NATIONAL ASSOCIATION OF Manufacturers

Charles Crain

Managing Vice President,
Policy

July 14, 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

Re: Docket number: AHRQ-2025-0001: Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again

Dear Secretary Kennedy,

The National Association of Manufacturers ("NAM") appreciates the opportunity to submit comments to the Department of Health and Human Services ("HHS") in response to its Request for Information ("RFI") on "Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again." Manufacturers commend the Trump Administration for its commitment to reversing the regulatory onslaught of the previous administration, which imposed regulatory costs of more than $350 billion per year on the manufacturing industry. All sectors of manufacturing have been affected by these unbalanced regulations, including biopharmaceutical manufacturers that are impacted by regulations from HHS.

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 Food and Drug Administration ("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 person employed by a biopharmaceutical manufacturer.[4] Rescinding or revising unworkable regulations would unlock biopharmaceutical innovation and further cement the United States as the leader in this field.

Medicare Drug Price Negotiation Program

[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.
[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

The Inflation Reduction Act (”IRA”) directed the Centers for Medicare and Medicaid Services (“CMS”) to implement the Medicare Drug Price Negotiation Program. 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 research and development (“R&D”) may ultimately harm patients. The United States’ leadership in biopharmaceutical innovation could be at significant risk if government price controls persist. Manufacturers urge policymakers to reconsider the potentially disastrous effects of this program and the threats it could pose to patient access to innovative medications.

The NAM submitted a letter to CMS Administrator Mehmet Oz in response to the Draft Guidance for Initial Price Applicability Year (“IPAY”) 2028, which included comments on the pill penalty and definitions for “qualifying single source drugs (“QSSDs”) and “marketed,” as discussed below.

Pill Penalty: Disparity Between Small Molecule Drugs and Biologics

Under the price controls program, pharmaceutical manufacturers are disincentivized from developing small molecule drugs, as they are eligible for negotiation four years sooner than large molecule biologics—and thus have a shorter time frame for manufacturers to recoup the high costs of R&D. Parity between small molecule drugs and biologics at thirteen years of exclusivity for both would remove this disincentive. This is particularly important for patients—small molecule drugs are often the first line of prevention and treatment, as they can be taken at home rather than administered in a hospital setting. For certain therapeutic areas, small molecule drugs may be the only treatment method.

Data shows that negative consequences of the IRA, and the pill penalty in particular, are materializing when it comes to investment in drug development. A Vital Health report published in the Therapeutic Innovation and Regulatory Science journal showed an overall decline in the development of therapies for patient populations over the age of 65 and an even greater decline in small molecule therapies.[5] Vital Health’s report also revealed that investments in small molecule therapies decreased 68% after passage of the IRA. Pharmaceutical manufacturers are proud of the innovative, life-saving, and life-improving treatments they develop. Disparity in the exclusion periods before eligibility for price controls is already harming patients counting on manufacturers to develop the therapies they need. Parity should be a top priority to mitigate negative ramifications for patients.

“Qualifying Single Source Drugs” Definition

As discussed in the NAM’s June 2025 letter regarding the Draft Guidance for IPAY 2028 and April 2025 letter regarding Executive Order (“EO”) 14219, CMS’s novel definition of QSSDs is at odds with the criteria in the statute. 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 draft guidance for IPAY 2028, 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 guidance states 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 guidance states 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

[5] Vital Transformation. “The Inflation Reduction Act’s Impact Upon Early-Stage Venture Capital Investments” (April 2025). Available at https://link.springer.com/article/10.1007/s43441-025-00773-3

moieties or active ingredients. 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.

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 drug price control program. Additionally, the criteria disincentivizes innovation in a way that will be detrimental to patients. By treating distinct products as interchangeable, CMS overlooks the unique benefits that tailored treatments can provide and will reduce manufacturer incentives to develop important innovations that have significant benefit to patients and caregivers. Manufacturers ask that CMS use only the criteria for defining a QSSD included in the statutory text to prevent such negative impacts to treatments and patients.

