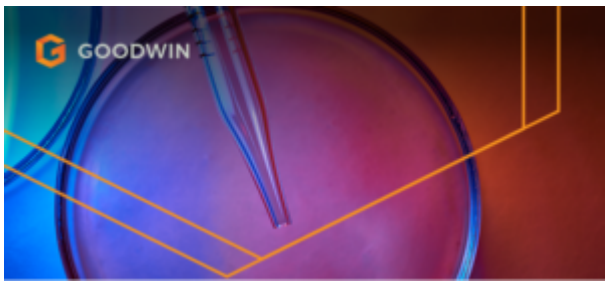
# Webinar: 2022-2023 Key Trends and Updates: Securities Litigation Against Life Sciences Companies

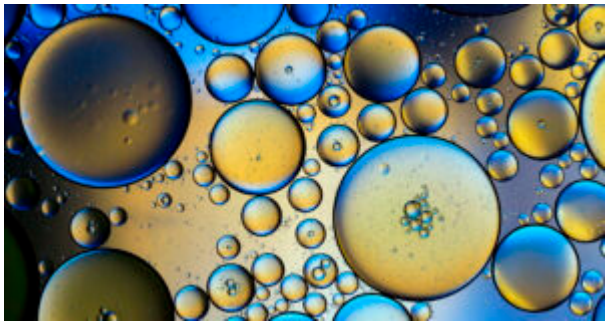



Publicly traded life sciences companies continue to be the primary target of the plaintiffs' bar, facing far more securities class action lawsuits compared to other sectors. What does this mean for your business, and what practical steps can you take to make informed choices? Join **Caroline Bullerjahn**, **Courtney Orazio**, and **John Barker** as they speak to these pressing issues in Goodwin's webinar, "2022-2023 Key Trends and Updates: Securities Litigation Against Life Sciences Companies," taking place on Thursday, June 8th from 2:30 – 3:30 PM ET.

**Register** today!

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# Psychedelics & Drug Development — Key Considerations for Healthcare Industry and Life Sciences Companies as Congress Seeks to Tap Into Psychedelics' Therapeutic Potential



Based on recent regulatory changes at the state and local level and the efforts by the federal government and certain foreign agencies, investors, clinical trial sponsors, life sciences companies, and investigators operating in the psychedelics industry may have reason to be optimistic about the future regulatory landscape for therapeutic psychedelic product candidate development, approval, and commercialization. The proposed Breakthrough Therapies Act is one such reason.

On March 8, 2023, US Sens. Cory Booker (D-NJ) and Rand Paul (R-KY) **introduced** an **updated version** of the Breakthrough Therapies Act. If passed, the bipartisan bill would amend the federal Controlled Substances Act (CSA) to enable the Drug Enforcement Administration (DEA) to reclassify from Schedule I to Schedule II drugs and biologics, including therapeutic psychedelics, that receive breakthrough therapy designation or are authorized for expanded access by the US Food and Drug Administration (FDA). Therapeutic psychedelics are Schedule I substances and include LSD, MDMA, and psilocybin. According to the bill's sponsors, the "legislation [would] remove regulatory hurdles that inhibit research and compassionate use access to potentially lifesaving treatments that are heavily restricted by Schedule I of the [CSA]."

The bipartisan effort behind the Breakthrough Therapies Act signals the federal government's evolving position on psychedelic substances, their therapeutic potential, and access. This evolution, discussed in greater detail in our Client Alert, presents an important opportunity for investors, clinical trial sponsors, life sciences companies, and investigators.

Accordingly, we have identified and answered 8 key questions that stakeholders should consider as they develop and innovate in the psychedelic space:

- What Is the Difference Between a Schedule I and a Schedule II Drug?
- What Diseases and Conditions Can Potentially Benefit From Therapeutic Psychedelics?
- What Are the Key Provisions of the Proposed Breakthrough Therapies Act?
- How Does a Drug or Biologic Obtain Breakthrough Therapy Designation From FDA?
- What Is Expanded Access?
- What Are Some Key Limitations in the Proposed Breakthrough Therapies Act?
- What Is the Status of Therapeutic Psychedelics at the State and Local Level?
- What Regulatory Changes Are on the Horizon for Therapeutic Psychedelics?

Read the full client alert **here**.

