (1990), op. cit. note 16.

24 Philen RM, Hill, RH Jr, Flanders WD, et al., "Tryptophan contaminants associated with eosinophilia-myalgia syndrome. The Eosinophilia-Myalgia Studies of Oregon, New York and New Mexico," *Am J Epidemiol* 138 (1993): 154-59; Hill, R.H. et al., "Contaminants in L-tryptophan Associated with Eosinophilia-Myalgia Syndrome," Archives of Environmental Contamination and Toxicology 25 (1993): 134-42.

25 Love, L.A., Rader, J.I., et al., "Pathological and Immunological Effects of Ingesting L-Tryptophan and 1, 1'-Ethylidenebis (L-Tryptophan) in Lewis Rats," *Journal of Clinical Investigation* 91 (March 1993): 804-11.

26 Hill, R.H. et al., "Contaminants in L-tryptophan Associated with Eosinophilia-Myalgia Syndrome," Archives of Environmental Contamination and Toxicology 25 (1993): 134-42.

27 Ibid.

28 Ibid.

29 Love et al. (1993), op. cit. note 25, stated that the research indicates that several factors were probably involved. Further, EBT may have sometimes played a subordinate role. Although it was not significantly related to a lot's harmful status, there was a positive association, which suggests it may have sometimes acted in combination with other factors to facilitate the occurrence of EMS (even though the disease was often induced in its absence).

30 Yanofsky, C., email to William Crist, June 2, 1998.

31 Yanofsky, C., quoted in Raphals, P., "EMS deaths: Is recombinant DNA technology involved?," *The Medical Post*, November 6, 1990.

32 Yanofsky, C., email to William Crist, June 2, 1998.

33 Personal communication from Gerald Gleich, M.D. to Jeffrey Smith, as reported in Smith, J., *Seeds of Deception: Exposing Industry and Government Lies About the Safety of the Genetically Engineered Foods You're Eating* (Fairfield, IA: Yes!Books, 2003), 275.

34 Email from William Crist.

35 Edwin M. Kilbourne et al., "Tryptophan Produced by Showa Denko and Epidemic Eosinophilia-Myalgia Syndrome," *Journal of Rheumatology Supplement* 23, no. 46 (October 1996): 81-92.

36 National Eosinophilia-Myalgia Syndrome Network, position statement, approved quote by Gerald J. Gleich, M.D., Mayo Clinic and Foundation, May 25, 2000.

37 Mayeno, A.N. and Gleich,G.J., "Eosinophilia-myalgia syndrome and tryptophan production: a cautionary tale," *Trends in Biotechnology* (TIBTECH) (September 1994), Vol. 12, pp. 346-352.

38 Email from Dennis Mackin of January 31, 2012. Mr. Mackin and other plaintiffs' attorneys eventually received this information, which included the dates on which the various strains had been used. Years later, Bill Crist obtained a chart listing the strains and dates from Mackin, and I received a copy from Crist. Although this latter document was not the copy of the fax the FDA had sent in September 1990, it contained the critical information.

39 Hill, Robert H. et al., "Contaminants in L-tryptophan Associated with Eosinophilia-Myalgia Syndrome," *Archives of Environmental Contamination and Toxicology* 25 (1993): 134-42. (This study indicates that Strain IV was more toxic than III.)

40 Email from William Crist.

41 "Bitter Pill," Dateline NBC, NBC News, August 22, 1995; NHK Special in Japan, "Product Liability Litigation in America," August 5, 1995.

42 Torigoe memo of Aug 23, 1988, Exhibit 90 in specific lawsuits against Showa Denko, 3.

43 Email from Adrian Gibbs, Emeritus Professor of Virology, Australian National University,

44 Although there's currently insufficient basis for determining whether the viral problem arose within Strain III or IV, the erratic employment of IV suggests that it was the affected strain.

45 SD records obtained by attorneys during the lawsuits indicate such a shutdown; and Paul Rheingold (an attorney who represented hundreds of victims) confirmed in a phone conversation in January 2012 that a significant shutdown did occur.

46 Within SD records that follow Torigoe memo, op. cit., in what appears to be part of Exhibit 90 at official reference number 333755 0885.

47 Email from William Crist that included a copy of the Maryanski letter.

48 Emails from William Crist regarding information received from Don Morgan (of Cleary, Gottlieb, Hamilton & Steen) via phone and emails of March 5 and April 19, 2001. According to Morgan's March 5 email: "SDK invited FDA to send someone to Japan to receive the bacteria and learn how to care for them and run jar fermentations correctly. FDA never followed up on this offer, or expressed any criticism of SDK's reluctance to send live bacteria by mail."

49 Crist conveyed this information to me via email.

50 Ibid.

51 Bains, William, *Biotechnology from A to Z* (Oxford: Oxford University Press, 1993), 10. This false statement is repeated in the second edition, published in 1998.

52 Report of the Royal Commission on Genetic Modification (New Zealand, 2001), 43.

53 Ibid.

54 Ibid.

55 The Royal Commission's report gave no specific reference for any assertion it made in the tryptophan section. Rather, it listed all fifteen sources for the entire section in one large reference note. These sources include submissions to the commission by interested persons as well as several journal articles and even a special report prepared for the commission. But none of the assertions in the tryptophan section was specifically linked with any of these sources, nor were any page numbers provided to indicate which parts of these sources contained the relevant information. Consequently, it is extremely difficult to discover from which source each assertion was supposedly derived and to ascertain its reliability. Moreover, as of the time of this writing, neither the submissions by interested persons nor the special report on which the Commission relied are provided on the government site at which the report can be downloaded – and it's not clear for how long, if ever, they were readily available. http://www.mfe.govt.nz/publications/hazards/report-royal-commission-genetic-modification.

In effect, this strange way of reporting references has essentially barred people from checking the sources for the Commission's assertions about the tryptophan incident.

56 Douglas L. Archer, Deputy Director Center for Food Safety and Applied Nutrition (CFSAN), FDA, Testimony before the Subcommittee on Human Resources and Intergovernmental Relations, US House of Representatives, July 18, 1991. As for the agency's knowledge that the bacteria had been engineered, Jeffrey Smith reports that a former FDA employee was astounded when he informed her that Archer had failed to mention that fact, declaring that by then "everyone in the agency" knew about the bioengineering, Smith, *Seeds of Deception* (cited in note 33), 121.

57 Cited in Beisler, Joshua, H., "Dietary Supplements and Their Discontents: FDA Regulation and the Dietary Supplement Health and Education Act of 1994,"

Rutgers Law Journal (Winter 2000): 531. Although this particular report was issued in 1993, a few years after Archer's testimony, it indicates that the agency's desire to regulate supplements had continued unabated for decades, and had not been satiated by the ban imposed on LT.

58 Ibid. In the law journal, the entire piece is termed a *note*, but that does not indicate it is either short or otherwise minor. Law journals typically reserve the term *article* for pieces authored by professors, judges, and practicing attorneys and refer to those written by members of their staff, who are law students, as *notes*. But notes receive the same editorial scrutiny as articles, they are often of similar length, and they're frequently cited in judicial opinions and articles in other journals. Because Mr. Beisler's piece runs forty pages and is carefully reasoned and thoroughly researched, I decided to refer to it as an article rather than a note to avoid conveying the false impression that it's a short statement of opinion that's also short on supportive evidence.

59 Manders, Dean, "The FDA Ban of L-Tryptophan: Politics, Profits and Prozac," *Social Policy*, vol. 26, no. 2, Winter 1995: http://www.ceri.com/trypto.htm (accessed February16, 2012).

60 FDA Public Affairs Office, Press Release of May 18, 1994. The enzyme was introduced in 1990, and Showa Denko first marketed GE-derived LT in 1984.

61 Stephen Naylor, personal communication.

62 "Genetically Modified Foods," Australia New Zealand Food Authority, November 2001. (downloaded from the agency's website on March 3, 2002.) The agency's name was later changed to Food Standards Australia/New Zealand.

63 Fedoroff, N. and Brown, N.M., *Mendel in the Kitchen: A Scientist Looks at Genetically Modified Foods* (Washington, DC: Joseph Henry Press, 2004); Ronald, P. and Adamchak, R., *Tomorrow's Table: Organic Farming, Genetics, and the Future of Food* (New York: Oxford University Press, 2008).

64 Charles, *Lords of the Harvest*, op. cit. note 19, 224.

65 Aldridge, Susan, *The Thread of Life: The Story of Genes and Genetic Engineering* (Cambridge: Cambridge University Press, 1996), 185-86.

66 http://www.bastyrcenter.org/content/view/1828/ (accessed 1-24-12)

67 http://www.bastyrcenter.org/content/view/590/#top (accessed 1-24-12)

68 Lambrecht, B., *Dinner at the New Gene Café: How Genetic Engineering Is Changing What We Eat, How We Live, and the Global Politics of Food* (Thomas Dunne Books: St. Martin's, 2001); Hart, K., *Eating In the Dark: America's Experiment With Genetically Engineered Food* (Pantheon: Random House, 2002).

69 Mann, L.R.B., Straton, D., and Crist, W. E., "The Thalidomide of Genetic 'Engineering.'" http://www.gmfoodnews.com/trypto.html

70 The FDA rescinded its ban on LT in 2006. Of course, if the fatal batches of LT had not been marketed in 1989, there would not have been a ban in the first place, and no barriers for a new engineered line of LT to face. Regarding Europe, a report by the BBC indicated that the toxic LT would gain entry there too. (*Seeds of Deception* [op. cit. note 33 above], p. 275, n. 20.)

71 Schubert, David, *Journal of Medicinal Food* 11(4) (December 2008): 601-05

72 Hill, R.H., Caudill, S.P., et al, "Contaminants in L-Tryptophan Associated with Eosinophilia Myalgia Syndrome," *Archives of Environmental Contamination and Toxicology* 25 (1993): 134-42.

73 In technical terms, AAA is "an unsaturated fatty acid conjugate of tryptophan," email from Stephen Naylor.

74 Email from Stephen Naylor.

75 So there is no question as to the accuracy of my account of Dr. Naylor's research, he executed a notarized affidavit confirming the facts as conveyed in this chapter. It's reproduced at www.alteredgenestwistedtruth.com/stephen-naylor-affidavit/

4. Genes, Ingenuity, and Disingenuousness

1 Miller, Henry, I., "Happy Earth Day, Mr. Rifkin," *Washington Times*, April 22, 1997.

2 Wald, George, "The Case Against Genetic Engineering," in *The Recombinant DNA Debate*, Jackson, D. and S. Stich, eds. (Prentice-Hall, 1979), 127-28.

3 Wald, George, speaking at a press conference in Washington, D.C. March 1977; Quoted in Kimbrell, A., *The Human Body Shop: The Engineering and Marketing of Life* (New York: Harper Collins, 1994), 159. Although Wald's statement that genetic engineering is the "biggest break in nature" occurred at a press conference, I think it's appropriate to include it along with statements he wrote in an earlier article because doing so does not in any way misrepresent his thinking – and enables it to be expressed in a compact manner.

4 Bains, William, *Biotechnology from A to Z* (Oxford: Oxford University Press, 1993). The introduction was written by G. Kirk Raab, President and CEO of Genentech, Inc., vi-viii.

5 Ibid., 224.

6 For example, in 2004 a sociologist who has conducted many surveys of consumer attitudes in the US observed that although two-thirds of the respondents voice support for GE foods, they know very little about the issue and that the minority who oppose them tend to be most educated about the facts. "Change of Heart By Thomas Hoban," September 23, 2004: http://www.lobbywatch.org/archive2.asp?arcid=4387 (accessed Aug. 15, 2012)

7 Communications Programmes for EuropaBio, January 1997; Prepared by Burston Marsteller, Government and Public Affairs: http://home.intekom.com/tm_info/geleak1.htm (accessed Aug. 15, 2012).

8 Miller, Henry, I. "Happy Earth Day, Mr. Rifkin," *Washington Times*, April 22, 1997. In subsequent years, Dr. Miller has continued to sound the "seamless continuum" theme. See e.g., Miller, H.I., Point of View, Dec 1, 2007 (27, no. 21): http://www.genengnews.com/keywordsandtools/print/1/12239/ (accessed Aug. 15, 2012).

9 May, Sir Robert, BBC Interview, March 9, 2000.

10 Viruses are an interesting case. They are not full cells, and most biologists do not consider them to be living organisms in their own right. They cannot

reproduce on their own and can only do so when they have invaded a living cell of another species, commandeered its genetic apparatus, and re-directed it to generate their components.

11 While overall, there is still a net loss of the capacity of energy to perform work, the dissipation is far more gradual within living systems, more of the energy contributes to the formation of organized structure, and the degree of organization is much higher than in the processes that typify nonliving nature.

12 Grace, Eric., *Biotechnology Unzipped* (Washington, DC: Joseph Henry Press, 1977), 22.

13 While the mature red blood cells of mammals have shed their nucleus (and the DNA within it), they did possess a DNA- packed nucleus in their earlier stages and so functioned as information processing machines as they developed.

14 Most bacteria possess one main molecule of DNA (referred to as a chromosome) and several smaller, auxiliary molecules (called plasmids). This will subsequently be discussed in more detail.

15 Gitt, W., *In the Beginning Was Information* (Green Forest, AR: Master Books, 2007), 98.

16 In plants and animals, most genes can generate multiple proteins because the transcriptional machinery can arrange the information they contain in various ways.

17 Sex chromosomes are an exception. The sex chromosome of the human male (the Y chromosome) does not contain all the genes in the female chromosome (the X chromosome).

18 Although some plants fertilize themselves, they usually also send some of their pollen outward to fertilize the female gametes of other plants while some of their female gametes receive pollen from other plants. Some plants also have four or more sets of chromosomes instead of two. But their gametes will still contain only one half of the number possessed by their parental cells, so if the plant's cells contain four different sets of chromosomes, its gametes will have only two.

19 http://link.springer.com/chapter/10.1007/978-94-011-5794-0_3

20 Thomas, C. and Nielsen, K., "Mechanisms of, and Barriers to, Horizontal Gene Transfer between Bacteria," *Nature Reviews Microbiology* 3 (September 2005): 712.

21 Griffiths et al., *An Introduction to Genetic Analysis*, Sixth Edition (New York: W.H. Freeman, 1996), 424.

22 Ibid.

23 Not all restriction enzymes make staggered cuts, but biotechnicians are able to draw on a wide variety of those that do. Further, they've learned how to add sticky ends to fragments that are cut with enzymes that leave sheer edges. But this ability could not have developed without the application of the enzymes that do make staggered cuts.

24 Although evidence indicates that restriction enzymes probably have additional roles, and that they at times may have facilitated the integration of

foreign DNA into bacterial genomes, it's clear that their primary function is to inhibit such integration. For instance, Werner Arber, who received a Nobel Prize for discovering these enzymes, has postulated that there are two basic types of what he terms "evolution gene products." These products act either to generate genetic variation or to modulate it "to low levels that are tolerable for the long-term maintenance of a given strain or species." He classes restriction enzymes as modulators because they "seriously reduce both the chance of DNA acquisition and the size of a DNA segment that may eventually be acquired by the recipient cell." And he does so even though he thinks that they stimulate "occasional DNA acquisition to occur in small steps." (Arber, W., "Molecular Evolution: Comparisons of Natural and Engineered Systems, The Challenges of Sciences, A Tribute to Carlos Chagas," Pontifical Academy of Sciences, *Scripta Varia* 103 [Vatican City 2002]): www.pas.va/content/dam/accademia/pdf/sv103/sv103-arber.pdf; Arber, W., "Genetic Variation and Molecular Evolution," *Encyclopedia of Molecular Cell Biology and Molecular Medicine* (2006).

In contrast, bioengineers employ restriction enzymes not only to radically increase the rate at which genomes are altered by alien DNA, but to vastly expand the range of species that can interact – to the point where none of the natural species barriers remains intact.

25 One experiment did find that when *E. coli* are within river or spring water that naturally contains a sufficient level of calcium ion, they can take up plasmid DNA without additional calcium or abnormal shifts in temperature (Baur, B. et al., "Genetic Transformation in Fresh Water: *Escherichia coli* is Able to Develop Natural Competence," *Applied and Environmental Microbiology* 62 (Oct. 1996): 3673-78). And increasing evidence suggests that many species of bacteria that aren't ordinarily able to take up external DNA can do so under some naturally occurring conditions. But such instances appear to be relatively rare. In any case, the fact remains that biotechnicians have routinely resorted to unnatural means to induce *E. coli* to receive external DNA.

26 The only bacteria in which these particular elements have been found belong to the Archaebacteria kingdom, bacteria that exist in extreme environments, such as boiling water. These bacteria are rarely used in commercial applications of bioengineering.

27 For a good discussion of reverse transcriptase, see: http://www.nature.com/scitable/topicpage/the-biotechnology-revolution-pcr-and-the-use-553.

28 *Biotechnology from A to Z*, First Edition, (cited in note 4), 131.

29 Chang, Shing and Cohen, Stanley N., "*In Vivo* Site-Specific Genetic Recombination Promoted by Eco RI Restriction Endonuclease," *Proceedings of the National Academy of Sciences* 74 (November 1977): 4811-15.

30 Although genes are sometimes inserted to block the expression of another gene rather than to express any of their own proteins, this was seldom the aim of commercial applications when Cohen's experiment was performed; and even today, the predominant goal of commercial bioengineering is to produce a functional protein from the inserted gene.

31 Chang, A. C. Y., Lansman, R. A., Clayton, D. A. & Cohen, S. N., "Studies of Mouse Mitochondrial DNA in Escherichia coli," Cell 6 (1975): 231-44, at 241. This study was performed two years prior to the one on which Cohen based his influential claim. It's discussed more fully in the following note.

32 Actually, one cannot know to what extent (if any) mitochondrial proteins were produced in the 1977 experiment conducted by Chang and Cohen because their technical report makes no mention of that topic. But in 1975 Cohen and three other colleagues published a paper that did discuss the protein production that was observed after mouse mitochondrial genes were inserted into *E. coli*. And the degree of production was disappointing. Those are the results I reported in describing the 1977 study. In the absence of data directly bearing on the level of production in that study, I think it's reasonable to assume that the results were no better than in the 1975 experiment, because if the authors had determined that the production was more impressive, they would have made that fact known. However, it appears that in 1977, they didn't even try to make such a determination. Performing one in the earlier experiment had been a complicated, time consuming endeavor, so because there was little likelihood it would reveal better results, they probably decided it wasn't worth the effort. Of course, the results in 1977 might even have been worse; but I decided to give Cohen the benefit of the doubt by reporting the 1975 data as if they applied to the 1977 experiment.

One might wonder why Cohen even performed that experiment if he had already discovered that the proteins encoded by the genes of mouse mitochondria will not be adequately produced within *E. coli*. The reason, it seems, was to provide the basis for arguing that bacteria can integrate plant and animal genes in a natural manner. The 1975 experiment fell short of providing such a platform. In that research, rDNA technology was used to splice the mouse DNA into plasmids that were *outside* the *E. coli*, and only thereafter did the fully engineered plasmids enter the bacteria. But in his subsequent study, Cohen wanted to show that the splicing could occur *within* the bacteria. He aimed to demonstrate that fragments of mouse DNA and fragments of plasmid DNA could be taken up by the bacteria and then joined together *inside* the bacterium. However, as we've seen, he failed to demonstrate that this process can occur through purely natural means because he induced the uptake through means that were highly unnatural. (These were the same means he'd employed in 1975 in order to get the fully engineered plasmids into the bacteria.) Moreover, he compounded the artificiality by cutting both the plasmid and mouse mitochondrial DNA with the same restriction enzyme to make it easier for them to fuse together after they entered the bacteria.

33 Quoted in Wright, Susan, *Molecular Politics: Developing American and British Policy for Genetic Engineering 1972-1982* (Chicago: University of Chicago Press, 1994), 82.

34 Itakura, K. et al., "Expression in Escherichia coli of a chemically synthesized gene for the hormone somatostatin," *Science* 198(4321) (Dec 9, 1977): 1056-63. When human insulin was produced from bacteria the following year, the same

set of techniques was employed (Crea, R. et al., "Chemical Synthesis of Genes for Human Insulin," *PNAS* 75, no. 12, 5765-69).

35 Fedoroff, N. and Brown, N.M., *Mendel in the Kitchen: A Scientist Looks at Genetically Modified Foods* (Washington, DC: Joseph Henry Press, 2004), 4-5.

36 One other species of soil bacteria, *Agrobacterium rhizogenes*, is known to have capacity for inducing plants to express some of its genes. The result is a malady termed "hairy root disease."

37 Ibid., 129.

38 In recent years, biotechnicians have found other promoters that are suited for some of their purposes; and several GE plants have been developed (or are in the developmental pipeline) that do not rely exclusively on the 35S, while some don't contain it at all. Further, some of these promoters derive from plants as well as viruses. Yet, as will be discussed in subsequent chapters, in almost every case, the inserted genes are still impelled to express in unnatural ways; and the regulatory integrity of the engineered organisms continues to be compromised.

39 Charles, Dan, *Lords of the Harvest: Biotech, Big Money, and the Future of Food* (Cambridge: Perseus, 2002), 75.

40 Ibid., 78.

41 Dr. Sherri Brown, quoted in *Milling and Baking News*, August 4, 1997, as cited in Kneen, B., *Farmageddon: Food and the Culture of Biotechnology* (British Columbia: New Society Publishers, 1999), 26.

42 Latham, J. R. et al., "The Mutational Consequences of Plant Transformation," *Journal of Biomedicine and Biotechnology* Article ID: 25376, (2006), 1-7.

43 Ibid., 3.

44 Quoted in Reese, A., *Genetically Modified Food: A Short Guide for the Confused* (London: Pluto Press, 2006), 46-47.

45 Srivastava, M., Eidelman, O. & Pollard, H.B., "Pharmacogenomics of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) and the Cystic Fibrosis Drug CPX Using Genome Microarray Analysis," *Mol. Med.* 5 (1999): 753-67. The researchers assessed a sample of 588 genes and found significant changes in 5% of them.

46 Schubert, D., "A different perspective on GM food," *Nat Biotechnol* 20 (2002): 969.

47 Personal communication from David Schubert.

48 See discussion in: Clark, E. Ann, "Parliamentarians and Technology: Meeting the Challenges for the New Millennium, Workshop on Ensuring Food Safety," uoguelph.ca, May 9, 2000: http://www.uoguelph.ca/plant/research/homepages/eclark/Hc.htm. See also Document #4 at: http://biointegrity.org/24-fda-documents

49 Ordinarily, only a relatively small number of an organism's genes are continuously active; and they are the ones whose products are constantly required. It's unnatural for a gene to be expressed during times when there's no need for its product.

50 Elmore et al., "Glyphosate-Resistant Soybean Cultivar Yields Compared with Sister Lines," *Agron J* 93 (2001): 408-12.

51 Wilson, A., J. Latham, and R. Steinbrecher, "Genome Scrambling -Myth or Reality? Transformation-Induced Mutations in Transgenic Crop Plants," *Technical Report* (October 2004): 1, http://www.econexus.info/taxonomy/term/12.

52 *Lords of the Harvest* (cited in note 39), 85.

53 See e.g., Kaeppler et al., "Epigenetic aspects of somaclonal variation in plants," *Plant Molecular Biology* 43 (2000): 179–88; 181.

54 Although tissue culture is used in embryo rescue too, because a seed is involved, there tend to be less perturbations than when genetically engineered cells are cultured. Chapter 9 provides further discussion of the risks of tissue culture in producing GE crops.

