Loper-Proofing Next-Generation Biosecurity Policy

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Keywords: Loper-Bright; Supreme Court; biosecurity; bioeconomy; Chevron; regulation; agency

Executive Summary: Chevron Deference, recognizing that Congress often drafts statutes broadly, allowed administrative agencies to use their expertise to make policy decisions within those boundaries. Considered settled law for 40 years, this principle played a pivotal role in federal court rulings. However, the decision in Loper-Bright Enterprises v. Raimondo reversed this precedent, creating significant ramifications for biosecurity regulations, including in the domains of public health, biotechnology, and the bioeconomy. After an additional ruling loosened limitations on when suits may be filed, dissatisfied individuals or organizations are enfranchised to contest settled agency decisions without the protection of Chevron. At the heart of Loper-Bright lies the question: how much influence should subject-matter experts hold over the interpretation of ambiguous laws? This article examines the potential ripple effects of overturning Chevron, focusing on the impact on biosecurity and the bioeconomy, while offering recommendations to advance meaningful policy in the Congressional, Executive, and Judicial branches after Loper-Bright.

I. Legislation and regulation

"Legislation" and "regulation" are closely-associated sources of law which lay audiences may confuse. Useful distinctions, however, lie in their sources and functions. Legislation is created by legislatures, while regulation originates from the Executive branch and its administrative agencies, reflecting a division of labor (Kosti, Levi-Faur, & Mor 2020). Legislation establishes the overarching principles of public policy, whereas regulation operationalizes these principles, ensuring their implementation and enforcement. Despite this distinction, overlap (and significant tension) exists. Legislators may overrule regulation by passing superseding statutes or vacating an agency's ability to make certain determinations entirely.

In the United States, federal legislative powers lie solely with Congress, which has the authority to issue laws. However, Congress is deliberative, and lawmakers often lack subject-matter expertise in science and technology, permitting Executive branch agencies to issue regulations that are codified and published in a process known as rulemaking (Curington 2024). The Administrative Procedure Act (APA; 1946) outlines and constrains agency rulemaking powers. Regulations promulgated by agencies under the APA carry the full force and effect of law, as they derive from and implement statute.

Delegating regulatory authority to agencies results in policy benefits downstream. Agencies are staffed by subject-matter experts who can craft responsive, granular, and applicable rules, and can respond more quickly to developments in industry and technology than Congress. The APA ensures the rulemaking process is transparent and responsive to the regulated industry.

For instance, Congress may seek to promote safe and effective medical devices. When drafting the Federal Food, Drug, and Cosmetic (FD&C) Act in 1938, Congress defined *medical devices* to include "instruments, apparatus, and contrivances … for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." Congress could not have anticipated, let alone regulated, every medical innovation, such as *in vitro* diagnostics (IVDs). Instead, under the FD&C Act, the Food and Drug Administration (FDA) is empowered to determine when and whether *in vitro* diagnostics meet this definition. The FDA did so in 1976, promulgating a rule that IVDs are devices and most fall under regulatory control (Labeling for in Vitro Diagnostic Products 1976). The FDA, however, initially declined to regulate laboratory-developed tests (LDTs), IVDs designed, manufactured, and used within a single clinical laboratory. As LDTs became increasingly prominent and applied for critical purposes such as predicting cancer risk and aiding in diagnosing Alzheimer's Disease, it became necessary to regulate them for safety and efficacy. In April 2024, the FDA issued a final rule regarding the regulation of LDTs, deeming that they fall under the definition of IVDs, namely "devices" under the FD&C Act ("Medical devices; Laboratory Developed Tests" 2024). In this manner, agencies may gradually revise their remit to accommodate emerging science and technology.

