A CASE FOR UNITED STATES OVERHAUL OF ITS CURRENT BIOTECHNOLOGY REGULATION SCHEME THROUGH THE IMPLEMENTATION OF BIOTECHNOLOGY-SPECIFIC LEGISLATION TO CLARIFY EXISTING UNCERTAINTIES SEEN IN THE COLLECTIVE FRAMEWORK

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I. INTRODUCTION

Biotechnology[1] is a dynamic field that has profound, global effects on issues such as the national economy, scientific innovation, and public health.[2] Further complicating this is the nature of its rapid evolution which supersedes the rate of policy development sustained by our current approach.[3] Given that the United States ("U.S.") is a major player in this field, and must continue to be in order to sustain its economic and competitive advantage, it is crucial that the U.S. adapt its current regulatory approach to one that more efficiently addresses the national needs in both the domestic and international spheres as they develop.[4]

This Note will first provide a background discussion on the development of biotechnology and how it has evolved into an essential component of the U.S. economy. Next, it will discuss the U.S. regulation of the industry from its beginnings to date, focusing on developments in biotechnology regulation under the Obama Administration and assessing whether these developments will be sufficient to address present and future concerns.

In doing so, the writing will draw attention to the significance of what was left out of the recent update by narrowing the discussion to a small but significant subcategory of biotechnology: genetically

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1 JOHN RAIDT, PATENTS AND BIOTECHNOLOGY, U.S. CHAMBER OF COMMERCE FOUNDATION 8 (2014) (citing U.S. Office of Technology Assessment: "Biotechnology: 'Any technique that uses living organisms (or parts of organisms to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses.'")).

2 *Id.* at 7.

3 *See* Memorandum from John P. Holdren et al. to the Heads of the Food and Drug Admin., Envtl. Protection Agency, and Dep't of Agric. 15 (July 2, 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf [hereinafter July 2015 Memorandum] (calls for the changes to modernize and maintain the regulatory system for biotechnology products, noting that "[d]ue to the rapid pace of change in this arena, an external analysis should be completed at least every five years").

4 U.S. CONGRESS OFF. OF TECH. ASSESSMENT, OTA-BA-494, BIOTECHNOLOGY IN A GLOBAL ECONOMY 174-75 (1991) [hereinafter BIOTECHNOLOGY IN A GLOBAL ECONOMY] ("[D]ifferences in approach [to regulation] from nation-to-nation, particularly through their effects on investment and innovation, will influence the ability of the United States to remain competitive in biotechnology on the international scene.").

engineered or modified organisms. This specific example is just one of many that can pose obstacles for biotechnology industry stakeholders due to regulatory uncertainty, and it will lend context and perspective to the problem at hand. Building on this discussion about genetically engineered or modified organisms and the background provided, this Note argues that while the Obama Administration's efforts to update regulatory measures were a start, they will likely be insufficient to cure previous shortcomings.

In the following sections, this Note will first show how the U.S. has fallen behind the international trajectory on biotechnology regulations and make recommendations on how it can and should catch up before it is too late. Then, this Note will elucidate various problems that arise from continued reliance on outdated authorities, problems which this Note contends are unlikely to be cured by the proposed 2016 Update.

This Note will identify numerous benefits that would be derived from updated statutory authorities, to support the contention that the U.S. Congress must update the statutory framework that governs biotechnology regulatory agencies. This must be done either through the creation of new statutes or revision of existing authorities, in a way that fills regulatory gaps to cover all of today's products, is consistent with international norms, and accurately reflects the U.S.' regulatory policy.

Additionally, this Note posits that such changes should be executed sooner than later so that the U.S. can effectively fulfill its objectives with respect to biotechnology regulation and achieve its goal to be the biotechnology superpower of the twenty-first century.

II. BACKGROUND

A. The Significance of the Biotechnology Sector

Since the first cloning of a gene in 1973,[5] the biotechnology industry has progressed extraordinarily in a relatively short period of time, infiltrating numerous industries such as health, agriculture, food, among others.[6] By the year 2000, the biotechnology landscape in North America had expanded from "a handful of companies . . . to a behemoth . . . of more than 1,280 companies, with a market capitalization exceeding $200 billion."[7] This growth has continued into the twenty-first century, and

5 *See id.* at 30.

6 *See generally id.*

7 Peter Gwynne & Guy Page, *Biotechnology: North America – Personal Portraits of an Evolving Industry*, SCIENCE MAG. (March 24, 2000), http://www.sciencemag.org/site/products/btechna.xhtml

"revenues for the global biotechnology segment are projected to grow at an annual rate of nine percent during the five years of 2019, to $444.9 billion," according to the Deloitte's 2015 Global Life Sciences Outlook.[8]

While biotechnology revenue in the U.S. has shown consistent growth throughout the years, domestic sales have reportedly exhibited slower revenue growth rates than other regions, and there are expectations that this trend will continue as other emerging markets continue to develop.[9]

Aside from the direct effects the biotechnology industry has on the American economy through job creation and revenue derived from product sales, it has the potential to affect the U.S. economy indirectly as well. For example, the healthcare industry is where biotechnology is expected to have its most profound impact.[10] This will affect the U.S. in a variety of ways.

For one, it is said that the "next great leap forward is the area of personalized medicine,"[11] the implications of which should not go underestimated. Indeed, there have been estimates that this new form of personalized medicine, which would more accurately diagnose and assess ailments as applicable to the specific individual, has the potential to "help stop health care costs in their tracks."[12] Given that healthcare expenditures in the U.S. comprised 17.9 percent of GDP in 2010,[13] which continue to expand at a greater rate than our productivity, such savings are economically imperative.[14] Additionally, while it goes without saying that as these various methods of diagnosis and treatments become cheaper, expenditures on healthcare will decrease,[15] it also follows that the general health of Americans is likely to improve and further decrease domestic spending on healthcare.

[https://web.archive.org/web/20150709031645/http://www.sciencemag.org/site/products/btechna.xhtml].

8 *2015 Global Life Sciences Outlook: Adapting in an Era of Transformation*, DELOITTE 7 (2014), https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015-life-sciences-report.pdf

9 *See id.* at 5.

10 RAIDT, *supra* note 1, at 12.

11 *Id.* (the concept of personalized medicine is one where an individual is able to have his or her personal genome sequenced in order to provide "individualized data on hereditary susceptibility to disease and enabling prevention and customized therapies that could 'transform the practice of medicine'"); *Id.* (it is expected that such sequencing methods will soon be available for one thousand dollars, substantially cheaper than current methods of data collection); *see id*.

12 *Id.*

13 *Id.*

14 *Id.*

15 *Id.*

Furthermore, if the direct and indirect economic effects are not sufficiently persuasive on their own to justify the U.S.' need for a competitive position in the future of biotechnology, it is also expected that the biotechnology industry will "factor heavily in achieving global energy, water, and food security."[16] To name a few examples: (1) with respect to the food industry, over thirteen million farmers use agricultural biotechnology to optimize results globally;[17] and (2) with respect to energy, at least 50 bio-refineries are under construction across North America to experiment and develop technologies "to produce biofuels and chemicals…which can help reduce greenhouse gas emissions."[18]

As noted above, while the breadth of benefits to be derived from current applications of biotechnology is already astounding, an article in *Science Magazine* states that "most observers believe that biotech's best years are yet to come."[19] Accordingly, it is clear that the future of biotechnology will have profound effects on the American economy from job creation to product development. Therefore, in order to foster continued advancement in this industry in the future, it is critical that the U.S. have an effective regulatory approach that removes uncertainties and is consistent with international norms.[20]

B. A Brief History of Biotechnology Regulation: Initial Efforts, the 1986 Coordinated Framework, and the 1992 Update

Regulations are a key component of government activity that impacts the "structure and conduct of industries and sets in motion major shifts in economic value."[21] Indeed, with respect to "network industries,"[22] like biotechnology, "regulation is the biggest uncertainty affecting capital expenditure decisions, corporate image, and risk management."[23] Consequently, in creating regulations, governments

16 *Id.* at 13.

17 *Id.*

18 *Id.*

19 Gwynne & Page, *supra* note 7.

20 BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 4, at 196 ("When regulations differ from the international norm, either in policy approach or in stringency, investors and researchers may move to other locations or shift investments . .. . . . An uncertain regulatory climate also inhibits investment. Long delays in developing regulations make analysis of the potential return on an investment much more difficult . .. . . . Ultimately, this loss of investment results in less innovation and lower technological competitiveness.").

