NATIONAL ASSOCIATION OF Manufacturers

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The Honorable Martin A. Makary, M.D., M.P.H.
Administrator
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane
Rockville, MD 20857

Re: FDA Docket No. FDA-2025-N-2489 for "Onshoring Manufacturing of Drugs and Biological Products; Public Meeting; Request for Comments"

Dear Administrator Makary,

The National Association of Manufacturers ("NAM") appreciates the opportunity to submit comments to the Food and Drug Administration ("FDA") in response to the request for public comment on the "FDA PreCheck Program" proposal.

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 the 13 nearly 13 million manufacturing workers. Manufacturing contributes $2.94 trillion annually to the U.S. economy and accounts for nearly 53% of all private-sector research in the nation.

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]

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[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

To further drive economic growth through this significant investment in innovation, manufacturers support the FDA's efforts to strengthen the domestic pharmaceutical supply chain through the proposed PreCheck program. This program will provide the opportunity for early engagement and communication between manufacturers and the agency, which, in return, should allow for smoother processes and quicker timelines, both of which are critical for making new facilities operational.

As the RFC proposes, FDA involvement in facility design, construction, and equipment installation will lead to quicker operability with fewer delays. Inspections and review activities occurring earlier in the review process will shorten timelines for facility operability, as any issues that arise could be resolved before the decision date. Earlier feedback on Chemistry, Manufacturing and Controls will ease burdens on manufacturers and allow facilities to produce newly approved pharmaceuticals more quickly post-approval. The sooner newly approved drugs are manufactured and made available to patients, the stronger the return for America's manufacturing economy and the greater the hope and health delivered to the American people.

The NAM recommends FDA address several additional pain points within the current approval process in the PreCheck program:

- **Consistent Inspector and Liaison:** Maintaining the same inspector and review team throughout would enhance the benefits of the PreCheck program and create a smoother process. The NAM also supports FDA providing a liaison for manufacturers, which would ensure companies have a point of contact for questions and communication throughout the inspection and application process. For example, a liaison could visit a new facility prior to inspection to provide feedback and input earlier in the process. A liaison could also spur cooperation and communication among other agencies to speed up similar inspections and processes required for approval.

- **Decoupling Inspections and Approvals:** Decoupling facility inspections from drug approval submissions would allow for earlier inspections as they would not be dependent on a drug approval submission and could happen prior to a submission. For example, inspections of facilities that manufacture biologics are currently only conducted if the product under review is being manufactured. However, biologics may not need to be manufactured during the review process, and the need to start manufacturing them only for an inspection could lead to cost burdens. Alternatively, the FDA could consider substitutes for inspections, such as remote regulatory assessments.

- **Drug Master Files (DMFs):** Review of DMFs upon their submission would save time and prevent future delays. Currently DMFs are only reviewed when they are cross-referenced by a drug application. However, earlier review and clarification of the review process would enable any questions to be answered earlier.

- **Adequate Resources:** As the PreCheck program is finalized and implemented, appropriate resources will need to be allocated to prevent a reduction of resources for existing programs. Additional reviewers and inspectors will likely be necessary to actualize time savings in the build out of facilities. Manufacturers encourage FDA to ensure that the PreCheck program is appropriately resourced—without threatening existing critical programs—to ensure it is maximally effective at speeding facility inspections and helping biopharmaceutical manufacturers accelerate delivery of treatments to patients.

- **Scope of Program:** Manufacturers recommend that FDA broaden the scope of the PreCheck program to include expansions of existing domestic manufacturing facilities. Expansions of existing facilities only need to use Phase 1 of the PreCheck program. This broadened scope would have a substantial impact on the onshoring of manufacturing in the short term.

Reducing the time it takes to operationalize a new or expanded manufacturing facility will reduce the time it takes to onshore additional pharmaceutical manufacturing. This in turn will strengthen manufacturing in the U.S. and the U.S. drug supply chain. A stronger supply chain will reduce drug shortages for Americans, including manufacturing workers.