II. Chevron Deference

As will be seen in the case of the FDA and IVD regulation, stakeholders may disagree with some agency interpretations of ambiguous statutes. The 1984 opinion *Chevron U.S.A. v. Natural Resources Defense Council* (1984) established a "principle of deference to administrative interpretations" of ambiguous statutes in the federal judiciary. At issue was an Environmental Protection Agency (EPA) decision defining an entire industrial facility as a "stationary source" of pollution, rather than treating each pollution-emitting device as a separate source. The Supreme Court of the United States (SCOTUS), in ruling for the EPA, outlined a two-step test for federal courts to use when determining the validity of agency regulations deriving from ambiguous statutes. First, the court must determine "whether Congress has directly spoken to the precise question at issue." Second, "If the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Called Chevron Deference, this precedent raised the threshold plaintiffs were required to meet to challenge administrative actions in court, enfranchising agencies to apply their expertise to the development of regulations.

Chevron Deference quickly became one of the most frequently-cited SCOTUS decisions, referenced in more than 18,000 federal court decisions by 2024 (Barnett & Walker 2024). Many cases decided in whole or in part by Chevron have bioeconomy and biosecurity implications. The D.C. District Court in *Doe v. Sullivan* (1991) upheld the Department of Defense's (DOD) prerogative to decide when informed consent was "not feasible" for military service-required vaccinations, allowing the DOD to inoculate service members against biological threats using drugs which had not yet received FDA approval. The Tenth Circuit relied on Chevron Deference in *Pharmanex v. Shalala* (2000). While it may have been "linguistically possible" that Congress only intended the FDA to regulate finished drug products, the court upheld the FDA's determination that it may also regulate a drug's active ingredients. Pharmanex was selling a product rich in the cholesterol-lowering drug lovastatin, arguing that it was a nutritional supplement. In *Association for Community Affiliated Plans v. United States Department of Treasury* (2019), the D.C. District Court held under Chevron that agencies are empowered to define what Congress intended by "short-term limited duration [health] insurance." As gaps in health insurance coverage heighten vulnerability for disease morbidity and mortality (Campbell et al. 2022), the ability to quickly promulgate rules regarding health insurance is an essential tool for biosecurity.

III. Loper-Bright Enterprises v. Raimondo

During the 2024–2025 term, SCOTUS revoked Chevron Deference in the decision *Loper-Bright Enterprises v. Raimondo.* Loper-Bright Enterprises sued Gina Raimondo in her capacity as Secretary of Commerce to challenge a rule promulgated by the National Marine Fisheries Service (NMFS) requiring fisheries to pay for on-board federal monitors. The authorizing legislation did not specify which party, the fisheries or NMFS, would pay for monitors. Under Chevron, the D.C. and First Circuits found that the agency's interpretation of the statute was a permissible construction and ruled for NMFS.

