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CLIMATE CHANGE AND BIOTECHNOLOGY

Donald T. Hornstein [*] ***& Eli D. Hornstein*** [**]

The legal regimes governing biotechnology and climate change took shape at approximately the same time, but for their first twenty years the two were viewed as independent of one another, with few if any areas of overlap. But in the years since, their potential areas of interconnection have started to grow. And within the last few years, the interconnections have come even more strongly into focus, but with only modest recognition in the legal literature. This Article seeks to set forth the ways in which biotechnology might affect, compound, and/or ameliorate the problems posed by climate change. The Article urges further attention to all of these possibilities.

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* Aubrey L. Brooks Professor of Law, University of North Carolina School of Law.
** PhD (Plant Biology) & Miller Fellow, North Carolina State University; President, Blue Flag Consulting, LLC. Dr. Hornstein thanks the NCSU Genetic Engineering and Society Center and the NSF Agricultural Biotechnology in Our Evolving Food, Energy and Water Systems National Research Traineeship/Fellowship for their support and training. The authors thank John Conley, Jonas Monast, Kendra Klein, and Jason Delborne for their very helpful comments on earlier versions of the Article.

I. INTRODUCTION

Within the span of a few years in the 1970s, the world witnessed both the birth of modern biotechnology and one of the earliest political expressions of concern over climate change. The birth of biotechnology is typically dated to 1973, when scientists first proved that a human gene could be isolated and mass produced.[1] A few years later, one of the first federal measures regarding climate change was adopted in 1978, when Congress enacted the National Climate Program Act,[2] requiring a federal investigation of the matter. There was, at the time, almost no interconnection seen between the two.

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[1] Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids* in Vitro, 70 PROC. NAT'L ACAD. SCI. 3240, 3240–44 (1973).
[2] National Climate Program Act, 15 U.S.C. §§ 2901–2908 (2018).

Fast forward to 2022–2023. In early August 2022, Congress enacted the Creating Helpful Incentives to Produce Semiconductors ("CHIPS") and Science Act.[3] Although the legislation is known mostly for its attempt to insulate the country from supply-chain disruptions as to Chinese-made semiconductors, the Act also authorized billions of dollars in federal support for microbial-based research advances in biotechnology.[4] Within the following weeks, Congress also enacted the Inflation Reduction Act ("IRA"),[5] legislation since described as the "single largest infusion of federal cash aimed at tackling the climate threat in U.S. history."[6] Included in the $369 billion in funding made available by the Act are funding streams for biofuels (including sustainable aviation biofuels), biotech-based approaches to soil conservation and carbon sequestration, and methane-reducing cattle feed.[7] Building on these two pieces of legislation, President Biden announced a National Biotechnology and Biomanufacturing Initiative in September 2022, designed, among other things, to create an entirely new manufacturing ecosystem designed to be independent of petroleum based inputs.[8] In June 2023, the White House more formally launched this initiative by prioritizing the development of an "American bioeconomy" that can, among other things, directly

[3] Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act, Pub. L. No. 117-167, 136 Stat. 1366 (2022).

[4] *See, e.g.*, *How the CHIPS and Science Act Benefits Microbiology*, AM. SOC'Y MICROBIOLOGY (Aug. 10, 2022), https://asm.org/Articles/Policy/2022/Aug2022/How-the-CHIPS-and-Science-Act-Benefits-Microbiolog [https://perma.cc/EM9H-69JS].

[5] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (2022).

[6] *Good Day BIO: Inflation Reduction Act and Ag Biotech*, BIOTECH. INNOVATION ORG. *(*Aug. 23, 2022), https://www.bio.org/gooddaybio-archive/good-day-bio-inflation-reduction-act-and-ag-biotech [https://perma.cc/RF62-E6B6].

[7] *See id.*

[8] *See Fact Sheet: President Biden to Launch a National Biotechnology and Biomanufacturing Initiative*, WHITE HOUSE (Sept. 12, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/12/fact-sheet-president-biden-to-launch-a-national-biotechnology-and-biomanufacturing-initiative/ [https://perma.cc/UBR3-7TRY].

support "climate change solutions."[9] Simply put, climate change and biotechnology no longer operate on parallel tracks.

Part I of this Article describes the technological advances in biotechnology and situates them within the regime that was created to regulate them. Part II summarizes the core features of the modern law of climate change. Part III then more fully develops the Article's central claim: that biotechnology is being increasingly incorporated into the country's policies for attaining the Paris Treaty's climate target of 1.5 degrees Celsius, and also into the need to adapt to the new climate realities that are upon us already.

II. THE "STANDARD" LAW OF BIOTECHNOLOGY

A. Early Scientific Development and the Supreme Court's Chakrabarty Patent Case

Throughout its first twenty-five years, the two areas of biotechnology's greatest legal developments were found in intellectual property law and in early issues in biotechnology's agricultural applications and their potential effects on the environment. Technologically, the seminal early breakthroughs were techniques for selectively recombining DNA molecules, first reported in 1973 by Stanley Cohen of Stanford University and Herbert Boyer of the University of California, San Francisco,[10] and methods for introducing these recombinant DNA molecules into living cells.[11] Legally, the biggest breakthrough came in 1980, when the Supreme Court in *Diamond v. Chakrabarty*[12] held that patent protection could be extended to the products of these recombinant

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[9] *See Fact Sheet: Biden-Harris Administration Announces New Action Plan to Bolster, Expand, and Diversify America's Biotechnology and Biomanufacturing Workforce,* WHITE HOUSE (June 27, 2023), https://www.whitehouse.gov/ostp/news-updates/2023/06/27/fact-sheet-biden-harris-administration-announces-new-action-plan-to-bolster-expand-and-diversify-americas-biotechnology-and-biomanufacturing-workforce/ [https://perma.cc/LQ8D-WMEV].

[10] *See* Cohen et al., *supra* note 1.

[11] *See, e.g.*, Jeff Schell & Marc Van Montagu, *The Ti-Plasmid of Agrobacterium Tumefaciens, a Natural Vector for the Introduction of Nif Genes in Plants?*, 9 BASIC LIFE SCI. 159 (1977).

[12] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

DNA techniques.[13] Subsequently, courts have had little trouble affording patents not only to particular recombinant molecules, but also to the techniques used to analyze or create them.[14] Patent protection was similarly afforded to later discoveries in the field that went well beyond recombinant DNA. In late 1985, there appeared a celebrated published paper on polymerase chain reaction ("PCR"),[15] patented that same year. The development of PCR was quickly followed by the advent of commercialized DNA Sanger sequencing in 1986, with successive improvements leading up to the development of next-generation sequencing ("NGS") by the early 2000s.[16] The combined ability to amplify and read DNA at will exploded the range of biotechnology through new methods in gene cloning,[17] discovery, and manipulation.[18] In the early 2010s, these advances included the development of the programmable gene-editing technique, clustered regularly interspaced short

[13] *Id.* at 303–04. *See, e.g.*, Vickie V. Valentine, *Genetically Engineered Microorganisms:* Diamond v. Chakrabarty*, 447 U.S. 303 (1980),* 48 TENN. L. REV. 454 (1981).

[14] *See, e.g.,* Clemens Kerle, *International IP Protection for GMOs – a Biotech Odyssey*, 8 COLUM. SCI. & TECH. L. REV. 147, 154 (2007) ("[A] variety of [intellectual property rights] are now available for the result[s] of modern biotechnological research.").

[15] *See, e.g.*, Randall K. Saiki et al., *Enzymatic Amplification of ß-Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia*, 230 SCI. 1350 (1985).

[16] The core method of Sanger sequencing, originating in the academic work of Fred Sanger at the University of Cambridge in the 1970s, was not patented but many developments relating to chemical, enzymatic, and instrumentation did receive patent protection. *See* Christopher M. Holman, *Advances in DNA Sequencing Lead to Patent Disputes,* 30 NATURE BIOTECHNOLOGY 1054, 1054 (2012). Unlike Sanger sequencing, most NGS methods were patented in their early stages by universities, or directly developed in the private sector. The first commercially available NGS was "454" technology, in 2005. *See* Stephen C. Schuster, *Next-Generation Sequencing Transforms Today's Biology,* 5 NATURE METHODS 16, 16–18 (2008).

[17] *See, e.g.*, Daniel G Gibson et al., *Enzymatic Assembly of DNA Molecules up to Several Hundred Kilobases*, 6 NATURE METHODS 343 (2009).

[18] *See* Jonathan D. Kaunitz, *The Discovery of PCR: ProCuRement of Divine Power,* 60 DIGESTIVE DISEASES SCI. 2230 (2015).

palindromic repeats ("CRISPR"),[19] which provided a revolutionary new biotechnology technique,[20] a patent for which was awarded in 2022 to the Broad Institute at Harvard and MIT.[21]

The early scientific discoveries and their protection under United States ("U.S.") patent laws launched the biotechnology industry. Herbert Boyer became one of the co-founders of Genentech, a company that in 1978 became the first to clone the human insulin gene.[22] Genentech licensed that drug to Eli Lilly and Company which, after it became the first recombinant drug approved by the U.S. Food and Drug Administration ("FDA") in 1982,[23] became in turn the "first biotechnology product to achieve significant commercial success."[24] Throughout the 1980s and 1990s, the commercialization of biotechnology especially into areas of medical diagnoses and treatment were especially pronounced,[25] followed by early visible applications to agriculture.[26]

B. A Quick Fast Forward: Contrasting Chakrabarty with West Virginia v. EPA

Before expanding on the emerging regulation of biotechnology as to agriculture and the environment, it is worth pausing to contrast the *Chakrabarty* Court's approach in 1980 as to the biotechnology issues before it, with the Court's approach in 2022 in *West Virginia*

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[19] *See* Howard Hochster, *CRISPR Patent Battle: Beautiful Science, Poor Public Policy,* 36 ONCOLOGY 263, 323 (2022).

[20] *See, e.g.*, Paul Enriquez, *CRISPR GMOs*, 18 N.C. J.L. & TECH. 432, 435 (2017) ("A genome editing revolution of unprecedented magnitude – spearheaded by a scientific breakthrough called 'CRISPR' . . . is underway.").

[21] *See, e.g.*, Jacob S. Sherkow, *Patent Protection for CRISPR: An ELSI Review*, 4 J.L. BIOSCIENCES 565 (2017).

[22] *See, e.g.*, Darius Kharabi, *A Real Options Analysis of Pharmaceutical-Biotechnology Licensing*, 11 STAN. J.L. BUS. & FIN. 201, 203 (2006).

[23] *See* Christopher M. Holman, *Developments in Synthetic Biology are Altering the IP Imperatives of Biotechnology*, 17 VAND. J. ENT. & TECH. L. 385, 390 (2015).

[24] *See id.*

[25] *See id.* at 392 ("[M]ost of the important products of conventional biotechnology have been human drugs.").

[26] *Id.* ("Probably the most commercially significant non-pharmaceutical application of conventional biotechnology has been in the area of agriculture and genetically modified crops.").

v. EPA,[27] as to climate-change issues. Although the two cases arose under different statutory regimes, both focused on the need for further congressional legislation (or not) when presented with a major social issue before the court that was not addressed specifically in existing law. The contrast between these two cases, both in terms of overall social impact and the Court's jurisprudential reasoning, is notable. The Court's decision in *Chakrabarty* launched an entire industry with a market capitalization in 2023 estimated in excess of 1.2 trillion dollars.[28] In contrast, in *West Virginia*, the Court found it to be a "major question" requiring new congressional authorization before an Environmental Protection Agency ("EPA") rulemaking could change the "Nation's overall mix of electricity generation . . . from 38% coal to 27% coal by 2030,"[29] a shift that had already been largely accomplished.[30]

And it was not just the results, but the reasoning, that distinguish the *Chakrabarty* Court from the Court in *West Virginia*. In *Chakrabarty*, the Court majority dismissed the argument that then-existing congressional legislation involving the patentability of hybridized plants carried with it the negative implication that Congress meant to delegate nothing more.[31] Rather, the *Chakrabarty* Court stated, "[t]his Court frequently has observed that a statute," when delegating broad authority to an agency, "is not to be confined [merely] to the 'particular applications[] . . . contemplated by the legislators.' "[32] In contrast, in *West Virginia*, the Court found that in "extraordinary cases," its precedent provided "reason to hesitate before concluding that Congress in fact meant to

[27] West Virginia v. EPA, 142 S.Ct. 2587 (2022).

[28] *Biotechnology,* STOCK ANALYSIS, https://stockanalysis.com/stocks/industry/biotechnology/# [https://perma.cc/X3VE-XLCL] (last visited Sept. 18, 2023) ("The Biotechnology Industry has a total of 718 stocks, with a combined market cap of $1,242.7 billion.").

[29] *West Virginia*, 142 S.Ct. at 2605.

[30] *Id*. at 2638–39 (Kagan, J., dissenting) ("[T]he industry exceeded that target all on its own . . . and overwhelmingly supports EPA in this case.").

[31] Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980) ("We find nothing in the exclusion of bacteria from plant variety protection to support the petitioner's position.").

[32] *Id*. at 315–16 (quoting Barr v. United States, 324 U.S. 83, 90 (1945)).

confer" the power the agency asserted.[33] In *Chakrabarty*, the Court found it especially noteworthy that the general patent laws spoke of "any" inventions[34] from which there could be implied a wide-ranging delegation to the agency to grant patents,[35] yet in *West Virginia* the Court ignored a similar conclusion that the Court itself had emphasized in its first climate-change case, *Massachusetts v. EPA*,[36] when the Court highlighted Congress' reference to the regulation of "any" air pollutants in the Clean Air Act ("CAA") itself.[37] In *Chakrabarty*, the Court found that, in cases when Congress uses broad language to authorize agency action, "broad general language is not necessarily ambiguous when congressional objectives require broad terms,"[38] whereas the *West Virginia* Court held that "something more than a merely plausible textual basis for the agency action is necessary . . . [t]he agency instead must point to clear congressional authorization for the power it claims."[39] And finally, it must be noted that in *Chakrabarty*, it was Justice Brennan, one of the Court's most liberal members, who found it to be "the role of Congress, not this Court, to broaden or narrow the reach of the patent laws,"[40] whereas that position was staked out by the conservative majority in *West Virginia*.[41]

Had the Roberts Court's "major question" doctrine been applied in 1980, then, for better or worse, it is possible that the early commercialization of biotechnology, especially as to areas of medicine and health care, would have been delayed, if it were allowed by the Court and its ever-changing approach to statutory interpretation, to have happened at all.