"Marketed" Definition

CMS has further diverged from the statutory text of the IRA by narrowing the meaning of "marketed" with regard to generic or biosimilar competition in its draft guidance for IPAY 2028. 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.

In the draft guidance, CMS stated that it would "consider a generic drug or biosimilar to be marketed when…the manufacturer of that approved generic drug or licensed biosimilar is engaging in bona fide marketing of that drug or biosimilar." 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 draft guidance 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.

Manufacturers respectfully encourage CMS to terminate its 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.

Modernization of Cosmetics Regulation Act of 2022

The Modernization of Cosmetics Regulation Act of 2022 ("MoCRA") became law as part of the Consolidated Appropriations Act, 2023. The statute requires the Secretary of Health and Human Services to "establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products." On December 27, 2024, President Biden's FDA issued a Proposed Rule, which contains significant flaws that will severely damage the U.S. economy.

The NAM submitted a comment letter in response to the proposed rule, which stated—

> "This Proposed Rule is important to manufacturers across the country, spanning multiple industries, as well as the people who make things in America – those who will face the serious potential economic consequences that the rule, if finalized, would impose. Absent revision, these consequences pose substantial risks to manufacturing in the U.S. The economic analysis undertaken in support of the Proposed Rule fails to account for the high likelihood of false positives resulting from the Proposed Rule. It also fails to account for the host of costs and burdens such findings will introduce, and as such ignores the widespread impact the Proposed Rule is likely to inflict on the broader U.S. economy."

> "The Proposed Rule's approach to talc testing and mineral identification risks misidentification of non-asbestos minerals as "asbestos'"…[but] does not allow for additional testing to clarify or confirm initial results. This poses the risk of widespread and substantial economic consequences, a reality that the FDA impermissibly fails to account for in its narrow cost-benefit analysis. For example, while the FDA quantifies the "costs to talc suppliers and to cosmetics manufacturers to read and understand the rule and to test talc for asbestos,"(*see* 89 FR at 105492), it fails to calculate any costs for replacement goods, mandated yet unnecessary product recalls, reformulation of products with other as-yet-identified raw materials, and similar outcomes that necessarily will be triggered by routine "positive" findings of "asbestos" in talc. Accordingly, the FDA's conclusion that "the proposed rule would impose small costs on affected firms, relative to annual revenue," and "will not have a significant economic impact on a substantial number of small entities[,]" (*id*. at 105499), is counterfactual and ignores the more robust analysis required under the circumstances."

On May 20, 2025, the FDA convened an Expert Panel on talc safety that presented a one-sided perspective that portended FDA's intention to ban the use of talc as an ingredient in food and drugs, which will lead to massive costs across multiple sectors of the economy if enacted. A more expansive ban would adversely impact not only cosmetic manufacturers and sellers, but other industries that use talc in their manufacturing processes or in products themselves, including paint, ceramics, automotive parts, paper, plastics, rubber, and roofing. Collectively these industries consist of 76,000 companies employing 6.5 million Americans.[6]

This RFI seeks information regarding regulations that are conflicting. The Occupational Safety and Health Administration ("OSHA") and the National Institute for Occupational Safety and Health ("NIOSH") have already issued their own criteria for asbestos testing and exposure analysis. Therefore, it would be impossible to explain how a mineral particle might be reported as "asbestos" when found in cosmetic talc, yet that exact same particle would not be "asbestos" when found in other material. When viewed in this way, the proposed rule has severe economic consequences beyond cosmetic talc.

The proposed rule could lead the aforementioned industries that are already governed by OSHA[7] and NIOSH-issued[8] criteria for asbestos testing and exposure analysis, to adopt a new testing methodology that is in line with this proposed rule. This could lead to devastating economic impacts across industries.

