Thinking across Time: A 20-Year Perspective on Biotech Policy

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Memorial Day weekend, I was in search of patio furniture and stopped at the Plow and Hearth moving sale. I bought a metal sign for my patio wall that is a reproduction of an old seed packet: "Reeds Flower Seeds, To Plant a Garden is to Believe in the Future." Love it. I brought it to the register for purchase, and the college-age kid behind the counter said "Yeah, love the fake vintage sign, kind of like how Monsanto tries to sell GMOs." What? In these moments, I don't know whether to laugh or cry. This is just the latest example in which I encounter people of all shapes and sizes with strongly held but poorly informed positions on agricultural biotechnology (ag-biotech). After working on biotechnology policy for 28 years, I am still surprised by the public's reaction to the technology, and I am mostly discouraged.

How did we get here—this place of nonsensical debate over a technology that has left many Americans and others across the globe in opposition to it, despite the technology's promise to contribute significantly to solving some of the world's pressing problems? Of course, I have a thesis: the biotechnology industry did this to itself, a sort of self-inflicted wound. I readily admit that I base my thesis largely on my own experiences; I do not have peer-reviewed data to share, nor have I written an academic book on the topic. But over many years, I have had a front-row seat at many critical ag-biotech policy discussions. What I'd like to do this morning is share a very small sample of those critical moments. I ask that you suspend your own beliefs and try to see the world as I've experienced it.

I will conclude this morning with a brief discussion of a current policy controversy: the effort to achieve what has become known as "peaceful coexistence," the goal of which is finding a way forward so as to allow farmers growing various kinds of identity-preserved crops to coexist without compromising one another's livelihood through unintended

commingling of genetic material. Specifically, I will suggest that the potential re-write of ag-biotech regulations by the Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture provides a pivotal opportunity for industry to alter its historic opposition to stringent regulation and join forces with non-biotech farmers and environmentalists, and in doing so, radically change the policy environment, mend old wounds, and rebuild trust in the technology.

Entering the Ag-Biotech Arena

I beg patience from my many old friends in the crowd, because I begin with a very brief history of my involvement with ag-biotech policy for those who do not know me. I hate to take time with a résumé recitation, but I feel it necessary because if you Google me, or if you talk with certain industry leaders, many of whom have never met me—you would likely be left with the impression that I'm an anti-biotech activist or at least someone who holds views harmful to the industry. I disagree with this characterization.

In the spring of 1987, I came to Washington straight from graduate school. Political strategist John Podesta hired me to work for Senator Patrick Leahy of Vermont. Leahy was the new chair of the Senate Committee on Agriculture, Nutrition and Forestry as well as chair of the Judiciary Committee Subcommittee on Technology and the Law. Because of these committee assignments and the Senator's interest in the emerging biotech sector—note this was just months after the birth of the Coordinated Framework for the Regulation of Biotechnology—it was determined that he needed a staff member to work full time on ag-biotech and help nurture the industry. I was that person. I got to work right away, and I helped organize a hearing on opportunities for the biotech industry and met most of the first wave of entrepreneurs setting up companies—names that are now legendary. I remember one of the first articles I helped write for Senator Leahy was a piece in the December 1987 issue of *Biotechnology* arguing that the government should make greater research investment in this sector. All was good initially.

Then the regulatory review of synthetic bovine growth hormone (BST) became an explosive issue, and I found myself center stage. An FDA staffer who was initially in charge of the BST review at FDA had become a whistle-blower, and he came to my office claiming that the agency had mishandled the scientific review. Because Senator Leahy's home state of Vermont was in an uproar about BST—it's a big dairy state as well as a big organic and sustainable agriculture state—and because of the Senator's leadership position, I found myself as the unfortunate point person in Congress, leading the congressional aspects of an investigation to ascertain whether the FDA review was adequate. As I interviewed people, reviewed documents, and requested the help of the Government Accountability Office, one problem kept emerging, and it was one that I found exceedingly difficult to overcome. That problem was finding scientists with adequate scientific credentials and expertise who had not, at one point or another in their career, been on the payroll of one of the four companies then developing BST. If a scientist had received compensation from industry, even if it was many years past, she/he did not have the necessary credibility with the public. You and I could argue that was unfair, but nevertheless, that was the reality.