55 Finnegan, H. and McElroy, "Transgene inactivation: plants fight back!" *Biotechnology*, 12 (1994): 883-88.

56 Hansen, Michael, "Genetic Engineering is Not an Extension of Conventional Plant Breeding," Consumer Policy Institute/Consumers Union, Jan. 2000, http://www.mindfully.org/GE/GE-Not-Ext-Michael-Hansen.htm.

57 Ibid.

58 Lambrecht, Bill, *Dinner at the New Gene Café: How Genetic Engineering Is Changing What We Eat, How We Live, and the Global Politics of Food,*(Thomas Dunne Books: St. Martin's Press, New York, 2001), ix.

59 Fox, M. W., *Superpigs and Wondercorn* (New York: Lyons and Burford, 1992), 102 and 117; Commoner, Barry, "Unraveling the DNA Myth: The spurious foundation of genetic engineering," *Harper's* (February 2002).

60 *Superpigs and Wondercorn* (cited above), 102.

61 Ibid.

62 Jabed, A. et al., "Targeted microRNA expression in dairy cattle directs production of β-lactoglobulin-free, high-casein milk," *PNAS* 109, no. 42 (2012): 16811-16, http://www.pnas.org/content/109/42/16811.full.

63 Reddy, A.S., Thomas, T.L., "Modification of Plant Lipid Composition: Expression of a Cyanobacterial D6 – desaturase Gene in Transgenic Plants," *Nature Biotechnology* 14 (1996): 639-42.

64 Inose, T. and Murata, K., "Enhanced Accumulation of Toxic Compound in Yeast Cells Having High Glycolytic Activity: A Case Study on the Safety of Genetically Engineered Yeast," *International Journal of Food Science and Technology* 30 (1995): 141-46.

65 "Making Crops Make More Starch," BBSRC Business, UK Biotechnology and Biological Sciences Research Council, January 1998, 6-8.

66 Yamada, Ken, "Genetic Vegomatics Splice and Dice With Weird Results," *Wall Street Journal* 18 (April 1992).

67 *Mendel in the Kitchen,* op. cit. note 35, x; also back cover.

68 Nina Fedoroff quoted at http://sciblogs.co.nz/guestwork/2010/02/15/is-genetic-engineering-just-like-breeding/ (accessed April 11, 2012).

69 Within recent years, evidence has accumulated indicating that, although still rare compared to point mutations, larger mutations that lead to adaptive

change occur more frequently than biologists had recognized. *See* Shapiro, James, *Evolution: A View from the 21st Century* (FT Press, 2011). However, there are significant differences between such natural changes and those induced by the artificial modes of bioengineering.

70 Even when breeders intentionally induce mutations with radiation or chemicals, the selected changes are usually small and could have occurred through natural means. No alien promoters are introduced, nor are several other hazards imposed that are inherent to rDNA technology. Such purposely induced mutations are more thoroughly discussed in Chapter 9 and Appendix D.

71 Dreifus, C., "A Conversation With Nina V. Fedoroff," *New York Times*, August 19, 2008.

72 Although she does say that "a gene from a bacterium can, with the proper switches added, work in a plant cell", she is evidently referring to the promoters and terminators that must be added, not to the codons that require revision. Moreover, she goes on to make a misleading statement about the results of such cross-kingdom transfers. She asserts: "The plant cell will make the *very same* protein from that gene that the bacterium made." (*Mendel in the Kitchen,* op. cit., note 35, 91. [*emphasis added*]) However, as will be discussed in Chapter 6, plants can add sugar chains to these proteins that are never added by bacteria; and these changes could render the protein toxic or allergenic.

73 Although an experiment that combined different species of tobacco via grafting resulted in transfer of chloroplast DNA from cells in one section of the grafted plant to cells in the other, this phenomenon, too, significantly differs from what occurs in genetic engineering. (Stegemann, S. and Bock, R., "Exchange of Genetic Material Between Cells in Plant Tissue Grafts," *Science*, vol. 324, no. 5927 [May 1, 2009]: 649-51.)

Chloroplasts are small units within plant cells that perform *photosynthesis*, the process through which the energy in sunlight is transformed into the plant's food. Like mitochondria (the cell's power houses), chloroplasts possess their own genomes; and their genomes are substantially different from those that reside in the cellular nucleus.

In this grafting experiment, none of the nuclear DNA transferred between the genetically distinct cells. It all stayed at home. Nor did any of the mitochondrial genes relocate. The only genes that moved across the graft junction were those of chloroplasts. And they did not move piecemeal. A large section of chloroplast DNA (perhaps all of it) moved as a unit and functioned as a unit in its new cellular location, performing essentially the same useful function as the cell's native chloroplasts. And these genes operated within chloroplasts, not within the nucleus. This phenomenon contrasts starkly with genetic engineering, where isolated segments of nuclear DNA from one species are wedged into the nuclear DNA of another species – and then act independently of their neighbors in performing unregulated activities that are alien to the host cell.

Further, for transfer of chloroplast DNA to occur via grafting, not only must the biological distance between the species be small (again in contrast to GE), so must the physical distance between the cells that are involved. Only cells in close proximity to the splice junction between the two parts of the plant are involved in the transfer. Thus, the phenomenon is restricted to a tiny fraction of the total cells, whereas in most engineered plants, all the cells contain some DNA that was transferred from another species.

Moreover, a search I performed did not detect any published reports of such transfers occurring in grafts involving other species, so it's possible the phenomenon is restricted to tobacco plants.

74 When I refer to genes in their "natural" state, I'm denoting genes whose internal chemical structure has not been directly reconfigured by human artifice in a way that could never otherwise occur. According to this denotation, the genes restructured via recombinant DNA technology are unnatural whereas most of those mutated via intentional application of ionizing radiation are not, because the same types of radiation-induced mutations could have occurred via natural sources of radiation, without any human intervention. Of course, if the dose of radiation is much greater than would ordinarily be received absent human intervention, then unusual mutations that result would be considered unnatural. Further, even in most of the cases where the individual mutations are not deemed unnatural, the overall pattern of mutations would be, because the entire seed would have been subjected to an extraordinary application of radiation. Even so, as Chapter 9 and Appendix D discuss, the use of radiation in plant breeding significantly differs from genetic engineering – and entails a lower level of risk.

75 *Mendel in the Kitchen*, op. cit. note 35, 127. In her exact words: "It is as natural – or as artificial – as an apple tree." Although the specific reference is to the recombinant DNA molecule, it logically extends to the organism in which that molecule functions.

76 Ibid.

77 Even when branches from several different species are grafted onto the same root stock, the various fruits remain on separate branches in the mature tree, and their respective genes do not intermingle. Further, although it may be possible for chloroplast DNA to move between the sections of a grafted tree (as can occur in grafted tobacco plants, described in note 73 above), it appears that no such cases have been observed. Moreover, even if such transfers do occur in trees, they wouldn't "combine" genes from different species. According to the American Heritage Dictionary of the English Language (4th Edition), to "combine" is "to bring into a state of unity," to "merge," "to join (two or more substances) to make a single substance." But, although foreign genes *are* joined to form a single molecule in bioengineering, when chloroplast genes move to chloroplasts in a neighboring foreign cell, they do not suddenly enter the nucleus and merge with its DNA. And even though, over the lifetime of the tree, it's possible that a few foreign chloroplast genes would migrate to the nucleus that would hardly make grafting a

significant combiner of foreign genes. This is especially so considering that only a miniscule fraction of the tree's cells (those along the splice junction) would even be candidates for such combination. Further, there would be no migration of foreign genes into the leaves or fruit.

There's another important point. When Fedoroff wrote her book, there was no evidence to suggest grafting might enable even the trivial level of foreign gene transfer just discussed. Her book was published in 2004, and the experiment showing the transfer of chloroplast DNA in grafted tobacco plants wasn't published until 2009. Thus, at the time she made it, Fedoroff's claim that grafting combines foreign genes was not even *remotely* supported by the known evidence; and it conflicted with the prevailing scientific consensus – which indicates her willingness to ignore (and even contradict) the best available biological knowledge in order to promote GE foods.

78 *Mendel in the Kitchen,* op. cit. note 35, 123-27.

79 Ibid., 127.

80 For one thing, the bacteria don't ordinarily attack the region where the gametes form. Moreover, if somehow a gamete did become infected and then survived to participate in forming an embryo, if the bacterial tumor-inducing genes were active, the embryo would probably become tumorous – as would any cells derived from it. So it's highly unlikely that a mature organism would ever emerge with a functional gene from *A. tumefaciens*.

Further, although there's another species of soil bacteria, *Agrobacterium rhizogenes*, that also inserts some of its genes into plants (inducing a malady known as "hairy root disease"), and although there's evidence implying that in the distant past it transferred four of these genes into the germ line of a tobacco species, there's no evidence that any of the proteins they code for is being expressed (Aoki, S. and Syono, K., "Horizontal gene transfer and mutation: Ngrol genes in the genome of Nicotiana glauca," PNAS 96, no. 23 [Nov. 9, 1999]: 13229–34).

Recent research confirms that transfer of *Agrobacteria* genes to the germ line of plants is indeed extremely rare. In a study published in December 2012 to determine if any plant species besides tobacco contained such genes, 127 were screened and *none* was found to contain any genes from *A. tumefaciens*. Further, only one of them was observed to contain some DNA from *A. rhizogenes* – and that DNA is apparently not being expressed. (Matveeva, T. et al., "Horizontal Gene Transfer from Genus Agrobacterium to the Plant Linaria in Nature," *Mol Plant Microbe Interact* 25, no. 12 [December 2012]: 1542-51).

81 Although *Agrobacteria* have been used to create more varieties of GE food than the gene gun, because the latter has been used to create commercialized GE corn and soy, it has produced the greatest volume of GE organisms actually consumed.

82 ANZFA Occasional Paper Series No. 1, *GM foods and the consumer* (June 2000): 28. When the guide was released, the agency was called the Australia/New

Zealand Food Authority (ANZFA). In July, 2002, it was renamed Food Standards Australia New Zealand (FSANZ).

83 On February 15, 2001 I met with ANZFA's chief scientist, biotechnology manager, and general standards manager for almost two hours and informed them about the false statement regarding promoters, as well as some other errors the document contained. They invited me to submit further comments to them at their personal email addresses. On July 25, 2001 I sent them formal comments more fully explaining these falsehoods. It is evident that they read my comments, and I also sent them to several other officials within the agency.

Nonetheless, the agency continued to distribute the document in pamphlet form for many months after being informed of the errors; and as of September 12, 2002, more than a year later, it was still offering the document on its website for downloading with the false statements intact. This indicates a severe lack of integrity, since making corrections to the digital version would have been quite simple. (The uncorrected document may well have been available long thereafter, but I stopped checking at that point. I don't know how many more months or years elapsed before it was finally removed.)

84 Neither the first edition of Baines' book, published in 1993, nor the second edition, published in 1998, even mentioned the term "promoter," although they did indicate that a foreign gene would generally not express within the host cell without being given a suitable "genetic context" (as in p. 132 of the first edition). And, while the third edition (in 2004) does enlarge this discussion by noting that an "appropriate" promoter sequence must be part of the context, there's still no indication that, in a transgenic plant, the promoter is derived from a virus – or that as a result, the expression of the foreign gene is completely deregulated.

85 Ronald, P. and Adamchak, R., *Tomorrow's Table: Organic Farming, Genetics, and the Future of Food* (New York: Oxford University Press, 2008), xiii. The quotes from the journals appear on the book's front and back cover.

86 The index has no entry for "promoter" or "cauliflower mosaic virus," and in my reading of the book, I found no reference to either of them in the main text. The only appearance of the word "promoter" that I discovered is within the definition of "transgene" in the glossary at the back of the book. According to the pertinent sentence, "Along with the genes of interest, may contain promoter, other regulatory, and marker genetic material." (p. 177) However, because the term "promoter" has (as far as I could ascertain) not been previously defined or discussed (there's not even an entry for it in the glossary), most readers would not even know what a promoter is. And even if someone did already understand a promoter's general role in gene expression, this sentence implies that the gene's native promoter is transferred along with it. There's no indication that virtually all the foreign genes inserted in commercialized GE crops are attached to a powerful promoter derived from a plant virus.

87 The terms "particle bombardment," "bioballistics," and "gene gun" are not in the index and, to my knowledge, they don't appear in the rest of the book either.

88 *Field Testing Genetically Modified Organisms: Framework for Decisions*, The National Academy of Sciences (1989), 14.

89 Antoniou, Michael, quoted in Smith, Jeffrey, *Genetic Roulette* (Fairfield, IA: Yes!Books, 2007), 8.

90 The bizarre statement appears in the report's introduction. As Chapter 2 noted, the introduction was written by NRC staff, not by the university scientists who wrote most of the rest of the report.

91 Grace, Eric., *Biotechnology Unzipped* (Washington, DC: Joseph Henry Press, 1977), xiii. The Joseph Henry Press is an imprint of the National Academies Press.

92 Ibid., xiii-xiv.

93 Ibid., 45.

94 Ibid., 29.

95 Ibid., xv. While Fedoroff was not on the review team that interacted with Grace, she was sent a review copy so that she could write a comment about the book (email from Eric Grace).

96 The email to him was sent on March 1, 2012; he replied on March 5.

97 The Dr. Oz Show, December 7, 2010: http://www.doctoroz.com/videos/genetically-modified-foods-pt-3.

98 *Mendel in the Kitchen*, op. cit. note 35, xii.

99 There were only two other speakers that morning: a Monsanto official to represent the views of the biotech industry and an executive from a public interest organization to represent the viewpoint of consumers.

100 Alliance for Bio-Integrity/ICTA Press Conference, National Press Club, Washington D.C., May 27, 1998.

5. Illegal Entry

1 Regal, Philip, "Are Genetically Engineered Foods Safe? A Scientist's Quest for Biosafety": http://www.iatp.org/files/Are_Genetically_Engineered_Foods_Safe_A_Scient.htm.

2 Ibid.

3 Lloyd, T., "Monsanto's new gambit: Fruits and veggies," *Harvest Public Media*, April 8, 2011: http://bit.ly/LQTNxp

4 Goodman, M.M., "New sources of germplasm: Lines, transgenes, and breeders." Paper presented at: Memoria Congresso Nacional de Fitogenetica; 2002; Univ. Autonimo Agr. Antonio Narro, Saltillo, Coah., Mexico.

5 Millstone et al., "Beyond 'substantial equivalence,'" *Nature* (Oct. 7, 1999) estimated that a combination of short and medium-term tests would cost at least an additional $25 million; and Dr. Millstone informed me that full long-term testing would be significantly more expensive – and that if multi-generational testing were included, the cost would be even higher. Because Major Goodman put the cost of developing a GE crop at around $60 million (absent any toxicological testing), adding $25 million to the cost would amount to an increase of over 40% (See Goodman, 30).

6 Regal, op. cit., note 1.

7 For a basic history of the regulation of food, see http://www.fsis.usda.gov/Fact sheets/Additives_in_Meat_&_Poultry_Products/index.asp (accessed April 26, 2012).

8 "Profiles in Toxicology," *Toxicological Sciences* 70, (2002): 159-60: http://toxsci.oxfordjournals.org/content/70/2/159.full.pdf; accessed April 26, 2012.

9 S. Rep. 2422, 1958 U.S.C.C.A.N. 5301- 2.

10 21 U.S.C. § 321

11 Although one of the provisions of the 1958 reforms (the so-called Delaney Act) was repealed by Congress in 1996 that did not change the fundamentals of the food additive requirements.

12 Document #4 at: http://biointegrity.org/24-fda-documents

13 Ibid. All the quotes in this paragraph are from #4.

14 Ibid.

15 Document #5 at: http://biointegrity.org/24-fda-documents

16 Document #2 at: http://biointegrity.org/24-fda-documents

17 Comments from the Division of Food Chemistry and Technology and the Division of Contaminants Chemistry, "Points to Consider for Safety Evaluation of Genetically Modified Foods. Supplemental Information" (November 1, 1991). Document #6 at: http://biointegrity.org/24-fda-documents

18 Ibid. This statement is in a section that is not reproduced on the Alliance for Bio-Integrity website. Its page number in the FDA administrative record (A.R.) for the lawsuit is 18613, and this is the way it was referenced in the briefs that were filed with the Court.

19 The statement cited is at page 18744 of the administrative record.

20 Document #9 at: http://biointegrity.org/24-fda-documents

21 Document #10 at: http://biointegrity.org/24-fda-documents

22 Ibid., at A.R. 18990-91.

23 Document #7 at: http://biointegrity.org/24-fda-documents

24 Document #1 at: http://biointegrity.org/24-fda-documents

25 Eichenwald et al., "Biotechnology Food: From Lab to Debacle," *New York Times*, January 25, 2001. In this article, executives who directed Monsanto's policy during the 1980's purported that they had pushed for meaningful regulation from 1986 until the early 1990's, when "a new management team" took over, decided to reverse course, and convinced the White House that it should scrap plans for such regulation. However, this account is suspect. It does not square with Regal's observations of the realities during the late 1980's, and it's also dubious in light of the industry's persistent anti-regulatory efforts during the previous years. As earlier chapters have shown, the industry has consistently endeavored to avoid regulation while projecting the illusion that responsible regulations were in place. Accordingly, one could reasonably surmise that the Monsanto executives interviewed for the article were attempting to shift blame for the company's unpopular policies to their successors – and that whatever differences existed between their agenda and the one pursued in the early 90's were not about whether meaningful regulations

should be implemented but about how best to create the impression that they had been.

26 "What Would You Do with a Fluorescent Green Pig?," Ecology Law Quarterly 201, no. 34 (2007): 238.

27 Document #1 at: http://biointegrity.org/24-fda-documents. In her memo, Dr. Kahl stated that this forced conclusion "is because of the mandate to regulate the product, not the process," p. 2.

28 Document #4 at: http://biointegrity.org/24-fda-documents

29 Document #21 at: http://biointegrity.org/24-fda-documents

30 Document #23 at: http://biointegrity.org/24-fda-documents

31 Document #24 at: http://biointegrity.org/24-fda-documents

32 The letterhead on his stationery says: Executive Office of the President
Office of Management and Budget

33 "From Lab to Debacle," op. cit. note 25.

34 "Statement of Policy: Foods Derived From New Plant Varieties," May 29, 1992, *Federal Register* 57, no. 104, sec. VI.

35 Ibid., 22991.

36 21 U.S.C. § 321(s)

37 The text of the statute states that the substance must be ". . . generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use . . . . ," 21 U.S.C. § 321(s).

38 The agency did not extend the presumption to genes that are known to produce a toxin or an allergen. But manufacturers would want to avoid such genes anyway.

39 Document #8 at: http://biointegrity.org/24-fda-documents.

40 21 CFR Sec. 170.30(b); 21 CFR 170.3(i)

41 21 CFR Sec. 170.30 (b)

42 Document #1 at: http://biointegrity.org/24-fda-documents

43 Document #19 at: http://biointegrity.org/24-fda-documents. "FDA Regulation of Food Products Derived from Genetically-Altered Plants: Points to Consider." The authorship of this document is not indicated, and it is also undated. However, its page numbers in the administrative record support an inference that it was written in July or August of 1991.

44 Ibid., at A.R. 18195.

45 Ibid., at A.R. 18196.

46 Maryanski, J., "Safety Assurance of Foods Derived by Modern Biotechnology in the United States," July 1996. In January 1999, the FDA affirmed that it still was not conducting scientific reviews, stating: "FDA has not found it necessary to conduct comprehensive scientific reviews of foods derived from bioengineered plants . . . consistent with its 1992 policy" (Reported in *The Lancet* 353 (May 29, 1999): 1811.)

For a detailed discussion of the unreliability of the FDA's voluntary program, see Freese, W. and D. Schubert, "Safety Testing and Regulation of Genetically Engineered Foods," Biotechnol Genet Eng Rev. 21 (2004): 299-324.

47 Lacey Declaration, *Alliance for Bio-Integrity v Shalala*.

48 Regal Declaration, *Alliance for Bio-Integrity v Shalala*. http://alteredgenes twistedtruth.com/declaration-of-philip-regal/.

49 Defendants' Opposition to Plaintiffs' Cross Motion for Summary Judgment, 1.

50 *Alliance for Bio-Integrity v. Shalala.,* 116 F. Supp. 2d 166 (D.D.C. 2000) at 172-73.

51 116 F. Supp. 2d at 174, 175.

52 The exception is for foods containing genetic material transferred from one of the most commonly allergenic species. To date, it does not appear that any such food has come to market.

53 If the judge had ruled that the FDA had violated the Administrative Procedure Act by not holding formal notice and comment, or had violated NEPA by not performing an environmental assessment, it would also have meant that the FDA's policy had been implemented in violation of the law. But neither of these rulings would have cast doubt on the safety of GE foods for human consumption

54 116 F. Supp. 2d at 177; Citing 21 *C.F.R.* Sec. 170.30 (a-b); 62 Fed. Reg. 18940.

55 116 F. Supp. 2d at 177; Citing 62 *Fed. Reg.* At 18939.

56 116 F. Supp. 2d at 177

57 *United States v. Seven Cartons . . . Ferro-Lac*, 293 F. Supp. 660, 664 (S.D. Il. 1968*),* modified on other grounds, 424 F. 2d 136 (7th Cir. 1970).

58 *Statement of Policy: Foods Derived From New Plant Varieties*, May 29, 1992, Federal Register 57, no. 104 at 22991.

59 A.R. at 11723-24.

60 A.R. at 37744-45.

61 Document #8 at: http://biointegrity.org/24-fda-documents

62 Document #1 at: http://biointegrity.org/24-fda-documents

63 Ferro-Lac, 293 F. Supp. 660 (S.D. Il. 1968). Cited in note 57.

64 Ibid., at 664.

65 Ibid., at 665.

66 While some biotech proponents claim that a proposed rule the FDA introduced in 1997 independently legitimizes the presence of GE foods on the market, in actuality, it does not. That proposal aimed to simplify procedures through which manufacturers can interact with the agency in establishing the GRAS status of additives. (*Federal Register* 62 (1997): 18938-964) But it has never formally moved beyond the stage of a "proposed" rule. Although the FDA has been treating it as an "interim policy," it has not been finalized and lacks the force of law that officially enacted rules possess. So, despite what many people have been led to believe, it has no legal authority or effect. Accordingly, when the Alliance

for Bio-Integrity lawsuit was litigated in 1998-99, the FDA did not try to assert the relevance of that proposed rule, and it is not mentioned in the court's opinion.

Moreover, that proposed rule makes no attempt to alter the two basic criteria that must be satisfied in order for an additive to validly possess GRAS status (technical evidence of safety and general recognition within the scientific community that such evidence in fact exists.) And, as the analysis in this chapter has demonstrated, neither of those criteria has ever been met by any GE food. So even if the rule *had* been finalized, it would not have rendered GE foods GRAS.

67 21 U.S.C. § 321(n)

68 116 F. Supp. 2d at 179.

69 Defendants' Opposition to Plaintiffs' Cross Motion for Summary Judgment, pp. 2 &4.

70 "Proposed Rules," *Federal Register* 66, no. 12 (January 18, 2001): 4709.