21 Scott Beardsley, Luis Enriquez & Denis Bugrov, *The Role of Regulation in Strategy*, CFO.COM (Dec. 14, 2005), http://ww2.cfo.com/strategy/2005/12/the-role-of-regulation-in-strategy.

22 *Id.*

23 *Id.*

must balance competing societal and stakeholder interests,[24] which can prove exceedingly difficult in areas of novel technology where risk evaluation almost seems like a guessing game.[25]

The inherent imperfections in shaping regulatory policy within areas of novel technology can be seen in the U.S.' approach to biotechnology regulation. Initially, the National Institute of Health ("NIH") issued research guidelines regulating laboratory practice and making NIH funding contingent on compliance.[26] However, once products of biotechnology emerged within the national market, they were expected to conform to regulatory standards set forth by various Federal agencies depending on the planned use of the product as opposed to how it was created, i.e., if a product was intended to serve as a pesticide, then it would be regulated under the Environmental Protection Agency ("EPA"), whereas if the product was intended to serve as a food or drug, it would be subject to Food and Drug Administration ("FDA") and/or U.S. Department of Agriculture ("USDA") regulations.[27]

This product-based-designation approach led to jurisdictional uncertainties within Federal agencies, which the Office of Science and Technology Policy ("OSTP") sought to answer in its publication of the "Coordinated Framework for Regulation of Biotechnology"[28] in 1986 (the "1986 Coordinated Framework"), which was the first major publication explaining the way new biotechnological products would be regulated under existing law.[29] Nevertheless, given that "it is no simple matter to base scientifically sound biotechnology regulation on legislation written for other purposes,"[30] certain regulatory problems remained even after the 1986 Coordinated Framework publication.[31]

To address some of these problems, the 1986 Coordinated Framework was updated in 1992 (the "1992 Update") with the purpose of "guid[ing] the exercise of agencies' oversight, within the scope of authority afforded by statute, to ensure the safety of planned introductions of biotechnology products into the environment while not unduly

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24 *Id.*

25 *See* BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 4, at 173.

26 *Id.*

27 *Id.*

28 *Id*. at 173.

29 *See id.* at 174.

30 *Id.* at 14.

31 *Id.* at 16. For example, "[m]echanisms established to provide Federal coordination of activities related to biotechnology, have, instead, become the center of inter-agency, ideological disputes over the scope of proposed regulations." *Id.*

inhibiting the benefits of such introductions."[32] Overall, the 1992 Update did not modify the 1986 Coordinated Framework structure, but instead served to further clarify the national policy on the imposition of biotechnology regulation within the existing statutory scheme.[33]

The 1992 Update directed agencies to employ a risk-based approach in determining the products over which such oversight should occur, where the risks of introducing the product were weighed against potential benefits.[34] The risk-based approach to regulation was chosen as the preferred method because its application was said to be based on scientifically sound principles while simultaneously fulfilling the policy goal of ensuring public safety without stymieing useful innovation.[35]

Overall, however, the 1992 Update seemed to endorse a heavily cautionary position on imposing biotechnology regulations, positing that "[b]ecause technological innovation holds the promise of providing new and better ways to meet the very objectives of…regulations, those regulations that burden or penalize innovation are self-perpetuating burdens of American industry."[36] The 1992 Update promulgated a position of non-interference by suggesting that the free market will, in most instances, correct itself in the absence of regulations.[37]

The 1992 Update then states that the existing statutory scheme, that is not specific to biotechnology products, is sufficient to account for "those limited instances where private markets fail to provide adequate incentives to avoid unreasonable risks to health and the environment."[38] This position of non-interference is further supported in the 1992 Update's assertion that "the Administration has sought to eliminate unneeded regulatory burdens for all phases of the development of new biotechnology products."[39]

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32 Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753, 6755 (Feb. 27, 1992).

33 *See generally id.*

34 *See id.* at 6753.

35 *Id.* at 6755-56.

36 *See id.* at 6761. The 1992 Update then advances principles regarding agency discretion to impose regulations, which seem to create more confusion than clarify. *See id.* The 1992 Update notes that regulations "should be issued only on evidence that their *potential* benefits exceed their *potential* costs." *Id.* (emphasis added). However, the 1992 Update then asserts that in conducting this cost-benefit inquiry, the regulations should only "address risks that are real and significant rather than hypothetical and remote." *Id.* at 676. While it is true that not every effect of a regulation can be contemplated in advance, it seems that in an area like biotech where the technology and its attendant risks are admittedly uncertain, a more scientifically sound cost-benefit approach would be to consider both remote and significant threats to public safety. *See id.*

37 *Id.*

38 *Id.*

39 *Id.* at 6761.

While it is true that excessive regulation could hamper international competitiveness, so too will regulatory uncertainty,[40] and reluctance to implement new biotechnology-specific regulatory statutes may have already had this effect.[41] Indeed, a central critique of the 1992 Update is that "Congress wrote many of the laws used to govern biotechnology before scientists even knew that rDNA modifications were possible, and the laws are not keeping pace with new technological developments."[42] This continued lack of congressional action specific to Federal biotechnology regulation, combined with state preemption principles,[43] has resulted in regulatory uncertainty among states, and therefore their political constituents, through the creation of "loopholes in current federal regulation"[44] where the need for uniform application is paramount.

An additional problem with the 1992 Update is that:

> [t]he complexity of the array of regulations and guidance documents developed by [each of] the three primary Federal agencies with jurisdiction over biotechnology products…can make it difficult for the public to understand how the safety of biotechnology products is

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40 BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 4, at 196 ("An uncertain regulatory climate also inhibits investment. Long delays in developing regulations make analysis of the potential return on an investment much more difficult.") .

41 *Id*.

42 Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. LAW 439, 457 (2007).

43 *See generally id.*; *see also id.* at 443 (explaining the concept of state preemption, noting that "When congress acts in accordance with the Constitution, it preempts state laws in conflict with its actions . . . Preemption is either express or implied. In either case, courts look to congressional intent in determining whether federal action preempts a state law, using the purpose of Congress as 'the ultimate touchstone'").

44 *Id.* at 457 (the loopholes exist where, as a result of statutes not sufficiently updated to account for new developments in technology, certain products do not fit into any area of the Federally regulated framework). Farquhar & Meyer reference the GloFish™, "the nation's first officially sanctioned genetically engineered pet," to provide an example of a product that falls within such a loophole, explaining that since GloFish™ is considered a pet rather than livestock, the USDA Animal and Plant Health Inspection Service is without the requisite authority to impose regulations on it. *Id.* In the same vein, the EPA cannot regulate the GloFish™ because it contains no pesticides, and the FDA's authority to regulate the GloFish™ is confined within the New Animal and Drug applications since the GloFish™ is not produced for consumption or introduction into the environment. *See id.* Farquhar & Meyer state "[a]lthough there is little concern that the GloFish™ poses a risk to human health or the environment, critics contend that this decision creates a precedent for light regulations of transgenic pets currently anticipated, including flea-resistant dogs and cats with non-allergenic fur." *Id.*

> evaluated. Navigating the regulatory process for these products can be challenging, especially for small companies"[45]

that do not have the financial resources it can take to assure compliance, effectively driving them out of the market.

C. The Obama Administration's Push for Regulatory Reform

Undoubtedly, biotechnology is not the only industry in the U.S. in which the public experiences confusion and overlap when trying to obtain information or navigate the regulatory system. This is evident from the Obama Administration's efforts to curtail existing regulatory burdens by directing Federal agencies in Executive Order 13563 (on Jan. 18, 2011) to submit a preliminary plan of operational reassessment to ensure that the regulatory system continues to fulfill its objectives to "protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness and job creation."[46] This mandate recognized the importance of public participation in the regulatory process and directed agencies to solicit public responses to assist in the development of these reports.[47]

On May 10, 2012, President Obama subsequently issued Executive Order 13610: "Identifying and Reducing Regulatory Burdens," acknowledging that Federal agencies had submitted reports in reply to Executive Order 13563 that proposed over 500 changes to existing practices.[48] In the May 10 Executive Order, President Obama indicated that "[a] small fraction of those initiatives…are anticipated to eliminate billions of dollars in regulatory costs and tens of millions of hours in annual paperwork burdens."[49] To state the obvious, this sort of savings is by no means insignificant.

