AGRICULTURAL BIOTECHNOLOGY AND THE LAW

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Thank you for having me here today. It is an absolute privilege. I also want to thank Stephen Vaden and Rachel Pick from the United States Department of Agriculture's (USDA) Office of General Counsel for their role in having me speak. I want to congratulate Stephen Vaden on his nomination to be a judge on the Court of International Trade. I have worked closely with Stephen in his role as the General Counsel at USDA. He is a good man and a great lawyer. It will be a huge loss for USDA, but an even greater gain for the judiciary.

Today, I am Counsel at Sidley Austin in Washington, D.C. Up until last week, I served in the Office of White House Counsel as Senior Associate Counsel to the President and Special Assistant to the President. But, I must stress that my remarks here today are my own personal reflections based upon my experience, and they do not necessarily reflect the views of the Administration.

Spending nearly three years in the White House was one of the greatest honors of my professional career. It was also the fulfillment of a childhood dream. As the son of an Italian immigrant and having been raised by a single mother, I do not think that I ever really expected that dream to be realized.

I had high expectations for what it would be like to be a lawyer in the White House. Fortunately, I was not disappointed. I expected to work with smart lawyers. And, I did. In every Administration, the Office of White House Counsel contains the densest concentration of legal talent in the world. What I did not expect was that my colleagues would be such good people. Never before had I worked with such a nice group of people who were truly committed to working collaboratively to serve the country and the rule of law. I have made many lifelong friends.

The best part of working in the Office of White House Counsel is that the

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work is always meaningful. Only the most interesting and important legal issues are handled by the office, and those issues must be addressed at warp speed.

In the Trump Administration, the office is best known for its role in nominating federal judges at a record pace. Many people believe that President Trump's judicial nominations will be one of his longest lasting and most influential legacies. I agree, and I am proud to have been part of the team that made those appointments possible. However, I am equally proud of the work that the Administration has done in the realm of agriculture, and I believe that the regulatory decisions made in this space may represent one of the longest-lasting contributions of this Administration.

What interested me the most in handling agriculture-related legal issues were issues pertaining to biotechnology and other new and emerging technologies. Although it has been the trend for decades, the lines between science and agriculture are becoming increasingly blurred. Whether you want to call it an inflection point or a revolution, we are in the middle of something big that will change food and agriculture forever. The opportunities are astounding. Over the coming decades, agricultural biotechnology promises to reduce starvation, end diseases, make the food supply healthier, and ease the lives of farmers. In 1970, Norman Borlaug rightfully won the Nobel Peace Prize for launching the Green Revolution, increasing the world's food supply, and saving countless lives in the process.[1] As monumental as Borlaug's contributions were, it seems likely that they will be dwarfed by the strides that will be made in agricultural biotechnology in the near future.

Fulfilling the promise of these technologies will primarily be the responsibility of the world's immensely talented scientists, farmers, and producers. However, lawyers and regulators will also play a crucial role. If you want to understand a society at any given point, look at its laws. Although frequently hidden by the stilted legal lexicon, the law will tell you a society's hopes, fears, and priorities. In deciding how new agricultural biotechnologies should be regulated, lawyers and regulators will need to decide how these considerations should be balanced in accordance with applicable laws.

Whenever there is a tectonic technological shift such as the one we are seeing with agricultural biotechnology and other emerging technologies, lawyers and regulators are charged with creating new legal frameworks to address concepts that have never before been considered. And, the regulatory regimes must be not only detailed enough to provide stakeholders in new industries with

1. *Norman Borlaug Biography*, THE NOBEL PRIZE, https://perma.cc/JRN2-2RJS (archived Aug. 11, 2020).

enough notice and guidance, but also flexible enough to allow the industries to grow in ways that we cannot yet fully imagine. In some ways, it is a burden. You frequently have inexperienced players, regulatory turf wars between agencies, and usually a tension between getting products to market quickly while also ensuring their safety. But, I prefer to look at this time as a privilege and an opportunity. We—lawyers and regulators—have the opportunity to sit down like adults, put our differences aside, and work together to create a system that will allow for the development of thriving new industries that will not only help the country's bottom line but will also help improve the human condition. This might sound overly optimistic, but I want to talk to you today about some examples of how this is already happening.

