What's the Beef? The FDA, USDA, and Cell-Cultured Meat

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Abstract

Over the past ten years, administrative law scholarship has increasingly focused on interactions between multiple agencies. As part of this trend, most scholars have called for policymakers to combine multiple agencies, rather than rely on a single agency, to solve policy problems. The literature in this area espouses the benefits of shared regulatory space. But very little of this scholarship addresses when shared jurisdiction is problematic. This is particularly concerning when an agency opts into or cedes oversight authority to another agency at will, with little regard for whether the second agency is an appropriate regulator. The case of cell-cultured (or lab-grown) meat presents one such example. In 2018, both the U.S. Food and Drug Administration and the U.S. Department of Agriculture separately announced that regulating cell-cultured meat fell under their sole purview,

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to the exclusion of the other agency. After much back-and-forth, the agencies issued a joint statement announcing a shared system of regulatory oversight.

This Article argues that the FDA should not have ceded any of its regulatory authority to the USDA because joint regulation of cell-cultured meat, as between the FDA and USDA, is both inappropriate and unnecessary. USDA involvement is inappropriate because the Department suffers from a mixed mandate problem. Not only is the Department tasked with maximizing agricultural industry profits (and minimizing losses), but it is also tasked with nourishing Americans (and improving nutrition and health). In the case of cell-cultured meat, these two goals are diametrically opposed. Further, USDA involvement is inappropriate given the Department's purview, as set by Congress, and its concomitant expertise. As it relates to meat, the USDA exists specifically to monitor the safety and sanitation of the nation's farms, slaughterhouses, and meat processing and packaging plants. Consequently, all the Department's meat-related regulations and expertise are in these areas. USDA involvement in the regulation of cell-cultured meat is also unnecessary because it is redundant. Accordingly, this Article's analysis belies the notion that all agency collaboration is good collaboration.

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INTRODUCTION

The cellular agriculture industry, with cell-cultured meat at the forefront, is poised to become a significant industry disruptor. The cell-cultured meat market alone is projected to reach $140 billion over the next ten years.[1] While there were just a handful of cell-cultured meat start-ups in 2016, there are at least sixty today.[2] This past year, the market's potential—combined with the industry's commitment to "humane and environmentally sustainable" protein sources—"has attracted record venture capital funding."[3] Moreover, countries around the world have begun to approve the sale of cell-cultured meat products. Singapore became the first in December 2020 when it approved Eat Just Inc.'s sale of

1. *See Meating Demand—The Lean, Green, Money-Making Machine*, EDISON (Oct. 2020), https://perma.cc/EY6N-VWXA. ("Longer-term growth projections vary greatly, with revenue estimates for the global market in 2030 ranging from $140bn (Barclays) to $252bn (Kearney).").

2. Agnieszka de Sousa, *Lab-Grown Meat Is Getting Closer to Supermarket Shelves*, BLOOMBERG GREEN (Dec. 9, 2020, 7:09 PM), https://perma.cc/9KMK-W255 (last updated Dec. 10, 2020, 11:49 AM).

3. *Id.*

cell-cultured chicken.[4] And several start-up companies are promising to bring cell-cultured meat to market as early as 2022.[5]

Despite all of its potential, both economic and otherwise, the United States has yet to approve the sale of cell-cultured meat. In fact, the U.S. government only recently determined which federal agencies would oversee the production and sale of these products, after many months of back and forth.[6] The current plan calls for the Food and Drug Administration (FDA) to oversee cell collection, cell banks, and tissue maturation.[7] Oversight will then shift to the U.S. Department of Agriculture (USDA) for processing, packaging, and labeling.[8] In essence, the FDA will oversee all processing prior to the existence of a matured tissue product, and the USDA will then oversee all subsequent processes.[9] The agencies have yet to allocate oversight responsibility for the product once it leaves the lab.[10] Beyond these practical considerations, there are broader questions to raise about the need for and appropriateness of shared jurisdiction in this instance.

This Article makes the normative claim that, in the case of cell-cultured meat, the FDA should not have ceded any of its regulatory authority to the USDA because joint regulation of cell-cultured meat, as between the FDA and USDA, is both inappropriate and unnecessary. USDA involvement is inappropriate, on one hand, because the Department suffers from a mixed mandate problem. Not only is the Department

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4. *Id.*

5. *See id.* (introducing start-ups like Memphis Meats (now Upside Foods), BlueNalu, and Aleph Farms).

6. *See* News Release, FDA, *USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry* (Mar. 7, 2019), https://perma.cc/V3AF-CDTN.

7. *Id.*

8. *Id.*

9. *See id.* ("This shared regulatory approach will ensure that cell-cultured products derived from the cell lines of livestock and poultry are produced safely and are accurately labeled.").

10. *See id.* ("FSIS and FDA released a formal agreement to address the regulatory oversight of human food produced using this new technology. The formal agreement describes the oversight roles and responsibilities for both agencies and how the agencies will collaborate to regulate the development and entry of these products into commerce.").

tasked with maximizing agricultural industry profits (and minimizing losses), but it is also tasked with nourishing Americans (and improving nutrition and health).[11] In the case of cell-cultured meat, these two goals are diametrically opposed. Given the Department's long history of capture, we can expect that it will favor industry when forced to choose between the two.[12] On the other hand, USDA involvement is inappropriate given the Department's purview, as set by Congress, and its concomitant expertise.[13] As it relates to meat, the USDA exists specifically to monitor the safety and sanitation of the nation's farms, slaughterhouses, and meat processing and packaging plants.[14] Consequently, all the Department's meat-related regulations and expertise are in these areas. Yet, the cell-culturing process has very little in common with the traditional raising, slaughtering, and processing of meat from the carcass of an animal.[15] Cell-culturing in a lab actually has more in common with the development of drugs than with traditional meat processing processes.[16] Related to the questions of mandates and expertise is the question of whether the USDA

11. *See* Food, Agriculture, Conservation, and Trade Act of 1990, Pub. L. No. 101–624, pmbl., 104 Stat. 3359, 3359 (authorizing the USDA to "extend and revise agricultural price support and related programs"); *About the U.S. Department of Agriculture*, USDA, https://perma.cc/3CJA-GUNU (highlighting that the USDA's vision of "promot[ing] agriculture production that better nourishes Americans").

12. *See infra* Part III.A.4.

13. *See infra* Part III.A.4.

14. *See Summary of Federal Inspection Requirements for Meat Products*, USDA, https://perma.cc/4ZK6-MPYZ (PDF) (last updated Sept. 2015) ("The Federal Meat Inspection Act (FMIA) requires that all meat sold commercially be inspected and passed to ensure that it is safe, wholesome, and properly labeled. The USDA Food Safety and Inspection Service (FSIS) is responsible for providing this inspection.").

15. *See What Is Cultured Meat*, MAASTRICHT UNIV., https://perma.cc/YP85-QH5E (detailing how scientists create cell-cultured beef "by painlessly harvesting muscle cells from a living cow" and "feed[ing] and nurtur[ing] the cells so they multiply to create muscle tissue").

16. *Compare id.* (explaining cell cultures' role in developing meat), *with* Karol Jaroch et al., *Cell Cultures in Drug Discovery and Development: The Need of Reliable* In Vitro-In Vivo *Extrapolation for Pharmacodynamics and Pharmacokinetics Assessment*, 147 J. PHARM. & BIOMEDICAL ANALYSIS 297, 297 (2018) ("[C]ell cultures have been a part of drug development for many years.").

lawfully has jurisdiction over cell-cultured meat.[17] According to the definitions in the Federal Meat Inspection Act (FMIA),[18] cell-cultured meat is not a meat product.[19] This view coincides completely with the various approaches to the product elsewhere under the law.

USDA involvement in the regulation of cell-cultured meat is also unnecessary because it is redundant. In the proposed regulatory scheme, the USDA will solely be responsible for (1) overseeing establishments that conduct cell harvesting from livestock or poultry; (2) using appropriate USDA marks of inspection to confirm that oversight; (3) overseeing product testing and review to ensure that products are unadulterated and, again, properly labeled as such; and (4) managing all pre-approval and verification processes.[20] The proposed scheme also authorizes the USDA to develop additional requirements as necessary and to conduct necessary enforcements to ensure that misbranded, mislabeled, and adulterated products do not enter the market or, if they do, that they are quickly removed when identified.[21] Yet, the FDA is already responsible for all of these same tasks *and* in areas far more akin to cell-culturing. For example, the FDA routinely inspects certain types of establishments including vaccine and drug manufacturers (which use culturing), blood banks (which use culturing), and food processing facilities—which, apparently, now use culturing.[22] Moreover, the FDA has a long-established pre-approval process that is activated once a company applies to

17. *See* JOEL L. GREENE & SAHAR ANGADJIVAND, CONG. RSCH. SERV., IF10947, REGULATION OF CELL-CULTURED MEAT 1–2 (2018) ("Some argue that cell-cultured meat will be produced in facilities that are similar to food manufacturing or biologics facilities that FDA currently regulates, whereas cell-cultured production will not look like slaughter plants that FSIS regulates.").

18. Federal Meat Inspection Act (FMIA) of 1906, Pub. L. No. 59-384, 34 Stat. 669 (codified as amended at 21 U.S.C. §§ 601–695).

19. *See* 21 U.S.C. § 601 (lacking any reference to cell-cultured meat).

20. *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, FDA (Mar. 7, 2019) [hereinafter *Formal Agreement Between FDA and USDA*], https://perma.cc/VB45-86V5.

21. *Id.*

22. *See What Does FDA Inspect?*, FDA (Mar. 28, 2018), https://perma.cc/J5RP-9WNT.

market a new product.[23] Finally, the FDA can implement a "for-cause" inspection to investigate any problems that are brought to the agency's attention, including issues of misbranding, mislabeling, and adulteration.[24] These existing regulations are sufficient to oversee the safe processing, packaging, and labeling of cell-cultured meat.

This Article proceeds in four parts. Part I serves as a brief primer on cell-cultured meat, presenting the science behind the product, sharing some of the health and safety concerns, and addressing the benefits associated with its use and the potential business ramifications. Part II of the Article describes the interplay between the FDA and USDA in the race to regulate cell-cultured meat. Part III of the Article argues that USDA involvement in the regulation of cell-cultured meat is inappropriate because of (1) the problems associated with the Department's mixed mandate; (2) the agency's jurisdiction and expertise; (3) the definition of meat product under the Federal Meat Inspection Act; and (4) the need for horizontal coherence in the law. Part IV of the Article argues that the FDA had very little incentive to cede any of its regulatory authority to the USDA—namely because the FDA is more than capable of seeing cell-cultured meat safely to market, as it does with most other processed foods and drugs, without USDA involvement and the associated risks. Part V of the Article considers and dispenses with various legal strategies that might be employed to remedy the problem. The Article concludes with a few remarks on how best to disentangle this problematic relationship.

While on its face this issue may seem minor, there are in fact broader implications for how society views the regulation of emerging technology. As innovation and technology continue to advance at a rapid clip, Congress will have to either continuously expand the mandates of the existing federal agencies or be willing to continually create new agencies. As another, seemingly more practical approach, federal agencies may begin partnering up more frequently to address complicated new products. To the extent that these partnerships will become more ubiquitous, Congress should create systems to

23. *See* AGATA DABROWSKA & SUSAN THAUL, CONG. RSCH. SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 1 (2018).

24. *See What Does FDA Inspect?*, *supra* note 22.

ensure that they are both necessary and appropriate. Federal agencies should not have unfettered ability to negotiate or barter for authority amongst themselves without any formal oversight or checks on this power. As it stands, the story of cell-cultured meat sets a chilling precedent such that one agency (the FDA) can opt into oversight based on its mandate or cede that authority to another agency (the USDA), with little regard for whether the second agency is an appropriate regulator. Case studies of this sort are arising more frequently given the volume of new technology and the frequency of overlapping mandates.

I. A CELL-CULTURED MEAT PRIMER

To understand the kerfuffle around the regulation of cell-cultured meat, one must first understand a few things about the product. Cellular agriculture describes the process whereby conventional animal products are made for consumption without the involvement of those animals.[25] Due, in part, to the presence of a manufacturing process and small distinctions between conventional meat (or traditional meat) and the product resulting from that manufacturing process, there has been a great deal of debate about whether cell-cultured meat can be accurately described as meat and whether it is truly safe for consumption.[26] For some people, the distinction between conventional meat and cell-cultured meat is of very little importance.[27] These people are more concerned with the benefits that will inure to people, animals, and the environment as humanity moves away from the consumption of domesticated

25. *See* Natalie R. Rubio et al., *Plant-Based and Cell-Based Approaches to Meat Production*, NATURE COMMC'NS (2020), https://perma.cc/CTS5-WH65 (PDF) ("[L]ab-grown meat or cultured meat is meat produced by cultivating cells as opposed to farming animals.").

26. *See* Sghaier Chriki & Jean-François Hocquette, *The Myth of Cultured Meat: A Review*, 7 FRONTIERS NUTRITION, Feb. 7 2020, at 1, 6, https://perma.cc/2UKT-SYFQ (PDF) (explaining that advocates of cell-cultured beef are concerned with some consumers' perception that cell-cultured meat is "fake"); Rose Eveleth, *Is Lab-Grown Meat Really Meat?*, FUTURE TENSE (July 11, 2018, 8:32 AM), https://perma.cc/7VM5-KDMX (recounting a naming controversy between cultured meat companies and a meat industry organization).

27. *See* Chriki & Hocquette, *supra* note 26, at 5 (stating that acceptance of cultured meat will differ based on differences in culture, gender, and information access).

animals (and their many by-products) towards cellular agriculture.[28] Others are principally concerned with the health and safety implications of these novel manufacturing processes.[29] Finally, there are those who are most concerned with the economic implications resulting from the growth of the cellular agriculture industry.[30] Each of these distinct interest groups has had a hand in the regulatory discourse.

A. *Cell-Cultured Meat and Conventional Meat*

Cell-cultured meat is a food product derived from bovine animal cell cultures (typically stem cells) that have been harvested from a healthy animal and grown by scientists in a lab.[31] The process begins with the removal of a small sample of muscle tissue from a live cow (a biopsy).[32] The piece of muscle tissue is then cut to liberate the stem cells.[33] Once the stem cells have been extracted, they are placed in a culture that will provide nutrients, hormones, and growth factors.[34] That culture will also allow the stem cells to divide on their own.[35] Eventually, the cells will merge and arrange themselves into small fibers called myotubes.[36] The myotubes will convert into primitive muscle fibers before bulking up to form muscle

28. *See id.* at 4 (discussing survey data that suggests cultured meat is most popular among consumers who want to be more socially responsible).

29. *See id.* at 5 (underscoring that "consumers will not be willing to accept any compromises in terms of food safety").

30. *See Meating Demand*, *supra* note 1 ("The cell-based meat industry is still nascent, where global investments in 2018 [totaled $50 million], equivalent to only 6% of the amount invested in plant-based food; however, as cell-based meat becomes revenue generating there will be scope for greater investment . . . .").

31. While broader interpretations of the term meat include pork, poultry, and the like, for purposes of this Article the focus is on products that have been traditionally viewed as "beef."

32. Mark J. Post, *Cultured Beef: Medical Technology to Produce Food*, 94 J. SCI. FOOD & AGRIC. 1039, 1040 (2014).

33. *Id.* at 1040.

34. *Id.*

35. *Id.* One of the most common mediums is Fetal Bovine Serum (FBS), which is made from the blood of a dead calf. *See* Carlo E.A. Jochems et al., *The Use of Fetal Bovine Serum: Ethical or Scientific Problem?*, 30 ALTS. TO LAB'Y ANIMALS 219, 220 (2002).

36. Post, *supra* note 32, at 1039.

tissue.[37] To achieve a more muscle-like end product, the "meat"[38] must be grown on a lattice or frame known as scaffolding.[39] Throughout the process, the cells and their warm, body-temperature environment must be closely monitored using a bioreactor.[40] Significantly, tissue-engineering in this way does not require any genetic modification.[41]

In sum, cell-cultured meat is artificial muscle (or muscle proteins) created by tissue-engineering in a lab.[42] The relationship between muscle tissue and meat is uncomplicated. Meat comes from muscle tissue that has had the opportunity to mature.[43] For example, cow muscle tissue is very tough, and for beef to be tender enough to eat, a consumer must wait at least a few days after the animal was slaughtered to consume it.[44] Researchers do not fully understand these naturally occurring processes, however, and therefore they cannot truly replicate

37. This methodology was inspired by techniques in regenerative medicine for reconstructing patients' deteriorated muscle tissue from their own cells. *See id.* at 1040.

38. This is an implicit recognition that the word meat has positive connotations. *See, e.g.*, Jean-François Hocquette, *Is* In Vitro *Meat the Solution for the Future?*, 120 MEAT SCI. 167, 169 (2016) ("[F]or example, meat is a symbol of force (inherited from the fact that primitive hunters had to be strong to hunt wild animals) and of high nutritional value (meat provides proteins in quantity and quality and many micro-nutrients which are beneficial for health).").

39. *See* Neil Stephens et al., *Bringing Cultural Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture*, 78 TRENDS FOOD SCI. & TECH. 155, 159–60 (2018).

40. *See* Hocquette, *supra* note 38, at 170.

41. *See* Stephens et al., *supra* note 39, at 157 (stressing that cultured meat is "genetically identical" to agriculturally produced meat).

42. *See* Hocquette, *supra* note 38, at 170 (asserting that the term "artificial muscle proteins" is more accurate than "artificial meat").

43. During the maturation process, "important biochemical transformations gradually take place as the pH of the muscle falls as a result of the absence of oxygen following the slaughter of the animal." Hocquette, *supra* note 38, at 169. More specifically, "intramuscular glycogen is broken down into lactic acid" which results in a decline in muscular pH, which in turn activates in sequence a succession of enzyme families whose activity leads to the breakdown of muscle proteins and the tenderization of meat. *Id.* at 170.

44. *See* Ahmed Ouali et al., *Biomarkers of Meat Tenderness: Present Knowledge and Perspectives in Regards to Our Current Understanding of the Mechanisms Involved*, 95 MEAT SCI. 854, 855–56 (2013).

them in the manufacture of cell-cultured meat.[45] Despite these differences, cell-cultured meat rises to the level of "biological equivalence," producing "molecularly and genetically identical material that delivers viscerally equivalent eating or usage experiences."[46]

There are various distinctions between cell-cultured meat and conventional meat. While real muscle tissue is largely composed of muscle cells formed by myoblasts, it also contains a small amount of nerve, blood, and fat cells.[47] These nerve, blood, and fat cells are either absent in cell-cultured meat or present in very low proportions.[48] Likewise, where beef from a steer or a heifer naturally includes muscle, adipose tissue, connective tissue, cartilage, and blood vessels, cell-cultured meat is not nearly as complex.[49] Finally, there are notable differences in visual appearance,[50] taste,[51] and nutritional makeup[52] that distinguish cell-cultured meat from conventional meat. Cell-cultured meat producers must, therefore, introduce food coloring to make the product pink, adipose cells to emulate the well-known taste of beef, and vitamins and minerals (particularly micronutrients, like iron) to make the product as palatable and as healthy as conventional meat.[53]

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45. *See generally id.*

46. Stephens et al., *supra* note 39, at 157.

47. Hocquette, *supra* note 38, at 170.

48. *Id.*

49. *See id.* at 169–70.