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# Seven Tips for Healthcare & Life Sciences Companies Engaging Independent Monitors and Compliance Experts



For a healthcare or life sciences company settling a government enforcement action, the prospect of being subject to an independent monitor, independent review organization (IRO), or other government-mandated compliance expert may become a reality. (We collectively refer to all of these individuals and entities as monitors

throughout this update.) Hiring an independent monitor is a sensitive topic, as a company subject to a monitorship is required to open up its records and files, financial information, proprietary and confidential materials, IT assets, and employees to a third party — often at frequent and regular intervals, and often for a period of five years — not to mention the potential multimillion-dollar expense associated with the engagement.

Read the client alert **here**.

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# Antitrust & Competition Life Sciences Quarterly Update Q1 2023



While a number of factors suggest that deal activity, including those with material antitrust issues, will increase throughout 2023, recent enforcement activity could potentially chill the largest transactions from moving forward. But FTC's filing of a complaint to block Amgen/Horizon may signal a revived enforcement push for large transactions.

Read the full Antitrust & Competition Healthcare Quarterly Update for Q1 2023 written by Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Sarah Jordan**, **Elliot Silver**, and **Charlie Stewart** **here**.

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# Supreme Court Affirms Amgen Patents' Invalidity in Closely Watched Enablement Case

The U.S. Supreme Court has decided a closely watched case regarding patent law's enablement requirement, *Amgen Inc. v. Sanofi*. The Supreme Court affirmed the Federal Circuit's decision that Amgen's patent claims were invalid, holding that the patents' disclosures "offer[ed] persons skilled in the art little more than advice to engage in 'trial and error.'"

The Court's decision was unanimous. Although Amgen and various amici had urged the Court to adjust the standard for enablement in ways that would favor patent validity, the Court's decision announced no major changes to the doctrine.

Read the full client alert **here**.

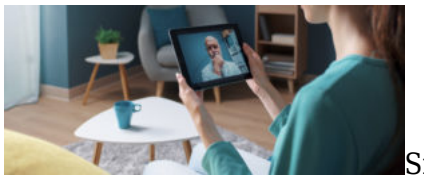
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# The European Commission Proposes First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years: Regulatory Data Protection

We recently published an **alert** in relation to the European Commission's legislative proposals to replace the current EU regulatory framework for all medicines (including those for rare diseases and for children). One of the major elements of the proposals is a change to the period of regulatory data protection for medicines, which we examine in more detail in the client alert **here**.

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# DEA Publishes Temporary Rule on the Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Substances

Since the declaration of the public health emergency due to the COVID-19 epidemic, Drug Enforcement Administration (DEA) registered practitioners have been able to prescribe controlled substances, without a prior in-person visit with a patient, subject to certain conditions as outlined in our earlier **blog post**. Additionally, DEA waived the requirement for practitioners to obtain additional registrations with DEA in the states where the dispensing (including prescribing, and administering) occurs, for the duration of the public health emergency, if the practitioner registers with DEA in at least one state and has permission under state law to practice using controlled substances in the state where the dispensing occurs.

In anticipation of the expiration of the public health emergency on May 11, 2023, on March 1, 2023, DEA and the Department of Health and Human Services issued two notices of proposed rulemakings (NPRMs), reviewed in our earlier **blog post**, to authorize the prescription of controlled substances based on a telehealth consultation in certain limited circumstances. The NPRMs received over 38,000 comments from the public, all of which DEA will review to implement revisions to the NPRMs and develop a permanent rule.

Since the permanent rule is still in development, on May 10, 2023, just one day before the end of the public health emergency, DEA and the Substance Abuse and Mental Health Services Administration published a **temporary rule** that extends the public health emergency telemedicine flexibilities**[1]** for the prescription of controlled substance medications until November 11, 2023.

The temporary rule, which took effect on May 11, 2023, allows DEA-registered practitioners to prescribe controlled substance medications under the public health emergency telemedicine flexibilities to all patients through November 11, 2023. Additionally, until November 11, 2024, DEA-registered practitioners are further permitted to prescribe controlled substance medications under the public health emergency telemedicine flexibilities to patients if the practitioner established a telemedicine relationship with the patient on or before November 11, 2023. In other words, if a provider and patient established a telemedicine relationship on or before November 11, 2023, the same public health emergency telemedicine flexibilities that previously governed the relationship will apply until November 11, 2024.