The first example that I want to talk to you about is cell-cultured meat. Now, I am aware that there is a lot of controversy surrounding what this new group of products should be called. Please know that I am not taking a position here. I had to call it something, and "cell-cultured" is the term currently being used by regulators.

At a high-level, cell-cultured meat is meat produced by in vitro cultivation of animal cells.[2] Cells are collected from animals and cultivated into meat. Cells are collected, grown in a culture medium, and, in some cases, scaffold material might be used to aid in the structural growth process.[3] Thereafter, the cells mature into tissues that can be harvested for human consumption. It is vastly more complicated than that, but you get the picture. Although cell-cultured meat is not yet on the market, American and foreign companies have already made great strides. Among other things, companies have produced hamburgers, meatballs, and chicken.[4] Costs of production have fallen dramatically over time, and companies intend to bring cell-cultured meat products to market over the next few years.[5] The potential benefits and new markets presented by cell-cultured meat are manyfold. There is a potential to reduce environmental impacts and supplement the traditional food supply to feed the world's growing population, particularly with respect to protein production. There is also the potential opportunity to expand the market for meat to new populations, including vegetarians and those with religious-based food restrictions.

I am not here to sing the praises of cell-cultured meat. Others can do that. It

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2. *See* Zuhaib Fayaz Bhat & Hina Fayaz, *Prospectus of Cultured Meat—Advancing Meat Alternatives*, J. FOOD SCI. TECH., MAR.-APR. 2011, at 126-28.

3. *See id.* at 134.

4. Brian Kateman, *Will Cultured Meat Soon Be A Common Sight In Supermarkets Across The Globe?*, FORBES (Feb. 17, 2020), https://perma.cc/93ZF-UA8Z.

5. *Id.*

suffices to say that there is a lot of interest on all sides as to how and when these products will be brought to market. A key piece of that puzzle is how the new products will be regulated. This is an issue that the Administration has had to address over the last few years.[6] Initially, it was a contentious process, but all of the stakeholders worked together to arrive at a framework that I believe should serve as a model for the future.

One of the most fundamental questions that arose was: Which agency should be responsible for regulating cell-cultured meat? Should it be the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug, and Cosmetic Act?[7] Or, should it be the USDA pursuant to the Federal Meat Inspection Act[8] and the Poultry Products Inspection Act?[9]

This was a controversial issue, to say the least. Aside from statutory interpretation, there were also serious prudential concerns. Some argued that it made sense for the FDA to have jurisdiction because it had experience regulating cell-growth technologies in other areas. Others argued that USDA should have jurisdiction because USDA has a rigorous inspection regime, and there was a view that cell-cultured meat should be treated the same as traditional meat. The Administration solicited input from the public and met with stakeholders on numerous occasions.[10] The vigorousness of the process was appropriate, given that we were establishing the initial regulatory framework for what is expected to be a multi-billion-dollar industry.

What happened during this process was both remarkable and encouraging: People actually listened to each other. While participants may have entered these discussions with their own interests and preconceived notions, they were generally willing to hear and address others' concerns. Of course, conversations were heated at times, but, ultimately, a reasonable and balanced approach was agreed upon.

In the beginning, most people thought that we were headed for a zero-sum result. The thinking was that either USDA or FDA would win sole jurisdiction over cell-cultured meat. There was no way that a nascent industry would tolerate being subjected to the burden of regulation by two federal agencies. But, that thinking was wrong. As we listened to industry stakeholders, it became clear that

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6. *USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry*, USDA (March 7, 2019), https://perma.cc/6PTK-QZSC.

7. 21 U.S.C. §§ 301-399 (2018).

8. 21 U.S.C. §§ 601-695 (2018).

9. 21 U.S.C. §§ 451-472 (2018).

10. *See USDA and FDA Announces a Formal Agreement*, *supra*, note 6.

they saw value in bringing to bear the expertise of both agencies at different steps of the process.

