

Statement for the Record: Massachusetts Biotechnology Council (MassBio)

U.S. House of Representatives
Committee on Energy and Commerce, Subcommittee on Health Hearing:
*“Maintaining America’s Leadership in Biomedical Innovation:
FDA’s Role in Advancing U.S. Drug Development”*
July 15, 2026

The Massachusetts Biotechnology Council (MassBio) appreciates the opportunity to submit this statement. MassBio represents more than 1,700 member organizations spanning every stage of the biopharmaceutical lifecycle, from first-time founders to global manufacturers, all united by the mission of bringing breakthrough medicines to patients. We commend the Subcommittee for examining the single most consequential question facing our industry: whether the United States will remain the place where the world’s most important and impactful medicines are discovered, developed, and brought to patients.

The United States remains the global leader in drug development, but that leadership is eroding. The cause is not a decline in our science. It is policy and regulatory unpredictability. Innovation is not leaving the United States because the FDA’s standards are too high; it is leaving because the process has become too uncertain, too slow, and too costly to plan around. That is a solvable problem, and it is within the power of Congress and the FDA to solve it without lowering the gold standard for safety and effectiveness that patients depend on.

Massachusetts: The Nation’s Leading Life Sciences Hub

Massachusetts is the center of gravity for global biopharmaceutical innovation. Our industry snapshot captures the breadth of our footprint.¹ Companies headquartered in Massachusetts account for 15.7% of the U.S. drug development pipeline and 6.4% of the entire global pipeline. Massachusetts is home to more than 700 active clinical trials and roughly 23% of the nation’s biopharma research and development workforce. In 2024 alone, 23 companies with a Massachusetts presence secured FDA approvals for therapies spanning RSV, schizophrenia, leukemia, and advanced cancers.²

This concentration is precisely why Massachusetts is an early warning system for the health of the national ecosystem. For the first time in the history of our annual Industry Snapshot, Massachusetts recorded a decline in R&D employment, and venture capital investment fell to its lowest level since

¹ https://www.massbio.org/wp-content/uploads/2025/08/FINAL-2025_IndustrySnapshot.pdf

² <https://www.massbio.org/news/recent-news/massbio-year-end-funding-report-released/>

2017. When the leading hub contracts, it signals stress that will be felt nationwide. The policy choices this Subcommittee examines will shape whether that stress reverses or deepens.

Early-Stage Research Is Moving Offshore

There is a clear trend across the ecosystem of research shifting abroad. China, Australia, and Europe have seen growing preclinical, Phase 1, and Phase 2 research, aided by faster and more predictable early-stage pathways abroad. MassBio's members are living this shift in real time. In a recent MassBio survey of biotech executives, the overwhelming majority representing small, early-stage companies that drive first-in-human innovation, the data is unambiguous.

- **On a level regulatory playing field, 78% of respondents rank the United States as their first choice for first-in-human (FIH) trials.** The American preference is overwhelming. Not a single respondent would choose China first if the regulatory environments were equivalent.
- **Under the current FDA environment, only 29% still rank the United States first.** The U.S. falls from an average rank of 1.5 to nearly 4 out of eight regions. Australia rises to the top choice, and China (chosen first by no one on a level field) draws first-place votes from five companies.
- **Half of all respondents say recent FDA changes make them less likely to run FIH trials in the United States.** 70% report they were already hesitant to run FIH trials here because of the regulatory framework.

The survey findings point to a clear result: American companies want to stay. Our science and our scientists remain the world's best, and no company is eager to move its most sensitive early work overseas. The variable pushing them abroad is the regulatory experience. Fortunately, this variable is fully within our control.

The Driver Is Cost and Uncertainty

It is essential to be precise about what is deterring domestic investment, because the answer refutes any suggestion that industry is seeking a weaker FDA. When asked to identify their top reasons for hesitancy in launching US-based trials, respondents pointed to economics and process, not scientific rigor. The cost of delay from a clinical hold was cited by 67% of respondents. The absence of clearly defined preclinical data requirements was cited by 42% of respondents. 37% of respondents cited Risk of not understanding/remediating pre-IND FDA feedback. Companies demand rigorous safety review. What deters them is the unpredictable financial consequences of a hold, especially when the preclinical data requirements aren't clearly defined upfront.