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[33] *West Virginia*, 142 S.Ct. at 2608 (internal quotation marks omitted).
[34] *Chakrabarty*, 447 U.S. at 307.
[35] *Id.*
[36] Massachusetts v. EPA, 549 U.S. 497 (2007).
[37] *See id*. at 528–29 ("The Clean Air Act's sweeping definition of 'air pollutant' includes '*any*' pollution agent . . . including *any* . . . substance emitted into . . . the . . . air.").
[38] *Chakrabarty*, 447 U.S. at 315.
[39] *West Virginia*, 142 S.Ct. at 2609 (internal quotation marks omitted).
[40] *Chakrabarty*, 447 U.S. at 322 (Brennan, J., dissenting).
[41] *West Virginia*, 142 S.Ct. at 2609.

C. *The Early Development of Biotechnology Regulation After Chakrabarty*

But, of course, the Court did hand down its *Chakrabarty* decision in 1980 and the genie was out of the bottle. Biotechnology's most significant early regulatory dispute involved the experimental release of genetically engineered ("GE") bacteria[42] and, more specifically, a weather-related, recombinant-DNA-created gene known as "ice-minus."[43] Although this experiment happened to be weather-related, it was directed at what might commonly be thought of as a farmer's "normal" concern about weather, rather than a particularized concern that human activity was causing the climate itself to change. The purpose of the experiment was to test whether the genetically modified bacteria could provide potato, tomato, and bean plants the ability to better withstand damage from early frosts.[44] Although the experimental release had been approved by the National Institutes of Health ("NIH") under guidelines it had finalized in 1976 and revised in 1978,[45] it was challenged by environmentalists for lack of an Environmental Impact Statement ("EIS") under the National Environmental Policy Act of 1970 ("NEPA").[46] In the country's first major appellate court decision on the environmental aspects of genetic engineering, the D.C. Circuit in *Foundation on Economic Trends v. Heckler*,[47] upheld a district

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[42] The unmodified bacteria, *Pseudomonas syringae*, grow ubiquitously on plants. They are an important natural cause of frost susceptibility because the proteins on the surface of bacterial cells provide sites for the formation of ice crystals to begin ("nucleation"). The ice-minus engineered strain had alterations to its surface proteins that made it harder for ice crystals to form. Ice-minus was sprayed directly onto the plant leaves where it displaced wild *Pseudomonas* and subsequently lowered the threshold for frost damage by several degrees. *See, e.g.*, Steven E. Lindow, *Competitive Exclusion of Epiphytic Bacteria by Ice-*Pseudomonas Syringae *Mutants*, 53 Applied Env't Microbiology 2520 (1987).

[43] *See* Connie Kimball, *Deliberate Release of Genetically Altered Frost Inhibiting Bacteria: Judicial Intervention in the Genetic Age*, 4 UCLA J. Envt'l L. & Pol'y 241 (1985).

[44] *See* Lindow, *supra* note 42. *See also* Robert K. Colwell & Stan Eisen, *The Ice Minus Case and a Scientifically Informed Judiciary*, 237 Sci. 10 (1987).

[45] *See* Found. on Econ. Trends v. Heckler, 756 F.2d 143, 150 (D.C. Cir. 1985).

[46] 42 U.S.C. § 4321 (2012).

[47] Found. on Econ. Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985).

court's injunction against NIH approval of the experimental release without completion of the full EIS.[48] It is not hard to find in the Court's opinion a fear that the risks of genetic engineering were being evaluated through a process the Court found to be idiosyncratic.[49] Nor is it hard to find in the academic and popular commentary on NIH's decision as to "ice-minus" the fear of unforeseen consequences imagined in Kurt Vonnegut's 1963 novel, *Cat's Cradle,* as to the cataclysmic, albeit fictional, molecule, "ice-nine."[50]

Within a year of *Heckler*, President Reagan's Office of Science and Technology Policy established the Coordinated Framework for the Regulation of Biotechnology[51] to put federal policy on a more regularized basis.[52] Not only did the Coordinated Framework anchor

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[48] *Id.* at 160.

[49] *See id*. at 154 ("In light of this complete failure to address a major environmental concern, NIH's environmental assessment utterly fails to meet the standard of environmental review necessary before an agency decides not to prepare an EIS.").

[50] *See* Kimball, *supra* note 43, at 241 ("What hope can there be for mankind, when there are such men to give such playthings as ice-nine to such short-sighted children as almost all men and women are?") (quoting KURT VONNEGUT, CAT'S CRADLE 199 (1963)). This imagery was also invoked in another controversy beginning soon after, involving a theoretical release of genetically engineered *Klebsiella planticola* yeast with the ability to produce ethanol from plant waste. The release never occurred and actual effects of the yeast were unclear, but because ethanol at high concentrations is toxic to plants the incident drew quotes such as, "[i]n 1992 the Environmental Protection Agency was only a few weeks away from ending life on the planet as we know it," and "[h]ow a biotech company almost killed the world." *Commentary: Searching for a Fair Resolution Concerning Controversial Story on Possible Effects of Klebsiella P on the Environment*, GMWATCH (2001), https://www.gmwatch.org/en/main-menu/news-menu-title/archive/40-2001/8951-full-story-of-the-dr-elaine-ingham-controversy-over-klebsiella-p [https://perma.cc/HCC5-K3V6]; Robert Brockway, *How a Biotech Company Almost Killed the World (with Booze)*, CRACKED (Apr. 3, 2010), https://www.cracked.com/article_18503_how-biotech-company-almost-killed-world-with-booze.html [https://perma.cc/ZH8C-J8BX].

[51] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

[52] *See* Rebecca M. Bratspies, *Consuming (F)ears of Corn: Public Health and Biopharming,* 30 AM. J. L. & MED. 371, 378 (2004) ("A successful legal challenge to decisions made under those [NIH] guidelines forced the Reagan Administration to develop a more overarching regulatory policy to guide federal decisionmaking

federal agencies' authority over genetically modified organisms to their existing substantive statutes, but, as a general approach to policy, it suggested that constraints should be imposed only if necessary to address "unreasonable" risks.[53] Although the dispute precipitating the Coordinated Framework involved a gene related to weather, nothing in the evolution of the Coordinated Framework had, at that time, anything to do with political concern about climate change as the issue is understood today.

D. Regulation Under the Coordinated Framework

Since 1986, biotechnology regulation is traditionally analyzed as moored to the Coordinated Framework.[54] The Framework has two key features. The first is its reliance on pre-existing statutes and agencies, seeking to operate as a type of traffic conductor assigning particular products or applications to the agency believed to have the most relevant expertise and statutory authority, and emphasizing that regulation should address only "significant risk."[55] And, as made clear in *Heckler*,[56] NEPA also applies to all federal agencies making decisions involving bioengineered applications to the extent that agency action may cause "significant" environmental effects.[57]

Both of these features of the Framework were in play in *Monsanto Co. v. Geertson Seed Farms,*[58] the first case involving genetically engineered seeds to reach the U.S. Supreme Court. At issue in *Geertson* was Monsanto's "Roundup Ready Alfalfa," the first patented product designed to allow a grower to spray the herbicide glyphosate (marketed by Monsanto as "Roundup") on a crop grown from seeds genetically engineered to tolerate the herbicide ("Roundup Ready"), thereby allowing the grower to

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about biotechnology research and products . . . [t]o that end, the [White House] Office of Science and Technology Policy issued the Coordinated Framework for Regulation of Biotechnology.").

[53] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23319, 23323–24, 23328.

[54] *Id*.

[55] *Id*. at 23348.

[56] Found. on Econ. Trends v. Heckler, 756 F.2d 143, 150 (D.C. Cir. 1985).

[57] *Id*. at 147.

[58] Monsanto Co. v. Geerston Seed Farms, 561 U.S. 139 (2010).

control weeds without mechanical weeding. Under the Coordinated Framework, the biotechnology issue belonged to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS") pursuant to the Plant Protection Act ("PPA").[59] Under the PPA, APHIS had promulgated a regulation presumptively finding genetically engineered plants to be "plant pests" due to the risk that the Roundup Ready gene (in this case) could be transmitted to other growers' non-genetically-modified alfalfa (negatively affecting its marketability)[60] or transmitted to naturally occurring weeds (thereby triggering an evolutionary process that can end in "superweeds").[61] APHIS' regulations, however, allowed companies to petition their way out of this presumption upon a sufficient showing that the risk could be eliminated or minimized.[62] One issue in the case was the authority of APHIS to relax its presumptive policy under the PPA pursuant to a protocol it believed reduced the risk of cross-contamination from Round Up Ready Alfalfa, on which APHIS prevailed.[63] The other issue involved NEPA and whether APHIS properly found there to be no significant environmental impact justifying a full-fledged Environmental Impact Statement, on which APHIS lost.[64] Nevertheless, the case reflected the normal operation of national bioengineering policy under the Coordinated Framework on both counts.

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[59] Agriculture Risk Protection Act of 2000, 7 U.S.C. § 7701.

[60] *See* Michael H. Carpenter, Jr., *Beware of the Genetically Modified Crop: Applying Animal Liability Theory in Crop Contamination*, 23 BUFF. ENV'T L. J. 63, 70 (2015–2016) (genetic drift of GM crops can destroy a neighboring farm's crops of their qualification for the organic-food market).

[61] *See infra* text accompanying notes 67–69 (discussing risk of super-weeds).

[62] *See* Rebecca Bratpies, *Is Anyone Regulating? The Curious State of GMO Governance in the United States*, 37 VT. L. REV. 923, 934 (2013) ("Anyone may petition APHIS to deregulate a GE crop.").

[63] *Geerston*, 561 U.S. at 156 (holding that no environmental impact statement needed as to the policy of allowing case-by-case determinations, thus district court's injunction on this issue reversed).

[64] *Id*. at 165 (holding that full environmental impact statement under NEPA is needed before the release of "ice-minus" in this case, and thus district court's injunction upheld).

1. Two Notable Developments in Genetic Engineering and the Environment

That said, public perception of biotechnology was diminished by what is sometimes described as "the Monsanto mistake."[65] The moniker typically derives from what is viewed as Monsanto's aggressive use of intellectual property law to pursue patent infringement cases against farmers whose crops and seeds had been unintentionally mixed with the Roundup Ready gene.[66] But it also could describe the evolutionary development of "super-pests" and "super-weeds"—from random individual animals and plants that happened to be naturally immune to bio-engineered products and which therefore survive and pass on genetic resistance to their next generation.[67]

Though early fears centered on the prospect of direct horizontal transfer of recombinant sequences from genetically modified organisms ("GMOs") to other organisms, this turned out to be neither a necessary mechanism for biotechnology to alter the genetic makeup of wild species in the environment, nor even the dominant one.[68] Instead, the applications of consistent and large-scale selection pressure on these wild pest populations constituted a sort of "population-level" genetic engineering, taking place outside of any laboratory, that resulted in novel changes to the DNA makeup of many individuals of these species.[69] The rapid natural

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[65] *See* Jennifer Kahn, *The Gene Drive Dilemma: We Can Alter Entire Species, But Should We?*, N.Y. TIMES (Jan. 8, 2020), https://www.nytimes.com/2020/01/08/magazine/gene-drive-mosquitoes.html [https://perma.cc/M8EV-ZX5U] (attributing the "Monsanto Mistake" comment to a researcher's opinion that Monsanto was too defensive about scientific questions in its early years of marketing GM products, and overly concerned about preserving its intellectual property rights).

[66] Rebecca K. Stewart, *Weeds*, *Seeds & Deeds Redux: Natural and Legal Evolution in the U.S. Seed Wars,* 18 STAN. TECH. L. REV. 79, 93 (2014) (Monsanto brought over 150 lawsuits against farmers for patent infringement).

[67] *See supra* note 61. *See also infra* text accompanying notes 71–75 (discussing genetic resistance).

[68] *See, e.g.*, Carpenter, *supra* note 60, at 65 ("an organic farmer may lose his organic plants if pollen from GM crops contaminate his fields.").

[69] *See, e.g.*, Dale L Shaner et al., *What Have the Mechanisms of Resistance to Glyphosate Taught Us?: Glyphosate Mechanisms of Resistance*, 68 PEST MANAGING SCI. 3 (2012).

development of weeds in the current regime is met at first by increased usage of the herbicide, and as that fails, development of new herbicides and corresponding engineered crops, and now, increasingly, crops resistant to combinations of multiple herbicides.[70] The original "Roundup Ready" glyphosate resistance trait is now rarely used alone, instead replaced or combined with newer herbicide pairings, such as 2, 4-D, dicamba, and glufosinate.[71] Naturally occurring resistance in weeds and insects is now the driving factor for usability and commercial development of the herbicide-resistant and *Bt*-crops[72] that are currently the world's most popular GMOs.[73]

Public perception of biotechnology, as well as scientific lessons learned from the development of resistance, were also relevant to the rise of another new tool in the biotechnology toolbox: gene drives. A gene drive consists of an engineered genetic mechanism, which allows a gene to spread in a population, even though it reduces the fitness of the individuals that carry it—contrary to the standard rules of evolution—and can therefore be used over time to suppress a population or even cause local extinctions.[74] Gene drives

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[70] Some weeds, like the famously resilient Palmer amaranth, have now been exposed to so many different herbicides that they have developed mechanisms that make them resistant even to herbicides they have never seen before. *See* Bob Hartzler, *Metabolic resistance in Palmer amaranth,* IOWA ST. U. EXTENSION & OUTREACH (Feb. 1, 2021, 6:44 AM), https://crops.extension.iastate.edu/blog/bob-hartzler/metabolic-resistance-palmer-amaranth [https://perma.cc/Q46M-T8UL].

[71] Each of these novel herbicides arrives with a different profile of weeds which it can initially control, and different requirements and risks for application. Dicamba, is known for drifting far afield from application sites and damaging wild plants and crops lacking the resistance trait. In at least one case these side effects contributed to a murder. *See* Andrew Amelinckx, *Pesticide Drift Leads to Alleged Murder*, MODERN FARMER (Nov. 4, 2016), https://modernfarmer.com/2016/11/pesticide-drift-leads-alleged-murder/ [https://perma.cc/JE4W-9A3N].

