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Client Alert

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Can FDA Be a Driving Force to Increase Access to Innovative Biomedical Technologies?

The United States is at a critical moment for the advancement of the biomedical industry. Despite the struggling U.S. economy, American pharmaceutical, medical device and biotech companies continue to maintain a competitive advantage in the global marketplace. Our track record of innovation includes not only breakthrough technologies that have created new therapeutic paradigms, but also a steady pace of product enhancements that over time have resulted in major improvements in health outcomes.

However, there are some signs that the health and growth of this industry is at increasing risk. The Food and Drug Administration (FDA) plays a central role in determining the success of medical product innovation, and the inability of the FDA to keep up with advances in regulatory science and medical innovation will jeopardize our country's continued leadership in medical innovation. In turn, such regulatory failures will obstruct access to new therapies that can save lives and make the delivery of healthcare in this country more effective and affordable. There is little debate that biomedical companies will waste less time and money navigating the regulatory and review process at the FDA when the process is more predictable, more transparent, better resourced and current with the latest advances in technology. These types of reform in the regulatory process will foster innovation, which will create a more robust product development pipeline. But is the FDA up to this challenge, and if so, what actions are needed at the FDA to adapt to the changing landscape and drive American biomedical innovation forward?

James Greenwood, president and CEO of the Biotechnology Industry Organization (BIO), recently wrote a thoughtful commentary on whether the FDA—in the 21st century—can improve its operations and approval processes to keep up with our nation's healthcare needs.[1] The average time between treatment discovery and commercial availability to patients in the U.S. is between 10 to 15 years, and Mr. Greenwood argues this pace of biotech innovation is much too long and insufficient to improve healthcare and reduce the human and financial burden of chronic and acute disease on society. It is well documented that biomedical innovation can save lives and dollars. Indeed, advances in new medical therapies offer real solutions to our most pressing healthcare needs. For example, Medicare is spending over $91 billion

1 Greenword, James C. "Can a 21st Century FDA Accelerate Biotech Innovation To Cure Disease and Save Lives," *Food and Drug Law Institute Food and Drug Policy Forum, Vol.1, Issue 18* (Sept. 2011). [Hereinafter: "Greenwood."]

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caring for people with Alzheimer's and other dementias, and Mr. Greenwood notes that delaying the onset of Alzheimer's by just five years could save the Medicare program $50 billion per year.[2] Such evidence underscores the critical need for the FDA to reassess how our regulatory review system should be structured and implemented to get the safest and most effective treatments to market at a faster and more efficient pace.

Shortly after Mr. Greenwood's article was published, the FDA released its own report on the challenges the agency faces in promoting the science and innovation it takes to ensure our nation is fully equipped to address the health challenges we face today and will see in the future. This report, titled "Driving Biomedical Innovation: Initiatives to Improve Products for Patients," sets forth how the FDA is working to position itself as a positive driving force as a regulator, but also to facilitate overall medical product innovation.[3] The report offers a candid assessment of what does and doesn't work in the current FDA regulatory framework, and is recommended reading for anyone with an interest in how our country can best reinvigorate the biomedical industries quest for new, state-of-the art medical products that patients and healthcare professionals need and on which they can rely.

A summary of the FDA report follows.

Rebuilding FDA's small business outreach services

The report acknowledges that innovation begins with the small business community. Small businesses have built much of the foundation of innovative FDA-approved medical products, including drugs, devices, biologics and diagnostics. After an internal review of the small business resources at the FDA, as well as discussions with small business owners, it became clear that the FDA needs to strengthen its outreach to small businesses and ensure that individuals with small business expertise can serve as a resource to others on FDA issues. To that end, the FDA announced it will establish an FDA Small Business Liaison program and a Young Entrepreneurs program, as well as establish a new partnership with the U.S. Small Business Administration. Through these efforts and others, the report states the FDA's intention to address the needs of small medical product companies through efforts to make the review process easier and more transparent, as well as by providing information that can help businesses prepare for the final phases leading to product approval and marketing.

Building infrastructure to drive and support personalized medicine

One of the most profound changes to medicine is the move toward tailored therapies, or personalized medicine. The ability to treat a certain type of patient who has a specific form of a disease eliminates the current trial-and-error process, reducing the need to expose patients to drugs that won't work for them. The report notes the FDA's intention to continue its leadership role in this area by building a system to support the development of these more personalized medicines, including investments in regulatory science and by clarifying agency policies.

2 *Id.* at 2.
3 "Driving Biomedical Innovation: Initiatives to Improve Products for Patients," *U.S. Food and Drug Administration* (October 2011). The report can be accessed at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM274464.pdf.