The end result of the discussions was a March 2019 interagency agreement between the FDA and USDA.[11] Pursuant to this agreement, FDA will oversee tissue collection, cell banks, and cell growth and differentiation through the time of harvest.[12] After that point in the process, primary jurisdiction will transfer to USDA, which will be responsible for overseeing the production and labeling of food products derived from the cells.[13] Although the process to arrive at this agreement was lengthy and sometimes contentious, the agreement itself beautifully reflects something that is often lacking in the law—common sense. FDA does indeed have expertise in the science related to cell line development and growth, and it makes perfect sense for the agency to play a big role in the early stage of the process. Similarly, USDA has both the expertise and credibility when it comes to the inspection of meat and poultry products. Not only will USDA help ensure the continued safety of the food supply, but its stamp of approval will likely help these new products gain the trust and acceptance of the buying public.

The March 2019 agreement is only the start when it comes to the regulation of cell-cultured meat. There are a lot of issues and details that still need to be fleshed out, and I would urge regulators to quickly provide further guidance on safety, labeling, and inspection oversight. However, the fruitful cooperation between industry and the relevant government agencies thus far is a hopeful sign. In my opinion, the interagency agreement should serve as a model for future discussions in both the context of cell-cultured meat and other agricultural biotechnology products. The interagency agreement should serve as a reminder that these types of endeavors should be treated as collaborative efforts rather than zero-sum games. We are in this together, and we will have to live with the frameworks that we create for a long time. We need to listen to one another, keep an open mind, and be prepared to make sensible compromises.

Another promising development in this area is the Executive Order signed by President Trump in June 2019, entitled the "Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products."[14] The title is more descriptive than pithy. I joined President Trump and Secretary Perdue on

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11. FORMAL AGREEMENT BETWEEN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION AND U.S. DEPARTMENT OF AGRICULTURE OFFICE OF FOOD SAFETY 1 (Mar. 2019), https://perma.cc/R99G-TNED.

12. *Id.* at 2.

13. *Id.* at 3.

14. Exec. Order No. 13,874, 84 Fed. Reg. 27,899–27,902 (June 11, 2019).

Air Force One for their trip to Iowa for the signing of the Executive Order. The excitement in Iowa about the Executive Order was palpable. There is good reason for that.

There was a well-founded concern that the United States regulatory process for the evaluation of agricultural biotechnology products was opaque, inefficient, and overly burdensome. The regulatory environment was confusing, and government approvals were taking far too long. Secretary Perdue echoed this sentiment in a statement that he made around the time that the Executive Order was signed: "Our current regulatory framework has impeded innovation instead of facilitating it . . . We need all the tools in the toolbox to meet the challenge of feeding everyone now and into the future[—]if we do not put these safe biotechnology advances to work here at home, our competitors in other nations will."[15]

We all can think of examples of food and agricultural products that have involved novel technologies and have taken decades to come to market due to complex and lengthy regulatory processes. In some cases, the process for biotechnology products has taken well over twenty years!

Let me put this in perspective. In the mid-1990s, the first flip phone was introduced (black and white screen and all). By 2015, the iPhone 6s was introduced. Cell phones had grown from crude methods of verbal communication to a point where they had become our connection to the outside world, allowing internet access, video conferencing, photography, social media, etc. In 1994, Amazon.com was founded as an online marketplace for books. By 2015, Amazon had become the world's largest online marketplace, disrupting numerous industries and allowing everyday Americans to have nearly anything delivered to their doors within a day or two. Can you imagine if other technologies and industries were subjected to the same regulatory inefficiencies as agricultural biotechnology? We would all be on our "dumb" phones talking to Amazon customer support about why it has taken two weeks to deliver our copies of *Jurassic Park*.

So suffice it to say, something needed to be done. This is where the June 2019 Executive Order comes into play. The Executive Order mandates that federal regulatory agencies implement policies to modernize and streamline the regulatory frameworks for agricultural biotechnology. The purpose of the order is set forth in the text itself:

> Recent advances in biotechnology have the potential to revolutionize

15. Press Release, USDA, Secretary Perdue Statement on President Trump's Biotech EO (June 11, 2019), https://perma.cc/WJU4-MSF9.

