BIOSECURE Update – 1260H List Released

 The Department of Defense has published its updated Section 1260H list of "Chinese military companies" this week, and WuXi AppTec along with 27 other new entities were identified on the list. (Federal Register notice available here: **https://public-inspection.federalregister.gov/2026-11571.pdf**.) DoD noted that WuXi AppTec is named on the basis of indirect ownership by China's state enterprise body (SASAC) and indirect affiliations with China's defense science agency (SASTIND) and the People's Liberation Army. The list also includes BGI Group (and 7 listed affiliates), MGI Tech Co., Ltd., Novogene Company Limited, and Origincell Technology Co., Ltd.

What does this mean?

Under the enacted BIOSECURE Act (Section 851 of the FY2026 NDAA), a 1260H listing is the first step toward becoming a "biotechnology company of concern" (BCC) that triggers BIOSECURE's federal procurement/contracting restrictions. Next, OMB must still separately publish a list of BCCs, which will include entities identified on the updated 1260H list. This list must be published by December 2026. Once the list is published, the Act's prohibitions do not take effect until 60 days after the regulations are subsequently revised (likely sometime in 2027). Pre-effective-date contracts are grandfathered for five years from that FAR revision date.

What should companies do?

Companies should review their existing agreements with entities named on the 1260H list to understand whether any BIOSECURE-related provisions may have been triggered and should continue to operate with awareness of the likelihood of forthcoming BCC designations. We can also expect the OMB biotechnology determination process to move quickly given continued recent Congressional pressure.

For further information, please feel free to connect with Matt Wetzel (**mwetzel@goodwinlaw.com**), Liza Craig (**lcraig@goodwinlaw.com**), Justin Pierce (**jpierce@goodwinlaw.com**), David Chen (**DavidChen@goodwinlaw.com**) and Gozde Guckaya (**gguckaya@goodwinlaw.com**) to schedule time.

DOJ-HHS Announces False Claims Act Working Group, Emphasizes Healthcare

Fraud Enforcement Priorities

 The Trump administration recently announced the renewal of a new cross-agency collaboration between the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) in the form of the **DOJ-HHS False Claims Act Working Group**. The Working Group will be jointly led by Deputy Assistant Attorney General (DAAG) of the Commercial Litigation Branch Brenna Jenny, HHS Acting General Counsel Sean Keveney, and HHS Office of Inspector General Acting Chief Counsel Susan Edwards, and will include the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity and U.S. Attorneys' Offices.

Read the full alert **here.**

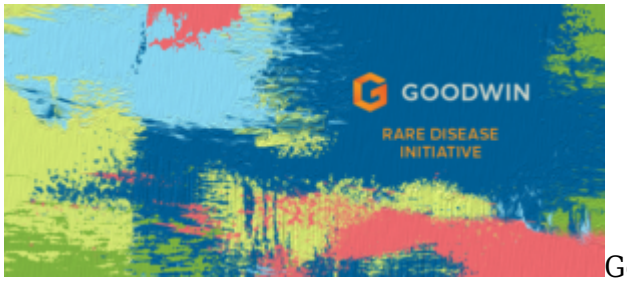
FDA Publishes Its First Draft Guidance On Use of Artificial Intelligence in the Development of Drugs and Biological Products

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**.

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 &

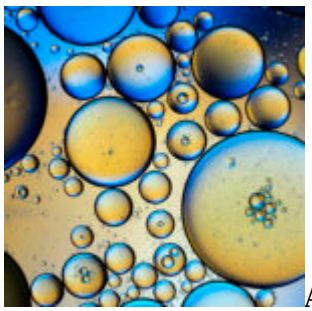
Operations – Rare Disease Parent & Founder, Wheeler's Warriors

- **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

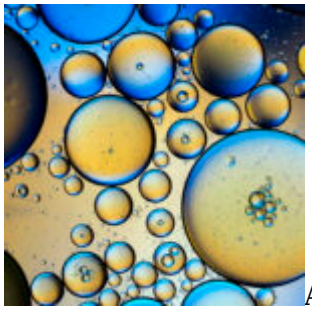
4:30 PM – 5:30 PM EDT | Networking Reception

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

A Look Ahead in Life Sciences: What We Are Tracking in Q2 2024 and Beyond

 As the life sciences, medtech, and diagnostic industries continue to expand and grow increasingly complex, so does the legal, regulatory, and compliance landscape. 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 Q2 2024 updates **here**.

A Look Ahead in Life Sciences: What We Are Tracking in Q1 2024 and Beyond

 As the life sciences, medtech, and diagnostic industries continue to expand and grow increasingly complex, so does the legal, regulatory, and compliance landscape. 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 2024 updates **here**.

A Practical Look at OIG's New Compliance Guidance

 On November 6, 2023, for the first time in 15 years, HHS OIG issued a new reference guide for the health care compliance community – **the General Compliance Program Guidance, or GCPG**. While the GCPG does not set new legal standards and largely reinforces existing guidance, it is a tremendous tool to help health care and life sciences companies advance their compliance efforts. Indeed, within its 91 pages, the GCPG provides the most comprehensive and user-friendly trove of health care compliance insights, tips, and guidance ever provided by the federal government.

Read the full alert **here**.

Significant 340B Drug Pricing Program Litigation May Impact 340B Scope

 Two recent federal court cases signal new significant developments with respect to the 340B Drug Pricing Program. Specifically: (1) new federal district court litigation challenging a recent HRSA Notice involving 340B Program "child site" registration and eligibility; and (2) a court decision in other litigation that implicates the scope of the 340B "eligible patient" definition. Details regarding these developments are in the client alert.

