

A Challenge to Monsanto

By Steven M. Druker
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Alliance for Bio-Integrity

Theme: <u>Biotechnology and GMO</u>, <u>Science</u> and Medicine

In this challenge, which was delivered to Monsanto's headquarters on May 20, 2015, American public interest attorney Steven Druker calls on that corporation to find any inaccurate statements of fact in his new book, **Altered Genes, Twisted Truth** – How the Venture to Genetically Engineer Our Food Has Subverted Science, Corrupted Government, and Systematically Deceived the Public. This acclaimed book thoroughly exposes the substantial risks of genetically engineered foods (also called GM foods and GMOs) and the multiple misrepresentations that have enabled them to permeate world markets. Druker asserts that if Monsanto cannot prove that his book is essentially erroneous, the world will have a right to regard these controversial foods as unacceptably risky – and to promptly ban them.

A CHALLENGE TO MONSANTO

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Face Up to the Extensive Evidence Demonstrating that Genetically Engineered Foods Entail Unacceptable Risks and Should Be Promptly Removed from the Market

An Open Letter to Robb Fraley, PhD Chief Technology Officer Monsanto Company

From

Steven M. Druker, JD Executive Director Alliance for Bio-Integrity

May 19, 2015

Dear Dr. Fraley,

Although Monsanto and other proponents of genetically engineered foods (also known as genetically modified foods and GMOs) have been able to instill the widespread impression that these novel products are not only safe but necessary to meet the nutritional needs of the developing world, this impression is in fact an illusion; and it is based on disinformation.

Some prime examples of this disinformation are contained in a brochure published in 2013 by Monsanto titled "The Safety & Benefits of Biotech Plants Used in Agriculture." For

instance, the document declares that genetically engineered foods (GE foods) are just as safe as natural ones, and it cites an assertion by the board of directors of the American Association for the Advancement of Science (AAAS) that "every respected organization that has examined the evidence" has reached this conclusion. But the authors of that assertion appear to have overlooked, or intentionally obfuscated, the fact that several respected organizations have examined the evidence and concluded otherwise. Among them are the British Medical Association, the Public Health Association of Australia, and the Royal Society of Canada.

Further, the reports issued by these organizations provide cause for concern. For example, the one issued by the Royal Society of Canada declares (a) that it is "scientifically unjustifiable" to presume that GE foods are safe and (b) that the "default presumption" for every GE food should be that the genetic alteration has induced unintended and potentially harmful side effects.[1] In describing the report's criticism of the current approach to regulating GE foods, 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."[2] Moreover, as described in the *British Medical Journal*, a report by the British Medical Association asserted 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." [3]

Monsanto's brochure also proclaims: "Since farmers first planted GM crops in 1996, there have been no documented safety issues." But in reality, a substantial number of well-conducted research studies have clearly documented safety issues with such crops by detecting statistically significant instances of harm to the laboratory animals that were consigned to consume them. These studies have been published in peer-reviewed scientific journals,[4] and several are described in a recently released book that I wrote:

Altered Genes, Twisted Truth

How the Venture to Genetically Engineer Our Food Has Subverted Science, Corrupted Government, and Systematically Deceived the Public

Furthermore, Monsanto's bogus boast about the absence of safety issues is doubly deceptive, because it also misrepresents the date when commercialized GE crops were initially planted. This is significant because the first such crop (the Flavr Savr™ tomato), which came to market in 1994, also entailed a documented safety issue. As the aforementioned book reveals, through memos pried from the files of the US Food and Drug Administration (FDA) via a lawsuit that I initiated, the scientists in the agency's Pathology Branch (along with other specialists) who examined the data from the animal feeding studies conducted with this altered tomato concluded that they raised a safety issue that was never satisfactorily resolved. However, that did not deter FDA administrators (who have acknowledged that the agency has an agenda "to foster" the biotechnology industry[5] from falsely claiming that all safety issues *had* been resolved.