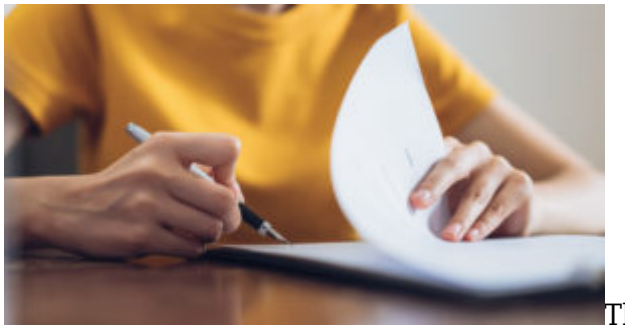
In the text of the rule, DEA notes that it plans to issue one or more final rules, based on the two proposed rules, which will extend certain telemedicine flexibilities on a permanent basis and ensure a smooth transition for patients and practitioners that rely on the availability of telemedicine for controlled substance medications.

*Follow our **blog** to receive additional updates and alerts on the DEA's proposed rules regarding extension of the COVID-19 telemedicine flexibilities for the prescription of controlled substance medications.*

[1] In the temporary rule, the DEA references the **DEA letter** that authorized certain telemedicine flexibilities, including the waiver exceptions related to DEA registrations in individuals states and the in-person evaluation requirement.

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# Proposed USPTO Fee Changes Will Make It Much More Expensive to Patent and to Challenge Patents on Therapeutics. You Have an Opportunity to Comment...

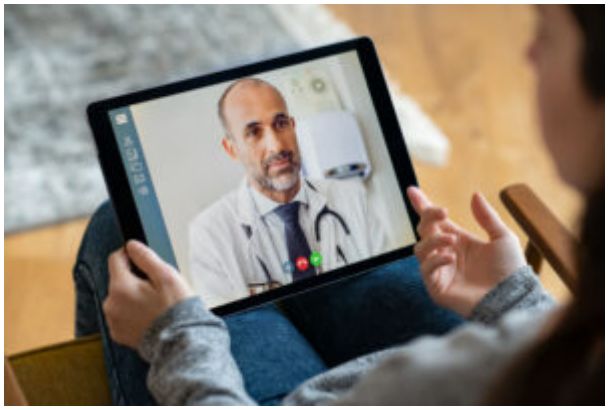


The United States Patent & Trademark Office (USPTO or PTO) recently announced **proposed changes** to certain fees it charges with respect to patent applications, design patents, and America Invents Act (AIA) trials. These changes may significantly increase costs associated with building a robust patent portfolio for New Chemical Entities (NCEs) and Biologics, and to challenge patents at the PTAB. An oral hearing on the proposed changes will be held on **May 18, 2023**, and the USPTO is accepting written comments until **May 25, 2023**.

Read the client alert **here**.

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# The ABCs of DCTs: New FDA Guidance Provides Recommendations for the Conduct of Decentralized Clinical Trials



On May 2, 2023, the U.S. Food and Drug Administration ("FDA") published draft guidance titled "***Decentralized Clinical Trials for Drugs, Biological Products, and Devices***" (the "Draft Guidance"). The Draft Guidance expands on the FDA's **2020 recommendations** issued in response to the COVID-19 pandemic and its **2021 draft guidance** on the use of digital health technologies ("DHTs") in clinical trials, and fulfills the directive under **Section 3606 of the Food and Drug Omnibus Reform Act** to "issue or revise draft guidance [ ] to clarify and advance the use of decentralized clinical studies to support the development of drugs and devices" no later than December 29, 2023.

The Draft Guidance defines a decentralized clinical trial ("DCT") as a clinical trial where some or all of the trial-related activities occur at locations other than traditional trial sites. The FDA clarifies that its regulatory requirements for clinical investigations are the same for DCTs as for traditional clinical trials; however, the Draft Guidance outlines how clinical trial sponsors, investigators, and other stakeholders may meet these requirements in the context of DCTs given the FDA's recognition of the significant potential benefits of DCTs, such as expanding access to clinical trials, increasing trial efficiency, and improving trial participant engagement, recruitment, enrollment, retention, and diversity.

