Deadline Approaching: OIG Seeks Input on Anti-Kickback Safe Harbors for Clinical Trial Participant Remuneration

On June 24, 2026, the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") issued a **Request for Information** ("RFI") seeking stakeholder input on payments received by individuals in connection with clinical trial participation. Specifically, OIG is seeking to identify ways it might: (i) modify or add new safe harbors to the Federal anti-kickback statute ("AKS") or exceptions to the civil monetary penalty provision prohibiting inducements to beneficiaries (the "Beneficiary Inducements CMP"); or (ii) issue or revise guidance addressing arrangements intended to facilitate clinical trial participation while safeguarding against fraud and abuse.

The RFI follows on the heels of HHS's Operation TrialBlazer initiative, which has identified patient access and engagement as a priority area for revitalizing U.S. clinical research. That initiative has already acknowledged that trial participation imposes real financial burdens on patients (i.e. things like cost-sharing, unplanned tax consequences from trial-related payments, and potential effects on program eligibility (e.g., Medicaid)). Accordingly, OIG appears to be leveraging this RFI to explore whether the fraud and abuse rules themselves serve as a form of barrier or burden to Americans' – and especially government beneficiaries' – ability to access clinical research.

Current OIG Thinking and Issue at Hand

- The AKS and the Beneficiary Inducements CMP were both written broadly, and neither statute carves out an exception for remuneration tied to clinical trial participation. As a result, OIG currently treats remuneration provided to clinical trial participants, including cost-sharing waivers, transportation, childcare expenses, and stipends, as potentially falling within the broad reach of the AKS and the Beneficiary Inducements CMP, meaning such payments may be considered presumptively suspect unless they fit within an existing safe harbor or exception.
- OIG has issued 10 favorable advisory opinions over the past two decades allowing for certain forms of cost-sharing waivers for clinical trial participants, but has not addressed other forms of remuneration to clinical trial participants. Further, while these opinions establish that OIG is comfortable with cost-sharing relief in the right circumstances, the advisory opinions themselves are fact-specific and binding only on the requesting party.

OIG's Request

Rather than proposing specific regulatory text, OIG has opted to cast a wide net. The RFI poses 14 questions spanning from whether remuneration works as an enrollment tool in the first place to the

mechanics of a potential safe harbor (i.e. value caps, permissible payors, IRB oversight, and clinical research phase-specific distinctions). OIG has asked that commenters back their positions with data, studies, or concrete examples where possible. In other words, a generalized comment expressing support for "more flexibility" is unlikely to carry the same weight as specifics tied to actual trial experience.

The RFI poses 14 specific questions to stakeholders, and OIG asks that commenters support claims with relevant data, studies, analyses, and other citations.

Topics covered include:

- Whether offering Federal health care program enrollees remuneration actually facilitates clinical trial participation;
- Whether the AKS or Beneficiary Inducements CMP are perceived as barriers to providing appropriate remuneration;
- What categories and levels of remuneration (e.g., travel, lodging, childcare, stipends, time compensation) are useful to facilitate participation, and which carry heightened fraud and abuse risk;
- What value caps, limits, or restrictions on who may provide remuneration would guard against fraud and abuse;
- The role of Institutional Review Boards (IRBs) as a safeguard over the type, amount, and frequency of remuneration;
- Whether remuneration considerations differ across trial phases (Phase 1–4) and types of trials (e.g., government-sponsored vs. industry-sponsored);
- Whether safeguards are needed to prevent participants from being steered toward non-trial items or services offered by the party providing the remuneration;
- Whether limitations on advertising remuneration are needed to protect trial integrity;
- What additional or modified safe harbors or CMP exceptions may be necessary, and what key provisions they should include; and
- Whether OIG could address some issues through guidance (e.g., Special Advisory Bulletins, FAQs) rather than formal regulation.