The book further reveals that the very first ingestible product of genetic engineering (a food supplement of the essential amino acid L-tryptophan) entailed the biggest documented safety issue of all, because in 1989 it induced an epidemic that killed dozens of Americans and seriously sickened thousands, permanently disabling many of them. Moreover, contrary to the claims of biotech proponents, the evidence points to the genetic engineering

employed in the production process as the most likely cause of the unusual contamination that rendered the supplement toxic – which, as the book explains, is additional indication that genetic engineering is in itself a risk-laden procedure and that the foods it produces pose greater risks than their conventional counterparts.[6]

Furthermore, not only does my book refute Monsanto's claims about the existence of expert consensus and the utter absence of documented safety issues, it refutes the other major claims made by that brochure (and by the proponents of GE foods) as well. And it does so decisively.

In her foreword, Jane Goodall hails it as "without doubt one of the most important books of the last 50 years"; and several other scientists have also attested its importance and its soundness. For instance:

- David Schubert, a Professor and Head of Cellular Neurobiology at the Salk Institute for Biological Studies, has praised it as "incisive, insightful, and truly outstanding" – and noted that it's "well-reasoned and scientifically solid."
- Joseph Cummins, Professor Emeritus of Genetics at Western University in London, Ontario, has called it "a landmark" that should be required reading in every university biology course.
- John Ikerd, 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."
- Philip Regal, Professor Emeritus of Biology at the University of Minnesota, has commended it as exceptionally well-researched and well-written" and declared: "I am very impressed with the book as a whole and expect that a large number of other scientists will be too."
- The biochemist Stephen Naylor, who during his ten years as a professor at the Mayo Clinic extensively investigated the epidemic caused by the toxic GE tryptophan supplement, has described the book's discussion of that tragic event as "the most comprehensive, evenly-balanced and accurate account that I have read."
- Belinda Martineau, a molecular biologist who was a co-developer of the Flavr Savr™ tomato, has described the book as "thorough, logical and thoughtprovoking" and declared that she "strongly" recommends it.

In all, the book demonstrates that:

The genetic engineering process is inherently risky, and the foods it creates entail abnormal risks.

- 1. The risks have been systematically misrepresented by the products' proponents.
- 2. The key misrepresentations have been made by eminent scientists and scientific institutions and some of the most pivotal deceptions have been perpetrated by the US Food and Drug Administration (FDA).
- 3. Besides deceiving the public about the risks of GE foods, the FDA allowed them to enter the US market in blatant violation of federal food safety law and they continue to be on the market illegally.
- 4. Not only is the GE food venture unsound from the perspective of biological science, it is unsound and outright reckless when examined in light of computer science; and compared to the careful manner in which software engineers revise life-critical information systems, the rash and radical way in which biotechnicians alter complex cellular information systems is not really "bioengineering" butbiohacking.
- 5. Even if GE crops didn't entail excessive risks, they would still not be the solution for meeting the world's prospective food needs, which is clear from a major study on the future of farming sponsored by four United Nations agencies and the World Bank that concluded they are not necessary[7]- and also from numerous studies in a variety of African nations demonstrating that safe and sustainable agroecological methods can outperform industrialized approaches (even when GMOs are employed).[8]

MY CHALLENGE TO MONSANTO

Dr. Fraley, several months ago you sent Jane Goodall an email in response to a statement she made in a television interview that was critical of GE foods. You included the Monsanto brochure noted above in the hopes it would convince her that these foods are not merely acceptable, but desirable. However, your hopes were misplaced, because she recognized that the basic claims in the document are inaccurate – and that the evidence actually reveals that GE foods are not an acceptable option. Further, she passed that email on to me so that I could reply as I see fit.

