NATIONAL ASSOCIATION OF Manufacturers

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Vice President,
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The Honorable Elizabeth Warren
Chair
Subcommittee on Personnel
Committee on Armed Services
U.S. Senate
Washington, DC 20510

The Honorable Rick Scott
Ranking Member
Subcommittee on Personnel
Committee on Armed Services
U.S. Senate
Washington, DC 20510

Dear Chair Warren and Ranking Member Scott,

The National Association of Manufacturers appreciates the Subcommittee holding today's hearing on servicemembers' access to safe, high-quality pharmaceuticals.

The NAM is the largest manufacturing association in the United States, representing manufacturers in every industrial sector and in all 50 states. Biopharmaceutical manufacturers accounted for $355 billion in value-added output to the U.S. economy in 2021 and directly employed 291,000 workers in the United States, with each of these jobs supporting an additional 4.1 jobs. The average employee in the industry earns roughly 3.5 times the U.S. workforce average income, and roughly 25% of all jobs in pharmaceutical and medicine manufacturing are STEM-related.[1]

Beyond the sector's economic impact, biopharmaceutical companies are innovative manufacturers that discover and bring to market incredible new medicines to treat and cure challenging conditions. In 2023, the Food and Drug Administration approved a record-breaking 71 new medicines that will improve the lives of patients, including U.S. servicemembers.[2] The investment necessary to bring these treatments to patients is immense: the average cost of developing a new drug was $2.3 billion as of 2022.[3]

These high development costs are reflective of the complex nature of groundbreaking R&D. Only 12% of investigational drugs that enter a Phase I clinical trial ultimately receive FDA approval[4]—to say nothing of the hundreds of discoveries that never make it into clinical trials. Further, breakthrough scientific discoveries take immense time, with early-stage research, clinical trials, FDA approval and manufacturing accounting for 10-15 years in most cases.[5]

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[1] 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.
[2] Senior, Melanie. "Fresh from the biotech pipeline: record-breaking FDA approvals." *Nature Biotechnology* (February 2024). *Available at* https://doi.org/10.1038/s41587-024-02166-7.
[3] 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.
[4] 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.
[5] 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.

Biopharmaceutical companies are committed to these extraordinary efforts, which in recent years have revolutionized treatments for COVID, cancer, HIV/AIDS, sickle cell disease, diabetes, obesity and more. Across the industry, biopharmaceutical manufacturers spent $139 billion on R&D in just 2022 alone.[6]

The NAM respectfully encourages members of the Subcommittee to be mindful that the costs of manufacturing a branded medicine include potentially decades of research and billions of dollars of investment—well before a single pill or injection is produced for public consumption. Additionally, a biopharmaceutical company likely will have undertaken years of research and millions or billions of dollars of investment into any number of *other* projects that may or may not prove scientifically viable.

Further, it is important to note that a treatment's list price is often significantly different from the price a patient pays at the pharmacy counter given biopharmaceutical manufacturers' efforts to reduce out-of-pocket costs via rebates and other programs that help patients afford needed treatments. The list price of a drug also includes external costs and pressures from other areas of the health care system that biopharmaceutical companies do not control. For example, the prices that Americans pay are heavily influenced by middlemen like pharmacy benefit managers. PBMs often dictate which medicines are covered by which health insurance plans, all while pocketing manufacturer rebates rather than passing them on to patients. Their compensation structure, under which higher list prices lead to higher PBM profits, means that patients pay more: in 2020, more than half of every dollar spent on brand medicines went to stakeholders other than the medicine's manufacturer.[7]

Congress must therefore exercise caution in considering policies that seek to address health care costs. Critically, policies like price controls, compulsory licensing and weaker intellectual property protections would hurt patients by reducing access to life-saving treatments.

Unfortunately, however, biopharmaceutical companies have already been subjected to these harmful policies in recent years, each of which will limit innovation and slow efforts to develop life-saving medicines. First and foremost is the Medicare Drug Price Negotiation Program, which subjects life-changing biopharmaceutical innovations to government price controls. At the same time, the Biden Administration has proposed unlawfully expanding the government's ability to "march in" on private sector patents, undermining the IP rights that are foundational to the biopharmaceutical business model. And the Federal Trade Commission has promulgated a new rule that will disincentivize, delay and potentially destroy innovative companies' ability to access capital via mergers and acquisitions.

These policies can harm product development at all stages of the biopharmaceutical life cycle. In particular, policies that undermine innovation will limit the early-stage capital available to finance novel research. Biopharma investors—both venture capitalists and larger biopharma companies that partner with or acquire smaller businesses—understand the uncertain and difficult nature of scientific advancement. They often fund a broad portfolio of projects, knowing that many will never make it to FDA approval. These investors need to know that the projects that do become life-changing treatments will be able to succeed in a fair marketplace and benefit from robust IP protections. Absent these policy guarantees, early-stage capital for the

[6] DiMasi et al., *supra* note 4.
[7] Brownlee, A., and Watson, J. "The Pharmaceutical Supply Chain, 2013-2020." Berkley Research Group (January 2022). *Available at* https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/.

industry will be under threat—as will potential treatments and cures for devastating diseases, and the innovation ecosystem that supports thousands of well-paying jobs across the country.

All Americans, including servicemembers, deserve access to high-quality, affordable health care. Biopharmaceutical manufacturers invest heavily in groundbreaking research in order to discover and commercialize medicines to save and improve these patients' lives. The NAM respectfully encourages Congress to avoid adopting policies that will stymie this life-saving innovation. Limiting drug development would significantly harm Americans from all walks of life, including servicemembers and their families.

Sincerely,

Charles Crain
Vice President, Domestic Policy