The allegation that milk from BST-treated cows was unsafe was very unsettling, especially given the importance of milk in the diets of young children. And as a 28-year-old staffer, I had a great deal of authority in the BST review (remember this when you visit those young staffers on the Hill!). I had many sleepless nights worrying whether I was making the right call. Eventually, as you know, the FDA approval was upheld. But I learned a very important lesson from this experience that has informed my policy work ever since: for ag-biotech to succeed, our government must provide funding to support a cadre of independent scientific experts with no ties to industry. This is essential to establish and maintain public trust.

Risk Assessment Research

I turned this lesson into what I believe today was a big win, and that was the Biotechnology Risk Assessment Research Program that was included in the 1990 Farm Bill. This program established a competitive grants program to support the generation of new information to assist federal regulatory agencies in making science-based decisions about the effects of introducing into the environment genetically engineered organisms. For example, it has funded some of the research related to the impact of certain genetically engineered crops on the monarch butterfly population, which has been a focal point of public concern. When the program began, the statutory requirement was that 1% of whatever USDA spent on biotechnology research be devoted to risk assessment research. In other words, if NIFA and ARS combined spent $100 million on various kinds of ag-biotech research, $1 million would necessarily be spent on risk assessment research under this new program. In later years, this was raised to 3%. In 2015, $4 million will be spent through this program.

But people still don't appreciate the importance of this sort of research expenditure and see it as an implicit criticism of the industry. Let me share an example that illustrates this sentiment. In 2003 I was a new assistant professor at Tufts University running a master's/Ph.D. program called Agriculture, Food and the Environment. My first task was to organize an ag-biotech meeting on nutritional aspects, challenges, and opportunities presented by the technology. I raised the funding for the symposium and organized the speakers. I was getting a little pat on the head by my dean and was really quite proud of my achievement. But when I gave my presentation at the symposium, titled "Resolving Uncertainty through Government-Sponsored Research," I was stunned by the response. In it, I discussed the Biotechnology Risk Assessment Research Program and argued that, given the growing complexity of the products of ag-biotech, there was a need for greater public investment in risk assessment research than this mighty, but little, program could provide. To support my argument, I referenced articles in *Science* and research by the Royal Society of Canada as well as US government reports. I was very excited that a famous scientist had come to my conference and was sitting in the front row as I gave my presentation. I had admired him and the work he did from afar for many years. I won't say his name, but you all know of him. At the end of my presentation, he stood up and pointed a finger at me and said "It's people like you that cause 10,000 people a day to die of starvation." What? There I was, an assistant professor in the first six months of my

dream job, and I had put together this really big conference, initiated a very reasonable scientific discussion on identifying the gap in public sector funding, and that was how I was received! I learned that debate is not welcome. Disagreement, even reasonable questioning, is labeled as anti-biotech. This situation is unhealthy, and it is unnecessarily divisive.

Research on Resistance

I wrote an article in 1995, "Herbicide-Tolerant Plants: A Case of Science Gone Astray." It was published in the *Health and Environmental Digest*. The journal no longer exists, but the article still haunts me in my career. There was a lot of commentary on it when I was nominated to be the deputy secretary of agriculture in 2009. So what did this very controversial article say that somehow is the evidence that I'm a biotech hater? Did it say that ag-biotech should be abandoned or is evil? No, it simply laid out the case that without adequate regulation, we would likely encounter herbicide resistance and that we needed to require things like set aside or refuge acreage of non-GMO crops to slow down the likely resistance problems that would be encountered. Fast-forward 15 years, and where are we today?