[72] *See infra* notes 167–77 for discussion of *Bt* (*Bacillus thuringiensis*).

[73] *See* Fred Gould, Zachary S. Brown & Jennifer Kuzma, *Wicked Evolution: Can We Address the Sociobiological Dilemma of Pesticide Resistance?*, 360 SCI. 728, 728 (2018).

[74] The importance, speed, and extent of unintentional open-air alteration of wild pest gene pools presaged the development of gene drives, a tool to intentionally engineer the genetic makeup of whole wild populations. *See generally* Nicolas O. Rode et al., *Population Management Using Gene Drive: Molecular Design, Models of Spread Dynamics and Assessment of Ecological Risks*, 20

are primarily oriented at pest control. For example, the British company Oxitec developed a gene drive for *Aedes aegypti*, the mosquito that spreads Zika, dengue, chikungunya, and yellow fever.[75] In Oxitec's gene drive, male mosquitos carry a gene which causes their female offspring to die as larvae, but their male offspring to develop normally.[76] Each mating of a gene-drive male and a wild female therefore produces half as many new mosquitos as that of a wild male and wild female.[77] Gene drives offer the prospect of pesticide-free control of mosquito-borne diseases, either via "mild" versions that involve periodic release of GMO insects to suppress local populations, or, at the extreme, by "strong" versions capable of wiping these species off the face of the earth for our convenience.[78] The Oxitec mosquito was tested in a large-scale field

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CONSERVATION GENETICS 671 (2019); Albert C. Lin, *Mismatched Regulation: Genetically Modified Mosquitos and the Coordinated Framework for Biotechnology*, 51 U.C. DAVIS L. REV. 205 (2017).

75 Lin, *supra* note 74*,* at 208; *Fighting the World's Deadliest Animal*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/globalhealth/stories/2019/world-deadliest-animal.html#:~:text=Spreading%20diseases%20such%20as%20malaria,other%20creature%20in%20the%20world [https://perma.cc/67QT-T4GT] (last updated Aug. 17, 2023).

76 *See* Lin, *supra* note 74, at 208–09 ("Large numbers of adult males containing the lethal gene are then released, in the expectation that they will breed with wild females and produce offspring that cannot survive in the wild.").

77 Rather than being lost from the population due to its harmful effect, the gene drive persists and spreads due to the survival of the male offspring, ultimately lowering the population size since male mosquitos do not bite. *See id*; *see also Following Review of Available Data and Public Comments, EPA Expands and Extends Testing of Genetically Engineered Mosquitoes to Reduce Mosquito Populations,* ENV'T PROT. AGENCY (Mar. 7, 2022), https://www.epa.gov/pesticides/following-review-available-data-and-public-comments-epa-expands-and-extends-testing [https://perma.cc/CU8C-UBPU].

78 Here, again the imagery of Vonnegut's ice-nine is not far off. In point of fact, though multiple mechanisms of gene drive work well in the lab, they tend to be far less effective in natural conditions and often fail to penetrate the wild population at all. Contemporary gene drive research, therefore, has two major tracks: developing mathematical models and genetic mechanisms specifically to limit the most extreme risks of the most theoretically powerful gene drives gone out-of-control, and, on the other hand, trying to get any of them in practice to work at all. *See, e.g.*, Jason Delborne et al., *Mapping Research and Governance Needs for Gene Drives*, 5 J. RESPONSIBLE INNOVATION S4 (2018); Sumit Dhole, Alun L. Lloyd & Fred Gould, *Gene Drive Dynamics in Natural Populations: The*

trial in southern Florida in Spring 2021 with apparent success.[79] Gene drives, as the cutting edge of biotechnology, are unique in the toolbox for the extent to which they offer environmental benefits—a pesticide-free answer to the climate-driven spread of disease—to match their potential risks.[80]

2. Developments in Regulation Under the Coordinated Framework

It is hardly surprising that the Coordinated Framework has been the subject of criticism.[81] The Framework, after all, was adopted on relatively short notice by the White House in 1986 following the D.C. Circuit's 1985 decision in *Heckler*, and was based on the assumption that other regulatory issues that might arise could easily fit within the existing statutory mandates of USDA, FDA, and EPA.[82] In fact, the Framework has demonstrated both the strengths and weaknesses of these assumptions.

Undoubtedly the Framework's weakest performance has been found in its inability to regulate the ecological risks of weed and insect resistance caused by products such as Roundup Ready crops. As Rebecca Bratspies wrote in 2013:

> Despite overwhelming adoption of genetically engineered . . . corn, soybeans, and cotton, crop yields have largely held steady or decreased, while pesticide use has skyrocketed. As a result, at least ten species of

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Importance of Density Dependence, Space, and Sex, 51 ANNU. REV. ECOLOGY, EVOLUTION, & SYSTEMATICS 505 (2020); Nina Wedell, Tom Price & Anna Lindholm, *Gene Drive: Progress and Prospects*, 286 PROC. ROYAL SOC'Y B: BIOLOGICAL SCI. 1 (2019).

[79] *See* Sara Kuta, *First U.S. Open-Air Test of Genetically Modified Mosquitoes Deemed a Success*, SMITHSONIAN MAG. (Apr. 21, 2022), https://www.smithsonianmag.com/smart-news/first-us-open-air-test-of-genetically-modified-mosquitoes-deemed-a-success-180979960/ [https://perma.cc/4V2C-Y5DM].

[80] *See* Rode et al., *supra* note 74; Delborne et al., *supra* note 78.

[81] *See, e.g.*, Rebecca M. Bratspies, *Is Anyone Regulating? The Curious State of GMO Governance in the United States*, 37 VT. L. REV. 923, 940 (2013) ("There are some very serious environmental, social, and economic risks that the existing regime is systematically unable to address.").

[82] *See id*. at 930.

so-called "superweeds"—weed plants resistant to glyphosate—have been documented in more than twenty states.[83]

The Framework allocates the regulation of such genetically engineered crops between APHIS (within the USDA) and EPA.[84] Among other things, APHIS' decisions are required by NEPA to consider the indirect and cumulative effects of its decisions, yet in an Environmental Impact Statement accompanying its decision to deregulate "Enlist(R) crops" (i.e., corn and soybeans designed by Dow AgroSciences to be resistant to the accompanying herbicide 2, 4-D), APHIS in 2014 released an EIS finding that any increased use of 2, 4-D, and its potential contribution to super-weeds with genetic resistance to the herbicide, lay " 'outside the scope' of the [Enlist] EIS because . . . EPA [regulates herbicides] under FIFRA."[85] In turn, EPA eschewed the need to perform an EIS of its review of Enlist(R) crops because its procedures under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") have been found to displace the need for independent NEPA analysis.[86] Yet, EPA's analysis under FIFRA did not consider such indirect environmental effects,[87] and, in fact, in its 2, 4-D, and Enlist Duo(R) decisions "EPA did not assess whether the registration of those herbicides would have an adverse effect on the environment."[88] Unsurprisingly, given that these kinds of Alphonse-Gaston machinations could arise in the Framework, it is little surprise that "the introduction of

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[83] *See id*. at 924 (citing William Newman & Andrew Pollack, *Farmers Cope with Roundup Resistant Weeks,* N.Y. TIMES (May 3, 2010), https://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html [https://perma.cc/JVV9-KNYZ]). Indeed, this number has again risen: forty states now have at least one of eighteen known glyphosate resistant weeds, and several weed species have been documented with resistance for up to seven herbicides at once. *See* Ian Heap, *Herbicide Resistant Weeds by State*, INT'L HERBICIDE-RESISTANT WEED DATABASE, https://www.weedscience.org/Vmap/StateMap.aspx [https://perma.cc/W79Q-FFMP] (last visited Aug. 18, 2023).

[84] Bratspies, *supra* note 81, at 931–37.

[85] Michael Mahoney, *Perpetuating the Cycle: The Failure of APHIS and EPA to Consider the Cumulative Impact of Pairing Herbicides with Herbicide-Resistant Crops*, 40 COLUM. J. ENV'T L. 198 (2015).

[86] *Id.* at 203–04.

[87] *Id.* at 203.

[88] *Id.*

genetically engineered crops caused a 383 million pound increase in herbicide use from 1996 to 2008."[89] No one was minding the store.

The problem—and potential—of gene drives faced similar inconsistencies in the day-to-day operation of the Framework, an issue that presents one of the earliest regulatory links between biotechnology regulation and climate change. The prospect of using gene drives in the U.S. arose when Zika-carrying mosquitos were discovered in southern Florida, a northward expansion of the insect's range attributable to warmer temperatures in North America.[90] In 2008, Oxitec sought regulatory approval under the Framework for an experimental release of mosquitos whose genes it had altered to cause a population-crash among the insect's immediately subsequent generations.[91] Oxitec was originally told to submit its proposal to the USDA's Veterinary Services Office, only to be told by USDA that the application properly belonged to another office: the FDA's Center for Veterinary Medicine, which regulates animal drugs.[92] Oxitec thereafter sought FDA approval as an investigational new animal drug ("INAD"), something that normally does not require FDA approval.[93] At least one commentator has suggested that it should have been yet another agency altogether that had regulatory jurisdiction under the Framework for Oxitec's proposal.[94] Indeed, in 2020, EPA granted an "experimental use permit" for Oxitec to conduct trials in Florida and

[89] *Id.* at 187–88.

[90] *See* Luís Patriani, *Zika, dengue transmission expected to rise with climate change*, MONGABAY (Aug. 9, 2023), https://news.mongabay.com/2023/08/zika-dengue-transmission-expected-to-rise-with-climate-change/ [https://perma.cc/BG36-2RAK]; Lisa Schlein, *WHO Warns Climate Change Causing Surge in Mosquito-Borne Diseases,* VOA (Apr. 10, 2023, 8:45 AM), https://www.voanews.com/a/who/warns-climate-change-causing-surge-in-mosquito-borne-diseases/7043700.html [https://perma.cc/7NLF-3ZQU].

[91] *See* Lin, *supra* note 74, at 207.

[92] *Id.* at 216.

[93] *Id.* at 216 & n.71.

[94] *See id.* at 222 ("FDA issued draft guidance . . . in the waning days of the Obama Administration [under which] Oxitec's genetically modified mosquito would be regulated by EPA as a pesticide rather than by FDA as a new animal drug.").

Texas, and Florida officials approved the field tests for summer 2021.[95]

Thus, the tenuous basis for evaluation of gene drives under the Framework—a biotechnology that could be of immense value in a world disrupted by climate change—is found not only in the feel-your-way approach as to "which agency" was the correct one under the Framework, but also by the delay in obtaining EPA regulatory oversight as to the potential environmental risks that might arise in a world in which this subspecies of insect was suddenly eliminated from the local ecosystem (e.g., what other insects might fill its niche, what effects on animals that otherwise eat the now-extinct mosquito might arise, etc.). This is not to say that there are necessarily any lurking catastrophic risks. Rather, it is to say that the Framework's treatment of Oxitec's application insufficiently raised the issue.

The problems that have been evidenced in the Framework should not cloud those instances where the Framework seems to have worked well. This Article discusses and builds on those in Part IV.

III. THE "STANDARD" LAW OF CLIMATE CHANGE

In 1987, Congress enacted one of the first statutes directed specifically to climate change. The modest Global Climate Protection Act[96] directed the EPA and the U.S. State Department to report on the state of "international scientific understanding of the greenhouse effect,"[97] and to report on a strategy by which the U.S. "intends to seek further international cooperation to limit global climate change."[98] More substantively, in 1990, Congress enacted the Global Change Research Act,[99] to be a research-oriented (rather than policy-oriented) measure, which was significant in that it

[95] *See* Cynthia E. Schairer et al., *Oxitec and MosquitoMate in the United States: Lessons for the Future of Gene Drive Mosquito Control*, 115 PATHOGENS & GLOB. HEALTH 365, 372 (2021).

[96] Global Climate Protection Act of 1987, Pub. L. No. 95-367 § 2, 92 Stat. 607 (1978) (codified as amended at 15 U.S.C. § 2901).

[97] *Id.* § 2901 note (§ 1104(1)).

[98] *Id.* § 2901 note (§ 1104(3)).

[99] Global Change Research Act of 1990, 15 U.S.C. §§ 2921–2961.

mandated an ongoing, coordinated federal scientific investigation of climate change: the Global Change Research Program[100] ("GCRP"), which would thereafter generate climate assessments of great social significance in the development of substantive climate policies across national and international legal regimes.[101] In the Energy Policy Act of 1992,[102] Congress for the first time required an annual inventory of aggregate greenhouse-gas emissions, viewing climate change principally as an energy issue.[103] And perhaps most significantly, in 1992 the United Nations ("U.N.") adopted the U.N. Framework Convention on Climate Change,[104] to which the U.S. Senate gave its advice and consent, and which entered into force as to the U.S. in 1994.[105] Although the Convention did not impose on the U.S. any mandatory greenhouse gas ("GHG") emission reductions, by 2003 the Climate Change Research Program had adopted its first ten-year plan for climate change research,[106] which called for the issuance in 2004 of the country's first scientific assessment.[107] After litigation begun when the George Bush Administration failed to meet this deadline,[108] the federal Global Research Program (formerly the GCRP) issued the country's first assessment in 2009, finding among other things that "[g]lobal warming is unequivocal and primarily human-induced."[109]

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[100] *See* Yumehiko Hoshijima, *Presidential Administration and the Durability of Climate Consciousness*, 127 YALE L.J. 170, 208–210 (2017).

[101] *Id.*

[102] Energy Policy Act of 1992, Pub. L. No. 102-486, 106 Stat. 2776 (codified as amended in scattered sections of 15, 16, and 42 U.S.C.).

[103] *See, e.g.*, Arnold W. Reitze, Jr., *Federal Control of Carbon Dioxide Emissions: What Are the Options?*, 36 B.C. ENV'T. AFFS. L. REV. 1, 17–18 (2009) (analyzing reporting weaknesses in the inventory).

[104] U.N. Framework Convention on Climate Change, May 29, 1992, 1771 U.N.T.S. 107.