71 Ibid., 4710.

72 Ibid.

73 Ibid.

74 Ibid., 4710-11.

75 Ibid., 4711.

77 *Temp. Envtl. L. & Tech. J.* 225 (2000-2001): 19. Although this piece is 17 pages in length, in law review parlance, it's referred to as a "note" and not an article, because law review articles are not authored by law students and are much longer. But I'm referring to it as an article, since most readers would be misled by the term "note" into thinking that the piece is much shorter than it is.

77 Ibid., 229-30. It's noteworthy that although the author uncritically accepted the judge's erroneous rulings regarding the GRAS issue, she critiqued her handling of the labeling issue. This indicates that her acquiescence in the former was not due to excess deference but to deep confusion.

78 E.g., 22 *Rev. Litig.* 669 at 681 (2003); 22 Berkeley Tech, *L.J.* 671 at 698 (2007) (discussed at note 80).

79 34 Ecology L.Q. 201 (2007) at 224

80 22 Berkeley Tech., *L.J.* 671 at 695. The article stated that in contrast to the EU, "[t]he U.S. policy . . . is that GMOs should be permitted to flourish in the absence of proven hazards." Although this statement referred to food safety as well as the environment, there was not even a hint that the policy violates explicit mandates of the law – and illegally shifts the burden of proof to those who question the safety of GE foods.

This article also implied that we failed to present evidence of expert conflict. Its superficial (and somewhat misleading) statements about our lawsuit appear on p. 698 in the main text and also in note 156.

81 Lambrecht, Bill, *Dinner at the New Gene Café: How Genetic Engineering Is Changing What We Eat, How We Live, and the Global Politics of Food* (Thomas Dunne Books: St. Martin's Press, New York (2001), 51.

82 Glickman, Dan, quoted in Simon, Stephanie, "Biotech Soybeans Plant Seed of a Risky Revolution," *Los Angeles Times*, July 1, 2001.

83 Glickman, Dan, quoted at http://eap.mcgill.ca/MagRack/RH/RH_E_97_02.htm (accessed 6-14-12)

84 Glickman, Dan. March 1999. Quoted at: http://www.ces.ncsu.edu/depts/foodsci/ext/pubs/biotech.html (accessed: 7-17-12)

85 Pickett, M., "Ag Official Defends Rules for Biotech Crops," *Billings Gazette*, November 23, 2004.

86 Shacinda, S., "U.S. Needs Good Plan to Give AIDS Funds-health Chief," *Reuters*, December 1, 2003.

87 Lambrecht, B., "Outgoing Secretary Says Agency's Top Priority is Genetically Modified Food," *St. Louis Post- Dispatch*, January 25, 2001.

88 Clinton, Bill, Conference call with farm radio broadcasters from Hermitage, Arkansas (as reported by *Reuters*, November 5, 1999).

89 *Statement of Policy: Foods Derived From New Plant Varieties*, May 29, 1992, Federal Register 57, no. 104. See the discussion in Section V.

90 US Department of Health and Human Services. Press Release. May 3, 2000.

91 FDA quoted in: "Health Risks of Genetically Modified Foods," *The Lancet* 353, no. 9167 (May 29, 1999): 1811.

92 Weise, E., "FDA Tries to Remove Genetic Label Before it Sticks," *USA Today*, October 9, 2002.

93 Cole, M., "FDA Objects to Food Labeling Initiative," *Crop Choice News*, October 9, 2002, http://www.cropchoice.com/leadstry6df6.html?recid=1028.

94 Statement of Robert E. Brackett, Ph.D., Director, Center for Food Safety and Applied Nutrition before the Senate Committee on Agriculture, Nutrition and Forestry, June 14, 2005: http://www.fda.gov/NewsEvents/Testimony/ucm112927.htm (accessed: 7-17-12).

95 Leahy, Stephen, "Crop Testing Rules Menace Food Supply, Say Critics," IPS News Agency, November 25, 2004.

96 Ibid.

97 Philpott, Tom. Monsanto's man Taylor returns to FDA in food-czar role, *GRIST*, July 8, 2009. Taylor's most recent return to the agency was not made directly from Monsanto. After serving as one of the corporation's vice presidents, he worked for a few other organizations prior to rejoining the FDA.

98 http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/ucm196721.htm

99 Personal communication from Dr. Marion Healy, ANZFA Offices, Canberra, AU, February 15, 2001.

6. Globalization of Regulatory Irregularity

1 Millstone, E. et al., *"Beyond 'substantial equivalence'," Nature*, October 7, 1999.

2 Ibid.

3 Ibid.

4 Clark, E. Ann, "Food Safety of GM Crops in Canada: toxicity and allergenicity," GE Alert, 2000.

5 Faust, Marjorie, "Biotech Crops for the Dairy and Livestock Industries," *Proceedings of the 2001 California Animal Nutrition Conference*, 76-86.

Although by 2001, there had been tests in which animals were fed the whole GE food, they were not the kinds of tests the FDA experts had called for. Either they aimed to discover whether the foreign DNA and the resultant foreign protein that get implanted in the crops are later found in the animals, or they were designed as nutritional feeding studies, which gauge how well the animals grow but do not assess toxicological effects in a thorough manner. Chapter 10 discusses how biotech promoters have misrepresented the relevance of such studies.

6 "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada; An Expert Panel Report on the Future of Food Biotechnology prepared by The Royal Society of Canada at the request of Health Canada Canadian Food Inspection Agency and Environment Canada," The Royal Society of Canada, January 2001.

7 Calamai, P., "Ottawa Rapped, Expert Study Considered Major Setback for Biotech Industry," *Toronto Star*, February 5, 2001.

8 "Elements of Precaution," op. cit. note 6.

9 Ibid.

10 "Ottawa Rapped," op. cit. note 7.

11 Personal communication from Lucy Sharratt, Coordinator, Canadian Biotechnology Action Network, June 28, 2012.

12 Smith, Jeffrey, *Seeds of Deception: Exposing Industry and Government Lies About the Safety of the Genetically Engineered Foods You're Eating* (Fairfield, IA: Yes! Books, 2003), 7-9.

13 Ibid., 9.

14 The organization's name was subsequently changed to Food Standards Australia New Zealand (FSANZ).

15 Comments to ANZFA about Applications A346, A362 and A363 from the Food Legislation and Regulation Advisory Group (FLRAG) of the Public Health Association of Australia (PHAA) on behalf of the PHAA (October, 2000).

16 GE proponents might argue that changes between the GE plant and the control line might not necessarily be the results of the gene insertion but of the somaclonal variation that usually accompanies the generation of plants via tissue culture. However, even if the changes were due to tissue culture, that process is an essential part of plant genetic engineering. Therefore, unless rigorous testing eventually demonstrated that the changes were harmless, it would be proper to regard them as potential risks of the bioengineering process. Tissue culture and somaclonal variation will be more thoroughly discussed in Chapter 9.

17 Comments to ANZFA about Applications A372, A375, A378 and A379 from the Food Legislation and Regulation Advisory Group (FLRAG) of the Public Health Association of Australia (PHAA) on behalf of the PHAA (April 2001).

18 PHAA Report of 2000 (emphasis in original).

19 Millstone et al., op. cit. note 1.

20 Ibid.

21 Kawata, Masaharu ,"Inspection of the Safety Assessment of the Roundup Tolerant Genetically Modified Soybean: Monsanto's Dangerous Logic as seen in the Application Document submitted to Japan." The report was originally published in the Japanese journal *Technology and Human Beings*, vol.11 (Nov. 2000): 24-33. As of November 2014, it was available at: http://www.mindfully.org/GE/GE2/Monsanto-Safety-Japan-Inspection.htm

22 http://www.biosafety-info.net/article.php?aid=22 (accessed: July 5, 2012). Although the differences were not statistically significant, the 8% mortality rate was double the usual rate in the UK broiler chicken industry.

23 Ibid.

24 Ibid.

25 Lean, Geoffrey, "Europe Split Over Safety of GM Corn," *The Independent*, December 21, 2003.

26 Smith, Jeremy, "EU Lifts Biotech Ban," *Reuters*, May 19, 2004. See also: http://www.gmo-safety.eu/archive/218.moratorium-ends.html (accessed: June 22, 2012).

27 Ibid.

28 It's probable that the commissioner (David Byrne) was not intentionally deceiving the public but believed what he said because he himself had been deceived by pro-biotech forces. In fact, in light of his prior history, it's most reasonable to assume that this was the case.

29 Schubert, David, "A Different Perspective on GM Food," *Nature Biotechnology*, vol. 20, no.10, October 2002, 969: http://www.biotech-info.net/different_perspective.html

30 The transfer of the protein from bean to pea is described in: Shade, R. E. et al., "Transgenic pea seeds expressing the alpha-amylase inhibitor of the common bean are resistant to bruchid beetles," *Biotechnology* 12 (1994): 793-796.

The research that discovered the adverse effects occurred several years later and is described in: Prescott, V.E. et al, "Transgenic expression of bean alpha-amylase inhibitor in peas results in altered structure and immunogenicity," *Journal of Agricultural Food Chemistry* (2005) Nov 16;53(23): 9023-9030.

31 The test that's commonly used is the SDS gel test. The more sensitive test is the MALDI-TOF test.

32 Commoner, Barry, "Unraveling the DNA Myth: The spurious foundation of genetic engineering," *Harper's Magazine*, Feb 2002.

33 However, Mad Cow Disease has not resulted from genetic engineering; and although it can be induced by feeding cattle diseased tissue from sheep (thereby transgressing a natural boundary by crossfeeding), there is no known link between it (or any of its related diseases) and crossbreeding.

34 Hagan, N. et al., "The redistribution of protein sulfur in transgenic rice expressing a gene for a foreign, sulfur-rich protein," *Plant J*. 34 (2003): 1–11. This study is more extensively discussed in Chapter 9, note 111.

35 Gurian-Sherman, Doug, "Holes in the Biotech Safety Net," Center for Science in the Public Interest (2003), 14: cspinet.org/new/pdf/fda_report__final.pdf. *Note:* The report provides citations to the scientific studies that support Gurian-Sherman's assertions. For a major review published since his report, see: Latham, J., Wilson A. and Steinbrecher, R., "The Mutational Consequences of Plant Transformation," *Journal of Biomedicine and Biotechnology*, vol. 2006, Article ID 25376, 3. Chapter 9 discusses the messiness of the insertional process in more detail.

36 Ibid.

37 The first GE crop (a tomato) was commercialized in 1994.

38 Podevin, N. and du Jardin, P., "Possible consequences of the overlap between the CaMV 35S promoter regions in plant transformation vectors used and the viral gene VI in transgenic plants," *GM Crops Food* 3 (2012): 296–300; doi:10.4161/gmcr.21406.

39 De Tapia, M. et al., "Molecular dissection of the cauliflower mosaic virus translation transactivator," *EMBO J* 12 (1993): 3305-14.

40 Takahashi, H., Shimamato, K., Ehara, Y., "Cauliflower mosaic virus gene VI causes growth suppression, development of necrotic spots and expression of defence-related genes in transgenic tobacco plants," *Mol Gen Genet*. 216 (1989): 188–94.

41 Park, H.S., Himmelbach, A., Browning, K.S., Hohn, T., Ryabova, L.A., "A plant viral 'reinitiation' factor interacts with the host translational machinery," *Cell*. 106 (2001): 723-33.

42 Haas, G., Azevedo, J., Moissiard, G., Geldreich, A., Himber, C., Bureau, M., et al., "Nuclear import of CaMV P6 is required for infection and suppression of the RNA silencing factor DRB4," *EMBO J* 27 (2008): 2102-12.

43 http://www.independentsciencenews.org/commentaries/regulators-discover-a-hidden-viral-gene-in-commercial-gmo-crops/

44 http://www.efsa.europa.eu/en/faqs/faqinsertedfragmentofviralgeneingmplants.htm

http://archive.foodstandards.gov.au/consumerinformation/gmfoods/gmfactsheetsandpublications/gmfoodsandtheuseofdn5796.cfm

45 http://independentsciencenews.org/commentaries/gmo-regulators-hidden-viral-gene-vi-regulators-fail/

46 The Science and Environmental Health Network made the observation. Quoted at: http://www.precaution.org/lib/pp_def.htm)

47 The statute exempts specific classes of substances from being defined as "additives," such as pesticidal chemicals, which are regulated under the provisions of a different statute. See: 21 U.S.C. § 321(s).

48 Communication of April 30, 1997 on consumer health and food safety (COM(97) 183 final).

49 Resolution of March 10, 1998 on the Green Paper: General Principles of Food Law in the EU.

50 EC Communication on the Precautionary Principle, Feb. 2, 2000, Reference 11.

51 EC Communication on the Precautionary Principle, Feb. 2, 2000.

52 Kok, E.J. and Kuiper, H.A.. "Comparative safety assessment for biotech crops," *Trends in Biotechnology* 21 (2003): 439–44.

53 Hilbeck, A., Meier, M., Römbke, J., Jänsch, S., Teichmann, H. and Tappeser, B., "Environmental risk assessment of genetically modified plants - concepts and controversies," *Environmental Sciences Europe* 23, no. 13 (2011).

54 Dalli, John., "GMOs: Toward a Better, More Informed Decision-Making Process," March 17, 2011.

55 Séralini et al., "Genetically modified crops safety assessments: present limits and possible improvements," *Environmental Sciences Europe*, 23, no. 10 (2011): http://www.enveurope.com/content/23/1/10/ (accessed July 12, 2012).

56 Ibid.

57 Ibid.

58 Fleming, J., "No risk with GMO food, says EU chief scientific advisor." EurActiv.com, July 24, 2012: http://www.euractiv.com/innovation-enterprise/commission-science-supremo-endor-news-514072 (accessed August 2, 2012).

59 The meeting took place in the ANZFA offices in Canberra. I subsequently emailed the participants a letter that summarized what they had said and critiqued their policy. I also requested that they inform me of any factual errors I might have made in my recounting of the meeting. Dr. Healy, the chief scientist, sent an email acknowledging receipt of my letter and did not object to any of my statements about what she had said. On September 6, 2001 I sent her an email stating: "When I sent my comments, I asked that you inform me of any factual misstatements you might find in them. Over a month has passed and you have not pointed out any such misstatements. Therefore, I assume you assent to the correctness of my statements of fact." Copies of my initial letter and my follow-up are available at: www. alteredgenestwistedtruth.com

60 ANZFA Occasional Paper, Series No. 1, *GM foods and the consumer* (June 2000). As previously noted, the agency's name was subsequently changed to Food Standards Australia New Zealand (FSANZ).

61 The degree to which the agency's officials have evaded the implications of adverse evidence, misrepresented the facts, and persisted in derelict practices is driven home in the two letters I emailed them subsequent to our meeting that are referred to in note 59.

62 Séralini et al. (2011), op. cit. note 55.

63 Ibid; the authors state that it was necessary to obtain court orders, but they don't provide the details. Some of the relevant ones are as follows. The three GE plants involved were varieties of maize (corn) produced by Monsanto: MON863, MON810 and NK603. At the time approval was first sought for these plants, a manufacturer initiated the process by applying to the appropriate regulatory agency in an EU member state. Because Monsanto claimed that the raw data was confidential, the regulatory agencies that possessed the data refused to release it to

the public, or to the researchers. But the courts ruled that the public had a right to see the data and ordered the regulators to release it.

64 Quoted in Smith, Jeffrey, "An FDA-Created Health Crisis Circles the Globe," 3: http://www.seedsofdeception.com/utility/showArticle/?objectID=1477

65 "Elements of Precaution," op. cit. note 6, 214.

66 "Throwing Caution to the Wind: A review of the European Food Safety Authority and its work on genetically modified foods and crops," *Friends of the Earth Europe* (November 2004): 3.

67 Ibid., 13.

68 Ibid.

69 Ibid.

70 Ibid., 13 & 14. These two pages are the source for the various assertions made in the paragraph.

71 Seralini et al., "New Analysis of a Rat Feeding Study with a Genetically Modified Maize Reveals Signs of Hepatorenal Toxicity," *Archives of Environmental Contamination and Toxicology* 52, no. 4 (May 2007): 596-602.

72 *Friends of the Earth Europe and Greenpeace*, "Hidden Uncertainties: What the European Commission doesn't want us to know about the risks of GMOs," April 2006.

73 Ibid.

7. Erosion of Environmental Protection

1 Ingham, Elaine, "Ecological Balance and Biological Integrity," posted at http://www.purefood.org/ge/klebsiella.cfm.

2 Doyle, J.D. et al., "Effects of genetically engineered microorganisms on microbial populations and processes in natural environments;" in, Neidleman, S., Laskin, A.J. (eds.), *Advances in Applied Microbiology*, vol. 40 (Academic Press, San Diego, CA, 1995), 237-87; see also, Short et al., "Effects of 2,4 dichlorophenol, a metabolite of a genetic engineered bacterium and 2,4 dichlorophenoxyacetate on some microorganism-mediated ecological processes in soil," Appl. Environ. Microbiol. 57 (1991): 412-18.

3 Jones, R.P., "Biological principles for the effects of ethanol," *Enzyme Microbiol. Technol.* 11 (1989): 130-53.

4 Ingham, E.R., Doyle, J.D., and Hendricks, C.W., "Effects of Klebsiella planticola SDF20 on soil biota and wheat growth in sandy soil," *Applied Soil Ecology* 11 (1999): 67-78.

5 In fact, when Michael Holmes, the graduate student who initiated the study, continued the research, he discovered that in some circumstances the GE bacteria could out-compete the parent strain. (Elaine Ingham, the professor who supervised and participated in the original research, informed me of this in a personal conversation. She said that these findings were described in Holmes' doctoral dissertation, which has not been published.)

6 Ingham, E., "Ecological Balance," op. cit. note 1; Ingham, E., Letter to the Editor: "Engineered Bacterium Could Have Serious Implications for Human Life on Earth," *Agribusiness Examiner*, Issue 119, June 11, 2001.

7 Suzuki, D. and Dressel, H., *From Naked Ape to Superspecies: Humanity and the Global Eco-Crisis* (Vancouver: Greystone Books, 2004), 121.

8 Ingham, E., quoted in Luke Anderson, *Genetic Engineering, Food and Our Environment* (White River Jct., VT: Chelsea Green, 1999), 39-40.

9 Ingham, E., Letter to the Editor, op. cit. note 6.

10 Ingham, "Ecological Balance" op. cit. note 1.

11 In this context, "regulators" refers to those with the authority and capacity to set policy. It is not meant to include all employees of the regulatory agencies. From 1983 to the present, there have been many members of these institutions who endeavored to pursue a genuinely science-based and responsible policy on GMOs. However, their collective influence has been insufficient to shape outcomes.

12 Anderson, Luke, op. cit. note 8, 40.

13 US General Accounting Office, *Biotechnology: Managing Risks of Genetically Engineered Organisms* (Government Printing Office [GAO/RCED-88-27, Washington D.C., 1988, 108 pp.])

14 PEER White Paper, "Genetic Genie: The Premature Commercial Release of Genetically Engineered Bacteria," September 21, 1995; re-issued, January 25, 2000.

15 Roslin, Alex, "Germs gone wild," *Georgia Straight*, July 21, 2005: http://www.ibiblio.org/london/SoilWiki/message-archives/JoeCummins/msg00517.html

16 PEER White Paper, op. cit. note 14, v.

17 Ibid., reporting on the comments of Suzanne Wuerthele.

18 PEER News Release, Jan. 26, 2000.

19 Pollack, Andrew, "Lax in Tests of Gene-Altered Crops," *New York Times*, January 3, 2006.

20 Brasher, Philip, "Report Blasts Oversight of Field Tests," *Des Moines Register*, Dec. 30, 2005.

21 Weiss, Rick, "U.S. Rice Supply Contaminated, Genetically Altered Variety Is Found in Long-Grain Rice," *Washington Post*, August 19, 2006; Weiss, Rick, "Firm Blames Farmers 'Act of God' for Rice Contamination," *Washington Post*, November 22, 2006; A05.

22 See for example, Doering, Christopher, "ProdiGene to spend millions on bio-corn tainting," *Reuters News Service, USA*, December 9, 2002.

23 Ibid. The corn got mixed with the soybeans, but it did not cross-pollinate them (an outcome that is biologically barred).

24 Smith, Jeffrey, *Institute for Responsible Technology Newsletter*, August 2006.

25 Press Release, Center For Food Safety, February 6, 2007: http://www.centerforfoodsafety.org/GTBC_DecisionPR_2_7_07.cfm

26 Séralini, G.E. et al., "Genetically modified crops safety assessments: Present limits and possible improvements," *Environmental Sciences Europe* 23(10) (2011);

Freese, W. & Schubert, D., "Safety testing and regulation of genetically engineered foods. *Biotechnol Genet Eng*. (rev. 2004): 299-324.

27 Castaldini, M. et al., "Impact of Bt corn on rhizospheric and soil eubacterial communities and on beneficial mycorrhizal symbiosis in experimental microcosms," *Appl Environ Microbiol*. 71(11) (Nov. 2005): 6719-29; Zwahlen, C. et al., "Degradation of the Cry1Ab protein within transgenic Bacillus thuringiensis corn tissue in the field," *Mol Ecol*. 12(3) (Mar 2003): 765-75.

28 Ibid.

29 Cheeke, T.E., Pace, B.A., Rosenstiel, T.N., Cruzan, M.B., "The influence of fertilizer level and spore density on arbuscular mycorrhizal colonization of transgenic Bt 11 maize (Zea mays) in experimental microcosms," *FEMS Microbiol Ecol*. 75(2)(Feb. 2011): 304-12; Cheeke, T.E., Rosenstiel, T.N., Cruzan, M.B., "Evidence of reduced arbuscular mycorrhizal fungal colonization in multiple lines of Bt maize," *American Journal of Botany.* 99(4) (2012): 700–07.

30 Tank, J.L., Rosi-Marshall, E.J., Royer, T.V., et al., "Occurrence of maize detritus and a transgenic insecticidal protein (Cry1Ab) within the stream network of an agricultural landscape," *PNAS* 27 (September 2010).

31 Rosi-Marshall, E.J., Tank, J.L., Royer, T.V., et al., "Toxins in transgenic crop byproducts may affect headwater stream ecosystems," *Proc Natl Acad Sci USA* 104(41) (Oct 9, 2007): 16204-08.

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33 Marvier, M. et al. "A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates," *Science* 316(5830) (June 8, 2007): 1475-77; Losey, J.E., Rayor, L.S., Carter, M.E., "Transgenic pollen harms monarch larvae," *Nature* 399(6733) (May 20, 1999): 214; Jesse, L.C.H. and Obrycki, J.J., "Field deposition of Bt transgenic corn pollen: Lethal effects on the monarch butterfly," *J. Oecologia* 125 (2000): 241–48; Lang, A. and Vojtech, E., "The effects of pollen consumption of transgenic Bt maize on the common swallowtail, Papilio machaon L. (Lepidoptera, Papilionidae)," *Basic and Applied Ecology* 7 (2006): 296–306; Ramirez-Romero et al., "Does Cry1Ab protein affect learning performances of the honey bee Apis mellifera L. (Hymenoptera, Apidae)?," *Ecotoxicology and Environmental Safety* 70 (2008): 327–33.

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35 Mellon, M., "Introduction," *Now or Never: Serious New Plans to Save a Natural Pest Control* (Union of Concerned Scientists, 1998), 2.

36 Gassmann AJ, Petzold-Maxwell JL, Keweshan RS, Dunbar MW. "Field-evolved resistance to Bt maize by Western corn rootworm." *PLoS ONE*. 2011; 6(7): e22629.