50. When cultured meat is produced, for example, the muscles fibers appear yellow as opposed to pink or red like conventional meat. *Id.* at 170. This is because cells must be cultured in ambient oxygen conditions, which suppresses myoglobin expression. *Id.* Myoglobin expression provides conventional meat with its red coloring. *Id.*

51. It has also been extremely difficult to reproduce the taste of conventional meat because that taste "results from a complex interaction between proteins, carbohydrates, and the aromas of the lipid fraction." *Id.*

52. The vitamins (especially B12) and micronutrients that give conventional meat its nutritional benefits are not naturally occurring in cultured meat and must be added. *Id.*

53. *See id.* (explaining that to reproduce the taste of conventional meat, "adipose cells need to be introduced" to the culturing process); Robin Simsa et al., *Extracellular Heme Proteins Influence Bovine Myosatellite Cell Proliferation and the Color of Cell-Based Meat*, 8 FOODS 521, 522 (2019) (discussing the addition of myoglobin or hemoglobin to color cultured meat).

B. *Health and Safety Concerns*

Advocates of cell-cultured meat have argued that the product is safer than conventional meat because it is grown in a well-controlled laboratory environment without other organisms to contaminate it.[54] This is in direct contrast to the living conditions of animals raised for slaughter and human consumption. Those animals often live in confined spaces where they risk contracting diseases, like influenza, and must be heavily vaccinated against them.[55] The proximity to other animals also impacts the animal's internal environment. There is a risk of cross-contamination from digestive organs from other animals during slaughter.[56] In the absence of a significant number of other animals, it is highly unlikely for cell-cultured meat to encounter any diseases or intestinal pathogens including E. coli, Salmonella, or Campylobacter.[57] This is significant because these three pathogens cause millions of instances of illness each year.[58]

There are also notable concerns regarding the health and safety of cell-cultured meat. The public has expressed some doubts about the increasing use of food technology, including tissue-engineering, especially as it relates to the health effects of consumption.[59] One concern is the significant number of additives in cell-cultured meat and their concomitant impacts on humans.[60] Antibiotics and fungicides must be used throughout the culturing process to avoid contamination of cell

54. *See* Chriki & Hocquette, *supra* note 26, at 4 ("[T]he issue of spoilage and of pathogens are different between cultured meat and conventional meat . . . .").

55. *See id.* at 2–3.

56. *See id.* at 3 ("[W]ithout any digestive organs nearby . . . and therefore without any potential contamination at slaughter, cultured muscle cells do not have the same opportunity to encounter intestinal pathogens . . . .").

57. *Id.*

58. *Id.*

59. *See* Chriki & Hocquette, *supra* note 26, at 6 ("[C]onsumers may accept . . . cultured meat, but will require a trusted process of control and regulations to ensure complete safety of the product.").

60. *See id.* at 2 ("The research questions are now: how can these compounds be produced on an industrial scale, and how can [it] be ensured that none of them will have negative effects on human health in the short and long term?").

cultures.[61] This seems to amplify the antibiotic resistance problems already created by American livestock.[62] Moreover, the medium used to nurture cell-cultured meat must also contain added hormones and growth factors to sustain the required proliferation and differentiation.[63] Hormone growth promoters are already prohibited from conventional meat farming in the European Union because of health and safety concerns.[64] Further, there is no real strategy for adding micronutrients to cell-cultured meat, including B12 and iron, despite their vital role in elevating cell-cultured meat to a complete meat substitute.[65] To the extent that micronutrients can be successfully added, studies show that introducing micronutrients to the culture medium may diminish the health benefits.[66] Ultimately, the more additives that are introduced to the medium, the more "fake" the product will become in the eyes of the consumer.[67]

Another safety issue concerns the dysregulation of cell lines. Multiple cell multiplications of this sort raise a risk of the kind of cell dysregulation that takes place in cancer cells.[68] These deregulated cell lines must be eliminated before production or human consumption.[69] But even if they are

61. *See id.*

62. *See* Stephen P. Oliver et al., *Impact of Antibiotic Use in Adult Dairy Cows on Antimicrobial Resistance of Veterinary and Human Pathogens: A Comprehensive Review*, 8 FOODBORNE PATHOGENS & DISEASE 337, 338 (2011) ("Over the last two decades, antimicrobial resistance associated with agricultural use of antibiotics and the impending propagation of antimicrobial-resistant bacteria from food-producing animals to humans has become a significant global public health concern.").

63. *See* Chriki & Hocquette, *supra* note 26, at 2.

64. *See id.* at 7 (discussing regulation of conventional farming practices by the European Union).

65. *See id.* at 1 ("[T]he control of [cultured meat's] nutritional composition is still unclear, especially for micronutrients and iron.").

66. *See id.* at 7 ("[C]ontrolling the micronutrient composition of cultured meat is still a research issue.").

67. *See id.* at 3 ("[A]dding chemicals to the medium makes cultured meat more 'chemical' food with less of a clean label.").

68. *See id.* ("[G]iven the great number of cell multiplications taking place, some dysregulation of cell lines is likely to occur as happens in cancer cells . . . .").

69. *See id.* (theorizing that "deregulated cell lines can be eliminated for production or consumption").

eliminated, we do not know how this will affect the muscle structure, human metabolism, or human health upon consumption of cell-cultured meat.[70]

While these concerns bear mentioning, it is far too early to determine the impact of cell-cultured meat on public health. It is not as if traditional meat and the related overconsumption of animals have no health implications. In addition to the aforementioned risks of disease and food-born illness, overconsuming saturated animal fat (resulting from conventional meat) can cause non-infectious diseases, like heart disease.[71] As it relates to the health and safety of cell-cultured meat, we need more studies and more time to determine whether or not it is better than conventional meat.

C. *The Benefits of Cell-Cultured Meat*

The potential benefits of cell-cultured meat are numerous and varied. The media has done a great job of espousing these benefits at every turn.[72] The fact of the matter is, however, that the presentation of these benefits is often very one-sided. Rarely does the media address any of the studies that show cell-cultured meat in a less than glorious light.[73] Here, I present a more balanced approach. It would be dishonest to say that cell-cultured meat's advantages are so significant that they merit a change in our regulatory systems without acknowledging that some scholars dispute the idea that cell-cultured meat is the godsend that manufacturers say it is.

1. Environmental Benefits

If cell-cultured meat can be produced at scale, the environmental impact of meat consumption may dramatically

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70. *See id.* (pointing out that it is difficult to predict how cultured meat will affect the human body).

71. Hocquette, *supra* note 38, at 171.

72. *See id.* at 167 ("The production of *in vitro* meat regularly generates media interest because of the contribution it could, at first glance, make to the issue of feeding humankind while also protecting the environment and respecting animals.").

73. *See id.* at 169 ("[O]pposition to cultured meat . . . or ethical concerns regarding the production and consumption of *in vitro meat* are under-represented in media.").

decrease, particularly in the areas of water, land, and energy use. But the benefits are complicated. In the case of water, for example, the media tells consumers that 1,590 gallons of fresh water are required to produce one pound of conventional beef.[74] Advocates of cell-cultured meat are thus quick to retort that the creation of one pound of cultured meat requires no feed and merely 43.6 gallons of water.[75] These numbers are somewhat disingenuous. In reality, about 95 percent of the fresh water allocated to beef production in the first statistic is used to grow crops, plants, and forage that feed the animals.[76] The majority of that water would not be saved if there were no farm animals on pastures or living on land.[77] More honest accounts estimate that the production of one pound of beef requires 66–84 gallons of water.[78] Even so, under both metrics cell-cultured meat uses substantially less water than beef production.

Likewise, cell-cultured meat requires significantly less land for its production. Today more than six billion acres of land are dedicated to the production of feed for farm animals.[79] However, of the more than six billion acres of land dedicated to the production of feed, more than three billion of them are considered non-arable and only suitable for livestock.[80] Further, livestock play a key role in soil health, helping to maintain carbon content and soil fertility with the organic matter,

74. *See* Barbara Duckworth, *How Much Water Is Required to Produce a Pound of Beef?*, W. PRODUCER (Jan. 4, 2018), https://perma.cc/XB8B-VM2T (reporting on research from the University of Manitoba measuring water use in livestock production).

75. Jennifer Penn, Comment, *"Cultured Meat": Lab-Grown Beef and Regulating the Future Meat Market*, 36 UCLA J. ENV'T L. & POL'Y 104, 106 (2018) (citing Hanna L. Tuomisto & M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, 45 ENV'T SCI. & TECH. 6117, 6117 (2011)).

76. Chriki & Hocquette, *supra* note 26, at 4.

77. *See* Michel Doreau et al., *Water Use by Livestock: A Global Perspective for a Regional Issue?*, 2 ANIMAL FRONTIERS 9, 10 (2012) ("No evidence exists that the presence of livestock is related to the risk of water scarcity . . . .").

78. *See* Chriki & Hocquette, *supra* note 26, at 4 ("It is now accepted that the production of 1 kg of beef will require 550–700 L of water . . . .").

79. Anne Mottet et al., *Livestock: On Our Plates or Eating at Our Table? A New Analysis of the Feed/Food Debate*, 14 GLOB. FOOD SEC. 1, 5 (2017).

80. *Id.*

nitrogen, and phosphorus resulting from their manure.[81] Some scientists have argued that comparison of land use between cell-cultured meat and conventional meat is unfair because people often ignore the benefits of livestock farming systems, like carbon storage and the biodiversity of plants and animals.[82] Yet, cell-cultured meat will almost certainly slow down existing levels of deforestation.[83]

There is also some debate about energy savings. Advocates argue that much less energy is required to produce cell-cultured meat, estimating that cell-cultured meat requires up to 45 percent less energy than conventional meat.[84] The truth of the matter is that nobody can say with any certainty how much energy it will take to create cell-cultured meat at scale, as it will largely depend on the source of energy the companies choose to use.[85] Ultimately, the water, land, and energy savings resulting from the switch from conventional meat to cell-cultured meat, no matter how large, can be diverted directly to humanitarian needs.

In addition to a beneficial reallocation of resources, cell-cultured meat is also thought to lessen the production of greenhouse gases and slow global warming.[86] Today, livestock are responsible for 14.5 percent of the world's greenhouse gas

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81. *See id.* at 6 ("But livestock also make an indirect contribution to the bio-economy and overall food output by increasing crop productivity through manure and draught power.").

82. *See* Chriki & Hocquette, *supra* note 26, at 4 ("[I]t is obvious that cultured meat will need less land than conventional meat production . . . . [but] this does not equate to an advantage for cultured meat . . . .").

83. *See* Hanna L. Tuomisto & M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, 45 ENV'T SCI. & TECH. 6117, 6122 (2011) (explaining that a shift to cultured meat could promote reforestation).

84. *See id.* at 6121–22 ("[T]he energy input for cultured meat production is substantially lower compared to conventionally produced beef, sheep, and pork . . . .").

85. *See id.* at 6120 ("In this study, the energy input calculations of cultured meat production are based on many assumptions and, therefore, have high uncertainty.").

86. *See id.* at 6122 ("The replacement of conventionally produced meat by cultured meat could potentially contribute toward mitigating [greenhouse gas] emissions because, instead of clearing more land for agriculture, large land areas could be reforested or used for other carbon sequestration purposes.").

emissions, a significant portion.[87] Ruminants, such as cows, and other herbivores emit methane from their digestive tracts whenever they eat.[88] Cattle farming also produces carbon dioxide and nitrous oxide.[89] The reduction of these three greenhouse gas emissions would purportedly slow global warming.[90] Unlike conventional meat, the production of cell-cultured meat will only emit carbon dioxide that originates from the fossil energy used to warm the cultured cells.[91] Again, on its face, this benefit seems unassailable. However, one recent study has argued that global warming will only be lessened by cell-cultured meat initially.[92] Eventually the carbon dioxide emissions associated with cell-cultured meat production will begin to accumulate in the atmosphere in a way that methane does not.[93] The warming that results from such carbon dioxide is not only more likely to persist, but it will increase even at a low level of cell-cultured meat production, exceeding that of cattle production in some cases.[94]

The environmental advantage of cell-cultured meat over conventional meat may be astronomical, minimal, or negligible depending on whom you ask. As is the case with public health,

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87. Amy Quinton, *Cows and Climate Change*: *Making Cattle More Sustainable*, UC DAVIS (June 27, 2019), https://perma.cc/Z7WM-Q6ML.

88. *Id.*

89. *See* John Lynch & Raymond Pierrehumbert, *Climate Impacts of Cultured Meat and Beef Cattle*, FRONTIERS SUSTAINABLE FOOD SYS., Feb. 19, 2019, at 1, 2 (describing how cattle directly emit methane and nitrous oxide, and "conversion of land for pasture or feed production" leads to carbon dioxide emission).

90. *See id.* at 2 (suggesting that reduction in greenhouse gas emissions from livestock would likely have a positive effect on the environment).

91. *See id.* at 1 ("[C]ultured meat emissions are almost entirely [carbon dioxide] from energy generation.").

92. *See id.* at 8 (finding that although initial returns may be promising, "[r]eplacing cattle systems with cultured meat production before energy generation is sufficiently decarbonized . . . could risk a long-term, negative climate impact").

93. *See id.* at 8–9 (explaining how carbon dioxide, which cultured meat production would emit at a higher level than traditional meat production, lingers in the atmosphere longer than other greenhouse gases like methane, creating a "warming legacy").

94. *See id.* at 10 ("The scale of cattle production for the very high levels of beef consumption modeled here would result in significant global warming, but it is not yet clear whether cultured meat production would provide a more climatically sustainable alternative.").

it is too early to say with any certainty. However, the apparent consensus in the literature is that shifting to cellular agriculture will bring some environmental benefits.[95]

2. Social Benefits

Aside from global warming, an increase in cell-cultured meat consumption might help the world with another burgeoning problem: feeding the rapidly growing world population. Rapid population growth has resulted in a global population of 7.7 billion that is expected to surpass 9.7 billion by 2050.[96] According to the Food and Agriculture Organization (FAO), feeding these additional two billion people will require 70 percent more food, despite the existing resource and arable land limitations.[97] Moreover, the demand for meat has increased at a greater rate than global population as the growing number of middle-class consumers in countries like China, India, and Russia more frequently seek luxury goods, including meat, cheese, and other animal products.[98] Current agriculture methods are ill-equipped to sustain current levels of meat consumption.[99]

Many believe that cell-cultured meat can help address global food and nutrition insecurity by producing a larger quantity of high-quality, affordable meat in a more efficient

95. *See id.* at 1 ("Reducing the environmental impacts of meat production, and particularly greenhouse gas (GHG) emissions, is generally highlighted as a significant potential advantage of cultured meat.").

96. *Growing at a Slower Pace, World Population Is Expected to Reach 9.7 Billion in 2050*, UNITED NATIONS (June 17, 2019), https://perma.cc/SFX7-7ARK.

97. *See UN: Farmers Must Produce 70% More Food by 2050 to Feed Population*, GUARDIAN (Nov. 28, 2011), https://perma.cc/SBQ2-TKCN.

98. *See* David Abler, *Demand Growth in Developing Countries*, OECD FOOD AGRIC. & FISHERIES PAPERS No. 29, at 1 (2010) (finding that, consistent with economic growth in Brazil, Russia, India, Indonesia, and China, those countries exhibit a lower elasticity of demand for meat and other luxury food items).

99. *See UN: Farmers Must Produce 70% More Food by 2050 to Feed Population*, *supra* note 97 ("[T]o meet the world's future food needs, a major 'sustainable intensification' of agricultural productivity on existing farmland will be necessary . . . .").

manner than traditional and factory farming methods.[100] Beyond meeting the needs of the growing population and growing global middle class, the cost associated with the production of cell-cultured meat would, ideally, come down to a level that is globally accessible for low-income people as well.[101]

3. Animal Welfare

Today, ethical concerns exist at almost every stage of livestock production and concern for animal welfare is a growing priority in Western societies. Many people are turned off by the low standards of care on cattle feedlots and in pig and poultry industrial production units that lead to overcrowding and inhumane conditions.[102] Because the number of animals necessary for slaughter will decrease substantially with the production of cell-cultured meat, many animal rights defenders have become cell-cultured meat advocates.[103] They describe the product as "victim-less meat."[104] Yet, cell-cultured meat brings its own ethical concerns. Harvesting the cells is an invasive, nonconsensual procedure, and some animal rights groups find this practice problematic.[105] As between the two options, the consensus seems to be that mass production farming is worse

100. *See* Penn, *supra* note 75, at 112–13 (hypothesizing that cultured meat may play a key role in resolving humanitarian concerns).

101. *See* Brian Kateman, *Will Cultured Meat Soon Be a Common Sight in Supermarkets Across the Globe?*, FORBES (Feb. 17, 2020, 8:58 AM), https://perma.cc/7G68-6ME2 (reporting that although the first fake burger cost $325,000 to make, one company "hopes to get cost down to $10 per pound by 2022").

102. *See Factory Farming: Misery for Animals*, PETA, https://perma.cc/DJ4Z-74RT ("In the U.S. today, 99% of animals used for food live on massive industrial 'factory farms,' where they're crammed by the thousands into wire cages, metal crates, or other extremely restrictive enclosures inside filthy, windowless sheds.").

103. *See* Zuhaib Fayaz Bhat et al., In Vitro *Meat Production: Challenges and Benefits Over Conventional Meat Production*, 14 J. INTEGRATIVE AGRIC. 241, 241 (2015) (remarking that in vitro meat production is "winning the favour of animal rights activists for its humane production of meat").

104. *Id.* at 243.

105. *See id.* at 247 (presenting an argument "that *in vitro* meat [uses] original cells gathered from some animal in a morally suspect way and that the use of such cells will morally taint all future generations of tissue").

for animals' quality of life than slating one animal to undergo a biopsy to collect cells while under anesthesia.[106]

Ultimately, a neutral weighing of pros against cons of cell-cultured meat shows that cell-cultured meat has fewer negative impacts on the environment, society, and the ethical treatment of animals than conventional meat. Cell-cultured meat is thus being touted as the way of the future, a viable solution to the many concerns of conventional meat production that will fill the gap between meat supply and demand.[107] These potential benefits, among others, have generated excitement around these new food products.[108]

4. Economic Benefits

Cellular agriculture generally, and cell-cultured meat specifically, is poised to disrupt an important part of the U.S. economy.[109] The top seven publicly traded U.S. meat companies have a combined $71 billion valuation.[110] In 2018, the combined revenue of the top one hundred U.S. meat and poultry processors totaled $226.6 billion.[111] Moreover, market analysts project that global demand for animal-based foods is expected to rise by nearly 70 percent by 2050.[112]

While cell-cultured meat is only a tiny portion of the meat market today, its potential for growth is unlimited and the

106. *See id.* (concluding that, among other positives, improved animal welfare is a generally-accepted benefit of cultured meat production).

107. *See id.* (recognizing that "*in vitro* meat production system holds great promises as an alternative to conventional meat production").

108. *See, e.g.*, Michael Pellman Rowland, *Exciting New Partnership Creates a Blueprint for Sustainable Meat*, FORBES (Jul. 30, 2018), https://perma.cc/WYW4-ZEUB (describing popular enthusiasm for the cell-cultured meat).

109. *Our Meatless Future: How the $2.7T Global Meat Market Gets Disrupted*, CB INSIGHTS RSCH. (July 15, 2020), https://perma.cc/B8CZ-AT6C (discussing the threat to traditional meat market caused by increase demand for artificial meat).