Unfortunately, however, with regard to prioritizing the implementation of the proposed initiatives, President Obama gave limited

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45 Robbie Barbero, Ted Boling, Julia Doherty, Melissa Goldstein & James Kim, *Building on 30 Years of Experience to Prepare for the Future of Biotechnology*, WHITE HOUSE BLOG (Sept. 16, 2016, 11:19 AM), https://obamawhitehouse.archives.gov/blog/2016/09/16/building-30-years-experience-prepare-future-biotechnology.

46 Exe. Order No. 13,563, 3 C.F.R. § 215 (2012), *reprinted in* 5 U.S.C. § 601 app. at 102–03 (2012).

47 *See id.* § 2(c).

48 *See* Exec. Order No. 13,610, 3 C.F.R. § 258 (2013), *reprinted in* 5 U.S.C. § 601 app. at 106–07 (2012).

49 *Id.*

direction to Federal agencies.[50] In light of subsequent developments to be discussed *infra*, it is reasonable to infer that regulatory reform pertinent to the biotechnology industry did not get the attention it deserved.

Fortunately, the Obama Administration appeared to recognize this shortcoming and, in 2015, issued an Executive Memorandum to the heads of the FDA, EPA, and USDA, seeking to modernize the regulatory framework for biotechnology products.[51] The July 2015 Memorandum acknowledged that the existing system was creating "unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes."[52] The July 2015 Memorandum promulgated a set of directives to help facilitate the update and ensure that the improvements were consistent with regulatory goals established in Executive Order 13563.[53]

The July 2015 Memorandum listed the following one-year objectives: (1) update the Coordinated Framework to clarify specific tasks of the FDA, EPA, and USDA with respect to regulating biotechnology products, providing a means for timely reassessment and updates as needed;[54] (2) create a long-term strategy that ensures streamlined risk-assessment measures for future biotechnology developments;[55] and (3) commission an "independent analysis of the future landscape of biotechnology products" to advise in proactive policy implementation.[56]

To help achieve these objectives, the July 2015 Memorandum created a new Biotechnology Working Group ("Biotechnology WG"),

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50 *Id.* ("[A]gencies shall give priority, consistent with law, to those initiatives that will produce significant quantifiable monetary savings or significant quantifiable reductions in paperwork burdens" while continuing to promote regulatory objectives and "giv[ing] special consideration to initiatives that would reduce unjustified regulatory burdens or simplify or harmonize regulatory requirements imposed on small businesses.").

51 *See* July 2015 Memorandum, *supra* note 3 .

52 *Id.* at 2.

53 *See id.* Listing the goals of the improvements, the memorandum noted that while continuing to protect the public health and environment, "[f]ederal agencies that regulate biotechnology products should continually strive to improve predictability, increase efficiency, and reduce uncertainty." *Id.* at 3. Additional guidance included that the improvements should be founded on the "best available science . .. . . [and] promote public confidence . .. . . through clear and transparent public engagement." *Id.* at 3.

54 *Id.* The memorandum expects the updated framework to clarify the scope of each agency's responsibility to different biotechnology areas. *See id.* Additionally, the framework should particularly address biotechnology products that are encompassed by the regulatory sphere of multiple agencies and how the separate roles are related in assessing regulations. *See id.* The update is also expected to spell out a standard of communication and coordination among the agencies with respect to biotechnology product regulation. *See id.*

55 *Id.*

56 *Id.*

comprised of representatives of the three agencies and the Executive Office of the President, under the Emerging Technologies Interagency Policy Coordination Committee ("ETIPC").[57] After completing the three tasks, the Biotechnology WG is expected to submit an annual report on the specific actions that agencies are taking to implement the Biotechnology WG strategy.[58]

In response to the memorandum, the OSTP published an action in the Federal Register on October 6, 2015, requesting from the public relevant information that would assist in the update of the coordinated framework.[59] The request resulted in over 900 comment submissions.[60] The FDA, EPA, and USDA also held three public meetings in areas across the country, and analyzed the existing scheme for biotechnology product regulation.[61]

The Biotechnology WG used the information obtained from its analysis and public engagement to draft the proposed Update to the Coordinated Framework ("proposed 2016 Update") and its accompanying National Strategy for Modernizing the Regulatory System for Biotechnology Products ("Strategy"), which was issued on September 16, 2016.[62] The proposed 2016 Update is significant in that it "represents the first time in 30 years that the Federal government has produced a comprehensive summary of the roles and responsibilities of the three principal regulatory agencies with respect to the regulation of biotechnology products."[63]

On September 22, 2016, the OSTP issued in the Federal Register a Notice of Request for Public Comment on the proposed 2016 Update.[64]

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57 *Id*.

58 *Id.* at 5.

59 *See* Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology, 80 Fed. Reg. 60,414 (Oct. 6, 2015).

60 Barbero et. al, *supra* note 45.

61 *See* Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Public Meeting, 80 Fed. Reg 62,538 (Oct. 16, 2015); Modernizing the Regulatory System for Biotechnology Products; Notice of Second Public Meeting, 81 Fed. Reg. 10,858 (Mar. 2, 2016); Modernizing the Regulatory System for Biotechnology Products; Notice of Third Public Meeting, 81 Fed. Reg. 17,426 (Mar. 29, 2016).

62 *See Modernizing the Regulatory System for Biotechnology Products: An Update to the Coordinated Framework for the Regulation of Biotechnology*, WHITE HOUSE 1 (Sept. 16, 2016), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_coordinated_framework.pdf [hereinafter *2016 Update to the Coordinated Framework*].

63 Barbero et. al, *supra* note 45.

64 *See* Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology, 81 Fed. Reg. 65,414 (Sept. 22, 2016).

Specifically, the request solicits input about what in the proposed update needs additional clarification so that the goals set forth in the July 2015 Memorandum are sufficiently addressed.[65] Responses were due November 1, 2016, and they were considered in Final Version of the 2017 Update to the Coordinated Framework for the Regulation of biotechnology ("2017 Final Update").[66] Reviews of the proposed 2016 Update were mixed, with some generally supportive of it, and others generally opposed.[67] The arguments of those in opposition to the proposed update resonated with those raised in this Note. Notably, the 2017 Final Update indicated commenters expressed concern that, "current laws are severely outdated and inadequate to consider distinctive risks posed by biotechnology products and, therefore, FDA, USDA, and EPA do not have proper the statutory authority to regulate biotechnology products. . ."[68]

With respect to the third one-year objective in the July 2015 Memorandum, the National Academies of Sciences, Engineering, and Medicine commenced a study sponsored by the FDA, EPA, and USDA, which will elucidate the types of products that may be created with biotechnology in the next 10 years.[69] As noted earlier, this study will serve to guide future regulatory action in the biotechnology sector.

D. The Proposed 2016 Update to the Coordinated Framework and its Accompanying Strategy

The proposed 2016 Update reiterates that it was written with the intent "to clarify the *current* roles and responsibilities of the primary agencies involved in the regulation of biotechnology products,"[70] and the purpose of the *Strategy* is to delineate a plan of action to ensure that the regulatory scheme can effectively respond to novel products that result from scientific and technological advances.[71]

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65 *Id.*

66 *See Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology*, WHITE HOUSE 1 (Jan. 4, 2017), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf.

67 *Id.*

68 *Id.* at 58.

69 *See Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System*, NAT'L ACAD. OF SCI., ENGINEERING, & MED., http://nas-sites.org/biotech (last visited Nov. 5, 2016).

70 *2016 Update to the Coordinated Framework*, *supra* note 62.