37 Ibid; Associated Press, "Monsanto shares slip on bug-resistant corn woes," August 29, 2011; Gray M., "Severe root damage to Bt corn confirmed in northwestern Illinois," *Aces News*, August 24, 2011.

38 Fagan, J., Antoniou, M.C., and Robinson,C., *GMO Myths and Truths: An Evidence-Based Examination of the Claims Made for the Safety and Efficacy of Genetically Modified Crops*, 2nd Edition, version 1.0, (London: Earth Open Source, 2014), 249.

39 Freese, Bill, "Going Backwards: Dow's 2,4-D-Resistant Crops and a More Toxic Future," *Food Safety Review* (Spring 2012), 1: http://www.centerforfoodsafety.org/wp-content/uploads/2012/04/CFS_FSR_spring_2012.pdf

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43 Neuman and Pollack (2010), op. cit. note 42.

44 Benbrook (2009), op. cit. note 40.

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46 AAPCO (1999 & 2005), "1999/2005 Pesticide Drift Enforcement Survey," Association of American Pesticide Control Officials, survey periods 1996-1998 and 2002-2004, respectively.

47 Freese (2012), op. cit. note 39, 2.

48 Ibid.

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50 Gasnier, C., Dumont, C., Benachour, N., Clair, E., Chagnon, M.C., Seralini, G.E., "Glyphosate-based herbicides are toxic and endocrine disruptors in human cell lines," *Toxicology* 262(3) (August 21, 2009): 184-91.

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52 Food Standards Agency, *About mycotoxins*, undated: http://www.food.gov.uk/safereating/chemsafe/mycotoxins/about/

53 Alm, H. et al. "Influence of Fusarium-toxin contaminated feed on initial quality and meiotic competence of gilt oocytes," *Reprod Toxicol*. 22(1) (July 2006): 44-50; Diaz-Llano, G. and Smith, T.K., "Effects of feeding grains naturally contaminated with Fusarium mycotoxins with and without a polymeric glucomannan mycotoxin adsorbent on reproductive performance and serum chemistry of pregnant gilts," *J Anim Sci.* 84(9) (September 2006): 2361-66.

54 In September 2014 the US Department of Agriculture deregulated Dow's 2,4-D-resistant soybeans and corn

55 Freese (2012), op. cit. note 39, 2.

56 Press Release, Center for Food Safety, May 3, 2007: http://www.centerforfoodsafety.org/2007/05/03/federal-judge-orders-first-ever-halt-to-planting-of-a-commercialized-genetically-altered-crop/

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58 Leslie TW, Biddinger DJ, Mullin CA, Fleischer SJ., "Carabidae population dynamics and temporal partitioning: Response to coupled neonicotinoid-transgenic technologies in maize." *Environ Entomol*. 38(3) (Jun 2009): 935-943.

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61 Bindraban, P.S., Franke, A.C., Ferrar, D.O., et al., "GM-related sustainability: Agro-ecological impacts, risks and opportunities of soy production in Argentina and Brazil," *Plant Research International* (Wageningen, the Netherlands, 2009).

62 Neuman and Pollack (2010), op. cit. note 42.

8. Malfunction of the American Media

1 I can't recollect his name or the network he worked for.

2 Alliance for Bio-Integrity/ICTA Press Conference, National Press Club, Washington D.C., May 27, 1998.

3 Press Release, Grocery Manufacturers of America, May 27, 1998.

4 E.g., "FDA Sued Over Genetically Altered Food," *Omaha World-Herald*, May 28, 1998, at 9. (The statement was made by Eric Flamm, a senior policy adviser at the FDA).

5 Krimsky, S. and Wrubel, R., *Agricultural Biotechnology and the Environment: Science, Policy, and Social Issues* (Champaign, IL: University of Illinois Press, 1996), 163-64.

6 Ibid.

7 To refer to these scientists as not among the pro-biotech mainstream is not to imply that they were opposed to all forms of genetic engineering. Many believed that some of its applications might prove to be safe and beneficial. However, they were not partisan promoters of the technology but were willing to provide objective scrutiny and to critique aspects of the enterprise that they perceived to be problematic.

8 Lewenstein, B. et al., "Historical survey of media coverage of biotechnology in the United States, 1970 to 1996." Paper presented to AEJMC Annual Meeting, Baltimore, MD, August 8, 1998.

9 Priest, S. H., and Talbert, J., "Mass Media and the Ultimate Technological Fix: Newspaper Coverage of Biotechnology," *Southwestern Mass Communication Journal* 10(1) (1994): 76-85.

10 Susanna Priest quoted in "The Odd Couple: Biotechnology and the Media," *AgBiotech Buzz* 2 (11) (December 20, 2002).

11 http://www.commondreams.org/news2002/0429-06.htm (accessed 7-23-12)

12 Ibid.

13 Hencke, D. and Evans, R., "How US put pressure on Blair over GM food," *The Guardian*, February 28, 2000.

14 Hankinson, S.E. et al., "Circulating Concentrations of Insulin-Like Growth Factor 1 and Risk of Breast Cancer," *Lancet*, vol. 351, no. 9113 (1998): 1393-96; Chan, J. et al., "Plasma Insulin-Like Growth Factor-1 [IGF-1] and Prostate Cancer Risk: A Prospective Study," *Science* 279 (January 23, 1998): 563-66.

15 Smith, Jeffrey, *Seeds of Deception: Exposing Industry and Government Lies About the Safety of the Genetically Engineered Foods You're Eating* (Fairfield, IA: Yes! Books, 2003), 188.

16 "Can two reporters take on Murdoch and win?," *The Independent*, London, Sept. 14, 1999.

17 Ibid.

18 Quoted in *Seeds of Deception*, op. cit. note 15, 189.

19 *The Independent* (1999), op. cit. note 16.

20 Personal communication from Jane Akre.

21 *The Independent* (1999), op. cit. note 16.

22 Quoted in *Seeds of Deception*, op. cit. note 15, 190-92.

23 *The Independent* (1999), op. cit. note 16.

24 Ibid.

25 Oddly, although Wilson also sued Fox for the same reason, his claim was not successful.

26 http://www.foxbghsuit.com/2D01-529.pdf

27 At that point, the documents had not yet been posted to the Alliance for Bio-Integrity website. After they were, I no longer needed to fax them to interested individuals.

28 Weiss, Rick, "Biotech Food Raises a Crop of Questions," *Washington Post*, August 15, 1999. Although the article did note that some experts were concerned

that some of the inserted genes might be allergenic, greater space was devoted to the experts who stated that no unusual risk was posed. Further, the risk of toxicity was never even mentioned.

29 Eichenwald et al., "Biotechnology Food: From Lab to a Debacle," *New York Times*, January 25, 2001.

30 Licthblau, E. and Shane, S., "Vast F.D.A. Effort Tracked E-Mails of its Scientists," *New York Times*, July 15, 2012.

31 That headline was even more dramatic: "Vast Effort by F.D.A. Spied on E-Mails of its Own Scientists."

32 Brody, Jane, "Facing Biotech Foods Without the Fear Factor," *New York Times*, January 11, 2005.

33 In a special report marking the 40th anniversary of Watergate, the *Washington Post* noted how the White House had "continued to denounce" its coverage as "biased and misleading" and had also dispensed "unveiled threats and harassment": http://www.washingtonpost.com/wp-srv/politics/special/watergate/part1.html

34 Leonard Downie, Jr., who was the *Post's* deputy metro editor during that period and helped supervise the Watergate coverage, has recently recounted the strain that he and his colleagues endured: "We were ignored and doubted by the rest of the news media and most of the country, and under heavy fire from the Nixon administration and its supporters. It was a tense time . . . , with our credibility and our newspaper's future on the line;" Downie, Leonard, Jr., "Forty years after Watergate, investigative journalism is at risk," *Washington Post*, June 7, 2012: http://www.washingtonpost.com/opinions/forty-years-after-watergate-investigative-journalism-is-at-risk/2012/06/07/gJQArTzlLV_story.html.

35 See note 34.

36 While the *Post* and other members of the media may have sometimes refrained from revealing questionable government actions in matters of foreign policy, in the interest of national security, I'm not aware of any other instances in which it has suppressed facts about government fraud on the domestic front – especially fraud that compromises public safety.

37 Apple, R.W., "Lessons from the Pentagon Papers," *New York Times*, June 23, 1996: http://www.nytimes.com/books/97/04/13/reviews/papers-lessons.html.

38 Correll, John T., "The Pentagon Papers," *Air Force Magazine*, February 2007.

39 Ibid.

40 Ibid.

41 Ibid.

42 Ibid.

43 Although the government ultimately decided not to bring criminal charges against the newspapers, it did bring them against Ellsberg. However, due to gross irregularities in the behavior of the FBI and some other government employees in relation to his case, the judge eventually declared a mistrial and dismissed the charges against him. But he was never formally acquitted of violating the Espionage

Act, and had it not been for the government's bungling of the case, he would probably have been convicted (See Correll's article, cited above).

44 Downie, 2012, op. cit., n. 34. Downie was the *Post's* executive editor from 1991 to 2008. Although I don't know if he was directly involved in the decision to remove the revelations about the FDA from Weiss's article, it's difficult to believe that the editor with whom Weiss was interacting would have made such an important policy decision on his own – and it seems likely that he was acting within an editorial framework that had already been established at higher levels of authority. Thus, there's good reason to assume that Downie had in some significant way been involved in the formulation and implementation of a policy restricting what would be written about the risks of GE foods. After all, he held the same position at the *Post* during the first 15 years of the GE food era as had Ben Bradlee during the Watergate era; and those familiar with the book (or movie), *All the President's Men*, know how actively engaged Bradlee was in the supervision of the Watergate reporting.

Further, regardless of the degree to which Downie may have been involved, I think it's hypocritical for executives at the *Post* to sustain their chest-thumping about the paper's courageous actions regarding Watergate while they cling to their cowardly policy about GE foods. If Downie, who is currently a professor of journalism at Arizona State University's Walter Cronkite School of Journalism and Mass Communication, and is also a vice president at large of the *Post*, is sincerely committed to "accountability journalism," he will openly assume responsibility for whatever role he may have played in the *Post's* irresponsible behavior in regard to GE foods – or, if he played no role at all, he will identify those who should be held accountable. Moreover, he should use his influence to rescind the restrictive policy and replace it with one that allows full reporting of the facts. What's more, I think that he (and/or others at the *Post*) should start making amends by publishing a series of articles that communicate not only the facts that were removed from Weiss's report, but many of the other key facts that are documented in this book – facts that the American people have a right to know. Only then can their boasts about the paper's Watergate triumphs be free from hypocrisy.

45 *New York Times, Co. v. United States*, 403 U.S. 713 (1971).

9. Methodical Misrepresentation of Risk

1 http://www.aaas.org/news/releases/2012/media/AAAS_GM_statement.pdf

2 http://www.who.int/foodsafety/publications/biotech/20questions/en/

3 "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada; An Expert Panel Report on the Future of Food Biotechnology prepared by The Royal Society of Canada at the request of Health Canada Canadian Food Inspection Agency and Environment Canada," The Royal Society of Canada, January 2001.

4 Calamai, P., "Ottawa Rapped, Expert Study Considered Major Setback for Biotech Industry," *Toronto Star,* February 5, 2001.

5 "Genetically modified food and health: A second interim statement," British Medical Association Board of Science and Education, March, 2004.

6 Kmietowicz, Z., "GM Foods Should Be Submitted to Further Studies, says BMA," *British Medical Journal* 328(7440) (March 13, 2004): 602.

7 Public Health Association of Australia Letter to Government Officials, November 2, 2000.

8 *The Lancet* 353 (May 29, 1999): 1811.

9 Fedoroff, N., and Brown, N.M., *Mendel in the Kitchen: A Scientist Looks at Genetically Modified Foods* (Washington, DC: Joseph Henry Press, 2004), xii.

10 National Research Council and Institute of Medicine of the National Academies (NAS), "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects" (Washington D.C.: The National Academies Press, 2004). (As the report's title indicates, it was prepared by two of the NAS's divisions: the National Research Council and the Institute of Medicine.) It can be read online or downloaded at: http://www.nap.edu/openbook.php?record_id=10977&page=R1.

11 "Elements of Precaution," op. cit. note 3, 184.

12 Ibid., 185.

13 Ibid., 184.

14 Ibid., 22.

15 Ibid., 185.

16 Ibid., 186.

17 Ibid., ix.

18 Ibid., 48.

19 In previous parts of this book, where the discussion of risks was not technical, the terms have also sometimes been employed synonymously, according to customary usage.

20 For simplicity, this example assumes that every bite from a venomous snake in Arizona entails the same potential for death as every bite incurred in Ohio. Under this assumption, the degree of harm in each case – the death of one person – is the same, enabling the difference in risk to be determined merely by assessing the different probabilities of being bitten. However, in reality, some species of venomous snakes are more deadly than others. So to accurately calculate the risk differential, we would need to factor in the difference between the toxicity of the average venomous snake bite in Arizona and the average bite incurred in Ohio. This would render the Arizona walk even riskier.

21 According to a recent *New York Times* article, runway collisions are the biggest threat in aviation. It contained the following quote from the chairman of the National Transportation Safety Board: "Where we are most vulnerable at this moment is on the ground . . . . To me, this is the most dangerous aspect of flying," Wald, M. "For Airlines, Runways Are the Danger Zone," *NY Times*, April 25, 2008.

22 In 2008, the National Safety Council compiled an odds-of-dying table comparing the risks of flying and driving. The odds of dying in a motor vehicle were calculated to be 1 in 98 over a lifetime. In contrast, for air travel the lifetime

odds were only 1 in 7,178. http://traveltips.usatoday.com/air-travel-safercar-travel-1581.html.

23 *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues* (National Academy of Sciences, 1987), 6.

24 Ibid., 22.

25 *Field Testing Genetically Modified Organisms: Framework for Decisions* (The National Academy of Sciences, 1989), 14.

26 E.g., 40 and 43; although the report does cite the standard definition of risk (p. 41), and although it at times does speak about the "magnitude" of risk, its approach is inconsistent; and its language is loose. So is its reasoning. However, because the 2004 report makes similar mistakes that are also more varied, and because it's the broader and more important of the two, I'll focus on it and will not expend space examining the defects of the 2000 report in greater depth.

27 NAS 2004 Report, op. cit. note 10, 2.

28 Because the 2004 report was focused solely on human health effects, the 2000 report was broader in respect of issues addressed, since it also dealt with environmental ones. But it only dealt with those issues in regard to a limited class of GMOs, and so was narrower in that respect; and its conclusions weren't technically applicable to all engineered food crops.

29 The release was issued on July 27, 2004 by the National Research Council and the Institute of Medicine, the divisions of the NAS that had produced the report. It was titled: "Composition of Altered Food Products, Not Method Used to Create Them, Should Be Basis for Federal Safety Assessment."

30 NAS 2004, op. cit. note 10. This finding is stated on p. 180 (and also on p. 9 in the Executive Summary). The report states that "the policy to assess products based exclusively on their method of breeding is scientifically unjustified." Since this statement follows reference to the fact that the EU subjects GE foods to a higher level of assessment than other foods, it's clear that it intends to convey the idea that this practice is unjustified and that GE foods, as a class, should not be treated differently than conventional ones.

31 Jennifer Hillard quoted in: Pollack, A., "Panel Sees No Unique Risk from Genetic Engineering," *New York Times*, July 28, 2004.

32 Document #1 at: http://biointegrity.org/24-fda-documents

33 The NAS 1989 report states (on p. 2) that the maxim was a "fundamental principle" of the 1987 report; and it notes that this principle was then "adopted" by those responsible for preparing it (the 1989 report) and "reemphasized" in Chapter 2.

34 Ibid: In the PDF format, the chart appears on p. 64 and the explanatory text on p. 65. See: http://www.nap.edu/openbook.php?record_id=10977&page=64; The chart also appears in the Executive Summary on p. 4.

35 The committee specified that selection from a homogeneous population has less potential for unintended effects than selection from one that is heterogeneous.

36 Ibid., 65. In the chart, the category comprising both radiation and chemical-based processes is referred to as "mutation breeding." However, I prefer not to use this term, since it implies these are the only techniques that induce mutations, even though (as will be discussed) tissue culture-based breeding also generates new traits by inducing mutations. And genetic engineering causes mutations as well. Therefore, instead of employing the term "mutation breeding" to refer to the techniques that employ radiation and chemicals, I'll refer to them jointly as "radiation and chemical-based breeding."

37 As Chapter Four explained, although an actual rifle firing a .22-calibre bullet was initially employed in such transfers, as the gun evolved, macroscopic bullets were no longer used, and the microscopic particles were propelled by a blast of air. But the device providing the blast is still a type of gun. The process is often referred to as *particle bombardment*, *bioballistics*, or *biolistics*. The 2004 report uses the latter term.

38 NAS 2004, op. cit. note 10, 63.

39 For stylistic purposes, I'm substituting "dangerous" for "risky," with the intent that it conveys the same technical meaning. Further, the number 10 was arbitrarily selected for the sake of argument, not because bioengineering has been determined to induce that many side effects for every effect induced by pollen-based breeding. However, in this regard the hypothetical value may be on the low side, because in the report's comparative chart, the bar depicting the unintended effects of bioballistic gene transfer between distantly related species is around 14 times longer than the bar adjoining the least disruptive form of pollen-based breeding.

40 NAS 2004, op. cit. note 10, 63.

41 Ibid.

42 Ibid.

43 Nor do we "know" that any of the foods created through tissue culture is actually safe.

44 In this context, the words "proven safe" do not denote the certainty involved in a mathematical proof. They denote the standard of proof instituted by the FDA for purposes of evaluating food: a demonstration that there is "reasonable certainty" of no harm.

It's also important to note that the NAS report does not primarily attempt to establish its claim about the safety of GE foods by citing actual safety tests. Instead, it relies on the specious arguments that are critiqued in this chapter's analysis. Moreover, as Chapter 6 revealed (and as Chapter 10 will more fully elucidate), several of the tests on GE foods raise reasonable doubts. This research cannot be lightly dismissed, and it further undercuts the committee's claim about what we presently know.

45 While some tests have been conducted on whole foods that were irradiated for the purpose of reducing microbes, safety testing has not been performed on foods grown from irradiated seeds, which present a different set of hazards.

46 NAS 2004, op. cit. note 10, 27.

47 Ibid., 45.

48 The committee acknowledged the lack of records regarding radiation (on p. 28 of their report); and they also noted that it has not been feasible to track for effects of GE foods, while urging the FDA to institute practices that would facilitate it.

49 Schubert, David, "Pharmed Food: Consume with Caution," *The Ecologist*, November 2008.

50 Although the evidence doesn't prove that GE was the cause, it strongly points to that conclusion; and, as Chapter 3 explains, it's more likely than not that the process was to blame for the toxic contamination – which would be sufficient to hold the process liable in a court of law.

51 NAS 2004, op. cit. note 10, 47.

52 Ronald, P. and Adamchak, R., *Tomorrow's Table: Organic Farming, Genetics, and the Future of Food* (New York: Oxford University Press, 2008), 102. Although she doesn't explicitly cite the report as the basis for this particular assertion, her foregoing discussion demonstrates that the document is the primary source on which it relies. For instance, on p. 69 she states the report indicates that the GE crops currently on the market "are safe to eat."

53 While it is not in principle impossible that she could know they are safe, given the present state of the evidence, it's not currently possible.

54 NAS 2004, op. cit. note 10, 63.

55 NAS 2004, op cit. note10, 131-32. Although the committee's language lacks precision, they appear to include GE foods among those that need not be proven safe prior to marketing and can only be removed if obvious problems emerge later. And if they in fact were not confused, they should have avoided confusing language that imparts the impression they were unaware of what the law requires.

Further, besides accepting the basics of the FDA's hands-off policy in regard to GE foods, the committee also defended the lax regulatory policy in most of the rest of the world, where the concept of *substantial equivalence* reigns (Ibid., 129-30). But in doing so, they relied on the type of simplistic linear model that the Canadian experts had discredited. They indicated that putting primary attention on the protein the inserted gene expresses is a sound approach, while failing to acknowledge that, even if the protein is safe to consume, its unregulated expression (as well as the insertion process itself) could disrupt cellular function in deleterious ways. Thus, in explaining (approvingly) how the *substantial equivalence* approach is applied to almost all the GE foods then on the market (including *Bt* corn and Roundup Ready soybeans), the report noted that the assessment focuses "primarily on the introduced trait or gene product" (Ibid., 130). But, as their Canadian counterparts had demonstrated, the presumed sufficiency of this narrow approach is itself based on a presumption that's significantly flawed: the presumption that whatever unintended side effects are induced by the transformation process will be adequately detected by superficial compositional comparisons. And such constricted thinking is based on the notion that attention should mainly rest on

the product – and that the process has no significant bearing on the risk that the product will harbor harmful side effects that are difficult to discover.

Moreover, to the extent the NAS report faulted the regulatory policy of the European Union and other regions embracing the *substantial equivalence* approach, it was not for applying this approach to GE foods, but for requiring that it be applied to all of them while exempting all conventional products. In rejecting this aspect of the policy, the report emphasized that it's "scientifically unjustified" to set assessment criteria based exclusively on the manner of production (Ibid., 180).

56 Ibid., 29. Here's how the committee described the way GE plants are developed via the use of reconfigured bacteria: "By substituting the DNA of interest for the crown gall disease-causing DNA, scientists derived new strains of *Agrobacterium* that deliver and stably integrate specific new genetic material into the cells of target plant species. If the transformed cell then is regenerated into a whole fertile plant, all cells in the progeny also carry and may express the inserted genes."

57 The term "genomic shock" is used in connection with tissue culture by several biologists. One example is: Kaeppler et al., "Epigenetic aspects of somaclonal variation in plants," *Plant Molecular Biology* 43 (2000): 179–88; 181.

58 When genetically identical cells go through tissue culture, they tend to mutate in different ways. This differential in mutations is referred to as *somaclonal variation*. The NAS report generally employs this term in referring to the process of tissue culture, and it's used as the heading of the relevant section on page 26. Because I think it's simpler and more straightforward to speak of tissue culture instead, since it is the name of the technique through which somaclonal variation occurs, I don't employ the latter term.

59 NAS 2004, op. cit. note 10, 27.

60 Ibid., 28-29. It took twenty-seven more pages before they finally acknowledged that tissue culture is an aspect of the bioengineering process. In describing a few of the potential unintended effects of GE, they said: ". . . spontaneous mutation may occur in the tissue culture phase of the transformation regeneration processes" (p. 56). But, unless one already knew how widely the technique is relied on in producing GE plants, this sentence would be unlikely to induce such understanding. Further, as will be seen, when the committee subsequently presented a chart depicting differences in disruptive potential between the various modes of plant breeding, it treated tissue culture as distinct from bioengineering.

61 Although in the case of a few species, there are ways in which isolated cells can be regenerated without resort to tissue culture, it's the standard method through which engineered cells are transformed into mature plants.

62 Neelakandan, A. and Wang, K., "Recent progress in the understanding of tissue culture-induced genome level changes in plants and potential applications," *Plant Cell Rep* 31 (2012): 597-620; 611. I emailed Dr. Wang, the director of the Center for Plant Transformation at Iowa State University, inquiring if the statement about "high probability" of changes referred not merely to regenerated plants before they've been crossed, but to the final, commercialized products as well – even though

the total number of changes would have been reduced in those products via crossing. She emailed to confirm that the statement applied to the final products too.