110. *Our Meatless Future: How the $90B Global Meat Market Gets Disrupted*, MEDIUM (Nov. 16, 2017), https://perma.cc/M57F-KRUX.

111. Sam Gazdziak, *The 2018 Top 100 Meat and Poultry Processors*, NAT'L PROVISIONER (May 25, 2018), https://perma.cc/TK5W-NNB7.

112. TIM SEARCHINGER ET AL., CREATING A SUSTAINABLE FOOD FUTURE: A MENU OF SOLUTIONS TO FEED NEARLY 10 BILLION PEOPLE BY 2050, at 1 (2018), https://perma.cc/4DEJ-JR8B (PDF).

industry, though not nearly as established as the beef industry, is both rapidly growing and well-supported.[113] As interest in cell-cultured meat has grown, so has investor interest in the industry. Tyson Foods, for example, is one of the leading producers of pork and chicken in the United States and has invested in two cultured meat start-ups, Upside Foods (formerly Memphis Meats) and Future Meat Technologies.[114] Tyson also launched Tyson New Ventures LLC, a venture capital branch of the corporation tasked with investing in innovative meat products.[115] Cargill, one of the largest producers of the country's beef, is also an investor in Upside Foods.[116] One research firm estimates that the cultured meat industry is projected to reach $20 million by 2027.[117] Cell-cultured meat companies in the United States are positioned to grow exponentially if they can capture a share of the world's market.[118]

Given the alleged wide-ranging benefits associated with cell-cultured meat, including those for the American economy, it is vital to develop a cogently dynamic regulatory system that ensures the product's safety without compromising the likelihood of its purchase and consumption. Much of the industry's success hangs on how successfully it can develop a market for these products.[119] This is a significant hurdle to

113. Financial contributions from the likes of Richard Branson and Bill Gates, combined with marketing from companies such as Tyson and Cargill, have placed many of the industry's start-ups in a position ripe for success. *See* Chloe Sorvino, *Tyson Invests in Lab-Grown Protein Startup Memphis Meats, Joining Bill Gates and Richard Branson*, FORBES (Jan. 29, 2018, 10:00 AM), https://perma.cc/2MRU-WBA9.

114. Jonathan Shieber, *Tyson Foods Investment Arm Backs Another Lab-Grown Meat Manufacturer*, TECHCRUNCH (May 2, 2018, 11:03 AM), https://perma.cc/W9FG-NLLM.

115. *See id.* ("The venture investment arm of massive meat manufacturer Tyson Foods is continuing its push into potential alternative methods of poultry production . . . .").

116. *See* Sorvino, *supra* note 113.

117. Kat Smith, *Clean Meat Market Set to Hit $20 Million in Value by 2027*, LIVE KINDLY, https://perma.cc/JB9M-XQ22.

118. There are presently cell-cultured meat companies in the United States, Israel, the Netherlands, Spain, and Japan. *See* Rhonda K. Miller, *A 2020 Synopsis of the Cell-Cultured Animal Industry*, 10 ANIMAL FRONTIERS 64, 68 (2020).

119. *See Our Meatless Future: How the $2.7T Global Meat Market Gets Disrupted*, *supra* note 109 ("The greatest concentration of alternative meat

overcome, even without the government's propensity to overcomplicate things.[120] The U.S. government has a history of mismanaging emerging technology, especially in the food industry; see, for example, the decades-long debate and litigation over the naming of alternative milk products, such as soy milk and almond milk.[121] It would be a mistake for our regulatory authorities to unnecessarily complicate the regulatory landscape, exacerbating an already tenuous relationship between cell-cultured meat manufacturers and the beef and cattle lobby.[122]

II. THE RACE TO REGULATE CELL-CULTURED MEAT

Before cell-cultured meat can reach a grocery store shelf, it must first be scrutinized against the existing regulatory frameworks. This process began in early 2018, when both the FDA, an agency of the Department of Health and Human Services, and the Food Safety and Inspection Service (FSIS), an agency of the USDA, announced their intention to regulate cell-cultured meat.[123] On April 18, 2018, USDA Secretary Sonny Perdue testified before Congress that any product labeled as meat, including cell-cultured meat, fell under the sole purview

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deals has occurred in the US . . . [a]t the same time, there are also developed and fast-growing meatless markets in Europe and Asia.").

120. *See* Brian Kateman, *If the U.S. Is a Nation of Innovation, Why Aren't We Embracing Cell-Cultured Meat?*, FORBES (Apr. 12, 2021, 9:39 AM), https://perma.cc/R393-3L78 (describing U.S. cell-cultured meat companies as "wait[ing] with their hands tied for the U.S. government to give them the green light").

121. The dairy industry has long argued that the term milk should not be applied to plant-based products (e.g., almond milk or soy milk). *See* Iselin Gambert, *Got Mylk?: The Disruptive Possibilities of Plant Milk*, 84 BROOK. L. REV. 801, 802 (2019). To do so, they argue, is misleading and violates the FDA standards of identity for milk. *Id.* at 814–15. The Dairy Pride Act introduced in the 115th Congress would have limited the use of the term milk. H.R. 778, 115th Cong. (2017); S. 130, 115th Cong. (2017). In July 2018, the FDA also announced that it would review the labeling of plant-based milk and yogurt products. *See* Alexander Nieves, *Gottlieb: FDA to Crack Down on Labeling Nondairy Products as "Milk"*, POLITICO (July 17, 2018, 11:25 AM), https://perma.cc/5D2S-NV6T.

122. *See* Kateman, *supra* note 120 ("Instead of standing in the way, the U.S. could be championing cell-cultured meat as a solution to our urgent public health and environmental crises.").

123. *See* GREENE & ANGADJIVAND, *supra* note 17, at 1.

of the USDA.[124] Seemingly in agreement with the USDA, in May of 2018, the House Appropriations Committee reported a bill requiring the Secretary of Agriculture to regulate "products made from cells of amenable species of livestock, as defined in the Federal Meat Inspection Act, or poultry, as defined in the Poultry Products Inspection [A]ct, grown under controlled conditions for use as human food."[125] Further, the Appropriations Committee mandated the Secretary to "issue regulations prescribing the type and frequency of inspection required for the manufacture and processing of such products, as well as other requirements necessary to prevent the adulteration and misbranding of these products" for fiscal year 2018 and thereafter.[126] In direct opposition to this measure, the FDA issued its own statement in June 2018, claiming that, under the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA would be solely responsible for the regulation of cell-cultured meat.[127] After much back and forth and a joint public meeting on the issue,[128] the agencies issued a joint

124. It is worth pointing out that Secretary Perdue first formulated this opinion after receiving a petition from the U.S. Cattlemen's Association asking the USDA, via the Food Safety and Inspection Service, to establish labeling requirements differentiating cell-cultured meat products from traditional meat products, which are derived from the carcasses of slaughtered animals. *See id.* at 2 (detailing Secretary Perdue's testimony and providing a timeline of relevant events).

125. H.R. 5961, 115th Cong. (2018).

126. *Id.* This language received some pushback in the House. The minority views of Representatives Nita Lowey (D-NY) and Sanford Bishop, Jr. (D-GA) show that there was an amendment to strike this language from the bill because such a determination before the products were commercially available was premature and beyond the scope of a single appropriations bill. This suggests that at least some appropriators agree that the manner of regulation of cell-cultured meat remains to be determined. *See* H.R. REP NO. 115-706, at 183 (2018).

127. *See* GREENE & ANGADJIVAND, *supra* note 17, at 2 ("FDA Commissioner Gottlieb issued a statement on cell-cultured meat announcing that under the FDCA, the FDA has oversight over cell-cultured meat."). The FDA also called for a public meeting on cell-cultured meat that it hosted and moderated without the USDA. *Id.* This meeting, "Food Produced Using Animal Cell Culture Technology," was held in Washington, D.C. on July 12, 2018. *Id.*

128. *See Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry*, FDA (Oct. 26, 2018), https://perma.cc/EDL9-795F (providing meeting recordings and copies of presentations).

statement on November 16, 2018, announcing a shared system of regulatory oversight of cell-cultured meat.[129]

Under the terms of the agreement, the agencies will have both compartmentalized and shared roles. The FDA will evaluate production materials and processes, and manufacturing controls, using existing rules and regulations—including facility registration, the Current Good Manufacturing Practices and preventive controls regulation, and any other requirements applicable to substances that will become food (or components of food).[130] The FDA must share its results with the USDA before a product is approved for market.[131] The FDA will also oversee cell collection, cell banks, and cell growth and differentiation.[132] During the cell harvest stage, oversight will shift from the FDA to the USDA.[133] Here, the FDA is supposed to disclose to the USDA whether the harvested cells are eligible for processing into meat or poultry products worthy of bearing the USDA mark of inspection.[134] The proposed scheme also authorizes the FDA to develop additional requirements on cell bank and cell culturing facility conditions and processes as necessary to ensure that the biological materials are safe and not adulterated under the FDCA, and to conduct follow-up activities and enforcement actions to guarantee the same.[135]

The USDA will then be responsible for the oversight of production and the labeling of food products derived from the cells of livestock and poultry.[136] Specifically, the USDA must inspect any cell-harvesting establishment that uses livestock or

129. During the meeting, FDA and USDA officials discussed their respective regulatory frameworks and how each could be applied to ensure the safety of cell-cultured meat. *See* Press Announcement, Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry (Nov. 16, 2018), https://perma.cc/73E8-MS5A.

130. *Formal Agreement Between FDA and USDA*, *supra* note 20 (outlining the FDA's pre-market evaluation process).

131. *Id.*

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. *See id.* (explaining that each organization that harvests cells from meat or poultry must obtain a certificate of inspection from the USDA).

poultry subject to FMIA or Poultry Products Inspection Act (PPIA)[137] oversight, along with any establishment that processes the cells, or packages and labels the resulting human food products.[138] These establishments must carry the appropriate marks of inspection.[139] The USDA must also use existing FSIS regulations (including sanitation and physical product inspection, Hazard Analysis and Critical Control Point (HACCP) verification, product testing, and records review) to ensure that "resulting products are safe, unadulterated, wholesome and properly labeled."[140] Any labels that appear on cell-cultured food products derived from livestock and poultry are to be both preapproved and verified in accordance with FSIS regulations.[141] The proposed scheme also authorizes the USDA to develop additional requirements on safety and labeling as necessary, and to conduct enforcement actions to ensure that misbranded, mislabeled, and adulterated products do not enter the market or, if they do, that they are quickly removed when identified.[142]

The key for success in this joint venture will be openness. Both agencies must share information and collaborate with each other under the terms of the agreement.[143] The agencies have openly stated that they intend to work together to guarantee that the actions of both agencies are consistent and transparent.[144] According to the FDA, this approach "will leverage both the FDA's experience regulating cell-culture

137. 21 U.S.C. §§ 451–473.

138. *Id.*

139. *Id.*

140. *Id.*

141. *See id.* ("USDA-FSIS will . . . [r]equire that the labeling of human food products derived from the cultured cells of livestock and poultry be preapproved and then verified through inspection, as required by FSIS regulations.").

142. *See id.* (providing that the USDA may, "[a]s needed, develop additional requirements to ensure the safety and accurate labeling of human food products derived from the cultured cells of livestock and poultry subject to the FMIA and PPIA").

143. *See id.* (highlighting, throughout the agreement, a collaborative working arrangement between the two agencies).

144. *See id.* ("The Parties will develop joint principles for product labeling and claims to ensure that products are labeled consistently and transparently.").

technology and living biosystems and the USDA's expertise in regulating livestock and poultry products for human consumption."[145] Further, the agencies are confident that they can successfully implement this regulatory framework using existing statutory authority, which will ensure the safety of these products without the need for new legislation on the topic.[146] The rationale for these justifications seems to score one for efficiency in oversight and one for expediency of process.

The agreement, as established between the two agencies alone, was formalized on March 7, 2019.[147] Then, in December 2019, senators from Wyoming and Montana introduced the Food Safety Modernization for Innovative Technologies Act,[148] seeking to codify the terms of that agreement.[149] The Act would amend the FDCA to add a new section specifically regarding "Food Produced Using Animal Cell Culture Technology," and would require the Secretary of Health and Human Services to collaborate with the Secretary of Agriculture on overseeing food that is intended for human consumption and produced using animal cell-culture technology (specifically those cell lines derived from livestock or poultry).[150] At no point did any other agency or congressional source question the agencies' decision to share oversight. Instead, to the extent that there was commentary, the government focused on how it would accomplish shared oversight. [151]

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145. Press Announcement, *supra* note 129.

146. *See id.* ("Because our agencies have the statutory authority necessary to appropriately regulate cell-cultured food products derived from livestock and poultry the [FDA] does not believe that legislation on this topic is necessary.").

147. *Formal Agreement Between FDA and USDA*, *supra* note 20.

148. S. 3053, 116th Cong. (2019).

149. The bill was introduced on December 16, 2019, in the Senate, where it was read twice and then referred to the Committee on Agriculture, Nutrition, and Forestry. *All Actions § S.3053—116th Congress (2019-2020)*, CONGRESS.GOV (2019), https://perma.cc/C49N-DMD4. There has been no movement on the bill since then. *Id.*

150. *See* S. 3053, 116th Cong. § 2 (2019) (detailing the proposed amendment to the FDCA).

151. Since then, only one federal body has spoken on the regulation of cell-cultured meat. The Government Accountability Office (GAO) issued a report—FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat—in April 2020. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-20-325, FDA AND USDA COULD STRENGTHEN

The story, when told in this way, seems like a most propitious turn of events. After an initial regulatory turf war, the agencies jointly decided to work together towards a common goal, capitalize on their own expertise, and introduce no new regulations to oversee this new food technology.[152] This explanation may be either overly optimistic or overly simplistic. Serious questions remain. Aside from the looming question of whether public agencies should voluntarily cede power at their own discretion,[153] one must ask whether the USDA's

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EXISTING EFFORTS TO PREPARE FOR OVERSIGHT OF CELL-CULTURED MEAT 1 (2020). The GAO made three distinct recommendations to the FDA and USDA: (1) the Commissioner of the FDA and the Secretary of Agriculture should more fully incorporate the seven leading practices for effective collaboration in the agencies' interagency agreement for the joint oversight of cell-cultured meat; (2) as the three cell-cultured meat working groups move forward, the Commissioner of the FDA and the Secretary of Agriculture should more fully incorporate the seven leading practices for effective collaboration, such as identifying specific outcomes and a way to monitor and evaluate progress toward outcomes; and (3) the Commissioner of the FDA and the Secretary of Agriculture should clearly document in their interagency agreement, or other publicly available document, which agency will oversee cell-cultured seafood other than catfish. *Id.* at 31–32. The GAO's insistence on the seven leading practices for effective collaboration is notable.

152. *See* GREENE & ANGADJIVAND, *supra* note 17, at 1–2. Whether it is truly possible to regulate a novel food product (with no comparators) without a single new regulation is debatable.

153. According to Jason Marisam, Minnesota Assistant Attorney General and former law professor, both the Constitution and the Economy Act, 31 U.S.C. § 1535 (2006), constrain exchanges in this interagency marketplace. *See* Jason Marisam, *The Interagency Marketplace*, 96 MINN. L. REV. 886, 888 (2012). Under the Constitution, if Congress has specifically delegated authority to an agency, that agency cannot redelegate that authority. *Id.* at 887. Likewise, an agency cannot transfer funds appropriated by Congress to another agency. *Id.* The Economy Act further limits the agencies by providing rules and procedures to govern the marketplace. *Id.* Significantly, the Act prohibits the redelegation of tasks unless (1) the agency retains responsibility over the tasks, (2) tasks are not part of the agency's primary administrative function, and (3) tasks do not involve significant decision-making authority. *Id.* at 888. Whether the FDA's agreement to give labeling authority to the USDA can be seen as a redelegation is beyond the scope of this Article. It is worth noting that, to the extent it can, the more significant and central to the agency's core mission a regulatory power is, the less likely it is that it can be redelegated under the Economy Act. *See id.* at 906. There is no doubt that the FDA is also responsible for regulating safety issues associated with animal cell-culture technology, such as growing organs. *See* GAO-20-325, *supra* note 151, at 2. It is unclear why the technology should be distinguished from the end product in this space, but not in any others.

involvement in the regulation of cell-cultured meat is either necessary or appropriate.

III. THE USDA'S INVOLVEMENT IN THE REGULATION OF CELL-CULTURED MEAT IS INAPPROPRIATE

Both the FDA and the USDA play an important role in providing for the safety of human food.[154] The USDA is responsible for the implementation and enforcement of the FMIA, the PPIA, and the Egg Products Inspection Act.[155] Under these authorities, the USDA regulates the meat that comes from amenable species, like: cattle, hogs, sheep, goats, equines, poultry (chicken, turkeys, ducks, geese, squab, guinea fowl, and ratites), catfish, and egg products.[156] In other words, the USDA oversees domestic and imported meat and poultry (excluding game meat), meat- or poultry-containing products (such as stews, pizzas, and frozen foods), processed egg products (liquid, frozen, or dried), and catfish.[157] The FDA, on the other hand, is responsible for all other foods, including: game meat, fish and seafood (excluding catfish), processed meat products (containing 2-to-3 percent meat), and shell eggs.[158] The FDA, in other words, oversees all domestic and imported food sold across state lines, except for meat and poultry.[159]

Because regulating the country's food is such a large task and because the delegations of authority are broad, oversight

154. Although it is not relevant to this Article, it bears mentioning that a number of other agencies are also involved with protecting the U.S. food supply, such as the Centers for Disease Control and the Environmental Protection Agency, to name a few. *See About FSIS: Food Safety Agencies & Partners*, USDA (2019), https://perma.cc/4MG6-W9QK.

155. 21 U.S.C. §§ 1031–1056 (2018).

156. *See* GAO-20-325, *supra* note 151, at 2.

157. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-05-213, OVERSIGHT OF FOOD SAFETY ACTIVITIES: FEDERAL AGENCIES SHOULD PURSUE OPPORTUNITIES TO REDUCE OVERLAP AND BETTER LEVERAGE RESOURCES 2 (2005) https://perma.cc/E89G-KY67 (PDF) ("USDA is responsible for ensuring the safety of meat, poultry, and certain egg products . . . .").

158. *Id.*

159. The FDA implements and enforces the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301–399i), the Food Safety Modernization Act (21 U.S.C. §§ 2201–2257), the Public Health Service Act (42 U.S.C. §§ 201–300mm), and the Fair Packaging and Labeling Act (15 U.S.C. § 1451–1461). *See* GAO-05-213, *supra* note 157, at 1.

often overlaps between the FDA and the USDA. Take soup for example. The USDA will inspect a canning facility that produces food containing meat and poultry.[160] The FDA will also inspect that same facility if it produces canned soups that contain beans or seafood.[161] Packaged sandwiches present another interesting example. The USDA regulates open-faced sandwiches so long as the ratio of meat to bread (and other ingredients) is more than 50 percent.[162] Yet, the FDA regulates closed sandwiches, those with two slices of bread,[163] because the ratio of meat to other ingredients is less than 50 percent.[164]

Overlap in oversight in the case of cell-cultured meat, however, is completely unnecessary and will certainly lead to problems with implementation. There are three primary reasons that the USDA and the FMIA are not the appropriate governing body and mechanism for cell-cultured meat. First, cell-culturing is outside the scope of the USDA's mandate, and the agency's oversight expertise in this context is largely irrelevant. The FMIA's primary purpose is to prevent meat adulteration or contamination.[165] The greatest risk of contamination to cell-cultured meat will occur in the lab, which is under FDA oversight. Second, the FMIA may be read to proscribe USDA oversight of cell-cultured meat. Finally, since the broader law and policy arena have already distinguished cell-cultured meat from conventional meat, the USDA should

160. *See id.* at 16 ("For example, USDA inspects a canning facility at least daily if it produces food containing meat and poultry.").

