NATIONAL ASSOCIATION OF
Manufacturers

**Charles Crain**

*Managing Vice President,
Policy*

April 17, 2025

The Honorable Russell Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Dear Director Vought:

The National Association of Manufacturers ("NAM") strongly supports efforts to rebalance manufacturers' regulatory burden. Costly and unworkable regulations can divert capital from job creation, investment, and growth—harming manufacturers' ability to drive economic expansion here at home and support American competitiveness on the world stage.

President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity. In other words: when manufacturing wins, America wins.

Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM is submitting for your consideration a series of overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to EO 14219. We have also submitted these policy recommendations to the departments and agencies under whose jurisdiction they fall, and manufacturers respectfully encourage the entire Administration to work collaboratively with the Office of Management and Budget ("OMB") to rebalance the regulatory landscape for our industry.

President Trump has already taken meaningful steps to shift the government's focus away from excessive regulation and toward encouraging innovation, investment, and job growth. Revising or rescinding the attached regulations and policies would further underscore the Administration's commitment to a globally competitive U.S. manufacturing sector that fosters entrepreneurship and supports the growth of small and medium-sized manufacturers across the country.

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Using these recommendations as a guidepost, manufacturers look forward to continuing to work with the Administration to fix unworkable rules that divert funds from manufacturing growth, trap projects in red tape, chill investment, and harm the 13 million people who make things in America. The NAM

welcomes the opportunity to help OMB and the entire Administration deliver on President Trump's promise to make the United States the best place in the world to build, grow, and create jobs.

Sincerely,

Charles Crain
Managing Vice President, Policy

CC: Dominic Mancini, Acting Administrator, Office of Information and Regulatory Affairs

NATIONAL ASSOCIATION OF
Manufacturers

**Charles Crain**

*Managing Vice President,
Policy*

April 17, 2025

The Honorable Lee Zeldin
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Administrator Zeldin:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the Environmental Protection Agency ("EPA") to consider several overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to President Trump's EO.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

Many of the previous Administration's burdensome and unworkable regulations were issued by the EPA. Manufacturers strongly believe that the U.S. does not have to choose between economic development and protecting the environment and public health—we can do both, and balanced regulations can empower manufacturers to grow our economy and innovate new solutions to the environmental and public health challenges we face. In responding to the President's February 19 Executive Order, this letter outlines several regulations that the EPA can and should target for modification and potential rescission to achieve these twin goals.

## Office of Air and Radiation

### National Ambient Air Quality Standards (PM2.5 NAAQS)

On February 7, 2024, the Biden EPA issued its final rule setting the National Ambient Air Quality Standards ("NAAQS") for fine particulate matter ("PM2.5"). The new standard was lowered from 12 micrograms per cubic meter to 9 micrograms per cubic meter ("μg/m3")—a 25% reduction. The Biden EPA pursued this discretionary reconsideration outside of the Clean Air Act's normal five-year review cycle and did not consider the tremendous costs and burdens that will now come with attempting to meet this new standard.

Across the country, there continue to be areas of the U.S. that are in nonattainment with the older 12 μg/m3 PM2.5 standard. Yet the Biden EPA was determined to leave those nonattainment areas

further behind by pursuing stricter PM2.5 standards. By lowering the standard to 9, which is essentially the same as the background levels that naturally occur in the environment across the nation, the Biden EPA was knowingly increasing the number of industrial centers and U.S. population hubs that would be placed into nonattainment status. This means that local communities will experience direct negative consequences to their economies because businesses will be unable to obtain the necessary permits to build, grow and develop their facilities and operations.

It should be noted that the Biden EPA admitted that 70% of particulate matter comes from nonmanufacturing sources. Since 2000, PM2.5 emissions have declined by 42%, driven by major reductions from both mobile sources and the power sector. Manufacturers are doing their part with new technology and should not be held to a standard that is impossible to meet.

The NAM appreciates the EPA's recent announcement that it plans to reconsider this standard and would encourage the Administration to return it to 12.

**National Ambient Air Quality Standards (Ozone NAAQS)**

While this letter is primarily focused on correcting the regulatory onslaught of the previous Administration, given how poorly air regulations were handled over the past four years, particularly in the PM2.5 NAAQS process, that it is imperative for manufacturers that the next ozone NAAQS be prioritized and made durable.

Ground-level ozone, the primary component of smog, is formed when nitrogen oxides react with volatile organic compounds in sunlight. Ozone is generally a byproduct created by factories, power plants, vegetation, vehicles, volatile chemical products and wildfires.

As required by the Clean Air Act (42 U.S.C § 7409), ozone NAAQS levels will need to be reconsidered this year. Lowering the ozone NAAQS below 70 parts per billion—the current standard, established in 2015—would seriously disadvantage manufacturers in the U.S. and make it significantly more difficult to make and expand investments that the U.S. will need to compete in the decades to come, while failing to meaningfully effectuate improvements to public health. As such, manufacturers respectfully encourage the EPA to maintain an ozone standard of 70 parts per billion when it commences its NAAQS review in 2025.

In 2015, the NAM conducted a study to project the cost of attaining a more stringent ozone NAAQS. The study found that lowering the ozone standard to 65ppb would reduce U.S. GDP by up to $140 billion annually from 2017 to 2040. This substantial economic burden would also lead to job losses and the opening of fewer new manufacturing facilities.

Similar to PM2.5, ozone NAAQS levels in many parts of the nation are already essentially at background levels. In other words, there are no additional control measures that can be taken for stationary sources that would enable areas already in nonattainment to reach an even more unattainable standard. That is why it is critical that this Administration follow all the necessary procedures, such as the Clean Air Act's process requirements and those of the Administrative Procedure Act, to ensure the standard remains unchanged at 70ppb.

Manufacturers urge the EPA to begin the revision process in earnest by appointing a new Clean Air Scientific Advisory Committee and by nominating members that are committed to rigorous scientific analysis. A new CASAC would represent a concrete first step to protect manufacturing jobs and investments.

Along with maintaining the current ozone NAAQS at 70 ppb, the NAM urges the EPA to take a serious look at revising outdated guidance on how wildfires and international emissions count against areas in non-attainment for ozone.

**Power Plant Rules**

On April 24, 2024, the Biden EPA finalized new rules setting greenhouse gas emissions standards for certain fossil fuel-fired power plants, including existing coal-fired and new natural gas-fired power plants. To avoid early retirement, these plants were required to cut or capture 90% of their GHG emissions by 2032 using carbon capture and sequestration/storage ("CCS") technologies on their facilities.

Unfortunately, without enacting comprehensive permitting reform and building out CCS technology to commercial scale, it is impossible to achieve these highly aspirational mandates within the allotted timeframe. Thus, the Biden EPA chose to jeopardize U.S. energy security and grid reliability by imposing another set of regulations that will burden an already overtaxed national electric grid.

Given the growing demand for more electricity on the grid due to greater electrification and the growth of data centers, now is not the time to needlessly remove baseload generation from the grid, particularly affordable and reliable natural gas-fired generation.

The NAM appreciates the EPA's recent announcement that it plans to reconsider these standards, and manufacturers encourage the EPA to work with industry to ensure future proposed GHG emissions standards do not again threaten grid reliability and baseload power generation.

**Methane Fee**

The Inflation Reduction Act directed the EPA to create the Methane Emissions Reduction Program, which included the collection of a Waste Emissions Charge ("WEC") on waste emissions of methane from certain oil and gas facilities. The WEC has been commonly referred to as the 'Methane fee' and is applied to oil and gas facilities that emit more than 25,000 metric tons of CO2 equivalent per year as reported under subpart W of the Greenhouse Gas Reporting Program, that exceed statutorily specified waste emissions thresholds set by Congress and that are not otherwise exempt from the charge.

On November 18, 2024, the Biden EPA finalized a rule to implement the methane fee. Earlier this year, both the House of Representatives and the Senate passed a Congressional Review Act resolution that disapproved of this final rule. Manufacturers appreciate Congress taking this important step to eliminate this burdensome emissions fee.

The methane fee is unnecessary and counterproductive, as it penalizes manufacturers critical to an all-of-the-above energy approach and undermines efforts to find innovative ways to control methane emissions. Manufacturers appreciate the work by Congress and the Administration to move towards repealing the fee, and we look forward to working with the EPA to ensure that no further action is taken to impose a similar fee or charge that would undermine energy security.

**Good Neighbor Rule**

On March 15, 2023, the Biden EPA finalized its Cross-State Air Pollution rule, which is also known as the "Good Neighbor" rule. This regulation would require certain states to mitigate interstate ozone air pollution from power plants and other industrial sources. However, on June 27, 2024, the U.S. Supreme Court issued a stay on implementation to allow for additional time for legal challenges to the rule to be heard.

While manufacturers have long been committed to clean air and healthy communities, this final rule could have significant negative effects on energy reliability and prices, economic growth and jobs. The NAM appreciates the EPA's recent announcement that it plans to reconsider this rule to ensure the full economic costs of the rule, as well as the rule's workability, are taken into account.

**New Source Review Rule**

On May 3, 2024, the Biden EPA proposed a new rule under the Clean Air Act's New Source Review ("NSR") preconstruction permitting program. Specifically, the Biden EPA proposed revising the definition of "project," mandating that decreases in emissions included in the first step of a project's accounting process be "enforceable." The proposed rule would have also broadened monitoring, recordkeeping and reporting requirements.

If this regulation were to go into effect, it would expand the EPA's powers over all air pollution control agencies at the state, local and tribal levels responsible for issuing preconstruction permits pursuant to the major NSR programs. Many of these pre-construction permits are non-controversial, and the states have proven to be capable of reviewing and processing them in a timely manner so as to not disrupt business planning and operations. Involving the EPA in these permitting decisions would slow the process considerably, delaying job-creating investments across our industry.

The NAM respectfully encourages the EPA to abandon the previous Administration's NSR proposal and to preserve the longstanding ability of the states to make permitting decisions for programs they have administered for decades, especially over minor sources of emissions.

**Ethylene Oxide Emissions Standards under the National Emissions Standards for Hazardous Air Pollution**

On April 5 and May 16, 2024, the Biden EPA released its final rules for Commercial Sterilization Facilities NESHAP and Synthetic Organic Chemical Manufacturing Industry NESHAP, respectively. Ethylene oxide is an essential chemistry used to sterilize billions of pieces of medical equipment annually; its use is critical for the medical community and military alike. The previous Administration had no statutory requirement nor authority to conduct a second risk review for these uses of ethylene oxide. Furthermore, the Biden EPA used its flawed Integrated Risk Information System to determine the new rules. The compliance values set in these final rules are over restrictive and unattainable.

The NAM appreciates the EPA announcing it will reconsider multiple NESHAP rules finalized by the Biden Administration. Manufacturers encourage the EPA to reevaluate these two rules and to propose new rules that are attainable and legal.

## Office of Chemical Safety and Pollution Prevention

**Toxic Substances Control Act**

*Existing Chemicals*

One critical authority given to the EPA through the Toxic Substances Control Act ("TSCA") is assessing risks posed by existing chemistries, assessing both hazards and exposures while evaluating them during the chemical management process. The process, starting with the designation of priority chemicals, should be based on sound and data-driven science. The Biden EPA did not take this approach when evaluating existing chemicals.

In many of its risk evaluation and management assessments, the previous Administration relied on many scientific studies that were neither published nor peer reviewed – setting standards that were not driven purely by scientific data. Risk assessments should be based on sound scientific evidence and should appropriately balance costs and benefits; they also should require a peer and external public review prior to considering the toxicity value final.

The data quality in many of the Biden EPA's draft and final risk assessments and management rules were based on assumptions about exposures, leading to unnecessary regulation and greater costs to not only manufacturers subject to these rules, but also to businesses throughout the entire supply chain.

The NAM appreciates the EPA acting swiftly to pause and extend the comment period of many of the previous Administration's proposed risk evaluations. As the EPA continues to reevaluate previous risk assessments, we hope it will consider addressing the draft risk assessment for 1,3 Butadiene (December 2024) and the final risk assessment for formaldehyde (December 2024), among others.

*New Chemicals*

Manufacturers are producing innovative new chemistries that would advance products and technologies throughout the supply chain. Unfortunately, the EPA has often not met its statutory deadline to review these groundbreaking chemistries. TSCA requires EPA to make a decision on allowing a new substance to enter commerce after a 90-day review period, with an option to extend the review period by an additional 90 days.

As of March 6, 2025, of the total 445 new chemicals under review, 405 have exceeded the initial 90-day review period, and 295 chemicals have been pending review for more than a year.

The delays endemic to the new chemical review process means many manufacturers are unable to commercialize products they have spent years and millions of dollars researching, developing and testing. Manufacturers are committed to developing new chemistries and innovating in the United States, but companies need more certainty and predictability in the face of increased global competition.

The NAM encourages the EPA to ensure it meets its statutorily required 90-day deadline to ensure new chemistries are brought to the market to help spur innovation and manufacturing in the U.S.

**TSCA 8(a)7 Reporting and Recordkeeping Requirements for PFAS**

The Biden Administration's rule to implement the reporting requirements under TSCA Section 8(a)7 significantly expanded, likely unachievably, the reporting requirements for PFAS for all manufacturers. The Biden rule went beyond the statutory requirements and imposed significant costs on manufacturers of all sizes without addressing the remediation needs at sites of serious concern.