[105] 138 CONG. REC. S33520–27 (daily ed. Oct. 7, 1992) (reporting Senate approval of ratification of the resolution).

[106] *See* John C. Dernbach & Robert Altenburg, *Evolution of U.S. Climate Policy*, *in* GLOBAL CLIMATE CHANGE AND U.S. LAW 83, 85 (Michael B. Gerard & Jody Freeman eds., 2014).

[107] *Id.*at 86.

[108] Ctr. for Biological Diversity v. Brennan, 571 F. Supp. 2d 1105 (N.D. Cal. 2007).

[109] Dernbach & Altenburg, *supra* note 106, at 86.

A. *Regulation of Greenhouse Gases Under the Clean Air Act: The Short Course*

In 2007, the Supreme Court in *Massachusetts v. EPA*[110] held that greenhouse gases were "air pollutants" under the federal Clean Air Act, leading to the release of an "endangerment finding" by the Obama Administration in 2009[111] and the adoption in 2010 of regulations limiting vehicle emissions of greenhouse gases from motor vehicles.[112] The endangerment finding was upheld by a unanimous panel of the D.C. Circuit in June 2012,[113] and in that same decision the Court also upheld the Obama Administration's interpretation of its power to regulate GHG emissions from stationary sources under the Title V ("permitting") and Prevention of Significant Deterioration ("PSD") provisions of the CAA, albeit with a notable dissent by then-D.C. Circuit Court of Appeals Judge Brett Kavanaugh from the Court's denial of a rehearing en banc petition.[114] Since, President Biden has proposed vehicle emission standards significantly higher than any previously issued standards that "could lead to electric vehicles comprising 67 percent of new car sales by 2032."[115]

As for stationary sources, the Supreme Court has allowed some regulation of their GHG emissions but has also twice notably scaled back more ambitious efforts by the EPA. In 2014, in *Utility Air Regulatory Group v. EPA* ("*UARG"* or "*Utility Air*"),[116] the Court

[110] Massachusetts v. EPA, 549 U.S. 497 (2007).

[111] Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act, 74 Fed. Reg. 66496 (Dec. 15, 2009) (to be codified at 40 C.F.R. ch. I).

[112] Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards, 75 Fed. Reg. 25324, 25327 (May 7, 2010) (to be codified at 40 C.F.R. pts. 85, 86, & 600).

[113] Coal. for Responsible Regul. v. EPA*,* 684 F.3d 102 (D.C. Cir. 2012).

[114] Coal. for Responsible Regul. v. EPA, 2012 WL 6621785 *18 (D.C. Cir. Dec. 20, 2012) (Kavanaugh, J. dissenting) ("Courts do not lightly conclude that Congress intended such major consequences absent some indication that Congress meant to do so.").

[115] Will Sullivan, *EPA Proposes Tightest-Ever Emission Limits for Cars*, SMITHSONIAN MAG. (April 30, 2023), https://www.smithsonianmag.com/smart-news/epa-proposes-tightest-ever-emissions-limits-for-cars-180981983/ [https://perma.cc/L9RD-J8CV].

[116] Utility Air Regul. Grp. v. EPA, 573 U.S. 302 (2014).

limited EPA stationary source regulation under the CAA's Title V and PSD statutory provisions to emissions from what might be called the "core footprint" of a powerplant's energy-producing facility.[117] And in 2022, in *West Virginia v. EPA*,[118] the Court rejected a more extensive attempt by the EPA under CAA Section 111.[119] This provision gives the EPA the ability to regulate emissions from "new sources of pollution" and then to extend the regulatory command to existing sources of that pollutant by requiring the "best system of emission reduction" ("BSER").[120] The *West Virginia* Court found that the EPA had overreached its authority under Section 111 to the extent that it defined BSER to include a requirement that power generators adopt alternative, off-site electricity generation such as that produced by solar or wind-turbine installations.[121] Such an expansion of agency authority was viewed by the Court as a "major question" requiring more explicit statutory authorization from Congress.[122] That being said, the Court's decision once again affirmed EPA's ability to regulate GHG emissions more directly from what might be called the "core footprint" of a powerplant's energy-producing facility.[123]

The ink was barely dry on the Court's June 2022 *West Virginia v. EPA* decision when its impact was affected by several subsequent developments. First, in August 2022, Congress passed the Inflation Reduction Act,[124] the innocuously-named statute described as "the single largest infusion of federal cash aimed at tackling the climate threat in U.S. history."[125] Among other impacts, as for stationary

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[117] *See* Zachary Hennessee, *Resurrecting a Doctrine on its Deathbed: Revisiting Federal Common Law Greenhouse Gas Litigation After* Utility Air Regulatory Group v. EPA, 67 DUKE L. J. 1073, 1092–93 (2018) ("The Court held that BACT requirements could still apply to 'anyway' sources . . . that were already subject to the [CAA] because of their criteria pollutant emissions.").

[118] 142 S.Ct. 2587 (2022).

[119] *Id.* 42 U.S.C. §§ 7411(a)(1), (b)(1), (d).

[120] *West Virginia v. EPA*, 142 S.Ct. at 2599.

[121] *Id.* at 2603 (referring to EPA's "generation-shifting" policy to move power generation to offsite wind and solar).

[122] *Id.* at 2609 (discussing the "major question" label).

[123] *Id.* at 2615–16 (referencing the power plant's single course of emissions).

[124] Inflation Reduction Act of 2022, 26 U.S.C. § 55 (2022).

[125] *Good Day Bio: Inflation Reduction Act and Ag Biotech*, *supra* note 6.

sources, the Act authorized large subsidies for carbon capture and sequestration ("CCS") whether from individual fossil-fuel-burning powerplants or otherwise.[126] As to existing fossil-fuel power plants, this might be viewed as a "carrot," encouraging them to reduce GHG emissions from their "core" facilities. Second, however, came a variety of regulatory "sticks." In May 2023, EPA proposed "Greenhouse Gas Standards and Guidelines for Fossil Fuel-Fired Power Plants,"[127] that, among other things, will set GHG emission limits from "core" natural-gas and coal-fired power plants. These emission limits will be based on the implementation at each plant's core facility of such "adequately demonstrated control technologies" as CCS and/or the "co-firing"[128] at natural-gas powerplants of a mixture of natural gas and "30 percent low-GHG hydrogen."[129] There are estimates that the proposed rule would require coal and gas-fired power plants that run full-time to eliminate nearly all of their climate-warming carbon dioxide emissions in just a little over a decade.[130] Separately, EPA also in 2023 has proposed a variety of regulations that would reduce emissions from fossil-fuel-fired powerplants of non-GHG

[126] *See, e.g.*, Greg Dotson & Dustin J. Maghamfar, *The Clean Air Act Amendments of 2022: Clean Air, Climate Change, and the Inflation Reduction Act*, 53 ENV'T. L. REP. 10017, 10029 (2023) ("IRA incentives for clean power generation and carbon capture could significantly affect state and federal determinations about what constitutes 'best available control technology.' ").

[127] *See Greenhouse Gas Standards and Guidelines for Fossil Fuel-Fired Power Plants*, ENV'T PROT. AGENCY, https://www.epa.gov/stationary-sources-air-pollution/greenhouse-gas-standards-and-guidelines-fossil-fuel-fired-power [https://perma.cc/M42L-RLW2] (last updated Aug. 3, 2023).

[128] *See Fact Sheet Greenhouse Gas Standards and Guidelines for Fossil Fuel-Fired Power Plants*, ENV'T. PROT. AGENCY, https://www.epa.gov/system/files/documents/2023-05/FS-OVERVIEW-GHG-for%20Power%20Plants%20FINAL%20CLEAN.pdf [https://perma.cc/FD9J-AQGC] (last visited Sept. 18, 2023).

[129] *Id.*

[130] *See* Jeff Brady, *Utility Group Calls for Changes to Proposed EPA Climate Rules*, NAT'L PUB. RADIO (Aug. 8, 2023, 5:58 PM), https://www.npr.org/2023/08/08/1192445638/utility-group-calls-for-changes-to-proposed-epa-climate-rules [https://perma.cc/56N4-738J]. *See also* Timothy Puko, *EPA Plan Would Impose Drastic Cuts on Power Plant Emissions by 2040*, WASH. POST (Apr. 22, 2023, 8:38 PM), https://www.washingtonpost.com/climate-environment/2023/04/22/epa-power-plant-emissions-climate/ [https://perma.cc/A2UM-WASD].

pollutants, such as mercury, nitrogen oxides, and particulates,[131] adding to the expense energy companies, and their downstream electricity consumers, will face in continued reliance on such facilities.

B. *Other Greenhouse Gas Regulations and Efforts: Another Short Course*

The most significant parallel development in U.S. law as to GHG emissions involves energy law and energy-related developments. In the wake of the OPEC oil embargo of 1973–1974, Congress passed the Energy Policy and Conservation Act of 1975,[132] delegating to the U.S. Department of Transportation the obligation to create motor vehicle fuel efficiency standards to reduce dependence on foreign oil more than out of any concern over emissions. In the Energy Policy Act of 2005,[133] Congress delegated to the U.S. Department of Energy the obligation to create energy-efficiency standards for over twenty different types of products.[134] These standards are estimated to save a reduction in GHG emissions that would be equivalent to the emissions of 118 coal-fired power plants by 2035.[135]

A parallel development involved the growth of ethanol use in the U.S., including both corn-based ethanol and cellulosic ethanol. Of the two, corn-based ethanol has attracted more attention. Originally encouraged in reaction to the Arab Oil Embargo in the 1970s, the use of fuel ethanol slowly grew to two million gallons in 1981 but

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[131] *See EPA Moves to Cut Toxic Air Pollution from Coal Plants*, IMPACT NEWS SERV. (Apr. 5, 2023), https://plus.lexis.com/document?pdmfid=1530671&pddocfullpath=%2Fshared%2Fdocument%2Fnews%2Furn%3AcontentItem%3A67Y7-VMC1-JDG9-Y30N-00000-00&pdcontentcomponentid=438631&prid=42bc0dfd-671d-46f3-b50e-9fd41c1d3e26&crid=71cffc23-4acf-4809-b299-fd0c2b9deea8&pdisdocsliderrequired=true&pdpeersearchid=b1f696d5-2d12-470f-9692-43e3facf380f-1&ecomp=L7ttk&earg=pdsf [https://perma.cc/CTH8-ZPTB] (proposing to cut mercury emissions from coal-fired power plants).

[132] Energy Policy and Conservation Act of 1975, Pub. L. No. 94-163, §§ 321-39, 89 Stat. 871.

[133] Energy Policy Act of 2005, Pub. L. No. 109-58, § 141, 119 Stat. 594.

[134] *See* Dernbach & Altenberg, *supra* note 106, at 92.

[135] *Id.*

has since exploded to 13.9 billion gallons consumed in 2021.[136] Between 1980 and 1990, ethanol use grew because the removal of lead from gasoline necessitated the use of octane enhancers (which ethanol improves), and subsequently because ethanol improved tailpipe emissions (among other reasons by positively improving the performance of onboard catalytic converters).[137] The Energy Policy Act of 2005 created a Renewable Fuel Standard that encouraged continued ethanol use as a fuel, primarily to reduce dependence on foreign oil and in part to reduce GHG emissions.[138] A vibrant debate exists, however, over the extent to which corn-based ethanol in fact offers net GHG improvements once one factors in the life-cycle GHG emissions associated with its production and delivery.[139] Cellulosic ethanol, in contrast, "has the potential to use virtually no fossil fuel in the conversion process because waste biomass material can itself be used as a fuel to drive the process, rather than fossil fuels."[140] Although the net carbon value of this type of biofuel depends significantly on the source of the biomaterials, a significant array of federal programs exists to encourage research on, and use of, forest biomass for energy.[141]

Other major federal responses to climate change fall into two categories. First, in terms of what is typically termed "climate mitigation" (reducing GHG emissions), the Securities and Exchange Commission ("SEC") proposed a rule in March 2022 that would require securities registrants to provide certain climate-related information in their registration statements and annual reports, with

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[136] *Biofuels Explained: Ethanol*, U.S. ENERGY INFO. ADMIN., https://www.eia.gov/energyexplained/biofuels/ethanol-use.php [https://perma.cc/AMH6-K4BL] (last visited Sept. 18, 2023).

[137] CALEY JOHNSON ET AL., U.S. DEP'T. OF ENERGY, HISTORY OF ETHANOL FUEL ADOPTION IN THE UNITED STATES: POLICY, ECONOMICS, AND LOGISTICS 1–2 (2021).

[138] *Id.* at 8.

[139] *See, e.g.*, Arnold W. Reitze. Jr., *Biofuels – Snake Oil for the Twenty-First Century*, 87 OR. L. REV. 1183, 1187 (2008) (explaining that because of the fossil fuel required to produce it, "ethanol does not materially reduce greenhouse gas emissions").

[140] Blake Hudson, *Agriculture and Forestry, in* GLOBAL CLIMATE CHANGE AND U.S. LAW 649, 663 (Michael Gerrard & Jody Freeman eds., 2014).

[141] *Id.*

the goal of internalizing any negative financial implications from a company's reliance on fossil-fuel assets that might become "stranded" or otherwise unreliable or expensive.[142] Separately, the White House Office of Information and Regulatory Affairs ("OIRA") is implementing a metric measuring the social cost of carbon into its evaluation of some agency rulemakings as an aid to OIRA's obligations to consider the costs and benefits of proposed regulations under Executive Order 12866.[143]

Second, in what is typically termed "climate adaptation," a suite of federal agencies and associated statutes and regulatory programs are increasing their oversight of, and support for, measures that will be needed in the coming decades for climate resiliency. These measures will be needed regardless of mitigation efforts due to the amount of "legacy" carbon already in the atmosphere.[144] In November 2021, President Biden signed an infrastructure bill earmarking $50 billion for "climate resiliency" projects in the U.S.,[145] and in November 2018 Congress enacted the Disaster Recovery and Reform Act,[146] creating what was then the "nation's largest federal financing program specifically for investments in pre-disaster resiliency."[147]

There has also been a significant uptick of climate-related mechanisms adopted at the state and local levels. As for climate mitigation, numerous states have adopted renewable fuel standards that have contributed to an on-the-ground explosion of major

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[142] *See* The Enhancement and Standardization of Climate-Related Disclosures for Investors, 87 Fed. Reg. 21334 (proposed Apr. 11, 2022) (to be codified at 17 C.F.R. pts. 210, 229, 232, 239, & 249). *See also* Cecilia Bremner, *Comment: The Value of Regulating Climate Disclosures,* 53 ENV'T. L. 107 (2023); Scott Hirst, *Saving Climate Disclosure,* 28 STAN. J. L. BUS. & FIN. 91 (2023).

