

# THE ARBITERS OF RISK

## How 'Regulatory Science' Is Leading to a Biotech Nightmare

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*Not long before this interview was conducted, Denise Caruso published an opinion piece in the New York Times about biopharma crops, plants that have been genetically engineered to produce drugs and other chemicals. It told a short version of the story in her remarkable new book, *Intervention*, of business interests and their hired scientists on one side, suspicious citizens and a few independent scientists on the other, and in the middle, “our appointed arbiters of risk, the government regulators.” The story she tells is about risk, and the disasters that can flow from mistaken or cynical notions of risk. Right now, she owns this story. Good books and articles have been published in recent years about biotechnology, and there is always a juicy target like Monsanto deserving of frontal assault. Caruso is the first writer to slide a hand under the biotech scaffolding and give it a vigorous yank.*

*A longtime technology reporter for the New York Times, Caruso took an unusual route to arrive at *Intervention*, leaving journalism to start a research foundation. Along with the reading and interviewing that consumes anyone writing a investigative book, she broke new ground by assembling a panel to test a new kind of risk assessment, one that involved experts from a variety of disciplines. Instead of merely looking at experimental data to see whether the technology under consideration — the test case involved a cross-species organ transplant — was likely to cause direct harm, this panel explicitly considered how a scientific breakthrough can play out in the real world. Greed, human fallibility and Murphy’s Law, among other factors, were all on the table. It’s a vivid and compelling conclusion to a book that quietly, thoughtfully, and thoroughly demolishes the faulty assumptions about risk that allowed transgenic crops out of the laboratory and into the world before anyone understood what that meant.*

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### *Denise Caruso*

**ACRES U.S.A.** *Intervention* approaches the subject of genetically modified organisms, which you prefer to call transgenic plants or animals to distinguish them from old-fashioned genetic hybrids, from a fresh angle. It’s all about risk — how it is defined, how technological innovations are evaluated in terms of risk, and how the whole process might be improved. What is the pivotal question that drove you to write this book?

**DENISE CARUSO.** The issue here from the perspective of risk is that never before have we been able to insert the genes of completely distinct species into the genomes of other species and allow them to become basically hybrid organisms. The traditional

cross-breeding methods, which have been done by humans for many centuries, involve carefully selecting traits from one variety of plant. Using all kinds of interesting means, we figured out how to get those traits into other plants of the same species. But biotechnology gives us the ability to move soil bacteria into the genomes of corn, for example, and that’s never been done before. One of the things that I have found to be disingenuous about the risk rhetoric around transgenic crops is the idea that this is just a continuation of what humans have done since the beginning of time, since we domesticated plants. It’s actually not true. There is no way to create transgenic plants except

forcefully and invasively. There's no natural way to do that.

**ACRES U.S.A.** It's often suggested that the biotechnologists are using the entire planet as a laboratory for a huge experiment. Now, the standard regulation laboratory experiment always has a control set in which conditions are unaltered, or with medicines a placebo group where one group is given a sugar pill. After a period of time, you compare the results. But there's really no control group here, is there?

**CARUSO.** No. There's no control.

**ACRES U.S.A.** It's fanciful to even imagine a control. For instance, if you could find a group of people who ate only organic food and just lived on an island somewhere, and were carefully isolated from any kind of biotech food, then you might call them a placebo group.

**CARUSO.** And then there are so many other variables in terms of their diets, you need to have the control group in the place where the crops are growing. And there's not even control from the perspective of the crops themselves. I'm not operating under any great hope that even organic crops have not been contaminated to some degree with transgenes. We may just not be able to avoid contamination, and the stuff is pretty hard to measure, too. The tests are expensive.

**ACRES U.S.A.** Did the original researchers undertake this project without really understanding the mechanisms of what they were monkeying with? Are the functions of a genome really that well understood? A lot of people have the impression that it's just a bunch of switches and we know how it works.