Creating rapid drug development pathway for targeted therapies

While there is general agreement that targeted therapies should be developed quickly, there is not a common understanding of how to speed up development while simultaneously gathering adequate evidence about the safety and effectiveness of the product. In response to this challenge, the FDA plans to host a series of scientific meetings with academic investigators, patient groups, drug developers, statistical and methodological experts, and ethicists to achieve a common understanding of steps needed when an investigational drug being studied for a serious disease shows exceptional promise during the early stages of development. The Center for Drug Evaluation and Research (CDER) will then publish draft guidance on an expedited development pathway.

Harnessing potential of data mining and information sharing, while maintaining strong privacy protections

Information technology is transforming the U.S. healthcare system and—through innovative capabilities—improving how we think about the development of new tools for medicines and how we can utilize patient information in a responsible way while protecting patient privacy. The FDA currently houses the largest known repository of clinical data, and its ability to analyze these data sets could revolutionize the development of new patient treatments that allow us to determine how different types of patients respond to therapy. To harness the potential of information sharing and data mining, the FDA states it will rebuild its IT and data analytic capabilities and establish science enclaves that will allow for the analysis of large, complex datasets while preserving patient privacy.

Increasing consistency and transparency in medical device review process

In January 2011, the FDA announced plans to make improvements to the medical device review process designed to encourage innovation within the medical device community. This effort included 25 actions that the FDA's medical device center announced it will take to improve the predictability, consistency, and transparency of its premarket review programs—important steps necessary to encourage innovation, address perceived barriers that can impede a product's timely progress to market while assuring that devices are both safe and effective. These FDA actions are designed to attract investors to innovative companies, predict estimated regulatory costs, and bring safe and effective products to patients more quickly.

Training next generation of innovators

One of our current economic challenges is the availability of jobs, including those in the biomedical enterprise that require highly technical and practical knowledge and expertise. Many of these jobs remained unfilled because there are not enough qualified candidates with the necessary skill sets to fill these positions. Building on the success of the FDA's Fellowship program, the FDA is designing a new Future Innovators Program that will bring practical regulatory science and policy training together to meet the scientific and technological demands of the 21st century. Under this competitive program, the FDA will bring promising candidates into the agency for training and experience that will provide the FDA with important outside expertise and perspective while equipping these innovators with highly marketable skills and experience.

Streamlining and reforming FDA regulations

In addition to developing new regulatory approaches designed to speed up access to innovative new therapies that are safe and effective for patients, the FDA is also taking proactive steps to reform its existing regulations. At the direction of the president and the FDA commissioner and based on public feedback, the agency is reviewing its current regulations to identify burdensome, unclear, obsolete, ineffective, or inefficient regulations. In addition, the FDA has been revising rules to spur innovation and access to care as a result of its existing retrospective review activities.[4]

Conclusion

The FDA Biomedical Innovation Report is a step in the right direction; however, the path forward will require additional communications and action among the FDA, industry, healthcare providers, clinical researchers, patient groups, and policy and legislative leaders. The FDA seems to recognize it must develop new approaches to manage the product approval process for the products of biomedical innovation, improve the regulatory science within the agency, and develop more effective institutional means to stay at the forefront of technological advances.

However, at times the FDA seems to lack an operational focus and drive within the executive branch and with Congress to accomplish these goals. Increased statutory responsibilities and globalization of FDA-regulated industries in recent decades have placed significant demands on the FDA and have at times diverted the FDA's ability and willingness to develop new strategies to meet today's pressing need to fast-track biomedical innovation. Thus, to accelerate biomedical innovation fully, Congress should consider steps to elevate the mission of the FDA for the challenges of today.[5] The Federal, Food, Drug, and Cosmetic Act provides that the FDA's mission is to promote and protect the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.[6] This is a broad Congressional delegation and is sufficient to outline the general priorities the FDA should follow. But it is not necessarily a clear action plan for today's challenges. We cannot rely entirely on the FDA's stated willingness to "drive biomedical innovation." A national directive is needed. The pathway for current advances, such as personalized medicine and other cutting-edge therapies should be more formally and forcefully recognized in the FDA's legislative mandate.[7] We should not accept any slippage in the initiatives the FDA has outlined to improve the medical product development ecosystem, and we need to hold the FDA, Executive branch, and Congress accountable for better strategic management perspectives and improvements within the agency. Only then will our nation be fully equipped to address the health challenges we face today.

4 For example, in 2011 the FDA issued a final rule modernizing the requirements for constituent materials in biological products and proposed a rule to update and make more flexible the sterility test requirements for biological products.
5 Greenwood, note 2, at 3.
6 21 U.S.C. § 393.
7 Greenwood, note 2, at 3.