> agriculture and thereby enhance rural prosperity and improve the quality of American lives. Biotechnology can help the Nation meet its food production needs, raise the productivity of the American farmer, improve crop and animal characteristics, increase the nutritional value of crop and animal products, and enhance food safety. In order to realize these potential benefits, however, the United States must employ a science-based regulatory system that evaluates products based on human health and safety and potential benefits and risks to the environment. Such a system must both foster public confidence in biotechnology and avoid undue regulatory burdens.[16]

The Executive Order then goes on to issue specific directives in order to achieve this purpose. Among other things, the Executive Order directs that:

"It is the policy of the Federal Government to protect public health and the environment by adopting regulatory approaches for the products of agricultural biotechnology that are proportionate responses to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies;"

- Regulatory decisions should be based "on scientific and technical evidence;"
- Regulatory applications for products of agricultural biotechnology should be reviewed "in a timely and efficient manner;" and
- Regulatory determinations should be "based on risks associated with the product and its intended end use[s]."[17]

The Executive Order also directs that:

- The Secretary of Agriculture, the Environmental Protection Agency (EPA) Administrator, and the FDA Commissioner identify regulations that can be streamlined and, as appropriate, exempt low-risk biotechnology products from undue regulation;
- Each relevant agency reviews its "regulations and guidance that may apply to genome-edited-specialty-crop-plant products designed to have significant health, agricultural, or environmental benefits." Based upon this review, "[E]ach of the agencies shall take steps to update its regulations and guidance . . . to remove undue barriers that impede" bringing innovative and safe genome-edited-specialty-crop-plant products to the marketplace;

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16. Exec. Order No. 13,874, 84 Fed. Reg. 27,899 (June 11, 2019).
17. *Id.* at 27,899-27,900.

- The Secretary of Agriculture, EPA Administrator, and FDA Commissioner develop a domestic engagement strategy "to facilitate engagement with consumers in order to build public confidence in, and acceptance of, the use of safe biotechnology in agriculture and the food system;" and
- The Secretary of State and the Secretary of Agriculture develop an international outreach strategy to increase international acceptance of products of agricultural biotechnology in order "to open and maintain markets for United States agricultural exports abroad."[18]

The Executive Order has received widespread support, reflecting a shared desire—both within industry and government—to ensure that new agricultural biotechnology products are brought to market safely and efficiently. Of course, the Executive Order only sets forth high-level directives, and there is a lot of work to be done to fulfill the Executive Order's promise. The regulatory streamlining called for by the Executive Order needs to be implemented vigorously and with all due speed. Society cannot afford to unnecessarily delay the realization of the benefits presented by technological advancement.

While there is still a lot of hard work to be done, the Executive Order stands as yet another optimistic sign that all stakeholders are prepared to work together to create a regulatory environment where agricultural biotechnology can responsibly thrive.

The final example that I want to cover is bioengineered food disclosures. In 2016, Congress passed the so-called National Bioengineered Food Disclosure Law,[19] which directed USDA to establish a national standard for disclosing bioengineered foods. In December 2018, USDA issued the final National Bioengineered Food Disclosure Standard.[20] The standard is of great interest across the food industry, and USDA received approximately 14,000 comments during the rulemaking process.[21]

The National Bioengineered Food Disclosure Law defines bioengineered food as food "(A) that contains genetic material that has been modified through in vitro recombinant [DNA] techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in

18. *Id.* at 27,900–27,901 (June 11, 2019).

19. National Bioengineered Food Disclosure Law, Pub. L. No. 114-216, § 293, 130 Stat. 835 (2016).

20. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814 (Dec. 21, 2018) (codified at 7 C.F.R. § 66).

21. *Id.*

nature."[22] Under the law, companies may choose among different options to disclose bioengineered food ingredients—including text specified by USDA, a symbol developed by USDA, and an electronic or digital link, such as a bar code or QR code.[23]

At a high-level, the final National Bioengineered Food Disclosure Standard fleshes out the details of the higher-level dictates of the National Bioengineered Food Disclosure Law. The final standard addresses a host of issues, including permissible terminology for describing bioengineered food[24] (use of the specific term "bioengineered" is required), the symbol that may be used,[25] and implementation dates (the standard will begin being implemented in January 2020 and compliance will become mandatory in January 2022).[26] USDA took into consideration helpful comments from stakeholders across the country on each of these issues.