161. *See id.* ("If the facility also produces canned soups containing beans or seafood, FDA inspects it every 1 to 5 years.").

162. *See* USDA, FOOD STANDARDS AND LABELING POLICY BOOK 155 (2005), https://perma.cc/E895-QN93 (PDF) [hereinafter FOOD STANDARDS AND LABELING POLICY BOOK] (defining open-faced sandwiches as "contain[ing] at least 50 percent cooked meat" and noting that "[s]andwiches are amenable only if they are open faced sandwiches").

163. *See* Meg Marco, *US Food Safety Is Broken: Different Agencies Oversee Open-Faced vs. Closed-Faced Sandwiches*, CONSUMERIST (Feb. 1, 2007, 7:35 PM), https://perma.cc/ZE9V-ZD96 (citing a GAO report that says "FDA inspects manufacturers of packaged closed-face . . . sandwiches (e.g., those with two slices of bread)").

164. *See* FOOD STANDARDS AND LABELING POLICY BOOK, *supra* note 162, at 155 (identifying that closed sandwiches are not amenable to inspection because they "contain at least 35 percent cooked meat and no more than 50 percent bread").

165. *See* 21 U.S.C. § 602.

decline responsibility for labeling to preserve horizontal coherence. It stands to reason that if cell-cultured meat is not technically meat, as has been established elsewhere in law and policy (often with tacit approval from the USDA), then the allocation of labeling authority to the USDA is improper and impermissible.

A. *USDA Mandates and Concomitant Problems*

1. The Multiple Mandate Problem

Given the structure of the United States government and its reliance on federal agencies for a large swath of governance, many federal agencies are assigned multiple mandates. Occasionally, these mandates conflict. For example, the National Park Service must protect the natural resources of the federal parks *and* permit their public use and accessibility to visitors.[166] The Federal Aviation Administration must "encourage the development of civil aeronautics" *and* provide for the safety of air commerce.[167] How should the National Park Service act if the best way to preserve our national parks is to close them to visitors?[168] What should the Federal Aviation Administration do if it finds that civilian-operated drones pose a large threat to the safety of public airways, but their use is the best way to expand our air transportation network and provide for its economic growth? Similar questions and concerns reverberate throughout the regulatory sphere.

166. *See* 54 U.S.C. § 100101 (setting the Park Service's responsibility to "conserve the scenery, natural and historic objects, and the wild life [therein] and to provide for the enjoyment of [the same] in such manner and by such means as will leave them unimpaired for the enjoyment of future generations").

167. *See* 49 U.S.C. § 40104(a) ("The Administrator of the [FAA] shall encourage . . . safety of air commerce in and outside the United States.").

168. Congress will, on occasion, provide guidance on how to balance conflicting mandates. In the case of the Park Service, for example, Congress prioritizes conservation over the enjoyment of visitors. *See* 16 U.S.C. § 668ee(1) (explaining that "compatible use" "means a wildlife-dependent recreational use or any other use of a refuge that, in the sound professional judgement of the Director, will not materially interfere with or detract from the fulfillment of the mission of the System or the purposes of the refuge").

In these instances, agencies must make tradeoffs between two congressionally mandated goals.[169] Professor Eric Biber, after an extensive review of economic and political science literature on the subject of principal-agent interactions, argues that federal agencies (acting as agents of Congress, the President, and the general public) with conflicting tasks "will systematically overperform on the tasks that are easier to measure and have higher incentives, and underperform on the tasks that are harder to measure and have lower incentives."[170] Once an agency prioritizes one goal over another, it becomes easier for that agency to continue to privilege that same goal going forward.[171]

2. The USDA's Congressional Mandate

The thirty-seventh Congress of the United States established the Department of Agriculture, and President Abraham Lincoln signed the Act into law, in 1862.[172] The enabling statute requires the USDA "to acquire and to diffuse among the people of the United States useful information on subjects connected with agriculture in the most general and comprehensive sense of that word, and to procure, propagate, and distribute among the people new and valuable seeds and plants."[173] The Commissioner of Agriculture was tasked with acquiring any knowledge on the science of agriculture; sourcing new and valuable seed varieties to cultivate, propagate, and distribute; and reporting to Congress.[174] At its inception, the organization's mission was primarily focused on improving agricultural productivity through scientific research, farm

169. *See* Eric Biber, *Too Many Things to Do: How to Deal with the Dysfunctions of Multiple-Goal Agencies*, 33 HARV. ENV'T L. REV. 1, 3 (2009) (explaining, for example, how the National Park Service must balance the harms of air pollution with wanting visitors to drive to national parks).

170. *Id.* at 9.

171. *See id.* at 3 (offering, as an example, the federal public land management agencies, which "have been accused of systematically privileging one or more of their goals—often related to economic development—over others—often related to environmental protection").

172. Act to Establish a Department of Agriculture, ch. 72, 12 Stat. 387 (1862) (codified as amended at 7 U.S.C. § 2201).

173. *Id.*

174. *Id.*

technology (including new seed varieties), and information on farming practices.[175]

Absent from the USDA's original congressional mandate is any discussion of financial support for farmers.[176] The Department was not assigned responsibility for the stabilization of farm incomes and rural development until the Great Depression and the New Deal.[177] To stabilize the downwardly spiraling wheat and cotton prices in the period leading up to the Great Depression, President Herbert Hoover established the Farm Board via the Agricultural Marketing Act of 1929.[178] To accomplish these goals, the Board was to set a price floor, and when the price of grain and cotton fell below the established threshold, the Board would buy and hold the surplus grain and cotton in storage and then resell it later when the prices rebounded.[179] Later, as part of the New Deal, President Franklin D. Roosevelt signed the Agricultural Adjustment Act of 1933.[180] The Act provided subsidies to farmers who agreed not to plant certain crops or to kill off certain livestock.[181] The goal of this policy was to prop up prices by reducing supply.[182]

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175. *Id.*

176. *See* JAYSON L. LUSK, THE EVOLVING ROLE OF THE USDA IN THE FOOD AND AGRICULTURAL ECONOMY 13 (2016), https://perma.cc/M6B2-H27P (PDF) ("Food safety, financial support for farmers, and environmental objectives were not a part of the USDA's initial focus.").

177. *See id.* at 13–14 (documenting the USDA's transition from farm innovation to farmer support during the New Deal).

178. Pub. L. No. 71-10, 46 Stat. 11 (1929).

179. *See* Kyle Engel, *An Examination of Several Aspects of Federal Farm Legislation*, 31 S.D. L. REV. 341, 343 (1986) (explaining the Agricultural Marketing Act of 1929's mechanisms, including paying each farmer for his share of his crop).

180. Pub. L. No 73-10, 48 Stat. 31 (1933).

181. *See* Harold F. Breimyer, *Agricultural Philosophies and Policies in the New Deal*, 68 MINN. L. REV. 333, 343 (1984) (explaining the process under the Act by which farmers were offered compensation for voluntarily suspending production of surplus crops).

182. *See* Guadalupe T. Luna, *The New Deal and Food Insecurity in the "Midst of Plenty"*, 9 DRAKE J. AGRIC. L. 213, 234 (2004) (documenting the Agricultural Adjustment Act's original goal of reducing supply to increase prices).

Although the Supreme Court eventually ruled the Act unconstitutional,[183] it was in fact the nation's first farm bill.[184]

The USDA's shift from purveyor of technological innovation to farmer support system marked a clear departure for the agency. By 1933, the Department could no longer claim to represent the interest of the American people but instead represented the interests of the American farmer. Further, the Department's attempts to stabilize farm incomes and support the sale of agriculture firmly aligned the agency with the business side of industry. After almost a century of new mandates, policy initiatives, and programs, the Department's ties to the agriculture industry have become much clearer. While it is now nearly impossible to provide a concise mandate for the USDA, Congress appeared to attempt it with the introduction of the Food, Agriculture, Conservation, and Trade Act of 1990,[185] which authorizes many of the Department's modern programs. There, Congress describes the mandate of the agency as: "to extend and revise agricultural price supports and related programs, to provide for agricultural export, resource conservation, farm credit, and agricultural research and related programs, to ensure consumers an abundance of food and fiber at reasonable prices and for other purposes."[186] In simpler terms, the Department seeks to maximize profits and minimize losses within the various agricultural sectors. These goals are totally wound up in the business of agriculture.

Beyond the congressional mandate, the Department's own mission statement is telling. The Department "ha[s] a vision to provide economic opportunity through innovation, helping rural America to thrive; to promote agriculture production that better nourishes Americans while also helping feed others throughout the world; and to preserve our Nation's natural resources through conservation, restored forests, improved watersheds,

183. *See* United States v. Butler, 297 U.S. 1, 68 (1936) (holding that the Agricultural Adjustment Act of 1933 was unconstitutional because it impermissibly infringed on states' rights by regulating agriculture—a purely "local" subject).

184. *See* LUSK, *supra* note 176, at 15.

185. Food, Agriculture, Conservation, and Trade Act of 1990, Pub. L. No. 101–624, 104 Stat. 3359.

186. *Id.* pmbl., 104 Stat. at 3359.

and healthy private working lands."[187] To accomplish these goals, the Department has established several primary working areas. These include: (1) Farm Production and Conservation;[188] (2) Food, Nutrition, and Consumer Services;[189] (3) Food Safety;[190] (4) Marketing and Regulatory Programs;[191] (5) Natural Resources and Environment;[192] (6) Research, Education, and Economics;[193] (7) Rural Development;[194] and (8) Trade and Foreign Agricultural Affairs.[195] For purposes of this

187. *About the U.S. Department of Agriculture*, *supra* note 11.

188. *See Mission Areas*, USDA, https://perma.cc/F52G-SCSQ ("FPAC agencies implement programs designed to mitigate the significant risks of farming through crop insurance services, conservation programs and technical assistance, and commodity, lending, and disaster programs.").

189. *See id.*

> Food, Nutrition, and Consumer Services works to harness the Nation's agricultural abundance to end hunger and improve health in the United States. Its agencies administer federal domestic nutrition assistance programs and the Center for Nutrition Policy and Promotion, which links scientific research to the nutrition needs of consumers through science-based dietary guidance, nutrition policy coordination, and nutrition education.

190. *See id.* ("Food Safety ensures that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled, and packaged.").

191. *See id.* ("Marketing and Regulatory Programs facilitates domestic and international marketing of U.S. agricultural products and ensures the health and care of animals and plants.").

192. *See id.* ("Natural Resources and Environment ensures the health of the land through sustainable management. Its agency works to prevent damage to natural resources and the environment, restore the resource base, and promote good land management.").

193. *See id.* (noting that the Research, Education, and Economics group "is dedicated to the creation of a safe, sustainable, competitive U.S. food and fiber system, as well as strong communities, families, and youth through integrated research, analysis, and education").

194. *See id.*

> Rural Development is committed to helping improve the economy and quality of life in all of rural America by providing financial programs to support essential public facilities and services [such] as water and sewer systems, housing, health clinics, emergency service facilities and electric and telephone service. Rural Development promotes economic development by providing loans to businesses through banks and community-managed lending pools, while also assisting communities to participate in community empowerment programs.

195. *See id.*

Article, Food, Nutrition, and Consumer Services and Food Safety are the most important working areas. Food, Nutrition, and Consumer Services works, in part, to "improve health in the United States," while Food Safety "ensures that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled, and packaged."[196]

3. The Department's Mixed Mandate

As the USDA continues to suffer from mission creep, more and more of its multiple objectives conflict. Paradoxically, the Department must:

> (1) increase the efficiency of agricultural production to produce more food at a lower cost, while trying to reduce obesity and promote organic practices that lower yields and increase costs; (2) help small, minority, and beginning farmers and promote farmers markets, while trying to ensure food security for the nation and promoting exports to consumers elsewhere; (3) pay producers to remove environmentally sensitive lands from production, which increases food prices and thus the amount of assistance needed by low-income households; and (4) create nutritional guidelines that recommend eating fewer animal products, while helping fund promotional campaigns that encourage consumption of those products and conducting research that makes such products less expensive.[197]

The primary conflict at issue here arises when the dictates of the USDA mandates require the Department to support either an industry or the public.[198] Said differently, the

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> Trade and Foreign Agricultural Affairs' (TFAA) role is to provide our farmers and ranchers with opportunities to compete in the global marketplace. TFAA is the Department's lead on trade policy with primary responsibility to ensure USDA speaks with a unified voice on international agriculture issues domestically and abroad. Within TFAA, the Foreign Agricultural Service is the lead U.S. agency tasked with promoting exports of U.S. agricultural products through market intelligence, trade policy, trade capacity building, and trade promotion programs.

196. *Id.*

197. LUSK, *supra* note 176, at 53–54.

198. *See* COURTNEY I. P. THOMAS, IN FOOD WE TRUST 72–73 (2014) (discussing the profit-maximizing strategies of industry players and how profit maximization affects the USDA's approach to consumer food safety).

Department is so often wedded to its mission to support the various agricultural industries, that it has often acted against the best interest of the public to further its industry-specific goals. As Biber explained, this could be because industry outcomes and dollar amounts are easier to measure and come with higher incentive, or because this has so long been the practice that institutional memory knows no other way.[199]

There are numerous examples of USDA mandates conflicting. For example, in the case of milk, the Department has employed its marketing and regulatory programmatic arms to partner with fast food companies to increase consumption of subsidized commodities (including dairy, corn, wheat, meat, and soy),[200] while simultaneously recommending that Americans avoid high-fat dairy products because of their harmful effects.[201] The USDA also purchases excess dairy (often high-fat dairy) from farmers and sells it directly to consumers.[202] To sell the surplus resulting from the 2008 Farm Bill,[203] the Department

199. *See* Biber, *supra* note 169, at 9, 41.

200. *See* Andrea Freeman, *Behavioral Economics and Food Policy: The Limits and Politics of Nudging*, *in* NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL 124, 130–31 (I. Glenn Cohen et al. eds., Johns Hopkins University Press (2016)) (explaining various commodity subsidies and how they contribute to large surpluses which need to be sold); *see also* Deena Shanker, *Milking It: How the US Government Helped McDonald's Climb Out of Its Sales Rut*, QUARTZ (Oct. 29, 2015), https://perma.cc/8P56-ANQ2; Kiera Butler, *How the US Government Helps McDonald's Sell Junk Food*, MOTHER JONES (June 23, 2014), https://perma.cc/NA6V-PCFK; Scott Fields, *The Fat of the Land: Do Agricultural Subsidies Foster Poor Health?*, 112 ENV'T HEALTH PERSPS. A820, A821–22 (2004).

201. *See* USDA & HHS, DIETARY GUIDELINES FOR AMERICANS, 2010, at 2 (7th ed. 2010) (documenting the USDA's nutritional recommendations for American consumers). Many of these actions can be explained by the Department's adherence to principles of corporate neoliberalism. *See, e.g.*, Andrea Freeman, *The Unbearable Whiteness of Milk: Food Oppression and the USDA*, 3 U.C. IRVINE L. REV. 1251, 1263 (2013) [hereinafter Freeman, *Unbearable Whiteness of Milk*] (explaining that the USDA functions much like a private corporation in its attempts to maximize profits or minimize losses for the dairy industry).

202. *See* Freeman, *Unbearable Whiteness of Milk*, *supra* note 201, at 1266 (discussing the USDA's decision under the 2008 Farm Bill to purchase excess supplies of milk and sell them directly to consumers). Notably, Americans drink less than a third of the milk produced by American dairy farmers. *Id.*

203. Food, Conservation, and Energy Act of 2008, Pub. L. No. 110–246, 122 Stat. 1651.

relied on the "Got Milk?" campaign, an extremely successful advertising campaign that has spanned over twenty years.[204]

The USDA must frequently employ these tactics because of its earlier decisions. For example, the government has historically subsidized corn farmers.[205] The corn farmers, then, have lower costs and can thus harvest and produce more corn.[206] The wide availability of corn combined with the lower costs results in lower prices,[207] resulting in consumers purchasing more corn.[208] Because corn (along with dairy, soy, and wheat) receives so much support from the USDA, it is ubiquitous in American life.[209] It is widely available in grocery stores, restaurants, federal food programs, etc. in a variety of forms (including high-fructose corn syrup).[210] Ultimately, the subsidy-created surplus incentivizes both the producers and the USDA (wearing its support hat) to increase sales to consumers.

In the case of corn, most subsidies go to large scale agricultural operations,[211] where the production methods result in corn that is unfit for direct human consumption.[212] Those

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204. *See* Freeman, *Unbearable Whiteness of Milk*, *supra* note 201, at 1266–67.

205. Jennifer Mosquera, *Corn, Cows, and Cash: How Farming Subsidies Work and What They Could Potentially Achieve*, 34 J. LAND USE & ENV'T L. 191, 194–95 (2018).

206. *See* Jonathan Foley, *It's Time to Rethink America's Corn System*, SCI. AM. (Mar. 5, 2013), https://perma.cc/7CXH-UCFA (analyzing the production effects of government subsidies on harvest yields and corn prices).

207. Anthony Kammer, *Cornography: Perverse Incentives and the United States Corn Subsidy*, 8 J. FOOD L. & POL'Y 1, 27–28 (2012).

208. *See id.* at 29–30 (explaining how consumers purchased more heavily-subsidized commodities, like corn, because of increased agricultural subsidies).

209. *See id.* at 32 ("[S]ubsidies have reduced the real cost consumers pay for a range of [unhealthy foods], while healthier foods such as unprocessed fruits and vegetables have seen significant real price increases.").

210. *See* Mosquera, *supra* note 205, at 198 ("Most of the corn produced for consumption in the United States is processed into the high-fructose corn syrup found in many processed foods.").

211. LUSK, *supra* note 176, at 26. Farms that sell less than $50,000 worth of products tend not to receive any USDA farm subsidy funds. *Id.* at 25. In contrast, 3.9 percent of American farms sell $1 million or more in products, and most of these farms receive payments averaging $40,559. *Id.* at 26. Payment amount increases with the size of or output from the farm. *Id*.

212. *See Field Corn vs. Food Corn*, NEB. CORN BD. (2021), https://perma.cc/9GY8-JBQ8 (distinguishing "field corn," which "must go

farmers must therefore sell their corn to other industries, namely sweetened beverage manufacturers.[213] The sweetened beverage manufacturers use the corn to create high-fructose corn syrup, which is used to sweeten soft, energy, and sports drinks.[214] Because the sweetened beverage manufacturers are now dependent on the corn growers, the USDA has a high stake in the sale of these beverages, and this has driven much of the government's policy on these drinks.

