HOW GMOS ARE DEFENDED BY DISTORTING THE FACTS

EXPOSING THE FICTIONS THAT WERE FOSTERED DURING THE DISCUSSION BROADCAST BY TVO'S "THE AGENDA"

Steven M. Druker, J.D. Executive Director Alliance for Bio-Integrity Public Interest Attorney and Author of *Altered Genes*, *Twisted Truth*¹

A spirited discussion about genetically engineered foods was broadcast January 25, 2016 on *The Agenda*, the flagship current affairs program of TVO, Ontario's public television network. (These products are also called "genetically modified organisms" or GMOs.) I presented evidence-based reasons for regarding these foods as abnormally risky and the current regulatory system as deficient, while Robert Wager, a biologist at Vancouver Island University, defended the foods and the system. However, his arguments substantially relied on assertions that were either flat-out false or significantly misleading. Some of his most serious distortions are detailed below, with citations to evidence that decisively demonstrates their erroneousness. (The program can be viewed at: http://tvo.org/video/programs/the-agenda-with-steve-paikin/judging-gmos)

A. Wager claimed that "every national academy of science, every health authority, and every food safety authority" agrees that the process of creating genetically engineered (GE) foods is safe; but his own country's national academy of science – the Royal Society of Canada – has explicitly concluded that the process entails abnormal risks.² Moreover, the British Medical Association, the Public Health Association of Australia, and the editors of *The Lancet* (a premier medical journal) have all expressed concerns about the risks; and in 2013, the Australian association even called for a freeze on the marketing of GE foods.³ So his claim is false in regard to health authorities as well.

It's amazing he advanced this claim, because in 2001 the Royal Society of Canada issued an extensive report which concluded not only (a) that it is "scientifically unjustifiable" to regard a GE food as safe unless its safety has been demonstrated by rigorous testing, but (b) that the "default prediction" for each should be that it has undergone unintended changes that could have rendered it toxic or allergenic.⁴ As I emphasized during the discussion, that report has never been refuted or retracted; and its analysis of the risks is just as relevant today as in 2001, especially since the kind of testing it called for is still not required in either the U.S. or Canada.

B. Wager further claimed (a) that there is a universally employed international standard for testing the safety of GE foods, (b) that the standard is fully adequate, and (c) that *"every single"* engineered food on the market has been thoroughly and sufficiently tested. But in reality, (a) there is no uniformly followed international standard, (b) whatever standards do exist are seriously deficient in light of the criteria set forth by the Royal Society of Canada, and (c) a significant number of commercialized GE foods have evaded even the laxest of the review processes.

The situation in the United States in itself refutes all three of Wager's claims. Although people are consuming a greater quantity of GMOs in that nation than in any other, those products are not subject to *any* regulation there in regard to food safety; and according to the policy of the U.S. Food and Drug Administration (FDA), whatever tests are performed are purely voluntary. Further, the consultation process that the FDA conducts with manufacturers is also entirely voluntary. Consequently, as revealed in a recent admission by one of the agency's top officials, around 30% of the GE foods that have entered the market have avoided undergoing that process.⁵ Moreover, because the process is extremely lax, it provides no reasonable assurance that the foods that actually do go through it are safe. In fact, FDA officials have themselves acknowledged that the manufacturers don't even submit original data – and that the process does not constitute a genuine scientific review.⁶

Circumstances in other nations likewise refute Wager's assertions. He claimed there's a set of OECD standards that are not only universally followed but are so rigorous they assure safety. However, those standards are in fact inconsistently applied guidelines, and they primarily rely on the concept known as "substantial equivalence," a lenient approach that was strongly criticized by the experts who produced the Royal Society of Canada's report. According to that report, every GMO should be subjected to rigorous toxicological testing employing the whole food; but the OECD guidelines do not routinely call for such testing.⁷ Further, the testing that *has* been done has often been poorly conducted, and the European Commission has acknowledged that the biotech industry's studies tend to be of low quality.⁸

What's more, although the EU has finally required that new GMOs undergo 90-day feeding studies with the whole food, that requirement was not fully instituted until December 2013 - 17 years *after* such products began to flood the market.⁹ And conditions in Canada are more deplorable because feeding studies with the whole GE food are still not required there.¹⁰