63 It's logical to presume that all the bars represent the potential for unintended effects to remain in the final products of the respective methods, because if they instead are meant to pertain to plants that have not undergone crossing, then they couldn't reflect differences in the potential for unintended effects that remain after crossing has occurred and the product is ready for marketing – the phase at which the differences are most important. And it's reasonable to think that such differences exist, as will be explained shortly.

64 Skirvin et al., "Sources and frequency of somaclonal variation," *Hort Sci* 29 (1994):1232-1237.

65 It's also more likely that the more intensive culturing processes would generate a higher percentage of dramatic mutations; but it's also likely that most of these would not remain in the final product, since they would either prevent plant development or result in observable (and more readily removable) abnormalities.

66 As we shall see, even without registering the effects of tissue culture, the bar associated with that mode of bioengineering should be substantially longer and darker.

67 Its bar, when adjusted, would extend 1.3 centimeters beyond the right vertical axis of the chart (the point at which the bar for radiation ends). In the context of the chart, this is a significant difference. Moreover, even if the GE bars are adjusted by adding only one-fourth the length of the tissue culture bar, the one associated with the most disruptive mode is longer than that of radiation; and the other is almost as long.

Note: In order to take measurements, I first reproduced the chart that's in the PDF version of the report on an 8.5 x 11 inch piece of paper. I then used a ruler to ascertain the lengths of the bars. It was difficult to be precise because of the way the gray tails shade toward the ends. Some of the values I obtained are: tissue culture (SCV): 5.6 cm; bacterial transfer of rDNA between distantly related species: 9.0 cm; biolistic transfer of rDNA between distantly related species: 10.2 cm; radiation breeding: 10.8 cm. Other people may get slightly different values; but the overall result will most likely be similar. Further, it's important to keep in mind that the lengths of the bars only reflect the committee's rough estimates.

68 While this analysis is illuminating, it's important to note that in neither the committee's chart nor the adjusted versions of it do the ratios between the lengths of the bars precisely reflect reality. The committee's calculations are not based on evidence that enables exact determinations; and the available data don't provide a basis for anything more than reasonable estimates – although the estimates the committee made did not always express this attribute.

69 Ronald and Adamchak, op. cit. note 52, 88. Of course, in stating that radiation is riskier, she's at odds with the committees' claim that there's no correspondence between placement on the chart and degree of risk. However, as

we'll see in Chapter 14, when discussing risks, Ronald not only contradicts the NAS, she even contradicts herself.

70 At the close of a section arguing that genes inserted via bioengineering are not drawn to "hotspots" in the DNA that foster genetic instability, they stated: "Similarly, there is no evidence to suggest the CaMV 35S promoter in GE plants is any more unstable than the CaMV 35S promoter in ordinary plants infected with CaMV" (NAS 2004, 61). The question of whether the 35S promoter inserted in plants is, itself, genetically unstable is separate from the other issues that I noted. Although there's still room for scientific debate about this additional issue, because properly presenting it would add a significant amount of text to an already long chapter, I've decided to forgo it.

71 Hohn, T. and Rothnie, H., "Plant pararetroviruses: replication and expression," *Current Opinion in Virology* 3 (2013): 621–28.

72 NAS 2004, op. cit. note 10, 60 & 62.

73 Ibid., 60.

74 E.g., Fedoroff, *Mendel in the Kitchen*, op. cit. note 9, 103; where it's stated that "neither genes nor transposons normally move."

75 E.g., Wu, R., Guo, W.L., Wang, X.R., Wang, X.L., Zhuang, T.T., Clarke, J.L., Liu, B., "Unintended consequence of plant transformation: biolistic transformation caused transpositional activation of an endogenous retrotransposon Tos17 in rice," ssp. japonica cv., Matsumae, *Plant Cell Rep* 28 (2009): 1043–51.

76 *Mendel in the Kitchen,* op. cit. note 9, 105.

77 David Schubert, personal communication. Mutation breeding via radiation and chemicals also stirs up transposons. But, as will be discussed, there's good reason to think bioengineering entails at least as great a transposon-related risk.

78 *Mendel in the Kitchen*, op. cit. note 9, 104-05. However, as the book points out, wide crosses between "very distantly related plants" can activate transposons.

79 As in several other sections of the report, the committees' discussion is not as coherent as one would expect, and it's difficult to discern the structure of their argument. But their words do create the impression that transposon mobilization is somehow separate from the GE process. Leaving aside the issue of whether this obfuscation was deliberate, it seems they may have been trying to advance the following argument:

(a) Plant genomes contain numerous transposons; (b) many of the associated insertion events either created, or could have created, disruptions; (c) any disruptions caused by insertions of rDNA would be no riskier than those associated with transposons; (d) therefore, such insertions present no cause for concern.

But such an argument is flawed. Not only does it disregard the fact that genetic engineering can induce transposon movement (through three distinct modes) and thereby impose additional transposon-related risks, it mistakenly equates whatever risks may linger from ancient transposon insertions with the risks entailed by present-day insertions of rDNA cassettes. Scientists recognize that transposons and their movements have played a significant role in the evolution of plants and have

contributed to important features that are found in contemporary varieties. And it's known that over great expanses of biological time, while positive effects of the transpositional events have been conserved, most deleterious effects have not been maintained. But the situation is otherwise with rDNA insertions. Instead of a long process of screening by natural selection, the screening for harmful effects in whatever plants survive the transformation process is performed by human inspection; and, as the 2001 Canadian report repeatedly warned, the current monitoring process is unable to detect all the subtle changes that could harm consumer health.

Moreover, even if effects of transpositional events in the distant past remain that don't impair the function of the plant but do impair the health of those that consume them, the insertional effects of bioengineering add to this baseline of risk to a more significant degree than does pollen-based breeding – and, as will be demonstrated, more greatly than do all other forms of breeding as well.

80 Forsbach A., Schubert, D., Lechtenberg, B., Gils, M., Schmidt, R., "A comprehensive characterization of single-copy T-DNA insertions in the *Arabidopsis thaliana* genome," *Plant Molecular Biology* 52(1) (2003): 161–76. The researchers selected only plants that contained a single insertion site.

81 Latham, J., Wilson, A. and Steinbrecher, R., "The Mutational Consequences of Plant Transformation," *Journal of Biomedicine and Biotechnology*, vol. 2006, article ID 25376, 3.

82 Ibid. (emphasis added). They noted that conclusions about particle bombardment had to be provisional, because very few of its insertion events were well-studied at that time.

83 NAS 2004, 66.

84 Regarding gene loss, e.g., Kaya, H., Sato, S., Tabata, S., Kobayashi, Y., Iwabuchi, M., Araki, T., "*hosoba toge toge*, a syndrome caused by a large chromosomal deletion associated with a T-DNA insertion in *Arabidopsis*," *Plant & Cell Physiology* 41(9) (2000): 1055–66. Re: deletion-related disruption of gene function, see e.g., Amedeo, P., Habu, Y., Afsar, K., Mittelsten Scheid, O., Paszkowski, J., "Disruption of the plant gene *MOM* releases transcriptional silencing of methylated genes," *Nature* 405(6783) (2000): 203–06. Re: potential disturbance of native genes through the influence of the inserted DNA; E.g., Hannon, G.J., "RNA interference," *Nature* 418(6894) (2002): 244–51; Bartel, B. and Bartel, D.P., "MicroRNAs: at the root of plant development?" *Plant Physiology* 132(2) (2003): 709–17."

85 Amedeo et al., op. cit. note 84; Ichikawa, T., Nakazawa, M., Kawashima, M., et al., "Sequence database of 1172 T-DNA insertion sites in *Arabidopsis* activationtagging lines that showed phenotypes in T1 generation," *The Plant Journal* 36(3) (2003): 421–29; Weigel, D., Ahn, J.H., Bl´azquez, M.A., et al., "Activation tagging in Arabidopsis," *Plant Physiology* 122(4) (2000): 1003–13.

86 Freese, W. and Schubert, D., "Safety testing and regulation of genetically engineered foods," *Biotechnology and Genetic Engineering Reviews* 21 (2004): 314 (emphasis added).

87 Latham et al., op. cit. note 81, 4.

88 Ibid., 3.

89 Ibid., 4.

90 Ibid.

91 Further, if plants are not grown from seed but are propagated clonally (as is usual with potato and banana), none of the genome-wide mutations are removed, and they'll be present in every future clone of the original GE plant.

92 Latham et al., op. cit. note 81, 4.

93 Ibid., 5. According to the molecular biologist Allison Wilson, who has extensively examined the data submitted to regulators, although the standard Southern analyses submitted in applications to the USDA are claimed to detect whether additional copies of all or parts of the cassette have been deposited in distant sites, the plants' developers do not submit sequence data for the entire genome. Therefore, subsequent whole genome sequence analysis will likely reveal transgenic inserts missed by Southern analysis – as was the case with the commercialized transgenic papaya. Comparison of the transgenic genome with the genome of the parent plant would also be necessary to determine the presence (and extent) of any additional genome-wide differences between the transgenic plant and its parent (e.g. movement of native transposons, rearrangements or deletions of plant DNA) [personal communication].

94 Latham et al., op. cit. note 81, 5.

95 E.g., Windels, P. et al., "Characterisation of the Roundup Ready soybean insert," *European Food Research and Technology* 213(2) (200):107–12; Hernandez, M. et al., "A specific real-time quantitative PCR detection system for event MON810 in maize YieldGard based on the 3-transgene integration sequence," *Transgenic Research* 12(2) (2003): 179–89.

96 Wilson, A. et al., "Genome Scrambling – Myth or Reality? Transformation-Induced Mutations in Transgenic Crop Plants," *EcoNexus Technical Report* (October 2004). The report presented such scrambling as a reality.

97 Numerous studies cited in the review were published in 2003 or earlier, so the committee could have taken account of them, since its report was not released until the summer of 2004. And although they did refer to four papers mentioned in that review, none of these were the ones that examined (or even expressly discussed) deletions and rearrangements in the regions surrounding the insertion site. Nor did any mention the insertion of superfluous DNA.

98 E.g., Latham et al., op. cit. note 81; Freese, W., Schubert, D., "Safety testing and regulation of genetically engineered foods," *Biotechnology and Genetic Engineering Reviews* 21 (2004): 299–324; Spok, A. et al., "Risk Assessment of GMO-Products in the European Union," *Bundesministerium f˙ur Gesundheit und Frauen*, 2004.

99 NAS 2004, 27.

100 NAS 2004; their main discussion runs from p. 41 through p. 45. Although they also noted that tomatoes could contain problematic levels of a naturally occurring toxin, they acknowledged this was due to environmental factors rather than to the breeding process.

101 Steiner, H.Y. et al., "Evaluating the Potential for Adverse Interactions within Genetically Engineered Breeding Stacks," *Plant Physiology*, April 2013, vol. 161 no. 4: 1588.

102 NAS 2004, op. cit. note 10, 43.

103 Ibid., 56.

104 http://wildflowerfinder.org.uk/Flowers/P/Potato/Potato.htm; http://www.sigmaaldrich.com/catalog/product/sigma/d5649?lang=en&region=US. Further, the fact that demissidine is present in potatoes was reported in the scientific literature as early as 1981: Jadhav, S.J., R.P. Sharma, D.K. Salunkhe, "Naturally occurring toxic alkaloids in foods," *Crit Rev Toxicol* 9 (1981): 21–104.

105 Ibid., 43.

106 Steiner, H.Y. et al., op. cit. note 101, 1588. It's noteworthy that these authors are proponents of GE foods, and one is employed by Pioneer Hi-Bred, a major biotech corporation. Yet, they admit there's no evidence that conventional breeding has produced novel toxins (or is even likely to), despite the NAS committees' contention that this has actually happened – and that it could well be happening in several cases of which we're unaware.

Further, although many people are under the impression that through the process of pollination, modern varieties of hybridized wheat have become endowed with one or another novel proteins, there appears to be no sound evidence this has actually happened. Instead, the relative concentrations of native proteins have changed. See, e.g., van den Broeck, H.C. et al., "Presence of celiac disease epitopes in modern and old hexaploid wheat varieties: wheat breeding may have contributed to increased prevalence of celiac disease," Theor Appl Genet (2010) 121:1527–1539. DOI 10.1007/s00122-010-1408-4.

107 Schubert, David, quoted in Smith, Jeffrey, *Genetic Roulette* (Fairfield, IA: Yes! Books, 2007), 56.

108 Hagan, N. et al., "The redistribution of protein sulfur in transgenic rice expressing a gene for a foreign, sulfur-rich protein," *Plant J.* 34 (2003): 1–11. For a discussion, see note 111.

109 Although the study on the allergenic effects of the protein produced by the GE peas was not published until after the committee had released its report, the study revealing that the foreign gene expressed in GE rice might have been misfolded was published the year prior to the report's release. Yet, the report makes no mention of it. Moreover, the potential for a protein synthesized within a foreign species to be adversely altered via either add-ons or misfolding was recognized well before the report was written.

110 It's clear that serious problems could result from either class of insertions. In regard to adverse outcomes induced by foreign genes, Philip Regal has pointed out that ". . . theory and evidence have suggested that the host's buffering or control systems will often be ineffective for those transgenes that can express well." He explains that because the foreign genes could induce "unusual conditions" that cannot be modulated by the buffering mechanisms, ". . . new factors may be added

to the host's biochemical milieu and cause quantitative or qualitative changes in the output of existing biochemical pathways." Regal, P., "Scientific Principles for Ecologically Based Risk Assessment of Transgenic Organisms," *Molecular Ecology* 3 (1994): 5-13 (The sentences cited above were from a section relevant to food safety as well as ecological safety).

On the other hand, when the inserted gene comes from a closely related species, the organism's control system could be stressed in trying to cope with the hyper-expression of a native substance, resulting in the formation of unusual toxins – as happened with Showa Denko's tryptophan-producing bacteria.

111 For instance, in an attempt to increase the sulfur content of rice, a transgenic variety was created containing a sunflower gene that expresses a protein rich in sulfur. However, the amount of sulfur in the rice did not increase, apparently because the high demand for sulfur imposed by the over-expression of the sunflower gene drew heavily upon the plants' sulfur pools and decreased the production of some of their own sulfur-containing proteins.

Further, there were at least two other types of change that were not directly related to the competition for sulfur production but were induced by some other mechanics. In one, the level of two native proteins significantly *increased*; and because they chaperone the correct folding of proteins, and because their levels tend to increase in plants in response to stresses that impair proper protein formation, the researchers regarded this result as a warning sign. They stated it ". . . raises the possibility that at least some of the SSA [the foreign protein] is misfolded."

The second unusual outcome that was not directly related to the competition for sulfur involved a failure to process another native protein [glutelin B] in a normal manner, which led to elevated levels of its unprocessed form.

Although the researchers didn't determine whether the various alterations could exert negative impacts on consumer health, or whether other potentially hazardous changes had also occurred, a process that can induce such significant shifts in the way a plant operates clearly has the potential for doing so. Hagan, N. et al., "The redistribution of protein sulfur in transgenic rice expressing a gene for a foreign, sulfur-rich protein," *Plant J.* 34 (2003): 1–11. See also, Islam, N. et al., "Decreased accumulation of glutelin types in rice grains constitutively expressing a sunflower seed albumin gene," *Phytochemistry* 66 (2005): 2534–39.

112 Nestle, Marion, "The AMA's Strange Position on GM Foods": http://www.theatlantic.com/health/archive/2012/06/the-amas-strange-position-on-gmfoods-test-but-dont-label/258968/ While her allegation was specifically directed at a particular, and glaring, instance of inconsistency between two of the report's main assertions, even when the document *is* self-consistent, it is *not* consistent with good science – as will be demonstrated.

113 American Medical Association, Policy Statement on Biotechnology and the American Agricultural Industry, 1990.

114 American Medical Association, Report 2 of the Council on Science and Public Health (A-12) (2012)2.

115 The AMA's opposition to labeling is clearly stated in the 2012 report, which was heavily relied on by the opponents of a California ballot initiative that would have required labeling. The initiative was narrowly defeated.

116 AMA (1990), op. cit. note 113. The first GE whole food that came to market was the *Flavr Savr* tomato, introduced in May 1994. It is discussed in Chapter 10.

117 Document #1 at: http://biointegrity.org/24-fda-documents

118 In one indication of deficient benefits, the *Des Moines Register* reported that studies of Iowa farmers conducted for 1998 and 2000 by Iowa State University economist Dr. Michael Duffy showed: "Farmers who plant genetically modified corn and soybeans fare no better financially than those who grow traditional crops. . . ." And it noted Duffy's statement that seed companies and chemical companies have reaped the primary benefits of biotechnology so far (Perkins, Jerry, "Biotech Crops Fail to Reap More Cash," *Des Moines Register,* January13, 2002). Dr. Duffy also found that, in both years, yields for the GE soybean (Monsanto's Roundup Ready variety) were lower than for the non-GE beans.

119 The yield drag of the Roundup Ready soybean was confirmed by researchers at the University of Nebraska. In controlled studies comparing RR soy with non-engineered sister lines, they found consistent yield decreases with the GE beans of 5%. They concluded that the study "demonstrates that a 5% yield suppression was related to the [foreign] gene or its insertion process. . . ." And they made it clear that the reduction was not due to the application of the herbicide, because they determined that it had exerted no effect on yields (Elmore et al., "Glyphosate-Resistant Soybean Cultivar Yields Compared with Sister Lines", *Agron J* 93 [2001]: 408-12). The other problems have been discussed in Chapter 7.

120 21 CFR 170.3(I)

121 American Medical Association, Policy Statement on Biotechnology and the American Agricultural Industry, 1990.

10. A Crop of Disturbing Data

1 As it turned out, this hypothesis was incorrect; and the translation of the PG gene was inhibited via a different mechanism.

2 As will be discussed later in this chapter, the tomato also contained a marker gene; and that gene had a bacterial origin.

3 Martineau, Belinda, *First Fruit: The Creation of the Flavr Savr™ Tomato and the Birth of Biotech Foods*, 2001 (McGraw-Hill: New York), 146.

4 Calgene also conducted acute oral toxicity tests of eight other lines of the Flavr Savr and five corresponding control lines. (Martineau, personal communication)

5 *First Fruit*, op. cit. note 3, 150. The term "gross lesions" was used by FDA pathologists who reviewed the data. They also referred to the lesions as "gastric erosions" (Document #14, p. 1 at: http://biointegrity.org/24-fda-documents).

6 Pusztai, A., "Can Science Give Us the Tools for Recognizing Possible Health Risks of GM Food?," *Nutrition and Health* 16 (2002): 73-84.

7 *First Fruit,* op. cit. note 3, 152.

8 Document #14, p. 2 at: http://biointegrity.org/24-fda-documents.

9 Document #17, pp. 2-3 at: http://biointegrity.org/24-fda-documents.

10 Document #16 at: http://biointegrity.org/24-fda-documents.

11 Document #15, p. 3 at: http://biointegrity.org/24-fda-documents.

12 *First Fruit*, op. cit. note 3, 181.

13 Agency Summary Memorandum, Re: Consultation with Calgene, Inc., Concerning FLAVR SAVR™ Tomatoes, May 17, 1994, U.S. Food and Drug Administration.

Because the Commissioner selects the FAC members, and because Kessler had had a long tenure, it's reasonable to assume he had appointed a substantial number of the standing members.

14 *First Fruit*, op. cit. note 3, 182.

15 Cony, A., "FDA Scientists find Flavr Savr Safe," *Sacramento Bee*, April 6, 1994. (The FDA's statement was released several days before this article was published; and the article referred to it as a past event.)

16 *First Fruit*, 182. Belinda Martineau, the author of the book, was a member of the Flavr Savr development team and made this observation first-hand.

17 Cony, A., "FDA Scientists find Flavr Savr Safe," *Sacramento Bee*, April 6, 1994; As cited in *First Fruit*, 252, n. 1. The FDA's subsequent public releases regarding the Flavr Savr continued to falsely assert that its scientists had determined that the tomato was safe, *e.g.* "First Biotech Tomato Marketed," U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *FDA Consumer*, September 1994.

18 FDA Food Advisory Committee Meeting, April 6-8, 1994, Transcript: vol. 2, 153.

19 Ibid., 159-61.

20 Ibid., 162; 167-68.

21 *First Fruit*, op. cit. note 3, 186. The words "love fest" were in quotation marks in Martineau's report.

22 FDA Public Affairs Office, HHS News, May 18, 1994.

23 "Biotechnology of Food," U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *FDA Backgrounder*, May 18, 1994.

24 "FDA'S Policy for Foods Developed by Biotechnology," U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, CFSAN Handout: 1995. The document was also published as a chapter in American Chemical Society Symposium Series no. 605, 1995.

25 *First Fruit*, 146. This page discusses the initial consensus, and the words in quotation marks are from Martineau's take on it.

26 Document #15, p. 3 at: http://biointegrity.org/24-fda-documents.

27 Ibid., 4.

28 Additionally, some substances have been granted a specific statutory exemption from meeting the test requirements.

29 According to the FDA's own regulations, foods claimed to be GRAS ". . . require the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive." (21 CFR Sec. 170.30[b])

30 Agency Summary Memorandum Re: Consultation with Calgene, Inc., Concerning FLAVR SAVR™ Tomatoes, May 17, 1994, US Food and Drug Administration.

31 Pusztai, A. et al., "Genetically modified foods: potential human health effects," in *Food Safety: Contaminants and Toxins*, in D'Mello, J.P.F., ed., Scottish Agricultural College, Edinburgh, UK, April 2003, 351.

32 Belinda Martineau's files attest that the deaths occurred in a different line than did the lesions.

33 Because the relevant files were not with me at the time but at the offices of the International Center for Technology Assessment (the attorneys of record in our lawsuit) in Washington, D.C., I conveyed the request to them; and they sent him the information.

34 Pusztai, A. et al., (2003), op. cit. note 31, 351.

35 http://www.responsibletechnology.org/posts/throwing-biotech-lies-at-tomatoes-part-1-killer-tomatoes/

36 Pusztai, A. et al. (2003) op. cit., note 31, 350. Although the quoted words were specifically made in discussing the acute toxicity study, they also applied to the 28-day studies, in which the variation in starting weights was even greater.

37 Ibid., 351.

38 Ibid., 351-52.

39 Although the administrators were apparently abetted by a few agency scientists, their scientific standards seem to have been significantly lower than were those of the experts who wrote the critical memos. Further, it's not clear if they scrutinized the data as carefully as did that set of experts.

40 When the cassette already contains a gene conferring resistance to an herbicide, that herbicide can be used to kill off the non-transformed cells, eliminating the need to add an antibiotic resistance marker gene.

41 Although biotech proponents have tried to discredit concerns by arguing that kanamycin has largely fallen into disuse and is no longer medically significant, the facts show otherwise. Not only is it used prior to endoscopy of the colon and rectum, it's used to treat ocular infections, and also in blunt trauma emergency treatment. It's additionally applied in veterinary medicine.