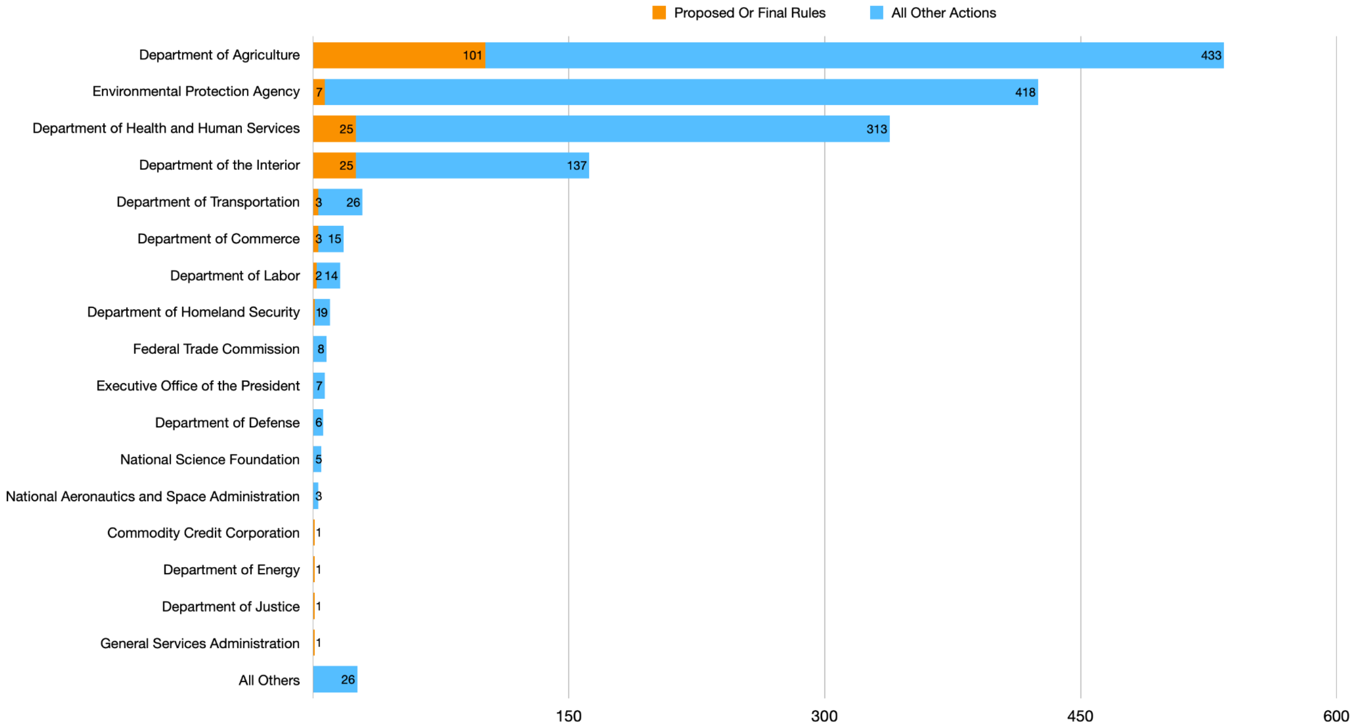

Figure 1: Agency actions containing the search term "biosecurity" listed at Regulations.gov (General Services Administration 2025). Agencies proposing or enacting no rules, and taking two or fewer other actions, are collected under All Others. Search covers all agency actions as of December 31, 2024.

However, in a 6-3 decision written by Chief Justice Roberts, SCOTUS not only ruled in favor of Loper-Bright but further determined that Chevron Deference was inconsistent with the APA. The majority opinion states, "agencies have no special competence in resolving statutory ambiguities" and that "statutory interpretation was exclusively a judicial function."

In overturning Chevron, the justices "[did] not call into question prior cases that relied on the Chevron framework." However, a separate case decided during the same term provided an expedient method to re-evaluate Chevron-based rulings. In *Corner Post v. Board of Governors of the Federal Reserve System* (2024), SCOTUS effectively abolished the statute of limitations on lawsuits against the federal government. Rather than constraining lawsuits against agency rulemaking under the APA to the first six years after a rule is promulgated, plaintiffs may sue within six years after they personally experience injury. This enfranchises plaintiffs to challenge settled regulations: they may establish new firms which then accrue new right of action to file suit against any regulatory decision, regardless of how many decades have passed since its issuance. Per the dissent, "administrative agencies can be sued in perpetuity over every final decision they make."

IV. Ripple effects of Loper-Bright

To better understand the ripple effects of Loper-Bright on biosecurity actions, we analyzed all-time regulatory activity by searching "biosecurity" on Regulations.gov (General Services Administration 2025). We uncovered 1,591 individual agency actions, including requests for information, public reports and assessments, regulatory impact analyses, and 171 proposed or final rules (11% of total actions). (See Figure 1 and Table 1.) Proposed rules outline an agency's plan to implement or exercise a statutory authority to achieve a goal. They are the first version of a new regulation shared with the public, allowing for feedback before final adoption. Final rules are published following public comment and are promulgated by the relevant administrative agency. The majority of the 1,591 actions were by the Animal and Plant Health Inspection Service (APHIS), EPA, FDA, and the Fish and Wildlife Service (FWS). Regulations without the word "biosecurity" may still

Table 1: Agency actions containing the search term "biosecurity" listed at Regulations.gov (General Services Administration 2025). Agencies proposing or enacting no rules, and taking two or fewer other actions, are collected under All Others. Search covers all agency actions as of December 31, 2024. Actions are listed at the agency level, unless only a department is listed at Regulations.gov. Actions are not duplicated across rows. For instance, five actions are attributed to the Department of Homeland Security, without indicating an agency, and five additional actions are attributed specifically to the Coast Guard, a component of the Department of Homeland Security.