I know resistance management is a topic for detailed discussion at our conference. It is widely acknowledged as a problem today, and much of what I wrote about in 1995 has become reality. I don't raise this as an "I told you so." I am saddened by the impact resistance has had on farmers and strongly believe that if the problem had been honestly confronted years ago, farmers would be in a better place today, and the ag-biotech industry would not be under such attack. Gary asked a critical question in his introduction: How do we sustain these technologies? Clearly, I am a policy scientist and don't work in a lab. Yet I have often found myself voicing the concerns of bench scientists afraid of saying anything critical about biotech. When writing this article in 1995, I spoke to countless scientists who were concerned about resistance but who did not want to be identified because they believed it would be detrimental to their careers. They were afraid of being labeled as anti-biotech. So, here is the key lesson I learned from this experience. People often argue that the anti-biotech crowd is anti-science, and in some cases that is certainly the case. But in the case of resistance management, I can say that many ag-biotech leaders were anti-science. My questioning the lack of resistance management strategies was based on science, and we would have all been better off if such questioning had been received as legitimate inquiry worthy of discussion.

One more thought on this: It is so important that we increase funding for agricultural research, and given that many of the people here are from the university sector, I'm probably not going to get a lot of disagreement in this room. I am currently co-chair of AGree, a group that launched in 2011 and is funded by some major foundations. It aims to build consensus about how to move forward in food and agricultural policy. The other co-chairs are Dan Glickman, former secretary of agriculture; Jim Mosley, former deputy secretary under President Bush; and Emmy Simmons, who was the assistant administrator at USAID under President Bush. We are bipartisan, and one of our core issues is trying to move policy makers on Capitol Hill toward greater investment in agricultural research. However, it is not just about more money, but also about how we allocate the

money. I'm hoping we prevail in our quest for more research funding and that, among other things, increased research support can be devoted to coming up with strategies to improve our risk assessment efforts.

GMO Labeling

Our second area of discussion today is labeling in trade markets. Let me begin by being clear on my position—first and foremost, I am a big advocate of transparency. The unwillingness of the industry to label for biotech has fueled the public's concern that there is something to hide. My gut tells me that if companies had chosen to label product years ago, consumers would have largely accepted biotech by now—in other words, by failing to embrace transparency the industry has itself to blame for creating this labeling storm of public criticism, referenda, and protest. That said, I have never been a supporter of mandatory GMO labeling because of the costs and complexity and because I think about food labeling in a way that has three categories: "right to know," "need to know," and "want to know."

Here again, my current-day thinking on labeling has been informed by history. Back when we were doing the organic rule-making in the late 1990s, the USDA Agricultural Marketing Service (AMS) was responsible for writing the hundreds of pages of rules that detail production and processing standards and an accreditation program to support enforcement. Interestingly, when publishing the first proposed organic rule in 1997, USDA did not include a prohibition on biotech. Why? Well, I suppose part of the reason was because of me. In writing the Organic Foods Production Act of 1990, I did not include an outright prohibition on biotech, even though the majority of existing private and state organic standards in the country at that time included such a prohibition. Yet in writing the organic law, which I hoped would stand the test of time, I wanted to leave the door open on biotech, anticipating that someday there would be an application that would be compatible with organic and helpful to the organic industry.

But the public reaction to the proposed rule was swift and powerful—a total of 275,603 public comments were received by USDA, and nearly all of them said organic should not include biotech, including my own. By the time the second proposed rule was issued (and by this time I was the AMS administrator overseeing that rule development), we put in a clear GMO prohibition. Monsanto was among the different entities that supported that GMO prohibition. The company submitted some of the most interesting and insightful commentary and stated that it was going to be very important in the marketplace to have GMO-free food products for people who wanted such products and that maintaining organic as GMO-free gave consumers that option. Fast-forward several years to the Obama administration. Because of increasing interest among consumers in non-GMO food products, several companies and certification schemes began popping up to address this market demand. Perhaps the best-known example of this is the Non-GMO Project, a private certification program. Because consumers were looking for a non-GMO label, several organic companies went to USDA and tried to get approval for a non-GMO label claim on meat and poultry products, and USDA refused to accommodate them. Officials from the Food Safety Inspection Service (FSIS) actually said to me, "How would we know if it's really not-GMO?" My answer was to suggest they walk down the hall and discuss

