Response by Dick Atlee
(http://dickatlee.com/issues/gmo/simpson_anti-druker_response.html)
1 September 2015
to the following critique:

Altered Genes: Druker's New Book is Filled with Logical Fallacies
(a review of *Altered Genes, Twisted Truth: How the Venture To Genetically Engineer Our Food Has Subverted Science, Corrupted Government, and Systematically Deceived the Public*)
Dr. Terry Simpson
March 10, 2015
http://www.yourdoctorsorders.com/2015/03/altered-genes-drukers-new-book-is-filled-with-logical-fallacies/

Note: I've prepared this response because after a skeptical scientific friend of mine had purchased and started reading Druker's book, she read this article and was persuaded by it to quit reading the book. Indeed, Dr. Simpson's web page header is "**Steven Druker's book: Not worth reading.**" In this response, I will endeavor to avoid the superficial, sometimes snide, and often misleading approach Dr. Simpson uses in attacking Druker and his book. To save space, I won't include the numerous blurbs of praise for the book from people with relevant credentials from the worlds of science, education, and law.

I will say at the outset that, yes, the book is long, and I found it extremely repetitive, presumably because Druker's legal background prods him to make sure his readers understand what he is trying to say. In spite of this, I found it fascinating, and extremely well documented.

Perhaps the best response to the first part of Simpson's piece can be found in a recent interview with Druker at

http://foodintegritynow.org/2015/08/25/altered-genes-twisted-truth-the-fdas-illegal-release-of-ge-foods/

The vitriolic foreword by Jane Goodall (the ethologist who spent her career studying chimpanzees) prompted me to read Steven Druker's book. On page after page, I discovered that his discussion of genetically modified organisms provided no new insights, and were filled with false and misleading information.

Simpson's description of Goodall's Forward as "vitriolic" is puzzling. There's nothing I can find that fits that label. I'm likewise puzzled by his "no new insights" comment. I come from a background of biochemistry and physiological chemistry, but my education occurred in the 1960s, with the only knowledge of genetics being that which was available back at the dawn of the genetic engineering (GE) enterprise. So Druker's detailed description of the knowledge of gene function and regulatory interaction that has been developing in this century were all new to me. Perhaps Simpson is well versed in that, so that it doesn't class as "new insight," but just because the material isn't new to him doesn't mean it isn't new to the majority of people who will read the book if they don't succumb to Simpson's clear attempt to prevent them from doing so. I found the book loaded with information new to me. And unfortunately, virtually nowhere in Simpson's review can I find details in support of his general "false and misleading information"

allegation.

Mr. Druker is riding the wave of the ongoing discussion in the lay public about genetically modified organisms. On Facebook pages, in newspapers, journals, in blogs, and other social media sites, there seems to be one group that asserts that any genetically modified organism is an unnatural beast that has no place in food. On the other side are the vast majority of scientists who know that humans have been genetically modifying our food since we began to cultivate it, and the use of molecular engineering is nothing more than a more precise way of doing the same familiar job.

This is a straw man dichotomy based on the world "unnatural." One can argue whether GE is more precise than breeding (and Druker does, I think, an excellent job in dispelling that notion in Chapter 9, using the 2004 NAS report), but the important thing is not natural-vs-unnatural, but whether GE creates real or potential problems. In considering Simpson's claim that a "vast majority of scientists" think GE is more precise needs to be analyzed on two counts:

* for how many of those scientists work in the field and have some basis for understanding the realities of the technology, and
* how many of them depend for their research on funding from the GE industry, since a peer-reviewed study of the literature has shown a very tight correlation between funding source and research results.

Given the many examples of "no-harm" studies whose design or data analysis has clearly been done to avoid showing harm, careful examination of studies is what is important, not whether someone uses the term "unnatural."

Druker's basic assumptions, as you can guess from his title, is that there is a vast conspiracy of industry that has potentially caused harm to our food source, and that science has been subverted and seduced by the process, that government oversight has been corrupted, and the public has been deceived. The book was self-published, and clearly not reviewed by a science editor (oh wait, the scientists were subverted). Druker seeks to show that there is a vast conspiracy on the part of corporations, biotechnology types, and the government to promote genetically modified foods, and he attempts to validate his points using pieces of science and a lot of assumptions (logical assumptions made by a lawyer that make no scientific sense).

There's no doubt Druker is a lawyer, but given that he has spent the better part of two decades studying this situation, snidely and cavalierly dismissing what he says on that account does not give me a lot of hope that this piece is going to be helpful (a concern that turned out to be justified as I went on). The one part of Druker's "lawyerishness" that does impact the book is his constant repetition of points, driving them home to an unwriterly extreme. That would be a valid criticism of the book in terms of style, but the book isn't about style. The comment about "self-publication," if true, relates to that issue, but not to whether the information in the book is valid.

But my main problem with this paragraph is the assertion that it is Druker's "assumption" that there is a vast conspiracy. There is no assumption, only presentation of documented proof. As a lawyer, Druker and his colleagues forced the FDA to turn over internal documents showing a deliberate covering up of safety issues in its development of the "essential equivalence /

generally recognized as safe (GRAS)" policy it still maintains. He further documents the efforts of the GE enterprise from its very early days to prevent public awareness of its dangers. This is no "assumption."

Starting in the first chapters, he reveals how he was the part of a failed lawsuit and has invested much time reviewing thousands of documents. What he doesn't share is that he was simply cherry-picking data. In the early 1990's scientists speaking, as scientists do, said that we need to monitor this, have appropriate studies. He took those bits of quotes and ran with them. He employed confirmation bias, seeking out bits of data that support his viewpoint. While he goes into agonizing detail in selected areas of his discussion, publications contrary to his perspective are ignored.

The reference to a "failed" lawsuit is a good example of the reviewer's bias that should raise the reader's wariness of further misleading statements. The key issue in the trial was the GRAS assertion, which legally involves (a) the existence of a scientific consensus on safety and (b) the availability of technical data that underlies this consensus. The plaintiffs provided internal FDA memos and correspondence showing that the FDA knew there was no consensus on safety and that no tests existed that could support such a consensus if it did exist. The judge did not permit oral arguments and thus permitted no questions or clarification. In a remarkable decision, she (a) held that the requirements for GRAS were not satisfied in 1998 at the time of the lawsuit (**hence all GE foods were on the market illegally**), but nevertheless (b) ruled against the plaintiffs by asserting -- against all the evidence she had earlier acknowledged -- that the FDA administrators had not acted arbitrarily in their 1992 policy development. An appeal was prepared, but the FDA suddenly announced a proposed (still insufficient) regulation, which, if adopted, would have mooted the case. The appeal was called off in expectation of filing a new suit after the regulation was adopted. However, the FDA waited until the time for appeal had expired, and then announced it was not going to act on the proposed regulation. The case did not fail on the merits, but on FDA evasion strategy. A valid question Simpson could have asked is why a second lawsuit was then not filed concerning the present illegality of GMOs, with which the judge had tacitly agreed. But he is apparently too interested in portraying Druker's case as incompetent.