[143] *See* Richard L. Revesz & Max Sarinsky, *The Social Cost of Greenhouse Gases: Legal, Economic, and Institutional Perspectives*, 39 YALE J. REGUL. 856 (2022).

[144] *See* Donald T. Hornstein, *Public Investment in Climate Resiliency: Lessons from the Law and Economics of Natural Disasters*, 49 ECOLOGY L. Q. 137, 137 (2022).

[145] *Id.* at 139 n.4.

[146] Disaster Recovery Reform Act of 2018, 42 U.S.C. §§ 5121-5172.

[147] Hornstein, *supra* note 144, at 155–56.

wind-turbine and solar installations nationwide.[148] Several east coast and mid-atlantic states, along with California, have formed the Regional Greenhouse Gas Initiative, to create a market for GHG-reduction efforts among utilities.[149] As to climate adaptation at the state and local level, there has been a "flurry of activity" that includes the adoption of statewide mitigation plans and the appointment of state resiliency officers.[150] Bond rating agencies are showing some signs of incorporating "resiliency metrics into their determinations of state and local credit risk.[151] And an increasing number of public bond-financed projects focus on resiliency-oriented construction projects."[152]

Lastly, at the international level, there is an increasing focus on the goal of keeping average annual global temperatures to the 1.5–2 degrees Celsius range. Although Congress ratified the U.N. Framework Convention on Climate Change in 1992, leading to U.S. participation in the semi-annual Conference of the Parties ("COP") meetings that take place under its umbrella,[153] Congress rejected an attempt to ratify the Kyoto Protocol that had been adopted internationally in 1997 (and went into effect in 2005) that required developed countries to reduce their GHG emissions by approximately five percent from 1990 levels by 2012.[154] In 2009, however, at COP 15 in Copenhagen, the U.S. played a key role in adoption of the "Copenhagen Accord," under which the U.S. pledged to reduce its GHG emissions by approximately seventeen

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[148] *See State Renewable Portfolio Standards and Goals*, NAT'L CONF. OF STATE LEGISLATURES, https://www.ncsl.org/energy/state-renewable-portfolio-standards-and-goals [https://perma.cc/B3ZK-XCK9] (last updated Aug. 13, 2021) ("Renewable energy policies help drive the nation's $64 billion market for wind, solar and other renewable energy sources.").

[149] *See, e.g.*, Bruce R. Huber, *How Did RGGI Do It? Political Economy and Emissions Auctions*, 40 ECOLOGY L. Q. 59 (2013).

[150] *See* Hornstein, *supra* note 144, at 143.

[151] *Id.*

[152] *Id.*

[153] *What Are United Nations Climate Change Conferences?*, U.N. CLIMATE CHANGE, https://unfccc.int/process-and-meetings/what-are-united-nations-climate-change-conferences [https://perma.cc/S6AR-8H7F] (last visited Sept. 18, 2023).

[154] *See* Dernbach & Altenburg, *supra* note 106, at 101.

percent from 2005 levels by 2020,[155] a drop in emissions that the U.S. in fact met due in part to the decrease in emissions occasioned by the COVID-19 outbreak.[156] In 2016, the international community agreed to the "Paris Accord," which contained the aspirational goal of keeping the worldwide increase in temperature to 1.5 degrees Celsius by the century's end, a goal that would require GHG emissions to peak before 2025 and decline forty-three percent by 2030.[157] As to the U.S.' obligations under the Paris Accord, the impact of the Inflation Reduction Act has been estimated by one research firm to put the country on track to lower GHG emissions by twenty-nine percent to forty-two percent by 2030 (compared to 2005 levels),[158] just shy of the effort needed by the U.S. to help the Paris Accord meet its 1.5 degrees Celsius target. The news elsewhere, however, is not quite so encouraging. At the COP meeting in Glasgow in November 2021, national pledges were "insufficient to prevent a 2 degrees Celsius increase over the next century."[159]

IV. THE RELEVANCE OF BIOTECHNOLOGY TO NATIONAL AND INTERNATIONAL CLIMATE GOALS

It is unsurprising that biotechnology may be poised for its climate change "moment." On the one hand, even with the Biden Administration's near-miraculous climate accomplishments, the U.S. still likely falls short of its climate-mitigation pledges under the Paris Accord, and as the actual climate worsens, the country faces mounting financial challenges for climate-disaster response and

[155] *Id.* at 102.

[156] *USA*, CLIMATE ACTION TRACKER (Aug. 16, 2022), https://climateactiontracker.org/countries/usa/#:~:text=The%20effects%20of%20COVID%2D19,by%2020050%20at%20the%20latest [https://perma.cc/S3TV-T5ZA].

[157] *See The Paris Agreement*, U.N. CLIMATE CHANGE, https://unfccc.int/process-and-meetings/the-paris-agreement [https://perma.cc/VA7R-JS3Q] (last visited Sept. 18, 2023).

[158] *See* Michael Copley, *The U.S. Could Slash Climate Pollution, But It Might Not Be Enough, A New Report Says*, NAT'L PUB. RADIO (July 23, 2023, 4:42 PM), https://www.npr.org/2023/07/20/1189060785/u-s-could-cut-climate-pollution-but-it-is-still-short-of-paris-agreement-pledge [https://perma.cc/EE2S-M3ER].

[159] *See* Melissa J. Durkee, *The Pledging World Order*, 48 YALE J. INT'L L. 1, 2–3 (2023).

climate-adaptation investments. The question then becomes: what might we learn from our last forty years of experience with biotechnology that may allow us to tap the benefits of the technology while at the same time minimizing its risks? After addressing the Biden Bioeconomy Initiative and suggesting some institutional adjustments, this Part discusses the potential applications of biotechnology to climate mitigation and climate adaptation.

A. The Biden Administration's "Bioeconomy" Initiative

Although this Article was introduced with a highlighting of the Biden Administration's National Biotechnology and Biomanufacturing Initiative, it is worth noting that the country may have been here before. Over a decade ago, President Obama made bioeconomy research and development ("R&D") one of his 2010 budget priorities,[160] and in 2012 released his "National Bioeconomy Blueprint."[161] Although the initiative sought to "help realize the full potential of the U.S. bioeconomy,"[162] in a 2022 report, the Congressional Research Service ("CRS") observed that "the extent to which the 2012 bioeconomy blueprint was implemented is unclear."[163] That said, this Part later explores the conclusions of the International Advisory Council on Global Bioeconomy which observed that the Obama blueprint was in fact marked by several initiatives "put forth by individual federal agencies."[164]

To the extent the Biden initiative may truly be intended as something new, it is worth making several observations about it, especially as it has yet to be discussed widely—if at all—in the legal literature. First, although biotechnology figures prominently in the

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[160] MARCY E. GALLO, CONG. RSCH. SERV., R46881, THE BIOECONOMY: A PRIMER 7 (2022).

[161] *National Bioeconomy Blueprint*, WHITE HOUSE (Apr. 2012), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf [https://perma.cc/B7FD-LR9H].

[162] *Id.* at 2.

[163] GALLO, *supra* note 160, at 8.

[164] INT'L ADVISORY COUNS. ON GLOB. BIOECONOMY, GLOBAL BIOECONOMIC POLICY REPORT (IV): A DECADE OF BIOECONOMIC POLICY DEVELOPMENT AROUND THE WORLD 40 (2020).

Biden announcement, the Administration's policy statements make clear that references to the bioeconomy include plans for what can be termed "biomass" programs with or without biotechnology applications.[165] The analog in U.S. climate policy would be ethanol, a biomass-as-substitute-for-fossil-fuel program that does not necessarily include significant biotechnology aspects.[166] In this vein, it is worth noting that references abound in a policy document issued in March 2023 by the White House Office of Science and Technology Policy propounding the goal of 1.2 billion tons of "purpose-grown plants" and "waste-derived" feedstocks for conversion to fuels and products—something that can take place with or without significant biotechnologies.[167]

Second, having said that, there definitely is an emphasis in the Biden initiative on an expanding role for biotechnology to enable a host of new applications. In its Report to the President on "Biomanufacturing to Advance the Bioeconomy" in December 2022, the President's Council of Advisors on Science and Technology described the need for advanced biomanufacturing capacity to "align[] with industrial growth in biotechnology,"[168] and then predicted that "biotechnology will soon provide us with the ability . . . to harvest meat without the worries of climate impacts, engineer microbes to break down plastic in landfills, and use

[165] *See generally* Nicolas Befort, Biotechnology vs. The Bioeconomy 4 (unpublished manuscript) (on file with Science Direct) ("[Although] the bioeconomy is [sometimes considered] a subsector of the biotechnology industry . . . the bioeconomy is also defined as the substitution of biomass for oil-based products.").

[166] Of course, biotechnology has played an indirect role in corn-based ethanol, not only because Roundup Ready corn can be the base biomass input for ethanol fermentation as a general matter, but also because, in the case of corn bioengineered by the Starlink corporation, the transgenic corn genes were at risk of causing an unintended allergenic response among sensitive individuals, making the crop primarily useful for nonfood uses such as ethanol production. *See* Dorothy Du, *Note, Rethinking Risks: Should Socioeconomic and Ethical Considerations be Incorporated into the Regulation of Genetically Modified Crops*, 26 HARV. J.L. & TECH. 375, 380 (2012).

[167] WHITE HOUSE, OFF. OF SCI. & TECH. POL'Y, BOLD GOALS FOR U.S. BIOTECHNOLOGY AND BIOMANUFACTURING, at ii (2023).

[168] PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., REPORT TO THE PRESIDENT: BIOMANUFACTURING TO ADVANCE THE BIOECONOMY 18 (2022).

biomass – in place of petrochemicals – to make the materials and chemicals we use in our daily lives."[169] Three months later, in March 2023, the White House Office of Science and Technology Policy again specifically underscored "bold goals" for "harnessing biotechnology and biomanufacturing" to "further climate change solutions."[170]

Finally, there are indications in these early iterations of the Biden program that the Administration is seeking to revise biotechnology regulation from the thirty-plus years of experience with the Coordinated Framework. Specifically, the desire to avoid the whack-a-mole problem of having three agencies (even operating under a "Coordinated" Framework) and the goal of a regulatory structure that is both effective in guarding the public interest and yet conducive to capitalizing on biotechnology's potential benefits. Thus, the President's Council of Advisors on Science and Technology describe regulation as "burdensome when it involves more than one agency, slowing the pace at which innovations can move to market."[171] Looking forward, this Section suggests two lessons that could be learned from regulatory developments under the Framework which could inform regulatory redesign.

1. EPA's Success in Regulating Bt and the Bt-resistance Problem

The problems that were highlighted regarding the Framework should not cloud those instances where regulators have innovated well, such as they did with the so-called "*Bt* trait." The *Bt* trait involves inserting a gene encoding a toxic protein from members of the *Bacillus thuringiensis* family of bacteria into the plant genome.[172] Individual *Bt* toxins are encoded by *Cry* and *Vip* genes which are highly specific in activity to particular groups of insects.[173] The use of *Bt* has markedly decreased the use of chemical pesticides, in contrast to the herbicide resistance risked by products

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[169] *Id.* at 2.

[170] WHITE HOUSE, OFF. OF SCI. & TECH. POL'Y, *supra* note 167.

[171] Befort, *supra* note 165, at 15.

[172] *See* Aaron J. Gassmann & Dominic D. Reisig, *Management of Insect Pests with Bt Crops in the United States*, 68 ANNU. REV. ENTOMOLOGY 31 (2023).

[173] *See* Mike Mendelsohn et al., *Are Bt Crops Safe?*, 21 NATURE BIOTECH. 1001, 1003 (2003).

such as Roundup Ready seeds, and thus offers *bona fide* environmental benefits.[174] However, this trait in which a plant self-produces a pesticide is an early example of science blurring the lines on regulatory boundaries—it is neither just a plant (under USDA's bailiwick) nor just a pesticidal substance (under EPA's) but both at once. Resistance also develops in insects to *Bt* just as it does to herbicides in Roundup Ready type crops.[175] Consequently, biotech developers are constantly updating the *Bt* trait in their crops by discovering, combining, and enhancing new *Cry* and *Vip* genes to extend the benefit of *Bt* to new crop species and new insect pests and to counteract resistance to previous versions of the trait.

To deal with the unique aspects of *Bt*, USDA and EPA developed the category known as Plant-Incorporated Protectants ("PIPs"). For protectants falling under this category, the EPA regulates both the *Bt* proteins, which are directly pesticidal to insects, and the genetic material that encodes them, while the USDA regulates the plant itself (incorporating the toxin as a whole organism).[176] Like other pesticides, EPA has the discretion to decide whether or not to extend the registration of PIPs and set new conditions. In fact, EPA has mandated Insect Resistance Management plans ("IRMs") for every new variety of *Bt* crops.[177] These IRMs primarily involve requirements to grow fractions of the same crop without the *Bt* trait in specific spatial orientations near *Bt* fields, known as "refuges."[178] Refuges lessen the selective pressure for resistance to develop and can be extensive: for some types of *Bt* traits, EPA mandates that fifty

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[174] *See* Gassmann & Reisig, *supra* note 172; *see also* NAT'L ACAD. OF SCIS., ENG'G & MED., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS (2016).

[175] *See, e.g.*, Bruce E. Tabashnik et al., *Insect Resistance to Bt Crops: Lessons from the First Billion Acres*, 31 NATURE BIOTECH. 510 (2013).

[176] *See EPA's Regulation of Biotechnology for Use in Pest Management*, ENV'T PROT. AGENCY, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management [https://perma.cc/LVY2-AT95] (last updated Apr. 6, 2023).

[177] *See Insect Resistance Management for Bt Plant-Incorporated Protectants*, ENV'T PROT. AGENCY, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/insect-resistance-management-bt-plant-incorporated [https://perma.cc/KDP9-NPYQ] (last updated Nov. 14, 2022).

