IADC COMMITTEE NEWSLETTER

PRODUCT LIABILITY

NOVEMBER 2026

IN THIS ISSUE

What a wonderful Roundtable at Pfizer headquarters in New York City! Many of you joined us for informative and fun presentations at this year's Product Liability Roundtable. It was great to see so many of you! We appreciate the contributions of everyone who developed this program and encourage anyone interested in getting involved next year. If you were unable to attend the Roundtable, here's a part of what you missed. This article surveys the EU's new strict-liability framework and emerging U.S. proposals and offers practical guidance on documentation, contracting, and insurance.

Federal Regulatory and Executive Action Survey: 2025–2026

A Comprehensive Agency-by-Agency Analysis of Recent Regulatory Changes

ABOUT THE AUTHORS



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ABOUT THE COMMITTEE

The Product Liability Committee serves all members who defend manufacturers, product sellers and product designers. Committee members publish newsletters and *Journal* articles and present educational seminars for the IADC membership at large and mini-seminars for the committee membership. Opportunities for networking and business referral are plentiful. With one listserv message post, members can obtain information on experts from the entire Committee membership. Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:



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Introduction

The period from early 2025 through mid-2026 has witnessed a concentrated wave of federal regulatory activity spanning environmental policy, pharmaceutical pricing, food safety surveillance, and drug development. Through a combination of executive orders, Congressional Review Act (CRA) resolutions of disapproval, presidential proclamations, and final agency rules, the current administration has fundamentally reshaped the regulatory landscape across multiple sectors. We survey thirteen significant federal actions, organized by the lead agency responsible for implementation, and identify cross-cutting trends with implications for regulated industries, practitioners, and the public.

The actions documented below reflect several overlapping policy priorities: broad environmental deregulation and compliance relief; aggressive intervention in pharmaceutical pricing and supply chains; selective reduction in public-health surveillance capacity; and the strategic use of statutory and constitutional authorities to achieve rapid policy change without traditional notice-and-comment rulemaking.

Environmental Protection Agency (EPA)

The EPA has been the subject of significant regulatory changes during this period, with seven distinct actions either directly promulgated by EPA or affecting EPA-administered programs.

Rescission of the 2009 Endangerment Finding and Vehicle GHG Standards

On February 12, 2026, the EPA rescinded the 2009 Endangerment Finding under Clean Air Act § 202(a)(1)—the legal determination that greenhouse gas (GHG) emissions from new motor vehicles and engines endanger public health and welfare. The Endangerment Finding had served since 2009 as the statutory prerequisite for all subsequent federal regulations of vehicle tailpipe GHG emissions. Subsequently, on April 20, 2026, the EPA finalized the repeal of all GHG emission standards for light-, medium-, and heavy-duty on-highway vehicles and engines. As a practical consequence, automobile manufacturers are no longer required to measure or report vehicle tailpipe GHG emissions under federal law.

This action represents the most structurally significant of the EPA changes, as it removes the foundational legal determination upon which an entire regulatory program was built, rather than simply modifying individual standards.

Source: Final Rule: Rescission of the Greenhouse Gas Endangerment Finding and Motor Vehicle Greenhouse Gas Emission Standards Under the Clean Air Act | US EPA

Two-Year Compliance Exemption Under Clean Air Act § 112(i)(4)

On March 24, 2025, the EPA announced a two-year compliance exemption under Clean Air Act § 112(i)(4) for affected facilities while the agency reconsidered air rules governing hazardous air pollutant (HAP) emissions from "American energy and manufacturing" sources. Section 112(i)(4) authorizes the EPA Administrator to grant compliance extensions to existing sources while the agency conducts rulemaking—effectively suspending enforcement of HAP emission standards for up to two years. This action principally concerns the Mercury and Air Toxics Standards (MATS), which regulate emissions of mercury, acid gases, and other toxic pollutants from coal- and oil-fired power plants.

The invocation of § 112(i)(4) is notable because it represents a rarely used statutory mechanism that allows executive-branch compliance relief without congressional action, providing immediate regulatory forbearance while preserving the option to promulgate revised standards.

Source: Clean Air Act Section 112 Presidential Exemption Information | US EPA

CRA Revocation of the 2024 Major-Source/Area-Source HAP Rule

On June 20, 2025, under the Congressional Review Act, Congress passed and President Trump signed a joint resolution of disapproval revoking the Biden-era 2024 rule titled "Review of Final Rule Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act." The resolution restored the 2020 rule permitting reclassification. The now-revoked 2024 rule had required certain sources of persistent and bioaccumulative hazardous air pollutants listed in Clean Air Act § 112(c)(6) to continue complying with major-source emission standards under § 112(d)(2) or § 112(d)(4) even after reclassifying as area sources.