Contrary to what Simpson says, the FDA scientists who opposed what became the FDA policy were not casually saying that monitoring and studies were needed, but that it would be foolhardy to proceed **until** such monitoring was formalized and studies were done. Neither happened. Saying Druker is "running with bits of quotes" is like saying that someone who passes on the call of "Fire" in a developing inferno is just running with a bit of a quote, which misses the whole point of the situation. And in fact, Druker provides a **large** number of quotes from the pro-GE side, though obviously, given the purpose of his book, he does so in the context of debunking them. He presents the evidence of risk that Monsanto actively attempts to suppress. (Note: the assertion of suppression is not controversial. Monsanto has stated that they have an entire corporate department devoted to that very task.)

He mistakenly believes that when molecular engineering was first done, scientists didn't understand the nature of what they were dealing with. The author provides a long, pedantic, and outdated view of how regulatory genes worked. My guess is that he obtained a college biology textbook sometime in the 1990's and used that as a basis.

I'd be very interested in what is "outdated" about Druker's elucidation of gene regulatory structure and function. I found it extremely helpful. He goes into great detail ("long, pedantic" is not a scientific criticism) on that topic and the discoveries that increased our understanding, and he is very clear that **none** of this was known during the first decade or more of the GE revolution when the technology being used today was developed. The technological assumption in recombinant DNA work is -- very explicitly and clearly -- that one gene makes one protein, and that insertion **in a random place** will have no effect on the rest of the genome, ignoring the regulatory function of both genes and their relative positions in the DNA. This material was **not** known in that detail prior to the completion of the Human Genome project in 2003, so where Simpson's "1990s college textbook" comment came from is unfathomable. Druker also provides commentary from researchers in the field who point out that even now we are only beginning to understand the huge complexity of all the mechanisms at work, a complexity great enough that we may never fully understand it. Druker fleshes out this problem in a chapter comparing the care with which computer programmers test safety-critical systems -- whose complexity is limited by the fact they are human-developed -- with the remarkable carelessness used in GE studies that have found no potential for harm. Simpson's denigrating comments are again completely at odds with the reality of the book, and clearly seem designed to prevent consideration of it.

L-Tryptophan and Eosinophilia-Myalgia Syndrome and GMO

Druker spends early chapters talking about the supplement L-tryptophan, which caused health problems with a disease called eosinophilia-myalgia syndrome (EMS). Druker is correct that a manufacturer that used bacteria that were molecularly engineered to make more L-tryptophan. In fact, most supplements used today (vitamins and amino acids) are made from genetically modified bacteria or yeast. Druker's theorizes that the cause of EMS was from an unknown metabolite of this engineered bacteria. In spite of a search for some evidence that contaminants in the tryptophan caused EMS (including metabolites of tryptophan), none of the other agents in the supplement have been found to cause EMS.

This characterization, too, is false. There was at least one identified molecular contaminant that caused EMS. His false claim about this key issue makes me wonder whether he's being truthful about his claim that most supplements are now being made from GMOs -- I'll have to suspend judgment on that, since I've never heard the claim before.

Druker is incorrect that EMS was not present before GMO, in fact, EMS was reported long before bacteria were genetically engineered. The syndrome called EMS was first defined in 1989 – however, there is clear histological evidence that in the 1980's contaminated rapeseed oil caused a similar disease. Druker cannot believe that L-tryptophan would be harmful, and states such – falling into the trap of many anti-vaccination types – that the body makes and uses many chemicals that in small amounts are useful and in large amounts can kill (like L-tryptophan and like formaldehyde).

Misleading. The EMS syndrome **was** defined in 1989 and was definitively connected to the **only** L-tryptophan supplement that was being made at the time using GE bacteria. No other L-tryptophan sources caused EMS. Whether another syndrome similar to EMS existed beforehand is completely beside the point. And of course there are substances for which taking too much can

kill, but what does that have to do with the subject? No one who got EMS was taking abnormal quantities of L-tryptophan.

The other issue with this argument is that 14% of the cases of EMS were not related to L-tryptophan. Excessive oral ingestion of tryptophan supplement inhibits histamine degradation by increasing formation of formate and indolyl metabolites, several of which block the degradation of histamine, thereby potentiating histamine effects. Increased histamine activity (from any source) can induce eosinophilia and myalgia symptoms. Patients with hypothalamic-pituitary-adrenal axis dysregulation who do not have EMS will manifest increased sensitivity to exogenous (supplemental) tryptophan and histamine. It appears people who suffer from histamine disequilibrium in their metabolic pathway lead to a final common pathway for EMS syndromes.That fact escaped Druker, but he uses the "mysterious metabolite" to be the theme for the book about GMO in general. That is, since crops are engineered to produce a new protein, or make more of a specific protein, we need to test them because look what happened with L-tryptophan. Druker's tryptophan story is incorrect, and yet throughout the book he refers to this as the basis for the view he hammers into the reader. What Druker also fails to realize is that the new proteins made in GMO have undergone extensive tests.

(1) Simpson throws in technical details on other things that can cause an EMS-like syndrome. It isn't clear how this is relevant. The GE-made L-tryptophan **did** cause such a syndrome, regardless of whether there are other causes. A related argument states that the cause was a change in the filtering process. However, through painstaking contacts with those involved in EMS lawsuits, Druker traced L-tryptophan EMS cases to earlier GE strains that preceded the filtering change. And the filtering argument makes no sense on its face -- if there was an EMS cause that needed to be filtered out, it had to have been produced by the GE bacteria.

(2) The assertion that new proteins have undergone extensive tests is wrong on several counts.
   (a) Simpson is apparently referring to tests on the **intended** protein, but these have little to do with the **actually generated** protein -- changes in unexpected folding and amounts generated can't be determined by testing an isolated theoretical protein, only on the functioning GE plant.
   (b) However, the primary concern is **different, unknown proteins** that might develop from the randomness (and violence, in the case of the gene gun) of the rDNA process. It is impossible to test ahead of time for what you don't know exists. And in fact, proteomic analysis has shown a variety of unexpected proteins, including known allergens and some of much lower molecular weight that are particularly potentially dangerous.
   (c) It would be interesting to know what the "extensive test" studies Simpson refers to actually did, and why, for instance, allergy cases almost doubled in the UK after the introduction of a GE soy.