Read the client alert **here**.

2023 State Drug Transparency Law Development Update

 In October 2021, we **reported** on an uptick in the passage of state drug price transparency legislation. As an update to that report, as of October 2023, approximately 22 states have now passed drug price transparency laws creating new requirements for drug manufacturers.

Each state has its own unique set of requirements, but reporting is often completed via an online portal administered by the state's implementing agency. Generally, these laws require manufacturers to report pricing and other information related to the cost, development, and sale of drugs to the state or state-affiliated entities. Some states will use this data to produce public reports about the cost of prescription drugs with the goal of creating pricing transparency for drug manufacturers as well as to educate the state legislature and public about the drug pricing process.

Read the full alert **here**.

Recent FDA Initiatives to Support

Development of Individualized Cell and Gene Therapies and Rare Disease Therapies

Last month, FDA issued a **Request for Information** (RFI) in the Federal Register seeking information and comments from interested stakeholders regarding "critical scientific challenges and opportunities to advance the development of individualized cellular and gene therapies (CGTs)." Individualized CGTs are therapies "developed for a single patient (or a very small number of patients) based on designing or engineering a product that specifically targets the mechanism underlying a patient's (or small number of patients') illness."

FDA's request focuses on three core areas:

1. Manufacturing: Manufacturing and product quality challenges and opportunities for individualized CGTs in light of, for example, small batch sizes, tailoring of batches to individual patients, and need for rapid testing and release.

On this topic, FDA asks:

i. *Given the challenges to develop consistent manufacturing strategies for CGTs designed for a very small number of patients or an individual patient, how can manufacturers leverage their prior experience manufacturing one CGT to support subsequent development and approval of another related, but distinct CGT (potential areas for leveraging may include manufacturing process validation, control strategy, assay validation, and drug product stability studies)?*

ii. *When the batch size of a CGT is very small, what are some challenges and solutions regarding the volume of product (or number of vials) needed for batch release testing, stability testing, retention of reserve samples, and comparability studies?*

iii. *What are some challenges and solutions for individualized CGTs that need to be tested and released rapidly, either because the product has a very short shelf life or because the patient's clinical status may be rapidly declining and treatment is urgently needed?*

iv. *For many individualized CGT products, each batch is tailored to an individual patient (e.g., autologous CAR–T cells, tumor neoantigen vaccines, certain genome editing products). For such products, what are some challenges and solutions for assuring that each batch has adequate potency to achieve the intended therapeutic effect?*

v. *What are some challenges and solutions for individualized genome editing products that aim to treat monogenic diseases for which the target gene has different mutations in different patients?*

2. Nonclinical development: The use of nonclinical data to support individualized CGTs, considering the lack of relevant animal models in many instances, the uniqueness or limited applicability of individualized CGTs, and the potential of using prior knowledge from other CGTs—for example, where gene therapy vector products use the same vector backbone.

On this topic, FDA asks:

i. *What nonclinical studies could be leveraged in support of a related product using similar technologies? What nonclinical studies are important to conduct with each final clinical product?*

ii. *What nonclinical development approaches could be considered when there are no relevant animal models or animal models are unable to replicate each individual disease/condition?*

iii. *For patient-specific products where evaluating each individual product is infeasible or impractical, what is the role for nonclinical studies conducted with representative product(s)?*

iv. *What are the opportunities and challenges with using computational approaches to support nonclinical development?*

3. Clinical Development: Clinical development of individualized CGTs, considering for example the infeasibility (for ethical or other reasons) of conducting randomized controlled studies, novel endpoints, and limitations in statistical analyses.

On this topic, FDA asks:

i. *What are challenges and strategies/opportunities with interpreting efficacy data from individual patients (including expanded access) and small groups of patients? What opportunities are there in leveraging prior and/or collective experiences?*

ii. *What strategies can be utilized to accumulate and interpret safety data in personalized/individualized CGTs?*

iii. *For genetic disorders with clear genotype-phenotype associations for disease manifestations or severity, what opportunities are there for tailoring treatments and study design to specific genotypes/phenotypes?*

FDA also requested input on several additional significant questions:

i. *What additional major scientific challenges to advance the development of individualized CGTs should be considered?*

ii. *What existing best practices or scientific approaches should be leveraged to address any of these challenges? Are there specific opportunities for collaborations to advance the development of individualized CGTs?*

iii. *Are there specific areas where flexibility in regulatory approaches would improve the feasibility of developing and commercializing individualized CGTs?*

Comments are due on November 20, 2023.

At the end of last month, FDA also **announced** a pilot program "to help further accelerate development of rare disease therapies." The program, titled Support for clinical Trials Advancing Rare disease Therapeutics ("START"), will include selected sponsors with an active IND for products meeting certain eligibility requirements. Products regulated by CBER are eligible for the program only if they are a gene or cell therapy treatment for a rare disease or condition that is "likely to lead to significant disability or death within the first decade of life." Products regulated by CDER are eligible only if they are "intended to treat rare neurodegenerative conditions, including those of rare genetic metabolic type." Participants selected for the pilot program will "be able to obtain frequent advice and regular ad-hoc communication with FDA staff to address product-specific development issues, including, but not limited to, clinical study design, choice of control group and fine-tuning the choice of patient population."

FDA will accept applications to the START program beginning January 2, 2024 and until March 1, 2024.