Department/Agency	Division (If Specified)	All Actions (% of total)	Proposed/Final Rules (% of total)
Commodity Credit Corporation		1 (0.1%)	1 (0.6%)
Department of Agriculture		34 (2.2%)	4 (2.3%)
	Agricultural Marketing Service	18 (1.2%)	8 (4.7%)
	Animal and Plant Health Inspection Service	466 (29.8%)	79 (46.2%)
	Food Safety and Inspection Service	15 (1.0%)	9 (5.3%)
	Rural Housing Service	15 (1.0%)	9 (5.3%)
Department of Commerce	Bureau of Industry and Security	2 (0.1%)	2 (1.2%)
	National Oceanic and Atmospheric Association	16 1.0%)	1 (0.6%)
Department of Defense	Corps of Engineers	6 (0.4%)	
Department of Energy	Energy Efficiency and Renewable Energy Office	1 (0.1%)	1 (0.6%)
Department of Health and Human Services		21 (1.3%)	4 (2.3%)
	Centers for Disease Control and Prevention	16 (1.0%)	5 (2.9%)
	Centers for Medicare & Medicaid Services	2 (0.1%)	2 (1.2%)
	Food and Drug Administration	266 (17.0%)	14 (8.2%)
	National Institutes of Health	33 (2.1%)	
Department of Homeland Security		5 (0.3%)	
	Coast Guard	5 (0.3%)	1 (0.6%)
Department of Justice		1 (0.1%)	1 (0.6%)
Department of Labor	Employment and Training Administration	1 (0.1%)	1 (0.6%)
	Occupational Safety and Health Administration	14 (0.9%)	
	Wage and Hour Division	1 (0.1%)	1 (0.6%)
Department of the Interior	Fish and Wildlife Service	162 (10.4%)	25 (14.6%)
Department of Transportation		9 (0.6%)	
	Federal Aviation Administration	8 (0.5%)	3 (1.8%)
	National Highway Traffic Safety Administration	12 (0.8%)	
	Environmental Protection Agency	425 (27.2%)	7 (4.1%)
Executive Office of the President	Office of Science and Technology Policy	4 (0.3%)	
	Office of the United States Trade Representative	3 (0.2%)	
	Federal Trade Commission	8 (0.5%)	
General Services Administration	Regulatory Information Service Center	1 (0.1%)	1 (0.6%)
	National Aeronautics and Space Administration	3 (0.2%)	
	National Science Foundation	5 (0.3%)	
All Others		26 (1.6%)	

have biosecurity implications, meaning this data is likely an underestimation. We compared year-over-year agency rulemaking to evaluate the effect Loper-Bright may have on the pace of rulemaking. (Figure 2.) When visualizing actions and rules published from 2013 to 2024, covering three presidential administrations, a trough is apparent from approximately 2017 to 2022, except for a peak in 2020 corresponding to the COVID-19 pandemic. This corresponds to a deprioritization of biosecurity on the part of the first Trump Administration, including proposed budget cuts to departments with biosecurity missions (National Association of Counties 2017; Collier 2017), moving relevant offices out of Washington (Guarino 2019), and dissolving the biodefense directorate of the National Security Council (Sun 2018). Under the Biden Administration, biosecurity rulemaking accelerated, with almost as many proposed or enacted rules issued in President Biden's last two years as during the entire first Trump Administration. This limited analysis cannot characterize the impact of these agency actions. Indeed, rules mentioning "biosecurity" may weaken oversight of the bioeconomy. However, Loper-Bright will likely dampen the pace and potency of agency rulemaking at a time when the bioeconomy is advancing rapidly.