The Pusztai Affair

Druker puts a lot of emphasis on two particular publications. One is by Arpad Pusztai, who did research with genetically modified potatoes at the Rowett Institute in the 1990's. Based on feeding rats both genetically modified and non-modified potatoes, Pusztai went on the television show "World in Action" to announce that his study showed there were major issues with

genetically modified potatoes. When multiple scientists examined the data, Pusztai's conclusions were not substantiated. Specifically, experts stated there were no meaningful differences between the control and experimental groups, and the same cellular differences could be seen in both groups, and too few animals were used to allow any statistical significance. Also, the diets were protein deficient, and some rats were even fed raw potatoes, which are toxic to rats. In addition, Pusztai had some fundamental flaws in how potatoes, and all plants, are not diploid but polyploid so that potatoes you engineer might not be what you thought.

This paragraph contains numerous falsehoods and misleads of the kind characteristic of biotech spin that shows up time and again in attacks on independent researchers. Perhaps the best way to get an overview response in this case is to read a couple of excellent articles which provide a description of -- and point-by-point refutation of -- the attack on Pusztai, at

http://www.huffingtonpost.com/jeffrey-smith/anniversary-of-a-whistleb_b_675817.html
http://www.huffingtonpost.com/jeffrey-smith/biotech-propaganda-cooks_b_675957.html

Pusztai announced the claims on television, not in a scientific forum; and while his research was published as a letter to "Lancet," not all the reviewers agreed with its publication. Typically when one peer reviewer has issues with a publication, it does not go to press. Because Pusztai went to the press, it brought up the issue to the parliament who demanded answers. The Royal Society, which is a group of scientists that advise the government, was asked to look at Pusztai's work. When his work was sent to six scientists – all came back with severe issues and concluding that Pusztai's conclusions DO NOT agree with his data, and they didn't agree with his work. In spite of this, Druker asserts that Pusztai's work was valid, and indicates that the scientists who were against his work were against it because of what it showed, not because it was shoddy research with conclusions that could not be reached. Pusztai continues to be considered a martyr for the anti-GMO cause, and Druker feeds into that genre.

It is interesting that Simpson accepts that idea that one dissenting peer reviewer should prevent publication, and yet he has nothing to say about the fact that virtual unanimity among FDA's scientists in 1990-91 about the potential dangers of GE food did not prevent promulgation of the FDA's policy asserting GRAS.

Again, for a clear picture of how misleading Simpson is being in this paragraph as well, see the above-mentioned articles.

Pusztai Did Not Account For Somaclonal Variation in the Potato

When Pusztai concluded that the differences he perceived were because of the transgenic plants, what he did not understand was that the process that the plants go through cause marked changes in the structure and the expression of genes. That process, culturing through a callus stage and then regeneration of the plant causes variation known as somaclonal variation – something plant breeders understand and Pusztai did not. This variation is terribly important for potatoes because potatoes produce glycoalkaloids that are highly toxic substances, and potato breeders understand this. Pusztai did not do a chemical analysis of the transgenic lines to look for this, and thus the variation is more likely due to the somaclonal variation than transgenic variation. Pusztai did not use an appropriate control group in his experiment, the control potato

she used had a different history than the transgenic potatoes – they did not have a culture procedure that induces a somaclonal variation. If there was a variation in his potatoes it was likely attributed to the from the culture procedure. In order to attribute deleterious effects of transgenic potatoes from a newly introduced gene he would have to make a comparison to potatoes with the same history and without the transgenic addition. This was not done.

It should be pointed out that all of major critics of GE, including Druker and Pusztai, point to tissue culture as a well-known cause of potential risks in GE foods, given that it is an essentialy component of the GE process. Simpson's statement about the control potato having a different history from the transgenics is simply false -- the control was, in fact, the **parent** from which the GE potatoes were developed. And I wonder about Simpson's use of "she" -- does he have inside information about which parts of the study Pusztai or his wife were responsible for?

Seralini Affair

Gilles-Eric Seralini, who was involved in feeding genetically modified corn to rats over their two-year lifespan, published the second paper that Druker quotes extensively. This was published in 2012. Once again, Seralini, taking a cue from Pusztai, first reported the results to news groups exclusively. The design of the study was flawed by using rats that normally develop tumors, the small sample size, and lack of reproduction of his work. The paper was retracted by the journal,because of study design and because the conclusions of the paper did not match the data in the article. Another journal re-published the paper, and Druker thinks this vindicates him; but the paper was republished without peer review.

Specific points with Seralini's paper include: he only used 20 control rats with 200 rats in the study, and no binding between control and the experimental group. There was a large number of small sub-groups, complicating design. Cherry picking the negative results. Poor statistical analysis. There was no dose-response curve for determining a toxic effect. The effect of feeding Roudup ready maize and feeding Roudup was the same (which is hard to imagine).

In part the retraction comes with the following statement: "***A more in-depth look at the raw data revealed that no definitive conclusions can be reached with this small sample size regarding the role of either NK603 or glyphosate in regards to overall mortality or tumor incidence. Given the known high incidence of tumors in the Sprague-Dawley rat, normal variability cannot be excluded as the cause of the higher mortality and incidence observed in the treated groups.***"

That Seralini did not allow outside comment on the paper before it was released, and released it to his select news outlets is always troublesome. But the journal retracted his paper after review of it.

This commentary is typical of the attacks on Seralini. It makes a big deal out of the journal retraction, a retraction violated the guidelines promulgated by the Committee on Publication Ethics, to which the publishers of the journal were signatories. The editor's justification for retraction -- that the study was "inconclusive -- is unprecedented. In terms of his claim (and the vast majority of other attacks on the paper) that the paper was a failed attempt to make a link with cancer, the independent research group CRIIGEN has pointed out:

> "The study of Séralini et al. was never intended to follow the experimental protocol used for carcinogenicity. Moreover, the term "cancer" is never mentioned in the article. As the title of the study says, it is an analysis of the potential "long-term toxicity". This is one of the first global studies conducted in this area over a period of two years and was intended to analyze a broader set of biological parameters (blood, organs, urinary...), the statistical analysis and results of which has not been disputed by the editor of FCT."

But if you want to look at the cancer issue anyway, the Sprague-Dawley rats are the same ones used by Monsanto in its studies, and have the same susceptibility to cancer that humans do, with the same increasing susceptibility with age. The difference between Monsanto and Seralini is that Seralini allowed this reality to appear by carrying the study beyond Monsanto's 90 days into the rats' lifespan. The first tumors didn't appear until 7 months, and most weren't apparent until 18 months, the equivalent of a human age in the 60s. The claim about "too-few-rats" is irrelevant when the statistical analysis of significance holds up. As Druker points out, the purpose of using a large number of rats is to avoid a false negative, in which incidence might be missed. The detection of a higher-than-expected incidence of tumors in a smaller study is more significant than in a larger study.

