

AIMBE POSITION STATEMENT

Engineering Solutions for the 21st Century

Issue: Ensuring an Adequate Approval Pathway for the Food and Drug Administration

The regulatory approval pathway for innovative, life-saving drugs, vaccines, biologics and medical technologies is lengthy, unpredictable and cumbersome. The Food and Drug Administration, a mission-critical public health agency, is struggling to keep pace with its increasing responsibilities, globalization and increased scientific complexity. The result is unfortunate delays in bringing job creating and life saving products to market, directly threatening the United States' leadership position in the medical innovation economy. The ability of start-up companies to navigate the approval pathway is especially difficult.

The solution is complex, but the cause largely derives from a combination of deficiencies in both the regulatory process and in regulatory science, as well as the accompanying engineering needed to translate these systems to the public. Improvements in the process are needed to make obtaining approval more predictable, less cumbersome, and less expensive ensuring the timely flow of new and safe therapeutics and medical devices to American patients while boosting U.S. economic productivity and global competitiveness. Just as operations research, industrial engineering, process engineering, and systems engineering were keenly important in the productivity ramp-up for World War II and growth of the post-war American era, so too are engineering and applied science the key route toward more effective delivery and regulation of biological and medical products for our world. *Current calls for improvements in regulatory science need to be seen in terms of regulatory science and engineering.* These efforts speak to the development and deployment of technologies, such as computer simulated human trials, specifically designed to enhance efficiency and lower costs associated with the evaluation of medical and pharmaceutical innovations. AIMBE advocates that the FDA must develop new tools, public education, technology, leadership and approaches to enhance the approval pathway and regulatory science environment. AIMBE urges Congress to:

- Establish a rigorous and urgent approach for improving the ability of the FDA to practice an efficient and effective approval process, ensuring maximum public benefit in a shorter amount of time.
- Provide the FDA and partners adequate resources and funding to accelerate the development and adoption of novel technologies that can enhance the efficiency and cost of regulatory science.

AIMBE stands ready to assist as an objective resource by providing access to its vast experience and expertise in academia, industry and professional societies.

Rationale:

The FDA's annual appropriation is comparatively small when matched against its mandate to ensure the safety and high quality of more than a trillion dollars worth of products critical for the survival and well-being of all Americans – products that include 80% of the United States' food supply, all pharmaceuticals, biologics, vaccines, medical devices, electronic products that emit radiation, animal drugs and feed, and cosmetics. The gap between the FDA's mandated responsibilities and their allocated resources jeopardizes the Agency's ability to protect and advance public health. FDA's leadership is committed to strengthening the science that supports medical product safety, but lacks the resources to



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improve, assess, redesign, and deploy a more efficient, transparent and flexible regulatory process and to enhance the science and technologies associated with the process. Thus, the regulatory pathway and continuous research, development, and innovation in medical and biological engineering has room for improvement.

Specific Recommendation:

AIMBE urges Congress to establish a mechanism that will rapidly lead to the changes and resources needed to improve the FDA's regulatory process. We also urge Congress to equip the FDA with adequate funding and resources to sustain and build its scientific expertise and to advance its regulatory science programs. This will ensure the Agency can effectively meet the emerging, complex challenges it faces in protecting America's public health. It will also serve as a direct investment in the economic health of the country, expediting the development and marketing of US-based medical technologies and therapeutics.

Additional Background:

Medical and biological engineering (MBE) is interdisciplinary – encompassing the development of medical and prosthetic technologies, pharmaceuticals, vaccines, biological agents, gene therapy, tissue engineering, regenerative medicine, personalized medicine, and health care information technology. Medical and biological engineers are continuously making new scientific discoveries that generate a “science of safety” – encompassing the entire life cycle of a drug or medical device. AIMBE is an organization that comprises the leading experts in all facets of this life cycle. AIMBE believes the government should take a special interest in supporting an improved pathway for the approval of drugs, devices and biologics at the FDA. Sluggish review of new products is costly, discourages investment or even engagement and denies patients access to the therapies they need. Additionally, AIMBE encourages a collaborative relationship with the FDA to facilitate the incorporation of biomedical engineers into the technical validation of new state-of-the-art technologies and procedures.

The Vast Contributions of Medical and Biological Engineering:

Medical and biological engineers play a vital role in keeping our citizens and our economy healthy. Americans reap the benefits of MBE every day – from X-rays or MRIs to pacemakers, prosthetics and new medicines to treat devastating diseases. Citizens have come to rely on the innovations that improve the quality of health care and extend and enhance our lives.

The American Institute for Medical and Biological Engineering (AIMBE) is a non-profit organization representing 50,000 individuals and the top 2% of medical and biological engineers. Also, AIMBE represents academic institutions, private industry, and other professional engineering societies. AIMBE was founded in 1991 to provide leadership and advocacy in medical and biological engineering for the benefit of society.