71 *Id.*

First giving a brief history on the regulatory background of biotechnology products similar to what has been discussed above,[72] the proposed 2016 Update discusses the July 2015 Memorandum, noting that while the regulatory system's purpose of protecting the public health and environment has been met, an update to the system was necessary to improve its "transparency, coordination, predictability, and efficiency,"[73] so that these objectives continue to be met while also fostering continued innovation and competitiveness.[74]

Referencing several documents leading up to it, the proposed 2016 Update proffers a set of principles for biotechnology product regulation, which will continue to aid the agencies in confirming the safety of such products.[75] Following these principles, the proposed 2016 Update provides a table that illustrates the three primary agencies responsible for regulating biotechnology products, the collection of statutes under which each regulatory agency's scope of regulatory authority is derived, and the protective goal sought to be achieved by each statute under which the respective agencies operate.[76]

The proposed 2016 Update then expounds upon various types of biotechnology products, classifying them by the agency/(ies) and statute(s) upon which their regulatory authority is based, and follows with case studies as examples for further clarification, particularly for products that may be subjected to regulation by multiple agencies.[77]

Looking to continue to implement a regulatory approach based on the best available science while increasing transparency, predictability, and efficiency, the proposed 2016 Update's accompanying (finalized) Strategy serves to inform of regulatory agency activities currently in progress to modernize the system for biotechnology products, and provides additional recommendations for the future.[78] Recommendations

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72 *Id.* at 2-4.

73 *Id.* at 5.

74 *Id.*

75 *Id.* at 7. Specifically, the principles recognize that biotechnology products will fall into a variety of different sectors. *See id.* The principles state that regulation will be based on the characteristics of the products and their intended use; that is, different products with the same use would be subjected to the same types of regulations. *See id.* Additionally, the principles continue to advocate the risk-based approach seen in the original 1986 Coordinated Framework, reiterating that the extent of agency oversight over biotechnology products will correspond to the degree of risk posed by a product's introduction as opposed the method by which it was produced. *See id.*

76 *Id.* at 10-11.

77 *See generally id.*

78 *See* Emerging Technologies Interagency Policy Coordination Committee, *National Strategy for Modernizing the Regulatory System for Biotechnology Products*, WHITE HOUSE (Sept. 2016),

for future agency action focus on increased public involvement, the review and/or creation of user-friendly resources for navigating the system, increased coordination and communication among the agencies, mechanisms for monitoring the biotechnology industry as it develops, and allowing opportunities for revision of the regulatory scheme as needed.[79]

While there is no doubt that the proposed 2016 Update and its accompanying Strategy are a favorable alternative to continued reliance on the 1992 Update, its review elucidates some glaring omissions. The definition it uses for biotechnology products, which originated in the original July 2015 Memorandum, is one example. A footnote in the July 2015 Memorandum qualifies the definition of biotechnology products to exclude human drugs and medical devices.[80] This is by no means insignificant. As noted earlier, it is expected that developments in biotechnology will impact the healthcare industry immensely.[81] It is without question that the future development of medical devices will involve the biotechnology industry, and the same is true with human drugs, as evidenced by the fact that "[a]t present, more than 350 biotechnology-based drugs…have started human trials[, and h]undreds more are in early clinical development."[82]

This Note does not seek to undermine the importance of an updated coordinated framework for biotechnology product regulation. Rather, it intends to shed light on certain limitations apparent in the proposed 2016 Update and accompanying Strategy that could prevent it from adequately achieving the increased clarity and efficacy sought.

In the following section, this Note will provide an overview of some criticisms of the proposed 2016 Update, particularly in the context of genetically engineered or modified products that fall through regulatory loopholes under existing statutory authorities. By using this example, this Note will demonstrate the reasons that, while the proposed 2016 Update

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https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.

79 *Id.*

80 July 2015 Memorandum, *supra* note 3, at 1 n.1. ("For the purpose of this memo, 'biotechnology products' refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations. Products such as human drugs and medical devices are not the focus of this memo.").

81 RAIDT, *supra* note 1.

82 Gwynne & Page, *supra* note 7, at 1. With respect to the drugs that have begun clinical trials, the article emphasizes their significance by noting that they were "designed to treat AIDS, Alzheimer's disease, diabetes, multiple sclerosis, and obesity, among other conditions." *Id.*

exhibits a "comforting commitment by the government,"[83] the 2016 Update will likely still fall short of regulatory goals and expectations had by biotechnology industry stakeholders. In doing so, this Note argues for congressional action that revises or creates new statutory authorities that are consistent with international norms to supplement the Obama Administration's effort to decrease regulatory uncertainty in the biotechnology industry.

III. DISCUSSION

A. The Proposed 2016 Update Falls Short of Public Expectations

Because confidence in the 1986 Coordinated Framework had begun to decline up until 2015 when the White House announced its forthcoming update,[84] the event was originally viewed in an optimistic light by industry players as an opportunity to review the outdated system and bring practices up to speed with modern science.[85]

Nevertheless, as an article in *Science Magazine* discusses, it didn't take long for a consensus of disappointment to develop among relevant stakeholders and interested members of the public following the proposed 2016 update's release.[86] Some of this frustration arose from news that the update was unlikely to result in revised or new authorities under which agencies would be governed,[87] effectively announcing that the 2016 update amounts to nothing more than pointing to a cracked wall rather than actually repairing the unstable foundation that caused it.[88]

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83 *See* Seán Finan, *The Once and Future Regulation of Biotechnology*, HARVARD LAW PETRIE-FLOM CENTER: BILL OF HEALTH (Sept. 28, 2016), http://blog.petrieflom.law.harvard.edu/2016/09/28/the-once-and-future-regulation-of-biotechnology.

84 Jennifer Kuzma, *A Missed Opportunity for U.S. Biotechnology Regulation*, 353 SCIENCE 1211 (2016).

85 *Id.*

86 *Id.*

87 *Id.* at 1212. Referring to the OSTP's announcement that old authorities would continue to be the statutory framework to govern biotechnology regulation in the modern century, Jennifer Kuzma notes that such news was "disappointing to many scholars and practitioners given that the CRFB had not been revisited in more than 30 years." *See id.* Robbie Barbero, assistant director for biological innovation at OSTP, has stated, "[m]uch like the original coordinated framework did not endow additional authorities upon the agencies, I don't anticipate that this work will." Emily Waltz, *A Face-lift for Biotech Rules Begins*, 33 NATURE BIOTECH. 1221 (2015).

88 Kuzma, *supra* note 84, at 1213. Given that it is Congress, not the executive, that is tasked with fashioning substantive policy under art. I of the U.S. Constitution, executive actions taken to update or reformulate federal policy could be abandoned by subsequent administrations. *See id.* Hence, in order to effectively address the pitfalls in the current system, congressional action is the most sound and stable approach. *See id.*

The concerns held by industry stakeholders about the ways in which the proposed 2016 Update failed to meet expectations are certainly warranted. As with any problem, the longer one waits to address it, the harder it is to solve; biotechnology regulation is no exception. Under the current framework, a significant number of biotechnology products do not fall within the jurisdictional ambit of any regulatory agency—which is defined by its respective statutory authority prescribed by Congress—and are therefore regulated in an unpredictable or inconsistent way.[89]

Two products developed by Oxitec, a UK-based developer of genetically modified insects, provide a prime example of such inconsistency: the sterile mosquito and the genetically modified diamondback moth.[90] Despite being strikingly similar organisms (genetically modified insects) that were created through the same process by the same company, each of the two insects were subjected to regulation by different agencies because the mosquito was classified as an animal drug—surprising to many given its intended use—and the moth a plant pest.[91]

The problem with this is that these are not isolated incidents, and the longer the U.S. waits to truly modernize the statutory framework to address today and tomorrow's biotechnology products, the more frequent these inconsistencies will occur, and products will either be subject to too much or too little regulation than is necessary. Indeed, numerous organizations like the Center for Food Safety have already brought lawsuits against the USDA, alleging that "the agency's environmental assessments have been inadequate" with respect to genetically modified foods.[92]

If anything, it is clear that there are questions about whether the current, product-based approach originally advocated for is still sufficient to meet regulatory goals, or if these objectives could be better met by employing either another or an additional approach where necessary. For example, assessing risk and appropriate regulations by looking at the process by which a certain product is formed, rather than its intended use. This sort of approach could potentially be more appropriate for those

89 *See* Waltz, *supra* note 87.

90 *Id*.

91 *Id.* After submitting a proposal to the USDA for a field trial in 2010 for the sterile mosquito—genetically engineered by scientists to control the carrier of human dengue fever in the wild, Oxitec waited a year and a half only to hear back from the USDA that the mosquito was beyond the bounds of USDA regulatory jurisdiction and will now be regulated by the FDA. *See id.* Alternatively, the GM diamondback moth was accepted by the USDA because it was found to fall under the plant pest classification. *See id.*

92 *Id*. at 1222.

products created through the use of techniques involving genetic modification.[93]

This Note does not necessarily advocate one approach to regulation over another, but instead intends to shed light on a number of shortcomings that the interested public and relevant stakeholders see with the current system and the proposed 2016 update. In response, this Note argues for, at a minimum, a congressional update to statutory authorities to ensure both agency confidence in applying regulations and stakeholder confidence that the process provides for adequate oversight to ensure public safety while promoting a predictable, transparent, and efficient regulatory environment for the biotechnology industry.