Stakeholder Considerations

OIG has signaled openness to addressing some issues through a Special Advisory Bulletin or FAQ rather than formal rulemaking. Given the length of the rulemaking process, stakeholders may consider advocating for interim guidance as the most pragmatic path to near-term certainty for sponsors currently designing or enrolling trials.

This RFI is a particularly timely opportunity for rare disease-focused sponsors, sites, and patient advocacy organizations. For example, qualified treatment centers for certain rare disease therapies are often limited to a small number of sites nationally (or globally), and participants frequently face significant travel and lodging burdens, caregiver support needs, and other questions about remuneration that OIG can squarely address through this guidance. Rare disease stakeholders may be best positioned to give OIG concrete, data-supported input on categories like qualified-treatment-center travel support and caregiver assistance that general commentary from more geographically distributed therapeutic areas may not capture.

Next Steps

Stakeholders wishing to submit comments must do so no later than **August 24, 2026 at 5:00 p.m. ET** (60 days from the Federal Register publication date of June 24, 2026).

Interested stakeholders should reach out to Matt Wetzel (**mwetzel@goodwinlaw.com**) and Amelia Nell (**anell@goodwinlaw.com**) with any questions or assistance with preparing and submitting a response to OIG's RFI.

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.

FDA Signals Potentially Evolving Stance Toward Compounding of Certain Peptides

On April 15, 2026, the U.S. Food and Drug Administration ("FDA") announced that it will convene a public meeting of the Pharmacy Compounding Advisory Committee ("PCAC") on July 23-24, 2026, to consider whether to recommend seven (7) peptide bulk drug substances for inclusion on the list of substances that may be used in compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act. Five (5) additional peptide and peptide-derived substances are also slated for separate PCAC evaluation through early 2027. On the same date, FDA also republished its interim 503A Bulks List, indicating its intent to remove 12 peptides from its Category 2 list ("Bulk Drug Substances that Raise Significant Safety Concerns"). This removal took effect following a seven calendar-day notice period.

These FDA actions follow comments in February by HHS Secretary Robert F. Kennedy Jr. on a show hosted by Joe Rogan, during which he expressed concerns about the gray-market nature of the current supply of certain peptide products and that he hoped there would be a pathway for consumers to obtain these products from "ethical suppliers".

The seven (7) peptide bulk drug substances expected to be considered by the PCAC in July, together with the uses identified for evaluation, are:

July 23, 2026:

- **BPC-157** (free base and acetate): ulcerative colitis
- **KPV** (free base and acetate): wound healing and inflammatory conditions
- **Thymosin Beta-4, Fragment (LKKTETQ)("TB-500")** (free base and acetate): wound healing
- **MOTs-C** (free base and acetate): obesity and osteoporosis

July 24, 2026:

- **Emideltide (DSIP)** (free base and acetate): opioid withdrawal, chronic insomnia, and narcolepsy
- **Semax** (free base and acetate): cerebral ischemia, migraine, and trigeminal neuralgia
- **Epitalon** (free base and acetate): insomnia

The peptide substances scheduled for consideration at the July 23-24, 2026, PCAC meeting are among those identified for removal from Category 2. FDA has also identified five (5) additional peptide and peptide-derived substances, including Cathelicidin LL-37, Dihexa acetate, GHK-Cu (injectable), Mechano Growth Factor (PEG-MGF), and Melanotan II, for removal from Category 2

and for later consultation with the PCAC at an advisory committee meeting expected before February 2027.

For those substances removed from the Category 2 list, such removal does not, in itself, establish eligibility for compounding under Section 503A. The regulatory status of these substances remains subject to further evaluation by FDA. FDA had previously identified a range of potential safety considerations associated with these substances, including risks related to immunogenicity, peptide-related impurities, and, in some cases, limited human exposure data. Against that backdrop, FDA's removal of these substances from the Category 2 list and its decision to seek PCAC input regarding their potential inclusion on the 503A bulks list suggests that the Agency is continuing to evaluate how such considerations should be weighed in light of other available data.