In terms of toxicity (rather than cancer), what the longer-term study showed was the logical development of what had already shown up in shorter studies, but which Monsanto's summary claimed was "not biologically meaningful," a claim shown to be false when the data was extracted by legal action.

In terms of Simpson's specifics:

(1) I can't speak on "binding," since I'm not sure what the concept means or how it relates to Seralini's work.

(2) The complaint about 20 controls is misleading. If a number of treatment variables are being examined, the number of untreated controls should be equal to those in each of the groups, not the sum of all the groups.

(3) The large number of small groups made it possible to sort out the effects of the various experimental variables. Of course it complicated the design. That was the intention. What's the problem?

(4) Cherry-picking negative data -- first of all, it's ironic that this is a complaint, given that Monsanto has a **long** and well-documented record of cherry-ignoring negative data. In any case, I'd want to know what data Simpson is talking about, but the point is that when studying safety, **any** data showing harm is relevant, whereas any data not showing harm is inconclusive, since it may have missed the harm.

(5) Simpson's assertion that it is "hard to imagine" the toxic effects of the GM corn and Roundup (oddly, Simpson can't seem to spell it right) being the same is strikingly unscientific. This isn't a matter for imagination. The biochemical chelating role of glyphosate (augmented by the Roundup adjuvants) in blocking fundamental metabolic pathways creates a huge potential for damage, and organ damage from GM corn has been clearly shown in the real world -- see, for instance, Dr. Judy Carman's 2013 pig study (http://gmojudycarman.org/).

Druker's Analysis – Conspiracy Everywhere

Druker opined that these scientists were poorly treated, unjustifiably ignored, and essentially martyrs to the vast conspiracy to bring genetically modified foods to the marketplace. Druker never considers the more obvious point: that the two papers he most often refers to are the equivalent of Andrew Wakefield's "Lancet" article about measles vaccines, or that those scientists' papers are not considered respectable. Druker ignores the over 600 papers in peer reviewed journals showing safety and testing of GMO. Druker also ignores the obvious- neither Puztai or Seralini's papers have ever been reproduced.

Quite apart from Simpson's assertion that two non-comparable papers are equivalent, it is interesting that he should bring up Wakefield, whose co-author has been vindicated in court, opening the way to Wakefield doing the same. The vaccine and GMO issues are identical with respect to a history of two powerful industries -- which fund most of the research -- vilifying and attempting to destroy the careers of scientists whose results create problems for them. Druker doesn't simply opine on this -- he documents examples, but only a few compared to the large number that I have seen documented elsewhere. In both of these issues, the conspiracy has been clearly documented by the industry's and government's own records. Simpson is providing an excellent example of the use of the "conspiracy theory" meme developed by the CIA in 1967 to stop rational consideration of a situation.

As to why those studies have not been reproduced -- what would you do if you were an independent scientist interested in doing so, but saw the wrecking of Pusztai's career and the incredible attacks on Seralini? When Pusztai -- a 35-year expert who had won out over 27 other applicants for the study (commissioned by the U.K government) -- applied for follow-up funding, he was refused. And if Seralini's method was so bad, why has the EU adopted it as the appropriate one for such studies?

His major logical fallacy is an appeal to nature, and that everything natural is good; and he denies that genetic variation in plants, and the modification that man has done for years, is less precise than genetically inserting a gene and having it expressed. He hammers this point time after time, ignoring the obvious reality that Mother Nature has been playing genetic roulette with our food supply for years. We call this evolution.

Druker does NOT assert that everything natural is good -- another straw man argument by Simpson and others. His assertion is that the GE approach is more risky than breeding, that millions of years of evolution have worked out genetic mechanisms that minimize harm. As mentioned above, Druker in his Chapter 9 uses the NAS's own ostensibly pro-GMO risk assessment to demonstrate this. But the truly remarkable part of Simpson's statement here is his appeal to evolution. Druker makes the obvious point that evolution takes place over extremely long periods of time, which allow for the many negative events that happen to sort themselves out and disappear. rDNA GE has existed for only a few decades. Like the short-term Monsanto studies, we haven't **begun** to see what the possibilities are on a human scale.

Druker states that "*New genes do not abruptly appear, nor are the internal structures of those already present routinely modified in radical ways….Even in the rare instances when a spontaneous mutation arises and is maintained in the specis gene pool, the change in the gene's*

structure ordinarily occurs at just one point (only with a single base pair affected)." The statement is blatantly false, and shows his lack of eduction in biology. Genes do go between species – and this transgenetic change has occurred in our own gut. Take the ability to digest seaweed – we don't have the ability to digest it, but our gut bacteria does. Our gut bacteria got the gene from a marine bacteria- that was the fundamental change. Druker doesn't understand that evolution happens not one base pair at a time, but with large changes in the genomic structures that have occurred.

[Note: the number of misspellings in this article is remarkable, something I didn't find in Druker's "self-published" book.] Druker may be wrong on his single-base-pair assertion, though Simpson deliberately avoids the fact that Druker may actually be right in the context of the fact that he is referring to mutations that are maintained in the gene pool (i.e., not fatal). In any case, to use this single observation as the basis for asserting that Druker lacks education in biology is to ignore the mass of extremely detailed and accurate biological information Druker offers.

I can't find a place where Druker says that interspecies genetic sharing never occurs, though he may have said it. But Simpson's example, of bacteria-to-bacteria interchange, is dishonest, in the sense that the plant and animal and bacteria/virus kingdoms' genomes have very specifically different structures that prevent them from functioning together. In every case, these have had to be technically overridden by genetic engineers, using alterations that could not and do not occur in nature. So **every** rDNA transfer that involves a switch between kingdoms (which, as far as I can tell, is most of them, given the almost universal use of the tobacco mosaic virus promoter gene) is functionally impossible in nature.

Druker uses many appeals to authority in the book, repeatedly citing the discredited scientists as proof of his theme while ignoring the vast majority of scientists who have been involved in molecular biology. There are reputable scientists who have instituted their own moratorium on genetic research in the early days of molecular engineering, and the misguided author dismisses those scientists as part of the vast conspiracy that is motivated by money placed into research and big agribusiness. He states there is no consensus to GMO, when in fact there is more of a science consensus about safety of GMO then there is about climate change (recent PEW study).

Simpson's use of the term "reputable scientists" and "consensus" is the same "appeal to authority" for which he denigrates Druker. If Druker's hundreds of footnotes to studies and reports is "appeal to authority," then Druker's work, like most scientific literature, is indeed an "appeal to authority."

Simpson conveniently ignores Druker's extensive documentation of the shenanigans that went on in the early days of GE -- secret selective conferences from which all dissenting voices were prevented from attending, the publicly announced results of which (according to attendees) bore little or no relationship to what transpired and sometimes were written ahead of time. All this was explicitly done to avoid regulation, an assertion for which Druker provides adequate documentation.