Thus, Health Canada has failed to implement the basic reforms that the Royal Society called for, and its approach to regulating GE foods is essentially the same as in 2001 – which means that it still deserves the rebuke the Society delivered at that time. In describing that rebuke, the *Toronto Star* stated: "The experts say this approach is fatally flawed … and exposes Canadians to several potential health risks, including toxicity and allergic reactions." ¹¹

So it's evident that the system for regulating GE foods has been, and remains, markedly defective world-wide and that a large number of these products have entered the market absent the kind of safety testing that has been called for by the experts at the Royal Society of Canada – and by many other eminent experts as well. Further, as will be discussed in the next section, several of the tests on which regulators have relied have actually demonstrated harm.

C. Wager created substantial confusion about an important study I described that exposed deficiencies in the way that regulators have been approving GE foods. Because he himself was seriously mistaken about the study, he alleged that it was badly flawed and had been retracted from the journal in which it was published. But in reality, it's a sound study that has *never* been retracted; and it stands as a solid testament to the defects of the regulatory system.

The research was conducted by university scientists who examined the data packages that manufacturers had submitted to regulators on behalf of 19 GE foods.¹² Those foods had been approved, had been on the market for a substantial time, and comprised 83% of the GE foods that North Americans have been regularly eating. This examination revealed that 9% of the measured parameters, including blood and urine biochemistry and organ weights, were significantly disrupted in the animals that ate the GE feed. Moreover, the greatest disturbances were to the kidneys of the males and the livers of the females; and the scientists emphasized that because livers and kidneys "are the major reactive organs" in cases of chronic food toxicity, these results should be viewed as danger signs – something the regulators had not seen fit to do.

This study was well-conducted, and it passed the standard peer-review process in order to be accepted by the journal. Further, it's important to keep in mind that the testing was not conducted by the authors but by the manufacturers. The authors merely analyzed the data that the manufacturers' tests had generated. And their analysis provides additional indication that the regulatory system is functioning poorly in regard to these novel products – and that, as stated in the study's conclusion, its practices have been "socially unacceptable in terms of consumer health protection."

It is also important to note that the scientists' written discussion made it clear that even if every GE crop had been subjected to rigorous 90-day feeding studies with the whole food and no problems had been detected (which has not been the case), that still would be insufficient to certify safety. They emphasized that such studies are too short to reliably detect chronic toxicity – and are also incapable of adequately monitoring problems in subsequent generations. Accordingly, they asserted that every GE food should be subjected to 2-year tests in combination with reproductive, developmental, and transgenerational studies.

Unfortunately, the GE foods on the market have not undergone such testing – and as long as they have not, consumers will have solid, science-based grounds for doubting the claims about their safety.

D. Wager asserted that critics of GE food spin "conspiracy theories" alleging that academies of science and food safety authorities "are all in cahoots with the biotech industry," and he insinuated that I've done so. However, although there's solid evidence that industry has unduly influenced regulatory agencies, I didn't aim to prove such a broad conspiracy during the TVO discussion or in my book, and the word "conspiracy" never appears in its pages. But it does document a shocking number of cases in which scientists, scientific organizations, and government regulators have seriously distorted the facts to protect the image of GE foods – regardless of whether they've colluded with industry. It also reveals how the actual evidence demonstrates that these foods entail abnormal risks. And it spotlights another crucial point: the irrefutable fact that this evidence has been systematically twisted is *in itself* compelling evidence of risk – and shows how strongly the evidence weighs against safety. That's because if this evidence was truly as favorable as the proponents claim, there would have been no need to distort it.