Perhaps the most controversial question raised during the rulemaking process was whether highly refined ingredients should be disclosed as bioengineered foods. Highly refined ingredients are those such as corn syrup that are produced from a bioengineered crop.[27] Because of the refining process, these products do not contain detectable DNA or protein from the bioengineered organism.[28] In essence, these products are biologically identical to the same ingredients made from non-bioengineered crops. There were forceful views on both sides of the debate. Some argued the disclosure requirements should not apply to highly refined ingredients, because DNA or protein from the bioengineered organisms are not readily detectable.[29] Others argued that the disclosure requirements should apply to highly refined ingredients because consumers would want to know that the ingredient was derived from a bioengineered organism and because there is some evidence suggesting that highly refined ingredients do contain genetic material, even if that material is not easily detectable.[30]

Ultimately, it was decided that highly refined ingredients should not be

22. *Id.*
23. 7 U.S.C. § 1639b(b)(2)(D) (2018).
24. 7 C.F.R. § 66.102(a)(1) (2020).
25. *See* 7 C.F.R. § 66.104 (2020).
26. 7 C.F.R. § 66.13 (2020).
27. 7 C.F.R. § 66.1(1)(i) (2020).
28. 83 Fed. Reg. 65,814.
29. *Id.*
30. *Id.*

disclosed as bioengineered food.[31] This seems like the correct result as a matter of statutory interpretation. A product cannot be said to "*contain[]* genetic material that has been modified through in vitro recombinant [DNA] techniques,"[32] unless and until that genetic material is detectable. However, in a helpful compromise, the standard allows producers of highly refined ingredients to voluntarily disclose that the ingredient was "derived from bioengineering" or "derived from a bioengineered source."[33]

The thoroughness and care with which USDA handled the drafting of the National Bioengineered Food Disclosure Standard has resulted in widespread praise for the standard. It also provides further confidence that all stakeholders will be able to effectively work together as we address other complex biotechnology issues in the future. The dedicated employees of USDA are working hard to implement the standard in a timely manner, and I am confident that USDA and private sector stakeholders will work collaboratively to ensure that the standard is implemented effectively.

The issues and technologies that I have discussed today offer just a small glimpse into the legal ramifications of agricultural biotechnology. Technologies such as gene editing will present potentially nuanced questions regarding regulation and oversight, but the actions that I have discussed should give you confidence that those issues can and will be overcome. In a March 2018 statement, Secretary Perdue already laid out a high-level approach to the regulation of gene edited crops.[34] I am hopeful and confident that Agricultural Marketing Service and Animal and Plant Health Inspection Service will continue to work together to help ensure that their policies are consistent with Secretary Perdue's statement.

All of the developments that I have discussed today give me confidence that there are adults in the room who are ready and able to establish efficient, responsible, and safe regulatory frameworks for agricultural biotechnology. We are just at the beginning, and I am sure that the next few years will present technologies and issues that we cannot even imagine today. That is okay. We are up to the task.

As Secretary of Agriculture, Sonny Perdue has instituted an informal motto at USDA: "Do Right and Feed Everyone." I am a big fan of this motto, and I think that it has implications for those who work on agriculture issues outside of

31. *See* 7 C.F.R § 66.9(a)(2) (2020).

32. 83 Fed. Reg. 65,814 (emphasis added).

33. 7 C.F.R. § 66.116(b) (2020).

34. Press Release, USDA, Secretary Perdue Issues USDA Statement on Plant Breeding Innovation (Mar. 28, 2018), https://perma.cc/A37E-MX4Q.

USDA. Food is literally what makes life possible, and that lifeblood is given to us by our farmers, producers, and scientists. Agricultural biotechnology has the potential to feed the hungry, save lives, help farmers, and make all of us healthier and more prosperous. So, as we—lawyers and regulators—go out and try to help shape the landscape that will allow these new technologies to grow in a safe and efficient manner, remember that this is both a solemn responsibility and the opportunity of a lifetime. You have the opportunity to help do right and feed everyone.