The EPA does not have the ability or resources to catalogue, process, and analyze the enormous amount of data the rule will produce. The reporting period was scheduled to begin in November 2024, but it is now delayed until July 2025. The NAM appreciates the Trump Administration's decision to extend the reporting period deadline.

The Biden regulation to implement congressional intent in Section 8(a)7 also does not provide a de minimis threshold nor exemptions for small businesses who simply do not have the capacity to comply with reporting on thousands of potentially covered substances going back more than a

decade. The statutory requirements of Section 8(a)7 do not preclude EPA from implementing a reasonable de minimis threshold, and the EPA should proceed to do so.

The NAM respectfully requests that the EPA extend the submission date by at least an additional six months, or until after the beta testing of the EPA's data reporting application (the CDX system) is complete, the application has been made public, and clear agency guidance is published.

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**Integrated Risk Information System**

The Integrated Risk Information System ("IRIS"), created by the EPA in 1985, has increasingly been used to develop overly burdensome regulations on critical chemistries used in essential products. It has never been authorized by Congress, and since 2009 the program has been flagged as a "high risk" program vulnerable to waste, fraud, abuse, or mismanagement by the U.S. Government Accountability Office.

Over time, findings from IRIS assessments have informed many different agency actions, including risk assessments for existing chemicals. Unfortunately, many of these studies fail to adequately incorporate high quality and relevant science, do not consistently utilize a "weight of the scientific evidence" approach, and often omit key information. Also, the process IRIS uses to prioritize and select chemicals for assessment lacks transparency.

IRIS fails to comply with regular rulemaking requirements, including public notice-and-comment, interagency review, and engagement with stakeholders on these assessments. As such, IRIS assessments should not be valid for use in regulatory settings. Unfortunately, the EPA has continued to utilize IRIS assessments, leading to inaccurate chemical reviews that potentially restrict or ban use of chemicals without scientific backing.

As stated previously, the IRIS program is not statutorily authorized and has been flagged by the GAO as vulnerable to waste, fraud, and abuse, both of which are specific criteria for reconsideration and removal per President Trump's February 19 EO. The NAM urges EPA to disband IRIS and prohibit the use of IRIS assessments as the agency develops, finalizes, and issues rules and regulations.

## Office of Land and Emergency Management

**PFOA and PFOS CERCLA Designation**

On May 8, 2024, the Biden EPA released a final rule that designated PFOA and PFOS as hazardous substance under Section 102(a) of CERCLA, creating a costly and ineffective way to address the cleanup of these chemistries. This designation imposes new legal liabilities on manufacturers instead of focusing on remediation of affected sites.

Designating these chemistries under CERCLA will cause significant economic impacts for not only manufacturers, but also municipal water and sewage treatment facilities, airports, farmers, and many more.

The NAM believes CERCLA is the wrong regulatory tool to accelerate cleanup of PFOA and PFOS at these critical sites. Instead, we ask the EPA to withdraw the previous Administration's rule and propose a new rule using one of its other regulatory authorities, like the Resource Conservation and Recovery Act, to address these chemistries in a targeted manner that focuses on the most critical sites rather than creating an unworkable mandate that only serves to increase litigation and not address public health needs.

**Risk Management Program Rule**

The Risk Management Program Rule is required by Section 112(r) of the Clean Air Act, as amended. The EPA must publish regulations and guidance for chemical accident prevention at facilities that use certain hazardous substances, and facilities using these substances must develop Risk Management Plans.

On March 11, 2024, the Biden EPA published its final rule amending the Risk Management Program ("RMP"), making changes to the program that were unwarranted and increased undue burden on manufacturers. The final rule creates unnecessary regulatory requirements that increase costs for manufacturing facilities and compromise national security by providing sensitive information to potential bad actors.

The NAM appreciates the EPA's recent announcement that it plans to reevaluate the 2024 rule. The safety and security of facilities, employees and communities is a priority for manufacturers, and we are committed to supporting a strong RMP rule.

## Office of Water

**PFAS Maximum Contaminant Levels Rule**

On April 10, 2024, the Biden EPA announced the final PFAS maximum contaminant levels ("MCL") rule for drinking water. The rule established the MCLs at 4 parts per trillion for PFOA and PFOS, and 10 parts per trillion for PFNA, PFHxS, and HFPO-DA. These levels are not only unattainable but are also set at a level that is incapable of being measured on a consistent basis by the nation's public drinking water utilities. The rule also contains a hazard index MCL that has never before been used in setting drinking water standards.

The NAM is leading the legal challenge to this onerous and incorrect rule to implement the requirements of the Safe Drinking Water Act. Specifically, from the NAM's opening brief in the case:

> Petitioners support rational regulation of PFAS that allows manufacturers to continue supporting critical industries, while developing new chemistries and minimizing any potential environmental impacts. But that requires a measured and evidence-based approach that the Rule lacks.
>
> Congress required as much when it enacted the SDWA. The Act requires EPA to follow strict, multi-step procedures and undertake detailed, multi-step analyses to justify regulation of any given substance. Recognizing that marginal benefits may impose prohibitive burdens for the public, the Act expressly requires the agency to weigh a proposed Level's foreseeable costs against its benefits. The Act also directs EPA to consider the feasibility of achieving any Level in light of costs and the limits of existing technologies, using the best available science. Here, EPA obscured the costs and benefits of each Level it proposed by lumping them together, allowing the net positives of some to compensate for the net negatives of others. Beyond that, the agency failed to consider meaningful regulatory alternatives and refused to consider or respond to public comments that undercut its judgment.
>
> Key aspects of the Rule also exceed the EPA's statutory authority and flout the Act's express procedural requirements. The Rule purports to regulate undifferentiated mixtures of substances, using a "hazard index" approach that EPA has never before used in the Act's 50-year history and is not permitted by the statute's text. EPA also unlawfully collapsed two distinct rulemaking steps into a

single step, forgoing Science Advisory Board review along the way. Congress baked those procedural safeguards into the Act not as mere formalities, but to discourage poor decision-making. This case proves the dangers of discarding them.

Finally, EPA's determination to regulate HFPO-DA was unsupported, as was the Level the agency selected for that substance. EPA lacked sufficient data to regulate HFPO-DA in the first place, and the Level it finalized was arbitrary and capricious several times over.[1]

The NAM supports safe drinking water standards, and manufacturers are committed to continuing to innovate ways to protect the environment and our communities. The EPA's MCL standards should allow for and encourage this important innovation while still setting attainable limits that manufacturers and water utilities can comply with. We encourage the EPA to explore options to set attainable and measurable National Primary Drinking Water Standards for these chemistries.

**Waters of the United States Definition**

For decades, manufacturers have dealt with uncertainty around the definition of "waters of the United States." Jurisdictional determinations for waters under the Clean Water Act impact manufacturers' ability to pursue projects and create jobs. Despite the Supreme Court's decision in *Sackett vs. Environmental Protection Agency,* the EPA in 2023 promulgated a narrow, revised rule – notably without appropriate public input – which failed to fully grapple with the Court's decision, sowing further confusion.

The NAM appreciates the EPA's announcement that the agency will review the WOTUS definition and promulgate a new rule utilizing input from affected stakeholders. The Supreme Court was clear: a party asserting federal jurisdiction over wetlands must show an adjacent body of water constituting WOTUS and a continuous surface connection between the waters and the wetlands such that the two are indistinguishable. Manufacturers look forward to working with the agency through this process to establish a clear, durable test in conformance with the law.

* * * *

The NAM strongly supports the early actions taken by the Trump Administration, including the President's February 19 Executive Order and the EPA's March 12 announcement of deregulatory actions, to reconsider burdensome regulations that are harming manufacturers' ability to compete. Manufacturers will continue to partner with the EPA to rebalance the regulatory framework to allow our industry to move ahead with transformational investments that will strengthen our manufacturing nation.

Sincerely,

Charles Crain
Managing Vice President, Policy

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[1] *National Association of Manufacturers & American Chemistry Council v. U.S. Environmental Protection Agency & Michael S. Regan*, Nos. 24-1188, 24-1191, 24-1192 (2024). Available at https://nam.org/wp-content/uploads/2024/10/2024-10-07-NAM-ACC-Chemours-Opening-Brief.pdf.

NATIONAL ASSOCIATION OF
Manufacturers

**Charles Crain**

*Managing Vice President,
Policy*

April 17, 2025

The Honorable Chris Wright
Secretary
U.S. Department of Energy
1000 Independence Avenue SW
Washington, DC 20585

Dear Secretary Wright:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the Department of Energy ("DOE") to consider several overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to President Trump's EO.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

**LNG Exports Economic and Environmental Studies**

In December 2024, the outgoing Biden Administration finalized a multivolume study updating the DOE's understanding of the potential effects of U.S. liquefied natural gas exports. These updated studies included misleading and incomplete conclusions based on flawed and missing data.[1] Manufacturers respectfully encourage that the Department retract, reconsider, and reissue new, accurate studies that reflect the true economic impact of LNG exports with a determination that LNG exports are in the public interest.

For background, manufacturers in the United States have been leading the global competition to build the necessary infrastructure to expand production of and export American energy, including LNG. The boom in U.S. natural gas has created tens of thousands of jobs, made the U.S. and its allies more energy secure and less reliant on adversarial nations like Russia, opened up a vital new source to address global energy poverty and helped reduce U.S. emissions by roughly 20% since

[1] National Association of Manufacturers. "DOE LNG Study Misses the Mark." December 18, 2024. https://nam.org/doe-lng-study-misses-the-mark-32879.

2005. According to a study commissioned by the NAM, the LNG export industry has the potential to support more than 900,000 jobs and add $216 billion to U.S. gross domestic product by 2044.[2]

In January 2024, the Biden Administration put these positive developments and the future of the LNG industry at risk when it announced a prolonged pause in approving export permits for new LNG projects to countries with which the U.S. does not have a free trade agreement. After announcing this pause, the DOE undertook a review of the energy, economic and environmental studies that have been used to determine if a project's approval would be in the public interest. The NAM provided comments on the updated studies on Mar. 10, 2025.[3]

In these updated studies, the Biden DOE made the broad and unsubstantiated assertion that there is insufficient job creation in the local communities where the LNG export industry operates.

However, the DOE immediately acknowledged that the Department "was not able to identify published data regarding these assertions." The DOE further acknowledged that "additional research is needed on the impact of LNG exportation on local communities [and] in particular, in areas with existing heavy industry, the cumulative impact of LNG exports has yet to be determined." In addition, the DOE said, "[s]ignificantly less research is available on the impact of LNG facilities themselves on local communities."

In addition to ignoring the impact on jobs, the Biden DOE ignored the tax contributions of LNG exports, leaving the public with the impression that the LNG export industry contributes an insignificant amount to the communities where their operations are located. This is misleading. Through the payments of taxes and royalties, the LNG export industry is a significant contributor to strong public finances. According to the NAM's study, the industry's total fiscal support to federal, state and local governments in 2023 was $11 billion. This includes personal income taxes, social insurance contributions, corporate, sales and property taxes and royalties generated from operations on federal lands. These contributions could grow to $47.7 billion annually by 2044.

Given the importance of LNG exports to the American economy, and to manufacturers' ability to drive investment and job creation in the U.S., the NAM respectfully encourages the Department to retract, reconsider, and reissue new studies that reflect an accurate economic analysis to ensure they reflect a true accounting of the public interest.

**Energy Policy and Conservation Act Reforms**

Manufacturers, including producers and users of energy, are committed to reducing our energy intensity and producing more energy-efficient consumer products to keep America leading in innovation, help reduce energy demand, save money and lower costs. Manufacturers strongly support sensible efficiency and waste reduction measures across all sectors of the economy.

Unfortunately, the Biden Administration exploited the Energy Policy and Conservation Act to unleash a regulatory onslaught of new energy efficiency regulations aimed at significantly changing the types of appliances and products that could be manufactured and sold to consumers. According to the Appliance Standards Awareness Project, the Biden Administration increased the energy efficiency standards for 28 product classes and proposed updates for eight more.

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[2] National Association of Manufacturers, *Quantifying America's Economic and Energy Opportunity through LNG Exports,* October 2024, https://nam.org/wp-content/uploads/2024/10/Quantifying-Americas-Economic-and-Energy-Opportunity-through-LNG-Exports.pdf.

[3] National Association of Manufacturers, *Comment Letter on LNG Export Study*, March 10, 2025, https://documents.nam.org/ERP/NAM%20comment%20letter%20LNG%20export%20study%20FINAL.pdf.

Manufacturers believe the DOE has an important role to play here, including providing private industry with support and incentives for the research and the development of advanced energy efficiency and waste minimization technologies in energy-intensive industries. Federal policies should provide a reliable investment environment for businesses of all kinds and sizes to pursue energy management technologies, practices and services.

The NAM supports joint government-industry initiatives that enhance private sector investment in public building efficiency improvement projects, policies that strengthen and harmonize standards for existing commercial, industrial and residential buildings and policies that recognize the incredible efficiency improvements manufacturers have made to products already.

The DOE should focus its efforts on these collaborative opportunities and provide assistance to Congress as it explores avenues to modernize the Energy Policy and Conservation Act.