Inclusion of any substance on the 503A bulks list historically has been implemented through rulemaking, with advisory committee input forming part of that process. Although PCAC's recommendations are not binding, they generally have informed FDA's ultimate determinations. Accordingly, the upcoming PCAC deliberations may provide an important indicator of how FDA intends to approach these substances going forward.

FDA has also opened a **public docket** (FDA-2025-N-6895) in connection with the upcoming PCAC meeting. Comments submitted by July 9, 2026 will be provided to the Committee for consideration, and the docket will remain open for submissions through July 22, 2026.

If you have any questions or would like to submit a comment to the public docket, please contact the authors or the Goodwin attorney with whom you typically work.

Navigating the EU Data Act: Key Obligations and a Spotlight on Switching Rights

Regulation (EU) 2023/2854 (the Data Act) entered into force across the EU on 12 September 2025. It forms a key part of the EU's broader data strategy and establishes a comprehensive framework for how data is accessed, used, and shared across connected products, digital services, and data processing services, including cloud and edge computing services. It applies to a wide range of businesses, such as connected product manufacturers, software as a service (SaaS), and infrastructure service providers, as well as third-party data recipients and public bodies. Read the full alert **here**.

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's Push for "Radical Transparency": Key Takeaways from the Agency's Publication of Complete Response Letters

On July 10, 2025, the U.S. Food and Drug Administration (FDA) **announced** publication of over 200 complete response letters (CRLs) issued in response to applications submitted to FDA for approval of drugs or biologics between 2020 and 2024. The FDA has described this move as a step toward the Agency's "broader initiatives to

modernize and increase transparency."

CRLs are formal communications sent to applicants when the FDA has completed its review of an application but determined that it cannot approve the application in its current form. Until now, the Agency has only made CRLs available as part of larger approval package files on the Drugs@FDA online database (i.e., after product approval). While the CRLs released this week continue to be limited to approved products—and have been redacted to remove trade secrets and confidential commercial information—the FDA has, for the first time, provided these documents in a central database on **openFDA**. A few key highlights:

- While many of these CRLs have already been disclosed as part of the "Other Action Letters" section of publicly posted drug approval packages, some have not.
- There are multiple CRLs for supplemental New Drug Applications (sNDAs) that had not yet been disclosed, reflecting the fact that approval packages for sNDAs are not consistently posted in the same manner as original NDA approvals.
- Some of these CRLs were issued for products approved before 2020, suggesting that the CRL database scope may exceed the time frame identified in the FDA's announcement.
- At least one CRL has been posted for a product approved as recently as June 2025. For this product, no other portions of the approval package (beyond the label and approval letter) have yet been posted on Drugs@FDA.

Notably, the FDA's announcement references a 2015 analysis conducted by FDA researchers, which found that sponsor disclosures of CRLs did not consistently provide full detail regarding the Agency's specific concerns. The FDA's highlighting of this finding, coupled with the Agency's statement that it plans to publish additional CRLs from its archives, warrants attention from sponsors, especially public company sponsors.

Sponsor disclosures regarding CRLs are always closely scrutinized, and the FDA's move to (1) centralize and regularly release CRLs, and (2) publish additional CRLs (e.g., those for sNDAs, or very recently approved products) is likely to invite further scrutiny—by investors, analysts, competitors, and patient communities. Sponsors should prepare disclosures around receipt of a CRL with the expectation that the CRL itself will become public upon approval of an application. Even where a product is ultimately approved, third parties may make comparisons between a sponsor's characterization of a CRL and the later-posted CRL itself.

According to the FDA, publication of CRLs is just one step in the Agency's broader transparency push. Our team will continue to monitor the frequency and scope of additional releases, as well as any opportunities for interested stakeholders to provide comments or feedback to FDA on its plans.