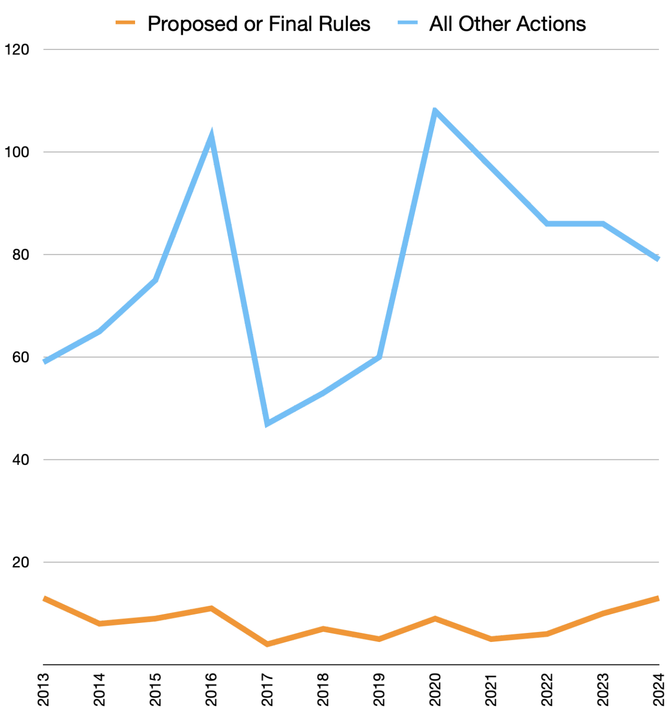

Figure 2: Agency actions containing the search term "biosecurity" from January 1, 2013, to December 31, 2024, listed at Regulations.gov (General Services Administration 2025).

Biosecurity actions have, to date, been on an upward trend and are distributed across a wide range of federal bodies, including key players like APHIS, EPA, FDA and FWS, but also in agencies which may not be recognized as having a biosecurity mission, such as the Wage and Hour Division of the Department of Labor, National Aeronautics and Space Administration, and Office of the United States Trade Representative. Agencies across the breadth of the federal government will likely be affected by the overturning of Loper-Bright. We describe below four ways revoking Chevron may impact regulatory actions.

i. Constraining administrative authority

Only hindsight will accurately account for the impact of the Loper-Bright decision, however, it will almost certainly curtail administrative authority. Most notably, the ruling makes explicit that judges, not agencies, will "say what the law is." Historically, agencies have interpreted Congressional authorization broadly to meet their missions, and Congress has permitted this by declining to narrow these statutes. For instance, while the Public Health Service Act (1944) allows for only the "apprehension and examination" of persons crossing state lines who are reasonably believed to be infected with a communicable disease, Center for Disease Control and Prevention (CDC) guidance in the Code of Federal Regulations claims the authority to subject them to "quarantine, isolation, or conditional release" (Apprehension and Detention of Persons with Quarantinable Communicable Diseases 2017). These and other potent biosecurity tools are now more vulnerable to legal challenges.

Already, in *American Clinical Laboratory Association v. United States Food and Drug Administration* (ACLA 2025), a judge followed the provisions of Loper-Bright to strike down an FDA rule which would enhance regulation of LDTs. Under Corner Post, future litigants could identify more ambitious targets. New laboratories could challenge not only a new rule but even the original rule under which the FDA determined it may regulate IVDs (Labeling for *in Vitro* Diagnostic Products 1976), which are neither squarely drugs nor devices.

