LDT Proposed Rule Remains Under OIRA Review



Throughout August 2023, the Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President ("OIRA") has **held stakeholder meetings** regarding a proposed rule which, if enacted, would amend the U.S. Food and Drug Administration's ("FDA's") regulations to make explicit that laboratory developed tests ("LDTs") are devices under the Federal Food, Drug, and Cosmetic Act. The next stakeholder meeting on the proposed rule is scheduled for September 6, 2023.

Per its **website**, OIRA received the proposed rule from FDA on July 26, 2023. The proposed rule was initially **published** this past spring on the Biden Administration's Unified Agenda of Regulatory and Deregulatory Actions with a target publication date of August 2023. The forthcoming stakeholder meeting on September 6th suggests that OIRA may continue its review process well into September, if not later.

The publication of the proposed rule would mark the first significant FDA action on LDTs since its two 2014 draft guidances (available **here** and **here**) and 2017 **discussion paper**. The proposed rule is also expected to be controversial after prior U.S. Department of Health & Human Services statements concerning regulation of LDTs and legislative attempts to further define the LDT regulatory framework. Once cleared by OIRA, the proposed rule will be published in the Federal Register and subject to public comment.

We will continue to monitor for updates on the LDT proposed rule. Contact Goodwin Life Sciences Regulatory & Compliance team members for any questions.

First Drugs Selected for Price Negotiations Under The Inflation Reduction Act

The Inflation Reduction Act's Medicare Drug Price Negotiation Program has now officially kicked off. Earlier today (August 29, 2023), **the White House announced the list of the first 10 selected drugs** under the program, prior to the statutory deadline of September 1.

The first 10 drugs selected are as follows:

- Eliquis
- Jardiance
- Xarelto
- Januvia
- Farxiga
- Entresto
- Enbrel
- Imbruvica
- Stelara
- Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill

The government notes that these selected drugs accounted for $50.5 billion in total Part D drug costs – or about 20% of the Part D spend for June 1, 2022 through May 31, 2023. For next steps, manufacturers of these drugs must enter an agreement with the government to agree to the negotiation program. The government will publish the agreed-upon negotiated prices for these selected drugs by September 1, 2024, with the prices going into effect January 1, 2026.

For those interested in more detail about the IRA, please visit our **Goodwin IRA webpage**, where you can view and download material from our previous webinars covering additional detail and background on the IRA, including guidance from the Centers for Medicare & Medicaid Services (CMS) on implementation of the Program, presented by Goodwin Life Sciences Regulatory & Compliance partner **Matt Wetzel**.

We will be monitoring pending legal challenges to the IRA and tracking updates on **Goodwin's IRA resource page**.

Spotlight on Life Sciences Collaboration and License Agreements



Goodwin's Intellectual Property team regularly works on the most important deals in the life sciences and biotech sector. Our close relationship with clients ensures that the best intellectual property strategies are in place to foster company and product growth and minimize risk. We take pride in structuring, negotiating, and executing complex license, collaboration and joint development agreements. Recently, our Cambridge team advised Renaissance Pharma Ltd., in its launch and exclusive license agreement with St. Jude Children's Research Hospital for the treatment of newly diagnosed high-risk neuroblastoma patients globally – announced on August 01, 2023.

Manchester, UK-based **Renaissance**, is a rapidly emerging company focused on the development of life changing therapies in paediatric rare disease.

St. Jude Children's Research Hospital is leading the way the world understands, treats and cures childhood cancer, sickle cell disease, and other life-threatening disorders.

Goodwin partner, **Malcolm Bates** said: "We wish Renaissance and St. Jude every success in this very important agreement."

Read the press release **here**.

Antitrust & Competition Life Sciences Quarterly Update Q2 2023



The second quarter saw significant enforcement and dealmaking in the life sciences space. The Federal Trade Commission (FTC) announced its attempt to block Amgen/Horizon, the first such challenge to a life science transaction since 2009, and issued a second request in Pfizer's proposed $43 billion acquisition of Seagen. In contrast, however, several sizable deals announced and closed within the normal waiting period, while the status of others is unknown at the time of publication.

Read the full Antitrust & Competition Healthcare Quarterly Update for Q2 2023 written by Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Sarah Jordan**, **Elliot Silver**, and **Charlie Stewart** **here**.