The practical effect is that facilities previously classified as major sources of HAPs may now reclassify as area sources—subjecting them to less stringent emission standards—without being required to maintain their prior major-source compliance obligations for persistent and bioaccumulative pollutants.

Source: Federal Register: Congressional Review Act Revocation of 2024 Review of Final Rule Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act

CRA Revocation of the Methane Waste Emissions Charge

On March 14, 2025, under the CRA, Congress passed and President Trump signed a joint resolution of disapproval revoking the annual waste emissions charge applicable to petroleum and natural gas systems. Originally enacted as part of the 2022 Inflation Reduction Act under the Methane Emissions Reduction Program, the charge imposed fees on oil and gas facilities emitting above 25,000 metric tons of carbon dioxide equivalent (CO_2e) per year. The rule

established procedures for facilitating compliance, including netting and exemption provisions.

This revocation eliminates the financial penalty mechanism designed to incentivize methane leak reduction at large-scale fossil fuel operations, removing a significant compliance cost for the upstream oil and gas sector.

Source: Understanding the Waste Emissions Charge for Methane: What's Changed and What's Next? – Environmental and Energy Law Program

CRA Revocation of the Rubber Tire Manufacturing NESHAP Amendments

On May 23, 2025, under the CRA, Congress passed and President Trump signed a joint resolution of disapproval revoking the 2024 amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the rubber tire manufacturing source category. The revoked 2024 rule had promulgated updated air emissions standards specifically for the rubber processing subcategory.

This action returns affected rubber tire manufacturing facilities to the pre-2024 emission standards, relieving them of compliance obligations under the more stringent amended NESHAP requirements.

Source: Federal Register – Congressional Review Act Revocation of 2024 Amendments to the National Emission Standards for Hazardous Air Pollutants

CRA Revocation of Three California Clean Air Act § 209 Waivers

On June 12, 2025, under the CRA, Congress passed and President Trump signed three joint resolutions rescinding recent waiver authorizations granted to California under § 209 of the Clean Air Act. Section 209 uniquely authorizes California to request waivers from the federal preemption of state motor vehicle emission standards, permitting the state to set vehicle emission standards stricter than the national baseline. Other states may then adopt California's standards under § 177.

The revocation of these three waivers represents a direct federal intervention in the historically unique California authority under the Clean Air Act, with cascading effects for the numerous states that had adopted California's standards.

Source: Active Battle Over the California Clean Air Act Waiver Continues | Insights | Jones Day

Two-Year Compliance Exemption for Ethylene Oxide Sterilization Facilities

On July 17, 2025, President Trump issued an executive proclamation providing regulatory relief for certain stationary sources subject to the EPA's National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities (the EtO Rule), 89 Fed. Reg. 24090. The proclamation declares that certain stationary sources identified in Annex I of the proclamation are exempt from compliance with the EtO Rule for a period of

two years beyond the Rule's relevant compliance dates. During the exemption period, the affected facilities remained subject to emissions and compliance obligations in effect prior to the EtO Rule's issuance.

This action is framed as necessary to protect the domestic supply of sterile medical equipment, reflecting a broader policy emphasis on supply-chain resilience.

Source: Regulatory Relief for Certain Stationary Sources to Promote American Security with Respect to Sterile Medical Equipment – The White House

Department of Health and Human Services / Centers for Medicare & Medicaid Services (HHS/CMS)

HHS and CMS have been the principal vehicles for the administration's aggressive pharmaceutical pricing and market-competition agenda, deploying executive authority to intervene in drug pricing.

Executive Order 14273: Lowering Drug Prices by Putting Americans First

On April 15, 2025, the Trump Administration issued Executive Order 14273, a sweeping directive addressing pharmaceutical pricing through five principal mechanisms:

- Encouraging the development of generic and biosimilar alternatives to higher-cost brand-name prescription drugs and biologics, including measures to promote competitive market entry;
- Establishing a pathway to expand access to lower-cost drugs imported from outside the United States;
- Reforming government-mandated discount programs to ensure that discounts are passed through to patients at the point of sale rather than being retained by pharmacy benefit managers and other intermediaries;
- Promulgating new price-transparency rules to allow patients, physicians, and employers to see actual prescription drug costs before purchase; and
- Capping insulin copayments for Medicare beneficiaries.

This order represents a multi-pronged approach combining supply-side competition policy (generics and biosimilars), demand-side transparency, intermediary reform, importation, and direct price controls (the insulin cap).

Source: Federal Register :: Lowering Drug Prices by Once Again Putting Americans First

Executive Order 14297: Most-Favored-Nation Prescription Drug Pricing

On May 12, 2025, the Trump Administration issued Executive Order 14297, directing HHS to pursue most-favored-nation (MFN) pricing for prescription drugs purchased through federal programs. The order directs

HHS to communicate MFN price targets to manufacturers and, if voluntary compliance proves inadequate, to pursue formal rulemaking to impose MFN pricing. The order further contemplates drug reimportation from lower-cost developed nations, antitrust enforcement against pharmaceutical companies, and export restrictions as additional enforcement mechanisms.

