Summary Testimony of Lowell Schiller
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We are at a pivotal moment for medical product innovation.

Scientific and technological advancements are accelerating development of novel products that hold remarkable promise for patients, from targeted therapies and regenerative medicines to increasingly sophisticated diagnostics.

Likewise, new product development tools can help bring products to market faster while meeting the same regulatory standards for safety, effectiveness, and protecting human research participants.

To fully realize these opportunities, it is critical for FDA to maintain a modern regulatory ecosystem that enables innovative products to reach patients efficiently without compromising scientific rigor.

As technology evolves, regulatory frameworks must adapt to avoid needless uncertainty about how reviewers will evaluate novel products or approaches. FDA has made progress over the last decade, including by delivering on congressional mandates in the 21st Century Cures Act and other recent legislation. But there is much more to be done.

FDA has the opportunity to modernize its approaches in key respects:

- **Facilitating more use of advanced evidence generation techniques**, like innovative trial designs and sophisticated uses of real-world data—for example, by addressing issues around data formatting and FDA's review of patient data, expanding the use of external controls, and updating regulations to better accommodate decentralized and community-based trials.

- **Advancing innovation for rare diseases**, which together affect an estimated 30 million Americans, by standardizing review approaches and facilitating tools that enable more scalable development, including streamlined review when multiple products leverage a common technology, or when a drug can be individualized for patients in the course of care.

- Updating internal processes, including by: (1) **building on existing efforts to leverage AI** and other advanced computing tools in product reviews, with refinement and appropriate guardrails, and (2) **strengthening confidence in the accelerated approval pathway** through procedural transparency and leveraging more real-world data to improve follow-through on confirmatory studies, which would help address challenges like retaining study participants.

- **Updating regulations to make operating in the U.S. more globally competitive**, particularly in areas where we've seen the most off-shoring, like manufacturing and early-phase clinical research—for example, by modernizing manufacturing regulations to facilitate the development of domestic advanced manufacturing facilities, and streamlining requirements for early-phase research while maintaining protections for human subjects.

FDA's regulatory system has long defined the global gold standard for ensuring that medical products are safe, effective, and innovative. This mature system instills confidence in novel products and serves as a key competitive advantage for the United States. With thoughtful modernization to keep pace with emerging science and technology, it can continue to do so.