**"Genes don't work discretely . . . They work in networks, and we don't actually know what else we're affecting when we take one out and put another one in."**

**CARUSO.** *We don't have any idea how it works.* Certainly one thing that struck me as remarkable was seeing how the risk regulations comprise a snapshot of what industry scientists told the regulators 30 years ago about how genetic mechanisms work. It wasn't true then either, and there were people then who said we don't actually know enough about how genomes work and how genetics work to be able to say that this isn't without

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risk. As I point out in the book, people inside the FDA said that at the time. When we started, when recombinant DNA was invented and shortly after Watson and Crick were able to describe the helical structure of DNA, the prevailing thought was that it looked like genes were discrete on/off switches the way you described them. There's one that controls this and there's another one that controls that and you knock one out, you put another one in, and presto changeo, you're able to eliminate disease and make things grow better and all kinds of stuff. But it really didn't take very long before people became aware that genes don't work discretely, even though we still don't know very much about it. They work in networks, and we don't actually know what else we're affecting when we take one out and put another one in. No one was hiding that science — it was published in all the major journals such as *Science* and *Nature*. But no one ever said, "Well, do you think we might want to revisit the risk regulations that we made up based on thinking that these things were discrete?" That question was never asked. It's a real puzzler

to me actually. I don't understand how someone could not have said, "Wait a minute, what might we be doing here if our first assumptions were not true?"

**ACRES U.S.A.** At the same time the biotech industry, usually without lying directly about it, has floated the myth that we are in control of this process, that genes are well understood and we know exactly what we are doing.

**CARUSO.** They don't have to lie. All they have to do is select the evidence that they want to use. Selective evidence has been the bane of this whole issue — the evidence that is presented to the regulators is the evidence that the industry chooses. It's their data that gets evaluated, and it's not until after the risk evaluation is complete that the public actually gets to comment on it. So there's no one far enough back in the process who can say, "You haven't thought of this whole entire realm of genetics called evolutionary biology." There are many disciplines and a lot of evidence that doesn't get included early enough in the process to be considered as part of these risks.

**ACRES U.S.A.** Back when the transgenic ball got rolling, how did they define risk?

**CARUSO.** The same way that scientists generally define risk — it's the crux of the issue. Scientists look at evidence, they conduct an experiment or they design an experiment, and if the results of the experiment don't reveal the mechanism by which some harm can occur, a hazard, then as far as they are concerned, there is no hazard. But risk is about uncertainty, and no matter how well intentioned these experiments may be, it's sort of like they're wearing a spelunker cap and they're illuminating a circle on the wall of a cave. They're saying, "Within this circle, we see no mechanisms for hazard, for risk. Ergo there is no risk." But the

tricky thing here is to make sure that you have enough spelunker caps in that cave looking around to see what else might be there, what other mechanisms might be involved. You have to accept — especially with a brand-new technology — that just because you don't see a hazard now, nothing is going to come up. The whole history of scientific inquiry shows that it will. There are ways to look for those things and prepare yourself for them without stopping scientific progress, and none of them were done. As my friend at Carnegie Mellon says, these assessments are done to prove that there's no harm; they're very focused. That's why there are people who have titles like "Vice President of Regulatory Science." Well, what is regulatory science? How is regulatory science any different from any other kind of science?

**ACRES U.S.A.** How *is* it different from regular science?

**CARUSO.** Regulatory science is designed to get your product past regulators. Clearly. It's kind of a dance they do that I think is probably done with the best of intentions. I can't impugn anybody's intentions — but certainly it does not meet the standards I would like to see in that risk assessment, and they certainly don't use the methods that I found — I didn't make them up — that really smart risk people over the past several decades have been using to figure out how you do these kind of assessments. They've done virtually none of that.

**ACRES U.S.A.** Your book didn't mention the British scientist Arpad Pusztai, whose experiments with potatoes produced alarming results and who ran into severe career trouble as result.

**CARUSO.** I cited some of his research in the book, but no, I didn't bring up the case. Maybe it would have made the book juicier, but I didn't need to use any of those really controversial cases. There was plenty of evidence without it. After the whole thing happened with the potatoes, they went back and did a review of the literature to see how many actual food studies there had been testing the safety of transgenic food, preferably on humans, but even on any kind of living

creature. The most shocking thing to me was that most of these "safety" tests, as they tested how these foods are broken down or not broken down, were done in beakers using simulated stomach acid and pure DNA, not as it is digested in a body. It's long been an assertion of regulators in the biotech industry that DNA doesn't survive digestion — based on swirling the stuff around in a beaker of *simulated* stomach acid. I cite lots of studies in the book that show this is actually not true.

**ACRES U.S.A.** What happened in Argentina, and what does Argentina tell us about how things happen outside the beaker and the laboratory?

