

REMARKS FOR Centre for Innovation in Regulatory Science (CIRS) ANNUAL MEETING PLENARY

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INTRODUCTION

Good morning. It is a privilege to join the Center for Innovation in Regulatory Science (CIRS) and this international regulatory community. I'm Mark Abdo, the FDA's Associate Commissioner for Global Policy and Strategy. My office ensures global considerations are fully integrated into the FDA policies and operational activities. We manage the FDA's foreign posts in eight - soon to be 12 - countries, function as the point of contact for many of the FDA's bilateral exchanges and global partnerships, lead FDA's engagement in international trade policy development, and are at the forefront of the collection, analysis and sharing of high-quality information – including inspection data – to advance the FDA's public health mission.

Today I want to share four focus areas that will shape the next five years of international regulatory cooperation: regulatory reliance frameworks, artificial intelligence in drug development and manufacturing, clinical trial modernization, real-world evidence and real-world data. While often discussed separately, these concepts are part of one strategy - building greater international convergence around evidence we can trust – that affords the FDA and other regulators tremendous opportunity. And tremendous risk in the form of fragmentation and divergent approaches. I am an optimist, however, and am going to focus the rest of my remarks on the opportunities these areas present.

FDA-regulated products account for about 21 cents of every dollar spent by consumers and many of these products originate from more than 150 countries outside of the United States. Each nation has its own regulatory authority, and oversight can vary from country to country. This creates added complexity for the FDA. To reduce that complexity in a global world, FDA supports both regulatory harmonization, the process of developing uniform technical guidelines across participating regulatory authorities in multiple countries and convergence, where regulatory requirements in different countries or regions become more similar or aligned over time.

REGULATORY RELIANCE

With that backdrop, let me share a few areas that we are focused on.

First, regulatory reliance. Reliance is not a shortcut, and it is not a retreat from sovereign decision-making. It is a disciplined way to use trusted information, reduce unnecessary duplication, and direct regulatory resources to areas of greatest public health risk.

The FDA's Mutual Recognition Agreements with the European Union, Switzerland, and the United Kingdom are one example of this model. These agreements allow the FDA and capable foreign regulatory authorities to rely on information from each other's drug inspections. Project Orbis is another model, providing concurrent submission and review of oncology products among international partners, supporting earlier patient access and greater alignment in global oncology standards.

FDA has also been focused on a one-way reliance model. In this model, less-resourced regulators are able to leverage FDA's evaluation of a medical product as part of their marketing authorization process, allowing them to bring innovative new products to their patients quicker and cutting red-tape for companies with products approved, licensed, or cleared by FDA.

We expect reliance frameworks will become more predictable and more operational over the next five years. That means reliance-ready submissions, clear authorization for information sharing, well-structured assessment materials, harmonized standards where appropriate, and early alignment on key review questions. FDA already uses confidentiality commitments, cooperative arrangements, and multilateral forums to exchange scientific and policy information with trusted partners. The next step is to turn those channels into pathways for shared scientific understanding while preserving each authority's legal responsibilities and FDA's standards.

ARTIFICIAL INTELLIGENCE

Second, artificial intelligence. CDER and CBER have seen a significant increase in submissions, with over 1000 submissions that include AI components and in fact, the FDA recognizes that AI is increasingly being used across the drug product life cycle. The FDA's 2025 draft guidance provides a risk-based credibility assessment framework for AI models used to produce output intended to support regulatory decision-making. The FDA has also collaborated with EMA on 10 guiding principles of good AI practice in drug development, emphasizing human-centric design, risk-based approaches, standards, clear context of use, data governance, model development practices, performance assessment, lifecycle management, and clear essential information.

There is a global opportunity to make AI-generated evidence more translatable across jurisdictions without making it less rigorous. Regulators should be able to understand what question an AI model is intended to address, what data were used, how bias and performance were assessed, how the model will be monitored over time, and when human judgment remains essential. The FDA can help lead international harmonization on the concepts such as

“context of use,” model credibility plans, and expectations for lifecycle management. If done well, we believe that AI has the potential to strengthen evidence, enhance trial design, advance RWD analytics, and accelerate development while maintaining patient safety.

There is also a global opportunity to integrate AI and machine learning into product manufacturing as part of using new automated and continuous manufacturing processes. These processes reduce the potential for human error that is prevalent in batch manufacturing, strengthening the overall quality of medical products available in the global marketplace. Within FDA’s Office of Pharmaceutical Quality is the agency’s Emerging Technology Program which works with pharmaceutical manufacturers to address concerns or regulatory challenges to implementing innovative approaches into their manufacturing processes.

