ALLIANCE FOR A STRONGER FDA

Senate Appropriations Committee
Biomedical Research: Keeping America's Edge in Innovation
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Good morning, Chairwoman Collins and Ranking Member Murray and Members of the Senate Appropriations Committee. My name is Cartier Esham, and I serve as the Executive Director of the Alliance for a Stronger FDA. Thank you for the opportunity to share with you our insights on what is needed to keep America's position as the global leader in biomedical research.

The Alliance for a Stronger FDA is a group of more than 150 FDA stakeholders, including consumer and patient advocates, research advocates, health professions societies, biopharmaceutical companies, and trade associations. This diverse group of advocates are united about the vital role the FDA plays in safeguarding health, fostering innovation, and maintaining the United States' global leadership in biomedical research and development. And while this hearing and my testimony are focused on the impact of FDA on biomedical research, I would like to convey the importance of the role FDA serves in ensuring the safety of our nation's food and cosmetic supply. FDA oversees and monitors the safety of domestic and imported foods, working to prevent contamination, foodborne illnesses, and fraudulent labeling. It also regulates drugs, devices, animal food and animal food additives for over 100 million companion animals and more than 10 billion food animals. Strong FDA support and oversight is essential for increasing consumer confidence in everyday products, from produce and dairy to packaged goods and dietary supplements.

The biomedical research ecosystem in the United States is propelled by:

1) Support for foundational research that continues to advance our understanding of the underlying causes of diseases and how to prevent, cure and treat them;
2) Support for research and policies that enable the advancement and adoption of new technologies that can, among other things, improve clinical outcomes, increase use of patient perspective data, support continued understanding of clinical benefits, and expedite the path from the bench to the bedside;
3) Support for biomedical research and policies that enable the timely advancement of scientific discovery to human clinical trials; and
4) An FDA that works to innovate the regulatory environment and has the expertise, tools and capacity required to keep pace with scientific and technological advancements and to provide efficient reviews and approvals of medical interventions that are based on a gold standard of efficacy.

Support for these biomedical innovation pillars are also drivers of private investment into next generation medicines and medtech.[1] An FDA that is not innovative, not able to keep pace with technological and scientific advancements or not able to manage its workload in an optimal manner will negatively impact continued investment in next generation medical interventions that could cure or vastly improve the quality of lives for millions of Americans and their families.

The U.S. biopharmaceutical industry directly employs over 1 million people and supports more than 3.8 million additional U.S. jobs.[2] In 2024 there were 5,318 clinical trial starts returning to pre-pandemic levels after a multi-year decline. The United States accounted for 35% of these clinical trial starts, China accounted for 30% and Europe for 21%. The majority of these clinical trial starts (63%) were launched by emerging biopharma companies.[3] This is a particular important statistic when you consider that these companies are mainly pre-revenue and their ability to continue to raise funds for clinical development programs is heavily influenced by whether there is a regulatory agency such as the FDA with the expertise, capacity and forward leaning approaches required to review novel medicines.[1]

In 2024 there were 14,870 active commercial and research investigational new drug programs at the Center for Drug Evaluation and Research Center (CDER) representing a 38% increase since 2014. Globally, clinical trial starts for cell and gene therapies have tripled since 2015 (171 vs 533).[4] CBER was managing 2,500 clinical trials in 2023 with more than 3,000 trials in pre-clinical development.[5] These pipelines represent the potential for improving the lives of millions of patients and their families. Right now, there are a tremendous number of trials focused on rare diseases and over 3,400 clinical trials focused on neurodegenerative, neuromuscular and psychiatric disorders. Alzheimer's disease, depression and Parkinson's disease each have had 200 trials launched over the past 5 years.[3,6]

In 2024 the Center for Drug Evaluation and Research approved 50 novel medicines - 34 of which were approved in the U.S. first, as well as 371 first time generics and 18 biosimilars.[7,8] The Center for Biologics Evaluation and Research approved 19 novel medicines.[9] Among these approvals was the first new mechanism of action approved for the treatment of schizophrenia in decades. This new treatment has the potential to improve the lives of the 3.7 million Americans who suffer from this disease. In 2024, the FDA also approved the first ever treatment for the 10-

[1] No Patient Left Behind Letter to Senate HELP Comm. on Preserving and Modernizing the FDA
[2] McClung, 2024. Biopharmaceutical industry supports jobs and drives economic growth across U.S.
[3] Global Trends in R&D 2025, IQVIA Institute for Human Data Science.
[4] FDA-TRACK: CDER
[5] Brennan. Endpoints. 2023
[6] IQVIA – From Orphan to Opportunity: Mastering Rare Disease Launch Excellence (2024)
[7] CDER: New Drug Approvals 2024
[8] Generic Drugs Programs Activities Report FY 2024
[9] Mulero. BioSpace.2023.