ii. Delaying agency rulemaking

Revoking Chevron will delay agency rulemaking on time-sensitive biosecurity issues. Already, the issuance of a finalized rule takes approximately four years on average (Government Accountability Office 2009). Loper-Bright requires agencies to re-evaluate the authorizing language they have traditionally cited to impose policies and regulations. This process will take time and may delay the issuance of rules on security-sensitive topics to "Loper-proof" the policy. Importantly, many emerging biosecurity issues, such as artificial intelligence (Tricot 2021), are associated with developing industries receiving millions of dollars in capital, which may be motivated to vigorously defend their equities through litigation. Even if an agency rule ultimately goes into effect, regulated industries may still find value in delaying or disrupting rules through litigation in order to buy time for further revenue. Rules that ultimately withstand litigation may still be delayed by court injunctions while the cases unwind. The COVID-19 pandemic illustrates the importance of a regulatory apparatus that can move quickly and robustly: federal agencies introduced new regulations to expedite the public health and medical response, such as requiring face masks on public transportation, providing proof of COVID-19 testing or recovery on arrival in the US, and a temporary halt on evictions. The overruling of Chevron, however, could hinder agencies' agility in addressing emerging challenges, potentially disrupting suppliers, providers, and patients and leading to avoidable morbidity and mortality.

iii. Complicating the regulatory landscape

Under Loper-Bright, SCOTUS now requires the federal judiciary to "use every tool at their disposal to determine the best reading of the statute and resolve the ambiguity," rather than defer to the agency. As such, in addition to constraining or delaying rulemaking, federal courts may choose to substitute their interpretation for ambiguous rules. While judges may be experts in the law, few are experts in biology, physics, or medicine. For example, *ACLA* hinged in part on whether an IVD, which consists in large part of a replicable process, is a "device" per the FDA's remit. A judge ruling broadly may have unintentionally included any tool-assisted healthcare process as a medical device, including tumor resections or physical exams. Conversely, a narrow definition of "device" may inadvertently excluded computer algorithms or even artificial intelligence applied in clinical contexts. While a decision with substantial inadvertent consequences is likely to be corrected through subsequent litigation, the uncertainty and expense may have outsized consequences on the healthcare industry. Loper-Bright risks adding 1,457 judges across 94 district courts and 13 appellate circuits as co-authors to regulations regarding nuanced science and advanced technology topics, such as synthetic biology, semiconductor manufacturing, and artificial intelligence (American Bar Association, 2024; Department of Justice, 2025).

iv. Burdening the Legislature and Judiciary

Loper-Bright will also burden Congress and courts with unnecessary minutiae. Congress relied on agencies to operationalize statutes to apply them flexibly to the changing circumstances of governance, and courts allowed agencies to reasonably interpret them to produce new rules. Now, with limited ability to defer to Executive agencies when these rules are challenged, the other branches must necessarily pick up the slack. Both Congress and courts may be forced to become fluent in contemporary biosecurity concepts such as agent-agnostic biodetection or benchtop nucleic acid synthesis to craft the policies agencies use to accomplish their mission. This increase in the knowledge demands placed on Congress and courts will require them to enhance their technical capacity to perform effectively. This may require spending long hours familiarizing themselves with cutting-edge scientific developments or state-of-the-art technological advances, or expanding their staff to include well-trained subject-matter experts. Legislators, in particular, may be compelled to rely more heavily on industry lobbyists or other stakeholders to draft applicable legislation. Courts and Congress will need to cultivate exacting technical specificity to produce enduring laws or opinions.

V. Guardrails after Loper-Bright

While many policy experts expressed deep concern about the Loper-Bright decision, some suggest the loss of Chevron may not change the biosecurity landscape dramatically. Even without Chevron Deference, courts may still turn to the earlier precedent of *Skidmore v. Swift & Co.* (1944). Under this non-determinative framework, courts evaluate an administrative rule by the "thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." Agency rules promulgated with rationale and revised with public comment under the APA may be persuasive under Skidmore. However, evidence which is persuasive for scientists may not be accessible for judges, who now (to borrow from the dissent in Loper-Bright) may be asked to determine "when does an alpha amino acid polymer qualify as a …'protein'" for the FDA's regulatory purposes?