**"Selective evidence has been the bane of this whole issue — the evidence that is presented to the regulators is the evidence that the industry chooses."**

**CARUSO.** I didn't go to Argentina, as much as I would have liked to, so I had to rely on a lot of research and reporting from other people. I think that there are two important aspects to the Argentina situation, wholly aside from the issue of whether transgenics are risky or not risky. Argentina is a classic example of what happens if you don't think about the social system in which you place a radical technology. What happened in Argentina is that soy was a way for them to make a ton of money fast. Everybody who could manage to do so stopped grazing cattle or growing other crops. Everybody planted soy, and everybody was making a ton of money from it. But they monocultured the land and, based on the research that I read, they have destroyed, or are in the process of destroying, the fertility of that fabulous soil down there. Plus, the transgenic soy they've been planting is now becoming resistant to the weed killer, so they have to apply more and more weed killer, and that's harder and harder on the soil. It's a cascading problem. And the government didn't stop it. Monsanto didn't stop it. Nobody advised these people that maybe it's not such a great idea to go whole hog into planting one kind of crop.

**ACRES U.S.A.** If there had been an intervening step in place, how would the risk assessment have been done to prevent this cascading fiasco?

**CARUSO.** You never know whether you're going to be able to prevent a fiasco, but you can certainly walk into a situation with your eyes far more open. In that situation it's a matter of who you would have invited into the conversation, who might have knowledge about consequences, short- and long-term consequences. You would have wanted to hear from people who understood soil chemistry, and what would happen with this intensive application of glyphosate on all of this land, because

they were dousing fertile soil with a chemical — and they needed people who understood about monoculture and people who understood certain economics of what might happen in the areas where these crops were being grown, and how it would affect the food supply of the Argentinians. People don't really eat soy there. They ended up exporting all of the soy as feed for cattle or other animals outside of Argentina, and their people started going hungry. So it's a matter of looking not just at the science, not just at the potential consequences in terms of science, but also looking at the potential impact on the people who are going to be using the technology. Argentina ends up being a classic example of what can go awry. Another one that we know well in the United States is what happens when you don't consider human factors in things such as nuclear power plants. If somebody falls asleep at the switch and doesn't notice that the meter is in the red or somebody forgets to change the battery in a box, suddenly you have a meltdown — it doesn't matter how much you know or think you know about the science of nuclear energy generation.

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## INTERVIEW

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**ACRES U.S.A.** Do the guys and gals wearing the spelunker helmets tend to ignore the role of accident and chance and human fallibility?

**CARUSO.** It's kind of a funny thing, because by virtue of what they do, they *have to* ignore it. Science is about reductionism, right? I mean, in order to create a successful experiment you have to draw the parameters around what you're going to measure, and you have to be very clear about it. You have to make assumptions, but you also have to

**ACRES U.S.A.** Have we allowed industry to manipulate the normal tendency of scientists to work within careful, narrow parameters?

**CARUSO.** I don't know that we've allowed them to manipulate it so much as that we've allowed them to take advantage of natural inclination. You could probably make a case for manipulation and someday maybe I will. I come pretty close to saying it in the book. There are ways of taking advantage of science and scientific evidence that make it sound

evolution and prompts genetic change is stress, environmental stress. That's well proven. What if this stuff gets out there? We don't really know.

**ACRES U.S.A.** Is someone working on that, on climate change and biotechnology?

**CARUSO.** Not that I know of. I hear some people are looking into transgenics and the disappearing honeybee situation. I'm trying to find out a little bit more about that.

**ACRES U.S.A.** But also there ought to be some kind of group working on the climate change and transgenics.

**CARUSO.** But here's the problem — it's widely accepted that there is no risk.

**ACRES U.S.A.** Right. Which takes us back to square one.

**CARUSO.** I mean, look around you now. Even though the majority of people in the United States oppose transgenic food, they don't even know they're eating it, and they're always shocked when they find out how much of their food has transgenics in it. There has been a very effective public relations campaign to keep this quiet. It's not public relations with the consumers as much as public relations with the media and with the scientists. Nobody stands up and says, "What are you doing?" That column that I wrote for the *Times* a couple weeks ago about biopharma crops — nobody knew this stuff. People were shocked, terrified, completely nonplussed by the whole thing, like they had no idea this was going on. I found that surprising, of course, because I've had my snout buried in this stuff for the last four years.