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The NAM supports the Trump Administration's efforts to rein in the regulatory onslaught from the previous Administration that impeded manufacturers' ability to compete. Manufacturers have a long history of collaborating with the DOE to drive energy productivity improvements and accelerate adoption of new energy technologies. Our industry is committed to working with the Department in its efforts to institute a regulatory regime that spurs economic growth and energy dominance.

Sincerely,

Charles Crain
Managing Vice President, Policy

NATIONAL ASSOCIATION OF
Manufacturers

**Charles Crain**

*Managing Vice President,
Policy*

April 17, 2025

The Honorable Doug Burgum
Secretary
U.S. Department of the Interior
1849 C Street NW
Washington, DC 20240

Dear Secretary Burgum:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the Department of the Interior ("DOI") to consider several overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to President Trump's EO.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

**Energy Leasing in the Arctic National Wildlife Refuge (ANWR)**

Under the Tax Cuts and Jobs Act of 2017, DOI was required to hold two oil and gas lease sales for tracts within the Coastal Plain of the Arctic National Wildlife Refuge. Nine leases were sold by the first Trump Administration during the first auction. Unfortunately, upon entering office, the Biden Administration directed the Department to review these sales, which resulted in the cancellation of two leases. On September 6, 2023, the Biden Administration announced the cancellation of the seven remaining leases.

When the Biden Administration held the second congressionally mandated lease sale on January 10, 2025, the Department added additional environmental restrictions and offered fewer acres to be developed. These terms discouraged bids from industry and ultimately resulted in the conclusion of the sale without further action.

Manufacturers have long supported the United States taking full advantage of its abundant supplies of oil, natural gas and other critical resources to meet its growing energy demands. Capitalizing on the potential of these natural resources carried out in a responsible and sustainable manner is critical to both competitiveness and improved environmental performance, contributing to increased productivity, lower costs and new products. By cancelling these lease sales, the previous Administration undermined efforts to secure domestic energy security.

The NAM urges the Department to reverse course and seek authority to hold new lease sales in the ANWR, with flexible terms to encourage competitive bids, to ensure American energy dominance.

**Aligning the Critical Minerals List**

Under the Energy Act of 2020, Congress directed DOI to identify and maintain a list of critical minerals to be routinely updated by the U.S. Geological Survey. Unfortunately, the items that USGS designated as critical minerals did not align with a separate critical materials list that was established under the same law to be maintained by the Department of Energy. This discrepancy is causing confusion among producers because eligibility for certain grant programs, tax credits, loan guarantees or improved permitting processes is only granted to items on the DOI list.

It is a priority for manufacturers to align these two lists by adding copper, electrical steel, silicone and silicon carbide to the national critical minerals list maintained by USGS to shore up supply chains of key minerals and materials. These materials are irreplaceable in crucial energy, technology and national security applications—from electrical equipment and batteries to grid transformers and semiconductors. American manufacturing is too often reliant on foreign sources of raw and refined inputs of these materials—when we can and must be doing more to produce them domestically.

The NAM requests that the DOI, through the head of the USGS and pursuant to its authority to update the list at the Secretary's discretion under 30 U.S.C. § 1606, take action to bring the national critical minerals list into alignment with the DOE's critical materials list. Additionally, the NAM requests that DOI and USGS maintain communication with the industry to update their list regularly as new critical minerals needs are identified.

**Reversing the Ban on Offshore Oil and Gas Leasing**

On January 6, 2025, the outgoing Biden Administration withdrew significant portions of the Outer Continental Shelf from future oil and natural gas leasing, including the entire U.S. Pacific and Eastern Atlantic coasts, the Eastern Gulf of America, and the remainder of the Northern Bering Sea Climate Resilience Area off the shore of Alaska. The withdrawal areas encompassed more than 625 million acres.

By limiting access to America's abundant oil and natural gas resources, this action undermined efforts to secure American energy dominance; if not fully reversed, it could have significant consequences on manufacturers' access to the energy resources needed to power the U.S. economy. Additionally, withdrawing such a significant area from future lease sales undermines Congress's intent in the Outer Continental Shelf Lands Act. Manufacturers support and appreciate President Trump's executive order to revoke the previous Administration's ban on offshore oil and gas leasing, as well as the Department's February 3 order to implement the President's EO.

Manufacturers look forward to working with the Department to unleash American energy dominance and ensure our industry can continue to access energy resources.

* * * *

The NAM supports the Trump Administration's efforts to secure American energy dominance through regulatory relief and smart executive actions. Manufacturers have a long history of collaborating with the DOI to achieve energy and resource security for the United States and the industrial sectors we represent. Our industry is committed to working with the Department to unlock America's natural resources to spur economic growth and energy dominance.

Sincerely,

Charles Crain
Managing Vice President, Policy

NATIONAL ASSOCIATION OF
Manufacturers

**Charles Crain**

*Managing Vice President,
Policy*

April 17, 2025

The Honorable Paul Atkins
Chairman
Securities and Exchange Commission
100 F Street NE
Washington, DC 20549

Dear Chairman Atkins:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the Securities and Exchange Commission ("SEC") to consider several overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to President Trump's EO.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

As you know, the SEC's tripartite mission is to facilitate capital formation, protect investors, and maintain efficient markets. Unfortunately, in recent years, the Commission's approach to regulation has skewed away from rules that support access to capital and toward burdensome requirements that dramatically increase compliance costs without sufficient investor benefit. Additionally, multiple rules have been proposed and finalized over the past four years that prioritize the interests of influential market actors like proxy advisory firms and activist shareholders over those of manufacturers and Main Street investors. The NAM respectfully encourages the Commission to reorient and right-size the regulatory environment for publicly traded manufacturers in order to support capital formation, job creation, shareholder value, and manufacturing growth at companies of all sizes.

**Proxy Advisory Firms**

In 2020, the SEC finalized an NAM-supported rule to provide much-needed oversight of proxy advisory firms.[1] The two leading proxy firms, ISS and Glass Lewis, maintain a duopoly over the proxy voting advice market. As such, these firms exercise outsized influence over public companies and their shareholders—despite their inflexible policies, lack of transparency, significant conflicts of interest, propensity for errors, and recommendations that often prioritize agendas unrelated to long-

[1] *Exemptions From the Proxy Rules for Proxy Voting Advice*, 85 Fed. Reg. 55082 (3 September 2020). Release No. 34-89372; *available at* https://www.govinfo.gov/content/pkg/FR-2020-09-03/pdf/2020-16337.pdf.

term shareholder value creation. The 2020 rule, developed over the course of a decade, instituted commonsense safeguards designed to increase transparency into these powerful actors. Critically, the rule required proxy firms to provide their final recommendations to impacted companies and notify investors of any company responses to those recommendations; it also required them to disclose their conflicts of interest.

In 2021, the SEC began to take steps to dismantle this important progress. In a series of coordinated actions in June 2021, then-Chairman Gary Gensler announced that the SEC would "revisit" the 2020 rule,[2] the Division of Corporation Finance suspended enforcement of the rule,[3] and the SEC granted ISS "relief" from the rule's requirements.[4] In a lawsuit brought by the NAM before the U.S. District Court for the Western District of Texas, the court found that the SEC violated the Administrative Procedure Act by suspending the rule outside the notice-and-comment process.[5]

In 2022, the SEC finalized a rule unlawfully rescinding critical portions of the 2020 rule—including the compromise requirement that proxy firms share their recommendations with impacted companies after they are finalized and take steps to ensure that investors have access to any company responses to those recommendations.[6] At the same time, the SEC also rescinded the robo-voting guidance that had been finalized concurrent with the 2020 rule,[7] which cautioned asset managers against outsourcing their voting authority to the firms. Manufacturers strongly opposed these rescissions.[8] The SEC's actions to rescind the 2020 rule were vacated in a lawsuit brought by the NAM before the U.S. Court of Appeals for the Fifth Circuit, which held that the SEC's actions were "facially irrational" and not "reasonable or reasonably explained."[9]

As the Gensler SEC sought to undo the substance of the 2020 rule, it was at least defending in court its authority to provide some degree of oversight of proxy firms. Shortly after the promulgation of the SEC's 2019 guidance clarifying that proxy voting advice generally constitutes a solicitation under the Exchange Act and thus that proxy firms were subject to existing anti-fraud standards under the proxy solicitation rules, ISS filed suit against the SEC. ISS expanded its lawsuit after the 2020 rule was finalized, seeking to nullify the rule and to undermine the SEC's ability to regulate proxy voting advice at all. For most of the Biden Administration, the SEC defended its authority before the U.S. District Court for the District of Columbia—and the NAM joined the Commission in that fight as an intervenor-defendant. But when a district court judge ruled in ISS's favor in 2024, the SEC abandoned its defense of its regulatory authority.[10]

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[2] *Statement on the Application of the Proxy Rules to Proxy Voting Advice*. Chairman Gary Gensler (1 June 2021). *Available at* https://www.sec.gov/news/public-statement/gensler-proxy-2021-06-01.

[3] *Statement on Compliance with the Commission's 2019 Interpretation and Guidance Regarding the Applicability of the Proxy Rules to Proxy Voting Advice and Amended Rules 14a-1(1), 14a-2(b), 14a-9.* SEC Division of Corporation Finance (1 June 2021). *Available at* https://www.sec.gov/news/public-statement/corp-fin-proxy-rules-2021-06-01.

[4] *See* Mtn. for Abeyance, *Institutional Shareholder Services Inc. v. SEC*, No. 19-cv-3275 (D.D.C.).

[5] *Nat'l Ass'n of Mfrs. v. SEC*, 631 F.Supp.3d 423 (W.D. Tex. 2022).

[6] *Proxy Voting Advice*, 87 Fed. Reg 43168 (19 July 2022). Release Nos. 34-95266, IA-6068; *available at* https://www.govinfo.gov/content/pkg/FR-2022-07-19/pdf/2022-15311.pdf.

[7] *Supplement to Commission Guidance Regarding Proxy Voting Responsibilities of Investment Advisers*, 85 Fed. Reg. 55155 (3 September 2020). Release No. IA-5547; *available at* https://www.govinfo.gov/content/pkg/FR-2020-09-03/pdf/2020-16338.pdf.

[8] NAM Comments on File No. S7-17-21 (24 December 2021). *Available at* https://documents.nam.org/tax/nam_proxy_comments_2021.pdf.

[9] *Nat'l Ass'n of Mfrs. v. SEC*, 105 F.4th 802 (2024).

[10] *Institutional S'holder Servs. Inc. v. SEC*, No. 24-5105 (consolidated with 24-5112) (D.C. Cir.), Mot. to Voluntarily Dismiss Appeal.

If ISS's case is successful, it will effectively block any future attempt to regulate proxy advisory firms via the proxy solicitation rules, by any Administration. That is why the NAM, as intervenor, has appealed the District Court ruling to the U.S. Court of Appeals for the District of Columbia Circuit—and we remain committed to defending the SEC's ability to provide commonsense oversight of these powerful actors. However, more must be done to undo the damage from the previous Administration and protect manufacturers and Main Street investors from proxy firms' outsized influence. Pursuant to EO 14219, the NAM respectfully urges the SEC to:

- Rescind the SEC's July 2022 rule that revoked critical provisions from the 2020 proxy firm rule and withdrew the 2020 robo-voting guidance;
- Reinstate the 2020 proxy firm rule and the 2020 robo-voting guidance;
- Vigorously enforce the 2020 rule, including its issuer engagement, conflicts of interest, and anti-fraud provisions;
- Robustly defend the 2020 rule and the SEC's authority to regulate proxy voting advice; and
- Propose a new rule that strengthens the reforms adopted in 2020, including by instituting a requirement that proxy firms allow companies to provide feedback on draft recommendations (as was proposed by the SEC in 2019).[11]

**Shareholder Proposals**

The NAM strongly supported the rule finalized in 2020[12] that increased the submission and resubmission thresholds for shareholder proposals under Rule 14a-8 in an effort to protect public companies from the costs and burden associated with proposals from activists with little-to-no interest in a business's growth or value.

Unfortunately, over the past four years the SEC took several steps to encourage and empower activists seeking to hijack public company proxy ballots in pursuit of agendas divorced from long-term value creation. In November 2021, the Division of Corporation Finance issued Staff Legal Bulletin 14L, which effectively prohibited companies from excluding from the proxy ballot any shareholder proposal related to environmental, social, and governance topics of "broad societal impact," irrespective of the proposal's relevance to the business or its long-term value.[13] The NAM said that SLB 14L would "accelerate the trend of politically motivated shareholder proposals and hamstring companies seeking to focus the proxy ballot on issues critical to business growth and investor returns."[14]

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[11] *See Amendments to Exemptions From the Proxy Rules for Proxy Voting Advice*, 84 Fed. Reg. 66518 (4 December 2019). Release No. 34-87457, *available at* https://www.govinfo.gov/content/pkg/FR-2019-12-04/pdf/2019-24475.pdf. The NAM strongly supported the 2019 proposal, which in many respects was more robust and responsive to issuer concerns than the 2020 rule (*see* NAM Comments on File No. S7-22-19; *available at* https://www.sec.gov/comments/s7-22-19/s72219-6735396-207626.pdf).

