



October 24, 2025

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

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

To whom it may concern:

I am writing on behalf of [We Work For Health](#), an alliance of national and local business leaders, labor, the biopharma sector, patient advocates and other healthcare-related stakeholders that support policies and initiatives that foster innovation and facilitate the delivery of lifesaving and life-enhancing medicines.

We Work For Health has long championed policies that encourage the development of new biopharmaceutical manufacturing and research facilities in the United States, generating significant economic growth and creating jobs with strong compensation and valuable benefits for American employees and their communities.

We Work For Health has been actively [tracking](#) every U.S. biopharma facility public announcement and news report in 2025. Thus far in 2025, more than \$425 billion has been publicly announced, collectively, by these companies to build new and expand and improve existing facilities in the U.S. This is a more than 13-fold increase in facility investment announcements over 2024 and will result in the creation of tens of thousands of new construction jobs alone.

These investments create seismic ripple effects across the economy. [Data](#) we published in 2022 analyzed biopharmaceutical company spending on vendors and contractors, focusing on the impact of 15 companies. These companies alone supported more than 1 million direct jobs across all 50 states, the District of Columbia and Puerto Rico. Moreover, their combined vendor spending – exceeding \$71 billion on budgets ranging from construction to custodial services – supported more than 4.9 million jobs, both directly and indirectly, across the country.

The positive momentum in current and future biopharma investment in the U.S. should be applauded and supported, especially as there is ongoing effort from China to supplant the U.S. as the world’s leader in biopharmaceutical innovation.

In recent years, China has been outpacing the U.S. in several drug development categories. In 2024, China registered approximately 7,100 clinical trials compared to roughly 6,000 in the U.S. last year. And between 2019 and 2023, China approved 256 new drugs, surpassing 243 approvals in the U.S. over the same period.



To maintain the U.S. position as a global leader in biopharmaceutical innovation, public policies must actively incentivize investment in research, development and manufacturing. Unfortunately, current policy trends are moving in the opposite direction.

If the U.S. continues down this path, the ramifications for the biopharmaceutical industry and the nation's health and economy will be severe. Ceding global leadership in biopharmaceutical innovation to China will not only result in lost jobs and diminished economic development, but also restrict American citizens' access to innovative treatments, therapies and cures.

It is essential that policymakers in both the legislative and executive branches re-evaluate policies that hinder current and future innovation, as well as those that make the U.S. vulnerable to global competitors aiming to eclipse the nation's world leadership role.

We applaud the FDA for its focus on increasing drug research and manufacturing facilities domestically. With several biopharmaceutical companies working towards that, there is now a need for productive policy formulations to allow this positive direction to continue.

We appreciate this opportunity to comment on the FDA's public meeting focused on bringing new pharmaceutical manufacturing facilities to the U.S. to strengthen the domestic pharmaceutical supply chain.

Sincerely,

A handwritten signature in black ink, which appears to read 'Dan Leonard'. The signature is fluid and cursive, with a large loop at the end.

Dan Leonard
Executive Director
We Work For Health
www.weworkforhealth.org