The pharmaceutical manufacturing sector is already committed to expanding domestic manufacturing capabilities. Numerous NAM member companies have announced investments in domestic manufacturing facilities, including:

- Johnson & Johnson announced in March that the company will spend more than $55 billion on manufacturing, research and technology in the U.S. over the next four years. These investments include a $2 billion state-of-the-art biologics facility in Wilson, North Carolina, which will support about 5,000 jobs during construction and create more than 500 permanent positions in the state.

- In February, Lilly announced $27 billion in new investments across four new U.S. manufacturing sites, which will create 3,000 permanent jobs and 10,000 construction jobs. Two of the locations have been announced: a $6.5 billion facility in Houston and a $6 billion facility in Goochland County, Virginia. This builds on previous announcements from 2020 to 2024 that totaled $23 billion, including: new sites in Research Triangle Park, Concord, North Carolina and Lebanon, Indiana; expansions of several different manufacturing facilities in Indianapolis, Indiana; and acquisition and expansion of Lilly's manufacturing site in Kenosha County, Wisconsin.

- AstraZeneca announced a further $3.5 billion investment to expand R&D and manufacturing in the U.S., including: specialty manufacturing in Texas, expanded cell therapy capacities on the West and East Coasts, a next generation manufacturing facility for biologics in Maryland, and a state-of-the-art R&D center in Massachusetts. This investment will create 1,000 new highly skilled jobs in the U.S.

- Novartis announced in April a planned $23 billion investment over 5 years in its U.S.-based infrastructure, ensuring all key Novartis medicines for U.S. patients will be made in the United States. The investment enables Novartis to expand its current manufacturing, research and technology presence with 10 facilities, including 7 brand new facilities, and is expected to create nearly 1,000 new jobs at Novartis and approximately 4,000 additional U.S. jobs.

- Merck has announced that, beginning in 2025, it will invest more than $70 billion to expand domestic manufacturing and research and development, not including any future business development transactions in R&D. So far this year, Merck has announced nearly $6 billion in manufacturing investments in North Carolina (a 25,000-square-foot vaccine manufacturing facility), Delaware (a state-of-the-art 470,000-square-foot biologics center of excellence), Kansas (a 200,000-square foot manufacturing facility),

and Virginia (a 400,000 sq. ft. state-of-the-art pharmaceutical center of excellence), which will create more than 1,600 new jobs in the U.S.

- Amgen announced a $900 million expansion of its biomanufacturing facility in Columbus, Ohio, bringing the total number of jobs created to 750 and the total investment in Central Ohio to more than $1.4 billion.

- Genentech and Roche announced a $50 billion investment that includes new state-of-the-art R&D site and new and expanded manufacturing facilities and will create more than 12,000 jobs. In August, Genentech broke ground on a 700,000-square foot manufacturing facility in North Carolina. This facility will create more than 1,900 jobs and support the production of next-generation metabolic medicines.

The PreCheck program could help increase the speed of these projects and help get domestically manufactured pharmaceutical products out the door. The quicker facilities are FDA approved and operational, the sooner pharmaceutical manufacturers can produce medications and put them in the hands of the patients who need them. This helps keep Americans healthy and strong and ensures a thriving workforce for all sectors within the manufacturing industry.

Perhaps the greatest hurdle manufacturers currently face, however, is not addressed by the proposed PreCheck program. The long timelines associated with permitting processes at the federal, state, and local levels and the lack of coordination amongst them create burdensome delays. This issue was included in Executive Order 14293 (titled “Regulatory Relief To Promote Domestic Production of Critical Medicines”) and it would be beneficial for FDA to push for collaboration with the appropriate agencies and entities to reduce onerous delays.

The NAM appreciates FDA’s consideration of these comments and manufacturers look forward to working with you to effectuate the PreCheck program and help ensure a strong future for domestic biopharmaceutical manufacturing.

Sincerely,

Jake Kuhns
Vice President, Domestic Policy