FDA Publishes Its First Draft Guidance On Use of Artificial Intelligence in the Development of Drugs and Biological Products

On January 7, 2025, the FDA issued a draft guidance called **Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products**. The document clarifies how sponsors, manufacturers, and other industry developers should approach artificial intelligence (AI) to support safe, effective development and marketing of AI-based tools.

The guidance discusses the use of AI models in the nonclinical, clinical, post-marketing, and manufacturing phases of the drug product life cycle, where the specific use of the AI model is to produce information or data to support regulatory decision-making as it relates to safety, efficacy, or the quality of the product. It does not cover AI use in drug discovery or operational efficiencies that do not affect patient safety, drug quality, or study reliability.

Read the full alert **here**.

How the Trump Administration Could Reshape Regulation in the Life Sciences Sector

 Based on recent policy signals and statements from incoming administration officials, a picture of potential regulatory and policy changes that could affect biotech, pharmaceutical, and medical device companies in coming months and years is emerging.

Anticipated changes span multiple regulatory fronts: a revamped approach to antitrust review at the Federal Trade Commission (FTC), continued momentum on biosecurity measures, and a fundamental rethinking of agency regulation to streamline "red tape" and accelerate patient access to innovative treatments. The Trump administration's stated focus on "making America healthy again" suggests a broader transformation in how healthcare is delivered and regulated, with emphasis on nutrition, prevention, longevity, enhanced physician autonomy, and a more holistic approach to health to reduce the burdens of chronic disease.

While some changes may create opportunities for innovation and growth, others could pose compliance and operational challenges. Understanding these emerging dynamics will be crucial for industry stakeholders as they position themselves for success under the new administration.

The following six sections are based on discussions from a regulatory panel held on January 15 at the **Goodwin + KPMG 6th Annual Symposium**, which was held during the 2025 JPM Healthcare Conference.

Read the full insight **here**.

Goodwin Invites You to Join Us For Our Rare Disease Symposium 2025

Goodwin's **Life Sciences** team is excited to host its Annual Rare Disease Symposium in Boston on February 5, 2025. Participants are invited to join for an afternoon of engaging fireside chats, inspirational presentations, and networking with peers in the rare disease community.

Please see the agenda below and register to attend **in-person** or via our **virtual webinar** to join us.

Agenda

12:00 PM – 1:00 PM EDT | Welcome & Networking Lunch

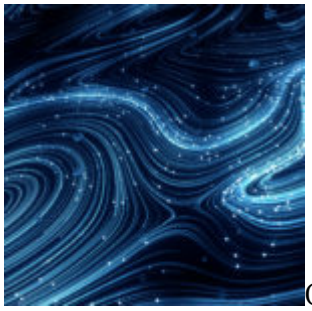
1:00 PM – 4:30 PM EDT | Rare Disease Symposium Program

- **The Patient View**
  - David Downing, GRIN1 Dad
  - Jaime McHugh, Rare Disease Mom and NORD Running for Rare Champion
- **The Research View**
  - Dr. Shira Rockowitz, PhD, Data Science Director, Boston Children's Hospital, Children's Rare Disease Collaborative Co-Leader
  - Dr. Piotr Sliz, PhD, Vice President, Chief Research Information Officer & Associate Professor, Boston Children's Hospital, Children's Rare Disease Collaborative Co-Leader
- **The FDA View**
  - Amy Rick, Director of Strategic Coalitions for FDA's Rare Disease Innovation Hub
- **The Policy View**
  - Karin Hoelzer, Senior Director, Patient Advocacy, BIO
  - Jack Kalavritinos, Founder, JK Strategies and the Washington Health Innovation Council, and Former Director, HHS Office of Intergovernmental & External Affairs
  - Judy Stecker, SVP, Burson, and Former HHS Deputy Chief of Staff for Strategy & Operations – Rare Disease Parent & Founder, Wheeler's Warriors
- **The View from the National Organization for Rare Disorders**
  - Pamela Gavin, Chief Executive Officer, NORD
- **The View from the Rare As One Network**
  - Heidi Bjornson-Pennell, Senior Program Manager, Science in Society, and Lead, Rare As One Network
- **The Biotech CEO View**
  - Paula Ragan, PhD, CEO, X4 Pharmaceuticals

4:30 PM – 5:30 PM EDT | Networking Reception

We look forward to kicking off **Rare Disease Month** with you!

How to (Finally) Get Your SIUU Out: FDA Issues Final Guidance on Communicating Off-Label Scientific Information

 On January 7, 2025, FDA announced the availability of a final guidance document titled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products." The **final guidance** supersedes the agency's revised draft guidance of the same title issued in October 2023 (see our analysis of the draft guidance **here**) and includes several key updates, including further describing scientific standards for appropriate source publications, providing additional examples of the separate dissemination of information on approved and unapproved uses in different scenarios, and expanding the section on firm-generated presentations with further context on what is permitted and what would be viewed as inappropriate when an SIUU communication includes a source publication and firm-generated content.

Several of these updates appear to be responsive to comments from industry stakeholders on the draft guidance. For example, the draft guidance stated that source publications for SIUU communications should describe "scientifically sound" studies and analyses that provide "clinically relevant" information. Multiple commenters requested that the "clinically relevant" and "scientifically sound" concepts be either removed or more clearly defined. The final guidance no longer contains the "clinically relevant" terminology, but provides some further recommendations on what constitutes a "scientifically sound" study or analysis, noting for example that certain early-phase studies *could* meet this standard.

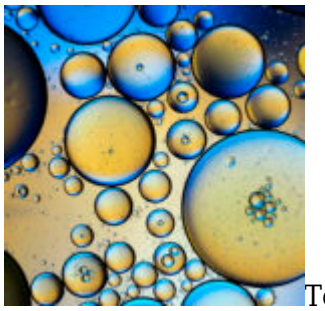
Similar to the draft guidance, the final guidance document is written in a question and answer format and addresses: (1) what firms should consider when determining whether a source publication is appropriate to be the basis for an SIUU communication; (2) what information should be included as part of an SIUU communication; (3) how SIUU communications should be presented (e.g., the format and accompanying disclosures); and (4) recommendations for specific types of materials (including reprints and clinical reference resources). The final guidance includes a new question and answer focusing specifically on recommendations for firm-generated presentations.

The final guidance also provides an expanded list of examples of communication techniques that FDA regards as "encouraging" an unapproved use of a medical product. In addition to celebrity endorsements, premium offers, and gifts (which were noted in the draft guidance), the final guidance identifies emotional appeals unrelated to scientific content, promotional tag lines, and jingles, along with "calls to value" that "pre-judge the benefit(s) of the medical product for individual patients" (e.g., "Click here to start improving your patients' lives today"), as techniques that would take a firm-generated presentation *outside* the scope of the guidance's enforcement policy.

FDA has submitted the guidance to the Office of Management and Budget for review and clearance of certain information collection provisions contained in the guidance. As such, the final guidance is not for current implementation, but we expect to see a Federal Register notice about the final guidance's applicability once this administrative step is complete.

Please contact any of the authors or your Goodwin attorney if you have any questions about this final guidance.

A Look Ahead in Life Sciences: What We Are Tracking in the First Quarter of 2025 and Beyond

 To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q1 2025 updates **here**.