[178] *Id.*

percent of the crop be non-*Bt* refuge.[179] IRMs also require active monitoring programs for resistance and action plans for what happens when resistance is detected. The IRM requirement was imposed by EPA specifically out of the agency's interest in preserving the efficacy and environmental benefits of *Bt* technology into the future.[180]

The active regulation applied to PIPs has also proven flexible and rapidly responsive. In 1999, not long after commercialization of the first *Bt* crops, a laboratory study[181] found potential evidence that *Bt* corn posed a danger to the celebrated monarch butterfly, which was (and still is) subject to a terrible and poorly understood population decline. Within that same year, EPA issued a data call-in to the industry, commissioned its own studies, and formed a Scientific Advisory Panel to confirm the laboratory results and determine if they extend to monarchs in the field.[182] In the end, the results of this undertaking found *Bt* not to be impacting monarch populations and its use on crops was permitted to continue. The rapid and successful mobilization of resources and knowledge on the part of regulators over this biotech-environment issue is distinctive in the history of U.S. biotech regulations and also instructive.

2. The Obama Administration's "Am I Regulated" Initiative

In 2012, the Obama Administration released its "National Bioeconomy Blueprint," identifying biotechnology as a decarbonization asset able to create enhanced biofuels, climate-adapted crops, chemical feedstocks, and industrial

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[179] *Id.*

[180] *Id.* ("EPA places a high value on the efficacy of Bt PIPs and on preserving their significant agricultural and environmental benefits. . . . The goal of IRM is to delay the onset of resistance for as long as possible, though it is important to note that it may not be possible to entirely prevent resistance from evolving.").

[181] John E. Losey, Linda S. Rayor & Maureen E. Carter, *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999).

[182] *See* ARS Directive, EPA Acts (U.S.D.A. 2016); *see also* NAT'L ACAD. OF SCIS., ENG'G & MED., *supra* note 174.

processes.[183] To be sure, the outcome of this initiative was modest relative to the industry-wide scale of the blueprint, primarily resulting in R&D support to academics and the private sector. The most durable result of the Obama Bioeconomy Blueprint, however, may in fact have manifested through its connection to Obama-era revisions of preexisting biotechnology regulations.

In 2011, President Obama signed Executive Order 13563, "Improving Regulation and Regulatory Review,"[184] resulting in USDA's establishment of an initiative to streamline its regulatory review.[185] Both actions were subsequently cited in the administration's Bioeconomy Blueprint under one of five strategic objectives, titled, "Reducing Regulatory Barriers."[186] The most concrete change of this initiative was USDA's establishment of an "Am-I-Regulated" ("AIR") process. The AIR process created a mechanism for GE crop developers using technologies that fell outside USDA's narrow then-definition of plant pest risk to obtain an exemption from agency oversight.[187] The exemption rested on the fact that these newer technologies did not incorporate DNA sequences derived from known plant pests into the end product. This prominently involved CRISPR, which is considered only to "take out" sequences. In addition, the initiative also enabled plants containing any number of transgenes to go without regulatory review—as long as the genes were sourced from things that were not plant pests and inserted in a certain way.[188]

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[183] *See National Bioeconomy Blueprint*, WHITE HOUSE (Apr. 2012), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf [https://perma.cc/F6H8-SBRW].

[184] Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011).

[185] WHITE HOUSE, OFF. OF SCI. & TECH. POL'Y, *supra* note 167, at 32.

[186] *Id.* at 29.

[187] *See* Wayne Parrott, *Outlaws, Old Laws and No Laws: The Prospects of Gene Editing for Agriculture in United States*, 164 PHYSIOLOGIA PLANTARUM 406 (2018).

[188] *Id*. APHIS's definition of biotech-derived plant pest risk relied on inclusion of DNA sequence of any length and kind from a known plant pest. Most prominently, this included the engineering tool *Agrobacterium*, the most popular means of inserting genes into plants. Use of *Agrobacterium* incorporates about one-hundred base pairs of bacteria-derived sequence along with the gene of interest. Because some strains of *Agrobacterium* are plant pathogens, the inclusion

AIR was undeniably deregulatory, providing a green light for biotech developers to avoid a review process costing some years and tens of millions of dollars.[189] For the same reason, it suddenly opened a door for atypical players in biotech (namely, universities and smaller companies), and for inventions outside of conventional commercial motivations.[190] In the twenty years prior to AIR, precisely one crop genetically engineered for climate adaptation had been released in the U.S., a drought-tolerant corn variety developed by Monsanto. But within a year of AIR's introduction, a gene-edited switchgrass with increased biomass potential had been submitted, and exemption-confirmed.[191] By 2021, when AIR was phased out, it had been used for additional switchgrass, sorghum, and sugarcane varieties for bioenergy, pine trees with higher wood density (for lumber, bioenergy, and paper), drought tolerant corn and soybean, enhanced *Camelina sativa* and *Thlaspi arvense* as combined cover/biofuel crops, and poplar trees designed to take up more carbon than usual from the air.[192] In contrast, over a thirty-year time period,[193] Monsanto corn remained the only explicitly

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of these one-hundred letters of "plant pest sequence" were used by APHIS as a basis for oversight of most GMO plants. As other methods of gene insertion that do not require using these traces of plant pest sequence (gene guns, nanoparticles, *Ensifer*) became more accessible, developers could avoid this hook. At least seventy-seven individual submissions to AIR used such exempt gene insertion methods. Theoretically, APHIS can also regulate an engineered plant over "weedy traits" regardless of the underlying genetic makeup, but it has never used this as a basis to execute a review of an otherwise-exempt plant.

[189] Here, we refrain from comment on whether the extreme extent of deregulation under AIR was appropriate relative to assessing (or not) potential risks of these products. We also note that it is difficult to determine at what rate most AIR-exempted technologies have progressed toward real-world application.

[190] *See* Dalton R. George et al., *Lessons for a SECURE Future: Evaluating Diversity in Crop Biotechnology Across Regulatory Regimes*, 10 FRONTIERS BIOENG'G & BIOTECH. 886765 (2022).

[191] *Id.*

[192] *Id*; *see also* APHIS Directive, *Regulated Article Letters of Inquiry* (U.S.D.A. 2023), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry [https://perma.cc/UC4M-KKFG].

[193] AIR and the Petition for Determination of Nonregulated Status have since both been replaced at USDA by its SECURE rule, which is essentially a mix of the two systems. *See* George et al., *supra* note 190.

climate-targeted GMO ever taken through the USDA's "normal"—and costly—deregulation process.[194]

In February 2023, the AIR-exempt poplar trees engineered to photosynthesize more efficiently[195] were planted on private forest land in Georgia by the company Living Carbon, in the country's first release of an engineered tree in a wild setting.[196] In a greenhouse experiment,[197] these trees grew fifty percent faster than their unmodified progenitors, and the company hopes to replicate this feat in the wild, capturing more carbon through this faster growth. The fact that the technology under the hood of the farthest-along, wild-released GE tree happens to be climate oriented is entirely unrelated to any government assessment of its potential for sequestering carbon (as none was ever made) and entirely thanks to

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[194] *Id*; *see also* APHIS Directive, *Legacy Petitions for Determination of Nonregulated Status* (U.S.D.A. 2023), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/petitions/petition-status/petitions-table [https://perma.cc/3HDV-RPTQ].

[195] Photosynthesis is the mechanism by which plants extract CO_2 directly from the atmosphere and convert it into molecules that make up the plant itself. When a plant dies, is harvested, or burns up in a wildfire, most of this fixed carbon is re-released to the atmosphere. The premise behind improving photosynthesis is that even though much of the CO_2 turned into plant matter is not permanently removed from the atmosphere, enhanced plants could fix carbon faster or hold more during their lifespan—which ranges from months to hundreds of years—increasing the equilibrium level of carbon stored in plant biomass despite the ongoing turnover.

[196] *See* Gabriel Popkin, *For the First Time, Genetically Modified Trees Have Been Planted in a U.S. Forest*, N.Y. TIMES (Feb. 16, 2023), https://www.nytimes.com/2023/02/16/science/genetically-modified-trees-living-carbon.html [https://perma.cc/Y245-CFEY]. Engineered trees have been released previously, but in controlled settings subject to regulation, for example field trials of American chestnuts genetically engineered to resist the blight fungus that caused their extinction in the U.S. *See The American Chestnut Project: Progress Report 2021*, SUNY COLL. ENV'T SCI. & FORESTRY, https://www.esf.edu/chestnut/progress-report/2021.php [https://perma.cc/9Z83-5Y7R] (last visited Sept. 18, 2023).

[197] *See* Popkin, *supra* note 196 (discussing comments by Don Ort, a prominent plant biotechnologist who developed the physiological concept used by Living Carbon in its trees); *see also* Paul F. South et al., *Synthetic Glycolate Metabolism Pathways Stimulate Crop Growth and Productivity in the Field*, 363 SCI. 1(2019).

the deregulatory AIR exemption for which Living Carbon explicitly engineered its trees.[198]

B. Biotechnology and Climate Mitigation

The most recent era of biotechnology research is filled with initiatives aimed squarely at taking carbon out of the atmosphere. In the vast majority of cases, these biological carbon capture and sequestration ("bio-CCS") technologies[199] remain in the research stage. Some of the audacious technologies at various points along the science-regulation-application pipeline include:

(i) Enhanced photosynthesis to let plants more quickly capture CO_2 as they grow. Living Carbon's trees planted in Georgia use a method known as a photorespiratory bypass to scavenge CO_2 that would ordinarily be wasted, particularly under hot and dry conditions.[200] Other approaches include improving the enzyme RuBISCo, the molecular part directly responsible in plants for taking CO_2 out of the atmosphere;[201] giving plants ways to concentrate CO_2 from the air;[202] and allowing plants to do exotic

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[198] Living Carbon performed its pilot research using *Agrobacterium*, which remains the tool of choice for plant transgenic work of all kinds. It then re-did the work for application using more difficult non-*Agrobacterium* methods in order to take advantage of the AIR exemption. The trees now growing in the field include foreign sequences from, among others, pumpkin, algae, corn, and *E. coli*. *See* Popkin, *supra* note 196; *see also* YUMIN TAO ET AL., ENHANCED PHOTOSYNTHETIC EFFICIENCY FOR INCREASED CARBON ASSIMILATION AND WOODY BIOMASS PRODUCTION IN HYBRID POPLAR INRA 717-1B4 (2022).

[199] In some contexts, bio-CCS is used to refer narrowly to the downstream capture of carbon produced from burning biomass in energy plants; here it refers to any biological means of removing more carbon from the atmosphere.

[200] *See also* Chang-Peng Xin et al., *The Benefits of Photorespiratory Bypasses: How Can They Work?*, 167 PLANT PHYSIOLOGY 574 (2015); *see, e.g.*, Jyoti Dalal et al., *A Photorespiratory Bypass Increases Plant Growth and Seed Yield in Biofuel Crop Camelina Sativa*, 8 BIOTECH. BIOFUELS 175 (2015).

[201] *See* Noam Prywes et al., *Rubisco Function, Evolution, and Engineering*, 92 ANN. REV. BIOCHEMISTRY 385 (2023).

[202] *See, e.g.*, Chenyi Fei et al., *Modelling the Pyrenoid-Based CO2-Concentrating Mechanism Provides Insights into Its Operating Principles and a Roadmap for Its Engineering into Crops*, 8 NATURE PLANTS 583 (2022); Luke C. M. Mackinder, *The Chlamydomonas CO_2-Concentrating Mechanism and Its Potential for Engineering Photosynthesis in Plants*, 217 NEW PHYTOLOGIST 54 (2018).

subtypes of photosynthesis known as C4 and CAM,[203] again with special additional benefits for heat and drought caused by climate change.[204] Applied to trees,[205] or algae and seaweed destined for intentional sinking to the deep ocean,[206] enhanced photosynthesis is meant to enable long-term sequestration on the scale of hundreds of years.[207] It may also, however, be applied even to crop plants that individually live only a few months, in a way that blends bio-CCS with agricultural climate adaptation.[208]

(ii) Increasing natural long-term storage mechanisms for carbon.[209] The Salk Institute's Harnessing Plants Initiative,[210] which has raised more than $65 million, aims to engineer plants with larger and deeper roots which transfer a greater portion of carbon below

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[203] *See, e.g.*, Cheng-Jiang Ruan, Hong-Bo Shao & Jaime A. Teixeira Da Silva, *A Critical Review on the Improvement of Photosynthetic Carbon Assimilation in C_3 Plants Using Genetic Engineering*, 32 CRITICAL REV. BIOTECH. 1 (2012).

[204] *See, e.g.*, Sajad Hussain et al., *Photosynthesis Research Under Climate Change*, 150 PHOTOSYNTHESIS RSCH. 5 (2021).

[205] *See, e.g.*, Christer Jansson et al., Phytosequestration: *Carbon Biosequestration by Plants and the Prospects of Genetic Engineering*, 60 BIOSCIENCE 685 (2010).

[206] *See* Robin Kundis Craig, *Promoting "Climate Change Plus" Industries Through the Administrative State: The Case of Marine Aquaculture*, 39 YALE J. REG. 479 (2021).

[207] Increased photosynthesis does not have a linear relationship with increased biological carbon sequestration which remains subject, in the short term, to other environmental and ecological constraints on plant productivity, and in the long term by variation and uncertainty about the fate of this living carbon in the environment. *See* Robert B. Jackson et al., *Trading Water for Carbon with Biological Carbon Sequestration*, 310 SCI. 1944 (2005); Julia K. Green & Trevor F. Keenan, *The Limits of Forest Carbon Sequestration*, 376 SCI. 692 (2022); David B. Lindenmayer et al., *Avoiding Bio-Perversity from Carbon Sequestration Solutions*, 5 CONSERVATION LETTERS 28 (2012).

[208] *See* Jansson et al., *supra* note 205.

[209] On land this refers almost always to moving a greater portion of plant-based carbon into the soil. *See, e.g.,* Christer Jansson et al., *Climate-Smart Crops with Enhanced Photosynthesis*, 69 J. EXPERIMENTAL BOTANY 3801 (2018).