Not one respondent said they were free of hesitancy. As one executive put it in the survey's open-ended responses: *"Regulations that keep patients safe are good. Regulation that adds tens of millions of*

dollars in cost for no safety reason is concerning.” That distinction is the heart of the matter, and the root of regulatory flight abroad.

Much of that unpredictability traces to instability at the agency itself. Companies describe reaching agreement on a pivotal study protocol with the FDA only to have a new reviewer reverse course, stranding tens of millions of dollars at the most expensive stage of development. High turnover and unfilled senior vacancies compound the problem. The mode of engagement makes it worse: over the past five years, roughly 78% of respondents’ FDA interactions were written responses only, and a majority of executives reported that written feedback was ambiguous or confusing. Less than a third involved face-to-face interaction with meeting minutes.

Recommendations for Congress and the FDA

The Subcommittee asked how Congress and the FDA can modernize early-stage regulation while upholding the gold standard. MassBio offers four priorities, each drawn directly from member experience and each designed to increase predictability and speed without touching the safety bar.

1. **Modernize IND requirements and fix the No Observed Adverse Effect Level (NOAEL) dosing standard.** Congress should press the FDA to adopt risk-proportionate IND submission requirements, enable rolling IND submissions, and issue clear guidance defining preclinical data package expectations, so companies know the requirements before they invest. A concrete, high-consensus starting point from our survey: 87% of surveyed companies support limiting the 1/10 NOAEL guidance to setting a maximum safe starting dose rather than capping the maximum clinical dose, with human safety data driving the dose ceiling.
2. **Harmonize U.S. nonclinical data expectations with international standards.** The clearest competitiveness lever is to align U.S. nonclinical data requirements with those of Australia, the EU, and the UK. Companies are not asking the FDA to lower its bar; they are asking it to stop maintaining a uniquely burdensome one relative to peer regulators, particularly for rare-disease indications where the benefit-risk calculus differs from typical Phase 1 populations.
3. **Restore stability and commit to real-time engagement.** Congress should support filling FDA vacancies, reducing reviewer turnover, and establishing a commitment to real-time, face-to-face meetings with documented minutes rather than written-only feedback, paired with predictable review timelines. Our members consistently rate live engagement as clearer and more actionable than written responses.
4. **Make Operation TrialBlazer durable.** MassBio has long pressed for exactly the kind of reform Operation TrialBlazer represents, and we commend HHS and the FDA for launching it. But a roadmap advanced under acting leadership only matters if it is built to last. Congress should ensure these reforms are implemented with sustained industry input, that pilot programs become permanent policy, and that the FDA stands up a dedicated emerging-biotech function empowered

to resolve misalignments before they become costly delays. When companies were asked whether they would pilot a substantively restructured IND pathway, 80% responded they were highly likely to do so.

NIH: The Foundation of the Innovation Pipeline

American biomedical leadership does not begin at the FDA. It begins with the federally funded basic and translational research on which the entire private pipeline is built. NIH-supported science is the foundation from which biotech companies form, raise capital, and advance therapies toward the clinic. That foundation came under significant strain over the past year and has exposed how vulnerable the research base is to sudden, unpredictable funding decisions.

That vulnerability threatens to be exacerbated by proposals now under consideration. MassBio has raised serious concerns about a proposed federal rule governing federal financial assistance that would expand agencies' authority to terminate grants mid-award, subject funding to pre-issuance review against shifting priorities rather than the statutorily grounded, merit-based peer review that has long governed NIH, and restrict the international collaboration and scientific exchange on which research depends. Peer review is the mechanism that ensures federal dollars follow the best science; layering political review on top of it undermines the very commitment to gold-standard science the government, and this Committee, has set for itself. Drug development runs 10 to 15 years, and research of that duration cannot survive funding that can be revoked at will or redirected mid-course. This instability falls hardest on the small, pre-revenue companies that form the backbone of the Massachusetts ecosystem, and, as with clinical development, it does not strengthen American competitiveness. When research teams lose funding, they are recruited by competing clusters abroad.