### "The way we've built our risk regulations is that we've allowed scientists to take small-t truth and extrapolate capital-T truth from it."

be clear about your assumptions. The thing that I see lacking in how we do risk assessments for innovative technologies in most places around the world is that somebody needs to take the step back and look at that evidence in the larger context of what we don't know. I hate to say it because it was so roundly trashed when Donald Rumsfeld said it, but that remark about the known knowns and the known unknowns — that's actually a real thing. He didn't make that up. This is something that the people who conducted these risk studies kept trying to tell the agencies, not just about transgenics, but about lots of different things — don't ignore the things that you know you don't know. They're important. My metaphor for it at one point was steering into the skid. It is counterintuitive for a scientist to focus on uncertainty because everything they want and strive for in their life is certainty. They want to understand. They want to know. They want data. They want to be able to repeat the data and then they feel, OK, I've got a little piece of truth here. But it's truth with a small t, not a capital T. What ends up happening, and the way we've built our risk regulations is that we've allowed scientists to take small-t truth and extrapolate capital-T truth from it — "We know this, ergo we know how the universe works." But they don't.

like you've really done your homework and you've really crossed all your t's and dotted all your i's and here's the deal, here's our data. You'll have a 2-foot high stack of basically meaningless statistics that may or may not have anything to do with whether or not this substance, this living thing planted out in nature, in five years or so is going to produce effects that we probably could have anticipated if we had been willing to look beyond that data.

**ACRES U.S.A.** Are you worried that there's going to be like a serious event, something awful that will make everybody sit bolt upright?

**CARUSO.** I think it's possible. I certainly think it's possible, and one of the reasons that I think so relates to one of the things that no one has considered: the effect of climate change on transgenic crops — whether you're getting drought

### "There could not be anything less precise than genetic engineering the way they do it. "

or you're getting flood, or you're getting more fungus or whatever . . . come up with your favorite climate change effect. One of the things that prompts

**ACRES U.S.A.** Does that kind of response typify the feedback you're getting as you go around talking about your book?

**CARUSO.** Yes. Totally. They have no idea. “What are we going to do?”

**ACRES U.S.A.** Does the success they’ve had in persuading the news media to self-censor this story explain why the European response to transgenic crops was so different?

**CARUSO.** I think that has a lot to do with it. But I don’t think that a lot of journalists have the luxury that I had. I did not take this on as a journalist; I left journalism and started this research institute. What happened for me when I started looking into this issue was that I realized I was taking it on the great authority of the scientists who insist that transgenics are safe. I kept asking them, “On what are you basing that perspective? Why do you say it is safe?” “Well, because nothing has happened,” was the answer. Well, let me think about all the times we’ve said that.

**ACRES U.S.A.** That was really their answer?

**CARUSO.** That was one of their answers. The other answer, the more scientific answer, was that there’s no science-based evidence for risk. I kept asking, “Whose science? What science? Show me the science.” That’s what started me off on this path, because I started to deconstruct these little vignettes of science that I was getting and realized that it was built on a house of cards in terms of science-based evidence. What have you looked at? What is the evidence you’ve looked at? What about this experiment? What about the fact that before the human genome was sequenced you guys all thought that we had millions of genes, one for every trait? And you were really surprised and humbled and awestruck by the fact that we shared about 95 percent of our genes with mice. Well, that’s great. I’m happy that you’re humbled by that. What that means to me is that you don’t have any idea what you’ve been doing for the last N-number of years, thinking that one sequence of DNA controlled one trait. So whose evidence are you looking at, and are you using the evidence that’s available to assess the risks of commercial products?

## “Even though the majority of people in the United States oppose transgenic food, they don’t even know they’re eating it, and they’re always shocked when they find out how much of their food has transgenics in it.”

**ACRES U.S.A.** What was your learning experience like as you wrote this book?

**CARUSO.** It was the most painful thing I have ever done in my life. I had to go back to first principles on everything. If you look at the source material for the book, you’ll see I didn’t read very many people’s books on this stuff. I went to the journals, which means I had to teach myself biology, I had to teach myself genetics, I had to teach myself probability theory and risk and statistics, and I questioned everything. It took me three and a half years to write *Intervention* because every time I wrote something I would think, well, how do I know that, or how do they know that? Then I’d scrape a little bit more, and then I’d find more, and then I’d go to the biotechnology industry organizations’ websites and look at the propaganda — and I use the term advisedly — where they still make these pronouncements about this being the most precise process imaginable. There could not be anything less precise than genetic engineering the way they do it.