this concern with their colleagues at AMS, the agency that regulates the organic label. In the end, FSIS approved meat and poultry to carry the Non-GMO Project seal, but would not allow organic producers to make a similar claim. This battle continues today. Former secretary of agriculture Dan Glickman and I wrote an op-ed on this topic that ran in the *LA Times* in December 2013. It seems to me that some of the FSIS opposition must have been generated by industry, and in the end, rather than building up the organic label as the alternative in the marketplace for people concerned about GMOs, we have instead created a multitude of labels in this area and pending state law.

So where are we now? A new effort was announced this past week by my colleagues at USDA to use a process-verified program as a way to address the public interest in having a non-GMO label. I used to run the process-verified program. In it, industry members propose their standards and pay a fee to the AMS, which then verifies that they are following their own protocol and provides them with a USDA process-verified label. But that means that Greg Jaffe can come in with his standards, Neil Hoffman can come in as another company with another set of standards, then Ralph Hardy could come in as a third company with his standards, and as long as AMS can verify their processes and they pay the fee, everything is fine. I don't see how this new announcement gets us out of the labeling pickle the industry finds itself in. Bottom line—the history lesson here is that the push-back on labeling by industry has always been doomed at some level, and the greatest opportunity to elevate organic as a pathway forward was bypassed.

Coexistence

Lastly, let me turn to coexistence, the big topic on your agenda today. Currently organic and non-GMO crop farmers are losing income, customers, and seed purity when their crops test positive for small amounts of GMO because pollen is drifting from neighboring farms. Even within the universe of GMO-crop farmers, conflict is roiling. Lack of adequate regulatory safeguards has resulted in GMO crops commingling, leaving farmers vulnerable to contamination from neighbors who plant different kinds of GMO crops.

The last thing this country needs to do is to pit farmer against farmer. But I believe that America's failure to adequately regulate biotech crops has done just that. And the divisiveness on the topic of GMO crops is threatening more than crop purity in the country. The average age of American farmers is 59. We need to convince young people that agriculture is a career worth embracing. It is tough grappling with the daunting cost of land and basic farm machinery and with working long hours, all while starting families. Our young farmers depend upon companionship and support from their communities, which Wendell Berry has defined as "the mental and spiritual condition of knowing that a space is shared." That sense of shared space is threatened by the GMO crop battles, and USDA must do all it can to stop it.

With the controversy over the potential deregulation of Roundup Ready alfalfa and issuance of a draft Environmental Impact Statement in late 2009, Secretary Vilsack asked me to conduct a behind-the-scenes process at USDA to identify coexistence strategies. An internal USDA team worked with me tirelessly for many months. After we delivered our work product to the Secretary, which provided numerous potential actions, including

some identified late in President Bush's term of office but which were not pursued for one reason or another, the Secretary decided that the best way forward was to appoint a coexistence citizen advisory committee. This coexistence committee assembled warring farmers, advocates, and corporate leaders in a series of meetings to identify voluntary actions that could be taken to limit pollen drift, such as establishing buffers around GMO crops and adjusting planting times.

Everyone loves market-driven voluntary solutions such as those identified by the coexistence advisory committee and embraced by USDA because they are politically easy. But from where I sit, the obvious and lasting solution is to update our biotech regulations. Fourteen years ago, Congress recognized the need for updated authority, given advances in the science, and it passed the Plant Protection Act of 2000. In this law Congress grants USDA authority to regulate noxious weeds, defined as any plants or plant parts that directly or indirectly cause damage to the interests of agriculture. That is a broad definition and therefore a broad delegation of authority by Congress to the USDA. It is time for USDA to act on the statutory authority it was given long ago and issue fair and transparent regulations to allow all farmers to prosper. I keep waiting for full-fledged discussion of Part 340, an insider reference to the portion of APHIS biotech regulations that would be updated, if USDA chose to act. Last year USDA asked the public for ideas on how to facilitate peaceful coexistence between farmers in an era of GMO crop production. It feels like we are on a treadmill, going nowhere. The time is past for advisory committees, and general public inquiries through the Federal Register. Rather, it is time for everyone to come together and pound out a regulation that protects the ag-biotech industry and all those seeking non-GMO products.