Furthermore, while the proposed 2016 Update does include some case studies for modern biotechnology products, giving the impression that genetically engineered biotechnology products can be regulated under the framework's current authorities, one of the problems recognized by public participants in the OSTP process was that the genetically engineered ("GE") products chosen for case studies were those which "could have been easily predicted by attentive scholars and practitioners before the start of the OSTP process."[94]

However, when public participants in these meetings asked officials responsible for conducting the meetings about current products that do not fit as neatly within a single agency jurisdiction—if at all—as those chosen for the case studies, officials failed to provide an explanation.[95] Thus, participants viewed this portion of the OSTP process as a rapid change from actually developing an update to the framework, to merely clarifying existing authorities for products easily assigned to begin with.[96] Clearly, this process did not do much to address the core issue at hand: the U.S. is regulating a massive industry with an outdated system which is based on antiquated authorities that fail to encompass all of today's biotechnology products, much less tomorrow's.[97]

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93 *See id.* Emily Waltz discusses various expert opinions on the best approach to updating the biotechnology regulatory system, noting that "opinions were divided" as to whether risk assessment should be "based on the process by which the product was made, or the risk of the product in its intended use." *Id.* Nevertheless, while there was not necessarily a consensus on the correct approach to updating the system, it seems clear the experts agree the current approach is outdated, and to merely clarify current regulatory agency roles under old statutes will be insufficient to address the long-term risks posed by introducing products without appropriate oversight, such as food safety and indirect environmental harm. *See id.*

94 Kuzma, *supra* note 84, at 1212.

95 *Id.*

96 *Id.*

97 *See generally* Brooke Borel, *The Tricky Process of Regulating Biology,* UNDARK MAG. (Jun. 30, 2016), http://undark.org/article/tricky-business-regulating-biology-genetic-engineering. In her

As reiterated in the final paragraph of the *Science Magazine* article discussed above, "Open policy windows to improve biotechnology governance are rare, as they depend on the confluence of policy, political, and problem streams…and appropriate use of GEOs [(genetically engineered organisms)] were missed at this key juncture in the biotech revolution, although it is poised to change nearly every sector and even our conceptions of nature."[98] While the article seemingly ends on a negative note, the message relayed is a real and critical one: if the U.S. expects to remain a relevant player in this vital industry, it must act quickly to repair the flaws in its regulatory practices in a way that is consistent with global norms, has a lasting effect (e.g., not subject to abandonment by subsequent administrations), and effectively addresses public concerns while meeting regulatory goals.[99]

B. The United States Has Failed to Demonstrate a Commitment to Align with International Norms with Respect to Biotechnology Regulation

The Cartagena Protocol on Biosafety (the "Cartagena Protocol") and the Nagoya-Kuala Lumpur Supplementary Protocol are the "two major international protocols that address genetically modified organisms" attached to the United Nations ("U.N.") Convention on Biological Diversity.[100] The purpose of the Protocols is to "contribute to ensuring an adequate level of protection in the field of the safe transfer and handling

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article, Brooke Borel references a number of different types of genetically engineered or modified products that fall outside the existing statutory framework and consequently receive little to no regulation, which could be troubling for certain products that could have adverse effects on public safety and health or the environment. *See id.* For example, Borel refers to "a plant pathologist at Pennsylvania State [who] successfully used new gene editing technology to delete a relatively small bit of DNA from the genome of a white button mushroom. The result: a mushroom that resists turning brown." *Id*. Borel uses the mushroom example to explain that since it was the sort of product that "tweaked the stuff of life itself . . . [, one would expect to] run into a maze of regulatory oversight and examination." *Id.* Quite the contrary, however; because the mushroom was a genetically modified product created from direct gene editing (a newer technology that directly modifies the organism's DNA) as opposed to employing the conventional (older) technique (introducing a plant pathogen (virus) into the mushroom to add or alter the DNA indirectly), the USDA determined the mushroom fell beyond the bounds of its regulatory jurisdiction. *See id.* Additionally, the EPA determined it had no jurisdiction since the mushroom was not engineered to make its own pesticides. *See id.* And the FDA "had not published a safety review of the mushroom — a voluntary procedure, anyway." *Id.*

98 Kuzma, *supra* note 84, at 1213.

99 *See id.* at 1213 ("Authorities under the CRFB are diffuse, outdated, and confusing, especially for newer biotechnology products. This situation is bound to get worse.").

100 Constance A. Johnson, *Restrictions on Genetically Modified Organisms: International Protocols*, LIBR. OF CONGRESS (Mar. 2014), https://www.loc.gov/law/help/restrictions-on-gmos/international-protocols.php.

and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity"[101] and "provid[e] international rules and procedures in the field of liability and redress relating to living modified organisms."[102]

While not perfect, at its conclusion, the Cartagena Protocol was praised for making an important advancement by "provid[ing] an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry."[103]

Despite receiving such accolades and the fact that the vast majority of countries, 166 of them, are members to the U.N. Convention on Biological Diversity (the "Convention") and its corresponding Protocols, the U.S. is not a participant in any of them.[104] The U.S. has, however, signed the Convention and therefore just needs to ratify it to become a bona fide party to the Convention and its corresponding Protocols.[105] Notwithstanding this deceptively simple fix, ratification is much easier said than done.[106]

It would be wise for the U.S. to ratify the Convention and protocols. Although there are no specific obligations with which party members must comply in trading with non-parties, the language is somewhat vague, thereby increasing the "risk of future disputes between parties and non-parties" about market access in international trade.[107] In other words, as international norms continue to develop for the regulation and trade of genetically modified organisms, non-parties could be ousted for failure to comply.

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101 Cartagena Protocol on Biosafety to the Convention on Biological Diversity art. 1, Jan. 29, 2000, 2226 U.N.T.S. 208 [hereinafter Cartagena Protocol].

102 Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety art. 1, Oct. 15, 2010, 50 I.L.M. 108 [hereinafter Nagoya Supplemental Protocol].

103 Cartagena Protocol, *supra* note 101.

104 Johnson, *supra* note 100, at 1.

105 Paul E. Hagen & John Barlow Weiner, *The Cartagena Protocol on Biosafety: International Trade in Living Modified Organisms*, 12 GEO. INT'L ENVTL. L. REV. 697, 700 (2000).

106 John Cary Sims, *The Asymmetrical Nature of the U.S. Treaty processes and the Challenges that Poses for Human Rights*, 30 HAMLINE J. PUB. L. & POL'Y 223 (2008) ("As a practical matter, treaty ratification is usually impossible without bipartisan support.").

107 *See id.* at 700, 713; *see also* William J. Snape, III, *Joining the Convention on Biological Diversity: A Legal and Scientific Overview of Why the United States Must Wake Up*, 10 SUSTAINABLE DEV. L. & POL'Y 6, 13 (2010) ("Failure to engage [the Convention on Biodiversity] will mean closed doors on access to genetic resources for U.S. companies and continuing market conflicts over U.S. biotech exports.").

Since the U.S. is not a party to the Convention, it is not required to implement legislation and ensure domestic compliance to the treaty. As a result, the U.S. could eventually be an unfavorable source of trade unless it complies with the provisions of the two corresponding protocols.[108]

As noted above, the statutory authorities governing U.S. biotechnology regulation are older than the Convention and its subsequent protocols fail to adequately cover current and emerging genetically modified products,[109] and may therefore be insufficient to constitute compliance with the international approach in the future if left unrevised.