**ACRES U.S.A.** Can you describe it for us?

**CARUSO.** You imagine somebody with little teeny tweezers, right? Little teeny-weeny tweezers and you take this little segment of DNA out and you splice something else in. Oh, no! You’re loading up a bunch of cells with a bunch of bacteria that have been defanged and are invading the nuclei of all these cells and depositing a bunch of foreign DNA all over the genome. You try to put stuff that will land your active trait where you want it to be in the genome, but it doesn’t happen. It only happens once in every however many attempts, and then

that’s the one they save. It worked in this one — let’s reproduce this one!

**ACRES U.S.A.** It reminds me a lot of dumping some really old red wine into the vat of marinara sauce. What the heck, it’s going to simmer off anyway.

**CARUSO.** Well, I wish it were that safe.

**ACRES U.S.A.** One of the things you found in your scraping was the *Daubert v. Merrill-DOW Pharmaceuticals* lawsuit, which resulted in a Supreme Court decision. You write that it “started as a well-intentioned attempt to keep ‘junk science’ from being admissible evidence in the courtroom” but ended up being “widely used to keep juries from hearing scientific evidence in product liability and personal injury cases.” The Supreme Court said that valid science had to derive from a reliable methodology that produces testable results which have been published in a peer-reviewed journal. On its face, this sounds reasonable. What is the importance of that case?

**CARUSO.** To me, the importance of *Daubert* had a lot to do with what a court of law will accept as scientific evidence. That’s important because if it comes to someone saying, “We have declared these things to be safe based on acceptable scientific principles of provocation and blah, blah, blah,” what that doesn’t take into account is that science is really a very social practice. It is governed by social norms, and there are people who are offended and people who can’t get their points of view heard. There are many different reasons that people publish or fail to publish articles in journals — and editors will or won’t let certain points of view be published. I don’t think people paid enough attention to *Daubert*. These

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things aren’t being challenged in courts of law, but they may be in the future if we start seeing events that can be traced back to genetic contamination.

**ACRES U.S.A.** The courts are where we work these things out.

**CARUSO.** Right. I talked to the guy who wrote this wonderful paper called something like “Give me two lines in a Supreme Court decision and I’ll change the face of science.” He’s a great guy — David Caudill at Washington & Lee University. He’s a social scientist, and he said that the problem is that the way they talked about science in the decision is an *idealized* version of science. It doesn’t take into account that it’s politics and not just literature, that it’s a socially embedded enterprise. What he and people who were arguing against *Daubert* when it happened were trying to say is that you can’t make determinations about what is acceptable in science if you don’t include in that conversation that the experiments themselves are influenced by funding and who funds what. Unless you talk about those things, you are misrepresenting the very same science-based evidence because it gives false impression of completely impartial science.

**ACRES U.S.A.** Another thing in your book that seemed like an important document that didn’t make the front pages — probably because there was such a heavy layer of verbiage underneath the important stuff — was the 2004 National Academy study on biocontainment. It painted a bleak picture of our prospects of isolating transgenic material should we ever decide that is an important task.

**CARUSO.** It’s such a nightmare, but see, here’s the thing. When you have transgenic plants and animals embedded in a system — and our culture has already deemed them to be safe — having a conversation about biocontainment doesn’t get taken seriously. The people who participate in the study certainly bloody well take it seriously. The people who understand what is at stake take it seriously. But when you try to move that perspective out into the public, and you’re operating in an environment where there are lots of well-funded people who are trying to make sure that the public, whoever that is, doesn’t question the safety of these products, then you’re going to run into a wall of apathy. The conversation about containment becomes theoretical when you don’t believe that there’s any risk to transgenic plants or animals.

The dialogue is restricted to “if something bad goes wrong,” not that maybe there’s something *inherently* unstable or unknown or uncertain that could turn on you later. After you’ve not paid any attention to this and the technology becomes established, then the organisms will be far beyond our ability to even find them again, let alone contain them.

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