Again, Simpson's pulls out the "vast conspiracy" canard, ignoring the endless documentation Druker provides of the actual existence of a conspiracy and its stated motivations. Simpson would clearly have been one of the nay-sayers in the tobacco case prior to the release of the

internal tobacco industry documents, which did indeed expose a vast conspiracy. Druker is one of the lawyers who has managed to dig out such documentation, and it isn't surprising that he is being attacked in this way. It seems fair at this point to wonder whether Simpson is just sublimely forgetful of past history, or is in some way financially connected to Monsanto or people being funded by Monsanto.

Druker uses the strawman argument throughout, such as, "*Thus, GE food venture was grounded on the belief that, at their deepest level, biological organisms do not display the orderly arrangement and coordination of parts that's commonly denoted by the term 'organic.'"* This is not true, and as many lawyers do, he attempts to get into the motives of the scientists who did the research without asking them.

I can't quite parse Druker's quote here -- perhaps he's referring to GE's one-gene-one-protein theory and its corollary that blasting a cassette containing a target gene, promoter, terminator and antibiotic-resistant marker, into a random position will not involve the risk of wider effects . But to expect him to "ask the scientists who did the research" is a little bizarre. That would require a major survey. As for straw-man arguments, Simpson is not, as pointed out above, innocent.

The News Media is Bought – Even Fair and Balanced

Druker continues with this conspiracy going to the news media, stating that big media is tied to agribusiness, that is tied to biotechnology, that has made the government weak and subverted it. He goes through the story of two Fox News reporters that were fired by the local news station in Tampa because of pressure placed on the station by Monsanto. What Druker doesn't tell in the book is that this went to trail and the jury did not believe the couple's claim that Fox News bowed to any pressure to change the news report. Nor does Druker mention that the Florida Court of Appeals reversed the ruling in 2003. The case involved the use of bovine growth hormone (BGH) made by Monsanto. Their report suggested milk coming from these cows was adulterated with this hormone. The facts of the case are less important than the facts about BGH: first BGH is NOT active in humans, while it may affect the cow, it does not have any biologic absorption in humans. Good journalism is reporting all the facts – nevertheless, the reporters got a Goldman Environmental Prize. The question remains: was the station in bed with Monsanto, or does one ask for two sides to the story and when Monsanto presented their side was it ignored. While the FDA did approve BGH for increased milk production, it does not affect humans, and it is used in less than one in five cows.

This paragraph is another example of either ignorance of the details or intent to mislead. The actual story of that news report is hair-raising. There is no question about pressure from Monsanto. The primary faxed letters from the Monsanto attorney to Fox's head Ayres exist, and their message is absolutely clear and unequivocal, citing "serious damages to Monsanto and dire consequences for Fox News."

But in any case, Simpson's implication that the trial was over Monsanto pressure is misleading -- it was over the reporters' whistle-blower claims that Fox had fired them because they threatened to go the FCC over Fox's attempt to falsify their news report, and Druker reports all this in detail. The jury in fact sided with them. The subsequent Appeals Court's basis for overturning that decision was only that FCC's policy against falsification was not considered a rule on the state

level, so the whistleblower provision didn't apply. Contrary to Simpson's implication, it had nothing to do with the merits of the rBGH concerns, which Druker actually doesn't cover in near the detail provided in other published sources.

Simpson is further misleading in his toss-off comment that rBGH does not affect humans. What it does is increase the presence in the milk of the IGF-1 hormone, and of non-penicillin antibiotics used to fight the bad mastitis the rBGH causes in cows. These show up in the people who drink the milk. IGF-1 is associated with cancer in humans.

Druker quotes is fellow plaintiff Dr. Phil Regal, “Phil Regal recounts that when he engaged reporters in extensive conversations, they often told him that they had ‘to be very careful’ about what they submitted because their editors ‘were very pro-biotech.’ He surmises that this is in part reflects the fact that several media companies have been acquired by massive corporations with substantial interests in sectors that would be adversely impacted by negative news about bioengineering:

It is hard to respond to such paranoia, in an age when we have seen Watergate and a president de-throned. But I suspect what Druker is saying is that since the news reports both sides of issues, and not just his agenda, there must be a conspiracy. Case in point, with Seralini’s paper that he tried to give to the press without proper scrutiny. The Columbia School of Journalism gave praise to science authors who questioned the “shenanigans” that Seralini tried to do. It appears Druker would have been happier with the shenanigans, and if you don’t come on board with media you must be “bought” by the evil Monsanto corporation.

The "interests" of these corporations is not only direct, but also in advertising. The pressure of the pharmaceutical, wireless, and military industries on the press, in terms of loss of advertising, is so well-known it leaves me wondering what world Simpson is living in with his implication that this is "paranoia." Is he saying that the huge biotech industry is somehow different from these others? As for Watergate, (a) it happened a decade before the news consolidation got seriously underway, (b) Nixon's ability and leverage to hurt the press was minimal compared to the current industries', and (c) it is becoming apparent that there were influential parts of the government that wanted Nixon out of the way for departing from their script. Watergate coverage was a piece of cake compared to going up against the biotech Big Four.

Druker even goes on to say that had the facts “..been fairly reported to the public, the GI food venture would have been brought to a stop – and probably couldn’t have continued.” He says that a dissemination was prevented – but alas, it wasn’t that a dissemination was prevented – it was in the press. What happened is that journalists do research, and when they smelled the rat of Serelini they didn’t go for the cheese. Druker goes on to say, “Although, thanks to Pusztai’s bravery, the essential information was transmitted throughout the UK, and eventually spread through Europe, the American media kept the US citizenry in the dark. And this crucial black-out, conjoined with the adroit disinformation campaign mounted by biotech advocates, has robbed the research of its rightful influence.” He neglects to point out that after the TV publicity of Puzstai, it was put through crucial tests and found to be a worthless paper.

Virtually every study that has raised questions about the safety of GE food has been "found worthless" by scientists whose bread-and-butter lies in more-research-is-necessary GE food. The

point being raised here (and then not addressed) is news suppression -- why the UK and Europe got the news, and the U.S. didn't, regardless of who did or didn't say the paper was worthless.

The government is bought

Throughout the book he contends that the regulatory agencies are corrupted. I don't know if he has read the FDA stand about genetic engineering but here it is:

> **While FDA regulates foods and ingredients, including foods made from GE plants, the agency neither supports GE plants based on their perceived benefits nor opposes them based on their perceived risks. FDA's priority is to ensure that all foods, including those derived from GE plants, are safe and otherwise in compliance with the FD&C Act and applicable regulations.**
> **However, FDA recognizes that there are diverse views among food manufacturers, the agricultural industry and the public.**

I have to wonder where he dug that one up. The actual FDA statement on policy, which is:

> The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."

came at the end of a progression of revision drafts in which the loudly-proclaimed concerns of its own scientists were progressively and politically removed from the drafts until there were none left -- a process supervised by Michael Taylor, a former lawyer for Monsanto, who returned to Monsanto as VP after his stint at the FDA. In one of the more egregious and scary examples of the revolving door, he is now the head of all food safety for the FDA.