[12] *Procedural Requirements and Resubmission Thresholds Under Exchange Act Rule 14a-8*, 85 Fed. Reg. 214 (4 November 2020). Release No. 34-89964; *available at* https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-21580.pdf.

[13] *Staff Legal Bulletin No. 14L*. SEC Division of Corporation Finance (3 November 2021). *Available at* https://www.sec.gov/corpfin/staff-legal-bulletin-14lshareholder-proposals.

[14] NAM Comments on Staff Legal Bulletin No. 14L (30 November 2021). *Available at* https://documents.nam.org/tax/nam_comments_slb_14l.pdf.

Then, in July 2022, the SEC proposed a rule to narrow the criteria under Rule 14a-8 by which companies can exclude activist shareholder proposals from the proxy ballot.[15] These criteria were designed to limit proposals that have already been substantially implemented by the company, are duplicative of other proposals on a given year's proxy ballot, or have been rejected by a large percentage of the shareholder base in previous years. The 2022 proposal would make it more difficult for issuers to utilize these exclusions, effectively creating a roadmap for activists to ensure that their preferred proposals are always included on the ballot. In response to the proposed rule, the NAM said that it would "make it easier for activists to flood the proxy ballot."[16]

The NAM appreciates that the SEC in the early days of the new Administration has already taken steps to prioritize the best interests of public companies and their long-term shareholders over the agendas of single-issue activists. The SEC rescinded SLB 14L and replaced it with SLB 14M in February 2025, a move that the NAM said will return the SEC's review of no-action requests under Rule 14a-8 to "a company-specific process based on relevance to a business's operations and its investors' returns"—which in turn will "allow manufacturers to focus on what they do best: investing for growth, creating jobs, and driving the American economy."[17]

Manufacturers encourage the Commission to continue to support public capital formation by reducing the damaging impact that activists can have on manufacturers and their investors. Pursuant to EO 14219, the NAM respectfully urges the SEC to:

- Withdraw the rule proposed in July 2022 regarding substantially implemented, duplicative, and resubmitted proposals;
- Maintain, enforce, and consider enhancing the amendments to Rule 14a-8 adopted in 2020 that increased the submission and resubmission thresholds for activist shareholder proposals; and
- Build on the rescission of SLB 14L and promulgation of SLB 14M with a proposed rule to amend Rule 14a-8 that would ensure public companies are free to exclude activist proposals that are irrelevant to or a distraction from their fiduciary duty to create value for shareholders.

**Climate Disclosures**

Manufacturers are committed to providing appropriate disclosures about their efforts to limit their impact on the environment and ensure sustainable business operations, to the extent they are material to investors. Indeed, federal securities laws already require the disclosure of material information necessary for investors to make an informed investing or proxy voting decision. Despite these existing requirements—and existing guidance for how companies can apply them to climate disclosures—the SEC in 2024 finalized an entirely separate disclosure regime for public companies' climate-related information.[18]

The SEC's final climate rule is much less onerous than its original proposal, with unworkable requirements related to Scope 3 emissions and financial statement reporting omitted or significantly

[15] *Substantial Implementation, Duplication, and Resubmission of Shareholder Proposals Under Exchange Act Rule 14a-8*, 87 Fed. Reg. 45052 (27 July 2022). Release Nos. 34-95267, IC-34647; *available at* https://www.govinfo.gov/content/pkg/FR-2022-07-27/pdf/2022-15348.pdf.

[16] NAM Comments on File No. S7-20-22 (12 September 2022). *Available at* https://documents.nam.org/tax/nam_14a-8_comments.pdf.

[17] *President Trump Reining in Regulatory Onslaught*. National Association of Manufacturers (12 February 2025). *Available at* https://nam.org/president-trump-reining-in-regulatory-onslaught-33270/.

[18] *The Enhancement and Standardization of Climate-Related Disclosures for Investors*, 89 Fed. Reg. 21668 (28 March 2024). RIN 3235-AM87; *available at* https://www.govinfo.gov/content/pkg/FR-2024-03-28/pdf/2024-05137.pdf.

scaled back—as the NAM suggested in our comments on the proposal.[19] Nevertheless, if implemented, this novel and complex reporting regime will impose significant burdens on publicly traded manufacturers. Further, the rule raises significant questions with respect to the SEC's authority to issue a rule mandating climate disclosures—especially to the extent that the required information is not material to investors. Manufacturers appreciate the SEC's recent decision not to assert in court expansive authority with respect to immaterial climate disclosures; however, if the rule is ultimately upheld in court, the NAM would urge the SEC to revisit the rule in order to substantially revise or rescind it. Reconsidering this novel and complex rule would provide the Commission an opportunity to ensure that public company disclosures remain focused on material information for investors.

**Cybersecurity Disclosures**

In August 2023, the SEC finalized a rule to require new cybersecurity disclosures from publicly traded companies.[20] Most notably, the proposed rule includes a requirement that companies disclose cybersecurity incidents to the public within four days. This rigid mandate grants businesses minimal flexibility to delay or forgo disclosure in order to investigate and respond to an incident, work with law enforcement, or avoid tipping off attackers. When it was proposed, the NAM said that the four-day reporting requirement "would increase costs and complexity for businesses, potentially mislead investors, and ultimately create significant risks for shareholders and the broader economy that would eclipse the potential benefits of reporting."[21]

Manufacturers remain concerned that the SEC's approach to cybersecurity disclosures could endanger businesses, shareholders, and national security. Pursuant to EO 14219, the NAM respectfully encourages the Commission to amend or rescind the 2023 cybersecurity disclosures rule; at a minimum, it is vital that the four-day reporting requirement be rescinded in favor of granting companies significant flexibility to adjust the timing of their cybersecurity incident reports, work with law enforcement, and take steps to protect public safety and national security.

**Private Company Bond Disclosures**

In 2020, the SEC adopted amendments to Rule 15c2-11 to require certain public disclosures from issuers of over-the-counter equity securities.[22] In September 2021, the SEC's Division of Trading and Markets issued a no-action letter expanding the application of Rule 15c2-11 (and the 2020 amendments thereto) to include fixed-income securities.[23] This reinterpretation of Rule 15c2-11, adopted without any opportunity for public comment, directly impacted issuers of fixed-income securities such as corporate bonds issued pursuant to Rule 144A.

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[19] NAM Comments on File No. S7-10-22 (6 June 2022). Available at https://documents.nam.org/tax/nam_comments_sec_climate_rule.pdf.

[20] *Cybersecurity Risk Management, Strategy, Governance, and Incident Disclosure*, 88 Fed. Reg. 51896 (4 August 2023). Release Nos. 33-11216, 34-97989; *available at* https://www.govinfo.gov/content/pkg/FR-2023-08-04/pdf/2023-16194.pdf.

[21] NAM Comments on File No. S7-09-22 (9 May 2022). *Available at* https://documents.nam.org/tax/nam_comments_sec_cybersecurity_rule.pdf.

[22] *Publication or Submission of Quotations Without Specified Information*, 85 Fed. Reg. 68124 (27 October 2020). Release Nos. 33-10842, 34-89891; *available at* https://www.govinfo.gov/content/pkg/FR-2020-10-27/pdf/2020-20980.pdf.

[23] Letter from Josephine Tao, Assistant Director, Office of Trading Practices, Division of Trading and Markets, SEC to Racquel Russell, Senior Vice President and Director of Capital Markets Policy, Office of the General Counsel, FINRA (24 September 2021). *Available at* https://www.sec.gov/files/rule-15c2-11-fixed-income-securities-092421.pdf.

Many privately held manufacturers issue Rule 144A debt to raise capital. Applying Rule 15c2-11 to Rule 144A offerings would force these private issuers to make detailed financial information about their business publicly available. Rule 144A already requires issuers to make their financial information available to institutional investors on a confidential basis, and these sophisticated institutions are the only investors allowed to participate in the Rule 144A market. This novel interpretation of Rule 15c2-11 would expose competitively sensitive information to the public, which cannot even purchase Rule 144A securities. Moreover, this drastic policy change was effectuated without public notice-and-comment or any cost-benefit analysis.

In November 2022, the NAM filed a petition with the SEC seeking emergency interim relief from this novel interpretation, as well as a petition for rulemaking and exemptive relief to reverse the staff determination.[24] In September 2023, the NAM filed a lawsuit in the U.S. District Court for the Eastern District of Kentucky challenging the SEC's actions as unlawful under the Administrative Procedure Act, as well as a parallel action in the U.S. Court of Appeals for the Sixth Circuit seeking review of the agency's failure to grant relief pursuant to our rulemaking and exemptive relief petitions.

In October 2023, in response to the NAM's litigation, the SEC walked back its harmful interpretation of Rule 15c2-11 by issuing an exemptive order exempting broker-dealers from the compliance requirements of Rule 15c2-11 with respect to Rule 144A fixed-income securities. This change was a significant win for manufacturers, and prevented privately held issuers of corporate bonds issued pursuant to Rule 144A from being forced to publicly disclose proprietary financial information. However, the SEC maintained its application of Rule 15c2-11 to *other* fixed-income securities even following the Rule 144A exemptive order.

Fortunately, a series of temporary no-action letters from the Division of Trading and Markets prevented this interpretation from taking effect, and in November 2024 the Division issued a final no-action letter granting exemptive relief in perpetuity. While the exemptive order with respect to Rule 144A fixed-income securities is permanent, Commission-level relief, the relief granted to other fixed-income securities now relies on this staff-level no-action letter that could easily be rescinded in the future, generating uncertainty in the market.

In order to reverse the erroneous interpretation that mistakenly applied Rule 15c2-11 to fixed-income securities, pursuant to EO 14219 the NAM respectfully encourages the SEC to:

- Rescind the September 2021 Division of Trading and Markets no-action letter that initially applied Rule 15c2-11 to fixed-income securities;
- Preserve the October 2023 exemptive order with respect to Rule 144A fixed-income securities; and
- Expressly clarify that fixed-income securities are exempt from Rule 15c2-11, either by promulgating amendments to Rule 15c2-11 or by issuing another exemptive order.

[24] *See* NAM, KAM Petition for Emergency Interim Relief and Emergency Request for a Stay Pending Commission Action or Judicial Review With Respect to Application of Rule 15c2-11 to Rule 144A Securities (22 November 2022), *available at* https://documents.nam.org/law/nam_kam_144a_interim_relief_petition.pdf; *see also* NAM, KAM Petition for Rulemaking and Application for Exemption With Respect to Rule 15c2-11 (22 November 2022), *available at* https://documents.nam.org/law/nam_kam_144a_permanent_relief_petition.pdf.

**Stock Buybacks**

In June 2023, the SEC finalized a rule designed to discourage the common practice of stock buybacks by publicly traded companies.[25] Though couched as a new disclosure requirement, the rule's intent was clearly to deter companies from repurchasing shares even when economically efficient and appropriate for their business.

It is critical to their success as publicly traded companies that manufacturers are able to attract shareholders and efficiently allocate shareholder capital—and corporate stock buybacks are important for both capital formation and capital allocation. These return-of-capital transactions allow excess capital to flow where it can most efficiently be used, creating value for shareholders and enabling companies throughout the economy to attract much-needed investment. The SEC's rule would have imposed a burdensome disclosure requirement for companies repurchasing shares of stock, forcing them to track buyback activity on a daily basis and to provide justifications of any repurchases.

The NAM strongly opposed the buybacks disclosure rule when it was proposed.[26] Fortunately, in December 2023, the U.S. Court of Appeals for the Fifth Circuit vacated the rule. As the SEC considers its regulatory priorities in the coming years, manufacturers respectfully encourage the Commission not to take any similar steps to limit efficient capital allocation by discouraging stock buybacks.

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America's world-leading capital markets—and the SEC's oversight thereof—are crucial to manufacturers' ability to raise the capital necessary to drive economic expansion and bolster America's competitiveness on the world stage. The NAM appreciates the Administration's commitment to supporting a regulatory landscape that empower manufacturers to grow, create jobs, and provide investment opportunities for Main Street investors. Pursuant to EO 14219, manufacturers are committed to working with the Commission to right-size regulations that limit capital formation or harm manufacturing.

Sincerely,

Charles Crain
Managing Vice President, Policy

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[25] *Share Repurchase Disclosure Modernization*, 88 Fed. Reg. 36002 (1 June 2023). Release Nos. 34-97424, IC-34906; ***available at*** https://www.govinfo.gov/content/pkg/FR-2023-06-01/pdf/2023-09965.pdf.

[26] NAM Comments on File No. S7-21-21 (1 April 2022). *Available at* https://documents.nam.org/tax/nam_buybacks_comments.pdf.

NATIONAL ASSOCIATION OF
Manufacturers

**Charles Crain**

*Managing Vice President,
Policy*

April 17, 2025

The Honorable Scott Bessent
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

Dear Secretary Bessent:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the Department of the Treasury ("Treasury") and the Internal Revenue Service ("IRS") to consider several overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to President Trump's EO.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

Tax policy plays a critical role in manufacturers' ability to thrive in the U.S. and compete effectively in a global economy. Tax certainty is critical to supporting growth and long-term investment in U.S. manufacturing: in a recent NAM survey, 93% of manufacturers reported that increased tax burdens on manufacturing activities would make it more difficult to expand their workforce, invest in new equipment, or expand facilities.[1]

Manufacturers are committed to working with Congress and the Administration on competitive, pro-growth tax policy; first and foremost, policymakers must preserve crucial pro-manufacturing provisions from the 2017 Tax Cuts and Jobs Act. Tax reform was rocket fuel for manufacturers, leading significant capital investment, job creation, and wage growth. With nearly 6 million jobs on the line if the TCJA is not extended, manufacturers are calling for urgent action to provide the industry with the tax certainty needed to support long-term, job-creating investments.