Perhaps even more significant, the effectiveness of other antibiotics could also be compromised. That's due to a phenomenon called *cross resistance*, wherein bacteria that become resistant to a particular antibiotic subsequently develop resistance to others within its family. And kanamycin belongs to an important family. Its relatives include antibiotics that are substantially relied on today. So it's a matter of concern that this family has displayed appreciable cross resistance (Onaolapo, J., *Afr. J. MedSci* 23 [1994]: 215-9). Moreover, according to the medical doctor Jaan Suurkula, two of kanamycin's cousins are of "great value" in treating serious infections because they

entail gentler side effects than their alternatives. See: http://www.psrast.org/antibiot.htm. Therefore, it's ominous that a strain of bioengineered bacteria in which the kanamycin resistance marker gene had been used was found to be cross resistant to these two valuable drugs (Smirnov, V.V. et al., *Antibiot-Khimiorec* 39(4) [Apr 1994]: 23-28). As Dr. Suurkula has observed, "it would be an important drawback" if resistance to these antibiotics were to increase.

42 *First Fruit*, op. cit. note 3, 161. Belinda Martineau has informed me that despite the fact people in both the FDA and the biotech industry routinely claim that Calgene decided to submit the application on its own volition, she was (as she reports in her book) in the office of the company's CEO when he received a call from an FDA official (which she heard via his speaker phone) informing him that the agency preferred to have Calgene's request for an advisory opinion converted into, and submitted as, a formal food additive petition.

43 Document #11 at: http://biointegrity.org/24-fda-documents

44 Document #12, p. 6 (at AR # 013136) at: http://biointegrity.org/24-fda-documents

45 Ibid. (at AR #013130)

46 Document #13 (at AR # 013139) at: http://biointegrity.org/24-fda-documents

47 The scientist was Nega Beru. FAC Meeting Transcript, op. cit. note 18, vol. 2, 178.

48 Dr. Beru's assertion that the FDA had concluded that the use of the gene is safe appears on page 187 of the above transcript.

49 As Appendix C explains, although the FDA did expressly approve the marker gene, it refrained from doing so in the case of the tomato itself. And in the agency's letter to Calgene regarding the latter, it cleverly chose its words to give the illusion that an approval was being granted while, in actuality, there was no express approval or certification of safety. But due to the artful illusion, Calgene declared, and the media reported, that formal approval had been received and safety certified.

50 Belinda Martineau's files indicate that Calgene had decided to market that particular line; and she informed me that, as far as she knows, it's the one that was commercialized.

51 *United States v. Seven Cartons . . . Ferro-Lac*, 293 F. Supp. 660, 664 (S.D. Il. 1968). That case is discussed in Chapter 5. In it, the FDA was challenging the GRAS status of an additive, the experts testified on behalf of its challenge, and they asserted that they were not aware of any studies in the standard literature demonstrating the substance was safe. Obviously, the outcome would almost surely have been different if those scientists had questionable credentials and were countering a large number of well-qualified experts whose opinion was based on solid evidence of safety published in standard peer-reviewed journals. But if even a few experts can show that a widely-held opinion is not based on such evidence and instead rests on assumptions and hypotheses that are open to reasonable doubt, then the substance they challenge cannot be legitimately deemed GRAS. (This ruling was subsequently

modified on other grounds by an appellate court, 424 F.2d 136 (7th Cir. 1970) – grounds that did not affect the holding about the sufficiency of two experts.)

52 Document #12, pp. 5 & 7 at: http://biointegrity.org/24-fda-documents

53 Ibid., 7.

54 Document #13, p. 3 at: http://biointegrity.org/24-fda-documents

55 Ibid., 2.

56 I asked Belinda Martineau, who was intimately involved in Calgene's endeavors regarding the tomato, whether any additional data about the spread of resistance to gut flora had been submitted in response to the concerns of the FDA experts. She graciously searched her files and reported that none had. (The only additional data that was submitted was unrelated to those specific concerns.)

57 21 CFR 170.3 (3) (I).

58 Because this fact was more than sufficient to negate any claim the gene was GRAS, it certainly could not be circumvented merely by converting Calgene's submission into a food additive petition, in which the same standard of safety is in effect.

Moreover, even if Calgene had decided to commercialize a Flavr Savr line that had not been linked with either lesions or deaths, that line would still have entered the market in contravention of the law. For one thing, it would have contained the illegally-approved marker gene. For another, its safety would still have been subject to reasonable doubt. Because the FDA experts had identified an unresolved safety issue, a shadow was cast on *every* line of the Flavr Savr. And until that issue was resolved, the shadow would remain. After all, if the lesions (or the deaths) were in some way caused by one or another aspect of the bioengineering, there would be a possibility that deleterious effects could be induced by other lines of tomato altered with the same cassette – and that these effects might not be evident unless more thorough studies were conducted.

59 *First Fruit*, op. cit. note 3, 203, 223.

60 Ibid., 221-22.

61 Ibid., 222.

62 Ibid., 221 (for the information that there was no public opposition).

63 As Appendix C explains, this profession about safety having been demonstrated went far beyond what the agency was willing to state in the actual letter it had sent Calgene in regard to the tomato.

64 "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada; An Expert Panel Report on the Future of Food Biotechnology," The Royal Society of Canada, January 2001, 48.

65 Pusztai, A., Submission to the New Zealand Royal Commission on Genetic Modification (2001).

66 Pusztai has stated that "our task was to establish novel testing methods." Pusztai, A., "Responses to the Royal Society's (RS) six referees' reviews on the Audit and Alternative Report." (placed on the internet by the Rowett Research Institute on February 16, 1999, but no longer accessible).

67 Pusztai, A, Transcript of testimony to the New Zealand Royal Commission on Genetic Modification, February 7, 2001, 3406.

68 Smith, Jeffrey, *Genetic Roulette* (Fairfield, IA: Yes!Books, 2007), 23.

69 The differences could also have been due to variable effects of tissue culture, as will be discussed subsequently.

70 Pusztai, A., SOAEFD flexible Fund Project RO 818: Report of Project Coordinator on data produced at the Rowett Research Institute (RRI): http://www.worldcat.org/title/soaefd-flexible-fund-project-ro-818-report-of-projectcoordinator-on-data-produced-at-the-rowett-research-institute-rri/oclc/041214388

71 Pusztai testimony, op. cit. note 67, 3430.

72 Ibid.

73 Ibid.

74 Ewen, S.W.B. and Pusztai, A., "Effects of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small intestine," *The Lancet* 354 (1999): 1353-54.

75 However, no tumors were observed.

76 Email from Susan Bardocz, one of the scientists on the research team (and Pusztai's wife).

77 Smith, Jeffrey, *Seeds of Deception: Exposing Industry and Government Lies About the Safety of the Genetically Engineered Foods You're Eating* (Fairfield, IA: Yes!Books, 2003), 13. Smith based his account of Pusztai's experiences and subjective reactions on extensive interviews. Unless otherwise specified, the following statements about Pusztai's subjective outlook are based on Smith's account, which provides a much more detailed and dramatic exposition of events than is provided in this chapter.

78 *GM-FREE Magazine*, vol. 1, no. 3, August/September 1999.

79 Transcript from, "World in Action," sent by Arpad Pusztai to Jeffrey Smith. Quoted by Smith in *Seeds of Deception*, op. cit. note 77, 15.

80 Ibid., op. cit. note 77, 16.

81 Ibid., 18.

82 Rowell, A., "The sinister sacking of the world's leading GM expert – and the trail that leads to Tony Blair and the White House," *Daily Mail*, July 7, 2003. http://www.gmwatch.org/latest-listing/42-2003/4305

83 Ibid.

84 Rowell, A., *Don't Worry, It's Safe to Eat* (London, UK: Earthscan, Ltd, 2003).

85 https://royalsociety.org/

86 Up until the 1960's, every issue of its journal *Philosophical Transactions* bore a notice that "It is an established rule of the Royal Society . . . never to give their opinion, as a Body, upon any subject."

87 The proactive nature of the policy was acknowledged in the President's Address in The Royal Society Annual Review 1998-99, which declared that "We have contributed early and proactively to public debate about genetically modified plants."

88 Flynn, L. and Gillard, M., "Pro-GM food scientist 'threatened editor'," *The Guardian*, October 31, 1999.

89 Jeffrey Smith reported (in the *Huffington Post*) that Pusztai informed him about having offered the data to the Society and being refused: http://www.huffingtonpost.com/jeffrey-smith/biotech-propaganda-cooks_b_675957.html

90 In his response to the review (op. cit. note 66) Pusztai pointed out that the Royal Society bore "a great deal of the blame" because it gave the reviewers internal documents that were "manifestly inappropriate for peer-review."

91 Ibid.

92 Ibid.

93 Ibid.

94 Ibid.

95 Ibid.

96 Editorial: "Health risks of genetically modified foods," *The Lancet* 353 (May 29, 1999): 1811. The editorial said that by May 22, 1999, the Society had completed its review; but a document issued by the Society in 2002 stated the report was published in June. Apparently, the editor of the *Lancet* had seen a copy of the report prior to formal publication.

97 Horton, R., "GM Food Debate," *The Lancet* 353, issue 9191 (November 13, 1999): 1729.

98 *The Guardian* stated it had "established that the Royal Society was involved in trying to prevent publication." And it noted that these efforts began *before* the Society learned that the *Lancet* was reviewing the research. Flynn and Gillard (1999), op. cit. note 88. (While this article did not employ the term "unsavory," it provided a comprehensive, and unflattering, report on the Society's actions to discredit Pusztai and his research that clearly revealed their unsavory character.)

99 Ibid.

100 Flynn and Gillard, op. cit. note 88.

101 Ibid.

102 Ibid. All words in quotation marks in this paragraph were in quotes within *The Guardian* article.

103 Bateson, P., "Mavericks are not always right," *Science and Public Affairs*, June 2002. Bateson's allegation distorts the truth by ignoring the fact that five out of the six referees voted for publication. Instead, he imparts the impression that more than one objected (which is false), and that no one with statistical competence voted for publication (which is almost surely false as well).

104 Royal Society, "Genetically modified plants for food use and human health – an update," February 2002, 5.

105 The review was published in June 1999, and the Lancet paper was not published until October 15th.

106 Royal Society (2002), op. cit. note 104, 5. The crucial sentences were: "In June 1999, the Royal Society published a report, *Review of data on possible toxicity*

of GM potatoes, in response to claims made by Dr. Pusztai (Ewen & Pusztai, 1999). The report found that Dr Pusztai had produced no convincing evidence of adverse effects from GM potatoes on the growth of rats or their immune function." Thus, the first sentence clearly implies that the review centered on the paper authored by Pusztai and Stanley Ewen that was published in the *Lancet*, not the incomplete summary that had been prepared for scientists at the Rowett Institute (which was the *only* submission the participants in the 1999 report examined). An extensive examination of the Royal Society's misbehavior in regard to Pusztai is contained in: Rowell A. *Don't Worry, It's Safe to Eat*. (London, UK: Earthscan Ltd, 2003).

107 Royal Society, *Review of data on possible toxicity of GM potatoes,* June 1999, 1 & 2.

108 http://www.publications.parliament.uk/pa/ld200001/ldhansrd/vo010216/text/10216-02.htm (accessed: June 2, 2014).

109 Ibid.

110 Arthur, Charles, "Scientists blame media and fraud for fall in public trust," *The Independent*, January 31, 2003: http://www.independent.co.uk/news/science/scientists-blame-media-and-fraud-for-fall-in-public-trust-609014.html

111 Report of the Royal Commission on Genetic Modification (New Zealand, 2001), 209.

112 For instance, the report alleges that differences detected in the feeding studies were due to the fact that raw potatoes were used – and that because rats don't like them, they were starving and the 110-day trial had to be abandoned after 67days. It then asserted: "Starvation affects gut histology, and the lining of the gut of control rats eating unmodified potatoes was shown to be abnormal."

But these assertions are erroneous. First, there were four major studies, and only one was designed to last 110 days. The others were completed in 10 days, and even though the longer one that used raw potatoes ended earlier than planned, it still yielded significant results. (Pusztai Witness Brief, p. 3) Second, all four tests showed significant differences in several physiological indices between rats fed GE potatoes and those fed on the non-GE ones. In all, 39 statistically significant differences were found (by independent multivariate statistical analysis), of which no more than five could have been the result of random error. (Pusztai Testimony, transcript of February 7, 2001, p. 3430.) Further, whatever negative effects the raw potato diet had on the control group were of significantly less magnitude than the effects observed in the rats eating the GE potatoes, which indicates that something unique to the GE potatoes was also a causative factor. Third, the rats were not "starving." They were continuing to put on weight, but not at the rate required by UK government regulations on animal feeding studies. (Ibid., pp. 3435, 3441.) Fourth, even starvation does not produce abnormal gut histology. It merely contracts the gut. (Private communication from Dr. Pusztai.) Fifth, trials were also conducted using *boiled* potatoes. On this diet, the longer study did run for a full 110 days. As in the case of the raw potato diet, there were statistically significant differences between the rats eating GE and non-GE potatoes. (Ewen Witness Brief;

Pusztai transcript, p. 3442.) Moreover, the commission was fully informed of these facts (except for the fourth) but nonetheless misrepresented them.

113 Fedoroff, N. and N.M. Brown, *Mendel in the Kitchen: A Scientist Looks at Genetically Modified Foods* (Washington, DC: Joseph Henry Press, 2004), 181-83.

114 Although the substance of this charge was made in her book, the precise wording was extracted from an article she posted on a pro-GE website on February 25, 2006, around 18 months after her book had been published. See: http://www.agbioworld.org/biotech-info/articles/biotech-art/pusztai-potatoes.html.

That article was for the most part the same as the section on Pusztai's research in her book, except that it elaborated more fully in some places and contained a few revisions.

115 In her words: "But oddly enough, in the entire poisoned rat debate no one seems to have seen the central flaw in Pusztai's experiments: the absence of appropriate controls," *Mendel in Kitchen*, op. cit. note 113, 182.

116 Royal Society, *Review of data on possible toxicity of GM potatoes,* June 1999.

117 Royal Society Report (2002), op. cit. note 104, 5. The relevant section discussed the Society's 1999 critique of Pusztai and then stated: "It concluded that the only way to clarify Dr Pusztai's claims would be to refine his experimental design and carry out further studies to test clearly defined hypotheses focused on the specific effects reported by him. Such studies, on the results of feeding GM sweet peppers and GM tomatoes to rats, and GM soya to mice and rats, have now been completed and no adverse effects have been found (Gasson and Burke, 2001)."

118 Although it eventually did get reviewed and published, that didn't occur until well *after* it was relied on to refute Pusztai's findings. And, according to David Schubert, the study was nonetheless deficient in several respects, and not nearly as strong as was Pusztai's. The paper was published as: Chen Z. et al., "Safety Assessment for Genetically Modified Sweet Pepper and Tomato," *Toxicology* 188 (2003): 297-307.

119 David Schubert pointed this out in an email to me.

120 Pusztai, A., Letter to Royal Society, February 6, 2002: http://ngin.tripod.com/300103f.htm

121 Ibid.

122 Email from David Schubert.

123 Gasson, M. and Burke, D., "Scientific perspectives on regulating the safety of genetically modified foods," *Nature Reviews Genetics* 2 (2001): 217-22.

124 Royal Society Report (2002), op. cit. note 104, 209.

125 In their paper, Ewen and Pusztai only discussed intestinal abnormalities. So the only tests that could cast serious doubt on the studies would have to demonstrate that the particular lectin involved actually causes the problems they detected in the rats. But it's extremely unlikely that such findings could be legitimately registered, since several published studies have demonstrated that that type of lectin is harmless to mammals at levels hundreds of times higher than was produced within the GE potatoes – and Pusztai's experiment showed that the

control potatoes that were spiked with the lectin used in his studies did not induce the problems that the GE potatoes did.

126 Burke, Derek, "GM crops: time to counter the scare stories and relax barriers," March 27, 2014: https://theconversation.com/gm-crops-time-tocounter-the-scare-stories-and-relax-barriers-24678 (accessed May 2014).

127 Burke specifically (and falsely) alleged that Pusztai made the claims in 1998. While it is true that in 2002 Stanley Ewen cautioned (in a submission to a committee of the Scottish Parliament) that the 35S viral promoter used in most GE foods could increase the risk of stomach and colon cancer by over-stimulating cellular growth, he did *not* claim that any GE foods had caused cancer. http://www.sundayherald.com/29821.

128 Fedoroff's article was posted February 25, 2006 at: http://www.agbioworld.org/biotech-info/articles/biotech-art/pusztai-potatoes.html. As of March 14, 2006, Pusztai had not received a reply from Fedoroff to his message informing her of her error, so he authorized his critique of her statements to be posted at: http://gmwatch.org/index.php/news/archive/2006/1937-pusztai-replies-to-fedoroff

As of Aug. 25, 2013, Fedoroff's article was still on the AgBioWorld site in its original, erroneous form.

129 Although the EMS epidemic caused by the toxic tryptophan supplement broke out during 1989, it extended into 1990, and the research linking it to Showa Denko's genetically engineered bacteria didn't occur until that year.

130 Gab-Alla, A.A. et al., "Morphological and biochemical changes in male rats fed on genetically modified corn" (Ajeeb, Y.G), *J Am Sci*. 8 (9)(2012): 1117–23.

131 Gab-Alla, A.A. et al., "Histopathological changes in some organs of male rats fed on genetically modified corn" (Ajeeb, Y.G.), *J Am Sci*. 8 (10)(2012): 684–96.

132 Finamore, A., Rosell, M., Britti, S., et al., "Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice," *J Agric Food Chem*. 56 (2008): 11533–39; doi:10.1021/jf802059w.

133 Krzyzowska, M., Wincenciak, M., Winnicka, A., et al., "The effect of multigenerational diet containing genetically modified triticale on immune system in mice," *Pol J Vet Sci*.13 (2010): 423-30.

134 Tudisco, R., Lombardi, P., Bovera, F., et al., "Genetically modified soya bean in rabbit feeding: Detection of DNA fragments and evaluation of metabolic effects by enzymatic analysis," *Anim Sci*. 82 (2006): 193–99. doi:10.1079/ASC200530.

135 Malatesta, M., Boraldi, F., Annovi, G., et al., "A long-term study on female mice fed on a genetically modified soybean: effects on liver ageing," *Histochem Cell Biol.* 130 (2008): 967–77.

136 Malatesta, M., Caporaloni, C., Gavaudan , S., et al., "Ultrastructural morphometrical and immunocytochemical analyses of hepatocyte nuclei from mice fed on genetically modified soybean," *Cell Struct Funct*. 27 (2002): 173–80; Malatesta, M., Caporaloni, C., Rossi, L., et al., "Ultrastructural analysis of pancreatic acinar cells from mice fed on genetically modified soybean," *J Anat.* 201 (2002): 409–15; Malatesta, M., Biggiogera, M., Manuali, E., Rocchi, M.B.L., Baldelli, B.,

Gazzanelli, G., "Fine structural analyses of pancreatic acinar cell nuclei from mice fed on genetically modified soybean," *Eur J Histochem*. 47 (2003): 385–388.

137 Interview in documentary film: Robin, M.M., "The World According to Monsanto [film]," 2008.

138 Séralini, G.E., Clair, E., Mesnage, R., et al., [RETRACTED:] "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize," *Food Chem Toxicol.* 50 (2012): 4221-31.

139 Hammond, B., Dudek, R., Lemen, J., Nemeth, M., "Results of a 13 week safety assurance study with rats fed grain from glyphosate tolerant corn," *Food Chem Toxicol*. 42 (2004): 1003-14. doi:10.1016/j.fct.2004.02.013.

140 European Food Safety Authority (EFSA); Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto (QUESTION NO EFSA-Q-2003-002): Opinion adopted on November 25, 2003, *EFSA J*. 2003(9) (2003): 1–14.

141 De Vendomois, J.S., F. Roullier, D. Cellier, G.E. Séralini, "A comparison of the effects of three GM corn varieties on mammalian health," *Int J Biol Sci*. 5 (2009): 706–26.

142 Even if the substance being tested has a tendency to induce tumors at a higher than normal rate, if each group of rats contains only 10 of each sex (as was the case in Séralini's study), no tumors might be observed, whereas if 50 per sex per group are used (as is ordinarily done in cancer studies), the study has a much better chance of detecting some tumors. However, that doesn't entail that using a lower number of rats somehow invalidates any statistically significant increase in tumors that *is* observed. As long as a sufficient number was used to reliably register such differences (which was enabled by the number Séralini employed), those differences are valid.

143 Thus, Peter Saunders, emeritus professor of mathematics at King's College London, has stated that the smaller number of rats "makes the results if anything *more* convincing, not less." He explained: "Using a smaller number of rats actually made it *less* likely to observe any effect. The fact that an effect was observed despite the small number of animals made the result all the more serious." Saunders, P., "Excess cancers and deaths with GM feed: The stats stand up," *Sci Soc.* (2012). Available at: http://www.i-sis.org.uk/Excess_cancers_and_deaths_from_GM_feed_stats_stand_up.php.

144 Only one in ten control rats developed a tumor, and even then it occurred late in their lives.

145 Committee on Publication Ethics (COPE), Retraction guidelines, 2009. Available at: http://publicationethics.org/files/retraction%20guidelines.pdf

146 Hayes, A.W., "Response to Letters to the Editors," December 2013. Available at: http://www.elsevier.com/about/press-releases/research-and-journals/food-and-chemical-toxicology-editor-in-chief,-a.-wallace-hayes,-publishes-response-to-letters-to-the-editors#sthash.tTW2LCGq.dpuf.

147 In his response to the retraction, Seralini pointed out: "It should be noted that tumorigenesis is not synonymous with cancer. Tumors can be in some cases more rapidly lethal than cancers because their size can cause hemorrhages and possible impairments of vital organs, as well as secretion of toxins." Séralini, G.E. et al., "Conclusiveness of toxicity data and double standards, Food and Chemical Toxicology" (2014), doi: http://dx.doi.org/10.1016/j.fct.2014.04.018

148 OECD guideline no. 452 for the testing of chemicals: Chronic toxicity studies: Adopted September 7, 2009.

149 He stated: "While the number of animals used may have been sufficient to reach conclusions regarding oral toxicity, it proved insufficient for conclusions related to the carcinogenicity of the test substances." Hayes Response (2013), op. cit. note 146.

150 As reported in the *New York Times:* "The editor of the journal, Food and Chemical Toxicology, said in a letter to the paper's main author that the study's results, while not incorrect or fraudulent, were 'inconclusive, and therefore do not reach the threshold of publication. " Pollack, A., "Paper Tying Rat Cancer to Herbicide is Retracted," *New York Times*, November 28, 2013. Seralini quoted that letter as having stated that the raw data were "'not incorrect'". Séralini et al., op. cit. note 147.

151 Schubert, D., "Science study controversy impacts world health," *U-T San Diego*: http://www.utsandiego.com/news/2014/jan/08/science-food-health/, published January 8, 2014.

152 The words "could have been caused" have been used because the results provided reasonable grounds for thinking that this had happened but did not decisively demonstrate it.

153 The research demonstrates that the level of herbicide residue on marketed Roundup-ready plants can induce substantial damage to animals that eat them, which entails that all such plants are dangerous; and it also indicates that harmful effects might be induced by the expression of the gene that's inserted to confer the Roundup resistance, which casts additional doubt on the safety of all the plants that contain it.

154 Pollack, A., "Paper Tying Rat Cancer to Herbicide is Retracted," *New York Times*, November 28, 2013.

155 Environmental Sciences Europe (ESEU, 2014, 26:14).

156 Fagan, J., Antoniou, M.C., and Robinson,C., *GMO Myths and Truths: An Evidence-Based Examination of the Claims Made for the Safety and Efficacy of Genetically Modified Crops*, 2nd Edition, version 1.0, (London: Earth Open Source, 2014), 147.