These deceptive practices are the result of two dueling mandates. In her research on the USDA's relationship with the dairy industry, Professor Andrea Freeman argues that the Department's mandate to "expand[] markets for agricultural products" directly contradicts its mandate to "improv[e] nutrition and health by providing . . . nutrition education and promotion."[215] Because the Department cannot both expand the market for dairy and improve overall health (given the science on dairy consumption),[216] it tends to favor industry at the expense of consumers.[217] Ultimately, Professor Freeman finds that this behavior disproportionately harms socially vulnerable consumers and attributes it to institutional design.[218] She argues, in part, that the USDA's multi-role status forces the Department to decide how to prioritize its goals and to resolve direct conflicts.[219]

As it relates to meat, we see this problem primarily within one particular agency. Of the USDA's eighteen primary agencies,[220] the Agricultural Marketing Service (AMS) is most

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through a mill and be converted to food products and ingredients like corn syrup" before humans can consume it, from other corn varieties that humans can consume without processing, like sweet corn and popcorn).

213. Kathryn Doyle, *Foods from Subsidized Commodities Tied to Obesity*, REUTERS (July 5, 2016), https://perma.cc/KD4L-DK9Q.

214. *Id.*

215. Freeman, *Unbearable Whiteness of Milk*, *supra* note 201, at 1263 (second alteration in original).

216. *See supra* note 201 and accompanying text.

217. *Id.* at 1263–64.

218. *Id.* at 1264.

219. *Id.*

220. These include: (1) Agricultural Marketing Service; (2) Agricultural Research Service; (3) Animal and Plant Health Inspection Service; (4) Economic Research Service; (5) Farm Service Agency; (6) Food and Nutrition Service; (7) Food Safety and Inspection Service; (8) Foreign Agricultural

directly tasked with promoting competition. AMS's mission is to "administer[] programs that create domestic and international marketing opportunities for U.S. producers of food, fiber, and specialty crops."[221] Notably, the agency is also tasked with "provid[ing] the agriculture industry with valuable services to ensure the quality and availability of wholesome food for consumers across the country."[222] This is the precise dichotomy that produces the aforementioned conflict. Moreover, AMS's Livestock and Poultry Program, formerly known as the Grain Inspection, Packers, and Stockyards Administration (GIPSA) (and absorbed by AMS in 2017), has always taken a very active role in promoting and ensuring the livelihoods of farmers, ranchers, and producers.[223]

GIPSA was a very active agency. Not only did it concern itself in the economic state and business practices of the livestock and poultry industries, but it also engaged in rulemaking, investigation, and enforcement activities.[224] Under the Obama administration, the agency drafted new rules seeking to regulate competition and held hearings related to accusations of imperfect competition in the meat sector (Congress ultimately stopped this effort).[225] The agency also conducted its own studies, initiated its own investigations, and

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Service; (9) Forest Service; (10) FPAC Business Center; (11) National Agricultural Statistics Service; (12) National Institute of Food and Agriculture; (13) Natural Resources Conservation Service; (14) Risk Management Agency; (15) Rural Development; (16) Rural Utilities Service; (17) Rural Housing Service; and (18) Rural Business-Cooperative Service. *See Agencies*, USDA, https://perma.cc/CG82-47E9.

221. *About AMS*, USDA, https://perma.cc/MQ9G-MUX7.

222. *Id.*

223. *See id.* (explaining that in 2017 Secretary Perdue realigned offices in the USDA to help the Department "better meet the needs of farmers, ranchers, and producers, while providing improved customer service and maximize efficiency").

224. *See* USDA, GIPSA, STRATEGIC PLAN FY 2016–2020 15 (2016), https://perma.cc/6YUF-LUDU (PDF).

225. *See* JOEL L. GREENE, CONG. RSCH. SERV., R41673, USDA'S "GIPSA RULE" ON LIVESTOCK AND POULTRY MARKETING PRACTICES 3–5 (2016) (documenting the regulations GIPSA drafted during the Obama Administration in response to consolidation of various agricultural sectors).

monitored outcomes.[226] In 2013, for example, GIPSA charged $106,387 in fines for violations of the Packers and Stockyards Act and won almost $3 million in litigation (primarily through rulings issued by an administrative law judge).[227] This all accords with Department efforts to promote the economic viability of the industry.

Not long before GIPSA was absorbed by AMS, its Packers and Stockyard Division (PSD) had begun to include plant-based and lab-created proteins in its list of industry concerns.[228] According to the agency's 2019 Annual Report:

> Consumer interest in non-meat-based proteins has accelerated in recent years. In response, investment has increased in plant-based proteins and biotechnological innovations such as cultured meat. While Beyond Meat and Impossible Foods are at the forefront offering alternatives to animal-based burgers, sausage, and chicken, several competitors have also developed their own brands of plant-based proteins, including Tyson Foods, Conagra, Nestle, and Kellogg.
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> Several animal industry trade groups are continuing to educate consumers and policymakers about differences between animal-based meat and alternative-meat products. These trade groups are also seeking protections from the Federal Government and State Governments in the marketing and labeling of plant-based and lab-created protein items to ensure they are not labeled as meat, beef, or burgers, for example.[229]

This blatant, pro-industry bias further demonstrates why the USDA should not regulate cell-cultured meat.

One problem with the USDA's conflicting mandates, specifically as they relate to meat, is that a large body of evidence suggests that the Department, when forced to choose, will always side with industry. The PSD, a formerly powerful

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226. *See* USDA, PACKERS AND STOCKYARDS PROGRAM 2013 ANNUAL REPORT 23 (2014), https://perma.cc/68J5-G65D (PDF) (documenting the various programs the Program initiated in support of its enforcement responsibilities).

227. *Id.* at 8.

228. USDA, PACKERS AND STOCKYARDS DIVISION ANNUAL REPORT 2019 1 (2020), https://perma.cc/E36Y-R36K (PDF).

229. *Id.*

arm of the USDA, was explicitly tasked with protecting competitive markets for livestock, meat, and poultry.[230] Moreover, the PSD had already identified lab-created proteins as an industry concern, and based on the language of its report, tacitly, if not openly, approved of attempts at protectionism being advanced by "several" animal industry trade groups.[231] There is no reason to suspect that these same principles and priorities were lost in the agency realignment. Further, given that the Department has already sided with industry in the cases of dairy and corn, there is no reason to expect a different outcome in the case of cell-cultured meat.

If we know that the Department has multiple mandates, which might often conflict and generally go against the greater good of the public, then it logically follows that the Department's involvement in the regulation of cell-cultured meat is inappropriate. Here, the Department is tasked with "improv[ing] health in the United States" on one side and with maximizing profits and minimizing losses for the beef and cattle industry on the other. These two goals cannot peacefully coexist.

4. Agency Capture

The mixed mandate problem has either created or exacerbated a capture problem whereby the animal agriculture industry exercises an outsized influence on the USDA.[232] Since its inception, the USDA has maintained a relatively cozy relationship with the beef and cattle industry.[233] The interests

230. *See id.* at 25 (analyzing the PSD's Competition Branch and the anti-competitive behavior it was responsible for preventing).

231. *See id.* at 22 ("Several industry trade groups are continuing to educate consumers and policymakers about differences between animal-based meat and alternative-meat products.").

232. Regulatory capture occurs whenever a federal agency prioritizes the interest of a specialized interest group over the public. *See* Scott Hempling, *"Regulatory Capture": Sources and Solutions*, 1 EMORY CORP. GOVERNANCE & ACCOUNTABILITY REV. 23, 24–25 (2014). The problem is that the rent-seeking, relatively small interest group can leverage its resources to command some or all of the benefits of a program that would otherwise be a public good. *Id.* Significantly, the costs are almost always borne by the taxpayers. *Id.* at 28.

233. Michael Taylor, the head of the Food Safety and Inspection Service (FSIS) under President Clinton, has stated, "It is just a political context, a culture that has developed over the years at the political level, the food safety program at the USDA thinking of the industry as the customer rather than

of the USDA and livestock lobby are so intertwined that the agency is incapable of promulgating regulations motivated solely by public interests.[234] This phenomenon is known as capture, and it completely dictates the agency's strategy.[235] This means that the USDA, as the long arm of the livestock industry, acts more like a lobbyist than like a public agency.[236] Further, once a regulator is "captured," industry representatives (lobbyists) seek to ensure that all new rules and regulations benefit the regulated parties.[237] Here, in the case of cell-cultured meat, the USDA must then prioritize the interests of the beef and cattle lobby over those of the general public.

While the USDA might have initially regulated in the public interest, Professor John Shepard Wiley, Jr. argues that it is difficult for an agency to remain independent, and that its regulations simply become "a method of subsidizing private interests at the expense of public good."[238] Moreover,

> [o]nce capture becomes an entrenched feature of agency culture, it can be difficult to uproot. . . . Efforts by Congress or the Executive Branch to eliminate capture are unlikely to pay political dividends and will probably antagonize

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the consumer, and thinking in terms of efficient inspection rather than protecting public health." Steve Johnson, *The Politics of Meat*, PBS: FRONTLINE, https://perma.cc/CTQ5-DM46. Taylor realized just how cozy the relationship between the USDA and the beef industry was upon entering his new office and discovering that of the two numbers programmed for speed dial on his telephone, one was for the American Meat Institute and the other was for the National Cattlemen's Association. *Id*.

234. *See* Dion Casey, *Agency Capture: The USDA's Struggle to Pass Food Safety Regulations*, 7 KAN. J.L. & PUB. POL'Y 142, 143 (1997) ("Often, it is only where there is a public outcry over industry practices that agencies step in to protect public interests . . . .").

235. *Id.* at 142.

236. *Id*.

237. *Id*.

238. John Shepard Wiley, Jr., *A Capture Theory of Antitrust Federalism*, 99 HARV. L. REV. 713, 723 (1986). It is important to note that the USDA is not the only captured agency. The Securities and Exchange Commission (SEC), for example, refused to investigate Bernie Madoff for ten years even though it had been repeatedly warned that Madoff's financial statements did not make sense. *See* Dick Carozza, *SEC Watchdog Monitors Agency's Progress After Madoff Case*, FRAUD MAG. (May 2010), https://perma.cc/NE8H-P74T. The SEC's inaction led to the loss of billions of dollars for investors. *Id*. Madoff was an influential member of the investment community and thus the SEC never satisfactorily supervised or audited him. *Id*.

> powerful interest groups. Complacency seems the better course—for everyone but the public at large.[239]

There is vast literature on the USDA's captured regulator status as the beef and poultry industries captured the agency long ago.[240] Professor Marion Nestle writes that "meat and poultry producers . . . generously support both political parties, form close personal relationships with members of Congress and officials of regulatory agencies, and often use the so-called revolving door to exchange their executives' positions for those in government and vice versa."[241] The result of this relationship is "decades of industry and government indifference, dithering, and outright obstructionism."[242] Naturally, it has followed that the USDA will protect the interest of the beef industry over the interests of the public.

Over time, the USDA—which is tasked with protecting the nation's interest—has come to identify itself with agribusiness generally, as well as the beef (the largest agribusiness industry) and poultry industries specifically.[243] This was possible, in part, because agribusiness has managed to keep a bevy of powerful allies in the upper levels of the USDA.[244] Previous Secretary of Agriculture, Sonny Perdue, for example, had deep ties to

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239. Nicholas Bagley, Response, *Agency Hygiene*, 89 TEX. L. REV. *SEE ALSO* 1, 1 (2010).

240. *See, e.g.*, Casey, *supra* note 234, at 147–56 (describing the USDA's inability to pass food safety regulations in the face of food-borne illnesses); Bruce Friedrich, *When the Regulators Refuse to Regulate: Pervasive USDA Underenforcement of the Humane Slaughter Act*, 104 GEO. L.J. 197, 202 (2015) (explaining that FSIS refuses to adequately administer the Humane Methods of Slaughter Act (part of FMIA)); MARION NESTLE, SAFE FOOD: THE POLITICS OF FOOD SAFETY 27–33 (2010) [hereinafter SAFE FOOD] (observing the resistance of the "major food industries" to agency oversight and regulation); MARION NESTLE, FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH 96–111 (2013) (describing the growth of "hundreds—if not thousands—of businesses, associations, and individuals attempting to influence federal decisions" about food); DAVID ROBINSON SIMON, MEATONOMICS: HOW THE RIGGED ECONOMICS OF MEAT AND DAIRY MAKE YOU CONSUME TOO MUCH—AND HOW TO EAT BETTER, LIVE LONGER, AND SPEND SMARTER 62–69 (2013) (describing USDA marketing efforts).

241. SAFE FOOD, *supra* note 240, at 62.

242. *Id*. at 27.

243. *See supra* note 233 and accompanying text.

244. *Id*.

agribusiness.[245] Perdue had started or otherwise been linked to more than a dozen agribusiness companies and limited liability corporations, and he had served on the board of the Georgia Agribusiness Council before he was appointed.[246] Further, Perdue had an extensive industry-friendly record evidenced by his years as Georgia's governor.[247] This record combined with other views—such as denying climate change—endear him to some of the largest groups that lobby the USDA.[248] Perdue's appointment was viewed as a gift to the agribusiness industry writ large.[249]

During his term, Secretary Perdue surrounded himself with other agribusiness leaders. His Chief of Staff, Heidi Green, for example, was formerly a partner in Perdue's shipping business.[250] The Deputy Secretary, Stephen Censky, came from a twenty-one-year stint as Chief Executive Officer of the American Soybean Association (which represents an industry worth tens-of-billions of dollars annually).[251] Ted McKinney, the former Undersecretary of Agriculture for Trade and Foreign Agricultural Affairs, spent his career in some of the world's largest multinational agribusiness companies, including Dow AgroSciences, DowElanco, and Elanco.[252] The list goes on.[253]

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245. *See* Colin O'Neil, *EWG Investigates: Trump's Agriculture Nominee Brings the Swamp to Washington*, ENV'T WORKING GRP. (Mar. 8, 2017), https://perma.cc/L52D-N2CQ (detailing Perdue's connections to agribusiness).

246. *Id*.

247. *See* Ricardo J. Salvador & Nora Gilbert, *Sonny Perdue Vows to Make American Agriculture Great Again—But for Whom?*, GUARDIAN (Jan. 29, 2017, 9:00 AM), https://perma.cc/SP34-LZUV (describing Perdue's record as governor of Georgia).

248. *See id*. (describing the positive industry reaction to Perdue's nomination as a "telling signal of what to expect").

249. *See id*. (sharing The National Chicken Council's, The National Cattlemen's Beef Association's, and The American Farm Bureau Federation's uniform praise of Perdue's appointment).

250. *See* Ian Kullgren, *How Perdue's Power Benefits His Friends*, POLITICO (Mar. 13, 2017), https://perma.cc/8APC-2MXP.

251. *See* Erica Shaffer, *USDA Deputy Secretary to Rejoin Soybean Group*, MEAT + POULTRY (Sept. 21, 2020), https://perma.cc/X8R6-PWHF.

252. *See Elanco Exec Becomes Ag Director*, INSIDE IND. BUS. (Aug. 18, 2015), https://perma.cc/B3RN-MNKX (describing McKinney's employment history).

253. For example, Rebeckah Adcock, a senior advisor in the Secretary's office who previously worked as a lobbyist for the Kentucky Farm Bureau, the

More important, however, are the policy decisions that these individuals helped to make.

A regulated industry is incentivized to lobby Congress and the politicians who oversee the specific agency—such as congressional committee and subcommittee members. The committees are important because they control an agency's legislative mandate and funding.[254] Thus, when an industry is unable to persuade the agency to see things its way, the industry can then focus its lobbyists on the congressional members serving on the committees that oversee the agency.[255] The beef and poultry industries are especially adept at this. It can be said that the meat industry has captured Congress. A report from the Center for Public Integrity, titled *Safety Last: The Politics of E. Coli and Other Food-Borne Killers*, evaluated congressional responses to food safety issues from the Reagan administration to the Clinton administration.[256] According to the report, meat interests have not only filled the campaign coffers of lawmakers, but also plied those lawmakers with all-expense paid trips and "dangl[ed] the possibility of lucrative post-employment opportunities."[257] In doing so, "the meat interests have overwhelmed the supposedly objective decision-making process in Washington."[258] In the context of food safety, for example, "attempts to give federal agencies the right to enforce food safety

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American Farm Bureau Federation, and CropLife America, all agribusiness groups. *See* Sara Wyant & Spencer Chase, *Meet Sec. Perdue's New Inner Circle at USDA*, AGRI-PULSE (May 10, 2017), https://perma.cc/272M-Z2KZ. Adcock has been accused of misusing her connections and positions during her time in office. She met with former CropLife colleagues to discuss pesticide impacts on water quality, an issue she was prohibited from working on at USDA because of her previous lobbying activities and despite having signed an ethics agreement prohibiting such contacts. *See* Danielle Ivory & Robert Faturechi, *U.S.D.A. Official's Emails with Lobbyists Are Sought After Hearing*, N.Y. TIMES (Nov. 14, 2017), https://perma.cc/YB6E-R4EF.

254. *See* Mark Sidenfeld, *A Big Picture Approach to Presidential Influence on Agency Policy-Making*, 80 IOWA L. REV. 1, 9–10 (1994) (describing Congress's ability to overrule agency policies and affect agency appropriations as "an important check on agency decision-making").

255. *See* Friedrich, *supra* note 240, at 208.

256. CTR. FOR PUB. INTEGRITY, SAFETY LAST: THE POLITICS OF E. COLI AND OTHER FOOD-BORNE KILLERS 1 (1998) [hereinafter SAFETY LAST], https://perma.cc/QZ4X-TFEE.

257. *Id*. at 3.

258. *Id*.

regulations have been blocked repeatedly by food producers and their supporters in Congress."[259]

The success of the meat lobby is due to its size and the size of its coffers. Combined, the meat and poultry industries make up the largest segment of U.S. agriculture.[260] Further, the country is the world's largest producer of beef and the world's fourth largest beef exporter (after Brazil, India, and Australia).[261] The country's beef production for 2019 was forecast at a record 12.7 million tons, an increase of 4 percent from 2018.[262] Beef exports for 2019 were forecast at a record 1.5 million tons, almost 12 percent of production, and up 3 percent from 2018.[263] Further, the growing global demand for beef is expected to provide opportunities for American exporters to increase their market share in the coming years.[264] The beef and poultry industries combined generate about $1.02 trillion in total economic output or 5.6 percent of gross domestic product (GDP).[265] The two industries combined are also responsible for approximately 5.4 million jobs and $257 billion in wages.[266] Given the importance of beef to the American economy, American agribusiness, and the American way of life,[267] it should come as no surprise that the American beef industry is one of the country's wealthiest and best-organized constituent groups.[268] Beef industry lobbyists spend millions of dollars each year to block legislation that would increase industry regulation

259. SAFE FOOD, *supra* note 240, at 29.

260. *Id*. at 19.

261. FOREIGN AGRIC. SERV., USDA, LIVESTOCK AND POULTRY: WORLD MARKETS AND TRADE 4, 5 (2018), https://perma.cc/85JB-T3AE (PDF).

262. *Id*. at 3.

263. *Id*.

264. *Id*.

265. *The United States Meat Industry at a Glance*, N. AM. MEAT INST., https://perma.cc/VK8V-XBDY.

266. *Id*.

267. *See generally* ROGER HOROWITZ, PUTTING MEAT ON THE AMERICAN TABLE (2006).

268. Most of the companies involved in the meat industry are represented by one or more of the powerful meat and trade organizations including the American Meat Institute, the National Meat Association, and the National Cattlemen's Beef Association. *See* Johnson, *supra* note 233.

and thus reduce production or the bottom line,[269] and to ensure the election of politicians who favor the industry.[270] The overall consequence is that some legislators cater to the interests of the beef and cattle industry and, in doing so, further tie the hands of the USDA.