Additionally, Treasury and the IRS have the opportunity, pursuant to EO 14219, to review and potentially rescind overreaching or unworkable regulations from the previous Administration that are stymieing manufacturing growth. The rules the NAM is highlighting were either implemented despite the damaging consequences for manufacturers, or else rushed through the door in the final hours of

[1] NAM Manufacturers' Outlook Survey, First Quarter 2024, https://nam.org/wp-content/uploads/2024/03/Outlook-Survey-March-2024-Q1.pdf

President Biden's term. Manufacturers respectfully encourage Treasury and the IRS to carefully review these rules' impact on manufacturers and to review, revise, or rescind them accordingly.

**Corporate Alternative Minimum Tax**

On September 13, 2024, Treasury and the IRS released the latest proposed regulations addressing the application of the corporate alternative minimum tax ("CAMT" or the "book tax"), which is imposed on the adjusted financial statement income ("AFSI") of certain corporations. The book tax was enacted by the Inflation Reduction Act and represents a damaging tax increase on job-creators in the manufacturing industry.

In general, CAMT imposes a 15% minimum tax on the AFSI of any corporation whose AFSI (with adjustments) averages at least $1 billion over the prior three-year period. Impacted corporations will owe tax under the CAMT regime if their book tax liability is greater than their regular tax liability plus the base erosion and anti-abuse tax.

By linking federal income tax liability to a complex set of domestic and foreign financial statement reporting rules that were designed and are maintained for purposes very different from raising tax revenue, CAMT has introduced an additional, significant layer of uncertainty to the taxation of U.S. corporations. This uncertainty is compounded by the need for complex statutory and regulatory carve outs, exceptions, and other special rules to ensure that implementation of CAMT is aligned with broader tax policy goals. For example, an alternative minimum tax based solely on book income would effectively eliminate congressionally sanctioned measures that are designed to use the tax law to stimulate investment, such as accelerated cost recovery.

Manufacturers fought for statutory adjustments to CAMT to keep these important provisions in place, and the IRA allows for certain adjustments to a company's book earnings, including for expensing of capital equipment purchases. Despite these adjustments, manufacturers continue to believe that alternative minimum taxes such as CAMT are an unacceptable way of addressing perceived deficiencies in the regular corporate tax system and add significant and unnecessary complexity to an already complex corporate income tax regime.

Reflecting its concerns with CAMT as enacted, the NAM submitted comments to Treasury and the IRS in response to interim guidance issued in Notice 2023-7, 2023-3 IRB 390,[2] and Notice 2023-64, 2023-40 IRB 974,[3] as well as to the September 2024 NPRM.[4] While implementation of the NAM's comments on the proposed regulations would reduce the significant compliance and enforcement burden that CAMT will place on taxpayers and the IRS alike, the NAM encourages Treasury and the IRS to review the current status of the CAMT regulations and determine what further action is necessary to protect manufacturers from undue tax obligations or increased compliance costs. The NAM also supports efforts to repeal CAMT entirely and prevent manufacturers from being forced to comply with this unworkable and costly tax burden.

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[2] *Comments on Notice 2023-7: Initial Guidance Regarding the Application of the Corporate Alternative Minimum Tax under Sections 55, 56A, and 59 of the Internal Revenue Code* (National Association of Manufacturers, March 20, 2023), https://documents.nam.org/tax/NAM_Comments_IRS_CAMT_Guidance.pdf

[3] *Comments on Notice 2023-64: Additional Interim Guidance Regarding the Application of the Corporate Alternative Minimum Tax under Sections 55, 56A, and 59 of the Internal Revenue Code*, (National Association of Manufacturers, October 12, 2023), https://documents.nam.org/TAX/NAM_CAMT_Comments_10.12.23.pdf

[4] *Comments on Proposed Regulations (REG-112129-23), Corporate Alternative Minimum Tax Applicable after 2022 (89 FR 75062)* (National Association of Manufacturers, January 16, 2025), https://documents.nam.org/tax/NAM_CAMT_Comment_Letter_1-16-25.pdf

**Certain Partnership Related-Party Basis Adjustment Transactions of Interest**

On June 18, 2024, Treasury and the IRS issued a multipronged rulemaking package targeted at certain related-party transactions that result in a partnership basis adjustment. The NAM provided comments on Notice 2024-54, which announced forthcoming proposed regulations regarding basis adjustments in certain partnership related-party transactions, on July 17, 2024.[5] The NAM also commented on Treasury's proposed reporting regulations (REG-124593-23), which trigger reporting and list maintenance requirements for taxpayers and material advisors under Code sections 6011, 6111, and 6122, on August 19, 2024.[6] In both instances, the NAM argued that the Biden Treasury Department was acting outside its statutory authority and imposing undue burdens on taxpayers that would exceed any theoretical compliance benefit. The NAM also noted that Treasury's focus on these transactions was in conflict with the stated information-gathering purpose of the transactions of interest category of reportable transactions.

Following the November 2024 elections, the NAM wrote to the outgoing Biden Administration, urging Treasury not to finalize the reporting regulations in the Administration's final days and outlining the legal flaws endemic to the proposal and to the rules contemplated by Notice 2024-54.[7] Despite these objections, the previous Administration finalized the new regulations on January 14, 2025, just one week before the end of President Biden's term.[8] The NAM then wrote to Treasury in the early days of the Trump Administration, urging Treasury to suspend enforcement of the reporting regulations in order to allow the new administration to review and ultimately rescind the rules.[9]

Manufacturers continue to have serious concerns with the previous Administration's approach to related-party transactions. As the NAM said in our February 18, 2025, letter, manufacturers encourage Treasury to retract the Biden Administration's finalized reporting regulations, and not to proceed with the forthcoming rules identified in Notice 2024-54. Rescinding the previous Administration's regulatory overreach with respect to related-party transactions—including by rescinding the reporting regulations, withdrawing Revenue Ruling 2024-14, and disbanding the associated enforcement campaign—would be consistent with EO 14219's directive that agencies' identify rules that are unlawful and that impose significant costs on the private sector.

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[5] *Comments on Notice 2024-54, Forthcoming Guidance Regarding Certain Partnership Related-Party Transactions (2024-28 I.R.B. 24)* (National Association of Manufacturers, July 17, 2024), https://documents.nam.org/TAX/NAM_Comment_Letter_to_IRS_re_Related_Party_Basis_Adjustment_Transactions_07-17-24.pdf

[6] *Comments on Proposed Regulations (REG-124593-23), Certain Partnership Related-Party Basis Adjustment Transactions as Transactions of Interest (89 FR 51476*) (National Association of Manufacturers, August 19, 2024), https://documents.nam.org/TAX/NAM_Comment_Letter_to_IRS_re_Related_Party_Basis_Adjustment_Transactions_08-19-24.pdf

[7] *Letter to U.S. Department of the Treasury and Internal Revenue Service Regarding Litigation Risk If Proposed Regulations (REG-124593-23 and REG-105128-23) Are Finalized In Their Present Form And If Forthcoming Proposed Regulations (Notice 2024-54) Are Issued and Finalized* (National Association of Manufacturers, December 27, 2024), https://documents.nam.org/TAX/NAM_Comment_Letter_to_Treasury_re_DCL_DPL_and_Reporting_Regulations_12-27-24.pdf

[8] *Certain Partnership Related-Party Basis Adjustment Transactions as Transactions of Interest*, 90 Fed. Reg. 2958 (14 January 2025). RIN 1545-BR07; *available at* https://www.govinfo.gov/content/pkg/FR-2025-01-14/pdf/2025-00324.pdf

[9] *Letter to U.S. Department of the Treasury and Internal Revenue Service Regarding the Biden Administration's Finalization of Proposed Regulations (REG-124593-23 and REG-105128-23)* (National Association of Manufacturers, February 18, 2025) https://documents.nam.org/TAX/NAM_Comment_Letter_to_Treasury_re_DCL_DPL_and_Reporting_Regulations_02-18-25.pdf

**Rules Regarding Dual Consolidated Losses and the Treatment of Certain Disregarded Payments**

On August 7, 2024, Treasury issued a notice of proposed rulemaking titled "Rules Regarding Dual Consolidated Losses and the Treatment of Certain Disregarded Payments" (REG-105128-23). The NAM provided comments on this proposal, noting in particular that Treasury lacked the authority to issue the rule.[10] The NAM reiterated these concerns in a letter to the outgoing Biden Administration in December 2024.[11] Ignoring these and other concerns raised by commenters, the previous Administration proceeded to issue final version of the DCL/DPL Regulations in January 2025, in the final days of President Biden's term, without the opportunity for further review by impacted taxpayers. The NAM then wrote to the Trump Administration in February 2025, alerting the new Treasury leadership to the damage that could be imposed by the previous Administration's unlawful rule.[12]

The NAM continues to believe that Treasury lacks the legal authority to issue the DCL/DPL Regulations, and thus that they should be withdrawn in full. Additionally, in promulgating these overreaching rules, Treasury failed to justify their severe costs, in clear violation of the Administrative Procedure Act. Finally, the DCL/DPL Regulations prioritize the policy interests of the OECD that do not necessarily align with the domestic policy interests and concerns of the American people—a topic which the Trump Administration has prioritized, beginning with the President's memorandum on the OECD Global Tax Deal issued on January 20, 2025. Given these clear problems of both authority and policy, manufacturers respectfully encourage Treasury to rescind the previous Administration's overreaching DCL/DPL Regulations.

**Form 6765 – Credit for Increasing Research Activities**

On December 20, 2024, the IRS released draft instructions for the updated Form 6765, via which companies can claim the Credit for Increasing Research Activities, also known as the R&D tax credit. Manufacturers perform 53% of all private-sector R&D in the U.S., and the R&D credit is an important tax incentive for job-creating, innovation-supporting research.

Updating Form 6765 was a multi-year process, with previous drafts of the form released in 2023 and 2024, both of which received extensive feedback from various external stakeholders, including the NAM.[13] Unfortunately, the final revised form requires taxpayers to submit significantly more information about their activities and business components, creating even more red tape and regulatory burden on manufacturers—and ultimately undermining the pro-innovation, pro-research benefits of the R&D credit.

The final version of Form 6765 is applicable for tax year 2024, with the notable exception of *Section G – Business Component Information*, which calls for highly detailed information that will make it significantly more difficult to claim the R&D credit. The IRS has stated that it is seeking feedback regarding the draft instructions, and specifically about Section G, through June 30, 2025.

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[10] *Comments on REG-105128-23, Rules Regarding Dual Consolidated Losses and the Treatment of Certain Disregarded Payments*, (National Association of Manufacturers, October, 7, 2024), https://documents.nam.org/TAX/NAM_Comment_Letter_to_IRS_re_DCL_and_DPL_10-07-24.pdf

[11] *See* NAM Litigation Risk Letter, *supra* note 7.

[12] *See* NAM Rescission Letter, *supra* note 9.

[13] *Comments Regarding Proposed Changes to Form 6765, Credit for Increasing Research Activities* (National Association of Manufacturers, October 31, 2023), https://documents.nam.org/TAX/NAM%20Comment%20Letter.RD%20Tax%20Credit%20Form%206765.FINAL.pdf

First, the NAM recommends that the IRS continue to receive feedback on Form 6765, which should illustrate that the new requirements, and particularly Section G, create a tremendous burden on manufacturers, greatly increasing the amount of information and time spent to simply complete the form. Following this review, the IRS should strongly consider rescinding or substantially revising the previous Administration's amendments to Form 6765 in order to ensure the implementation of the R&D credit remains aligned with congressional intent—reducing the cost of life-changing and life-saving innovation here in the United States.

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The NAM appreciates the Trump Administration's ongoing efforts to extend and make permanent crucial pro-manufacturing tax provisions from the Tax Cuts and Jobs Act. As a complement to preserving tax reform, right-sizing unworkable or unlawful tax regulations from the previous Administration would grant manufacturers additional tax certainty, making it easier and more cost-efficient to invest and create jobs in the United States.

Sincerely,

Charles Crain
Managing Vice President, Policy

NATIONAL ASSOCIATION OF
Manufacturers

**Charles Crain**

*Managing Vice President,*
*Policy*

April 17, 2025

The Honorable Andrew N. Ferguson
Chairman
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Dear Chairman Ferguson:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the Federal Trade Commission ("FTC") to consider several overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to President Trump's EO.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

**Hart-Scott-Rodino Coverage, Exemption, and Transmittal Rules**

The NAM has significant concerns regarding the FTC's amendments to the Hart-Scott-Rodino ("HSR") pre-merger notification rules finalized in October 2024. When the amendments were proposed in June 2023, the NAM submitted comments characterizing the FTC's actions as "stifl[ing] job-creating growth in the manufacturing industry without any corresponding benefit to the [federal antitrust] Agencies, merging parties, or the public."[1] Though the FTC made some changes to its proposed rule before finalizing, the final rule nevertheless poses serious risks to manufacturers' ability to grow and thrive.