The principle that should guide FDA reform should guide the research base as well: stability, predictability, and decisions grounded in scientific merit. Congress should protect NIH funding that is stable and merit-based and preserve the foundational basic research that keeps the United States at the center of global research.

What Is at Stake

The consequences of losing global leadership in clinical research are severe and cascading. Early-stage research sits at the front of the value chain: where first-in-human trials go it is reasonable to assume that later-stage development, manufacturing, intellectual property, and high-wage jobs will follow. And the competition is not just about where trials are run, but where innovation originates. China has become one of the world's largest sources of early-stage assets, with a rising share of first-in-class and best-in-class molecules discovered there. Between mid-2024 and mid-2025, China's drug pipeline grew by

nearly 17%, while Massachusetts grew 6.7%.³ China is projected to account for roughly 35% of FDA approvals by 2040 and already runs more registered clinical trials each year than the United States.⁴

This shift is compounded by the financing environment facing the companies that matter most. Public markets have reopened selectively, rewarding firms with mature clinical data and lower development risk. Capital increasingly finances clinical execution rather than scientific risk. Yet the companies carrying that scientific risk, such as those with first-in-class therapeutics, gene editing, RNA technologies, cell therapies, synthetic biology, are precisely those with the greatest long-term potential, and precisely those most exposed to FDA unpredictability. When regulatory friction is layered on top of a financing gap, the most scientifically ambitious companies are the first to stall, fail, or relocate.

A durable pipeline depends on a continuous supply of new early-stage companies. If the earliest stage becomes too costly and too uncertain to sustain, the ecosystem loses its capacity to replenish itself, and patients feel the consequence years later, in medicines that are never developed.

Ceding the earliest and most formative stage of drug development is therefore not merely an economic loss. It is a national security and public health vulnerability, surrendering influence over which medicines are developed, where they are manufactured, and under what data-integrity and patient-safety standards, to systems that do not share our own. Disruptions at one end of the scientific pipeline are felt at the other.

Faced with this competition, there is understandable pressure to respond with defensive measures, chief among them proposals to restrict the flow of American capital and investment abroad. MassBio shares the concern that biotechnology has become a strategic technology deserving of serious federal attention but urges that proper attention be paid to the secondary impacts of such policies. Measures that reduce capital formation or cut off access to promising science, without building new domestic capacity in their place, risk producing fewer medicines for patients rather than greater security. The strongest and safest way to counter a rising competitor is to strengthen our own capabilities rather than simply constrain others.

Conclusion

The United States has not lost its scientific edge, and its companies are not eager to leave. The single largest force pushing early research offshore is a regulatory experience that has become unpredictable and costly, but it is a problem entirely within our power to fix. We encourage Congress and the FDA to focus on the speed, clarity, and engagement that peer nations already provide. Do that, and the strongest

³ https://www.massbio.org/wp-content/uploads/2025/08/FINAL-2025_IndustrySnapshot.pdf

⁴ <https://www.biotech.senate.gov/wp-content/uploads/2025/12/NSCEB-Future-of-U.S.-China-Biotech-Competition-Dec-2025.pdf>

reason to develop anywhere but here disappears. Regulatory modernization is necessary, but it is not sufficient on its own. Sustaining American leadership will also depend on a healthy environment for early-stage financing and a strong federal research base to feed the pipeline the FDA then helps advance.

MassBio and our members stand ready to serve as a resource to the Subcommittee as it advances this work. We thank you for your leadership and for the opportunity to submit this statement for the record.

Respectfully,

A handwritten signature in grey ink, appearing to be 'KB' or similar initials, written in a cursive style.

Kendalle Burlin O'Connell
President & CEO
Massachusetts Biotechnology Council