Some of FDA's key recommendations include:

- An important initial determination is whether it is appropriate for a particular trial to be conducted as a fully decentralized or hybrid DCT. Whereas a fully decentralized trial may be appropriate for an investigational product ("IP") that is simple to administer, has a well-characterized safety profile, and does not require complex medical assessments, a hybrid approach may be more appropriate where the trial involves more complex medical assessments or supervision and monitoring of IP administration. The FDA recommends that questions related to the feasibility, design, implementation, or analysis of a DCT should be discussed early with the relevant FDA review division.
- Given that trial-related activities for a DCT may involve a network of locations where clinical trial personnel, local health care providers ("HCPs"), and trial-related services (e.g., labs) may be provided, for inspectional purposes the investigator should select a physical location, to be listed on Form FDA 1572 – Statement of Investigator or in the investigational device exemption ("IDE") application, where trial participant records will be stored and where trial personnel may be interviewed.
- Both sponsor and investigator should evaluate whether certain trial-related activities may be delegated to DCT personnel located near participants' homes. Such activities should not require detailed knowledge of the protocol or IP. Trial-related activities that are unique to the trial or require detailed knowledge of the trial protocol or the IP should be performed by qualified trial personnel who have been appropriately trained.
- Obtaining informed consent remotely may be appropriate for a DCT as long as the process is

adequate and appropriate. Oversight by institutional review boards ("IRBs") should ensure that electronic informed consent at remote locations meets applicable requirements, and the FDA recommends the use of a central IRB in DCTs to provide for more streamlined review of the informed consent documents as well the protocol and other trial-related documents.

- As with any trial, sponsors must ensure proper monitoring of DCTs based on the sponsor's risk assessment. Sponsors should also implement a safety monitoring plan that accounts for the decentralized nature of the clinical trial, including by prespecifying whether safety data will be collected via telehealth or in-person visits and whether DHTs will be used to collect certain safety information. The Draft Guidance underscores the importance of providing sufficient instruction and contact information to the trial participant should an adverse event occur and allowing the participant to arrange an unscheduled visit (either remotely or in-person), as appropriate. The FDA also recently finalized its **Q&A guidance on risk-based monitoring of clinical investigations**, which we blogged about **here**.
- FDA notes that the "variability and precision" of data obtained from a DCT may differ from data obtained in a traditional site-based clinical trial. For example, remote assessments may vary from on-site assessments, particularly if trial participants are performing their own assessments at home. Similarly, assessments performed by local HCPs may be less precise and consistent than assessments conducted by on-site trial personnel. FDA states that while such variability may not affect the validity of a finding of superiority, it could compromise a finding of non-inferiority relative to an active control drug that has been evaluated in a traditional site-based trial. FDA therefore recommends that sponsors consult with the relevant review division if planning a DCT with a non-inferiority design.
- For telehealth visits during a DCT, investigators should confirm a participant's identity during each visit and complete the relevant case report forms and other documentation for each visit. Additionally, the sponsor and investigator are responsible for ensuring that remote clinical trial visits comply with relevant state telehealth laws and as applicable, the telehealth laws of countries outside the U.S.
- Given multiple sources of data collection in a DCT, the sponsor should develop a data management plan that includes the data origin and data flow from all sources to the sponsor; methods for acquiring remote data from trial participants and personnel; and a list of vendors for data collection, handling, and management.

The Draft Guidance demonstrates the FDA's support of more widespread use of DCTs. At the same time, the Agency acknowledges that DCTs can be challenging to implement successfully, including because DCTs require coordination of trial activities with numerous parties in multiple locations that are not traditional trial sites. The Draft Guidance also notes that if significant safety risks emerge due to remote administration or use of an IP, or if other circumstances arise that warrant in-person visits, the sponsor should discontinue remote administration or use of the IP, inform the FDA, IRB, and investigators, and determine whether the trial should be amended or continue.

Interested stakeholders may submit comments on the Draft Guidance by August 1, 2023 to Docket **FDA-2022-D-2870**.

Contact the authors or another Goodwin FDA team member with any questions or if you would like to submit comments to the FDA on the Draft Guidance.

# DEA Announces Temporary Extension of COVID-19 Telehealth Flexibilities for Prescription of Controlled Medications

The Controlled Substances Act, as amended by the Ryan Haight Act, generally prohibits prescribing controlled substances via telehealth without a prior in-person examination, subject to certain very limited exceptions. Those exceptions include prescriptions issued during a public health emergency. Thus, since the January 31, 2020 declaration of a public health emergency due to the COVID-19 epidemic, eligible providers have been able to prescribe controlled substances, without a prior in-person visit with a patient, provided:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.

The public health emergency is scheduled to end on May 11, 2023.

Read the client alert **here**.