The Biden FDA and Office of Management and Budget also failed to account for harm to U.S. businesses and the American economy that would result from the litigation that would likely be brought against companies using minerals that would be deemed "asbestos" under the proposed rule. Even in the absence of the Proposed Rule, cosmetic talc litigation has become a multi-million-dollar business with more than 75,000 cases being filed to date. This is despite the FDA's release of results of its 2023 sampling assignment, which tested talc-containing cosmetic products for the presence of asbestos and did not detect asbestos in any of the 50 samples tested. The sudden and widespread reporting of false "positive" findings that will result from the proposed rule will undoubtedly make its way into such litigation and subject manufacturers to unjustified verdict risk.

By 2022, the total annual costs associated with litigation and compensation in the US tort system were estimated at $529 billion, representing approximately 2.1% of GDP.[9] Tort liability spend during the period of 2016–2022 increased at 7.1% annually, far faster than average annual inflation (3.4%) and

---

[6] The Statistics of U.S. Businesses (SUSB) data contain annual economic metrics for U.S. businesses. The data include the number of firms/establishments, as well as employment during the week of March 12, 2021.
[7] *See, e.g.*, 29 CFR § 1910.1001 Appx. A, B, & J.
[8] *See, e.g.*, NIOSH Method 7400, "Asbestos and Other Fibers by PCM,"; and NIOSH Method 7402, "Asbestos by TEM."
[9] U.S. Chamber of Commerce Institute for Legal Reform. *Tort Costs in America: An Empirical Analysis of Costs and Compensation of the U.S. Tort System* (3rd ed,) at 2, available at https://instituteforlegalreform.com/research/tort-costs-in-america-an-empirical-analysis-of-costs-and-compensation-in-the-u-s-tort-system-third-edition/.

annual GDP growth (5.4%) over the same period.[10] The proposed rule will inevitably further increase those costs of litigation by requiring companies to report "asbestos" in talc when no asbestos is present, in effect raising their hand for an onslaught of false claims against them.

Manufacturers urge HHS to rescind the proposed rule to ensure the economy is not harmed by this misguided regulation that does not achieve its aim.

Interim Final Rule (RIN 0694-AJ95) on Cytometers and Mass Spectrometry Equipment

EO 14219 relates to regulations that harm the national interest by significantly and unjustifiably impeding technological innovation and research and development. Although it does not directly fall under HHS authority, a Department of Commerce Interim Final Rule ("IFR") on cytometers and mass spectrometry equipment is relevant to the HHS regulatory review. On January 16, 2025, the Department of Commerce Bureau of Industry and Security revised the Export Administration Regulations to move high parameter flow cytometers and certain mass spectrometry equipment from their current control under export control classification number ECCN 3A999 into new ECCN 3A069. The IFR was issued by the Biden Administration in such a way that it bypassed standard rulemaking processes in order to take effect just prior to the change in administration. As the rule deals with technically complex biotechnology products, BIS should have followed federal rulemaking procedures, which include consultation with industry stakeholders and relevant agencies such as HHS.

Second, the export controls in the IFR are crafted in a way that will limit their ability to achieve their stated goals. Export controls are most effective when they meaningfully control all possible sources of an item and its substitutes. In this instance, high-parameter flow cytometry technology has existed for decades, and the equipment is extensively developed and manufactured globally, including in China. Chinese companies currently make biotechnology products that compete with the products of manufacturers who would be impacted by this IFR. Restricting U.S. companies' ability to export, reexport, and transfer such products to destinations such as China would not reduce the availability of high-parameter spectral flow cytometers in China but would harm commercial opportunities for U.S. manufacturers while enabling competing producers and products to reach the same end users. For these reasons, manufacturers ask that HHS seek that BIS consider revisions to the IFR that will enable BIS to achieve its stated goals while also ensuring that U.S. manufacturers retain their competitive advantage and position as suppliers of innovative biotechnology equipment in the global marketplace. The NAM sent a letter to BIS on March 17, 2025 sharing our concerns on the IFR.

*****

Manufacturers appreciate HHS's consideration of these regulations, which we believe are strong candidates to be rebalanced or rescinded. 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

[10] *Id.*