In that email, you stated: "I would be very pleased to provide you with any additional information." The time has come to take you up on that offer. But I do not want to receive more of Monsanto's misleading pronouncements that are passed off as genuine facts. Instead, I'm requesting some information that you had not planned to send. I want you to inform me of any inaccuracies you can find in my book. I want you and your colleagues to attempt to refute *Altered Genes, Twisted Truth* in the same manner this letter has refuted two of the main assertions in the brochure you submitted. Moreover, I *challenge* you to do so. I challenge you to read the book and send me a specific list of any inaccurate statements of fact that you detect in it, accompanied by an explanation of why the statement is erroneous and a reference to the evidence that conclusively corroborates your claim.

To clarify, I am referring to simple assertions about concrete facts that can be decisively falsified by incontestable evidence, such as the erroneous statements in your brochure that "every respected organization that has examined the evidence" has concluded that GE foods are as safe as naturally produced ones and that "there have been no documented safety issues." I am not referring to the broader conclusions the book draws from the primary facts, such as the conclusions (a) that the GE food venture has been chronically and crucially reliant on deception and (b) that its products are unacceptably risky and should be

banned.[9] I fully expect that you will disagree with these conclusions, but I am confident that the vast majority of fair-minded men and women who become aware of the basic facts will agree with them.

I also invite the other proponents of GE foods within industry and academia to assist Monsanto by scrutinizing the book and sending you their input. In that way, the response that Monsanto submits will represent the best collective effort of the biotech industry and its supporters.

It's important to emphasize that none of the factual assertions in my book can be invalidated merely by citing a contrary opinion by a particular scientist or group of scientists (unless the statement in question has misrepresented the opinion of that individual or group and the citation is offered to restore accuracy). Instead, incontestable evidence must be presented. Similarly, because the book has systematically refuted the standard claims made by the proponents of GE foods, it cannot be refuted merely by hurling those claims back at it – and any attempts to do so will demonstrate that Monsanto (or whoever has done so) is incapable of actually refuting the book's key assertions. Further, although promoters of GE foods have routinely launched personal attacks against anyone bringing out evidence that puts their safety in question, such attacks will do nothing to undermine the book's solidity and will only demonstrate the desperation of those who perpetrate them – and their inability to discredit the book through legitimate means.

If by July 20th you and your allies have not been able to refute the essential factual accuracy of *Altered Genes, Twisted Truth* according to the terms set forth above, the world will have a right to assume that it is as sound as the experts who reviewed it have affirmed – and to conclude that GE foods are unacceptably risky and must be banned.

I will send you (in a separate document) the address to which your response to this challenge should be submitted. That response will be posted on the book's website and Facebook page and also on the website of the Alliance for Bio-Integrity.

www.alteredgenestwistedtruth.com www.facebook.com/alteredgenestwistedtruth www.biointegrity.org

Further, I will readily acknowledge (on the above sites) any genuine errors you point out and will correct them in the next printing of the book. Concomitantly, I expect that, if Monsanto is as committed to the scientific spirit as it professes to be, there will be a prompt public acknowledgement and retraction of the erroneous assertions this document has pointed out along with an honest attempt to set the record straight. Please send me the evidence that this has occurred. Moreover, as you read the book, you will discern many other inaccuracies that Monsanto has propagated, and I request that you likewise publicly acknowledge and correct them.

It is well-recognized that although we're all entitled to our own opinions, no one is entitled to his or her own set of facts. And it is obvious that Monsanto and its allies have been propagating a distinctly different set of facts than are delineated in *Altered Genes, Twisted Truth*. Both versions of reality cannot be correct, and people have a right to know which one is valid and which is fictitious. The purpose of this challenge is to clearly and conclusively provide the answer.

References

[1]"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. This report has never been retracted, superseded, or revised; and it is just as relevant today as when it was issued. Further, neither the AAAS nor any other organization that has expressed support for GE foods has attempted to directly confront and refute its reasoning. Instead, they have essentially ignored it and pretended that it doesn't exist.

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

[3] "Genetically modified food and health: A second interim statement," British Medical Association Board of Science and Education, March., 2004. Described in: Kmietowicz, Z., "GM Foods Should Be Submitted to Further Studies, says BMA," British Medical Journal 328 (7440) (March 13, 2004): 602

[4] Five of the many research studies that detected harm to laboratory animals are:

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.