Conclusion

Will we ever be able to discuss ag-biotech in a less contentious environment? I hope so. In the meantime, I am going to continue to straddle the debate, which is not always comfortable, no matter how necessary.

From where I stand, and with the long view of 28 years of working in this domain, there is no organization that has been as important as NABC. I am really deeply grateful to this organization. NABC has been one of the few places, if not the only place, that has consistently considered other views and created a safe space for important discussions, building bridges between various factions in the biotechnology debate. I have been part of consensus-building dialogs on biotech over the years, including a couple in the 80's and 90's led by the Keystone Center. I was part of the Pew Ag Biotech Initiative in the early 2000s. These were short-term efforts and really were stakeholder rather than research driven. The staying power of NABC is impressive. With your continued thought leadership, the ag-biotech industry may someday live up to its promise.

Speaker Profile: http://provost.gwu.edu/dr-kathleen-merrigan

Q&A

R. Connelly, Penn State: I really appreciate your insights and your historical perspectives, but I think I'm confused even more now about the labeling issue. Who will actually benefit from labeling?

Merrigan: I think that depends on what kind of labeling we are talking about, and there are many ways to answer that question. One of the interesting things in the Organic Foods Production Act of 1990 is that we included in that law a state preemption, which added a level of difficulty. At the time the industry was facing very serious interstate commerce challenges because the growth of the organic sector had now gotten to the point where there were processed foods being produced, as opposed to just fruits and vegetables. Many of these processers were obtaining ingredients from various states, and there were 43 state and private standards in the country at the time. It was really tough to think about what it would mean for all of those entities, some of them states like Washington and Texas, to give up their own standards and their own rules of production. We succeeded with our arguments, and that is the interesting part of what is going on in the labeling battle now. If there is going to be mandatory labeling—which is not anything I support—will it be accompanied by state preemption, or will there be one labeling rule of the land?

My critique on "process-verified" is that while it sounds great, you are probably just giving birth to a whole other generation of labels that will confuse the marketplace even more. So it sounds like a really cool idea, but I don't think it works. I think labeling is a small issue. I wanted to say something about trade and markets because of our agenda, but of all the things I've said, the most important one, the one that holds the greatest promise to move us forward in this very thorny debate, is really tackling regulation. In my mind, that is the sleeper issue with the greatest potential.

T. Harding, Lehigh Valley Organic Growers: Kathleen, it is always nice to agree with you. I totally agree that labeling is the wrong direction, but I would like you to expand on the issue. As we look at coexistence and now resistance on the table, how do we move from market failure to a regulation that is fair and balanced? Does that mean tolerances?

Merrigan: I think among the solutions that those of us inside the beast were working on regarding coexistence, there were very few that didn't ultimately lead to some sort of thresholds. Those are complicated discussions, and there are a lot of political maneuvering and nuances that need to be a part of that discussion, because there is a lot of suspicion. What could in some ways be an easy issue is a challenge because we are in an environment where you are either pro- or anti-biotech. There is no place for the people in-between. That is the whole point of my talk.

M. Smith, Cornell University: First, thank you for both your work and your comments. I really appreciated them. I'd like to make sure I understand clearly your comment about coexistence and organic farmers losing money. My understanding of the organic standard

was that it does require that you use a variety that is not genetically engineered and that you take reasonable measures to avoid pollen contamination. It does not have a level that says, if you find this much in your crop you lose it. I get the idea of public perception and the importance of the perception that there might have been cross-pollination and contamination, but are there actually examples of organic farmers who have not been able to market their crops as organic because of this?