While the international protocols under the Convention are currently limited to genetically modified organisms as described above, given the industry's reach and its future implications, it is not a stretch to suggest there is likely to be other emerging international agreements on biotechnology product regulation for additional purposes, which will have a range of effects from public health to international trade.[110]

There are several reasons why it would be advantageous for the U.S. to participate in the Convention. These include having a role in the development of subsequent agreements and aiding in the interpretation of provisions which eventually become international norms.[111] Although the U.S. was an active participant in the development of the Cartagena Protocol—despite its non-party status[112]—this does not guarantee that participation will be permitted in the future. Indeed, yet another criticism of the proposed 2016 Update and its drafting process was the OSTP's failure to coordinate a public discussion regarding the potential pros and cons of U.S. participation in the U.N. Convention.[113]

Nevertheless, whether or not the U.S. elects to become a party to the U.N. Convention on Biodiversity and its corresponding Protocols (and/or future, related international agreements), the considerations noted above

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108 *See id.* at 713 ("The Cartagena Protocol requires that trade with non-parties be consistent with the objectives of the Protocol and urges the Parties to encourage non-parties to adhere to the protocol.").

109 *See generally* Kuzma, *supra* note 84.

110 *See generally id.*

111 *Id.* at 1213 ("For example, logical benefits of U.S. participation could be to have a voice in (i) drafting subprotocols under the BSP, (ii) interpreting the CBD-BSP statement on precaution less stringently in the formulation of risk assessment standards, and (iii) promoting the possibility (however remote) of harmonizing data packages to fit what U.S. companies do for risk assessment. U.S. participation could potentially increase global good will, perhaps inciting less controversy in trade disputes through the World Trade Organization.").

112 Hagen & Weiner, *supra* note 105, at 700.

113 *See* Kuzma, *supra* note 84, at 1213.

should, at a minimum, prompt the U.S. to update the statutes that govern its biotechnology regulatory scheme in order to reflect compliance with international norms and to ensure, for the future, that its coveted position at the forefront of the industry is not compromised by something well within its control.

C. A Modernized Statutory Framework Will Provide for a Plethora of Ancillary Benefits

An updated statutory scheme for the regulation of biotechnology would allow for each of the U.S. branches of government to better operate within the confines delegated by the Constitution. The forthcoming section recognizes the sensitive distribution of power prescribed by the U.S. Constitution which is comprised of the three branches of government. Moreover, the next section emphasizes how administrative agencies threaten that delicate balance when using discretion to make rules that carry the force of law.

1. The Executive Branch: The Problem with Excessive Agency Discretion

Because the executive branch is charged with enforcing laws created by Congress, it must not only interpret statutes but also exercise discretion consistent with each statute's purpose when acting in circumstances not explicitly covered by them.[114] Indeed, under the Administrative Procedure Act, agencies have the power to act by adopting a "rule, order, license, sanction, relief, or the equivalent."[115] In other words, agencies are often the source of regulatory rules that are created pursuant to the statutes from which agencies derive their authority and guidance.[116] Practically speaking, the consequence of this is that federal departments and agencies "wield power over vast segments of the economy, affecting almost every important facet of contemporary

114 *See generally* Cary Coglianese & Christopher S. Yoo, *The Bounds of Executive Discretion in the Regulatory State*, 164 U. PA. L. REV. 1587 (2016).

115 5 U.S.C., §551(13) (2012).

116 *See* Coglianese & Yoo, *supra* note 114, at 1597 ("[U]nder most statutes, Congress has delegated authority to administrators; they are the officials granted the express powers to command or defer in ways that carry out the aims and responsibilities contained in specific legislation.").

life."[117] Even more concerning, such discretion is not always subject to judicial review.[118]

Likewise, even when a court finds it appropriate to review agency action, courts are more likely than not to take a deferential approach to an agency's interpretation of its own rules.[119] For example, the Supreme Court in *Heckler v. Chaney* decided against requiring the FDA to enforce provisions of the Food Drug and Cosmetic Act on the grounds that agency discretion involved a number of factors deemed to be uniquely within the agency's expertise.[120] Therefore, to curb potential abuse[121] and minimize discretionary error, it is crucial to ensure that the actions regulatory agencies take are grounded in modernized statutes that do not provide for too much, or too little discretion.[122]

Considering the breadth of agency discretion noted above in the present context of biotechnology regulation under the coordinated framework, things become even more problematic. Since biotechnology products are subject to regulation by multiple agencies under authorities written well before many of today's products were contemplated, the very crux of the U.S.' approach falls within these agencies' hands.

Taking genetically modified or engineered organisms again as an example, it is hard to imagine how any one of the three agencies responsible for biotechnology regulation could possibly discern congressional intent with sufficient accuracy to regulate products that did not exist at the time the authorizing statute was written.[123] Indeed,

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117 *Id*. at 1589.

118 *See* 5 U.S.C. §701(a)(2) (judicial review is not provided where "agency action is committed to agency discretion by law"); *see generally* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984) (promulgating a test for administrative deference).

119 *See* Richard J. Pierce Jr. & Joshua A. Weiss, *An Empirical Study of Judicial Review of Agency Interpretations of Agency Rules*, 63 ADMIN. L. REV. 515, 515-16 (2011) ("Courts at all levels of the federal judiciary uphold agency actions in about 70% of cases . .. . . . The Supreme Court seems to take an extraordinarily deferential approach when it reviews agency interpretations of agency rules. William Eskridge and Lauren Baer found the Supreme Court upholds 91% of such agency actions.").

120 Heckler v. Chaney, 470 U.S. 821, 828, 831 (1985) ("[A]n agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise.").

121 Coglianese & Yoo, *supra* note 114, at 1588 ("Political polarization and gridlock have hampered Congress's ability to act and undoubtedly contributed to the fact that today's worries about the concentration and abuse of federal power usually center on the executive branch.").

122 *See id.* at 1606 ("How these officials exercise their executive discretion . .. . . will undoubtedly determine whether the government succeeds in fulfilling its responsibility to the public—or whether it fails or, worse still, abuses its discretion.").

123 *See* Patrick Stewart & A. Ann Sorensen, *Federal Uncertainty or Inconsistency? Releasing the New Agricultural-Environmental Biotechnology into the Fields*, 19 POLITICS AND THE LIFE SCIENCES 77, 78 (2000) ("Biotechnology policy, especially the new agricultural-environmental

permitting agencies to exercise such a presumptuous degree of discretion is a significant factor in the problems the proposed 2016 Update intends to correct. However, this Note also argues that while the proposed 2016 Update will likely mitigate the problem by "clarifying current roles and responsibilities"[124] in the short term, it is unlikely to be effective for the long term as statutes continue to age while new technologies emerge in the industry regularly.

While it is true that "Congress cannot anticipate every statutory consequence, implication, or nuance and there must be some means of deciding conflicts that arise in implementing [] statutes,"[125] there must be limits. Furthermore, an updated statutory framework governing agency action with respect to biotechnology regulation is necessary because it would not only minimize the need for agency discretion and decrease regulatory uncertainty, but also increase confidence in the system for private and public players across the board.

2. The Judiciary: Adjudication Based on Obsolete Statutes is Problematic

The judiciary is also implicated in matters concerning biotechnology regulation since it is responsible for interpreting regulatory statutes to determine the appropriateness of an agency's decision, for example, when a party asserts a claim of right under the Administrative Procedure Act.[126] As noted above, the Supreme Court held unanimously in *Heckler* that, "the APA did not authorize courts to compel FDA enforcement;"[127] however, "it did acknowledge that agencies cannot decline to take enforcement actions if doing so would contravene statutory guidelines."[128] Nevertheless, the problem is this: because the statutes were written before many of today's biotechnology products, they do not adequately cover them; thus, many of these products fall through a

biotechnology policy, is in a state of flux, with no obvious integrated agenda"); Stewart and Sorensen also discuss changes in field release regulations in response to various factors and inconsistencies among the approach taken by USDA and EPA, respectively. *Id.* at 78.

124 *See 2016 Update to the Coordinated Framework*, *supra* note 62.

125 Ronald H. Rosenberg, *The Ultimate Independence of the Federal Courts: Defying the Supreme Court in the Exercise of Federal Common Law Powers*, 36 CONN. L. REV. 425, 428 (2004).

126 *See* Coglianese & Yoo, *supra* note 114, at 1596 ("The APA makes plain that when agencies issue orders or rules, those who are adversely affected by them may seek to review the substantive and procedural legality of those actions.").

