FDA's New Efforts to Advance Biotechnology Innovation

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Scientific advances in biotechnology, such as genome editing and synthetic biology, hold enormous potential to improve human and animal health, animal welfare, and food security. And researchers and companies based in the United States helped pioneer these technologies. They position the U.S. as a global leader of this rapidly growing and highly promising field.

Scott Gottlieb, M.D., Commissioner of the U.S. Food and Drug Administration

To advance this progress, it's key that the FDA adopt a regulatory approach to these technologies that's as innovative and nimble as the opportunities that we're tasked with evaluating.

FDA is committed to helping ensure the safety of biotechnology products, while also facilitating innovation by applying a risk-based regulatory approach that provides developers with regulatory clarity and predictability and maintains public confidence in our regulatory system.

And we're taking some new steps to advance these goals. We know that products enabled by new techniques of biotechnology have the potential to significantly enhance public health.

For instance, these new methods can be used to alter animals to minimize or prevent their ability to spread human disease. Genome editing in animals and plants also can be used to produce human drugs, devices, or biologics, including tissues or organs for xenotransplantation. Scientists are also exploring editing the genomes of animals with the goal of improving the health and welfare of food producing animals and public health, for example by reducing their susceptibility to diseases like novel influenzas and resistance to zoonotic or foreign animal diseases.

Similar and equally beneficial applications of genome editing are currently being explored in food crops. These include our ability to develop disease-resistant plants and plants with increased

resistance to environmental stress. Such advances can have many advantages to consumers, including better yields, more product variety, and healthier nutrient profiles.

Anna Abram, FDA's Deputy Commissioner for Policy, Planning, Legislation, and Analysis

We believe the FDA is uniquely positioned — with the expertise, experience, credibility and trusted scientific framework — to advance innovation and support the development of products with immense potential for public benefit. And we're fully committed to these goals.

The breadth of FDA's statutory authorities and regulatory framework allows us to comprehensively review the potential impacts of products on both human and animal health. For example, for genetically engineered animals, FDA evaluates not only the safety of food or drug products derived from that animal, but also the effect of the genetic alteration on the health of the animal. FDA has decades of experience successfully evaluating products of complex technologies, such as recombinant DNA-derived plant foods, medicines made with nanotechnology, and cellular and gene therapy products.

Moreover, because of the wide spectrum of products that we regulate, and the in-depth scientific and policy engagement that the agency has with innovators and counterpart regulatory agencies around the world, FDA can help facilitate the progression of research and development. For example, we're focused on the timely transition of technologies from animal research models to products intended for use in humans. As our knowledge of genome editing applications increases over different product areas, we expect to build on those even greater synergies and increase our understanding to help with assessments of risks to human and animal health.

FDA will continue to apply a risk-based framework grounded in sound science to evaluate products of plant and animal biotechnology, and our framework will continue to evolve as science advances and experience with these technologies grows. We also look forward to working with stakeholders to help understand current scientific information and describe challenges and gaps in regulatory science that are important for our regulatory decision-making. We're also going to take new steps to help developers understand their responsibility to ensure product safety and we'll identify ways to help reduce unnecessary regulatory burden and undue barriers to bring potential beneficial products to commercialization while ensuring their safety.

Protecting and promoting public health is our mission and we're taking steps to help ensure the safety (and as applicable, effectiveness) of products that can benefit patients and consumers, while supporting innovation and sustaining public confidence.

To help advance these goals, in early May, FDA formed a new Biotech Working Group. This Working Group is comprised of representatives from multiple FDA centers and offices. In the coming months, we'll release an Action Plan that lays out the steps we intend to take to ensure that we have a flexible regulatory framework for evaluating the safety of products that also supports plant and animal biotechnology innovation.

Our actions will focus on three key areas:

First, advancing and protecting public and animal health by promoting innovation through an efficient and predictable science- and risk-based regulatory framework; second, strengthening public outreach and communication through strong, effective and transparent engagement with stakeholders; and third, increasing engagement with domestic and international partners through coordinated and collaborative actions to support regulatory alignment and efficiency.

The Working Group's efforts are well underway and we'll be providing more details soon.

Finally, we'll continue the work we began to modernize the regulatory system for biotechnology, including the effort in 2015 with USDA and EPA to ensure preparedness of federal regulatory agencies for future products of biotechnology; as well as the implementation of the 2018 recommendations of the Interagency Task Force on Agriculture and Rural Prosperity. We'll also continue to build on our Formal Agreement with the USDA, which commits the FDA and USDA to better align and enhance our efforts to develop regulatory approaches to biotechnology.

We're committed to all of these goals, and we look forward to working with the Interagency Task Force and sharing more of our important work with our stakeholders going forward.

FDA is taking concrete and proactive steps to help ensure the safety of plant and animal biotechnology products, while promoting innovation and enhancing public and market confidence in FDA's regulation of these products at home and abroad. We recognize the tremendous opportunities offered by this new technology. We're committed to developing a framework that allows these innovations to safely advance, to fulfill the potential envisioned by those who are pioneering these approaches, and to inspire public confidence in these methods.

The advance of these technologies holds significant public health promise. Unlocking their full potential and competitiveness depends on the trust we build now and in the years to come.

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