HHS and CMS subsequently established target prices based on the lowest price among OECD countries with a GDP per capita of at least 60 percent of U.S. GDP per capita. The administration sent letters to 17 drug manufacturers demanding compliance with MFN pricing within 60 days. This escalating enforcement structure—from voluntary compliance to mandatory rulemaking to antitrust action—represents an unusually aggressive posture toward pharmaceutical pricing. New federal data that shows U.S. prescription drug prices fell 0.8% in July and are down 3.1% from a year ago, the steepest year-over-year drop since 1963. The Trump Administration credits the MFN policy for this price decline.

Source: Federal Register: Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients

Food and Drug Administration (FDA)

The FDA appears in multiple actions during this period, both as the lead agency and in coordination with other departments, reflecting its central position in pharmaceutical and medical-device regulation.

Quality Management System Regulation Technical Amendments

On February 2, 2026, the FDA issued a final rule making technical amendments to medical-device regulations to conform references and language to the earlier Quality Management System Regulation (QMSR) final rule. The FDA explicitly stated that this rule does not impose any new requirements on affected parties. The action is editorial in nature, correcting errors, conforming regulatory references, and ensuring accuracy and clarity in the Agency's regulations. This is a joint action with HHS.

While this action has minimal substantive regulatory impact, it demonstrates ongoing FDA administrative maintenance of the device regulatory framework even during a period of broader deregulatory activity.

Source: Federal Register: Medical Devices; Quality Management System Regulation Technical Amendments

Executive Order 14293: Regulatory Relief for Domestic Pharmaceutical Production

On May 5, 2025, the Trump Administration issued Executive Order 14293 directing FDA, EPA, and HHS to pursue regulatory streamlining in support of domestic pharmaceutical manufacturing. The order contains several distinct directives with specific deadlines:

- FDA and EPA must streamline domestic pharmaceutical manufacturing regulations within 180 days to accelerate inspections and approvals;
- FDA must improve its risk-based inspection regime for overseas manufacturing facilities within 90 days, funded by increased fees imposed on foreign facilities; and
- EPA is designated as the lead agency for coordinating environmental permits for new domestic manufacturing capacity.

This order reflects a dual posture: relaxing domestic regulatory burdens to encourage onshoring of pharmaceutical production while simultaneously tightening scrutiny of foreign manufacturing through enhanced inspections and fee increases. The cross-agency coordination requirement—with EPA handling permitting for facilities that FDA regulates for product quality—is architecturally significant. (See also Section II above regarding EPA's broader environmental actions.)

Source: Regulatory Relief to Promote Domestic Production of Critical Medicines – The White House

Executive Order 14401: Accelerating Psychedelic Treatments

On April 18, 2026, the Trump Administration issued Executive Order 14401 instructing federal agencies—principally the FDA and the Drug Enforcement Administration (DEA)—to accelerate research, review, and potential approval pathways for psychedelic drugs intended to treat serious mental illnesses, including major depressive disorder and substance use disorder. The order directs agencies to identify and reduce regulatory barriers to clinical research and to expedite review timelines for qualifying therapies.

This action is notable for its intersection of FDA drug-approval authority with DEA scheduling authority, as most psychedelic substances remain Schedule I controlled substances.

Source: Accelerating Medical Treatments for Serious Mental Illness – The White House

Centers for Disease Control and Prevention / U.S. Department of Agriculture (CDC/USDA)

FoodNet Surveillance Reduction

Beginning in July 2025, the federal government shifted FoodNet tracking from mandatory to optional for six of the eight pathogens monitored by the program, retaining mandatory surveillance only for Salmonella and Shiga toxin-producing E. coli (STEC). FoodNet is a multi-agency collaboration among CDC, USDA, and FDA that tracks foodborne infections across a surveillance area covering approximately 16 percent of the U.S. population.

Prior to this change, surveillance of all eight identified pathogens was mandatory. The shift to optional tracking for six pathogens

raises questions about the completeness of future foodborne illness data and the ability to detect emerging outbreaks for pathogens no longer subject to mandatory reporting. Some experts have tied the reduction in FoodNet surveillance with the recent Cyclospora outbreak.

Source: CDC FoodNet – About | https://www.cdc.gov/foodnet/about/index.html

Drug Enforcement Administration (DEA)

The DEA appears in this survey as a co-implementing agency for Executive Order 14401, discussed in Section IV.C above. The order directs the DEA, alongside the FDA, to accelerate research and potential approval pathways for psychedelic treatments for serious mental illness. Because most psychedelic substances are classified as Schedule I controlled substances under the Controlled Substances Act, the DEA's scheduling authority represents a critical regulatory checkpoint for any expanded access or approval pathway. The specific mechanisms by which DEA would facilitate research access or modify scheduling classifications warrant monitoring as implementation proceeds.