Ultimately, the regulatory scheme, as proposed jointly by the FDA and the USDA, will be rife with inherent bias. Imagine, if you will, what labels the USDA might create for cell-cultured meat with the beef and cattle lobby as its guide. We can certainly expect labels that seek to clearly distinguish cell-cultured meat from traditional meat in an effort to dissuade consumers from the former.[271] These labels will ostensibly serve to protect the health and safety of consumers (disguised protectionism), but there is a strong possibility that they will also turn off potential buyers.[272] Terms have been bandied about such as "Franken" meat, "faux" meat, "fake" meat, and the like.[273] This would have a profound impact on the success of cell-cultured meat.[274]

269. *See* SAFETY LAST, *supra* note 256, at 76 (listing the top recipients in the Senate and House of Representatives of campaign contributions from the meat industry). For a listing of contributions made to federal candidates by political action committees within the livestock industry, broken down by election cycle, see *Livestock PAC Contributions to Candidates*, OPENSECRETS, https://perma.cc/PHA6-9RP3.

270. *See* Kerri E. Machado, Comment, *Unfit for Human Consumption: Why American Beef Is Making Us Sick*, 13 ALB. L.J. SCI. & TECH. 801, 826–29 (2003) (naming several Republican political appointees with extensive ties to the beef industry who instigated various beef industry-friendly policies). Interestingly, unlike the approach used by most big businesses, the meat industry targets a small number of key lawmakers and regulators—only the ones most likely to impact their business interests. *See* Johnson, *supra* note 233.

271. *See* Jenny Splitter, *The Name Game: Cultured Meat Could Suffer the Same Fate as GMOs, New Research Suggests*, FORBES (July 11, 2019), https://perma.cc/MU4J-EDM8 ("[L]egislation aimed at preventing companies from using the term 'meat' for anything other than conventionally raised meat has now been proposed or has already been passed in a number of jurisdictions.").

272. *See id*. (stating that technical descriptions of cell-cultured meat "seem[] to be a turn-off" for consumers).

273. *See infra* Part IV.B.

274. *See* Splitter, *supra* note 271 (noting "the vast body of research on media coverage and public perception of genetically modified foods" that "could serve as a cautionary tale for cultured meat advocates").

Consumers are extremely sensitive to food labels.[275] Our regulators should thus be mindful of promoting fairness and developing a schema based only on the science. Whether or not cell-cultured meat is truly an environmental blessing, its adoption should not be thwarted by an agency with such a long, sordid history of capture. Instead, consistent with a liberal market economy, our food policy should both combat disguised protectionism and support the consumer-citizen's quest for unbiased information.

B. *The Origins of the USDA's Jurisdiction and Its Expertise*

The USDA's relationship with meat, which we largely take for granted in modern times, did not always exist. It was not until Upton Sinclair published *The Jungle* in 1905 that meat health and safety were brought to the attention of the American public.[276] The book vividly described the unsanitary working conditions in a Chicago meatpacking plant that consumers began to fear that any meat consumption would lead to disease.[277] Consequently, in 1906, President Theodore Roosevelt signed the FMIA "for the purpose of preventing the use in interstate or foreign commerce . . . of meat and meat food products which are unsound, unhealthful, unwholesome, or otherwise unfit for human food."[278]

The Act gives the Secretary of Agriculture, at their discretion, the authority to appoint inspectors to examine "all cattle, sheep, swine, and goats before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in

275. *See id.* (describing research on consumer responses to different presentations of cell-cultured meat).

276. *See* Machado, *supra* note 270, at 802 (describing the federal government's response to the "public fears" and "mass hysteria" resulting from *The Jungle*'s publication).

277. *Id.*

278. Federal Meat Inspection Act (FMIA) of 1906, 59 Pub. L. 382, 34 Stat. 674 (codified as amended at 21 U.S.C. §§ 601–695). Prior to the enactment of the FMIA, there had been many reported incidents of "meat scandals" concerning health violations and unsanitary practices within the American Meat Industry. *See* A.R. Miller, *The Federal Meat Inspection Act*, 11 FOOD DRUG COSM. L.J. 565, 566 (1956).

interstate or foreign commerce."[279] The FMIA also specifies that no meat or meat food products "shall be sold or offered for sale by a person, firm, or corporation in interstate or foreign commerce under any false or deceptive name," but "established trade name or names which are usual to such products and which are not false and deceptive and which shall be approved by the Secretary of Agriculture are permitted."[280] In sum, the legislation's original purposes were to prohibit the sale of adulterated or misbranded livestock and derived products as food, to ensure that livestock were slaughtered and processed under sanitary conditions at meat processing plants, and to ensure that all meat was labeled accordingly.[281]

The USDA's focus on proper sanitation of slaughtering, packing, meat-canning, and factory operations makes sense in context. These spaces, especially in the early 1900s, were rife with opportunity for contamination.[282] In Sinclair's time, factory conditions were abysmal. Animal carcasses were often left in the open, rotting, with blood draining freely (along with fat, dirt, grime, and guts) into grates in the factory floor.[283] This tainted meat would later be sold to the public.[284] Likewise, the mandate prohibiting adulteration was especially necessary.[285] The work in these factories was so dangerous that factory workers often lost body parts, which would mingle with and become ground into the meat.[286] This accidental contamination existed separately from some of the intentional adulteration and

279. Federal Meat Inspection Act, 34 Stat. at 674.

280. *Id.* at 676.

281. *See* Miller, *supra* note 278, at 566–67. Primary responsibility for the regulation of manufacturers and labeling falls to the USDA's Food Safety and Inspection Service (FSIS). *See supra* note 140 and accompanying text.

282. *See* Roger Roots, *A Muckraker's Aftermath: The Jungle of Meat-Packing Regulation After a Century*, 27 WM. MITCHELL L. REV. 2413, 2417 (2001) (describing the "vile and despicable" conditions of meat plants in the early 1900s).

283. *See* UPTON SINCLAIR, THE JUNGLE 113 (1906) (describing how the carcasses of "tubercular" cattle were "left upon an open platform and carted away to be sold in the city").

284. *Id.*

285. *See id.* at 405 (noting the prevalence of adulterated goods in the early 1900s).

286. *See id.* at 117 (describing incidents of workers falling into vats and "go[ing] out into the world as Durham's Pure Leaf Lard").

deceptive practices that existed during this time.[287] The first well-known instance of mass meat adulteration, for example, came about in 1898 when Armour & Co., a Chicago meatpacking company, supposedly supplied U.S. servicemen in Cuba with spoiled canned beef during the Spanish-American War.[288] Many believed that rather than dispose of the bad beef, Armour packed the tins with a layer of boric acid to mask its stench.[289] Legend has it that when the troops consumed the meat, many of them fell ill and died.[290]

The majority of the USDA's rules and regulations around meat are meant to proscribe this type of behavior. The FMIA requires the inspection of meat before, during, and after slaughter, and during all processing steps.[291] It also requires approval of labels for all processed meat products and sanitation monitoring of all facilities and equipment used in packing plants.[292] To implement these mandates, the USDA places its own FSIS inspectors in the country's many meat and poultry slaughterhouses and processing plants.[293] These government inspectors are continuously present in all meat manufacturing plants.[294] Inspectors are tasked with identifying potential points of food safety risk and developing methods to mitigate those risks using the principles of Hazard Analysis and Critical

287. *See id*. at 160 (detailing the "miracles of chemistry" used to disguise spoiled meat).

288. *See* Edward F. Keuchel, *Chemicals and Meat: The Embalmed Beef Scandal of the Spanish-American War*, 48 BULL. HIST. MED. 249, 263 (1974) (describing "[c]ases of spoiled canned beef" that were "stamped 'inspected and passed'").

289. *Id.* at 253.

290. *Id*. at 249 (explaining the public perception that "'embalmed beef' was responsible for much of the sickness and death of the [Spanish-American] war").

291. Federal Meat Inspection Act, 34 Stat. at 674.

292. *Id*. at 676.

293. *See* USDA, 2021 USDA BUDGET EXPLANATORY NOTES—FOOD SAFETY AND INSPECTION SERVICE 24-11 (2021), https://perma.cc/A5FL-EHC6 (PDF). The USDA also determines the eligibility of other countries to export meat, poultry, and egg products into the United States, and inspects 100 percent of those imported products. *Id*.

294. *See id*. at 24-12 ("FSIS has a statutory mandate for carcass by carcass slaughter inspection, a once-per-shift per day presence for processing inspection of meat and poultry, and continuous inspection of processed egg products plants.").

Control Points (HACCP).[295] The inspectors are required to perform sanitation checks along with pathogen and residue testing multiple times a day.[296]

Cell-cultured meat does not fit squarely into this system. As previously established, the product is the result of a cell-culturing process that does not begin with an animal carcass. While a few cows may be involved at the beginning of the process, they will not be slaughtered, and thus there is no need to inspect them before they enter a slaughterhouse. Moreover, the animal biopsies will take place in an FDA-regulated laboratory.[297] The distinction here is critical. Labs are much more sanitary than slaughterhouses.[298] And while the risk of contamination will never fully dissipate, these labs are already, under the terms of the FDA-USDA agreement, responsible for ensuring that the cell lines are free of contamination and are unadulterated.[299] Because of the manufacturing processes inherent in cell-cultured meat, the greatest risks of contamination are in the lab.[300] Further, the most likely sources of contamination will be unlike those with which the USDA has the greatest amount of experience, including the diseases contracted from other animals and nearby digestive organs as previously discussed.[301] As such, the USDA's expertise, honed over more than a century and extremely important elsewhere in the areas of health and human safety, is unnecessary in this space.

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295. *See id*. at 24-2 ("HACCP requirements include meeting sanitation, facility, operational standards, and other prerequisite programs to control pathogen contamination and to produce safe and unadulterated food.").

296. *See* USDA, FSIS GUIDANCE FOR A SUGGESTED REPORTING TABLE FOR THE CERTIFIED ESTABLISHMENT LIST 2, https://perma.cc/7VVW-FSQD (PDF) ("The requirement for government inspection once per production shift during processing operations is not the same as inspection once daily; therefore, if an establishment has more than one production shift per day . . . a government inspector must be present at least once during each production shift.").

297. *See* Chriki & Hocquette, *supra* note 26, at 3 ("Advocates of *in vitro* meat claim that it is safer than conventional meat, based on the fact that lab-grown meat is produced in an environment fully controlled by researchers or producers . . . .").

298. *Id*.

299. *See supra* note 55 and accompanying text.

300. *See* Chriki & Hocquette, *supra* note 26, at 3 (describing cell-cultured meat's potential safety issues).

301. *See supra* notes 54–57 and accompanying text.

C. *The Federal Meat Inspection Act*

Putting aside the USDA's mandate and the expertise it may or may not bring to the regulation of cell-cultured meat, the USDA's involvement in such regulation may still be proscribed under the terms of the FMIA. The USDA defines "meat" as "[t]he part of the muscle of any cattle, sheep, swine, or goats which is skeletal," including any fat, bone, skin, sinew, nerve, and blood vessels "which normally accompany the muscle tissue."[302] While the FMIA does not set out a specific definition of meat, it does define "meat food product" as "[a]ny product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats . . . ."[303] Cell-cultured meat only requires the extraction of cells (mostly stem) from a living animal.[304] This does not align with the definition of meat product provided under the FMIA, which implies (if not dictates) that the meat product must originate with a carcass.[305] In the cell-cultured meat production process, there is no carcass, thus rendering cell-cultured meat outside the scope of the FMIA's definition.

The FMIA definition of meat food product also excludes from USDA coverage any food product that "contain[s] meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry . . . ."[306] The test used to determine whether the USDA is responsible for products containing a small portion of meat is referred to as "amenability."[307] Products that are not amenable are not subject to USDA rules and regulations, including FSIS inspection.[308] The determination turns on how a product is formulated, rather than the composition of the finished product.[309] Any

302. 9 C.F.R. § 301.2 (2021).

303. 21 U.S.C. § 601(j).

304. *See* Rubio et al., *supra* note 25.

305. 21 U.S.C. § 601(j).

306. *Id.*

307. *See* FOOD STANDARDS AND LABELING POLICY BOOK, *supra* note 162, at 6 (defining "amenability" for the purpose of the USDA).

308. *Id.*

309. *See id.* (stating that amenability is determined based on the proportion of "livestock ingredients" used to produce the product).

meat-containing product that is more than 3 percent raw meat, 2 percent cooked meat, or 30 percent fat or tallow falls under USDA jurisdiction; anything less falls under FDA jurisdiction.[310] Here, at the point of formulation, the only thing present is stem cells.[311] Even if one were to look beyond the stem cell, to the culture, there is no raw meat or cooked meat to speak of. The culture certainly does not contain 30 percent fat or tallow. As such, meat is not technically a significant portion of the product.

Finally, the definition provides that excluded products must comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions "to assure that the meat or other portions of such carcasses contained in such products are not adulterated and that such products are not represented as meat food products."[312] Again, the primary concerns are those of adulteration and misbranding.[313] Here, cell-cultured meat should be subject to the rules and regulations of the FDA, which will be responsible for ensuring that the products are not adulterated and not labeled as meat food products (which is extremely unlikely even with the USDA involvement).

Despite the clear intent of the FMIA, the USDA seems to have premised its participation in the oversight of cell-cultured meat on the fact that, at the end of cell-culturing process, there is a product that is best described as meat. Yet, cell-cultured meat is not meat because of the tissue engineering involved in its production and the fact that it is not actually any edible part of an animal. The end product is not meat, but rather a near-perfect meat substitute. Moreover, if the USDA's involvement in the regulation of cell-cultured meat is contingent upon a finding that cell-cultured meat is in fact meat, that raises a serious problem for horizontal coherence elsewhere in the government.

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310. *Id.* Examples of meat products that would fall under FDA jurisdiction include things like spaghetti sauces, pork and beans, pretzel dogs, and gravy mixes. *See id.*

311. *See* Post, *supra* note 32, at 1339–40.

312. 21 U.S.C. § 601(j).

313. *See id.* §§ 601–626.

D. *Horizontal Coherence*

Courts should read statutes in light of larger statutory and constitutional policy. This practice serves to maintain a coherent system of governance.[314] When courts draw inferences from both the common law and the regulatory and policy landscapes, they can ensure that old statutes comport with the current legal landscape.[315] Moreover, this approach ensures that public values bring a statute into the political and legal equilibrium.[316] A number of legal, regulatory, and policy venues have already considered the labeling of cell-cultured meat. In each of those venues, the conclusion has been that cell-cultured meat is not really meat.[317] This further shows that the USDA's guidance here is unnecessary.

Recently, states have begun defining meat through "real meat" laws, as they are colloquially known.[318] In 2018, Missouri became the first state to regulate use of the term meat on labels.[319] The Missouri law forbids "misrepresenting a product as meat that is not derived from harvested production livestock or poultry."[320] The law defines meat as "any edible portion of livestock, poultry, or captive cervid carcass or part thereof," and

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314. *See* WILLIAM N. ESKRIDGE JR. ET AL., STATUTES, REGULATION, AND INTERPRETATION: LEGISLATION AND ADMINISTRATION IN THE REPUBLIC OF STATUTES 566 (2014) (discussing coherence canons for interpreting statutes, like the Reenactment Rule and Legislative Acquiescence Canon).

315. See, for example, *Bob Jones University v. United States*, 461 U.S. 574 (1983), in which Chief Justice Burger relied on public policy (including the Constitution, Title VI and other provisions of the Civil Rights Act, other statutes, judicial precedents, executive actions, and regulations) to conclude that the political equilibrium at the time justified the Court's response.

316. *See* ESKRIDGE JR. ET AL., *supra* note 314, at 568–69.

317. *See, e.g.*, 1 JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 10.10 (4th ed. 2021) (describing the FDA and USDA's combined regulatory approach to cell-cultured meat); S.C. CODE ANN. § 47-17-510 (2021) (prohibiting the advertisement of cell-cultured meat as "meat" or "clean meat").

318. For an excellent discussion on how animal law can help promote the rights of alternative-meat companies and help plant-based and cell-based products reach more consumers, thus reducing consumer demand "for products that require the violent deaths of billions of animals a year," see Jareb A. Gleckel & Sherry F. Colb, *The Meaning of Meat*, 26 ANIMAL L. 75 (2020).

319. *See* S. 627 & 925, 99th Gen. Assemb., 2d Reg. Sess. (Mo. 2018).

320. MO. ANN. STAT. § 265.494(7) (2021).

"meat product" as "anything containing meat intended for or capable of use for human consumption, which is derived, in whole or in part, from livestock, poultry, or captive cervids."[321] As such, cell-cultured meat cannot be labeled as "meat" in Missouri. Similar laws have been passed elsewhere, including in Alabama,[322] Kentucky,[323] Montana,[324] North Dakota,[325] and South Carolina,[326] where the laws focus specifically on the labeling of cell-cultured meat. Interestingly, the North Dakota law goes one step further, forbidding the packaging of cell-cultured meat in a manner that is the same or "deceptively similar" to a conventional meat product.[327] A number of other states have passed laws regulating the labeling of cell-cultured meat and plant-based meat alternatives—including Arkansas,[328] Mississippi,[329] South Dakota,[330] and Wyoming.[331] It is safe to assume that, given the steady clip at which states have adopted this approach, there will be many more in the future.[332]

A federal bill has also recently entered the calculus. In October 2019, the Real Marketing Edible Artificials Truthfully Act (Real MEAT Act) was introduced in the House by a Republican from Kansas and a Democrat from New York.[333] If successful, the bill would prevent cell-cultured meat from using the word "beef" for labeling purposes. The bill would define "beef" as "any product containing edible meat tissue harvested

321. *Id.* § 265.300(7)–(8).

322. H.R. 518, 2019 Leg., Reg. Sess. (Ala. 2019).

323. H.R. 311, 2019 Leg., Reg. Sess. (Ky. 2019).

324. H.R. 327, 66th Leg., Sess. (Mont. 2019).

325. H.R. 1400, 66th Leg. Assemb., Reg. Sess. (N.D. 2019).

326. H.R. 4245, 2019 Gen. Assemb., 123d Sess. (S.C. 2019).

327. H.R. 1400, 66th Leg. Assemb., Reg. Sess. §§ 2–3 (N.D. 2019).

328. H.R. 1407, 92d Gen. Assemb., Reg. Sess. (Ark. 2019).

329. S. 2922, 136th Leg., Reg. Sess. (Miss. 2019).

330. S. 68, 94th Leg. Assemb., Reg. Sess. (S.D. 2019).

331. S. 68, 65th Leg., Reg. Sess. (Wyo. 2019).

332. At the time of submission, at least fourteen states had enacted meat labeling bills, but more than twenty-five bills on the topic have been introduced in state legislatures. *See* Jessica Almy, *States Attempt to Criminalize Using "Meat" on Cell-Based Meat Labels*, GOOD FOOD INST. (Mar. 12, 2019), https://perma.cc/3LUS-3L49 ("Lawmakers in over a dozen states are pushing for laws that would criminalize labeling cell-based meat with the word 'meat.'").