Additionally, courts are loath to interfere in national security and have historically given the Executive branch a wide berth in determining matters of public safety (*e.g.*, *Trump v. Hawaii* 2018). Unfortunately, the national security implications of some cases, such as potential agency rules regarding artificial intelligence, may not be the most salient factor. Further, capabilities such as artificial intelligence and nucleic acid synthesis are dual-use technologies with both significant civilian utility and capacity to cause harm. They also hold tremendous profit potential. Firms may pursue anti-regulatory litigation to protect their earnings by reducing the cost of compliance or opening new potential markets. Allowing dual-use technologies to proliferate without regulatory oversight raises the risk that they may be misused. While some factors may mitigate the impacts of Loper-Bright, the decision still tips the scales further toward plaintiffs. As such, Loper-Bright cannot go unaddressed.

VI. Recommendations

i. Executive agencies must audit their authorities

Federal policymakers should take steps to ensure the end of Chevron Deference does not compromise biosecurity. First, Executive agencies must review the authorizing legislation underlying their emergency preparedness and biosecurity functions to ensure they rest on Loper-proof language. This must include a careful evaluation of the alignment between delegated authorities in statute and resulting rules in the Code of Federal Regulations. For instance, the CDC may be loath to loosen its authority to quarantine persons crossing state lines, but updating the promulgated regulations now to resolve the discrepancy may be preferable to having its capabilities challenged in court during the next pandemic.

ii. Congress must write Loper-proof delegations

In recent years, Congress has passed fewer laws, and the 118th Congress was, by some metrics, the least productive legislative session (Library of Congress 2025). Impactful consensus legislation on artificial intelligence, pandemic preparedness, or dual use research of concern is unlikely to pass in the near future. Congress should ensure the legislation which does pass includes Loper-proof delegations to agencies, both in *de novo* bills and when amending existing biosecurity powers. The authorizing legislation must broadly and clearly delegate to Secretaries the ability to make determinations, promulgate rules, and take action when necessary. For instance, delegating authority to the FDA to regulate medical countermeasures beyond the definition of *drugs* or *devices* may better refine its regulatory authorities in a bioeconomy which increasingly blurs these lines. Further, Congress should increase its personnel appropriations to build scientific and technical capacity in member offices, Legislative Counsel, or in the Congressional Research Service to write Loper-proof legislation.

iii. Policymakers must support the Federal Judicial Center

The Federal Judicial Center (FJC; 2025) is a research and education agency within the federal court system which provides training, information, and technical support to federal judges. The FJC hosts programs which equip judges to make determinations in cases concerning developments in science and technology. Congress should expand the capacity of the FJC, ensuring judges have access to technical support and advanced expertise as they consider arcane cases. Appropriations may also be used for marketing to ensure judges are aware of the resources and utility of the FJC, and professional organizations may do their part to raise the profile of the Center in relevant professional media including law reviews and conferences.

VII. Conclusion

In *Loper-Bright*, the Supreme Court calls on the federal judiciary to substitute agency interpretation of statute with its own. The complexity and rapid evolution of the biosecurity enterprise, however, make this a particularly challenging task with potentially dangerous consequences. Biosecurity policy spans vast, technically intricate areas that demand coordination and specialized expertise.

Following *Loper-Bright*, courts are likely to scrutinize the routine work of agencies, including defining statutory terms, interpreting ambiguous language, and regulating in dynamic fields like biosecurity, biotechnology, and emerging technologies. While the recency of the ruling means any predictions remain speculative, stakeholders in biosecurity must consider its potential implications for their missions. The decision has introduced a new layer of uncertainty that could affect the ability of agencies to respond swiftly and effectively to evolving biosecurity challenges. Subject-matter experts in Executive agencies must be persistent in applying their technical skillset to these critical emerging issues.

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Authors' views do not necessarily reflect those of their respective departments or institutions. The authors declare no conflicts of interest.