Cross-Agency Trends and Analysis

The thirteen actions surveyed above, taken together, reveal several significant cross-cutting patterns in federal regulatory policy during the 2025–2026 period:

Broad Environmental Deregulation and Temporary Compliance Relief

Seven of the thirteen actions directly affect EPA-administered environmental programs, reflecting a systematic pattern of environmental deregulation. The approaches vary—outright rescission of the Endangerment Finding, CRA revocations of Obama- and Biden-era rules, two-year compliance exemptions, and California waiver revocations—but the cumulative direction is unmistakable. The temporary compliance exemptions (MATS and EtO) are particularly significant because they employ existing statutory authority to provide immediate relief without the permanence (or legal vulnerability) of full repeal.

Extensive Use of CRA and Presidential Authorities

Four of the thirteen actions employ the Congressional Review Act, while four others are executive orders and one is a presidential proclamation. The reliance on CRA—which allows disapproval of rules finalized within the lookback window without requiring traditional legislative majorities—and on unilateral executive action reflects a strategy of rapid policy change that minimizes the procedural constraints of notice-and-comment rulemaking. Only two actions (the Endangerment Finding rescission and the QMSR technical amendments) proceeded through traditional final-rule processes.

Asymmetric Domestic-Foreign Regulatory Posture

A pattern emerges from the juxtaposition of environmental and pharmaceutical actions: domestic environmental compliance burdens are being reduced while foreign pharmaceutical manufacturing oversight is being intensified. Executive Order 14293 simultaneously relaxes domestic manufacturing regulations and increases fees and inspection requirements for foreign facilities. This asymmetry reflects a deliberate supply-chain resilience strategy that uses regulatory policy to encourage production reshoring.

Aggressive Drug-Price Intervention

The pharmaceutical pricing actions (EO 14273 and EO 14297) represent an unusually aggressive federal posture toward drug pricing. The MFN pricing approach—benchmarking domestic prices to the lowest prices in comparable OECD nations—paired with 60-day compliance demands to 17 manufacturers and the threat of antitrust enforcement, constitutes an atypical degree of direct price intervention. The combination of competition promotion (generics/biosimilars), transparency mandates, intermediary reform, and direct price targets suggests a comprehensive market-restructuring agenda.

Selective Reduction in Public-Health Surveillance

The FoodNet change—making surveillance optional for six of eight tracked pathogens—represents a selective reduction in public-health monitoring infrastructure. While maintaining mandatory tracking for Salmonella and STEC (the two most commonly reported bacterial foodborne pathogens), the change introduces potential gaps in the detection of outbreaks caused by less common but nonetheless serious pathogens. This action is consistent with the broader deregulatory posture but is notable for applying that posture to public-health surveillance rather than industry compliance obligations.

Cross-Agency Coordination and Federal-State Conflict

Several actions require coordination across multiple agencies (FDA/EPA/HHS for domestic manufacturing; FDA/DEA for psychedelic approvals; CDC/USDA/FDA for FoodNet). At the same time, the revocation of California's Clean Air Act waivers represents a direct federal-state conflict over the historically unique authority granted to California under § 209. The simultaneity of enhanced inter-agency coordination and intensified federal preemption of state authority reflects a centralization of regulatory control at the federal executive level.

Practical Takeaways

For practitioners, regulated entities, and stakeholders monitoring this rapidly evolving landscape, several practical observations emerge:

- Environmental compliance counsel should evaluate client exposure to each of the seven EPA-related actions, particularly the interaction between CRA revocations (which bar agencies from promulgating "substantially similar" rules) and temporary exemptions (which preserve future rulemaking authority).
- Pharmaceutical and life-sciences companies face a dual compliance challenge: demonstrating MFN pricing compliance within aggressive timelines while simultaneously navigating potentially relaxed domestic manufacturing requirements and heightened foreign-facility oversight.
- Food-safety stakeholders should assess whether optional FoodNet participation will create surveillance gaps affecting their supply chains or regulatory exposure.
- State regulatory authorities, particularly in California and states that adopted California vehicle-emission standards, must evaluate the legal and practical consequences of the waiver revocations, including potential litigation strategies.
- Companies in the psychedelic-therapy development space should monitor DEA and FDA implementation of EO 14401 for concrete changes to scheduling and approval-pathway timelines.
- The reliance on executive orders and CRA resolutions—rather than traditional rulemaking—creates legal vulnerability to future reversals, and practitioners should counsel clients regarding the permanence (or impermanence) of each regulatory change.
- Vulnerability exists for product liability lawsuits, even though the government has decreased enforcement.

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