127 *Id.*

128 *Id.*

regulatory loophole that is in the realm of an agency's scope of discretion.[129]

It therefore appears that even if a court is of the opinion that, for example, a GMO should be regulated, and even if there is an agency rule providing for such regulation, the court could decline to compel an agency to enforce that rule if it decides to give deference to the agency's interpretation of its own regulatory rule, which courts often do.[130] This would be legally justified on the grounds that the agency is not contravening the purpose of its authoritative statute by neglecting to regulate an uncovered product since there is no "express statutory restriction to the contrary."[131]

Granted, federal courts are not without power to fill existing statutory gaps and make pronouncements as to the legality of agency actions,[132] but there are debates as to when and how often this should be done since it "raises concern about judges making law as well as separation of powers and federalism questions."[133] Moreover, another problem with this is that the decision whether or not to defer to an agency is dependent on the individual judge,[134] which could result in conflicting decisions about the same agency action and further contribute to the uncertainty that plagues the current regulatory climate for biotechnology products.

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129 *Id.* at 1590 ("It has long been accepted that, absent any express statutory restriction to the contrary, the executive branch possesses broad discretion over which cases it prosecutes [or enforces] and which ones it does not.").

130 *See* Pierce & Weiss, *supra* note 119.

131 *See* Coglianese & Yoo, *supra* note 114, at 1590. Coglianese & Yoo define an agency's decision not to enforce a regulation or rule as a form of exercising its power through inaction, which is an exercise of executive power most insulated from judicial review. *See id.* ("Legal restrictions on executive authority have typically applied only after the executive branch has decided to act, not before it acts. Before any final action occurs, the executive branch possesses what the Supreme Court has recognized as 'absolute discretion,' at least when it comes to enforcement.").

132 Rosenberg, *supra* note 125, at 436 ("[T]he Supreme Court has ruled that federal courts may create 'interstitial federal common law' when Congress has enacted a regulatory scheme and has granted, implicitly or explicitly, the federal courts the authority to create substantive rules to effectuate the scheme.") (citing Textile Workers Union v. Lincoln Mills of Ala., 353 U.S. 448, 450-51 (1957).

133 Kevin R. Johnson, *Bridging the Gap: Some Thoughts About Interstitial Lawmaking and the Federal Securities Laws*, 48 WASH. & LEE L. REV. 879, 881 (1991).

134 Jody Freeman & David B. Spence, *Old Statutes, New Problems*, 163 U. PENN. L. REV. 1, 69-70 (2014) ("Some judges might feel a heightened burden to scrutinize agency interpretations of outdated laws carefully, on the assumption that these are precisely the conditions under which agencies will be tempted to scour mouseholes for elephants. Other judges might be inclined to defer to agencies struggling in good faith to adapt obsolete laws to new conditions, giving them the benefit of the doubt at least where the statutory language is plausibly ambiguous.").

In light of the above, it is evident that courts would be better equipped to adjudicate controversies concerning biotechnology product regulation more confidently and consistently with federal policy if the statutes that govern such regulation (and adjudication) are updated to reflect that policy with respect to current biotechnology products, particularly those that fall through regulatory loopholes in the existing statutory scheme, such as GMOs.

D. A Potential Yet Unpersuasive Objection to Updating the Statutes that Govern Biotechnology Regulatory Agencies

Evidence, measured by quantity of bills passed, indicates that recent congressional sessions have become less productive than those in the past six decades.[135] This has led some scholars to suggest that we are "in an era of unprecedented congressional paralysis . . . [that] is likely to be enduring,"[136] as Congress is more polarized today than long before World War II.[137]

In their article, *Old Statutes, New Problems*, Freeman and Spence discuss what this means for agencies and courts with respect to the "challenge of managing statutes over time…in a period of rapid change and limited congressional productivity."[138]

In doing so, Freeman and Spence recognize that statutory obsolescence coupled with a relatively gridlocked Congress "puts tremendous pressure on agencies to do *something* to address new problems,"[139] and the authors seemingly accept that in such circumstances agencies will be tasked with taking the initiative to indirectly update statutes while courts will serve to check agency action.[140] Freeman and Spence, however, acknowledge the difficult paradox with which agencies are faced and the problems that ineffective agency action can create for society,[141] but they ultimately advocate for

135 *See* Chris Cillizza, *The Least Productive Congress Ever,* WASH. POST (July 17, 2013), https://www.washingtonpost.com/news/the-fix/wp/2013/07/17/the-least-productive-congress-ever.

136 *See* Freeman & Spence, *supra* note 134, at 4.

137 *Id.* at 2.

138 *Id.* at 4.

139 *Id.* at 5.

140 *See generally id.*

141 *Id.* at 4-5 ("When agencies charged with a regulatory mission fail to address new policy problems that arguably fall within their core domain, society might be deprived of important gains—public health, safety, environmental benefits, consumer protection, and market efficiencies—which may be hard to recapture later. Yet if agencies exceed their legal authority when addressing new problems, they realize our worst fears about bureaucracy run amok.") .

agencies to independently respond in lieu of waiting for congressional action.[142]

Undoubtedly, it is tempting to reference the discussion in *Old Statutes, New Problems*[143] to argue that because Congress is not particularly productive due to gridlock, the U.S. should just continue to rely on agencies and courts to fashion new rules under old and aging statutes. However, this misses the point entirely: while technology has been advancing at an exponential rate,[144] agencies and courts have been picking up the slack on biotechnology regulation for several decades of congressional acquiescence.[145] This is not to say that agencies should not exercise some discretion to make new rules or regulations in response to industry changes. Rather, agencies and courts have been doing so under outdated authorities for far too long, so long that such "well-intended 'adaptation'"[146] has resulted in a "costly, ineffective regulatory mess and undermine[d] the agenc[ies'] legitimacy in the process."[147] Indeed, the very purpose of the proposed 2016 Update was to address the numerous problems that have surfaced as a result of agencies' regulation of modern biotechnology products under existing laws.[148]

To accept the argument that Congress is dysfunctional and therefore we can allow it to continue to sit on its hands while the executive and judiciary shape regulatory policy is to disregard the governmental

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142 *Id.* at 75.

143 *See generally id.* Freeman & Spence discuss other scholars' recognition that agencies could be the best equipped to handle the task of updating obsolete statutes since they are "more nimble than Congress, more accountable than courts, and more expert than both in responding to changing conditions." *Id*. at 4. They also argue that agencies have reasons to (and do) exercise restraint in making new policy, like congressional budget cuts and embarrassment by courts for improper rules or regulations. *See id.*

144 David L. Chandler, *How to Predict the Progress of Technology,* MIT NEWS (Mar. 6, 2013), https://news.mit.edu/2013/how-to-predict-the-progress-of-technology-0306. Discussing Moore's Law, which was originally derived by Intel Co-Founder Gordon Moore in 1965 to quantify the rate at which computer chips improve, the Chandler notes that it "has since been generalized as a principle that can be applied to any technology; in its general form, it simply states that the rates of improvement will increase exponentially over time." *Id.*

145 Kuzma, *supra* note 84, at 1212.

146 Freeman & Spence, *supra* note 134, at 71

147 *Id.* The authors note an argument against agency improvisation by highlighting the sort of "unnecessary complexity" that can result. *Id.* (citing Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187, 229-30 (2006)).

148 *See* July 2015 Memorandum, *supra* note 3, at 2 ("Each of the Federal regulatory agencies with jurisdiction over the products of biotechnology have developed regulations and guidance documents to implement its authority under existing laws, resulting in a complex system for assessing and managing health and environmental risks of the products of biotechnology . .. . . [resulting in] unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes.").

structure contemplated in our Constitution.[149] While there is no doubt Congress has the authority to delegate certain powers as "necessary and proper" for carrying out its duties,[150] and debates as to the extent to which such delegation is permitted abound,[151] for Congress to neglect its Article I duty where there is a need for legislative action is contrary to our governmental scheme and should not be excused.

It is axiomatic that it is challenging to pass new legislation; indeed, some argue such difficulty was intentionally embedded into the scheme of our government.[152] Nevertheless, up until the mid 1990s, such difficulty did not stop Congress from "show[ing] the willingness and ability to modify [] existing regulatory regimes in substantive ways as necessary to adapt to new and changing understandings of the policy environment."[153] There is no reason Congress cannot show that same willingness now and fulfill its constitutional duty to update the authorities that govern biotechnology regulation.