[210] *Harnessing Plants Initiative*, SALK INST. BIOLOGICAL STUD., https://www.salk.edu/harnessing-plants-initiative/ [https://perma.cc/Y55Y-V3DN] (last visited Sept. 18, 2023).

ground, where it persists for a time even after the plant dies.[211] Salk also engineers its plants' roots to make more carbon into suberin, a waxy, durable chemical which it hopes will increase the length of time the carbon stays in the soil.[212] The Salk Institute proposes applying this trait to all major crop species—transforming the world's 3.5 billion acres of arable land into a carbon-capturing factory as well as a food-producing one.[213]

(iii) Using microbes or enzymes to convert carbon from air into durable chemicals. An extremely diverse set of technologies uses genetic engineering as part of a pipeline to sequester CO_2 not into long-term storage or biological carbon pools, but rather consumer goods and industrial materials.[214] In a prominent subset of examples, microbial carbon capture systems serve as CO_2 scrubbers for flue gas from power plants or factories. The carbon-rich gas is bubbled directly through a tank of living engineered bacteria (or specialized enzymes which capture and convert it to a new product).[215] In July 2023, Walmart announced that it would work with the company Rubi to make clothes out of CO_2 captured from flue gas.[216] Rubi's system uses enzymes to convert CO_2 directly into cellulose (the

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211 *See, e.g.*, Takehiko Ogura et al., *Root System Depth in Arabidopsis Is Shaped by EXOCYST70A3 via the Dynamic Modulation of Auxin Transport*, 178 CELL 400 (2019).

212 *See* Olga Serra & Niko Geldner, *The Making of Suberin*, 235 NEW PHYTOLOGIST 848 (2022).

213 *Harnessing Plants Initiative*, *supra* note 210.

214 *See, e.g.*, José Pires et al., *Carbon Dioxide Capture from Flue Gases Using Microalgae: Engineering Aspects and Biorefinery Concept*, 16 RENEWABLE & SUSTAINABLE ENERGY REVS. 3043 (2012); Natalie Hicks et al., *Using Prokaryotes for Carbon Capture Storage*, 35 TRENDS BIOTECH. 22 (2017); Manish Kumar et al., *Carbon Dioxide Capture, Storage and Production of Biofuel and Biomaterials by Bacteria: A Review*, 247 BIORESOURCE TECH. 1059 (2018).

215 Pires et al., *supra* note 214, at 3044.

216 Andrea Albright, *Walmart and Rubi Laboratories Breathe Fresh Air into Sustainable Fashion*, WALMART (July 27, 2023), https://corporate.walmart.com/newsroom/2023/07/27/walmart-and-rubi-laboratories-breathe-fresh-air-into-sustainable-fashion [https://perma.cc/2AXU-65EH].

same molecule that makes up cotton fibers),[217] which is then further processed into fabric.[218]

Even where bio-CCS technologies exist outside the lab, it is impossible to ignore that none of them has yet shown proof of real-world, cradle-to-grave carbon sequestration at scale. Especially for (i) and (ii), scientists are not in consensus on how to account precisely for carbon sequestration in living systems like the oceans, forests, and soils, where the standing pool of CO_2 is underlain by a constant flux of absorption and release.[219] This is compounded by the fact that molecular mechanisms used for bio-CCS, including photosynthesis, remain subjects of hot debate and rapid development in understanding, making it hard to assign specific value to the contribution of bio-CCS technologies above the existing biological systems from which they are engineered.

More contained technologies like (iii) can avoid some of the inherent difficulties of assessing nature-based and biogeochemical carbon flows but must grapple with lifecycle-based aspects of carbon capture, in which the infrastructure, energy, and materials that go into achieving the desired moment of CO_2 capture themselves contribute significant emissions while being vulnerable to inappropriately optimistic carbon accounting.[220]

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[217] *See* Yang Huang et al., *Recent Advances in Bacterial Cellulose*, 21 CELLULOSE 1 (2014).

[218] *Biomimicry for Manufacturing in the Symbiotic Sea*, RUBI, https://www.rubi.earth/technology [https://perma.cc/X5YV-3XUA] (last visited Aug 19, 2023).

[219] *See Insect Resistance Management for Bt Plant-Incorporated Protectants*, *supra* note 177.

[220] *See* Kenthorai Raman Jegannathan & Per Henning Nielsen, *Environmental Assessment of Enzyme Use in Industrial Production – a Literature Review*, 42 J. CLEANER PROD. 228 (2013); Nishit Savla et al., *Techno-Economical Evaluation and Life Cycle Assessment of Microbial Electrochemical Systems: A Review*, 4 CURRENT RSCH. GREEN & SUSTAINABLE CHEMISTRY 1 (2021); P. Senthil Kumar et al., *A Biotechnological Roadmap for Decarbonization Systems Combined into Bioenergy Production: Prelude of Environmental Life-Cycle Assessment*, 329 CHEMOSPHERE 1 (2023); Minoru Akiyama, Takeharu Tsuge & Yoshiharu Doi, *Environmental Life Cycle Comparison of Polyhydroxyalkanoates Produced from Renewable Carbon Resources by Bacterial Fermentation*, 80 POLYMER DEGRADATION & STABILITY 183 (2003); Jordan Chapman, Ahmed Ismail &

All that said, the uncertainties related to bio-CCS serve not to debunk the potential of these options but rather to highlight their early stage. As it relates to policy, the immediate implication is that R&D funding and capacity-building programs, like those set forth in the CHIPS and Science Act,[221] Inflation Reduction Act,[222] and Biden Executive Order[223] on the bioeconomy, may remain the most important conduit between government and bio-CCS in the short term. Only slightly farther down the road, however, the technical questions related to bio-CCS will come into direct contact with incentives and mandates set by law.

The IRA's update of the Section 45Q CCS Tax Credit[224] guarantees that the government will directly pay $130 per metric ton (up from $35) for Direct Air Capture of CO_2 which is then converted into useful products, or $60 per ton for capture from industrial point sources.[225] This credit specifies that uses of carbon meeting the standard for this type of capture include "the fixation of such qualified carbon oxide through photosynthesis or chemosynthesis, such as through the growing of algae or bacteria"[226] with the exception that direct air capture excludes "using natural photosynthesis."[227] In the crudest terms, those wishing to cash in on the subsidy bonanza via biotechnology have apparently had a substantial space carved out in which they can do so at recently-doubled or quadrupled prices. It also means that the government will need to make consequential decisions on the same

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Cerasela Dinu, *Industrial Applications of Enzymes: Recent Advances, Techniques, and Outlooks*, 8 CATALYSTS 238 (2018).

[221] Creating Helpful Incentives to Produce Semiconductors ("CHIPS") and Science Act, Pub. L. No. 117-167, 136 Stat. 1366 (2022).

[222] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818.

[223] Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, Exec. Order No. 14,081, 87 Fed. Reg. 56849 (Sept. 12, 2022).

[224] 26 U.S.C. § 45Q (2022).

[225] *Inflation Reduction Act (IRA) Summary: Energy and Climate Provisions*, BIPARTISAN POL'Y CTR. (Aug. 4, 2022), https://bipartisanpolicy.org/blog/inflation-reduction-act-summary-energy-climate-provisions/ [https://perma.cc/N238-TZNA].

[226] *See* 26 U.S.C. § 45Q(f)(5)(A)(i) (2022).

[227] *See id.* § 45Q(e)(3)(B)(ii).

scientific points currently casting doubt on the efficacy of biotech as a climate solution. Can Living Carbon's trees qualify for the direct air capture credit because the engineered photosynthesis they use to capture CO_2 is not "natural?" Answering such questions may require an assessment of Section 45Q credits calculated on a lifecycle basis[228]—meaning scientific consensus or not, the government will also need to resolve how it calculates the positive and negative emissions of such things as seaweed growing in the open ocean or whether being made into a Walmart t-shirt counts as "displaced from being emitted into the atmosphere."[229]

Similar questions may be posed by a number of climate "carrot" programs beyond the CCS tax credit. The IRA also provides $50 million in grants to "pay forest landowners for practices that increase carbon removal on private lands," establishes the Section 45Y credit, which pays for "net-negative emission electricity production using solutions like Biomass Energy with Carbon Capture and Storage" ("BECCS") and more.[230]

The government's interest in settling these questions is so obvious it bears repeating: to make sure the technology works. The programs in question here are, in fact, meant to make a difference in climate change. Although not novel relative to the history of environmental law and policy, where agencies routinely accomplish specific goals like "maintaining the national parks,"[231] or "reducing air pollution from diesel,"[232] this is *highly* novel in regard to biotechnology. Even setting aside questions of how well they do so,

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[228] *See id.* § 45Q(f)(5)(B).

[229] *Id.* § 45Q(f)(5)(B)(i)(II).

[230] *Inflation Reduction Act (IRA) Summary: Energy and Climate Provisions*, *supra* note 225.

[231] *See About Us,* NAT'L PARK SERV., https://www.nps.gov/aboutus/index.htm [https://perma.cc/R8MN-Y749] (last updated Aug. 18, 2023) ("The National Park Service preserves unimpaired the natural and cultural resources and values of the National Park System for the enjoyment, education, and inspiration of this and future generations.").

[232] *See Learn About Impacts of Diesel Exhaust and the Diesel Emissions Reduction Act (DERA)*, ENV'T PROT. AGENCY, https://www.epa.gov/dera/learn-about-impacts-diesel-exhaust-and-diesel-emissions-reduction-act-dera [https://perma.cc/URT5-HFD2] (last updated May 19, 2023) ("EPA offers funding for projects that reduce diesel emissions from existing engines.").

agencies under the Framework have mostly assessed whether a biotechnology someone wants to apply in the world poses a low enough risk to allow it. The telling exception is the approach described earlier as to actively managing *Bt* resistance. In that instance, the EPA regulated not just where *Bt* was *allowed*, but also how it was to be used and measured, *because the agency had an interest in making sure the technology works.*[233]

The fact that the EPA, with its particular history of active, ongoing, real-world-effect-motivated regulation of biotechnology, is also the country's uncontested lead climate regulator should not be under-weighted in handicapping the future directions for handling climate biotechnology. Indeed, considering the explicit linkage made by the Obama and Biden administrations between climate and biotechnology, and interest shared even by the Trump administration in further streamlining biotechnology regulation and/or assigning a "lead agency,"[234] it is possible that EPA should take the dominant role in oversight of climate biotechnology, or even biotechnology in general.

Bio-CCS also merges into another manifestation of climate biotechnology: biomanufacturing. Here, biotechnology replaces either a petroleum derived feedstock with a biological one (e.g., bioplastics made from plant material),[235] or an energy-intensive process with a biological tool (e.g., the use of cellulase and amylase to make processing of cellulose and starch, respectively, for biofuel more energy-efficient).[236] Most instances of biomanufacturing involve microbes which are genetically engineered to produce large amounts of enzymes which are known to do a very specific chemical task.[237] The microbes may be used live, in huge vats known as bioreactors, where they are mixed with the chemical ingredients

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[233] *See Insect Resistance Management for Bt Plant-Incorporated Protectants*, *supra* note 177.

[234] Modernizing the Regulatory Framework for Agricultural Biotechnology Products, Exec. Order No. 13,874, 84 Fed. Reg. 27899 (June 11, 2019). *See also* ARS Directive, *supra* note 179.

[235] *See* Akiyama et al., *supra* note 220.

[236] *See* Chapman et al., *supra* note 220.

[237] James M. Clomburg, Anna M. Crumbley & Ramon Gonzalez, *Industrial Biomanufacturing: The Future of Chemical Production*, 355 SCI., Jan. 2017, at 1.

they act upon, or used as a source from which to purify the enzymes which then do the same job.[238] Most cases of microbial biomanufacturing use sugar or corn syrup originating from agriculture as a starting feedstock, analogous to the production of bio-ethanol, and with a similar suite of environmental pros and cons.[239] Examples of biomanufacturing include the following companies:

(i) Allonnia is developing a microbe that can remove phosphorus and aluminum from iron ore, causing it to take less energy to smelt[240]—impactful considering that steel production accounts for eight percent of world greenhouse gas emissions and has been labeled one of the hardest industries to decarbonize.[241]

(ii) Solugen uses purified enzymes to make multiple industrial chemicals using corn syrup as a starting material.[242] The enzymes replace more energy-intensive, chemical synthesis steps, and some of Solugen's products have been labeled lifecycle carbon-negative.[243]

(iii) Checkerspot uses genetically engineered algae to produce molecules that are used to make oils, foams, plastics, and

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[238] Known as "cell free" biomanufacturing, as opposed to "fermentation" (referring to the ongoing metabolism of live microbes) with many technical gradations between the two approaches. *See, e.g.*, Blake J. Rasor et al., *Toward Sustainable, Cell-Free Biomanufacturing*, 69 CURRENT OP. BIOTECH. 136 (2021).

[239] *See* Yi-Heng Percival Zhang, Jibin Sun & Yanhe Ma, *Biomanufacturing: History and Perspective*, 44 J. INDUS. MICROBIOLOGY & BIOTECH. 773 (2017); Corinne D. Scown, *Prospects for Carbon-Negative Biomanufacturing*, 40 TRENDS BIOTECH. 1415 (2022); Congqiang Zhang et al., *Microbial Utilization of Next-Generation Feedstocks for the Biomanufacturing of Value-Added Chemicals and Food Ingredients*, 10 FRONTIERS BIOENG'G & BIOTECH. 1 (2022).

[240] *Technology*, ALLONNIA, https://allonnia.com/technology/ [https://perma.cc/47Z6-FDC3] (last visited Sept. 18, 2023).

[241] Hannah Ritchie, Max Roser & Pablo Rosado, *CO_2 and GHG Emissions, By Sector*, OUR WORLD IN DATA (2020), https://ourworldindata.org/emissions-by-sector [https://perma.cc/7ZYV-X6U4].

[242] SOLUGEN, https://solugen.com/ [https://perma.cc/5MGA-7G7V] (last visited Sept. 18, 2023).

