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The Honorable Dick Durbin
Chair
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

Dear Chair Durbin and Ranking Member Graham,

The National Association of Manufacturers appreciates the opportunity to share manufacturers' perspectives on today's Judiciary Committee hearing titled "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market."

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. Manufacturers make significant investments in research and development, accounting for more than half of all private-sector R&D in the United States. This research results in groundbreaking inventions that improve the quality of life for all Americans; it also supports well-paying jobs for the 13 million people who make things in America.

Biopharmaceutical manufacturers are a critical part of the manufacturing economy. These 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.[1] The average employee in the biopharmaceutical 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.[2] These manufacturers 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.[3] 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.[4]

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[5]—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

[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] *Ibid.*

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

[4] 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.

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

approval and manufacturing accounting for 10-15 years in most cases. 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 2022 alone.[6]

Biopharmaceutical companies and all innovative manufacturers depend on a regulatory environment that is conducive to innovation and R&D—and robust intellectual property protections are a cornerstone of a pro-innovation policy ecosystem. Strong IP rights enable innovators to develop and commercialize their discoveries, while weak IP frameworks disincentivize research into, investment in and commercialization of potentially revolutionary technologies.

Unfortunately, the Biden Administration took a step in the wrong direction last year when the National Institute of Standards and Technology proposed a new framework that would expand the government's ability to "march in" and seize manufacturers' IP rights. NIST's march-in proposal is fundamentally flawed and would have disastrous consequences on manufacturers, American innovation and the U.S. economy. The NAM respectfully encourages members of this Committee to call on the Administration to provide certainty to manufacturers and other stakeholders in the innovation economy by affirmatively and unequivocally withdrawing the proposed framework and making clear that the none of its recommendations will be implemented.

The Bayh-Dole Act, passed in 1980, allows recipients of federal research dollars to license groundbreaking technologies to private-sector companies to commercialize them. Prior to the act's passage, the government held approximately 28,000 patents—yet fewer than 4% of those patents were licensed to the private sector. Bayh-Dole includes a narrow march-in provision that allows the government to step in to ensure consumer access to certain products during times of crisis—but march-in has never previously been used during the 44 years since the law's enactment.

Allowing march-in based on the price of a product or technology, as the NIST guidance proposes, would not only violate the letter and intent of the Bayh-Dole Act: it would undermine manufacturers' IP rights and have sweeping ramifications for innovation in the United States and America's world-leading innovation economy. These impacts would be felt in the biopharmaceutical sector and at innovative companies across the country. In particular, start-ups and small businesses would bear the brunt of the drastic changes proposed, as the spectre of government march-in would disincentivize early-stage entrepreneurship and dissuade much-needed capital formation from outside investors. It would also hinder industry collaborations with research universities and laboratories across the country, stymieing manufacturers' efforts to develop the products and technologies of the future and bring them to the public.

In the biopharmaceutical sector, NIST's proposed march-in guidance will substantially weaken the incentives for companies to engage in, and for investors to fund, the work that goes into transforming a federally funded researcher's newly patented discovery into a commercialized medicine. Biopharmaceutical investors—both venture capitalists and larger biopharmaceutical 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, many with federally funded research at their core, 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. The proposed march-in guidance puts this early-stage capital under threat—as well as the therapeutic development pipeline that may include the secrets to unlocking treatments and cures for even more devastating diseases.

[6] Deloitte, "Seize the Digital Momentum," *supra* note 4.

In short, IP protections are critical to biopharmaceutical innovation. Biopharmaceutical manufacturers fuel the American economy, and biopharmaceutical products change and save lives around the world. Policies that threaten IP protections, like NIST's proposed march-in guidance, will cede one of our greatest advantages to our competitors. Manufacturers stand ready to work with the Committee to ensure the U.S. maintains the strongest IP protections in the world in order to spur the discovery and commercialization of inventions that improve health and quality of life for all people.

Sincerely,

Charles Crain
Vice President, Domestic Policy