157 It's become so standard, and so obvious, that it's been noted by several other commentators.

158 Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods, October 20, 2012: http://www.aaas.org/sites/default/files/migrate/uploads/AAAS_GM_statement.pdf

159 European Commission, A decade of EU-funded GMO research (2001–2010), 2010.

160 http://earthopensource.org/index.php/3-health-hazards-of-gm-foods/3-2-myth-eu-research-shows-gm-foods-are-safe

161 European Commission, A decade of EU-funded GMO research (2001–2010), 2010.

162 Snell, C., Aude, B., Bergé, J., et al., "Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review," *Food Chem Toxicol*. 50 (2012): 1134-48.

163 *Myths and Truths*, op. cit. note 156, 138, 140, 161.

164 Ibid., 162.

165 E.g., Fares, N.H., El-Sayed, A.K., "Fine structural changes in the ileum of mice fed on delta-endotoxin-treated potatoes and transgenic potatoes," *Nat Toxins* 6(6) (1998): 219-33.

166 *Myths and Truths*, op. cit. note 156, 105. I'm indebted to the authors of this document for this and the following insights about the weaknesses of the Nicolia review.

167 Ibid.

168 Ibid., 107-08. The authors of this critique point out that Nicolia and colleagues do not base their conclusion "on empirical data, reasoned scientific argument, or even peer-reviewed papers" but on four non-peer-reviewed opinion pieces "containing inaccuracies and unsubstantiated personal views."

169 Ibid., 106. Although another long-term study on a GE glyphosate-tolerant crop (a soybean) has been done, Claire Robinson has noted that it's doubtful the beans were sprayed with glyphosate – at least not to a degree even close to the amount that's typically applied by farmers. That's because the herbicide was detected at an extremely low level: far lower than when beans are sprayed in actual farming operations. So the test was limited to assessing the effects of the insertional event itself, and it was ill-designed to do so because the control bean was not the isogenic variety. (Sakamoto Y. et al., "A 104-week feeding study of genetically modified soybeans in f344 rats." *Shokuhin Eiseigaku Zasshi* 49 (2008):272-282. (An English translation of the study is available at: net.gedal.fr/knowledgebase/docs/A593742.pdf)

170 Ibid., Section 2.3. For example, the main review paper also failed to discuss a multigenerational study in which rats that consumed GE Bt maize over three generations not only displayed alterations in blood chemistry but suffered liver and kidney damage. (Kilic A, Akay MT., "A three generation study with genetically modified Bt corn in rats: Biochemical and histopathological investigation," *Food Chem Toxicol*. 46 (2008):1164–70. doi:10.1016/j.fct.2007.11.016.)

The other review papers that purport to demonstrate the safety of GE foods have likewise failed due to multiple deficiencies. One that's frequently cited is a survey of the data on livestock that were fed GE crops. (Van Eenennaam, A. and Young, A.E., "Prevalence of impacts of genetically engineered feedstuffs on livestock populations." J Anim Sci, 92 (2014):4255-4278.) But besides relying on

uncontrolled studies of animals with dissimilar digestive systems than humans to try to refute the adverse findings of well-controlled studies on standard laboratory animals that are much better models for our physiologies, this paper contains several other serious flaws that undercut its claims, as is incisively demonstrated at: http://www.gmwatch.org/index.php/news/archive/2014/15717-junk-science-and-gmo-toxicity and http://www.gmwatch.org/index.php/news/archive/2014/15669

In contrast, around the same time that defective review appeared, another review was published in a peer-reviewed journal providing further confirmation that the safety of the GE crops on the market has *not* been established. It focused on those containing at least one of the three most prevalent genes used in creating GE plants, and it investigated the extent to which these crops had been subjected to reliable tests employing standard laboratory animals and histopathological study of the digestive tract – a far more sensitive type of study than the superficial inspections relied on by the Van Eenennaam review. The researchers discovered that although there were 47 crop varieties with one or more of these genes that had been approved by regulators for animal or human consumption, only 9 (19%) had been tested via such histopathological study. Further, 76% of those tests were done *after* the crop had been approved for marketing, and half were published at least 9 years after approval. Worse, the researchers could not find a single study that was properly conducted or reported. Zdziarski I.M. et al., "GM crops and the digestive tract: A critical review," *Environment International* 73 (2014): 423-433. http://gmojudycarman.org/wp-content/uploads/2014/10/Zdziarski-et-al-14-GM-crops-and-rat-digestive-tract-review.pdf

171 For example, during the meeting of the Food Advisory Committee in regard to the Flavr Savr tomato, a participant asked the FDA to respond to a charge that had been made by Rebecca Goldburg (who represented a public interest organization) that its policy on GE foods had illegitimately shifted the burden of proof. But instead of admitting this obvious truth, the biotechnology manager, James Maryanski, engaged in denial. He argued: "The standards by which a substance must be determined to be GRAS are based on the case history and the law, and so we did not change that standard whatsoever." But Goldburg would not let him get away with it; and she pointed out how the FDA had, in practical effect, changed the standard. FAC transcript, op. cit. note 18, vol. 3, 138-41.

172 Document #15, p. 3 at: http://biointegrity.org/24-fda-documents.

173 Ibid.

174 Ibid.

175 Parrott, W., Chassy, B.M., "Is this study believable? Examples from animal studies with GM foods," 2009, 8. Available at: http://agribiotech.info/more-details-on-specific-issues.

176 Ibid., 6.

177 Folta, K., quoted in Johnson, N., "Food for bots: Distinguishing the novel from the knee-jerk in the GMO debate," *Grist*, August 22, 2013: http://grist.org/food/dodging-argument-bot-crossfire-to-revisit-some-gm-research-controversies/

Further, it's clear Folta was arguing that trying to discredit the belief that GE foods are as safe as naturally produced ones is on a par with trying to disprove that gravity exists – and not with merely attempting to replace an accepted theory about what gravity is with another that's alleged to explain the phenomenon better. That's because of how he illustrated his point that "pro- and anti-GM science" have different verificational thresholds. He stated: "For example: To test the hypothesis that gravity does not exist on earth I need some elaborate mechanisms, many replicates, tons of math and new models of thinking that change our understanding of basic fundamentals of natural science. To test the hypothesis that gravity exists, I have to push a pencil off of my desk. Two very different evidence thresholds."

178 21 CFR Sec. 170.30(b); 21 CFR 170.3(I). While I'm aware that it's impossible to prove a food is safe as conclusively as one can prove a mathematical proposition is true, I'm employing the terms "prove" and "burden of proof" as understood within the context of food safety regulation. And within the context of US law, the manufacturer bears the burden of proof; and the standard of proof is clearly defined: a demonstration that there's a "reasonable certainty" the product won't be harmful under its intended conditions of use.

179 *Myths and Truths*, op. cit. note 156, 142-144.

180 Ibid., 143.

181 Ibid.

182 Antoniou, Michael, email communication.

183 In *United States v. An Article of Food, etc.* 678 F. 2d 735 (5th Cir. 1982), the court upheld the FDA's charge that a substance was not GRAS based on the testimony of five doctors. And in *United States v. Seven Cartons . . . Ferro-Lac*, 293 F. Supp. 660, 664 (S.D. Il. 1968), the court denied GRAS status to a substance based on the affidavits of two scientists who said that they were not aware of any studies in the scientific literature showing it was safe. (This ruling was subsequently modified on other grounds by an appellate court, 424 F.2d 136 (7th Cir. 1970) – grounds that did not affect the holding about the sufficiency of two experts.)

184 http://www.ensser.org/increasing-public-information/no-scientific consensus-on-gmo-safety/. Although some of the signatories do not have graduate degrees in one of the directly relevant life sciences, a large number do; and their number is more than sufficient to defeat the claim that consensus about safety exists within the expert community.

185 Schubert, D., Letter to the *Los Angeles Times*, October 28, 2012.

186 This statement assumes there won't be any hasty, and successful, attempts to alter the laws.

11. Overlooked Lessons from Computer Science

1 Writing in 2002, Evelyn Fox Keller observed: "Computer metaphors have been commonplace in biology for almost half a century," Keller, E.F., *Making Sense of Life*, Harvard University Press, Cambridge, MA (paperback edition, 2003), 247.

2 http://scienceblogs.com/tomorrowstable/2012/09/24/rachel-carsons-dream-of-a-science-based-agriculture-may-come-as-a-surprise-to-those-who-believe-that-sustainability-and-technology-are-incompatible/

3 I'm employing the word "misrepresent" merely to denote that an inaccurate representation has been conveyed, not to imply that the inaccuracy was part of an intentional effort to mislead people. In regard to software, I think the erroneous statements of the GE proponents have stemmed from a failure to fully comprehend the facts, not from a desire to obfuscate them.

4 This example comes from: http://en.wikipedia.org/wiki/Data_(computing)

5 http://en.wikipedia.org/wiki/Computer_programming

6 A prevalent form of such programming is termed *object-oriented design*.

7 Although some programs are not command-based *imperative codes* and instead specify outcomes without dictating the discrete steps through which they're to be attained (and are thus called *declarative code*s), the programmers still aim to achieve predictable outcomes that follow linearly from the initial specifications.

8 For one discussion of ravioli code, see: http://www.techopedia.com/definition/26876/ravioli-code. Another alternative, in which the program is somewhat layered, is called *lasagna code*.

9 Strohman, Richard, "The Coming Kuhnian Revolution in Biology," *Nature Biotechnology* 15, March 1997.

10 Ibid., 197.

11 Ibid., 199.

12 Ibid., 197.

13 Strohman, Richard, "Beyond Genetic Determinism: Toward a New Paradigm of Life," *Pressing Times*, Spring 2002: http://www.mindfully.org/GE/GE4/Beyond-Genetic-Determinism-Apr02.htm

14 Keller, E.F., *The Century of the Gene* (Harvard University Press, Cambridge, MA, 2000), 100.

15 Ibid.

16 Ibid., 100-01.

17 Ibid., 101.

18 Ibid., 162, n. 52.

19 Strohman, "The Coming Kuhnian Revolution," op. cit. note 9, 194.

20 Even when one segment of code sometimes acts as an instruction and sometimes serves as data, the role it's playing is clear in any given instance.

21 Conrad, Michael, "The Importance of Molecular Hierarchy in Information Processing," in *Towards a Theoretical Biology* 4: *ESSAYS*, Waddington, C.H., ed. (Chicago: Aldine-Atherton, Inc., 1972), 222-28. The quoted text is on p. 224.

22 Ibid., 225.

23 Ibid., 226.

24 Whitehouse, D., "Scientists Hail New 'Map of Life'": http://news.bbc.co.uk/go/pr/fr/-/2/hi/science/nature/3223318.stm

25 A minority of the promoters are always in an open, receptive state. They will be discussed a bit later.

26 Yuh, Chiou-Hwa and Davidson, E.H., "Modular cis-Regulatory Organization of *Endo 16*," *Development* 12 (1996): 1069-82.

27 Yuh, Chiou-Hwa et al., "Genomic cis-Regulatory Logic: Experimental and Computational Analysis of a Sea Urchin Gene," *Science* 279 (1998): 1896-1902.

28 Yuh, Chiou-Hwa et al., "Cis-Regulatory Logic in the Endo 16 Gene: Switching from a Specification to a Differentiation Mode of Control," *Development* 128 (2001): 617-29.

29 Wray, G.A., "Promoter Logic," *Science* 279 (1998): 1872.

30 Keller, *Making Sense of Life*, op. cit. note 1 above, 338-9, n. 12.

31 Ibid., 339.

32 Wray, op. cit. note 29, 1871.

33 Ibid., 1872.

34 In fact, the knowledge regarding plant promoters may be even more deficient than in the case of animal promoters. According to molecular biologist Allison Wilson, greater resources have been expended on the study of the latter.

35 https://www.owasp.org/index.php/Race_Conditions

36 Lehman, M. M., "Program, Life-Cycles and the Laws of Software Evolution," *In Proceedings of IEEE* 68(9) (1980): 1060-76; Lientz, B., E. Swanson., *Software Maintenance Management* (Addison Wesley, Reading, MA, 1980).

37 Schach, R., *Software Engineering*, Fourth Edition (McGraw-Hill, Boston, MA, 1999), 11.

38 21 CFR Parts 807, 814

39 IEC 62304

40 This statement pertains to safety testing; and it describes the situation according to the standpoint of the FDA. If the inserted cassette produces a pesticidal protein, then the EPA has authority to regulate it, but it has rarely required meaningful safety testing of such substances either. See, e.g., Marden, E., "Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture," 44 B.C. L. Rev. 733.

41 For instance, FDA regulations state that in the case of "high risk devices that pose a significant risk of illness or injury" (Class III devices) safety claims must be supported by "the submission of clinical data" (21 CFR Part 814). Extensive non-clinical data is also required. In contrast, devices that entail lower risk (Class II) can gain approval by establishing that they're substantially equivalent with specific types of legally marketed devices (CFR Part 807 Subpart E). And some of the least risky (Class I) don't even require pre-market notification: http://www.millerassociates.net/files/SW_Risk_Mgmt_Arch.gif.

However, according to Tom Miller, whose company (Miller Associates, Inc.) performs quality assurance for software used in medical devices, the 'substantial equivalence' route doesn't eliminate the need for testing, and to satisfy FDA standards, the software in Class II devices must undergo "significant testing," albeit

not as stringent as for Class III (email communication). Mark Rainbow, a software engineer who works for a medical device company, concurs, stating that when substantial equivalence is claimed, "the FDA still requires full testing of the device operations and complete reviews of the design and an analysis of potential hazard" (email communication).

Further, the international standard for the testing of life-critical software, which the FDA recommends but does not formally require, is even stricter than the standard imposed by the latter. A flow chart on the Miller Associates website provides insight into the thoroughness with which software is assessed and tested in order to satisfy this standard enforced in the EU nations and other countries – and provides a glaring contrast between the toughness these nations exhibit in the case of life-critical software and the laxness they display when it comes to GE foods: http://www.millerassociates.net/files/SW_Risk_Mgmt_Arch.gif.

42 This presumption is made by the FDA in regard to the safety of GE crops. The agency sets GE animals in a different category.

43 Because a much greater percentage of the population consume a particular variety of GE food than rely on a particular type of pacemaker or are exposed to a specific kind of X-ray machine, that food could cause much more harm than either.

44 As discussed in previous chapters, most harmful alterations to food don't cause immediate problems but do damage incrementally; and so the majority of such changes in GE foods would likely go unnoticed absent epidemiological testing, especially if they cause common ailments such as cancer.

45 E.g., Michaels, D., *Doubt is Their Product: How Industry's Assault on Science Threatens Your Health* (Oxford University Press, 2008); Barnes, D.E. and Bero, L.A., "Why review articles on the health effects of passive smoking reach different conclusions," *JAMA* 279 (1998): 1566-70; Lexchin, J., Bero, L.A., Djulbegovic, B., Clark, O., "Pharmaceutical industry sponsorship and research outcome and quality: systematic review," *Br Med J*. 326 (2003): 1167; doi:10.1136/bmj.326.7400.1167; Lexchin, J., "Those who have the gold make the evidence: How the pharmaceutical industry biases the outcomes of clinical trials of medications," *Sci Eng Ethics* (2011); doi:10.1007/s11948-011-9265-3; Bekelman, J.E., Li, Y., Gross, C.P., "Scope and impact of financial conflicts of interest in biomedical research: a systematic review," *JAMA* 289 (2003): 454-65.

46 Diels, J. et al., "Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products," *Food Policy* 36 (2011): 197–203.

47 Schach, op. cit. note 37.

48 Larry Seese, quoted in *The Risks Digest* 9(62), February 26, 1990.

49 Gleick, James, "A Bug and a Crash," *New York Times Magazine*, December 1, 1996.

50 Quoted in Gleick, above.

51 A GE food would only pose less risk if there was scant likelihood that its associated hazards would manifest – which, in light of the analysis in Chapter 9,

does not appear to be the case. The issue of risk will be examined more thoroughly as the chapter continues.

52 Leveson, N., and Turner, C., "An Investigation of the Therac-25 Accidents," *IEEE Computer* 26(7), July 1993, 18-41. This article describes both the "impressive" behavior of the FDA and the less than impressive behavior of the manufacturer, including statements from FDA officials critical of how it withheld evidence.

53 Personal communication from Tom Miller, whose qualifications are described in note 41 above.

54 Glover, Ann, "Interview" by *Eur Activ*, July 24, 2012: http://www.euractiv.com/innovation-enterprise/chief-scientifc-adviser-policy-p-interview-514074

55 For instance, there's still debate about how much of the DNA has a function, and even the functions of many sections that are known to be functional are not well understood. And the genomes of some of the plants that are engineered have not been fully sequenced. More importantly, most commercial lines are poorly characterized on the molecular level and only one has been fully sequenced: papaya. Further, even though the examination of that GMO was not rigorous enough to detect unintended mutations (because it was not compared to the isogenic parent line), it yet revealed that the insertion of new DNA was not restricted to the site from which the foreign gene functioned and that many small fragments of that gene were lodged in other locations.

56 Although hackers sometimes know the source code of the program they're invading (as in the case of open source code), they usually don't; and hacking is generally performed in the absence of such knowledge.

57 Although hackers insert several types of sequences, which have distinct functions, each almost always harms the software system or injures the interests of the user. Accordingly, they're generally referred to as "malware," because they serve malicious purposes. And although a specific class of malware are referred to as "viruses," all malware exhibits some basic features of biological viruses; and those are the features described in the main text.

58 Christensen, D., "Beyond Virtual Vaccinations," *Science News*, July 31, 1999 (The words the article quoted were those of an expert at IBM, Steve R. White).

59 Brown, Patrick, "The Promise of Plant Biotechnology – the Threat of Genetically Modified Organisms," July 2000. Available at: http://www.campaignforrealfarming.org/2012/01/the-promise-of-plant-biotechnology-the-threat-of-genetically-modified-organisms/

60 Although there have been exceptions, such as the unintended consequences of the "Morris worm" released in 1988.

61 "DNA as Software," *All Things Considered, National Public Radio*, April 25, 2003: http://www.npr.org/templates/story/story.php?storyId=1244325

62 http://en.wikipedia.org/wiki/Northeast_blackout_of_2003

63 Hagan, N. et al., "The redistribution of protein sulfur in transgenic rice expressing a gene for a foreign, sulfur-rich protein," *Plant J.* 34 (2003): 1–11.

64 Regal, P., "Scientific Principles for Ecologically Based Risk Assessment of Transgenic Organisms," *Molecular Ecology* 3 (1994): 5-13 (The quoted sentences are from a section relevant to food safety as well as ecological safety).

65 This can occur when the transcription process starts at different locations, with the result that a single base can be part of one distinct three-base codon on one occasion and a constituent of a different codon on another, depending on where the transcription of RNA begins. In consequence, a discrete segment of DNA can participate in generating diverse segments of RNA. However, although a segment of DNA can be transcribed via alternate, overlapping reading frames, the amino acid code itself is nonoverlapping, which means that (barring errors) a single reading frame is always directly transcribed into the same RNA sequence (which can subsequently be altered via alternate splicing).

66 Segal, E. et al., "A Genomic Code for Nucleosome Positioning," *Nature* 442 (August17, 2006): 772-78. The word "superimposed" was employed by the journalist who reported the discovery in the *New York Times*: Wade, N., "Scientists Say They've Found a Code Beyond Genetics in DNA," *New York Times*, July 25, 2006: http://www.nytimes.com/2006/07/25/science/25dna.html

67 Weatheritt, R. and Babu, M., "The Hidden Codes that Shape Protein Evolution," *Science* 13: 342 (6164) (December 2013): 1325-26. The authors refer to the codes as "regulatory."

68 Stergachis, A. et al., "Exonic Transcription Factor Binding Directs Codon Choice and Affects Protein Evolution," *Science* 342(6164) (December 13, 2013): 1367-72.

69 "Scientists Discover Double Meaning in Genetic Code," *Press Release*, University of Washington December 12, 2013: http://www.washington.edu/news/2013/12/12/scientists-discover-double-meaning-in-genetic-code/

70 However, since the statement appeared in a press release, it may merely reflect the desire of the university's public relations department to hype the importance of the discovery. In any event, the resilience of ingrained presumptions to new evidence is a well-recognized phenomenon within the biological sciences, especially as regards the presumptions on which the GE venture relies.

71 Email to a group of concerned scientists, December 14, 2013.

72 Barbara A. Caulfield, executive vice president of Affymetrix, Inc., quoted in Caruso, D., "A Challenge to Gene Therapy, a Tougher Look at Biotech," *New York Times*, July 1, 2007.

73 Wilson, Stephen, "We're Not Ready for Genetic Engineering," January 15, 2011: http://lockstep.com.au/blog/2011/01/15/not-ready-for-gm

74 Ibid. Update of September 2012.

75 Ibid. Reply to a reader comment on September 11, 2012.

76 Dawkins, Richard, "Why Prince Charles is So Wrong," London Times, January 28, 2003.

77 The professorship was endowed by Charles Simonyi, who oversaw the development of Microsoft's suite of Office applications.

78 Gates, Bill, *The Road Ahead*, Penguin 1996, 228. Although Gates was referring specifically to human DNA, it's reasonable to presume that he would apply his comment to the DNA of other organisms; and it's doubtful he thinks humans have created software more advanced than the information systems of plants and animals.

79 In his speech at the World Food Prize event on October 15, 2009 he stated: "In some of our grants, we include transgenic approaches because we believe they can help address farmers' challenges faster and more efficiently than conventional breeding alone. Of course, these technologies must be subject to rigorous scientific review to ensure they are safe and effective." And it's evident he believes that adequate testing is regularly performed or readily can be. Otherwise, he would have refrained from putting so much money into developing GE crops – or at the least postponed it until after he had funded projects to develop a testing regime better suited to a technology that's altering the world's most complex information systems. Moreover, as the main text observes, if he carefully considered bioengineering in light of what's known about software engineering, he would not fund it at all and would exclusively foster sounder forms of food production.

12. Unfounded Foundational Assumptions

1 "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada," The Royal Society of Canada (January 2001): 184.

2 Caruso, Denise, "A Challenge to Gene Theory, a Tougher Look at Biotech," *New York Times*, July 1, 2007: http://www.nytimes.com/2007/07/01/business/yourmoney/01frame.html?pagewanted=1&_r=2&ref=yourmoney&

3 Bernardi, Giorgio, "The Role of Chance in Evolution," in *Scientific Insights into the Evolution of the Universe and of Life*, Pontifical Academy of Sciences, Acta 20 (2009): 233. www.pas.va/content/dam/accademia/pdf/acta20/acta20-bernardi.pdf

4 Hurst, Laurence, D. et al., "The Evolutionary Dynamics of Eukaryotic Gene Order," Nature Reviews Genetics, 5 (2004): 299-310. This paper stated that "gene order has typically been assumed to be random." This assumption pertained to organisms with cellular nuclei but not bacteria, which were known to contain structures (called *operons*) in which several genes are grouped together under the control of a single promoter.

5 Bernardi, op. cit. note 3, 233.

6 Ibid.

7 Hurst, op. cit. note 4, 308.

8 Michael Antoniou, Testimony to New Zealand Royal Commission on Genetic Modification.

9 Email from Michael Antoniou. The UK GM Science Review Panel sat for two sessions. Antoniou was a member of the second panel.

10 Although the word "organic" has several denotations, an important one refers to a systematic interconnection of parts suggestive of the structure displayed by living organisms.