[243] Craig Bettenhausen, *The Cleaning Industry Seems Serious about Sustainability*, CHEM. & ENG'G NEWS (Feb. 13, 2022), https://cen.acs.org/environment/sustainability/cleaning-industry-seems-serious-sustainability/100/i6 [https://perma.cc/QL8L-TVSR].

coatings.[244] All or most of the carbon in those materials originates in the atmospheric CO_2 taken up by the algae during photosynthesis. The company sells its materials to manufacturers of consumer goods as replacements for petroleum-based equivalents.[245]

Because biomanufacturing occurs largely in contained industrial settings, its interaction with the environment has often been treated differently, and sometimes overlooked in analysis and public discussion of biotechnology.[246] For instance, for Checkerspot, lifecycle analysis would be essential to quantifying the net environmental benefits of the technology.[247] But with such lifecycle analysis, biomanufacturing at this point has clear environmental wins to show. These are made clear primarily by the fact that the energy economics of what biomanufacturing replaces are both starker and easier to quantify than applications where all the environmental benefit derives from sequestration or agricultural efficiency. The enthusiasm for biomanufacturing in the recent Biden Executive Order[248] is therefore well-grounded.

The Biden Executive Order[249] directed all procuring government agencies to submit, within a year, strategies for prioritizing biomanufacturing-based materials in their purchasing plans. Agencies are directed to "strive to increase by 2025 the amount of biobased product obligations or the number or dollar value of

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[244] *Platform*, CHECKERSPOT, https://checkerspot.com/platform/ [https://perma.cc/YUQ3-PNR2] (last visited Sept. 18, 2023).

[245] Christopher Marquis, *How and Why Checkerspot Is Making Biomaterials Available and Accessible*, FORBES (Nov. 10, 2022, 8:43 AM), https://www.forbes.com/sites/christophermarquis/2022/11/10/how-and-why-checkerspot-is-making-biomaterials-available-and-accessible/ [https://perma.cc/4WUJ-HA9D].

[246] *See generally Successes and Challenges in Biomanufacturing: Proceedings of a Workshop – in Brief*, NAT'L ACADS. SCI., ENG'G, & MED. (2023), https://www.nationalacademies.org/event/10-24-2022/successes-and-challenges-in-biomanufacturing-a-workshop [https://perma.cc/Z3QG-UF5C].

[247] *See* George et al., *supra* note 190. *See also* David Lips, *Practical Considerations for Delivering on the Sustainability Promise of Fermentation-Based Biomanufacturing*, 5 EMERGING TOPICS LIFE SCI. 711 (2021).

[248] Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, Exec. Order No. 14,081, 87 Fed. Reg. 56849 (Sept. 12, 2022).

[249] *Id*.

biobased-only contracts."[250] Much of these activities are to be coordinated via the Secretary of Agriculture, including an order for all appropriate agencies to submit a coordinated plan for encouraging domestic biomass production (as feedstocks for biomanufacturing as well as bioenergy) and the overall biomanufacturing supply chain. The Secretary of Energy is also directly tasked with preparing "a report assessing how to use biotechnology, biomanufacturing, bioenergy, and biobased products to address the causes, and adapt to and mitigate the impacts, of climate change, including by sequestering carbon and reducing greenhouse gas emissions."[251]

Under the subheading of "Biotechnology Regulation Clarity and Efficiency," the Order directs the EPA , the USDA, and the FDA, in coordination with the White House Office of Science and Technology Policy, to have recommendations for regulatory reform submitted by June 19, 2023 and to provide a public-facing website "enabling developers of biotechnology products to submit inquiries about a particular product and promptly receive a single, coordinated response" by September 2023.[252] This provides the EPA the potential for an expanded role, particularly as it falls within the question of which agency will administer the "coordinated response" given the linkage to climate as the motivation for expanded development of the biotechnology sector. In addition, because the EPA's existing docket in the Coordinated Framework includes, under the Toxic Substances Control Act ("TSCA"), regulation of all genetically engineered microbes and industrial enzymes (e.g., biomanufacturing), the case for EPA taking the point becomes even stronger.

C. *Biotechnology and Climate Adaptation*

Setting aside for the moment social and political concerns over bioengineered "climate-ready" crops, there is an immediate dichotomy: on the one hand, there is evidence of significant commercial interest in the possibility, and on the other, there is only

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[250] *Id*. at 56854.
[251] *Id.* at 56851.
[252] *Id.*

modest evidence that the technology has delivered the goods. As to commercial interest, by 2010 there were reportedly over 1600 patents filed for "abiotic stress tolerance" in plants,[253] with over 500 of them described as patent applications for "climate-ready" genes.[254] As to questions over their efficacy, a good case in point is Monsanto's "DroughtGard," the first GMO drought-resistant maize approved by APHIS in 2011 under the Coordinated Framework.[255] Despite commercial success, APHIS stated in its final assessment report about DroughtGard that, "equally drought resistant corn varieties produced through conventional breeding techniques are readily available . . . [and the] reduced yield-loss phenotype of MON87460 [DroughtGard] does not exceed the natural variation observed in currently-available corn varieties."[256] Although one subsequent, large-scale study of corn/maize plantings found an increase in yields among farms using GE, drought-resistant crops,[257] the authors acknowledged the possibility of other factors that could also have influenced the results.[258]

All this said, it is worth noting that the need for plant traits that can tolerate a hotter, dryer-at-times, wetter-at-times world is beyond dispute. The IPCC acknowledges the point when calling for the use of agrobiodiversity, a wider variety of cultivated species and processes, including those developed by biotechnology.[259] And a variety of other research and international organizations also urge the need for crop adaptation. The Consultative Group on International Agricultural Research ("CGIAR") specifically urges the development, whether by GE means or otherwise, of

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[253] *See* Anne Saab, *Climate-Resilient Crops and International Climate Change Adaptation Law*, 29 LEIDEN J. INT'L L. 503, 509 (2016).

[254] *Id*; *see supra* note 37.

[255] *Id*; *see supra* text accompanying notes 52–67.

[256] *Id*; *see supra* text accompanying notes 95–97.

[257] Ariel Ortiz-Bobea & Jesse Tack, *Is Another Genetic Revolution Needed to Offset Climate Change Impacts for US Maize Yields?*, 13 ENV'T RSCH. LETTERS, Nov. 2018, at 1.

[258] *Id.* at 7 (acknowledging simultaneous adoption of advanced farm machinery and precision agriculture as additional factors that could have influenced the results).

[259] *See* Rafal M. Gutaker et al., *Scaling Up Neodomestication for Climate-Ready Crops*, 66 CURRENT OP. PLANT BIOLOGY, Apr. 2022, at 1.

"climate-ready crops."[260] Yet only ten percent of the patents on GE crops are held by international organizations, with the rest privately held, and with six corporations (DuPont, BASF, Monsanto, Syngenta, Bayer, and Dow) controlling seventy-seven percent of those patents.[261] Given the political fallout from the "Monsanto mistake" over Roundup Ready seeds, it is little wonder that the claim of "climate-ready" crops has been met with skepticism and resistance.

In contrast to the prominence of agricultural adaptation on the list of things we hope biotechnology will do, ecological adaptation is less often mentioned but no lower in potential. This refers to applying biotechnology tools directly to the environment. For example, the same gene drive technology cited as the contentious cutting edge of biotechnology in its usage against disease-carrying mosquitos, has been proposed for the sake of federally endangered birds like the Hawai'ian honeycreeper.[262]

This case in point deserves amplification. Mosquitoes are not native to Hawai'i but were introduced by human activity in the 1800s. Aside from the usual human maladies, these mosquitoes carried avian malaria, against which Hawai'ian birds had no resistance.[263] Most species of native Hawai'ian birds have now gone extinct in the lowlands. Only in the mountains, where cooler temperatures have kept away the mosquitos, can the birds still be found. Climate change, of course, now threatens these last refuges. As the temperature rises, the mosquitoes spread upwards, and the birds are left to retreat farther and farther up the mountain.[264] Gene drives have been considered as a potential means of combatting this

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[260] *See* Saab, *supra* note 253; *see also supra* text accompanying notes 229–30.

[261] Renee Cho, *Climate-Ready Crops: The Pros and Cons*, *State of the Planet*, COLUM. CLIMATE SCH. (June 13, 2011), https://news.climate.columbia.edu/2011/06/23/climate-ready-crops-the-pros-and-cons/ [https://perma.cc/JX6V-Y7RF].

[262] *See* Xuechun Feng et al., *Optimized CRISPR Tools and Site-Directed Transgenesis Towards Gene Drive Development in Culex Quinquefasciatus Mosquitoes*, 12 NATURE COMMC'NS., 2021, at 1.

[263] *See* Carter T. Atkinson & Dennis A. LaPointe, *Introduced Avian Diseases, Climate Change, and the Future of Hawaiian Honeycreepers*, 23 J. AVIAN MED. & SURGERY 53 (2009).

[264] *Id.*

problem since 2016,[265] and the IRA provided $14 million to the Department of the Interior for a new, multiagency strategy to prevent the imminent extinction of Hawai'ian birds by avian malaria, listing gene drives among the "next generation tools" it may deploy by 2032.[266]

Direct modifications of wild species' genomes have even been proposed as a means to save them from climate change. Coral bleaching, which is triggered by high ocean temperatures, occurs when the corals eject the symbiotic, photosynthetic microbes they depend on to survive.[267] Multiple engineering methods, including epigenetic engineering and gene editing, have been proposed and applied to both corals and their symbionts with the intent of increasing their heat tolerance and preventing bleaching—therefore increasing the survival—of coral reefs.[268] Australian researchers, in particular, have achieved success in heat tolerance through multiple methods (including hybridization and selection rather than genetic

[265] *See* John Min et al., *Harnessing Gene Drive*, 5 J. RESPONSIBLE INNOVATION S40 (2018); *see also* NAT'L ACAD. OF SCI., ENG'G, & MED., GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES (2016); Tibi Puiu, *Scientists Debate the Implication of Life-Altering Tools That Can Wipe out Species to Save Others*, ZME SCI. (2016), https://www.zmescience.com/medicine/gene-drive-debate-hawaii/ [https://perma.cc/7W4J-PKX4]; Rode et al., *supra* note 74.

[266] *Press Release, New Strategy Aimed at Saving Hawai'i Forest Birds*, U.S. FISH & WILDLIFE SERV. (Dec. 15, 2022), https://www.fws.gov/press-release/2022-12/new-strategy-aimed-saving-hawaii-forest-birds [https://perma.cc/G9BP-QFVH]; U.S. FISH & WILDLIFE SERV., U.S. DEPARTMENT OF THE INTERIOR STRATEGY FOR PREVENTING THE EXTINCTION OF HAWAIIAN FOREST BIRDS 2 (2022).

[267] *See, e.g.*, Kyle Frischkorn, *A Blueprint for Genetically Engineering a Super Coral*, SMITHSONIAN MAG. (Aug. 3, 2017), https://www.smithsonianmag.com/science-nature/blueprint-engineering-super-coral-180964309/ [https://perma.cc/74XL-BW72].

[268] *See, e.g.*, Rachel A. Levin et al., *Engineering Strategies to Decode and Enhance the Genomes of Coral Symbionts*, 8 FRONTIERS MICROBIOLOGY 1220, June 2017, at 1; Ken Anthony et al., *New Interventions are Needed to Save Coral Reefs*, 1 NATURE ECOLOGY & EVOLUTION 1420, 1420–22 (2017); Jie Li et al., *Microbiome Engineering: A Promising Approach to Improve Coral Health*, 27 ENG'G (forthcoming 2023).

engineering).[269] Australia is now considering release of modified corals into the wild. Notably, a 2022 study found that, despite the often-contentious reputation of GMOs, fifty-nine percent of Australians surveyed declared themselves in favor of releasing a genetically engineered, bleaching-resistant coral onto the Great Barrier Reef (twenty-nine percent were neutral and only eleven percent were against).[270] Indeed, Americans appear to be of a similar mind. Despite common preferences for non-GMO foods, negative perception of corporate players, and concern over the risks of biotechnology, Americans asked similar questions report nuanced, but most-often positive views when asked for comment on "pure" environmental applications of biotechnology.[271] In this regard, public opinion matches the government's enthusiasm for biotechnology as an environmental tool.

V. CONCLUSION

Although biotechnology may prove as important in addressing climate change as it has in medicine and medical research, the overriding purpose of this Article is not to advocate for any of its particular applications. Indeed, this Article has been forthright in

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[269] *See* Warren Cornwall, *Researchers Embrace a Radical Idea: Engineering Coral to Cope with Climate Change*, SCIENCE.ORG (Mar. 21, 2019), https://www.science.org/content/article/researchers-embrace-radical-idea-engineering-coral-cope-climate-change [https://perma.cc/VCH4-8DU7]; Patrick Buerger et al., *Heat-Evolved Microalgal Symbionts Increase Coral Bleaching Tolerance*, 6 SCI. ADVANCES, May 2020, at 1.

[270] *See* Aditi Mankad, Elizabeth V. Hobman & Lucy Carter, *Genetically Engineering Coral for Conservation: Psychological Correlates of Public Acceptability*, 8 FRONTIERS MARINE SCI., Nov. 2021, at 1; Elizabeth V. Hobman et al., *Genetically Engineered Heat-Resistant Coral: An Initial Analysis of Public Opinion*, 17 PLOS ONE, Jan. 2022, at 1.

[271] S. Kathleen Barnhill-Dilling & Jason A. Delborne, *The Genetically Engineered American Chestnut Tree as Opportunity for Reciprocal Restoration in Haudenosaunee Communities*, 232 BIOLOGICAL CONSERVATION 1 (2019); Michael S. Jones et al., *Does the U.S. Public Support Using Gene Drives in Agriculture? And What Do They Want to Know?*, 5 SCI. ADVANCES, Sept. 2019, at 1; Joshua D. Petit, Mark D. Needham & Glenn T. Howe, *Cognitive and Demographic Drivers of Attitudes Toward Using Genetic Engineering to Restore American Chestnut Trees*, 125 FOREST POL'Y & ECON., Apr. 2021, at 1.

highlighting many of the shortcomings of past biotechnology applications and certainly of its regulation to date. But as the country and the world now face, on almost a weekly basis, the often-calamitous effects of climate change, there is little question that biotechnology is one of the crucial tools that humanity has at its disposal to address both climate mitigation and climate adaptation. Indeed, the U.S. government has made these connections explicit in identifying biotechnology as the tool, second only to alternative energy, on which it plans to lean to bring about a sustainable future. This Article seeks to trigger an increase in attention to the connection.