In short, the amended HSR rules substantially increase the volume of information that manufacturers must submit prior to completing transactions such as mergers, acquisitions, capital investments, and licensing arrangements. Moreover, these amendments will not enhance the federal antitrust Agencies' ability to detect or investigate potentially anticompetitive transactions. Instead, they broadly discourage all business combinations in the manufacturing industry, overlooking the substantial benefits that mergers and acquisitions offer to manufacturers of all sizes. Such transactions often result in business efficiencies, improved product offerings, and reduced costs for consumers. Additionally, a vibrant M&A environment supports company formation and capital

[1] National Association of Manufacturers, *Comments on the FTC HSR Proposal*, September 27, 2023, https://documents.nam.org/tax/nam_comments_ftc_hsr_proposal.pdf.

raising, particularly for entrepreneurs and early-stage investors who rely on these activities as viable exit strategies. By imposing extensive disclosure requirements for all transactions, irrespective of their potential for anticompetitive impacts on the market, these amendments will stifle early-stage innovation and complicate collaborations and licensing arrangements that are vital to the industry's growth.

These amendments presume M&A activity to be inherently suspect, subjecting all reportable transactions to an unwarranted level of scrutiny that exceeds their actual competitive risks. The FTC's regulatory attention should be focused on specific transactions that genuinely pose a threat of competitive harm to consumers, thereby preserving the ability of businesses to expand and drive economic progress in the United States.

The NAM respectfully encourages the FTC to closely review the Biden Administration's amendments to the HSR rules and to promulgate a proposal that substantially revises these damaging changes.

**Noncompete Clauses**

On April 23, 2024, the FTC issued a final rule banning nearly all noncompete agreements between employers and their employees. The NAM opposed this rule and submitted comments through the rulemaking process that detailed its impact on the manufacturing workforce and the security of manufacturers' intellectual property.[2]

Manufacturers use tailored noncompete agreements as a tool to responsibly invest in their employees' development and protect trade secrets—in an industry that accounts for 53% of all private-sector research and development. Roughly half of manufacturers surveyed by the NAM said that noncompete agreements affect their investment in employee training. Additionally, the vast majority of respondents said that their agreements last no more than two years.[3] A ban would disrupt operations for approximately 66% of manufacturers.

On August 20, 2024, the U.S. District Court for the Northern District of Texas issued a decision setting aside the rule, which is now on appeal. The NAM requests that the FTC abandon defense of the rule; depending on the outcome of the case, manufacturers also would support the FTC taking regulatory steps to rescind or substantially revise the rule. Manufacturers look forward to working with the FTC to strengthen the dynamism of the American worker and safeguard manufacturers' operations.

**Right to Repair**

Manufacturers also urge the FTC to withdraw its policy statement[4] supporting legislative, regulatory, and enforcement actions that would require manufacturers to provide unrestricted access to the source code, technical data, and component designs that make their products competitive in the market. Such mandates represent an unnecessary regulatory burden that would undermine consumer safety, product integrity, and intellectual property protections. Manufacturers dedicate substantial resources to developing innovative products and maintaining rigorous quality standards, supported by authorized repair networks designed to ensure product safety, reliability, and

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[2] National Association of Manufacturers, *Comments on Noncompete Clause Rulemaking, Matter No. P201200,* April 18, 2023, https://documents.nam.org/IIHRP/NAM_Comments_on_FTC_Noncompetes_Rulemaking_April_18_2023_FINAL.pdf.

[3] *Ibid*.

[4] Federal Trade Commission, *Policy Statement of the Federal Trade Commission on Repair Restrictions Imposed by Manufacturers and Sellers*, July 21, 2021, https://www.ftc.gov/system/files/documents/public_statements/1592330/p194400repairrestrictionspolicystatement.pdf

regulatory compliance. The FTC's expansive support for unrestricted third-party repairs disrupts these market-driven mechanisms, undermining significant industry investments that effectively balance consumer choice, product dependability, and public welfare.

Moreover, the FTC's current stance inadequately addresses the serious cybersecurity risks and liability implications stemming from unauthorized repairs. Granting expansive access to proprietary tools, diagnostic systems, and confidential product information to unqualified third parties significantly elevates consumer data vulnerabilities and increases manufacturers' exposure to litigation and reputational damage. As such, the NAM respectfully requests that the FTC withdraw its policy statement that voices support for repair restrictions on manufacturers.

**Sound Amplifiers**

Finally, manufactures are concerned by the FTC's decision to retroactively apply its Amended Trade Regulation Rule Relating to Power Output Claims for Amplifiers Utilized in Home Entertainment Products (the "amended rule").[5] Retroactive application forces manufacturers, distributors and retailers of such amplifiers to re-test, re-package, and alter their disclosures. This "impose[s] significant costs upon private parties that are not outweighed by public benefits," which requires the rescission of the amended rule per sec. 2(a)(v) of EO 14219. Additional detail and justification can be found in the comments submitted by the NAM to the FTC in support of a petition for rulemaking with regard to the amended rule.[6]

* * * *

President Trump has already taken meaningful steps to shift the government's focus away from excessive regulation and toward encouraging innovation, investment, and job growth. Revising or rescinding these regulations and policies per the NAM's recommendations would further underscore the Administration's commitment to a globally competitive U.S. manufacturing sector that fosters entrepreneurship and supports the growth of small and medium-sized manufacturers across the country.

The NAM stands ready to help the FTC deliver on President Trump's promise to make the United States the best place in the world to build, grow, and create jobs.

Sincerely,

Charles Crain
Managing Vice President, Policy

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[5] Federal Register Vol. 89, No. 114, Wednesday, June 12, 2024

[6] National Association of Manufacturers, *Comments on Amended Trade Regulation Rule Relating to Power Output Claims for Amplifiers Utilized in Home Entertainment Products*, November 24, 2024, https://documents.nam.org/tech/FTC%20sound%20amplifiers%20rule%20-%20NAM%20submission%20-%20FINAL.pdf.

NATIONAL ASSOCIATION OF
Manufacturers

**Charles Crain**

*Managing Vice President,
Policy*

April 17, 2025

The Honorable Lori Chavez-DeRemer
Secretary
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Dear Secretary Chavez-DeRemer:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the Department of Labor ("DOL") to consider several overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to President Trump's EO.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

**Worker Walkaround Representative Designation Process**

On April 1, 2024, the Occupational Safety and Health Administration ("OSHA") promulgated a final rule, titled *Worker Walkaround Representative Designation Process*, that significantly broadens the criteria by which nonemployee third-party representatives may be designated to accompany walkaround inspections. Whereas the Occupational Safety and Health Act ("OSH Act") and agency precedent allowed experts and consultants to accompany inspections as reasonably necessary, the walkaround rule opens this right to nonemployee third-party representatives based on tangential qualifications.

As the NAM wrote in its comments pursuant to the notice of proposed rulemaking, the walkaround rule infringes on the constitutional rights of employers and conflicts with our nation's labor laws.[2] Under the expanded criteria, antagonistic third parties, such as trial lawyers and union organizers, may enter and occupy an employer's facility without an employer's consent, effecting a per se taking in violation of the Fifth Amendment to the U.S. Constitution. The rule also puts OSHA inspectors and the agency in the position of permitting or refusing requests for union organizers to enter

[2] *Comment Letter on Notice of Proposed Rulemaking for Worker Walkaround Representative Designation Process* (National Association of Manufacturers, November 13, 2023), https://www.regulations.gov/comment/OSHA-2023-0008-1953.

workplaces—whether they are unionized or not—in conflict with both the OSH Act and the National Labor Relations Act.

The NAM has filed suit to block this unconstitutional and overreaching rule. Pending the outcome of that litigation, the NAM requests that DOL and OSHA rescind this rule as an unconstitutional and overly broad interpretation of statute and return to the pre-rule regulatory scheme for designating nonemployee third-party representatives to accompany walkaround inspections. This will protect manufacturers' operations and keep OSHA focused on its mission of ensuring safe workplaces.

**Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings**

On August 30, 2024, OSHA filed its proposed rulemaking establishing a heat standard, titled *Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings.* The proposed rule would impose new requirements for employers to measure, record, and control for heat in their workplaces.

As the NAM wrote in its comments, the proposed rule is problematic for manufacturers, which operate in disparate locations and rely on tailored approaches to mitigate the effects of occupational heat exposure while sustaining productivity.[3] The requirements in the proposed rule fail to account for these differences, instead pursuing a one-size-fits-all approach. For example, the proposed heat triggers are nationally applicable, despite regional variations in climate and by extension acclimatization. And the proposed rule's mandates regarding rest breaks, acclimatization, heat monitoring, and the designation of heat safety coordinators will interfere with sustaining the responsive workforce on which manufacturers depend.

The NAM requests that OSHA reconsider the proposed heat rule and allow for further input from affected industry stakeholders before promulgating any new standard. Manufacturers in the U.S. are committed to maintaining safe work environments and have dedicated significant resources to protect employees from hazardous heat in the workplace. The proposed rule, however, is inflexible and creates burdensome requirements for employers.

Were OSHA to promulgate a heat rule, the NAM recommends, at the very least, that the agency:

- Adopt a performance-oriented approach that allows employers to tailor controls according to their respective workplaces;
- Conduct a rigorous review to determine regional variations in incidences of heat-related illness;
- Account for the implications of any final rule on employers' operations—in particular, by thoroughly determining the economic and technological feasibility of any proposed controls;
- Consider workforce availability and labor costs associated with hiring additional employees in any economic feasibility analysis;
- Assess the impact of any final rule on the movement of freight; and
- Preclude any references to employee representatives.

Manufacturers stand ready to support OSHA in its mission of safety and to communicate best practices already in use to protect employees from hazardous heat.

[3] *Comment Letter on Notice of Proposed Rulemaking for Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings* (National Association of Manufacturers, January 14, 2025), https://www.regulations.gov/comment/OSHA-2021-0009-25315.

**Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees**

On April 26, 2024, the Wage and Hour Division of DOL promulgated a final rule, titled *Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees.* The rule raises the minimum salary threshold above which employees are exempted from federal overtime pay requirements under the Fair Labor Standards Act (FLSA) from $684 per week ($35,568 annually) to $844 per week ($43,888) beginning July 1, 2024, and then to $1,128 per week ($58,656 annually) beginning January 1, 2025. The rule also establishes a new mechanism whereby that threshold automatically updates every three years.

As the NAM wrote in its comments to the agency, DOL's overtime rule threatens manufacturers at a time when the industry continues to struggle to find skilled workers—with 462,000 open jobs in the industry as of January 2025.[4] Labor costs will increase dramatically and employees' opportunities for career development will diminish because of the rule. These challenges will be felt most acutely by small and medium-sized manufacturers, with many lacking the headcount necessary to redistribute work.

On November 15, 2024, the U.S. District Court for the Eastern District of Texas issued a decision striking down the overtime rule, concluding that the new salary threshold conflicted with other criteria under the FLSA and that the automatic updates established by the rule improperly evaded the Administrative Procedure Act's (APA) notice-and-comment requirements. On December 30, 2024, the U.S. District Court for the Northern District of Texas likewise set aside the rule. Both cases are now on appeal to the U.S. Court Appeals for the 5th Circuit. In order to ensure that manufacturers are able to continue providing excellent employment opportunities to millions of American workers, the NAM requests that DOL abandon defense of the rule.

**Employee or Independent Contractor Classification Under the Fair Labor Standards Act**

On January 10, 2024, DOL finalized a rule, titled *Employee or Independent Contractor Classification Under the Fair Labor Standards Act*, that establishes a framework for determining, under the FLSA, whether a worker is an employee of a potential employer or an independent contractor. The framework consists of a six-part—albeit non-exhaustive—test to make such a determination. The rule also rescinds a 2021 rule that prescribed an analysis for determining worker status.

The NAM opposed the rule as proposed, arguing that it would exacerbate workforce challenges faced by manufacturers and impinge on the economic freedom of those independent contractors who work within our industry.[5] We also opposed the rule on procedural and substantive grounds, given that DOL did not provide sufficient justification under the APA to revisit the 2021 rule, and due to its inconsistency with the FLSA.

Review of the independent contractor rule is pending in separate courts. The NAM requests that DOL abandon defense of the rule, allowing manufacturers, their employees, and independent contractors to tailor work arrangements to specific operational needs and preferences.

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[4] *Comment on Notice of Proposed Rulemaking for Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees* (National Association of Manufacturers, November 7, 2023), https://www.regulations.gov/comment/WHD-2023-0001-25557.

[5] *Comment Letter on Notice of Proposed Rulemaking for Employee or Independent Contractor Classification Under the Fair Labor Standards Act* (National Association of Manufacturers, December 13, 2022), https://www.regulations.gov/comment/WHD-2022-0003-53508.

**Mental Health Parity and Addiction Equity Act Final Rule**

On September 9, 2024, DOL, along with the Department of Health and Human Services (HHS) and the Department of the Treasury, issued final rules for the Mental Health Parity and Addiction Equity Act (MHPAEA).

