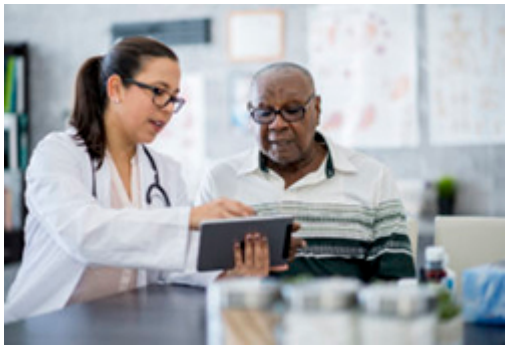
An Overview of the Latest Human Genetic Resources Regime in China

On July 1, 2019, the Administrative Regulations on Human Genetic Resources (人类遗传资源管理条例) (the "Regulations") issued by the State Council of the People's Republic of China (the "PRC") came into effect. On October 17, 2020, the Standing Committee of the PRC National People's Congress promulgated the Biosecurity Law (中华人民共和国生物安全法) (the "Biosecurity Law"), which came into effect as of April 15, 2021. Having replaced its predecessor, the Interim Measures for the Administration of HGR (人类遗传资源管理暂行办法), the Regulations now form the basis of PRC's regime on its human genetic resources, and govern the collection, preservation, use, and external provision of human genetic resources abroad. The Biosecurity Law further reinforces the Regulations by asserting PRC's sovereignty over its human genetic resources and re-iterating certain key provisions under the Regulations.

Read the **client alert**.

California Physicians Allege PE-Backed Provider Violates Corporate Practice Law



On December 20, 2021, a group of emergency medicine physicians in California filed suit against a private equity-backed health care services company, claiming that (among other things), the company has run afoul of the state's prohibition on the corporate practice of medicine ("CPOM") since it took over an emergency department at a California hospital. The plaintiff is the **American Academy of Emergency Medicine Physician Group**, or "AAEM"; and the defendant is Envision Healthcare ("Envision"), which is owned by the private-equity firm Kohlberg Kravis Roberts.

Generally, CPOM laws, which can be found in almost every state, are designed to prohibit

corporations, lay entities, or any non-licensed persons from practicing medicine, employing physicians, or owning physician practices or health care facilities. California's **CPOM law** is fairly strict and is more regularly enforced compared to other states that rarely enforce their statutory prohibition.

In the California matter, Envision contracts with health systems to provide practice management services, such as billing and collection, communication with vendors and financial reporting. In its **complaint**, AAEM provides several examples of how it believes Envision exercises "profound and pervasive direct and indirect control over the physicians' practice of medicine." For example, according to the plaintiffs, Envision appoints medical directors, who are employed directly by Envision, for each entity that Envision controls. AAEM alleges that, because Envision exercises control over the medical directors, it is actually *Envision* making medical decisions, not the licensed professionals. AAEM further claims that because Envision controls physician employment, physician scheduling, staffing levels, and number of patient encounters and denies physicians the right to appeal via traditional medical staffing mechanisms, it is again Envision – not the medical directors – that make decisions for contracted health systems, thereby violating the CPOM laws.

AAEM also claims that Envision is participating in illegal fee-sharing since Envision codes and bills on a physician's behalf, without physicians seeing what is billed in remitted in their names. Finally, AAEM takes issue with Envision's requirement of physician's executing restrictive covenants, prohibited the physician from assisting or joining any other emergency medicine group.

The AAEM lawsuit does not seek monetary damages; rather, the emergency medicine doctors are seeking an injunction to prevent Envision from operating the emergency department at Placentia-Linda Hospital and at least a dozen other emergency departments in the state. We will continue to monitor this case and its outcome, which could have a bearing on how the CPOM laws (at least in California) are applied to private equity-backed health care arrangements.

Propsci Perspectives: SmartLabs

The Goodwin **Propsci team** has partnered with several well-known companies for a short video series that explores what's happening in the real estate life sciences industry.

In this video, Goodwin's **Nicole Riley** is joined by Daisy Riquelme, Associate Director of Business Development, at SmartLabs, a lab platform that supports workflows at every stage of development.

We invite you to learn more about the SmartLabs business model and how companies in the life

sciences ecosystem benefit from their capabilities and offerings. Daisy and Nicole will also go into more detail on how SmartLabs has been problem-solving for the broad range of real estate needs that life sciences companies face during all stages of their lifecycle.

Watch the video **here**.

Medicare Agrees to Limited Payment for New Alzheimer's Drug

On January 11, 2022, the Centers for Medicare and Medicaid Services (CMS) **released** a proposed National Coverage Determination (NCD) decision memo limiting Medicare coverage for Biogen's new Alzheimer's drug, Aduhelm. Under the terms of the NCD – despite FDA's 2021 approval of the drug – CMS will only pay for Aduhelm for Medicare beneficiaries who are enrolled in a qualifying clinical trial to assess the drug's safety and its effectiveness in slowing the progression of Alzheimer's. CMS **stated**, "[B]ased on the public comments submitted previously and evidence CMS reviewed, the potential for harm, and important questions that remain, we have determined that coverage with evidence development through clinical trials is the right decision for Medicare patients, clinicians, and caregivers, and we look forward to receiving feedback on the proposal." The proposed NCD is **open** to public comment for thirty (30) days, and a final decision from CMS is expected **on April 11**. If the proposed NCD is finalized, CMS must evaluate each submitted clinical trial to verify that it meets the qualifying criteria specified in the proposed NCD.