11 Institute of Food Technologists, *IFT Expert Report on Biotechnology and Foods*, 2000, 17.

12 Schubert, D., "A Different Perspective on GM Food," *Nature Biotechnology* 20 (October 2002): 969.

13 Beachy, R. et al., Letter to the Editor, *Nature Biotechnology* 20 (December 2002): 1195.

14 Ibid.

15 For instance, an article published in 2012 by six scientists who advocate GE foods contrasts the allegedly precise modifications made through bioengineering with the "random genetic modifications that occur in conventional breeding." Weber, Natalie et al., "Crop Genome Plasticity and Its Relevance to Food and Feed Safety of Genetically Engineered Breeding Stacks," *Plant Physiology* 160 (December 2012): 1842.

16 National Research Council and Institute of Medicine of the National Academies (NAS), "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects" (Washington D.C.: The National Academies Press, 2004), 46.

17 When sexual breeding does introduce new risk, it's usually because a wild and weedy relative that is, itself, not wholesome for humans has been crossed with a domesticated variety. So the cases requiring caution are ordinarily known. Further, in such cases the harmful substance is usually a toxin or anti-nutritive factor that already exists within the species, that's present in higher concentration in the wild varieties, and that gets expressed in the hybrid at greater levels than is normal for the cultivated varieties. Consequently, it's easier to screen for such risks because breeders know what substance to monitor.

18 All of these defects have been thoroughly discussed in Chapter 9. Moreover, (as also discussed in that chapter), most engineered plants must undergo substantial backcrossing too, and (as Chapter 5 noted) the average GE crop takes longer to develop than traditionally bred ones and, for several reasons, entails much higher cost. Consequently, there's no trade-off between increased risk and reduced cost. Instead, risks and costs are both increased.

19 Pollack, Andrew, "Panel Sees No Unique Risk From Genetic Engineering," *New York Times*, July 28, 2004.

20 Of course, one of the main reasons that the testing has been inadequate is the unrealistic belief that very little data is needed in order to demonstrate that a GE food is substantially equivalent to it's naturally produced counterpart. So faith has been to a significant degree responsible for the deficient testing.

13. The Devolution of Scientists into Spin Doctors

1 Bronowski, J., Science and Human Values, (New York: Harper & Rowe, 1965), 28.

2 Ibid., 46.

3 Ibid., 25.

4 Dutton, Diana B., *Worse than the Disease: Pitfalls of Medical Progress* (New York: Cambridge University Press, 1992), 193.

5 Ibid.

6 Ibid., 194.

7 Ibid., 194-95.

8 Ibid., 195.

9 Ibid., 193.

10 Ibid., 195.

11 Ibid.

12 As reported in *Lords of the Harvest*, Monsanto spent at least one billion dollars on research involving GE plants before it had produced even one that was marketable. Charles, Dan, *Lords of the Harvest: Biotech, Big Money, and the Future of Food* (Cambridge: Perseus, 2002), xv.

13 When I speak of modern biotechnology corporations, I'm referring to those that employ rDNA technology. And the first one of these (Genentech) was not founded until April, 1976 (by the biochemist Herbert Boyer and the venture capitalist Robert Swanson). Further, it took a few years before that company had dispelled widespread doubts about the ability of rDNA technology to produce commercially valuable products, and it did not go public until 1980, http://www.gene.com/media/company-information/chronology. Although, as Chapter 4 noted, the Cetus corporation (which had been founded by scientists in Berkeley) was pitching the promise of genetic engineering to investors in 1975, it didn't start employing that technology until well after Genentech got going: http://en.wikipedia.org/wiki/Cetus_Corporation.

14 Although Monsanto had begun research on how to produce GE plants in the late 1970's, it did not actually produce one until 1982, and it apparently did not play a significant role in the lobbying efforts mounted by the biotech industry during that decade. For instance, in her comprehensive study of the development of US biotechnology policy, Mary Ellen Jones does not mention any involvement of Monsanto until the 1980's; and her first citation of a Monsanto communication to the government is a letter it sent to the NIH sometime between 1980 and 1982 (Jones, Mary Ellen, "Politically Corrected Science: The Early Negotiation of U.S. Agricultural Biotechnology Policy," a Doctoral Dissertation in Science and Technology Studies at Virginia Polytechnic Institute [1999], n. 289, 110). Further, the index of Susan Wright's exhaustive history of the development of US biotech policy between 1972 and 1982 provides only one mention of Monsanto: in connection with an agreement it formed with the Harvard Medical School in 1974 to fund research in medically related areas of biotech (Wright, Susan, *Molecular Politics: Developing American and British Policy for Genetic Engineering 1972-1982* [Chicago: University of Chicago Press, 1994]).

15 For instance, a 2003 survey by researchers at North Dakota State University found consumers ranked university scientists as the most trustworthy source of information about GE foods (along with the US Department of Agriculture), regarding them as far more reliable than public interest groups, and, due to the

technical nature of the issue, even the clergy. Wachenheim, C. J. and W. D. Lesch, "North Dakota Shoppers Perceptions of Genetically Modified Organisms and Food: Results of a Winter 2003 Survey," Department of Agribusiness and Applied Economics, *North Dakota State University*, Agribusiness & Applied Economics Report No. 540, June 2004, p.v. (This study specifically asked for opinions about the USDA but not the FDA. Others have found that when polled about the FDA, consumers place it in the top tier of reliability as well.)

Priest, S. H., and Talbert, J., "Mass Media and the Ultimate Technological Fix: Newspaper Coverage of Biotechnology," *Southwestern Mass Communication Journal*, 10 (1), (1994): 76-85.

16 Priest and Talbert (1994), op. cit. note 15.

17 American Medical Association, Policy Statement on Biotechnology and the American Agricultural Industry, 1990.

18 For example, a report issued in 2012 contains several misleading statements. (American Medical Association, Report of the Council on Science and Public Health, CSAPH Report 2-A-12, 2012.) A few of them follow.

On p. 2, the report states: "Bioengineered foods have been consumed for close to 20 years, and during that time, no overt consequences on human health have been reported and/or substantiated in the peer-reviewed literature. . . . However, a small potential for adverse events exists." But it doesn't document that last assertion, nor does it explain how its authors arrived at the conclusion that the potential is "small." Nor does it acknowledge that many experts think the potential is significant.

On p. 4 the report denigrates the Pusztai study (that was examined in Chapter 10) by stating that "the experimental design of this study is widely regarded as flawed, with subsequent studies unable to reproduce the findings." But Chapter 10 has demonstrated why both these assertions are deceptive. Moreover, the AMA report goes on to imply that whatever differences may have been found in the rats consuming the engineered potatoes were likely caused by consumption of the lectins that were expressed by the transgene, despite the fact that (as Chapter 10 has explained) the presence of the lectins was controlled for and cannot explain the differences.

Later on p. 4, the report claims that safety assessments based on the concept of "substantial equivalence" involve "a thorough comparison" between the GE crop and its conventionally bred counterpart – a statement at odds with the opinion of numerous independent experts, including the panel that produced the 2001 report of the Royal Society of Canada.

19 Mestel, Rosie, "Scientists defend safety of genetically modified foods," *Los Angeles Times*, October 24, 2012: http://www.latimes.com/news/science/la-scigmo-food-safety-20121025,0,5914417.story?page=2

20 Although a minority of the plant's genes are attached to promoters that induce them to express in a continual manner, those promoters don't ordinarily compel the level of expression that the viral promoters do. Moreover, because those genes are essential to the plant's function, their constant expression is harmonized with the operations of the other genes. But the incessant activity of the alien genes is not.

21 For instance, besides forcing the inserted genes to hyper-express in an unregulated manner, the viral promoters that are affixed to them can directly disturb the function of some native genes. Moreover, (as Chapter 6 discussed) there's evidence that the proteins expressed by the inserted genes can gain unintended add-ons or become misfolded, either of which pose a health risk.

22 Finz, Stacy, "Biotech food measure Prop. 37 on ballot," *San Francisco Chronicle*, August 15, 2012: http://www.sfgate.com/news/article/Biotech-food measure-Prop-37-on-ballot-3788811.php

23 The first bacterium endowed by humans with recombinant DNA was created in 1973, and the first GE plant was created in 1982 (and was publicly announced in January 1983): *Timeline of Plant Tissue Culture and Selected Molecular Biology Events*, University of Florida Horticultural Sciences Department.

24 If he had merely intended to convey the idea that GE crops are just as safe as naturally produced ones, he could have said so instead of calling them "the safest crops."

25 Finz, op. cit., note 22.

26 https://www.mcdb.ucla.edu/Research/Goldberg/the_seed_institute/Biotech_exploit.pdf

27 Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods, October 20, 2012: http://www.aaas.org/sites/default/files/migrate/uploads/AAAS_GM_statement.pdf

28 http://www.newyorker.com/online/blogs/elements/2014/04/a-civildebate-over-genetically-modified-food.html

29 Cook, Guy, *Genetically Modified Language: The Discourse of Arguments for GM Crops and Food*, (London: Routledge, 2004), 2.

30 http://www.psrast.org/promplantbiot.htm

31 Dutton, op. cit. note 4, 195.

32 Quoted in Charman, K., "Brave New Nature: Spinning Science into Gold," *Sierra Club Magazine*, July/August 2001: http://www.sierraclub.org/ sierra/200107/charman.asp

33 Ibid.

34 Quoted in Ibid.

35 The information in this paragraph and the one that follows was directly communicated to me by Elaine Ingham.

36 Philip J. Regal, PhD: Declaration submitted to the US District Court, *Alliance for Bio-Integrity v. Shalala*, 1998.

37 Reported in Charman, K., op. cit. note 32.

38 Email from David Schubert.

39 Ibid.

40 One prominent GE defender who refers to scientists with whom he disagrees as "outliers" is Jon Entine. See: forbes.comhttp://www.forbes.com/sites/jonentine/2014/08/14/got-soy-milk-not-consumer-reports-which-throws-science-under-the-bus-in-warning-about-gmo-soy/.

41 European Food Safety Authority (EFSA), "*Scientific opinion: Statistical significance and biological relevance*," *EFSA J*, 9 (2011): 2372.

42 Fagan, J., Antoniou, M.C., and Robinson,C., *GMO Myths and Truths: An Evidence-Based Examination of the Claims Made for the Safety and Efficacy of Genetically Modified Crops,* 2nd Edition, version 1.0, (London: Earth Open Source, 2014), 137.

43 For a discussion of the Piltdown fraud, see Broad, W. and Wade, N., *Betrayers of the Truth: Fraud and Deceit in the Halls of Science* (New York: Simon and Schuster, 1982), 119-22.

44 van Zwanenberg, P. and Millstone, E. "'Mad Cow Disease' 1980's – 2000: How reassurances undermined precaution, " in *Late Lessons from Early Warnings: The Precautionary Principle 1896 – 2000* (Luxembourg: European Environment Agency, 2001), 161.

45 Ibid.

46 *Betrayers of the Truth*, op. cit. note 43, 191.

47 Ibid.

48 Ibid., 189.

49 Lysenko's approach promised to boost yields much faster than alternatives, and it was based on the idea that acquired characteristics can be passed on to future generations, which dovetailed with the Marxist belief that altering external surroundings can induce profound inner change.

50 *Betrayers of the Truth*, op. cit. note 43, 190.

51 Ibid., 188, 191.

52 Although the first GE plants were not created until the early 1980's, the deceptions perpetrated in order to advance the genetic engineering venture in general began at least as early as the Bethesda Conference in 1976 and were forcefully employed during the summer and fall of 1977. As discussed in Chapter 1, these deceptions set the stage for the lax regulation of GE foods and their easy entry to the US market because they quashed legislative attempts to establish sound regulation of genetic engineering and shifted the burden of proof from the technology's proponents to those who thought it should be subject to such regulation.

53 *Betrayers of the Truth*, 20.

54 Nina Fedoroff has also alleged the existence of tests that apparently never happened. On page 175 of *Mendel in the Kitchen*, she states that the Flavr Savr tomato "was subjected to $2 million-worth of testing by the FDA on top of the testing done by Calgene." However, I couldn't find a specific reference for this statement in the note pages, and the FDA records provide no indication that such testing was undertaken – and instead impart the impression that none was. Further, the agency does not ordinarily conduct tests on new additives but instead reviews those submitted by the manufacturers. Moreover, Belinda Martineau, who had extensive first-hand knowledge about the interaction between the FDA and Calgene, informed me that to the best of her understanding, the FDA had not conducted any tests on the tomato.

55 Although Lysenko propounded ideas about inheritance that were unsubstantiated and dubious, it seems that he earnestly believed them; and it appears that he did not intentionally misrepresent well-established biological processes. In contrast, scientist-proponents of bioengineering (sometimes even in government agencies) have misrepresented fundamental biological facts. For instance, they've

proffered deceptive descriptions about how promoters operate, and some have disseminated misleading accounts of what occurs in the process of grafting.

56 Khachatourians, George C., University of Saskatchewan, writing in the *AgBiotech Bulletin*, February 1998.

57 Nuffield Council on Bioethics, *The use of genetically modified crops in developing countries,* June 2003.

58 *Bioengineering of Crops,* World Bank Panel on Transgenic Crops, 1997.

59 Borlaug, Norman, "Feeding a World of Ten Billion People: The Miracle Ahead," Lecture at De Montfort University, Leicester, UK, May 6, 1997. (I am not implying that Dr. Borlaug has engaged in or advocated deception. The point is that his concerns are shared by many other scientists who have felt motivated to engage in it.)

60 *Central Constr. Co. v. Home Indemnity Co.*, 794 P.2d 595, 598 (Alaska 1990).

61 To be innocent of fraud in such circumstances, not only would a scientist have had to lack intent to confuse people, he or she would also have had to be unaware that the statements issued were incorrect – or, even if technically correct, were likely to be misleading. While there may have been more than a few scientists in this category, it seems there have been many more who do not fit within it.

14. New Directions and Expanded Horizons

1 Comstock, Gary, "Ethics and Genetically Modified Foods," SCOPE GM Food Controversy Forum (July 1, 2001).

2 Brown, Patrick, "The Promise of Plant Biotechnology – the Threat of Genetically Modified Organisms," July 2000. Available at: http://www.psrast.org/promplantbiot.htm.

3 Xue, K., "Synthetic Biology's New Menagerie," *Harvard Magazine*, September-October, 2014.

4 Ibid.

5 Ibid.

6 "Former Pro-GMO Scientist Speaks Out On The Real Dangers of Genetically Engineered Food," September 24, 2014: http://earthweareone.com/former-pro-gmo-scientist-speaks-out-on-the-real-dangers-of-genetically-engineered-food/

7 Comstock, op. cit. note 1. He emphasizes the responsibility of scientists to accurately communicate facts and says, "If scientists are dishonest, untruthful, fraudulent, or excessively self-interested, the free flow of accurate information so essential to science will be thwarted." And he adds, "The public largely trusts scientists, and scientists must in turn act as good stewards of this trust." Accordingly, because he never expresses doubt about the soundness of the information that's been disseminated by the scientist-promoters of GE foods, he apparently believes that they've been honoring their obligation – a belief that's sorely mistaken.

8 Another prominent individual who apparently shifted his position on GMOs at least in part due to misapprehension of the facts is Peter Raven. As noted in Chapter 2, during the early 1980's he shared the concerns of Ernst Mayr and Phil Regal about the risks posed by environmental releases of GMOs, and he assisted in planning a workshop at which these risks could be examined. However, he eventually

became supportive of the GE food venture; and, as is the case with so many of its scientist-supporters, he has endorsed claims about it that are inaccurate. For instance, in 2009 he participated in a study group that released a statement describing genetic engineering as the newest addition to "a long and seamless continuum of progressively more precise and predictable techniques" of plant breeding. And the statement went on to more grossly overstate the degree of precision by asserting that the genetic engineering of a plant is "accompanied by a precise analysis of the genetic and phenotypic outcomes." Among its other inaccuracies, the statement also declared that the operations of genetic engineering "affect only one or a few genes." (Previous chapters have shown that all these assertions are misaligned with reality.) Thus, Raven's association with a statement containing such flawed assertions implies that his current position on GE foods is not firmly based on the facts. (The statement referred to is: "Transgenic Plants for Food Security in the Context of Development," PAS Study Week, Vatican City, 15-19 May 2009, pp. 4, 9.)

9 Taleb, N. et al., "The Precautionary Principle (with Application to the Genetic Modification of Organisms), *Extreme Risk Initiative – NYU School of Engineering Working Paper Series*, September 4, 2014: http://nassimtaleb.org/2014/08/precautionary-principle-paper/#.VE2ocRb63mE

10 Although other legal issues would be raised as well, such as whether the manufacturers have a right not to be compelled to speak, the most compelling defense would be to demonstrate that the FDA has not merely failed to preempt the field (because its policy is admittedly one of inaction), but that it has been deliberately misrepresenting the facts and willfully violating a federal statute and its own regulations – and that this delegitimizes its determination that GE foods do not require labeling.

11 Email communication.

12 Remarks of William Jefferson Clinton, Conference of the Biotechnology Industry Organization, Chicago, Illinois, April 11, 2006.

13 Ibid.

14 Brooks, David, "The Conservative Mind," *New York Times*, September 24, 2012.

15 Thus, when I speak of traditional theism, I am not referring to a belief system in which God has created the cosmos and its laws but has not directly planned for the development of life and has instead left whether and how life would develop up to the undirected interactions of naturally occurring phenomena.

16 'The Case Against Genetic Engineering' by George Wald, in *The Recombinant DNA Debate*, Jackson and Stich (eds.), 127-28 (reprinted in *The Sciences*, September/October 1976 issue).

17 Wald, G., quoted in Kimbrell, A., *The Human Body Shop: The Engineering and Marketing of Life*, Harper Collins (1994), 159.

18 http://www.theguardian.com/news/2002/jul/02/guardianobituaries.obituaries

19 Chargaff, Edwin, *Heraclitean Fire: Sketches of a Life Before Nature*, (New York: Rockefeller University Press, 1978).

20 Declaration of Rabbi Alan Green, *Alliance for Bio-Integrity v. Shalala*.

21 *Alliance for Bio-Integrity v. Shalala,* Plaintiffs' Second Amended Complaint for Declaratory and Injunctive Relief, Paragraph 36.

22 Consumers Union, Comments to US Food and Drug Administration on *Statement of Policy: Foods Derived From New Plant Varieties*, August, 1992, 2.

23 Although these experts state that when the strict precautionary principle is employed, the proponents of an activity have the burden of proving it's safe, in the case of GMOs, it's evident from their discussion that they do not think such proof could be practically accomplished – especially as regards the risk of irreversible environmental ruin. That's because they state that GMOs should be preemptively prohibited because there is not "scientific near-certainty" about their safety; so according to their standards, any attempted proof of safety would need to achieve such near-certainty to suffice. Consequently, for practical purposes, their position amounts to full prohibition of these products.

24 Fagan, J., Antoniou, M.C., and Robinson, C., *GMO Myths and Truths: An Evidence-Based Examination of the Claims Made for the Safety and Efficacy of Genetically Modified Crops*, 2nd Edition, version 1.0, (London: Earth Open Source, 2014), Section 5.12.

25 Ibid., 284.

26 Mellon, M, and Gurian-Sherman, D., "The cost-effective way to feed the world," *The Bellingham Herald*, June 20, 2011.

27 International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), "Agriculture at a crossroads: Synthesis report of the International Assessment of Agricultural Knowledge, Science" and "Technology for Development: A Synthesis of the Global and Sub-Global IAASTD Reports" (Washington, DC, USA: Island Press; 2009).

28 Lean, G., "Exposed: The great GM crops myth," *The Independent*, April 20, 2008.

29 Sherman, M., Q & A: Hans Herren on "Sustainable Agriculture Solutions," *GMO Inside*, April 9, 2014: http://gmoinside.org/q-hans-herren-sustainable-agriculture-solutions/

30 Hine, R., Pretty, J. and Twarog, S., "Organic agriculture and food security in Africa," New York and Geneva: UNEP-UNCTAD Capacity-Building Task Force on Trade, Environment and Development (2008). Available at: http://bit.ly/KBCgY0

31 De Schutter, Olivier, quoted in Leahy, S., "Africa: Save climate and double food production with eco-farming," *IPS News*, March 8, 2011: http://allafrica.com/stories/201103090055.html

32 De Schutter, Olivier, quoted in "Eco-farming can double food production in 10 years, says new UN report" (press release) *United Nations Human Rights Council*, March 8, 2011: http://bit.ly/Lkfa9U

33 Drinkwater, L. E., Wagoner, P. and Sarrantonio, M., "Legume-based cropping systems have reduced carbon and nitrogen losses," Nature 396, 1998, 262–65.

34 Rodale Institute, "The Farming Systems Trials; Celebrating 30 years," 2012: http://rodaleinstitute.org/assets/FSTbooklet.pdf

35 Alteri, Miguel, "Agroecology, Small Farms, and Food Sovereignty," *Monthly Review*, vol. 61, issue 3, July/August, 2009.

36 Ikerd, John, "Family Farms of North America," in *Deep Roots*, (Rome: The Food and Agriculture Organization of the United Nations, 2014), 30-32.

37 http://www.blackwellreference.com/public/tocnode?id=g9781405184649_yr2012_chunk_g97814051846491361

38 https://en.wikipedia.org/wiki/Pure_Food_and_Drug_Act

Appendix A

1 *San Luis Obispo Mothers for Peace v. U.S. Nuclear Regulatory Comm'n*, 789 F.2d 26, 33 (D.C.Cir.1986).

2 The courts have made it clear that "general recognition" is a matter of fact. e.g. *United States v. 4680 Pails*, 725 F.2d 976, 985 (5th Cir. 1984)

3 *State Farm Mutual Automobile Insurance Co. v. Dept. of Transp*., 680 F.2d 206, 220 (D.C. Cir. 1982).

4 Among the cases cited were *Ferro-Lac* (discussed in Chapter 5), *Natick Paperboard Corp. v. Weinberger*, 525 F.2d 1103 (1st Cir. 1975) (packaging); *U.S. v. Articles of Food . . . Pottery*, 370 F.Supp. 371 (E.D.Mi. 1974) (dinnerware).

5 Document #7 at: http://biointegrity.org/24-fda-documents (A.R. at 18960).

6 Document #19 at: http://biointegrity.org/24-fda-documents (A.R. at 18196). The FDA's dramatic shift in policy is noted in an article in the Boston College Law Review. 44 B.C.L. Rev. 733 2002-2003 at 749.

7 *SEC v. Chenery Corp*., 332 U.S. 194 (1947) at 196.

8 116 F. 2d at 177 citing *International Fabricare Institute* v. U.S. E.P.A., 972 F.2d 384 at 389 (D.C.Cir.1992).

9 972 F.2d 384 at 390, 396, & 398.

Appendix B

1 Royal Society, "Genetically modified plants for food use and human health – an update," (2002), 6.

2 Ibid., 8.

3 Ibid., 6.

4 Institute of Food Technologists, *IFT Expert Report on Biotechnology and Foods*, 2000.

5 Page 21 of the above report states that the risks of GE are "the same in kind" as those of traditional breeding.

6 Ibid., 15.

7 Ibid., 17.

8 Although a later section on the benefits of bioengineering did note the use of viral promoters, it ignored the fact they force hyper expression of the gene affixed to them and thus avoided confronting the related safety issues.

9 Ibid., 21.