Manufacturers are committed to providing mental health benefits to their employees, but this rule makes it more difficult to do so. This rule could cause the already high cost of health insurance to rise for manufacturers. Another unintended consequence from this rule is a reduction in access to critical mental health and substance use disorder (MH/SUD) benefits. In addition, this rule exceeds the scope of Congressional intent as MHPAEA is not a benefit mandate. In their 2013 final rules on MHPAEA, DOL, HHS, and Treasury stated that they did not intend to impose a benefit mandate, which the 2024 rule effectively does.

The final rule created a “meaningful benefits” requirement that requires plans that cover MH/SUD benefits in one classification (inpatient, outpatient, emergency services, and prescription drugs) to cover benefits in all classifications. This provision is slated to go into effect on January 1, 2026. Manufacturers that offer MH/SUD benefits but not in every classification will be forced to either incur additional health care costs to provide benefits that satisfy this requirement or forgo offering any MH/SUD benefits to their employees due to cost. This creates unnecessary and harmful problems for both manufacturers and manufacturing workers.

The final rule also contained an updated list of non-quantitative treatment limitations (NQTLs) that plans are required to apply to MH/SUDs comparable to and not more restrictive than medical and surgical benefits they offer. Plans are required to have a comprehensive comparative analysis, including explanations of any disparities between MH/SUD and medical and surgical benefits. This highly technical provision went into effect on January 1, 2025. Due to its complexity and the short timeline, compliance has been and continues to be exceedingly expensive for manufacturers.

The rule’s Regulatory Impact Analysis has documented costs to be over $656 million in the first year and over $131 million in subsequent years. Manufacturers are already in a difficult position—health care costs continue to skyrocket, yet they continue to offer health benefits for their employees.

Due to the extreme, expensive, and futile burdens this rule places on manufacturers, DOL should rescind the final rule. Manufacturers are committed to continuing to offer mental health and substance use disorder benefits to their employees. This rule makes that objective harder and less attainable.

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The NAM appreciates President Trump’s commitment to reconsidering burdensome regulations that harm our nation’s competitiveness. Manufacturers are committed to working with DOL to effect commonsense labor policies that support our operations and empower the American worker.

Sincerely,

Charles Crain
Managing Vice President, Policy

NATIONAL ASSOCIATION OF Manufacturers

**Charles Crain**

*Managing Vice President, Policy*

April 17, 2025

Craig Burkhardt
Deputy Under Secretary for Standards and Technology and Acting Director
National Institute of Standards and Technology
U.S. Department of Commerce
100 Bureau Drive
Gaithersburg, MD 20899

Dear Mr. Burkhardt:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the National Institute of Standards and Technology ("NIST") to formally withdraw the previous Administration's Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("the proposed guidance").

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

Manufacturing is the most innovation-dependent sector of the economy, accounting for 53% of private-sector research and development ("R&D"). This innovation allows manufacturers to commercialize products that improve and save the lives of countless Americans. Lifesaving medicines, advanced semiconductors, energy solutions and more: these innovations are the result of years or decades of manufacturing ingenuity and investment and of partnerships with and licensing from America's research universities.

Turning groundbreaking R&D into innovative products for the American people is only possible if creators—from university researchers to early-stage entrepreneurs to established businesses—can rely on strong intellectual property ("IP") protections. Unfortunately, the Biden Administration's proposed guidance would enable the government to "march in" and seize the right of a manufacturer to a patent that derives from federally funded research if the government arbitrarily decides that the price of a product or technology that incorporates this patent is too high. As the NAM noted in our comments in response to the proposed guidance,[1] the threat of price controls, which would be imposed after a company has invested and spent the years of work that are most often necessary to develop, manufacture and commercialize a product, inserts significant uncertainties into the

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[1] *Comment on Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, (National Association of Manufacturers, February 6, 2024), https://documents.nam.org/tech/20240206%20nam_march-in_comments.pdf

innovation ecosystem and tempers companies' willingness to embark on the years or decades of research and millions or billions of dollars of investment necessary to bring innovative products to market.

This would have significant, detrimental impacts throughout America's innovation economy—harming researchers, entrepreneurs, investors and manufacturers alike. At the earliest stages of research, the threat of march-in would disincentivize university researchers and entrepreneurs from getting projects off the ground—stymieing innovation and striking a blow to the local economies throughout the United States that depend on university-centered innovation hubs for job creation and economic growth. It would leave the fruits of taxpayer-funded research collecting dust on laboratory shelves—resulting in fewer groundbreaking technologies and a hobbled U.S. innovation economy.

For these reasons, manufacturers believe that the proposed guidance "harm[s] the national interest by significantly and unjustifiably impeding technological innovation, … research and development, [and] economic development" and "impede private enterprise and entrepreneurship," in contradiction with sec. 2(a)(vi) and (vii) of EO 14219.

The NAM also respectfully calls to your attention the contradiction between the letter and intent of the Patent and Trademark Law Amendments Act of 1980, also known as the Bayh-Dole Act (35 U.S.C. 18), and the proposed guidance. The Bayh-Dole Act allows the government to march in on the rights associated with federally funded patents only in very limited circumstances—so much so that march-in has never previously been used in the 45 years since the law's enactment. In fact, using price as a criterion for march-in would violate both the letter and intent of the Bayh-Dole Act—a limitation made clear by the law's authors, the late Sens. Birch Bayh and Bob Dole.[2] For this reason, manufacturers believe that the proposed guidance is "based on anything other than the best reading of the underlying statutory authority," in contradiction with sec. 2(a)(iii) of EO 14219.

The Biden Administration did not withdraw the proposed guidance, allowing any future Administration to quickly publish it as final guidance. This prospect chills technology transfers from universities to industry and the marketplace. That is why manufacturers respectfully urge you to immediately and unequivocally repudiate and withdraw this proposal.

* * * *

Technology transfer allows the private sector to take the important discoveries enabled by taxpayer-funded research and transform them into products that improve and save the lives of Americans and provide jobs for our nation's workers. Manufacturers stand ready to work with the Administration and NIST to ensure the U.S. maintains the strongest IP protections in the world.

Sincerely,

Charles Crain
Managing Vice President, Policy

CC: The Honorable Howard W. Lutnick, U.S. Secretary of Commerce

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[2] Birch Bayh and Bob Dole, "Our Law Helps Patients Get New Drugs Sooner," *The Washington Post*, April 11, 2002, https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

NATIONAL ASSOCIATION OF Manufacturers

**Charles Crain**

*Managing Vice President, Policy*

April 17, 2025

The Honorable Robert F. Kennedy Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Kennedy:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. All sectors of manufacturing have been affected by these unbalanced regulations, including the biopharmaceutical manufacturers that are impacted by regulations from the Department of Health and Human Services ("HHS"), the National Institutes of Health ("NIH"), and the Centers for Medicare and Medicaid Services ("CMS"). As such, the NAM encourages HHS to consider several overreaching and burdensome regulatory actions from the previous Administration as potential candidates for review, revision, or rescission pursuant to President Trump's EO.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

Biopharmaceutical companies are innovative manufacturers that discover and bring to market incredible new medicines to treat and cure challenging conditions. The average investment by a biopharmaceutical company to bring a medicine to market is approximately $2.3 billion[1] over 10 to 15 years.[2] Further, just 12% of the investigational drugs that enter a phase I clinical trial are ultimately approved by the FDA, meaning the other 88% fail along the way[3]—to say nothing of the hundreds of discoveries that never make it into clinical trials. This cycle of discovery and development makes biopharmaceutical manufacturers economic engines, accounting for $355 billion in value-added output to the U.S. economy in 2021 and supporting an additional 4.1 jobs for every

[1] Deloitte. "Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022" (January 2023). Available at https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf

[2] Pew Charitable Trusts. "From Lab Bench to Bedside: A Backgrounder on Drug Development" (March 2014). Available at https://www.pewtrusts.org/en/research-and-analysis/articles/2014/03/12/from-lab-bench-to-bedside-a-backgrounder-on-drug-development

[3] DiMasi, Joseph A., Grabowski, Henry G., and Hansen, Ronald W. "Innovation in the pharmaceutical industry: New estimates of R&D costs." J Health Econ. 2016; 47:20-33.

person employed by a biopharmaceutical manufacturer.[4] Rescinding or revising unworkable regulations in accordance with EO 14219 would unlock biopharmaceutical innovation and further cement the United States as the leader in this field.

**National Institutes of Health**

Manufacturers value their collaboration with scientists in the NIH's intramural research program. NIH staff scientists conduct important basic research in their labs, but that research cannot help patients unless it is turned into medicines or diagnostic products. Public-private partnerships with biopharmaceutical and medical diagnostics manufacturers, made possible by today's technology transfer system, can lead to substantial private sector investment in treatments and cures for devastating diseases. NIH research funding also yields significant economic benefits that reaches well beyond its original recipients: in FY 2024, the $36.94 billion awarded by the NIH to support research supported 407,782 jobs and $94.58 billion in new economic activity nationwide.[5]

Under the current technology transfer process, companies work with the NIH in a mutually beneficial research, development, clinical trial and commercialization cycle. The company, the NIH and patients all benefit tremendously when this cycle is successful. However, the Intramural Research Program Access Planning Policy ("licensing guidelines") published by the NIH on January 10, 2025 changed the licensing process to add conditions that inject more uncertainty into the commercialization process. This makes companies less willing or able to participate in the technology transfer cycle, leaving the NIH's inventions stuck in the lab and fewer life sciences discoveries becoming life-changing and life-saving treatments for patients. In other words, this would weaken one of the key differentiators of the U.S. health care policy architecture on the global stage: its commitment to bringing scientific innovations to market.

Specifically, the licensing guidelines require companies to submit a plan to promote patient access to a future product—with "patient access" defined to include affordability, availability, acceptability, and sustainability—along with a company's license application. The biopharmaceutical industry is committed to patient access but, at such an early stage of the drug development process, companies do not have meaningful insights into commercially relevant factors such as production costs, price, required partnerships, and associated intellectual property sublicensing terms, or into any of the other specific metrics for patient access laid out in the licensing guidelines. As such, requiring companies to submit such detailed access plans injects significant uncertainty into the drug development process.

In particular, manufacturers are concerned that the elements of the proposed access plan related to affordability represent de facto price controls on groundbreaking medical innovations. Biopharmaceutical manufacturers are committed to ensuring that patients can access their products, but imposing price controls before the decade-plus of work needed to commercialize a treatment inserts new uncertainties into the licensing process and tempers companies' willingness to collaborate with the NIH. More broadly, price controls at any stage of the development or commercialization process hamper innovation and limit companies' ability to bring life-changing and life-saving treatments to patients.

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[4] National Association of Manufacturers. "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing" (October 2023). Available at https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf

[5] See "NIH's Role in Sustaining the U.S. Economy," March 2025, by United for Medical Research, available at https://www.unitedformedicalresearch.org/wp-content/uploads/2025/03/UMR_NIH-Role-in-Sustaining-US-Economy-FY2024-2025-Update.pdf

For these reasons, manufacturers believe that the licensing guidelines “harm the national interest by significantly and unjustifiably impeding technological innovation, … research and development, economic development” and “impede private enterprise and entrepreneurship,” which requires their rescission per sec. 2(a)(vi) and (vii) of EO 14219.

The NAM also respectfully calls to your attention the contradiction between the letter and intent of the Patent and Trademark Law Amendments Act of 1980, also known as the Bayh-Dole Act (35 U.S.C. 18), and the licensing guidelines. The Bayh-Dole Act did, appropriately, seek to ensure that licensees of patents derived from federally funded research were intent on taking the invention to market, by requiring the submission of “a plan for development or marketing of the invention.” The guidelines’ access plans, however, go well beyond that statutory framework by requiring significant details about how licensees intend to make their products “affordable, available, acceptable, and sustainable” at a highly uncertain point of development.

For this reason, manufacturers believe that the licensing guidelines “are based on anything other than the best reading of the underlying statutory authority,” which requires their rescission per sec. 2(a)(iii) of EO 14219.

Technology transfer allows the private sector to take the important discoveries the NIH’s scientists make in the lab and transform those discoveries into products that improve the lives of patients. Together, the NIH and the private sector have made incredible strides in the areas of cancer, infectious diseases and neurological disorders, among many others. Manufacturers look forward to continuing such collaborations—and urge HHS and NIH to rescind the previous Administration’s licensing guidelines in order to facilitate these vital public-private partnerships.

**Centers for Medicare and Medicaid Services**

The Inflation Reduction Act (”IRA”) directed CMS to implement the Medicare Drug Price Negotiation Program via instruction or other forms of guidance. Manufacturers strongly oppose this program, as it has imposed devastating price controls on biopharmaceutical innovators. Price controls, and even the threat of price controls, stifle innovation and erode the United States’ standing in biopharmaceutical research and product development. Further, shifting the balance of incentives away from innovation and R&D may ultimately harm patients. The United States’ leadership in biopharmaceutical innovation could be at significant risk if government price controls persist. Manufacturers respectfully request that the Trump Administration take any and all steps possible to mitigate the risks to American innovation that the IRA creates.

CMS issued guidance in a March 15, 2023 memo titled “Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments.” CMS exceeded its authority under the IRA in how it defined certain terms in the memo, going beyond the statutory language and, as a result, imposing extra statutory limitations on biopharmaceutical manufacturers. In subsequent guidance memos, CMS maintained its definitions. The terms detailed below should be reconsidered per EO 14219.