333. H.R. 4881, 116th Cong. (2019).

in whole form from domesticated Bos indicus or Bos taurus cattle."[334] The bill also requires "any imitation meat food product, beef, or beef product" to "be deemed to be misbranded unless its label bears, in type of uniform size and prominence, the word 'imitation' immediately before or after the name of the food and a statement that clearly indicates the product is not derived from or does not contain meat."[335] Similar policies are underway internationally.[336]

If law and policy have already found that it is in the public interest to distinguish cell-cultured meat from conventional meat, then it stands to reason that the USDA should abdicate its oversight authority. As it stands, the livestock industry is most pleased with the proposed joint regulatory framework.[337] Its ultimate goal is to restrict market entry. The more barriers to entry that can be imposed, the larger share of the meat-consuming market the livestock industry is able to retain.[338] By splitting regulatory oversight between the USDA and the FDA, and by giving the USDA regulatory authority over labeling, the beef and cattle industry has the best of both worlds. Producers of cell-cultured meat will have to endure the frequent USDA inspections, to which incumbent beef producers are also subject, and cellular agriculturists will have to undergo pre-market label approval (likely with labels that will otherize their products)[339] as is also required of traditional beef

334. *Id.*

335. *Id.* Interestingly, the bill also gives the FDA thirty days from discovery to initiate enforcement measures. *Id.* If the agency fails to do so within that window, the USDA then has permission to enforce at will. *Id.* If the FDA is monitoring labeling violations, then the FDA should also be responsible for labeling decisions.

336. *See France to Ban Use of Meat Terms to Describe Vegetable-Based Products*, BBC NEWS (Apr. 20, 2018), https://perma.cc/9CSF-B998 ("Food producers will no longer be able to use 'steak', 'sausage' or any other meat term to describe products that are not partly or wholly made up of meat.").

337. *See Industry Groups Praise USDA, FDA Cell-Based Protein Agreement, But Are Still Opposed to Calling it Meat or Beef*, FENCE POST (Mar. 7, 2019), https://perma.cc/HZQ6-P25W.

338. Recognizing that there are many competing definitions to the term "barrier to entry," the author uses Franklin Fisher's definition, "anything that prevents entry when entry is socially beneficial." Franklin M. Fisher, *Diagnosing Monopoly*, 19 Q. REV. ECON. & BUS. 7, 23 (1979).

339. With USDA regulation, meat industry stakeholders may have a say in the labeling of cultured meat and can thus distinguish it from their own

producers.[340] But cell-cultured meat producers will also be responsible for reporting to the FDA, which is not required of traditional beef producers.

The benefits to the livestock industry cannot be overstated. Bifurcated oversight will restrict competition. The irony is that on the one hand these individuals and organizations argue that cell-cultured meat is not meat and should not be labeled as such, but on the other hand it is sufficiently meat-like to be subject to the meat regulations promulgated by the FMIA.[341] This can only be explained by the USDA's capture at the hands of the livestock industry. All of this is completely inappropriate, given the USDA's mixed mandate problem, related capture, the USDA's expertise, the terms of the FMIA, and the distinctions already established in the broader law and policy arena.

IV. ADEQUACY OF FDA CONTROL

When thinking about the regulation of cell-cultured meat, it is important to look at each step of the process in conjunction with each agency's tasks. To start, the USDA must oversee establishments where cells are harvested from livestock or

products; they will clearly depict the meat as "lab-grown," "cell-cultured," etc., and may position it as "fake" or "faux" meat, or another denigrating title depicting cultured meat as inferior to traditionally sourced meat. *See* Erica Shaffer, *U.S.D.A., F.D.A. to Jointly Oversee Cultured Meat Regulation*, FOOD BUS. NEWS (Nov. 20, 2018), https://perma.cc/3HUK-DPA6 ("Meat industry stakeholders have supported U.S.D.A. playing a leading role in regulating 'fake meat.'").

340. *See supra* notes 293–296 and accompanying text.

341. Oliver Roberts, one of my Research Assistants, helpfully pointed out that this irony actually cuts both ways. Producers of cell-cultured meat want the benefits that inure from a strong association with conventional meat, but they do not want the USDA regulations. Certainly, they should not be able to have it both ways either. The broader issue is that under the current scheme, cell-cultured meat producers are disadvantaged because they (1) do not get the benefits associated with having a simple meat label, but (2) are also subject to heavy-handed USDA regulations. If the product is not meat and should not be labeled as such, then the appropriate response is to allow for FDA regulations in totality. If the product is meat, then it should be labeled as such, and cell-cultured producers should be subject to rigorous USDA regulations. Under no circumstances should cell-cultured producers be subject to the disadvantages of both systems.

poultry.[342] Yet livestock farming is already heavily regulated by the USDA.[343] There are laws related to animal health and safety, their feed, hormone usage, etc.[344] All these regulations will carry over to cell-cultured meat because there is no difference between the livestock used for biopsy and the livestock used for conventional meat. The USDA also has preexisting regulations for the appropriate use of anesthesia on animals.[345] These USDA regulations already exist and none of them are specific to cell-cultured meat. The next stage of the manufacturing process is the in-vitro growing process, which will require FDA regulations and careful review to ensure product safety, quality, and consistency.[346] There is nothing that the USDA can do to help manage this part of the process. The final stage of the manufacturing process will include processing, production, packaging, labeling, cold storage, and handling at points of sale.[347] Here, the FDA-USDA requirement authorizes the USDA to inspect establishments where the products are processed, packaged, or labeled in accordance with the FSIS regulations.[348] In doing so, the USDA will ensure that the products are safe, unadulterated, and properly labeled.[349] Proper labeling will require USDA preapproval in addition to verification through inspection.[350] Yet the FDA is more than capable of inspecting these establishments and their products, and of handling labeling responsibilities.

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342. *See Formal Agreement Between FDA and USDA*, *supra* note 20; *see also* 7 C.F.R. § 205.239 (2021) ("The producer of an organic livestock operation must establish and maintain year-round livestock living conditions which accommodate the health and natural behavior of animals. . . .").

343. *See Health and Safety*, USDA, https://perma.cc/8FAC-SGAA ("USDA's Food Safety and Inspection Service (FSIS) ensures that our nation's meat, poultry and processed egg supply is wholesome, safe and properly labeled.").

344. *See, e.g.*, 21 U.S.C. § 603(a) ("[T]he Secretary shall cause to be made . . . an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment . . . .").

345. *See Analgesia and Anesthesia*, USDA, https://perma.cc/22DD-S7KP.

346. *See Formal Agreement Between FDA and USDA*, *supra* note 20.

347. *Id.*

348. *Id.*

349. *Id.*

350. *Id.*

A. *Regulation of Establishments*

The FDA and the USDA share[351] a focus on the prohibition of adulteration and misbranding.[352] This requires the agency to regulate the safety of any ingredients used in the production of food products, including meat and poultry products.[353] To accomplish this mission, the FDA routinely inspects any establishment that manufactures, processes, packs, or holds food (except for those establishments that are regulated exclusively by the USDA).[354] These inspections are completed periodically (every few years), except in the case of high-risk

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351. When the agencies share overlapping responsibilities for food products, they develop memoranda of understanding (MOU) to facilitate their interactions. *See, e.g.*, FDA, MOU 225-99-2001, MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD SAFETY AND INSPECTION SERVICE UNITED STATES DEPARTMENT OF AGRICULTURE AND THE FOOD AND DRUG ADMINISTRATION (2018), https://perma.cc/XH5H-C5PC (FDA and FSIS joint jurisdiction); FDA, MOU 225-14-0009, MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD SAFETY AND INSPECTION SERVICE UNITED STATES DEPARTMENT OF AGRICULTURE AND THE FOOD AND DRUG ADMINISTRATION (2017), https://perma.cc/U94R-NHDR (catfish inspection).

352. The FMIA's misbranding provisions state that food products are "misbranded" if their "labeling is false or misleading in any particular." 21 U.S.C. § 601(n)(1). According to § 342 of the FDCA, a food is adulterated whenever it "contains any poisonous or deleterious substance which may render it injurious to health"; "consists in whole or in part of any filthy, putrid, or decomposed substance," or is "otherwise unfit for food"; or "has been prepared, packed, or held under insanitary conditions whereby" it may be rendered injurious to health. *Id.* § 342(a)(1).

353. *See* 21 U.S.C. § 348(c)(1)(A)

> The Secretary shall—by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use) . . . .

354. *See, e.g.*, *Egg Safety Inspections*, FDA (Apr. 12, 2018), https://perma.cc/3G9C-ZGZE (discussing FDA inspections of egg production facilities). In addition to inspecting those locations where food is held in interstate commerce, the FDA also inspects any vehicle used for food conveyance, including boats, trains, and airplanes. *See Interstate Travel Program*, FDA (Nov. 28, 2017), https://perma.cc/LG8G-LY2J.

food facilities, with the help of state officials who are contracted to assist with many field inspections.[355] The outcome of these inspections depends on good manufacturing practices, a hazard analysis, and the presence of risk-based preventive controls designed to prevent any food safety problems.[356]

The FDA will use the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food as the foundation for its inspections.[357] These rules, in conjunction with "a thorough pre-market consultation [and registration] process," are sufficient to safely oversee "products derived from cultured animal cells."[358] This is a very thorough approach. First, the FDA hazard analysis identifies every known or reasonably expected biological, chemical, and physical hazard.[359] If any hazards are found, the establishment must institute preventative controls (including process, food allergen, sanitation controls, etc.).[360] The preventative control protocols must be in writing, ensuring that no food is adulterated as a result of the various hazards that have been identified, and outlining facility plans to oversee and monitor the controls that have been put in place.[361] Further, the rules require each manufacturer to have a risk-based supply chain program in place for any product associated with a known hazard that requires preventative control.[362] Whenever a hazard is identified in a food product, the plan must have a procedure in place to notify stakeholders and the public and to issue recalls.[363] Moreover, the FDA has the benefit of the Food Safety

355. *See* David Saxowsky, *Regulation of the U.S. Food Processing Sector*, N.D. ST. UNIV., https://perma.cc/6XM7-NKXV ("The FDA and a state agency in each state . . . are both authorized to inspect any food processing firm in the state. These inspections can occur at any time the business is operating and do not have to be announced before the arrival of the inspector.").

356. *See generally* 21 C.F.R. § 117 (2021).

357. *See id.* (creating and defining the standards).

358. *Food Made with Cultured Animal Cells*, FDA (Oct. 6, 2020), https://perma.cc/27WU-MWUJ.

359. *See* 21 C.F.R. § 117.130(b) (2021) (describing examples of biological, chemical, and physical hazards that must be identified if known or reasonably foreseen).

360. *Id.* § 117.135.

361. *Id.*

362. *Id.* §§ 117.405, 117.410.

363. *Id.* § 117.139.

Modernization Act (FSMA),[364] which gave the FDA mandatory recall authority and increased the frequencies of inspections at high-risk food facilities.[365]

Unlike the FDA's inspections, which seek to determine compliance, the USDA takes a stricter, constant-presence approach. These inspections take place on a periodic basis.[366] In contrast, the FSIS inspects establishments with a focus on Hazard Analysis Critical Control Points (HACCP).[367] This means that the FSIS agents will identify potential problem areas that risk food safety and help the organization develop methods to mitigate those risks.[368] The FSIS inspectors are in every federally inspected meat processing plant during every shift.[369] While there, they conduct their HACCP and sanitation checks, test for pathogens and residue, and perform other food safety activities.[370]

Under the joint agreement, the FDA rules will govern the production process and produced biological material, including tissue collection, cell lines, and cell banks, along with manufacturing controls, and all components and inputs.[371] In contrast, the USDA rules will govern cell-cultured meat processors, producers, and packagers.[372] This distinction seems arbitrary. One might argue that the USDA's constant-presence approach is more appropriate than the FDA's periodic approach. However, every FDA-regulated establishment understands that either the FDA or the state can appear at any time to inspect or to take samples of the product test.[373] As a result, these establishments must run a tight ship, constantly maintaining cleanliness and proper operating practices, as is the case with

364. Pub. L. No. 111-353, 124 Stat. 3885 (2011).

365. *See* 21 U.S.C. §§ 2221–2225.

366. 9 C.F.R. § 417.4 (2021).

367. *Id.* § 417.2.

368. *Id.* §§ 417.4, 417.8.

369. 2021 USDA BUDGET EXPLANATORY NOTES—FOOD SAFETY AND INSPECTION SERVICE, *supra* note 293, at 24-12.

370. 9 C.F.R. § 417.8 (2021).

371. *Formal Agreement Between FDA and USDA*, *supra* note 20.

372. *Id.*

373. *See* Saxowsky, *supra* note 355 ("[I]nspections can occur at any time the business is operating and do not have to be announced . . . .").

USDA-inspected establishments.[374] Further, if an establishment refuses an inspection, it will be subject to serious enforcement actions (as is also the case under the USDA).[375] More importantly, this process is sufficient to oversee processors, producers, and packagers of almost every other processed food (and drugs and biologics—which have more in common with cell-cultured meat than with conventional meat).

B. *Labeling*

Both the FSIS and the FDA are responsible for ensuring that food products contain labels that are truthful and not misleading.[376] Yet the USDA has been tasked with labeling preapproval.[377] FSIS's authority to mandate preapproval comes from a provision of the FMIA, which states that no food article "shall be sold or offered for sale by any person . . . in commerce, under any name or other marking or labeling . . . [except] established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary."[378] Thus, products that have been preapproved must bear the USDA mark of inspection before they can be offered for sale.[379]

FSIS requires prior approval for all labels used on its meat and poultry products before they can be marketed in interstate commerce.[380] As such, it is extremely likely that FSIS will

374. *See id.* ("Because an inspection can be conducted at any time, the firm must continuously be ready for an inspection. Cleanliness and proper operating practices must be maintained at all times, for example.").

375. *See id.* ("[T]he FDA or state agency can ask to view any part of the processing facility, to inspect the business' records, and take samples of the business' product for testing . . . [and] [a]ny plant that refuses to allow an inspection to allow an inspection will be subject to enforcement action . . . .").

376. *See Formal Agreement Between FDA and USDA*, *supra* note 20.

377. *Id.*

378. 21 U.S.C. § 607(d).

379. *See* 7 C.F.R. § 52.53 (2021) (discussing the requirements for a USDA inspection mark and the different Grades of the inspection marks).

380. FSIS evaluates upward of 60,000 labels each year when they are sent to the agency for evaluation and approval. USDA, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 7 (R. Post et al. eds., 2007), https://perma.cc/KT2G-6LL7 (PDF). However, not all labels need to be submitted to the Labeling Program and Delivery Staff (the unit within FSIS responsible for labeling oversight); FSIS has created specific

require that cell-cultured meat product producers undergo label approval before bringing their products to market. It is not clear how the USDA will regulate these labels under current guidance, but it is likely that any cell-cultured meat label containing words related to cell-culturing or meat will require special statements review prior to entering commerce.[381]

Here, again, the agencies have vastly different approaches. The FDA also regulates all aspects of labeling under its jurisdiction.[382] However, the FDA does not require prior label approval for every food product it oversees. Instead, it monitors compliance through various forms of post-market surveillance.[383] In practice, this means that the FDA chooses to review only a small portion of its food labels, but label reviews are often done at the request of a manufacturer.[384] They also can arise from a trade complaint by a competitor,[385] from a consumer inquiry,[386] or as the result of an on-site inspection of a manufacturing facility.[387]

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regulations for generically approved labels which are the labels that do not need to be submitted. 9 C.F.R. § 412.2 (2021). Generically approved labels are labels that bear all applicable mandatory labeling features in accordance with the Federal regulations. *Id.* Examples of these features are product name, safe handling statement, packer or distributor, net weight, legend, and nutritional labeling. *Id.*

381. *See* USDA, FSIS COMPLIANCE GUIDELINE FOR LABEL APPROVAL 20 (2020) (explaining that labels with special statements and claims must be evaluated by FSIS).

382. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 341–350 (governs food products under the FDA's jurisdiction); Fair Packaging and Labeling Act, 15 U.S.C. §§ 1451–1461 (sets packaging and labeling requirements for consumer goods).

383. *See* FDA, A FOOD LABELING GUIDE: GUIDANCE FOR THE INDUSTRY 31 (2013) ("FDA does not have the resources to analyze products upon request. However, FDA will collect surveillance samples to monitor the accuracy of nutrition information.").

384. *See id.* at 48 ("Firms in need of special allowances should make their request [to the FDA] in writing . . . .").

385. *See How to Report Product Problems and Complaints to the FDA*, FDA (Oct. 26, 2016), https://perma.cc/GW43-SAZV (describing the process for filing a complaint about any product the FDA regulates).

386. *See FDA Food and Cosmetic Information Center Answers Your Questions*, FDA (Mar. 7, 2017), https://perma.cc/EL9L-49SA (explaining the FDA's Food and Cosmetic Information Center's consumer inquiry process).

387. *See Inspection Classification Database*, FDA (Sept. 16, 2021), https://perma.cc/273L-23YA ("The Food and Drug Administration (FDA)

The FDA has the benefit of 21 C.F.R. § 130.8 to inform its approach to labeling. These regulations develop standards of identity for special food,[388] which is arguably the real issue at hand. "Milk," "chocolate," and "bread," for example, mean something very specific to the average consumer. These regulations ensure that the products that are labeled as such conform with those ideas.[389] Here, the only real question is whether cell-cultured meat can be described as "meat." As is the case with milk, chocolate, and bread, the FDA can issue a blanket ruling and then be done.[390] There is no need for the USDA's strict oversight of every label marking a cell-cultured product. The standards of identity also require producers to follow set guidelines about required ingredients, proportions, and manufacturing processes involved in each specific food.[391] Again, that is what is most important here. More important than, say, whether the USDA inspected the packing facility. Ultimately, the standard of identity prevents manufacturers from deceptive marketing (even as it relates to adulteration).

The big issue here is that the livestock industry, and thus the USDA, wants explicit labels that clearly distinguish meat from its lab-grown competitor (so that cell-cultured meat does not become a simple substitute). Proponents of USDA labeling of cell-cultured meat argued that the term "meat" should be reserved for products derived from traditional agriculture methods.[392] As noted earlier, cultured meat detractors have

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conducts inspections and assessments of regulated facilities to determine a firm's compliance with applicable laws and regulations . . . .").

388. *See* 21 C.F.R. § 130.8 ("[A] food does not conform to the definition and standard of identity . . . [i]f it contains an ingredient for which no provision is made in such definition and standard . . . .").

389. *See* John Agar, *Generally Recognized as Sour Cream: Treating Standards of Food Identity as a Success*, 44 FOOD, DRUG, COSMETIC L.J. 237, 246 (1989) (explaining that the use of standardized names is reserved for standardized products).

390. *See, e.g.*, 21 C.F.R. § 131.110 (setting specific requirements for standardized milk and cream).

391. *See, e.g.*, 21 C.F.R. § 139.110 (specifying the minimum and maximum requirements, optional ingredients, and prohibited ingredients for macaroni products).

392. *See* Candice Choi, *Meat 2.0? Clean Meat? Spat Shows the Power of Food Wording*, ASSOCIATED PRESS (June 19, 2018), https://perma.cc/S6FA-99EX ("The U.S. Cattlemen's Association . . . petitioned the USDA in February

compiled a long list of names that denigrate cultured meat; these names include lab-grown meat, synthetic meat, and faux meat.[393] Some jokingly refer to the product as franken meat.[394] This marked hostility towards cell-cultured meat is the result of the livestock industry's desire to prevent lab-grown proteins from competing with their products.[395] The cellular agriculture industry, on the other hand, wants to make no such distinction; they argue that cell-cultured meat is indistinguishable from slaughtered meat.[396] Consumers fall somewhere in the middle; they would like the labels to show that cell-cultured meat does not result from traditional animal agriculture methods but are not committed to the wholesale removal of any reference to meat.[397] How the product is labeled is outside the scope of this

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to enforce that 'beef' and 'meat' only be used for animals 'born, raised and harvested in the traditional manner.'").

