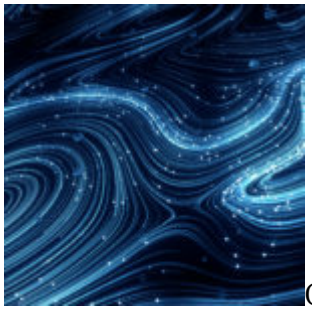
FDA Publishes Its First Draft Guidance On Use of Artificial Intelligence in the Development of Drugs and Biological Products

On January 7, 2025, the FDA issued a draft guidance called **Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products**.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 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 The **final guidance** supersedes the agency's revised draft guidance of the same title issued in October 2023 (see our analysis of the draft guidance **here**) and includes several key updates, including further describing scientific standards for appropriate source publications, providing additional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Several of these updates appear to be responsive to comments from industry stakeholders on the draft guidance. For example, the draft guidance stated that source publications for SIUU communications should describe "scientifically sound" studies and analyses that provide "clinically relevant"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.

New Momentum for a Time-Limited Conditional Approval Pathway for Rare Disease Drugs

 On October 4, 2024, a US House version of the revised Promising Pathway Act (PPA) 2.0 was introduced, sponsored by Rep. Bruce Westerman (R-AR). The bill (**H.R.9938**) mirrors a US Senate version that was introduced in May 2024 (**S.4426**) that would authorize the US Food and Drug Administration (FDA) to grant time-limited conditional approval to drugs for rapidly progressive, terminal diseases with substantial unmet need for treatments that are eligible for the Orphan Drug Act and result in a substantially shortened lifespan, substantial reduction in quality of life, or other substantial adverse health effects.

Read the full insight **here**.

FDA Finalizes Rule and Sets Course to Phase In Oversight of Laboratory Developed Tests

 On May 6, 2024, following more than a decade of discourse with interested stakeholders on potential approaches to regulation of laboratory developed tests (LDTs), the U.S. Food and Drug Administration (FDA) published its **final rule** setting forth its framework for oversight of LDTs. The final rule and accompanying policy to phase out the agency's general policy of "enforcement discretion" for LDTs comes roughly six months after FDA published its **proposed rule** that outlined the agency's proposed approach to increasing oversight over LDTs. As detailed in our prior analyses of the proposed rule (see **here** and **here**), FDA proposed to implement a **phaseout policy** that would, across five stages and within four years, apply to clinical laboratories offering tests as LDTs the same regulatory requirements applicable to in vitro

diagnostics (IVDs).

The proposed rule received more than **6,500 comments**, and while FDA did not change its amendments to the regulation or meaningfully modify the phaseout timeline, FDA has significantly modified its phaseout policy to extend full or partial enforcement discretion to additional categories of LDTs, creating a framework whereby the agency intends to take a more targeted enforcement approach, particularly in the near-term, to addressing LDTs.

You can read our more in our **Insight**, where **Steven Tjoe**, **Matt Wetzel**, and **Sukrti Thonse** highlight the key features of the final rule and five-stage phaseout policy. Be sure to bookmark our dedicated **LDT Resource Page** to stay informed on the latest news and analyses on LDTs.

FDA Issues Final Rule on Regulation of Laboratory Developed Tests

 On April 29, 2024, the U.S Food and Drug Administration (FDA) announced its **final rule** on Laboratory Developed Tests (LDTs). This final ruling amends the FDA's regulations to make explicit that *in vitro* diagnostic products (IVDs), including those manufactured by laboratories, are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Alongside the amendment, FDA issued its policy to phase in regulatory requirements for certain LDTs over the course of four years.

The FDA will host a webinar to provide an overview of the final rule on May 14, 2024. A link to register can be found **here**. The final rule is expected to have profound effects on many LDT developers. Goodwin's **Life Sciences Regulatory & Compliance Team** are ready to work with clients to navigate the challenges that the final rule may pose. Our breakdown and analysis of the rule will be upcoming on **Goodwin's LDT Resource page**.