The FDA may have a "priority to ensure that all foods, including those derived from GE plants, are safe and otherwise in compliance with FD&C Act and applicable regulations." But in actual fact, they do nothing to assure that safety. They do not require safety study data from GE producers, or even notice prior to marketing, and when they do get it in their toothless "consultations," they simply send a letter to the company acknowledging that (a) the company claims the product is safe, but (b) the FDA does not take a position on that claim. How does this "assure safety?"

And yet, Druker assumes the FDA, EPA, and USDA all are corrupted by special interests – even though they have a regulatory process and do NOT say that all GE is generally recognized as safe (GRAS). Druker clearly wants the reader to believe it, and some will. But, there is no evidence to support other than Druker's contention that if only people would read his book then they would understand.

Druker, as a good lawyer, goes through the FD&C Act and shows how all of its provisions are violated by the GE enterprise. He doesn't say that the FDA claims GE foods are GRAS, but that, because of the strict requirements for GRAS prior to release of foods, the fact that the foods are being released shows a "presumption of GRAS," when, in fact, those requirements haven't been

met. And yes, if people actually read his book without a pro-GMO bias, they will see this very clearly.

Druker even goes so far as to say that if someone would put his book in the hands of President Obama, and he would read the book, that he would take executive action based on Druker's book to get rid of GMO. My opinion – President Obama is a smarter and better legal mind first- and second, as a scientist – Druker's arguments don't hold water.

Druker's arguments are, in fact, supported by his 1145 endnotes, most of them referring to journal studies, articles, and scientific reports. Simpson has actually provided nothing so far to support that last clause, and its use again raises questions about how trustworthy his piece is.

The Texas Sharpshooter, Special Pleading, and others

Special pleading is a logical fallacy of moving the goal post. When Druker says, "Obviously, when even the most rigorous tests that have been employed in the testing of a GE food are compared to the set of tests prescribed aboe, they appear dismally deficient." I gather that he feels the bad tests of Pusztai and Serilini are ok, but that we can move the goalposts for the other tests that have been done for GMO safety.

The Texas Sharpshooter is a logical fallacy where you cherry-pick the data to fit the conclusion. Druker picked two papers that are terrible, and yet ignores the others.

Seralini did indeed move the goalposts. He used the same rats that Monsanto uses, but extended the test period from 90 days (9 human years) to 2 years (lifetime). Moving goalposts to make better science is hardly a logical fallacy. Simpson keeps harping on cherry-picking in a one-sided manner. When data shows up that indicates harm, highlighting it shows a lack of safety. When data shows up not showing harm, it doesn't in itself prove safety. And obviously in both cases you have to look at the study design and execution. Monsanto and pro-GMO researchers have a documented history of declaring statistically significant effects "biologically insignificant" -- an interesting method of cherry picking. In the case above, Simpson makes reference to a set of rigorous standards for testing GMOs laid out by Druker which Simpson doesn't present, instead transposing them with Pusztai/Seralini. However one feels about those latter studies, they aren't the standards Druker was talking about in Simpson's quote. In any case, Druker's assertion of "dismal deficiency" has been amply demonstrated not only by him but of many other scientists I've read and listened to.

Ad hominem is an attack on the character of others, or institutions- which Druker makes throughout the book, both about scientists who support GMO (which he denies there is a consensus), the government regulators, the news media, and industry.

This is one place where I can agree with Simpson, although it does not decrease the relevance or truth of the substantive material in the book, nor the fact that Simpson skirts dangerously close to being guilty of the practice.

The genetic logical fallacy, is "where something comes from defines if it is good or bad. Good stock is good." In this case, Druker dismisses evolutionary science, and says breeding is ok, but

putting and expressing a gene in a plant is not.

With this comment, Simpson is either missing the point, hasn't read the book, or is being deliberately misleading. Druker in no way dismisses evolutionary science, but in fact points out clearly that evolution occurs on a scale of millions of years, in which all kinds of horrible mistakes are cleared out of the system. Not just traits, but the methods by which genes interact, are products of that evolution. GE is the product of four decades of fallible human work, commenced at a time when we knew relatively nothing about gene interaction and regulation, and which violates numerous built-in safety barriers and creates the potential (and in many cases the demonstrated actuality) for unintended consequences which haven't had the evolutionary time scale to be ironed out.

The Environmental Card

No anti-GMO sentiment would be complete without showing devastation of the environment by these plants, and Druker does not disappoint, but of course he cherry picks his facts.

Druker states several times that GMO uses more herbicides and more pesticides than before. This is false. Not only are lest pesticides and herbicides used, but it has improved the environmental impact, decreased carbon emissions, and decreased tillage.

This statement is remarkable. The statistics showing increased herbicide and pesticide use are out there and incontrovertible. Simpson doesn't have a right to his own "facts." The GE enterprise has definitely reduced tillage, but how preventing CO2-uptaking weeds from growing decreases carbon emissions is beyond me. More seriously, the fact that GE genes are contaminating not only organic farms, but crops in places thousands of miles from where they are being grown, and are showing up in countries which have banned their use, is completely ignored by Simpson. If this isn't environmental contamination, one wonders how Simpson would define it.

Druker goes to length to show the problems with Roundup, stating, “And it was observed to be toxic to human cells and also to damage DNA at doses far below those used in agriculture.” First, Roudup (glyphosate) is 1/200 as toxic as caffeine (I like my coffee with cream). Second, the study he cites was with human cell lines, which is tissue culture. Tissue culture is not an organism, but when glyphosate was checked against human and animal studies it is found to be reasonably safe. Again, one aspirin is good, a bottle is not- Druker cannot differentiate with this, but he did cherry pick data that makes it look like Roundup is a major endocrine disruptor, because it is in tissue culture- ignoring that animal studies do not show that point. Tissue culture, for example, does not have the benefit of a liver to detoxify agents. This is why Roundup is less toxic than caffeine. But compare Roundup to other herbicides, which are more toxic, and which farmers must use if they don’t have the Roundup ready crops, and the impact to the environment is less.

This, too, is misleading. Raising the issue of tissue culture is irrelevant, and it's too bad if that's the only thing he can find in Druker to make his case. Druker, like many scientists who have commented on GMOs, emphasizes the mutational role of tissue culture, which is an essential part of the rDNA GE process. Is Simpson ignorant of this, or deliberately not mentioning it?