Seralini, G.E., 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.

Malatesta, M., F., 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.

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.

Seralini, G.E., et al., "Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize," *Environmental Sciences Europe* (2014): 26:14.

Although several of these studies have been attacked by proponents of GE foods, the attacks were unjustified and all of the research is in fact solid (as is thoroughly demonstrated in Chapter 10 of *Altered Genes, Twisted Truth.*) Moreover, the simple fact that such studies have been published in peer-reviewed scientific journals undermines the claim that there have been no documented safety issues with GE crops.

[5]"Genetically Engineered Foods," *FDA Consumer*, Jan.-Feb. 1993, p.14. The promotional agenda of the FDA, which is also followed by other agencies of the US executive branch, was adopted during the presidency of Ronald Reagan and has continued through each successive administration, including the present one.

[6] Although advocates of genetic engineering have argued that L-tryptophan itself was the likely cause of the epidemic, this claim starkly clashes with the evidence, as Chapter 3 of my book demonstrates. And, as this letter elsewhere points out, a biochemist who extensively investigated the epidemic during his ten years as a professor at the Mayo Clinic has described the book's discussion of that tragic event as "the most comprehensive, evenly-balanced and accurate account

that I have read."

[7]"Agriculture at a Crossroads: Global Report," International Assessment of Agricultural Knowledge, Science and Technology for Development (Washington, DC, USA: Island Press; 2009). This massive study was conducted by more than 400 experts from 80 countries, and 58 governments have endorsed it. Further, besides concluding that genetic engineering is *not* essential for solving the problem of hunger, it pointed out that yields of GE crops have been "highly variable," with some cases of "yield declines." What's more, when the project's director was asked at a press conference whether GE crops were the answer to world hunger, he replied, "The simple answer is no." (Lean, G., "Exposed: The great GM crops myth," *The Independent*, April 20, 2008.)

[8]For instance, a recent UN report that surveyed 114 farming projects in 24 African countries determined that through the adoption of organic or near-organic practices, yields increased on average by over 100%. [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).] Additionally, the UN Special Rapporteur on the Right to Food has pointed out: "Yields went up 214% in 44 projects in 20 countries in sub-Saharan Africa using agroecological farming techniques over a period of 3 to 10 years." And he noted that this accomplishment is "far more than any GM crop has ever done." (De Schutter, Olivier, quoted in Leahy, S., "Africa: Save climate and double food production with eco-farming," IPS News, March 8, 2011.)

[9]I expect you will also disagree with the conclusions that GE foods entered the US market illegally and that they continue to be marketed in violation of federal food safety law. But in order to convincingly counter this conclusion, it will be necessary for you to refute the factual assertions on which it rests. The book points out that the sole purported legal basis for the presence of GE foods on the US market is the FDA's presumption that they are *Generally Recognized as Safe* (GRAS). And it demonstrates that this presumption is invalid because *neither* of the two necessary criteria for GRAS status has ever been fulfilled in the case of any GE crop. Not only does it expose how memos pried from the FDA's own files by the lawsuit I initiated establish that these requirements had not been met when the FDA first announced (in 1992) that GE foods could be presumed GRAS, it demonstrates that even if this avowedly "rebuttable" presumption had initially been valid, it has been repeatedly and solidly rebutted over the ensuing years. For instance, a federal judge acknowledged that as of May 1998, there were "significant disagreements" among scientific experts about the safety of GE foods. (See *Altered Genes, Twisted Truth*, pp. 150-51.)

So you will need to address all the specific allegations of fact that the book employs to support the above-noted assertions and demonstrations, and you will have to establish that at least some of the crucial ones are false. If you cannot, people will be justified in concurring with the conclusions the book has drawn from these facts – and in regarding GE foods as having continuously been on the US market in violation of federal law.

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Druker

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