393. *See id.* ("The [National Cattlemen's Beef Association] prefers less appetizing terms such as 'in vitro meat,' 'synthetic meat' or even 'meat byproduct' for meat grown through cultured cells.").

394. *See, e.g.*, Alan Boyle, *It's (Not) Alive! Franken-Meat Lurches from the Lab to the Frying Pan*, NBC NEWS (Aug. 4, 2013), https://perma.cc/3TFJ-7SCB.

395. *See* Choi, *supra* note 392 ("The spat shows the power of language as a new industry attempts to reshape eating habits. It's why the $49.5 billion U.S. beef, poultry, pork and lamb industry is mobilizing to claim ownership of the term 'meat.'"). Currently, the definition of meat, per the USDA's regulations, reads,

> The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing.

9 C.F.R. § 301.2; *see also* 21 U.S.C. § 601(j) (defining "meat food product" as "human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats . . . .").

396. *See* Choi, *supra* note 392 ("The Good Food Institute, an advocacy and lobbying group for meat alternatives, is embracing 'clean meat,' which channels the positive connotations of 'clean energy'.").

397. A June 2018 nationally representative Consumer Reports phone survey found that 52 percent of respondents thought that cell-cultured meat should be labeled as "meat, but accompanied by an explanation about how it is produced," while only 43 percent said cell-cultured meat should be labeled as "something other than meat." CONSUMER REPS., FOODS PRODUCED USING ANIMAL CELL CULTURE TECHNOLOGY 4 (2018), https://perma.cc/DT6R-LKUZ (PDF). Only 5 percent thought it should be labeled as "meat without any further explanation." *Id.* Further, when given a list of seven terms and asked

Article. Resolution of the labeling issue is significant for would-be consumers because labeling will inform their views on the products and thus determine the overall viability of the industry. Regulators should make such an important determination in an unbiased manner.

In sum, the FDA is more than capable of overseeing establishments, labeling cell-cultured meat, and enforcing its own rules in regulations. The agency already has policies and approaches in place that will prove less detrimental for cell-cultured meat, while also maintaining safety and efficacy.[398] In fact, these are the same regulations that will govern cell-cultured products derived from animal species that are not subject to USDA jurisdiction, including all seafood (other than Siluriformes), fish, game meat, and foods intended for animal consumption.[399] This further suggests that existing law and policy do not require shared jurisdiction in this space.

V. LEGAL STRATEGIES

The problem, on its face, is simple. When it comes to the regulation of cell-cultured meat, there are too many hands in the pot. This problem only exists because early in the decision-making process the FDA voluntarily abdicated some of its oversight authority. There are many reasons why an agency might choose to engage in this redelegation of power. It is possible that the FDA believed that by collaborating with the USDA, each agency would be able to capitalize on the other's expertise and experience, and thus improve decision-making. But that does not appear to be the case here. Recall that in early 2018, both agencies issued statements claiming oversight authority for cell-cultured meat.[400] The more likely scenario is that shared jurisdiction came about as the result of some sort of political maneuvering or bartering. Whether or not that really is the case matters very little for purposes of this Article. More

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to choose which would constitute accurate labeling, the most chosen terms were "lab-grown *meat*" (35 percent) and "artificial or synthetic *meat*" (34 percent). *Id.* at 5 (emphasis added).

398. *See, e.g.*, 21 C.F.R. §§ 130.8, 131.110, 139.110 (providing examples of the FDA's ability to set specific standards of identity for cell-cultured meat).

399. *See* GAO-05-213, *supra* note 157, at 2.

400. *See* GREENE & ANGADJIVAND, *supra* note 17, at 1–2.

important are the broader questions it raises: is shared jurisdiction necessary here or is shared jurisdiction appropriate here? The answer is clearly no. The logical follow-up question then becomes—where do we go from here?

When Singapore became the first country to approve the sale of cell-cultured meat in December 2020, it did so via a "novel food" petition.[401] The Singapore Food Agency reviewed the petition under the safety standards that it has developed especially for novel foods.[402] Today, those standards have provisions specific to cultured meat.[403] They require that manufacturers of cultured meat produce a description of the overall manufacturing practice, a characterization of the cultured meat product (including nutritional composition); information related to the cell lines used (including the identity and source of the cell lines, a description of the methods used to select and screen for cells, information on how they are prepared and banked following their extraction from animals, etc.); information related to the culture media; information on the scaffolding material (when applicable); information on how the purity and genetic stability of cell culture is ensured during the manufacturing process; a safety assessment regarding possible hazards arising from the manufacturing process; and any other studies to support safety (including digestibility assays, allergen profiling, genetic sequencing, etc.).[404] In the European Union, cell-cultured meat will be governed by an existing regulation on novel food products.[405] This regulation also requires producers to file an application (with the European Food Safety Authority) and addresses many of the same manufacturing concerns.[406]

401. *See* David J. Ettinger et al., *Cultured Meat: Shaping the Future of Foods*, NAT'L L. REV. (Feb. 1, 2021), https://perma.cc/D27R-WAXR.

402. *Id.*

403. *See* SING. FOOD AGENCY, REQUIREMENTS FOR THE SAFETY ASSESSMENT OF NOVEL FOODS AND NOVEL FOOD INGREDIENTS 13–14 (2021), https://perma.cc/6AH7-U8B2.

404. *Id.*

405. *See generally* Council Regulation 2015/2283, 2015 O.J. (L 327) (EU) [hereinafter EU Regulation].

406. *See id.* at 4 ("In order to ensure the harmonised scientific assessment of novel foods, such assessments should be carried out by the European Food Safety Authority . . . .").

China also appears to be trying to bring cell-cultured meat to market, using a petition process for "new food ingredients."[407]

For the foregoing reasons, the United States should dispense with its shared jurisdiction gambit in favor of a process much like those utilized by other countries. With very few modifications, the FDA's Generally Recognized as Safe (GRAS)[408] process can be used to approve and oversee the manufacture of cell-cultured meat. The biggest difference between GRAS in the United States and Novel Foods in the European Union is that the European Union requires pre-market approval for the regulation of novel food products.[409] The United States GRAS process currently does not. Instead, a U.S. food manufacturer can convene an independent panel of experts to determine whether the potential food product is generally recognized as safe.[410] The panel's decision is based on findings in peer-reviewed scientific journals.[411] Once the panel has determined that a product is GRAS, the manufacturer can choose whether to consult the FDA.[412] If the FDA is not consulted, the process results in a self-affirmed GRAS status.[413] If the FDA is consulted and responds with a "no further

407. *See* Ettinger et al., *supra* note 401.

408. *See* 21 C.F.R. § 170.30 (establishing eligibility for classification as "generally recognized as safe," which exempts a food from pre-market approval if it has been generally recognized among qualified experts as safe under the conditions of its intended use).

409. *See* EU Regulation, *supra* note 405, at 4 ("Novel foods should not be placed on the market or used in food for human consumption unless they are included in a [European] Union list of novel foods authorised to be placed on the market within the Union . . . .").

410. *See* FDA, BEST PRACTICES FOR CONVENING A GRAS PANEL: DRAFT GUIDANCE FOR INDUSTRY 4 (2017), https://perma.cc/9SQR-2XXP (PDF).

411. *Id.* at 25–26.

412. *See* FDA, REGULATORY FRAMEWORK FOR SUBSTANCES INTENDED FOR USE IN HUMAN FOOD OR ANIMAL FOOD ON THE BASIS OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) PROVISION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY 5 (2017) ("A substance that is GRAS for a particular use may be marketed for that use without [FDA] review or approval.").

413. *See* Sanford Bigelow, *The Ability to Self-Affirm the Safety of Novel Food and Dietary Supplement Ingredients and Market Them on Your Own Recognizance*, EXPERTS (Apr. 10, 2012), https://perma.cc/34ZM-5Z3Z (explaining that GRAS self-affirmation occurs when a "company determines for themselves that the conditions of use of the novel ingredient in food . . . is generally recognized as safe, or GRAS").

question" letter, the product is FDA certified GRAS.[414] The key distinction between the European and American processes turns on whether there is existing data and published studies.

There are not many published studies on mass-produced cell-cultured meat in existence. With sole oversight authority, however, the FDA could eliminate both the self-affirmed GRAS process and the "no further questions" letter and require cellular agriculture manufacturers to undergo an abbreviated pre-market approval process that acknowledges cellular agriculture to be generally recognized as safe. The benefits here are threefold. First, by undergoing the more demanding process that we see in the rest of the world, cell-cultured meat will be safer. There will be no blanket regulations. Each manufacturer will be individually responsible for proving to the FDA that their processes are sanitary, and their products are safe for consumption. There will be no quick workarounds or shortcuts to undermine the efficacy of the process. This process would also allow manufacturers to bring their products to market much more quickly. Those that already have systems and facilities in place will no longer have to wait for the creation of new regulations or the establishment of new processes by which they might bring their products to market. Instead, they will be able to apply for recognition immediately and begin to sell once they are approved. Finally, this is a process that the FDA can easily implement as it is similar to approaches it has taken in both the food and drug spaces for decades.[415] The only real disadvantage of this approach is that such comprehensive review is resource intensive.[416] This seems like a small concern, however, given the monumental costs associated with cell-culturing today.[417] Very

414. *See About the GRAS Notification Program*, FDA (Oct. 2016), https://perma.cc/9CYD-AGEV.

415. *See History of the GRAS List and SCOGS Review*, FDA (Jan. 4, 2018), https://perma.cc/4FGM-74FL ("The FDA first published a list of these generally recognized as safe (GRAS) substances in the Federal Register of December 9, 1958.").

416. *See Great to Be GRAS*, NUTRITION INDUS. EXEC. (2011), https://perma.cc/QX87-ANLJ ("The estimated cost for GRAS affirmation is $75,000 and the time frame was approximately two years to complete . . . .").

417. *See* Joe Fassler, *Lab-Grown Meat Is Supposed to Be Inevitable. The Science Tells a Different Story*, COUNTER (Sept. 22, 2021, 1:19 PM), https://perma.cc/7BUN-AQ2Q (stating that the projected cost of a cultured meat facility is $450 million).

few companies are (or likely, will be) involved in this space.[418] Those that are can internalize the costs.

The best and easiest way to back out of the current regulatory morass would be for Congress to grant the FDA complete control over the regulation of all foods produced via cellular agriculture. Because Congress has thus far failed to take a stance on the issue,[419] this outcome seems unlikely. In the alternative, the USDA could cede its authority to the FDA in recognition of both the agencies' inherent biases and the superfluity of its involvement. The fact of the matter is that cell-cultured meat is produced in facilities that have a lot more in common with the food manufacturing or biologics facilities regulated by the FDA than the abattoirs overseen by the USDA.[420] Given the USDA's vested interest in the sale of cell-cultured meat, and the fact that it actively sought involvement in its regulation, this outcome also seems highly unlikely. Alternatively, the Supreme Court could weigh in on the issue and determine that the USDA is acting outside the scope of its mandate, requiring the agency to turn over its oversight and labeling jurisdiction to the USDA. Finally, cell-cultured meat manufacturers and product producers could file an action against the USDA once it has issued its directives on labeling. The USDA has a long history of being challenged in court.[421] Yet U.S. courts will not overrule the USDA's decisions on labeling unless the decision is determined to have been made

418. *See* LIZ SPECHT, AN ANALYSIS OF CULTURE MEDIUM COSTS AND PRODUCTION VOLUMES FOR CULTIVATED MEAT 2 (2020), https://perma.cc/7MV8-R6S7 (PDF) (stating that by the end of 2018, there were around two dozen companies, in nine countries, formed to commercialize cultivated meat technology).

419. *See, e.g.*, Cell-Cultured Meat and Poultry Regulation Act, S. 1056, 116th Cong. (2019) (a bill to clarify oversight and jurisdiction over the regulation, inspection, and labeling of cell-cultured meat that did not receive a vote).

420. *See supra* note 16 and accompanying text.

421. *See, e.g.*, Indep. Meat Packers Ass'n v. Butz, 526 F.2d 228, 231 (8th Cir. 1975) (contesting USDA regulations revising the grading standards for beef); Ctr. for Sci. in the Pub. Int. v. Perdue, 438 F. Supp. 3d 546, 553 (D. Md. 2020) (challenging a USDA final rule governing nutrition standards for school breakfast and lunch programs).

in bad faith with an abuse of discretion,[422] which almost never happens. Courts usually find that the USDA did not act arbitrarily or in excess of its authority when promulgating regulations, but rather acted in good faith.[423] Ultimately, the USDA has virtually untethered discretion in determining what is false or misleading, so long as it is not arbitrary.

My primary argument here is not that shared jurisdiction is inherently problematic. The FDA is no stranger to shared jurisdiction. The Environmental Protection Agency (EPA) and FDA, for example, share authority over the regulation of pesticides in food.[424] The EPA will set tolerable limits for the FDA to then enforce.[425] In times of crisis, such as immediately following an attack, the USDA and the FDA will collaborate to make food grade determinations.[426] Under this scheme, the agencies will work together to inspect meat and poultry products in an attempt to stave off any potential radiation.[427] Likewise, the Bureau of Alcohol, Tobacco and Firearms (ATF) and the FDA work together to regulate alcohol;[428] the Consumer Product Safety Commission (CPSC) and the FDA jointly oversee food, food containers, and food-related articles and equipment;[429] and the FDA helps to oversee the Department of Veterans Affairs' (VA) managed contracts for human drugs,

422. *See* 5 U.S.C. § 706(2)(A) (establishing that a court shall hold agency action unlawful if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

423. *See, e.g.*, Animal Legal Def. Fund v. USDA, 789 F.3d 1206, 1224 (11th Cir. 2015) (holding that USDA licensing regulations concerning animal welfare standards were not arbitrary or capricious).

424. *See Pesticides*, FDA, https://perma.cc/9G3M-8MWR (last updated Aug. 31, 2021) (describing the responsibilities of the FDA and EPA concerning pesticide residue on food and animal feed).

425. *Id.*

426. *See* Bijal Shah, *Uncovering Coordinated Interagency Adjudication*, 128 HARV. L. REV. 805, 847 (2015).

427. *Id.*

428. *See* FDA, MOU 225-88-2000, MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE BUREAU OF ALCOHOL, TOBACCO AND FIREARMS (2017), https://perma.cc/NF5U-QCSB.

429. *See* FDA, MOU 225-76-2003, MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. CONSUMER PRODUCT SAFETY COMMISSION AND THE U.S. FOOD AND DRUG ADMINISTRATION (2017), https://perma.cc/3R9P-V7EE.

biologics, and combination products,[430] among many other collaborative efforts. Instead, my argument is that as it relates to cell-cultured meat, shared jurisdiction is both inappropriate and unnecessary.

CONCLUSION

When an industry has captured an agency, that agency is incentivized to insert itself in ever-expanding areas to advocate that industry's interest. When the USDA declares that it has an interest in the regulation of any meat substitute, skepticism and concern should immediately follow. The FDA has voluntarily opened the door to potential sabotage at the hands of the USDA. Recognizing both the USDA's history of capture and the unbounded potential of the cellular agriculture industry, it came as no surprise when, in 2018, the USDA publicly declared its intention to regulate cell-cultured meat.[431] It did come as a surprise, however, when the FDA agreed to cede some of its oversight authority to the USDA. It was even more surprising to learn that the authority the FDA was willing to cede concerned product labeling. USDA involvement in the regulation of cell-cultured meat is unnecessary. Even if that were not the case, given the unique history of and relationship between the USDA and the livestock industry, this outcome is highly inappropriate from the perspective of minimizing the impact of regulatory capture.

Cell-cultured meat has the potential to yield numerous benefits to society, to the extent that consumers are encouraged to consume it.[432] The production of conventional meat imparts

430. *See* FDA, MOU 225-19-030, MEMORANDUM OF UNDERSTANDING BETWEEN THE DEPARTMENT OF VETERANS AFFAIRS AND THE FOOD AND DRUG ADMINISTRATION (2020), https://perma.cc/S9AJ-AE9H.

431. *See* GREENE & ANGADJIVAND, *supra* note 17, at 1.

432. Conventional meat manufacturers are so aware of this that meatpackers like Tyson Foods Inc. and Cargill, along with numerous other investors such as Richard Branson and Bill Gates, have invested millions of dollars to develop cell-cultured meat. Tyson, for example, launched a $150 million venture capital fund (Tyson New Ventures LLC) in December 2016 to invest in companies "developing breakthrough technologies, business models and products to sustainably feed a growing world population." *Tyson Foods Creates Venture Fund to Fuel the Future of Food*, TYSON FOODS (Dec. 5, 2016), https://perma.cc/J3UH-HMSH. Tyson President and CEO Tom Hayes admitted that the company's decision to invest in cell-cultured meats and

negative effects on the environment and human health. If it is true that cell-cultured meat production will eliminate environmental contamination from animal waste runoff, remove antibiotics and artificial hormones from the human diet, and reduce the likelihood of bacterial contamination, then consumers of cell-cultured meat would generate diffuse benefits to society. Moreover, a study from the University of Oxford estimates that cell-cultured meat could be produced with up to 96 percent lower greenhouse gas emissions, 45 percent less energy, 99 percent lower land use, and 96 percent lower water use than conventional meat.[433] If cell-cultured meat is truly capable of feeding the world's growing population while also cutting emissions and saving energy and water, why wouldn't we want to promote this more efficient and environmentally friendly way of putting meat on the table? To wit, if cell-cultured meat is even capable of partially realizing some of these things, why wouldn't we want to promote it?

Given the potential benefits of cell-cultured meat and the risk that the USDA, in its labeling capacity, can easily thwart its adoption, the USDA should have no role in the oversight of cell-cultured meat. The FDA should bear sole responsibility for regulating cell-cultured meat. But as it stands, the agencies have not considered any of the externalities associated with their proposed regulatory system. Ultimately, the goal should be to reduce interest group manipulation and its harmful effects on consumers, so agencies can return to their proper roles of advancing the interests of the people. To that end, Congress must act to ensure that any agency partnerships are both necessary and appropriate.

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plant-based proteins "seemed counterintuitive to some inside our company," but that meeting the growing worldwide demand for protein in sustainable ways "will take a combination of innovative and traditional approaches." Tom Hayes, *Why We Are Investing in Alternative Proteins*, TYSON FOODS (Jan. 29, 2018), https://perma.cc/7Q8C-THGX. In 2018, Upside Foods, a San Francisco-based cell-cultured meat start-up received $17 million in venture capital funding from a group of investors that included Cargill, Virgin Group founder Richard Branson, and Microsoft founder Bill Gates. Paul Sawers, *Lab-grown Food Startup Memphis Meats Raises $17 Million from DFJ, Cargill, Bill Gates, Others*, VENTURE BEAT (Aug. 23, 2017, 6:58 AM), https://perma.cc/LF7H-EN75.

433. *Lab-Grown Meat Would 'Cut Emissions and Save Energy'*, UNIV. OXFORD (June 21, 2011), https://perma.cc/X5W5-WSCV.