CLINICAL TRIALS

Third, clinical trial modernization. FDA is moving toward trials that are more efficient, more representative, and closer to how care is delivered. FDA’s decentralized trials guidance supports remote trial activities, including telehealth, in-home visits, and visits with local health care providers. FDA’s draft guidance on integrating randomized trials into routine clinical practice supports streamlined protocols and essential data collection. And ICH E6(R3) provides a global foundation for flexible, risk-based trial conduct, driven by quality by design, to support innovation and efficiency while ensuring participant protections, and reliable results.

FDA is now extending that principle to real-time evidence flow, moving toward continuous trials across phases of development. Last month, FDA announced two real-time clinical trial proof-of-concept studies that will report endpoints and data signals to the agency in real time, along with a request for the public to comment on a proposed summer pilot on AI-enabled optimization of early-phase trials. The pilot focuses on one of the most persistent bottlenecks in drug development: early-phase trials, where uncertainty in dosing, safety, efficacy, limited patient populations, and inefficient progression decisions can slow development. FDA is seeking input on how AI and data science can help.

The FDA supports innovative evidence generation methodologies to maximize clinical trial efficiencies. FDA’s Complex Innovative Trial Design program supports complex adaptive, Bayesian, and other novel clinical trial designs through our Complex Innovative Trial Design program. FDA has been clear that adopting complex innovative designs won’t result in less rigorous clinical trials – they must remain sufficient to evaluate safety and effectiveness in the intended population, including pertinent subsets. FDA’s Model-Informed Drug Development program supports quantitative approaches that can improve trial efficiency, optimize dosing, and inform regulatory review. FDA’s C3TI Demonstration Program is designed to test and scale

innovative approaches in clinical trials, including Bayesian statistical analysis, selective safety data collection, and streamlined trials embedded in clinical practice.

In addition, FDA Commissioner Makary said earlier this year that advances in drug development means that relying on two pivotal clinical trials no longer makes sense and so he is moving to support reliance on one clinical trial plus confirmatory evidence to demonstrate substantial evidence of effectiveness for drug approval.

Together, these policies point to a more efficient and scientifically focused development model. For global regulators this creates an opportunity to converge around modern evidence packages that are rigorous, transparent, and less duplicative, while preserving the FDA's commitment to safety, effectiveness, and public health.

REAL-WORLD DATA AND REAL-WORLD EVIDENCE

Finally, I want to discuss real-world data and real-world evidence. The FDA defines real world data as data relating to patient health status or health care delivery routinely collected from sources such as electronic health records, claims, registries, and digital health technologies, while RWE is the clinical evidence about the use, potential benefits, or risks of a medical product derived from RWD analyses. The FDA has a long history of relying on RWD and RWE to monitor and evaluate post market safety and since the passage of the 21st Century Cures Act of 2016, the Agency has been committed to expanding the use of RWD/RWE beyond safety to inform regulatory decisions regarding the effectiveness of medical products.

FDA's commitment to real world evidence is demonstrated through the establishment of a dedicated RWE Program which has published comprehensive guidance for industry, and funded a broad range of complex demonstration products while maintaining robust external stakeholder engagements.

In addition, the Advancing RWE Program seeks to assist sponsors with improving the quality and acceptability of RWE-based approaches for new labeling claims, new indications, and post-approval study requirements, while promoting consistent decision-making and shared learning across FDA centers. FDA website¹ publishes illustrative examples of when RWE has been used, at least in part, for safety and effectiveness determinations, with plans to update these regularly.

CONCLUSION

In conclusion, the FDA's global leadership over the next five years should be measured not only by how quickly we review applications, but by how clearly we communicate expectations, how

¹ <https://www.fda.gov/science-research/real-world-evidence/fda-use-real-world-evidence-regulatory-decision-making>

consistently we apply science, how effectively we use trusted global information, and how well we help the world converge around evidence that is reliable, transparent, and fit for purpose.

The four concepts I've discussed are not separate reforms but the architecture of a more connected regulatory future. If we build that architecture with transparency, scientific rigor, and international cooperation, we can reduce duplication without lowering standards, accelerate innovation without compromising safety, and strengthen public trust while fulfilling FDA's enduring mission: to protect and promote public health.

Thank you.