The evidence presented in my book is extensive and solid, and its impact can be profound. That's why Jane Goodall's foreword hails it as "without doubt one of the most important books of the last 50 years." Moreover, many other scientists have similarly praised it. For instance, David Schubert, a Professor and laboratory director at the prestigious Salk Institute of Biological Studies, has extolled it as "incisive, insightful, and truly outstanding" and stated: "Through its masterful marshalling of facts, it dispels the cloud of disinformation that has misled people into believing that GE foods have been adequately tested and don't entail abnormal risk." In the same vein, John Ikerd, a Professor Emeritus of Agricultural and Applied Economics at the University of Missouri, has called it a "great book" and stated: "The evidence is comprehensive and irrefutable; the reasoning is clear and compelling. No one has documented other cases of irresponsible behavior by government regulators and the scientific establishment nearly as well as Druker documents this one. His book should be widely read and thoroughly heeded." And Frederick Kirschenmann, a Distinguished Fellow in the Leopold Center for Sustainable Agriculture at Iowa State University, has called it "a remarkable work" and asserted: "If the numerous revelations it contains become widely known, the arguments being used to defend genetically engineered foods will be untenable."

In light of these statements, it's obvious why the products' proponents routinely strive to suppress the key facts or else to seriously misshape them. And it should also be obvious that if the media enable a more open airing of those facts, as TVO has done, the proponents could no longer succeed in their unsavory endeavor.

² "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.

³ The British Medical Association has clearly expressed reservations about the safety of these novel products. As described in the British Medical Journal, the Association released a 2004 report stating that "more research is needed to show that genetically modified (GM) food crops and ingredients are safe for people and the environment and that they offer real benefits over traditionally grown foods." (Kmietowicz, Z. "GM Foods Should Be Submitted to Further Studies, says BMA," British Medical Journal, 2004 March 13; 328(7440): 602)

The Public Health Association of Australia has likewise (and more recently) indicated its opinion that the safety of genetically modified foods has not been adequately demonstrated. Its policy statement on genetically modified (GM) foods adopted in 2013 states:

"Thorough, independent research into the effects of GM foods on agronomy, health, society, the environment and the economy should be undertaken, and until this work is completed, all governments in Australia should impose an immediate and indefinite freeze on: the growing of GM crops for commercial purposes; the importation of GM foods and food components; and the patenting of genetic resources for food." <u>http://www.phaa.net.au/documents/item/235</u>

The Lancet criticized the presumption that genetically engineered foods entail no greater risks of unexpected effects than conventional foods, stating that there are "good reasons to believe that specific risks may exist" and that "governments should never have allowed these products into the food chain

¹ Altered Genes, Twisted Truth: How the Venture to Genetically Engineer Our Food Has Subverted Science, Corrupted Government, and Systematically Deceived the Public, (2015). www.alteredgenestwistedtruth.com

without insisting on rigorous testing for effects on health." (The Lancet, Vol. 353, Issue 9167, p. 1811, 29 May 1999.)

⁴ "Elements of Precaution," cited in note 2, pp. ix and 185.

⁵ Statement of Susan Mayne, PhD, Director, FDA Center for Food Safety and Applied Nutrition, before the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, October 21, 2015.

⁶ For instance, the FDA's Biotechnology Strategic Manager has stated: "The FDA requests that firms submit a summary of their assessment to the agency. The FDA does not request the original data and, therefore, does not conduct a scientific review of the firm's decision." (Maryanski, J., "Safety Assurance of Foods Derived by Modern Biotechnology in the United States," July 1996.)

⁷ As documented in my book, years before the release of the Royal Society of Canada's report, the scientists on the U.S. FDA's Biotechnology Task Force had stipulated that testing with the whole GE food is necessary, but the agency's administrators, who have been following an explicitly acknowledged policy to promote biotechnology, disregarded their experts' input and failed to require any testing at all.

⁸ 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.

⁹ EFSA Journal 2013;11(12): e11121 [5 pp.]. **DOI:** 10.2903/j.efsa.2013.e11121.

¹⁰ See, for example, Canadian Biotechnology Action Network's Report 3. September 2015, p. 31. <u>http://gmoinquiry.ca/wp-content/uploads/2015/09/Are-GM-crops-better-for-consumers-E-web.pdf</u>

¹¹ Calamai, P., "Ottawa Rapped, Expert Study Considered Major Setback for Biotech Industry," Toronto Star, February 5, 2001

¹² Séralini, et. al., "Genetically modified crops safety assessments: present limits and possible improvements," *Environmental Sciences Europe*, 23:10 (2011).