IV. CONCLUSION

Much has changed in the world over the past 30 years, particularly with respect to science and technology. The biotechnology industry's global explosion evidences what is possible when the two converge: products and techniques once considered impossible, or perhaps not considered at all, are now mainstream; imagination runs wild at the thought of what tomorrow will bring. This means the opportunity for economic windfall abounds, and countries and private companies all over are looking to get a piece of the pie.[154] However, because of the difficulties associated with developing biotechnology products,[155] an environment that is conducive to such development is pertinent for

149 U.S. CONST. art. I, § 1 ("All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.").

150 U.S. CONST. art. I, § 8, cl. 18.

151 *See generally* William Baude, *Sharing the Necessary and Proper Clause*, 128 HARV. L. REV. 39 (2014).

152 *See* Freeman & Spence, *supra* note 134, at 72-73.

153 *Id.* at 9.

154 *2013 Policy Principles to Promote Biotechnology*, BIOTECH. INDUSTRY ORG. 1 (2013), https://www.bio.org/sites/default/files/files/GPP-FINAL-2-1-2013.pdf ("Countries all over the world are recognizing the importance of biotechnology to their economies, the health and well-being of their citizens, their food supply, and their ability to generate clean energy. Nearly every major country has adopted programs to generate a homegrown biotechnology sector and the well-paying jobs it supports.").

155 *Id.* ("Developing biotech products is scientifically demanding, capital-intensive, time-consuming, and involves significant commercial risk.").

success; this includes a regulatory pathway that is "transparent and predictable . .. . . [,] science-based and internationally recognized."[156]

Unfortunately, due to the rapid pace at which the industry has advanced, the U.S. has not kept the statutory scheme governing biotechnology regulation sufficiently up to date to cover all of today's products. Instead, Congress has delegated power to create new rules and regulations for novel products to the USDA, FDA, and EPA under existing authorities. This acquiescence, combined with the fact that biotech product regulation under the existing scheme was already complex at its genesis—spanning three federal agencies, each with different and overlapping roles—resulted in a web of regulatory uncertainty and unpredictability. This has had detrimental effects on many small businesses in the industry that cannot afford the high cost of navigating the regulatory pathway.

Building on this premise, while there is a wide range of political theory literature on the effect(s) globalization has on state sovereignty—ranging from reinforcing sovereignty to undermining it—most schools of thought, with the exception of the sceptic thesis, recognize globalization as an existing phenomenon that has economic implications which states must consider in policymaking.[157]

Indeed, the complex globalization thesis, which sits moderately between the sceptic and hyper-globalization theses, acknowledges that the world in which we live today is much different from the past. Proponents of the complex globalization thesis argue that the role of the state has been transformed by the globalization process, redefining its position within the "context of a polycentric political-economic system" in which the "shift in power from states to markets is believed to have heightened competitiveness between nations, such that governments must increasingly give priority to the need to compete in economic terms."[158]

The reality of globalization—combined with unprecedented technological advancement—speaks clearly to the U.S.' need to remain competitive in this industry. Other countries have recognized this, too. Take India, for example, whose Association for Biotechnology LED Enterprises ("ABLE") set a goal to grow India's bioeconomy to more than $100 billion by 2025. Unsurprisingly, as part of this effort, ABLE made recommendations for achieving this goal which included regulatory

156 *Id.*

157 *See generally* David Marsh, Nicola J. Smith & Nicola Hothi, *Globalization and the State*, *in* THE STATE: THEORIES AND ISSUES 172-90 (Colin Hay, Michael Lister & David Marsh eds., 2006).

158 *Id.* at 175.

reform as a key aspect.[159] The point is, "India matters,"[160] as do all current and potential stakeholders on the global landscape, and it would be a mistake to dismiss them.

Fortunately, the Obama Administration recognized this, and should certainly be credited for illuminating problems with the current approach to biotechnology regulation and lauded for taking the initiative to make an effort for reform.[161] However, given the nature of our government under the U.S. Constitution, the power of the President to commission a truly substantive overhaul of an ineffective regulatory scheme designated by Congress is limited since this would constitute a violation of separation of powers.[162]

As a result, the proposed 2016 Update, while certainly better than nothing and a viable short-term solution, is unlikely to repair the systemic damage resulting from decades long congressional neglect.[163] Nevertheless, even more poignant is the possibility that the Obama Administration's efforts could potentially be all for naught.[164]

Since it has been decades since Congress updated the statutory framework while the biotechnology landscape has continued to change dramatically in the interim,[165] it is imperative that Congress fulfill its duty and affirmatively act[166] in order to ensure that the U.S. does not

159 *See* JAMES C. GREENWOOD & P.M. MURALI, ACCELERATING GROWTH: FORGING INDIA'S BIOECONOMY 5 (2014), https://www.bio.org/sites/default/files/files/Burrill_AcceleratingGrowth_India-6-9-final.pdf.

160 Joya Chatterji, Toby Wilkinson & Bhaskar Vira, *Cambridge & India*, UNIV. OF CAMBRIDGE: RESEARCH (Oct. 5, 2015), http://www.cam.ac.uk/research/discussion/cambridge-and-india ("We cannot hope to address the major global challenges without an Indian Perspective and Indian involvement. .. . . . Partnership with India—the rising power of the 21st century—is both a demonstration and affirmation of that commitment [to contribute to society].").

161 *See* July 2015 Memorandum, *supra* note 3.

162 *See* U.S. CONST. art. II.

163 *See* July 2015 Memorandum, *supra* note 3, at 2.

164 *See* Kelly Servick, *Proposed U.S. Biotech Rules Raise Industry Hopes and Anxieties*, SCIENCE MAG. (Jan. 27, 2017), http://www.sciencemag.org/news/2017/01/proposed-us-biotech-rules-raise-industry-hopes-and-anxieties (with reports of plans to cut corporate regulations by at least 75%, "many researchers are unsure how the nebulous deregulatory agenda endorsed by the new administration of President Donald Trump might influence the final rules").

165 Barbero et al., *supra* note 45.

166 *See* Borel, *supra* note 97. Discussing possible approaches to cure existing problems with the current regulatory framework, Peter Jenkins, president of the Center for Invasive Species Prevention, said, "What we would argue is that Congress needs to adopt a more plenary, fulsome, appropriate new laws [sic] to regulate genetically engineered animals of all kinds instead of trying to cram them into existing policies and frameworks" in response to a suggestion for a more drastic approach than advocated by this note: to scrap all current regulations and start over from scratch. *Id.* Jenkins, too, recognized that starting from scratch would be impractical, but still pressed for more than what would be achieved under the update to the Coordinated Framework. *See id.* To be

compromise its position at the forefront of the biotech revolution,[167] or compromise the safety and health of the American public.[168]

sure, this note recognizes the impracticality of starting from scratch but argues for updates to existing statutes to reflect federal policy for today's biotechnology products. *See id.*

167 *See* BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 4, at 196 ("An uncertain regulatory climate also inhibits investment. Long delays in developing regulations make analysis of the potential return on an investment much more difficult.") .

168 *See* Borel, *supra* note 97. Discussing the genetically modified mushroom created using direct gene-editing technique by the plant pathologist at Pennsylvania State, the Borel noted, "[b]iotechnology experts don't seem particularly worried about the safety of the edited mushroom, and it doesn't appear to pose major health of environmental concerns. But it's worth noting that the white button didn't so much pass a regulatory test as fail to find an agency with proper authority to administer one — and as such, it begs a simple question: *What other biological innovations might slip through these regulatory cracks?*" *Id.* (emphasis added). *See also* Lydia Wheeler, *Groups Press Feds to Overhaul Regulations*, THE HILL (Nov. 15, 2015, 12:37 PM), http://thehill.com/regulation/energy-environment/260269-groups-call-on-obama-administration-to-overhaul-gmo-regs ("The groups are asking the administration to rework the existing guidelines, known as the Coordinated Framework for Regulation of Biotechnology, that were created in 1986 before GE crops were commercialized. They claim the framework, as it stands fails to protect consumers and the environment from the harmful effects of the pesticides used on GE crops. .. . . The Coordinated Framework is not equipped to handle the risks associated with GE foods already on the market, let alone what's coming down the pike."). Given that there are no current plans to revise old or draft new authorities for the Coordinated Framework's update and the case studies chosen for the proposed update do not adequately reflect the true complexity of agency jurisdiction for GE products, it begs the question whether the update will adequately assess such concerns since it will, more or less, merely constitute the same framework with additional guidance; *see* Kuzma, *supra* note 84.