NATIONAL ASSOCIATION OF Manufacturers

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The Honorable Bill Cassidy, M.D.
Chair
Committee on Health, Education, Labor, and Pensions
United State Senate
Washington, DC 20510

Dear Chair Cassidy,

On behalf of the National Association of Manufacturers and the 13 million people who make things in America, thank you for holding today's hearing of the Senate Committee on Health, Education, Labor, and Pensions ("HELP") on the future of biotech.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Small and medium-sized manufacturers make up the majority of manufacturing businesses in the United States and employ approximately 40% of manufacturing workers.

Biopharmaceutical companies are among the most innovative manufacturers, researching, developing, and producing incredible new medicines that treat and cure complex conditions. On average, bringing a medicine to market requires an investment of 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 many discoveries that never make it to the clinical trial phase. 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]

Biopharmaceutical manufacturers are committed to continuing to innovate and develop new and better cures and therapies. The NAM supports targeted policy solutions to maintain U.S. competitiveness and ensure that the biotech industry can continue to deliver lifesaving cures to patients:

- Medicare Drug Price Negotiation Program ("MDPNP"): The MDPNP was created by the Inflation Reduction Act ("IRA"). Manufacturers strongly oppose this program, as it has imposed devastating price controls on biopharmaceutical innovators. Price controls, and

[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

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 may ultimately harm patients. The United States' leadership in biopharmaceutical innovation could be at significant risk if government price controls persist. Manufacturers urge the reconsideration of the potentially disastrous effects of this program and the threats it could pose to patient access to innovative medications.

- Pill Penalty within the MDPNP: Under the MDRNP, pharmaceutical manufacturers are disincentivized from developing small molecule drugs, as they are subjected to price controls four years sooner than large molecule biologics—and thus have a shorter time frame for manufacturers to recoup the high costs of research and development. 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 method for treating a disease or condition. 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] The 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. Should repeal of the MDPNP as a whole not be possible, parity should be a top priority to mitigate negative ramifications for patients.

- Most-Favored-Nation ("MFN") Drug Pricing: As NAM President and CEO Jay Timmons said earlier this year, "European-style price controls will stifle innovation—undermining R&D and limiting future access to breakthrough treatments." Many foreign countries have government policies that fail to properly value innovation, including clawback and other revenue return mechanisms. For decades, some of the largest markets for U.S. innovative medicines, including Canada, Europe, Japan, and South Korea, have imposed discriminatory and nontransparent policies that undervalue American innovation, limiting the resources available to support U.S. research and development and jobs associated with manufacturing in the U.S. However, foreign governments use price controls and reimbursement delays among other practices to, in effect, discount the innovation in U.S.-manufactured pharmaceuticals. Domestic price controls would further impede biopharmaceutical innovation. The NAM submitted a comment letter to USTR's RFC *Regarding Foreign Nations Freeloading on American-Financed Innovation*, which argued that USTR should engage our trading partners to secure non-discriminatory and fair market access terms through changes to market access policies in foreign markets, as well as pursue robust intellectual property rights that are adequately enforced. This would level the playing field and ensure that U.S. patients do not bear an unfair burden of funding global innovation without importing price controls to the domestic market.

- Trade Policy: For manufacturers in the U.S. to sustain our nation's global advantage in the discovery, development, production and delivery of pharmaceuticals, it is essential to

[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

safeguard a stable, reliable, and diversified pharmaceutical supply chain network. The NAM submitted a comment letter responding to the Department of Commerce's Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, which argued that immediate and broad-based tariffs on imports of pharmaceutical inputs and finished products, many of which are sourced from allies and through related party transactions, undermines that very supply chain network. That not only harms our global advantage — it also imposes severe and preventable costs at home, particularly in the risk that undermining the pharmaceutical industry's supply chain network will in turn drive health care costs for American patients while causing shortages for American consumers.

The NAM appreciates this Committee's commitment to ensuring manufacturing workers can access affordable health care. Manufacturers have a deep commitment to providing health benefits to their workers, even as rising health care costs remain a top challenge for the industry. Sixty-five percent of all manufacturers, 67.5% of small manufacturers, and 78.9% of medium-sized manufacturers cited health care and insurance costs as their primary concern in the NAM's most recent Manufacturers' Outlook Survey.[6] Despite this challenge, 95% of manufacturing employees are eligible for health insurance benefits, 80% of whom participate, which underscores the urgent need for action to reduce health care costs for manufacturers and manufacturing workers alike.[7]

The NAM supports policies that would reduce health care costs for manufacturing employers and employees while protecting biopharmaceutical innovation.

- Pharmacy Benefit Manager ("PBM") Reform: PBM reform is urgently needed. PBMs are underregulated middlemen that design, negotiate, and administer prescription drug benefits on behalf of health insurance companies and employers that self-fund health insurance plans for their employees. PBMs contribute to the skyrocketing cost of health care by tying patient cost-sharing to list prices, pocketing manufacturer rebates, and obscuring their concerning business models. Necessary reforms include increased transparency, the delinking of PBM compensation from the list price of medicines, and full rebate passthrough to the plan and its beneficiaries in the commercial market.

- Reform of the 340B Program: The 340B program has rapidly and massively expanded beyond its intent to provide lower cost medicines and expand care for low-income and underserved patients. Covered entities have taken advantage of the program to increase their profits, which has become a cost driver of employer sponsored insurance. The 340B program allows participating hospitals to charge patients' insurance the full list price (without rebates) for drugs acquired at 340B prices, which results in patients and employers paying more and hospitals keeping the spread. The expansion of this program was associated with approximately $23 billion in additional employer-based healthcare expenses in 2023, of which employees paid about $4.5 billion per year in added insurance premiums. An IQVIA study found that the 340B program increases drug costs for self-insured employers and their workers by 4.2% due to the manufacturer rebates that are lost when drugs are purchased at the 340B discount price. This corresponds to a $5.2 billion increase in healthcare costs for self-insured employers and the 103.4 million workers they employ. Manufacturers commend the Committee for issuing a report on this important topic

[6] National Association of Manufacturers, Q3 2025 Manufacturers' Outlook Survey (May 30, 2025). Available at https://nam.org/wp-content/uploads/securepdfs/2025/09/NAM_Q3_2025_Outlook_Write_Up.pdf.
[7] Kaiser Family Foundation, *2025 Employer Health Benefits Survey* (Oct. 22, 2025). Available at https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2025-Annual-Survey.pdf

in April and holding hearing on 340B earlier this month; we encourage you to build on this progress with legislation that returns the program to its original intent.

Manufacturers appreciate the Committee's timely hearing on biotech innovation. The NAM looks forward to continuing to work with the HELP Committee to ensure biopharmaceutical manufacturers can continue to develop, and bring to market, life-saving drugs, while safeguarding the United States' position as a global leader.

Sincerely,

Jake Kuhns
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