**Qualifying Single Source Drug**

In its March 2023 memo, CMS stated its intent to identify qualifying single source drugs (“QSSDs”) in accordance with section 1192(e) of the IRA. Once identified as a QSSD, drugs are eligible for price control negotiation. However, CMS’s novel definition of QSSDs is at odds with the criteria included in the statutory text.

The IRA's criteria for a QSSD includes approval by the FDA at least seven years (for drugs) or eleven years (for biologics) prior to selection for negotiation, the drug being marketed under a New Drug Application ("NDA") and there being no approved and marketed generic or biosimilar competition.

In its March 2023 memo, however, CMS stated that it would aggregate as a QSSD any drugs marketed under separate NDAs when determining drugs eligible for selection and negotiation. Specifically, the memo stated that "all dosage forms and strengths of the drug with the same active moiety and the same holder of an NDA" would be considered one drug under this QSSD definition, even if the drugs are marketed under different NDAs. For biologics, the memo stated that all dosage forms and strengths of a biologic "with the same active ingredient and the same holder of a Biologics License Application (BLA)" would be considered the same QSSD, even if the products are marketed under different BLAs. While the IRA permits aggregated data to be used in determining a QSSD, it does not require that all dosage forms and strengths be considered the same QSSD nor does it mention moieties or active ingredients, unlike CMS's March 2023 memo. Unlike using aggregated data to *identify* a QSSD, aggregating multiple individual NDAs or BLAs to *define* them as a single QSSD eligible for negotiation undermines both the text and the intent of the statute. Indeed, CMS's use of erroneous criteria has led to drugs being selected for negotiation that would otherwise not have been, expanding the reach of the IRA's damaging price control program.

Manufacturers continue to believe that the IRA's drug price controls pose a significant risk to life-saving innovation in the United States. To the extent that CMS continues this program, it should prevent its impact from spreading to treatments outside the scope of the statute by rescinding the definition of QSSD adopted by the Biden Administration and instead using only the criteria for defining a QSSD included in the statutory text.

**"Bona Fide Marketing" Requirement**

In its March 2023 memo, CMS further diverged from the statutory text of the IRA by narrowing the meaning of "marketed" with regard to generic or biosimilar competition. The IRA's price controls only apply to treatments without approved *and marketed* generic or biosimilar competition—so narrowing what categories of competitors qualify as "marketed" effectively broadens the reach of the program.

CMS stated in its March 2023 memo that it would "consider a generic drug or biosimilar biological product to be marketed when…the manufacturer of that drug or product has engaged in bona fide marketing of that drug or product." To implement this requirement, CMS stated that it would monitor generic drug and biosimilar manufacturers to determine whether they are engaging in "bona fide marketing." The memo lacks sufficient detail to define what constitutes bona fide marketing, instead relying on case-by-case judgement calls by CMS. This "the government will know it when it sees it" standard creates significant uncertainty for biopharmaceutical manufacturers, which could easily be obviated by relying on marketing definitions already found in other programs. As with the criteria used for QSSDs, the use of the "bona fide marketing" requirement has led to the inclusion of drugs in the program that would otherwise not have been subjected to price controls.

In response to stakeholder comments and other critiques regarding CMS's lack of authority to create the "bona fide marketing" requirement, CMS has stood firm in its position. Given its lack of authority, manufacturers respectfully encourage CMS to terminate the previous Administration's use of the "bona fide marketing" requirement and instead to use the term "marketed" as directed by the IRA. Adhering to the statutory text in implementing this requirement would prevent CMS from expanding the price controls program and its threats to innovation beyond what Congress intended.

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Manufacturers appreciate HHS's consideration of these regulations, which we believe are strong candidates to be rescinded per President Trump's EO. As previously stated, the existing regulatory onslaught created by the previous Administration is stifling biopharmaceutical manufacturing and harming patients. The United States can, and must, remain the leader of this industry—and repealing unworkable regulations is an important step towards that goal.

Sincerely,

Charles Crain
Managing Vice President, Policy

CC: Dr. Jay Bhattacharya, Director, National Institutes of Health
Dr. Mehmet Oz, Administrator, Centers for Medicare and Medicaid Services

NATIONAL ASSOCIATION OF Manufacturers

**Charles Crain**

*Managing Vice President, Policy*

April 17, 2025

The Honorable Bridget Bean
Executive Director
Cybersecurity and Infrastructure Security Agency
1100 Hampton Park Boulevard
Capitol Heights, MD 20743

Dear Executive Director Bean:

The National Association of Manufacturers ("NAM") respectfully submits this letter in response to President Trump's Executive Order 14219, entitled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which sets in motion agency review processes designed to enable a new chapter of balanced, sensible, and pro-growth regulations. Manufacturers have faced a regulatory onslaught in recent years, with annual compliance costs on our industry exceeding $350 billion. As such, the NAM encourages the Cybersecurity and Infrastructure Security Agency ("CISA") to withdraw the rule[1] proposed by the Biden Administration to implement the reporting requirements of the Cyber Incident Reporting for Critical Infrastructure Act of 2022 ("CIRCIA") and to promulgate a revised rule that implements the law within the bounds of congressional intent and minimizes unnecessary regulatory burdens on manufacturers.

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that supports and empowers the 13 million people who make things in America. As the largest manufacturing association in the U.S., the NAM's membership includes businesses of all sizes, across all industrial sectors, and in all 50 states. Manufacturers collectively contribute $2.93 trillion to the U.S. economy—and right-sized, commonsense regulations are critical to sustaining the manufacturing strength that underpins our nation's prosperity.

Manufacturers of all sizes and in all sectors understand that protecting their enterprises from cybersecurity risk is critical to their success in today's economy. Through comprehensive and connected relationships with customers, vendors, suppliers and governments, manufacturers are entrusted with vast amounts of highly sensitive data and intellectual property. The industry takes seriously its responsibility to secure information, networks, facilities and critical infrastructure ("CI") against attacks by nation-states, criminals and other malicious actors. Manufacturers also know that cybersecurity is a shared responsibility, and the industry appreciates efforts by CISA and the Department of Homeland Security to build a collaborative and productive partnership with the private sector.

However, manufacturers believe that CISA erred as it sought to implement the reporting requirements created by CIRCIA. CISA should only require cyber incident information in such quantity that it can actually process and act upon. CISA has acknowledged that its proposed rule would lead to tens of thousands of reports a year, well beyond the capacity of its current or future automated systems and teams of human analysts to analyze and from which to extract and disseminate actionable intelligence. Manufacturers believe that CISA should have drastically

[1] Federal Register Vol. 89, No. 66, Thursday, April 4, 2024, available at https://www.govinfo.gov/content/pkg/FR-2024-04-04/pdf/2024-06526.pdf.

reduced the number of entities required to report cyber incidents and the number of incidents and amount of information they would be required to report. In particular, the NAM's comments on CISA's proposed rule offered several opportunities to improve the rule and make it more workable for both manufacturers and CISA:[2]

- **Narrow the scope of "covered entities"**—CISA should focus on entities that own or operate CI systems and assets, rather than include any entity that is "in a critical infrastructure sector." CISA also should exclude small businesses even if they own or operate CI systems and assets.[3] Additionally, CISA should develop a clearer and narrower criterion for the critical manufacturing sector, to only cover entities upon whose uninterrupted production operations the security of our homeland is dependent.

- **Narrow the scope of reportable cyber incidents**—CISA should develop a narrower definition of "substantial cyber incident" in order to curb overreporting, focus reporting on threats to CI systems and assets and prevent inconsistent and excessive reporting of threats to cloud-based systems. In keeping with the President's agenda of re-balancing federal regulations, CISA also should more vigorously pursue harmonization of cyber incident reporting requirements across federal agencies.

- **Lighten and protect the contents of cyber incident reports**—CISA should significantly trim down the data elements to be reported under CIRCIA, to avoid placing a heavy and intrusive burden on the cyber incident response teams of CI owners and operators while they are in the midst of stopping, mitigating and recovering from cyber incidents. The rule should also extend full legal protections to all information and documents pertaining to incident analysis and response, and to any incident report made by an employee or service provider even if the reporter does not have authority from the entity to report on its behalf.

For these reasons, manufacturers believe that the Biden Administration's rule "impose[s] significant costs upon private parties that are not outweighed by public benefits," "harm[s] the national interest by significantly and unjustifiably impeding … infrastructure development, disaster response, economic development, [and] energy production," and "impose[s] undue burdens on small business," in contradiction with sec. 2(a)(vi) and (vii) of EO 14219.

Additionally, manufacturers share the concern expressed by congressional cybersecurity policy leaders, such as House Committee on Homeland Security Chairman Mark Green,[4] Subcommittee on

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[2] A more detailed account of manufacturers' concerns with the proposed rule, and their recommendations for improving it, is in the NAM's submission, available at https://documents.nam.org/tech/CIRCIA%20-%20NAM%20submission%20FINAL.pdf, as well as the related submission of the NAM and 50 other trade associations, available at https://documents.nam.org/tech/20240701%20trade%20association%20letter%20re%20CIRCIA%20FINAL.pdf.

[3] Sec. 226.2(a) and (b) of the proposed rule exclude small businesses only if they do not own or operate CI but are more broadly in a CI sector.

[4] Chairman Green: "There are now at least 50 cyber incident reporting requirements in effect across the federal government. These regulations are often duplicative and complex, requiring private sector owners and operators to invest significant sums into regulatory compliance rather than security. This patchwork of conflicting and complex regulations place a significant burden on reporting entities. Let's be clear: improving our nation's cyber regulatory regime will bolster our national security. Current cyber incident reporting regulations require too much of the private sector, drawing their attention away from securing their networks. Injecting consistency and efficiency into the cyber regulatory regime is necessary to protect our nation from digital threats to our critical infrastructure. The security of our homeland depends on effective cooperation between the private and public sectors, and it is our duty to help remove any unnecessary barriers to collaboration. Since CIRCIA is still in the rulemaking process until later this year, there is still time to ensure that regulatory effectiveness and harmonization are core features of our national cyber

Cybersecurity and Infrastructure Protection Chairman Andrew Garbarino,[5] House Committee on Homeland Security Ranking Member Bennie Thompson[6] or original CIRCIA sponsor Rep. Yvette Clarke,[7] that the proposed CIRCIA rule is “based on anything other than the best reading of the underlying statutory authority,” in contradiction with sec. 2(a)(iii) of EO 14219.

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Manufacturers look forward to continuing to work with CISA to support the development of a rule implementing CIRCIA that contributes to improved public-private, sectoral and cross-sectoral information sharing and supports rather than impeding the incident response efforts of critical infrastructure owners and operators that are targeted by malicious cyber actors.

Sincerely,

Charles Crain
Managing Vice President, Policy

CC: The Honorable Kristi Noem, U.S. Secretary of Homeland Security

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incident reporting requirements.” Opening statements at the hearing on “Regulatory Harm or Harmonization? Examining the Opportunity to Improve the Cyber Regulatory Regime,”, March 11, 2025, available at https://homeland.house.gov/2025/03/11/chairmen-garbarino-green-deliver-opening-statements-in-hearing-on-cyber-regulatory-harmonization/

[5] Chairman Garbarino: “When organizations face their most vulnerable moment, they should only be thinking about one thing: securing their networks. Hours of duplicative compliance tasks and hundreds of thousands of dollars invested to navigate the landscape must come to an end. With President Trump’s mandate to increase government efficiency and reduce regulatory burden, we have an opportunity to reset the regulatory regime once and for all. … Unfortunately … the scope of the proposed CIRCIA rule went far beyond congressional intent. Knowing that the deadline for the final rule is approaching, we will dig into the value of CIRCIA and what the future of the rule should look like. This new administration presents an opportunity to get cyber incident reporting right. We should seize it.” Opening statement at the hearing on “Regulatory Harm or Harmonization? Examining the Opportunity to Improve the Cyber Regulatory Regime,”, March 11, 2025, available at https://homeland.house.gov/2025/03/11/chairmen-garbarino-green-deliver-opening-statements-in-hearing-on-cyber-regulatory-harmonization/

[6] Ranking Member Thompson: "The administration should work expeditiously to engage the private sector on CIRCIA to calibrate the scope so a final rule can be issued without undue delay." Statement to Politico Pro Morning Cybersecurity, March 11, 2025, available at https://subscriber.politicopro.com/newsletter/2025/03/saying-no-to-cyber-regs-00222466 (subscription).

[7] Rep. Clarke stated that the “consensus” among CIRCIA’s congressional champions was that the implementation of CIRCIA would “benefit from a well-scoped incident reporting framework,” and that Congress “[did] not expect all critical infrastructure owners and operators to be subject to [CIRCIA’s] reporting requirement.” Remarks by Rep. Yvette Clark, hearing on “Surveying CIRCIA: Sector Perspectives on the Notice of Proposed Rulemaking,” Subcommittee on Cybersecurity and Infrastructure Protection, Committee on Homeland Security, U.S. House of Representatives, May 1, 2024, available at https://homeland.house.gov/hearing/surveying-circia-sector-perspectives-on-the-notice-of-proposed-rulemaking/