Unlike Druker's documentation of his claims, Simpson's provides none for his 1/200 figure, so it is impossible to determine what "toxic" means in this case. Glyphosate inhibits the shikimate metabolic pathway by means of chelation of minerals necessary for enzymes involved in that pathway. That pathway only exists in plants and bacteria, but since most of the human immune system and ability to absorb nutrition is based on the bacteria in the gut, it is far from benign, though that aspect of its damage is indirect. But its chelating doesn't stop with the shikimate enzymes. It also damages the cytochrome-450 enzymes, which may be part of the cause of the liver and kidney damage demonstrated in animal studies. (See a couple of fascinating and detailed interviews with Drs. Don Huber and Stephanie Seneff.)

http://dickatlee.com/issues/gmo/mp3/don_huber_perdue_glyphosate.mp3
http://dickatlee.com/issues/gmo/mp3/ss759.mp3

Further, Roundup is now found in atmospheric and ground water around the country, does not biodegrade as originally claimed by Monsanto, and is found in human tissues and breast milk.

Druker then talks about superweeds, as if they are an issue because of GMO. Super weeds happen much like antibiotic resistance happens. The more herbicides are used, weeds grow that are resistant. Super weeds are a problem, and it is not a problem because of GMO, it is a problem that man will fight for a long time. There is no solution to our warfare on weeds, which man has had since the dawn of time. We use herbicides, the question is which ones will we use, what is the toxicity of them, which ones will cause us harm in our food supply. GMO is not the problem with herbicide resistant weeds, but neither is “organic” farming.

Interesting. Organic farming obviously has to deal with weeds, and has its own solutions, but they are not chemical. A major problem with Roundup (among many) is that it kills the soil bacteria which make soil healthy. It has been observed that when the Mississippi River flooded into Iowa several years ago, one could distinguish between fields that were organic and those which weren't, because the organic fields absorbed the water, while the Roundup fields remained flooded because the soil had lost its loft and was compacted. Superweeds are not a problem in organic agriculture -- they're just weeds to be dealt with like any other -- they don't develop resistance to mechanical removal or physical suppression. However, they **are** a problem in chemical agriculture because they destroy the desired low-labor-input weed-free paradigm, thus progressively demanding stronger and more dangerous herbicides (as we are now seeing) to maintain that paradigm.

An Ig Nobel Prize

Even if you happen to agree with Druker’s point of view, the book is long and tiresome reading. It reads like a Supreme Court brief where the members of the Supreme Court would say, “Make it brief.”

It’s clear that a lawyer authored this manifesto. Because the fundamental truth of science is that we test things. You cannot make logic fit into biology. While I would never disagree that we should test products brought to the market, he strongly indicates these items are not tested. In fact, they are.

I fully agree with Simpson's characterization of the book as long, and would add that it is extremely repetitive -- but probably necessarily so, from a lawyer's point of view, to make sure the reader gets the points. For someone who is familiar with the scientific literature that raises concerns about GE, it is hardly tiresome -- he provides many insights that undoubtedly new to many. However, Simpson's statement that "you cannot make logic fit into biology" is about as strikingly anti-science as you can get. And his clever use of the word "indicates" gets around the fact that Druker actually **doesn't** say the items aren't tested, but rather that the tests that are done are incapable of determining safety.

When I learned that this book was self-published I could see why – no editor would have allowed such long and pedantic arguments, and a science editor would have corrected many of the basic mistakes in his book.

If there is a Nobel Prize for logical fallacies, the author should be nominated. The book is a lengthy editorial, filled with some simplistic explanations of biology (many too simplistic) and factual errors. The forward by Dame Goodall gave the book its best lines – and who doesn't like Jane Goodall and her extraordinary sense of humor?

I must admit, if the book is an editorial, I've never read an editorial so packed with documented and referenced facts. That Druker has a position is, of course obvious. But so do the authors of many scientific papers. If the complexity that Druker elucidates in such detail is "simplistic," one has to wonder what Simpson might offer in the way of a more comprehensive presentation that isn't a multi-volume encyclopedia of genetics. And I haven't seen Simpson actually provide any specifics on factual errors.

With respect to the references below, I've provided links above to useful articles on the Pusztai affair. Perhaps the most useful links with respect to critiques of Seralini are on the website dedicated to his work:

http://www.gmoseralini.org

I'll provide comments below on the Columbia Journalism Review's attack on Seralini and the FDA statement on GMO safety evaluation.

References for L-Tryptophan

Smith MJ, and Garrett RH (2005). Review. A heretofore undisclosed crux of Eosinophilia-Myalgia Syndrome: compromised histamine degradation. Inflammation Research 54: 435–450.

FDA, U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition Office of Nutritional Products, Labeling, and Dietary Supplements, (February 2001) Information Paper on L-tryptophan and 5-hydroxy-L-tryptophan www.cfsan.fda.gov/~dms/ds-tryp1.html accessed Dec 7 2008.

Curr Opin Rheumatol. 1993 Nov;5(6):802-8. Eosinophilia-myalgia syndrome, toxic-oil syndrome, and diffuse fasciitis with eosinophilia.

Silver RM1.

References for Pusztai's paper

Here is his original paper:

Ewen SW and Pusztai A (1999). Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. Lancet 354 :1353-1354.

In that same issue of Lancet there was a critical review of Pusztai's methods and conclusions:

Kuiper HA, Noteborn HPJM , and Peijnenburg ACM (1999).Adequacy of methods for testing the safety of genetically modified foods.

Here is in pdf form – the Royal Society's review of Pusztai:

Annual Review Plant Biology 59:771–812. Royal Society UK (1999) Review of data on possible toxicity of GM potatoes. royalsociety.org/Review-of-data-on-possible-toxicity-of-GM-potatoes/PDF file. Accessed Dec 6 2008.

References for Seralini Paper

Here is the original paper:

Séralini GE1, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D, de Vendômois JS.Food Chem Toxicol. 2012 Nov;50(11):4221-31. doi: 10.1016/j.fct.2012.08.005. Epub 2012 Sep 19.Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize.

Here is the retraction notice:

Food Chem Toxicol. 2014 Jan;63:244. Retraction notice to "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" [Food Chem. Toxicol. 50 (2012) 4221-4231]. Retraction of Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. [Food Chem Toxicol. 2012]

Other GMO References – Safety studies

Shokuhin Eiseigaku Zasshi. 2007 Jun;48(3):41-50.
[A 52-week feeding study of genetically modified soybeans in F344 rats]. Sakamoto Y1, Tada Y, Fukumori N, Tayama K, Ando H, Takahashi H, Kubo Y, Nagasawa A, Yano N, Yuzawa K, Ogata A, Kamimura H. <– no differences between rats fed GMO and non GMO

Toxicol Int. 2010 Jul;17(2):99-101. doi: 10.4103/0971-6580.72680.Sero-biochemical Studies in Sheep Fed with Bt Cotton Plants.
Anilkumar B1, Reddy AG, Kalakumar B, Rani MU, Anjaneyulu Y, Raghunandan T, Reddy YR, Jyothi K, Gopi KS. <*In conclusion, the results of the present investigation enunciated that*

feeding of genetically modified (Bt) cotton plants to sheep was without detrimental effects in the biological system of sheep.