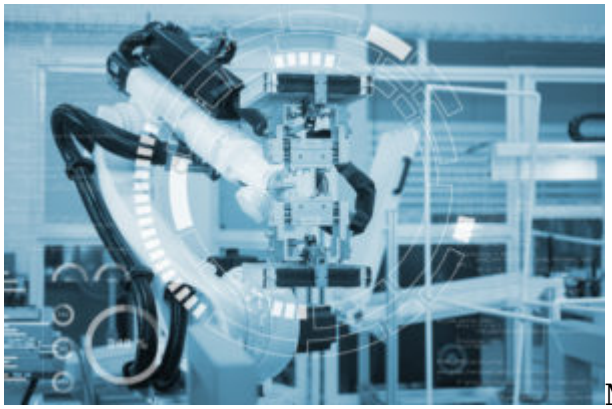
Charting a Conditional Approval Pathway for Rare Disease Drugs – A Top Priority for a Revamped FDA?

On April 18, U.S. Food and Drug Administration (FDA) Commissioner Marty Makary **announced plans** to roll-out a new approval pathway for rare disease drugs. Commissioner Makary's comments build on sentiments expressed across both the patient community and industry that rare disease drug development needs greater regulatory flexibility in order to speed access to treatments for patients with no or limited options. This is an initiative that has also been **trumpeted by Janet Woodcock**, former Principal Deputy Commissioner and Acting Commissioner of the FDA, in her work since retiring from the FDA. Prior legislative proposals (including the "Promising Pathway Act" **proposed** in 2024) have attempted to create a time-limited conditional approval pathway in the rare disease space, and Commissioner Makary's remarks may signal a renewed push for action.

In last week's interview, Commissioner Makary emphasized the following potential eligibility factors in how he is thinking about a new "conditional" approval pathway: rare conditions affecting only a small number of people, where a randomized clinical trial has not been conducted and is not feasible, but where a "plausible mechanism" physiologically exists. Commissioner Makary also noted that post-approval monitoring of adverse events and other data may be an important tool to support more flexible regulatory decision making about drug approvals.

Whether *and when* the FDA or Congress will take further steps in outlining a conditional approval pathway, and what form that outline may take (e.g., Agency guidance, expansion of the current accelerated approval authorities, or new legislation), remains unclear at this time. This is an area rare disease researchers and developers should monitor for developments, including any opportunities to provide comments to the FDA on its potential plans.

Medtech M&A and VC Signal Positive Momentum Entering 2025


Medtech mergers and acquisitions (M&A) and venture capital (VC) showed signs of life in 2024, contributing to an overall optimistic outlook for the sector

this year despite lingering headwinds.

Strategic investments are expected to continue as medtech companies innovate, particularly in areas such as AI-driven diagnostics, wearables and remote monitoring devices, and advanced surgical technologies.

Private, venture-backed M&A activity for medical devices—which picked up in the second half of last year and started 2025 strong with two ten-digit acquisitions and two spin-offs by strategics—could continue rising amid a more deregulatory backdrop under the new presidential administration.

Still, challenges persist that could slow growth. Early-stage VC deals in the sector have faced difficulties, and private M&A exit timelines have increased. Uncertainty regarding the path of interest rates and the broader economy also muddy the outlook.

Read the full insight **here**.

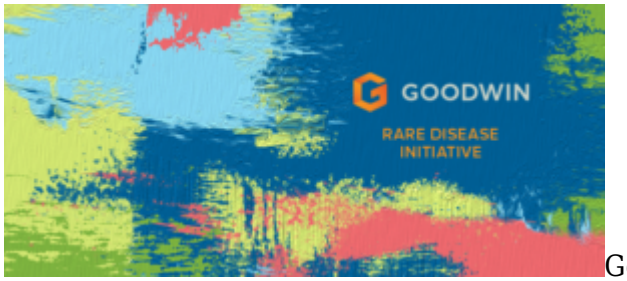
FDA Publishes Its First Draft Guidance On Use of Artificial Intelligence in the Development of Drugs and Biological Products

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!