15 million Americans suffering from non-alcoholic steatohepatitis (NASH) and a new cell therapy treatment for solid cancers (tumor-infiltrating lymphocytes cell therapy).[10] Over the past 5 years there has been 143 orphan drug treatments launched in the U.S., and while this is sign of great progress, much more work needs to be done with 95% of patients with rare diseases still without substantive treatments.[6]

Most of the novel medicines approved in 2024 continued to be launched in the U.S. first (48), 60% of which were first-in-class medicines.[3] Among the U.S. launches, 63% were done by emerging biopharma companies. Four EU member countries (France, Germany, Italy and Spain) and the UK has the second highest number of novel medicine launches (38, a 23% increase from 2023), and 35 were launched in China (a 47% increase from 2015-2019). China has continued to reduce the time between its first global launch and launch in China to 3.7 years (down from 9.6 years from 2005-2009). Interestingly, most international R&D merger and acquisitions and licensing deals involving Chinese companies were outward with an international entity acquiring or in-licensing from China.[3] This year Chinese companies have accounted for 42% of deals worth $50M or more, an increase of 20% from 2023 according to data from DealForma.[11] The strength of the FDA is an important influencing factor in determining where first launches occur.[1]

Medtech is responsible for two million direct and indirect jobs in the United States.[12] The U.S. is a global leader in the medical device industry supporting $43 billion in exports. It is important to note that China has identified medical devices as a priority for increasing its domestic capabilities.[13] This sector is projected to continue to grow over the next five years with global sales projected to reach $800 billion by 2030 due to increasing demand for wearable medtech and health data collection services.[14] Approximately 82% of medical device companies are small companies which like biopharmaceutical companies depend on an FDA that has the expertise and capacity to conduct timely review of their product to advance their innovations.[12]

The Center for Devices and Radiological Health manages 248,400 regulated devices and there are over 7,000 different types of devices including pacemakers, hearing aids, vascular stent systems, lasers and ultrasound equipment. In 2024 CDRH authorized 120 novel devices and received over 24,400 submissions. The number of innovative medical devices authorized by CDRH has increased 5-fold since 2009.[15]

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[10] Mullard. Nature Reviews. 2025. Vol. 24
[11] Whitlock. Endpoints. 2025
[12] AdvaMed Annual Report. 2024 Year in Review
[13] Medical Devices Fact Sheet1 – U.S. Chamber
[14] KPMG Medical Devices 2030
[15] CDRH 2024 Annual Report

Over the past ten years, the FDA has worked to improve the regulatory environment for medical devices.[16] There has been a statistically significant increase in the proportion of U.S. first launches from 2013 and 1 in 5 of those had expedited review, an indicator of how regulatory reforms can influence global trends.[17] The overall number of devices that were launched first in the U.S. or in parallel with other countries increased from 54.8% in 2022 to 64.9% in 2024.[14]

Over the past few years, FDA has authorized exciting new medtech including the first over-the-counter continuous glucose monitor, an AI enabled system for pediatric autism diagnosis, Air pods now cleared as over-the-counter hearing aids, a spine simulator that is designed to restore the function of the upper extremities for patients with spinal cord injuries, and an artificial heart that was implanted in human for the first time.[15,18]

As we look at the advancement of technology and medicine, in 2024 there were 12 AI/ML (artificial intelligence/machine learning) biopharmaceutical deals to support, among other things, protein optimization, drug discovery, and patient cohort identification and we saw the launch of the world's first AI-generated gene editor (OpenCRISPR-1). The number of drug and biologic applications submitted to the FDA using AI/ML increased 12-fold between 2020 and 2022.[3] Over the past 10 years FDA approvals of AI/ML enabled medical devices has increased quite significantly with nearly 1,000 authorized as of December 2024.[15,19] These are examples of why it is critically important that the FDA be provided the necessary resources to keep pace with medical and technological advancements, so the benefits of these technologies are fully realized by the American public.

Closing Remarks

It cannot be overstated how critical the role of the FDA is for safeguarding health, fostering innovation, and maintaining the United States' global leadership in biomedical research and development. The agency's highly skilled cadre of scientists, medical experts, and regulatory professionals, with employees stationed in all 50 states, allow medical breakthroughs to reach patients safely and efficiently. From overseeing the clinical development of new medical devices, drugs and biologics, to determining whether a medical intervention met the gold standard for approval and continued oversight of approved products, the FDA's workforce acts as a bridge between groundbreaking science and patient access, facilitating the transformation of laboratory discoveries into real-world treatments. We all share a common goal and understanding that a strong, well-functioning and innovative FDA is essential to the well-being

[16] Shuren J. CDRH announces expansion of the Total Product Life Cycle Advisory Program. July 1, 2024. Accessed October 10, 2024.
[17] Kadakia et. al. JAMA Netw Open. 2024 Dec 6;7(12):e2449298. doi
[18] https://www.fda.gov/medical-devices/device-approvals-and-clearances/recently-approved-devicesCDRH
[19] Tjoe et. al. Insight.2024. FDA Approvals of AI Medical Devices Rises Rapidly

of millions of Americans and for ensuring American leadership and global competitiveness in emerging science and technology and we are here to help achieve that goal.