The Fate of Genetically Modified Protein from Roundup Ready Soybeans in Laying Hens1J. Ash2, C. Novak3 and S. E. Scheideler*,J Appl Poult Res (2003) 12 (2): 242-245. <-*In conclusion, the digestive process of the laying hen effectively broke down the GM protein from the soybean meal portion of the diet, hence no modified protein was found in the liver, egg, or feces in this brief field trial.*

Int Arch Allergy Immunol. 2007;144(1):29-38. Epub 2007 May 11. A proteomic study to identify soya allergens–the human response to transgenic versus non-transgenic soya samples. Batista R1, Martins I, Jeno P, Ricardo CP, Oliveira MM. <*Conclusion: Soybean endogenous allergen expression does not seem to be altered after genetic modification.*

Epidemiologic studies of glyphosate and non-cancer health outcomes: a review.Regul Toxicol Pharmacol. 2011 Nov;61(2):172-84. Mink PJ1, Mandel JS, Lundin JI, Sceurman BK. <*Our review found no evidence of a consistent pattern of positive associations indicating a causal relationship between any disease and exposure to glyphosate.*

A meta-analysis of the impacts of genetically modified crops. Klümper W, Qaim M PLoS One. 2014 Nov 3;9(11):e111629. <-*On average, GM technology adoption has reduced chemical pesticide use by 37%, increased crop yields by 22%, and increased farmer profits by 68%. Yield gains and pesticide reductions are larger for insect-resistant crops than for herbicide-tolerant crops. Yield and profit gains are higher in developing countries than in developed countries.*

Environmental impacts of genetically modified (gm) crop use 1996-2013: impacts on pesticide use and carbon emissions. Brookes G, Barfoot P.GM Crops Food. 2015 Mar 11:0<-*The technology has also facilitated important cuts in fuel use and tillage changes, resulting in a significant reduction in the release of greenhouse gas emissions from the GM cropping area. In 2013, this was equivalent to removing 12.4 million cars from the roads.*

US Food and Drug Administration. Report on the Food and Drug Administration's Review of the Safety of Recombinant Bovine Somatotropin. 4/23/2009. Accessed at http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm130321.htm on June 17, 2014.

Link to Columbia School of Journalism about the Serilini Paper here.
http://www.cjr.org/the_observatory/genetically_modified_corn_roun.php

This CJR attack on Seralini's embargo at the time of his report's release doesn't seem to consider the context of their statement that the Science Media Centre "quickly distributed a list of detailed comments." One wonders where these "detailed comments" came from -- comments that arose and were echoed around the world so immediately, given that they couldn't have been based on a full reading of Seralini's paper. This pattern is one Monsanto is on record as having done. The CJR doesn't mention that major funding for the SMC comes from BASF, Bayer, and Syngenta, all major GMO/pesticide players, and that, while the SMC had promised a pro- and anti-GMO scientist, they explicitly reneged on that promise. The flaws the CJR points out as having been

listed by the SMC are the same ones I've responded to above. The CJR quotes random bloggers using undetailed, unsubstantiated terms such as "flimsiest of evidence" and "no matter how tenuous--or dubious," and refers in an update to a European Food Safety Authority claim that the "design, reporting, and analysis of the study...are inadequate." This is the same EFSA whose principal scientist is notorious for making unsubstantiated claims for GMO safety and ignoring scientific evidence to the contrary while running roughshod over the sovereign wishes of European countries on GMO policy.

How the FDA evaluates GMO click here
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm352067.htm

Here's their section on Safety:

> Food and food ingredients derived from GE plants must adhere to the same safety requirements under the Federal Food, Drug, and Cosmetic (FD&C) Act that apply to food and food ingredients derived from traditionally bred plants.
>
> FDA encourages developers of GE plants to consult with the agency before marketing their products. Although the consultation is voluntary, Keefe says developers find it helpful in determining the steps necessary to ensure that food products made from their plants are safe and otherwise lawful.
>
> The developer produces a safety assessment, which includes the identification of distinguishing attributes of new genetic traits, whether any new material in food made from the GE plant could be toxic or allergenic when eaten, and a comparison of the levels of nutrients in the GE plant to traditionally bred plants.
>
> FDA scientists evaluate the safety assessment and also review relevant data and information that are publicly available in published scientific literature and the agency's own records.
>
> The consultation is complete only when FDA's team of scientists are satisfied with the developer's safety assessment and have no further questions regarding safety or other regulatory issues.

As mentioned above, Druker clearly points out why GE foods meet none of the FD&C Act requirements. Note that, among other things,

* consultation is only voluntary
* when studies are submitted, the data behind them are not necessarily provided and are not public
* the FDA does no independent studies itself, and
* (seemingly inconsistent with the final paragraph) in the end the FDA explicitly avoids making any claim as to the food's safety, only acknowledging that the company claims it is safe.

Simpson, to his credit, links to the document, but doesn't elaborate on these points.

Comments: This paper generated lots of comments – many of them not on point about the book itself. I have trimmed some comments off point, and most ad hominem comments. In summary – this book is about GMO and it is filled with assertions that are unproven, and does not add to the general discussion about GMO. I have supplied some references for the comments made in the book.

It would be interesting to see a list of Druker's "unproven" assertions. To take exception with Dr. Simpson: the book adds a tremendous amount to the general discussion, among other things:

* the regulatory-avoidance "shenanigans" surrounding the early history of GE
* a detailed understanding of the illegality of the GRAS assumption
* a detailed elucidation of the complexity of gene interaction, regulation, and position dependence
* the difference between computer programming and GMO studies in the evaluation of safety-critical processes
* a careful analysis of the relative risks of breeding versus rDNA GE (if one accepts the NAS report's approximations.

to mention just a few.

Dr. Terry Simpson received his undergraduate and graduate degrees from the University of Chicago where he spent several years in the Kovler Viral Oncology laboratories doing genetic engineering. He found he liked people more than petri dishes, and received his MD. Dr. Simpson, a renowned weight loss surgeon, is a leading advocate of culinary medicine. A frequent contributor to media outlets discussing health related topics and advances in medicine, he is also a proud dad, husband, author, cook, and surgeon “in that order.” For media inquiries, please visit www.terrysimpson.com.