Merrigan: Absolutely. This has been part of the deliberations of the coexistence advisory committee appointed by Secretary Vilsack and myself. I take responsibility and some pride in those appointments. There was a lot of suspicion of the committee members. Much concern was expressed that this was a hyped-up issue and that they wanted a lot of data and declarations from the organic interests about actual testing results and residues, and what was happening was to "screw them" in the marketplace. If I am an organic producer and you are asking me to hand over data that may torpedo my business, I may feel that some of the back-and-forth between the GMO industry and the organic industry is unreasonable, is unreasonably intrusive. Given what we know of the science today, given that I could write an article in 1995 about pollen that elicited an "Oh my God" response, couldn't we just give the benefit of the doubt to the organic producers who were presenting cases, just not giving all the names, dates, and addresses? That became a kind of third rail. It did not set up very productive dialog.

G. Jaffe, CSPI: I agree with you completely that revising Part 340 would be a great way forward. I think that we spent a lot of time on plant pest issues when the reality is we should have been spending time on resistant weeds, resistant pests, on economic issues and things like that. I think Part 340 had some good parts. It didn't address all these issues. It didn't address coexistence. I guess the question is how we can get the USDA to do this in under six or seven years. Even if they follow your suggestion, an idea I agree with, and use noxious weed regulations, by the time they do the market will already have moved forward and done whatever it is going to do. How can we get the agency to move on this quicker so it will actually have impact on this debate?

Merrigan: That's an excellent question. The USDA first pulled back a rule that had been proposed years and years ago and said they were going to go back and start over. I think that was the right thing to do, because if they had proceeded with that rule it would have obviously been easy to challenge it under the Administrative Procedures Act. So going back and starting from square one and putting in place the new proposed rule, you still have all that paperwork and all that information that may end up in your new proposed rule, but procedurally that would make a lot of sense. I have extreme confidence the civil servants at the USDA can work fast and produce a really thoughtful rule. I am calling out to you, Neil Hoffman. We worked some pretty long hours on that coexistence stuff, didn't we? And we put together some really thoughtful things. There are many great people involved, and it requires political will at the top to do the dodge-and-tackle with Congress, and with industry, to allow the civil servants to do their great work.

R. Roush, Penn State: I want to come back to this issue about the cost to organic, and not so much to your individual data. One of the issues some of us have been working on for a long time is, what's the composite? What are the trends? Where do people run into problems? I want to cite a court case about this in Australia, where everything got dumped on the table. The guy who was claiming he had found contamination and sued his neighbor was absolutely unable to prove any losses. The judge came down harder on the certifier than he did on the GM grower. Is there any advice or indication you can give us as to what the trends are? Where have the problems been? Because that is what we really need to know so as to avoid it. Not individual cases of losses, but where overall the problems are.

Merrigan: The best data and analysis are from Lynn Clarkson. Wave your hand, Lynn! He is actually the point person for the industry to collect that data. I will let him engage in that discussion and lead the discussion from the organic industries point of view. I know that there is now a move in the National Organic Standards Program to do more testing of organic crops, sporadic testing for GMO content. That will create a government-led database that might provide background data that will be helpful. What I find really interesting, as I look at this new AMS labeling scheme, is this: If a producer is in the process-verified program, it is the process that is verified. It does not deal with a residue level. It is not a threshold-based program. So there might be GM present, but it is a program that gives the organic producer a level playing field. This is where I got my start. I could have been doing any kind of policy, but I am always for the David and Goliath stories. The organic industry seemed like a little guy trying to fight his way out of a hole. We are now going to have an AMS Process-Verified label that the industry can use and put a non-GMO Process-Verified claim, on a USDA label, with no testing for threshold. But the organic guys, who have followed that rule since it went into place in 2002, are being tested. I just don't get that. I still think there are opportunities to make sure that an organic label is strong and is a really viable choice for consumers who are concerned about these things or for whatever reason want an alternative.