Aduhelm has been approved by FDA for the treatment of Alzheimer's since June 2021. This is the first drug approved by FDA for the treatment of Alzheimer's in almost 20 years. In 2019, two clinical trials for Aduhelm were **paused** due to data showing the drug was of no benefit to patients' cognitive function. However, after Biogen re-analyzed one of its trials, it decided to apply to the FDA for approval. The FDA used the accelerated approval process but can withdraw Aduhelm from the market if Biogen's new clinical trial demonstrates that the drug is ineffective. The FDA **pivoted** on the approval itself, later **recommending** Aduhelm only in patients with mild cognitive impairment or mild dementia. Patient advocacy groups such as the Alzheimer's Association **played** an important role in pressuring FDA to approve Aduhelm, given the minimal advancements in drug treatment in the space.

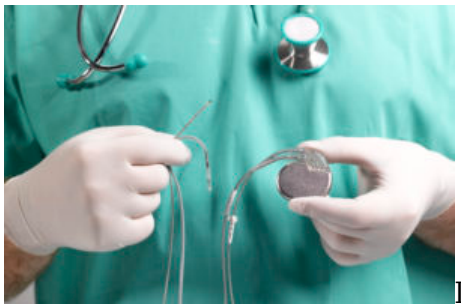
Since receiving FDA approval, Biogen has faced tough scrutiny about Aduhelm's efficacy and cost. Aduhelm's initial annual price of $56,000 elicited widespread criticism. In December 2021, Biogen **announced** that it would reduce the drug's price to $28,200 for some patients. Biogen most likely reduced the price in response to slower than anticipated sales and CMS's announcement

it would increase Medicare's monthly Part B premium for outpatient care in anticipation of the Aduhelm's price impact. Adding to Biogen's challenges, an FDA advisory committee agreed almost **unanimously** that the clinical trials did not provide strong enough evidence to corroborate Aduhelm's efficacy data. However, based on the clinical trials it did review, FDA **claimed** that Aduhelm could reduce clumps of plaque in the brain, which is likely to slow dementia. The discrepancy between the advisory committee's and FDA's findings coupled with broad criticism of the FDA led the Department of Health and Human Services Office of Inspector General to conduct a **probe** into the FDA's approval process for Aduhelm.

Adding to the complexity, State Medicaid programs have also been vocal in protesting CMS's decision. Unlike Medicare, Medicaid is required to cover all FDA-approved drugs regardless of a drug's clinical efficacy. Therefore, had Medicare determined not to cover Aduhelm, all costs would **shift** to the state Medicaid programs. Though some states and insurers have already **declined** to cover Aduhelm, CMS's ruling is likely to influence other payors to refuse coverage.

While some commenters and industry observers have questioned whether CMS's decision with respect to Aduhelm somehow creates a new, default secondary clinical testing and approval threshold for drug makers, it is more likely that the Medicare agency's decision on Aduhelm reflects the unique circumstances posed by the drug (*i.e.* unclear efficacy concerns, conflicting FDA guidance, and an unusually high price point). Whether CMS will make a habit of limiting coverage for innovative drugs only to beneficiaries participating in additional clinical trials remains to be seen, but is not likely. We will continue to monitor trends and developments at CMS with respect to coverage and payment decisions on new therapeutics and treatments, including additional research and testing requirements that the agency may impose.

Planning For The End: Goodwin FDA attorneys Steve Tjoe and Susan Lee highlight key takeaways From FDA's draft guidances proposing transition plans for medical devices marketed under EUAs or enforcement policies during the COVID-19 Public Health Emergency

 During the COVID-19 public health emergency, the United States Food and Drug Administration (FDA) has issued hundreds of Emergency Use Authorizations (EUAs) and numerous enforcement policies to facilitate the availability of important medical devices. On December 23, 2021, FDA published two draft guidances setting forth the Agency's proposed process

for transitioning the multitude of devices brought to market under these circumstances to full compliance with FDA requirements:

- Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "EUA Transition Draft Guidance"); and
- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "Enforcement Policies Transition Draft Guidance").

In our **recent Alert**, we summarize some key takeaways from FDA's proposed transition plan for manufacturers of devices marketed under a COVID-19 EUA ("EUA Devices") and devices marketed under one of more than 15 COVID-19 enforcement policies listed in the guidance ("Enforcement Policy Devices"). **Read More**

Review of FDA's 2021 Drug Approvals – Small Molecules Dominate

The FDA's Center for Drug Evaluation and Research (CDER) approved 50 new drugs and biological products in 2021 (not including the vaccines, cellular and gene therapy products, or other products approved in 2021 by the Center for Biologics Evaluation and Research). As in past years, small molecule drug approvals dominated the list.

Of the 50 approved new drugs and biological products, 33 were small molecule drugs and 17 were monoclonal antibodies and other big molecules drugs. A new ADC (antibody drug conjugate) was approved, Tivdak®, and a bispecific antibody was also approved, Rybrevant®. Notably, a small interfering RNA drug was approved, Leqvio®, for the treatment of atherosclerotic cardiovascular disease.

As small and big molecule drugs enter the clinic, Goodwin's patent attorneys focus on securing not only composition of matter patent protection, but additional patent protection derived from clinical data. Learn more about additional patent protection secured from the clinic in **Goodwin's Patent Savvy Executive video**.

Each new drug and biological product can be found in the FDA's **Orange Book** or the FDA's **Purple Book**. To learn more about the Orange Book and how to determine patent terms on approved drugs, visit **Goodwin's Patent Savvy Executive video**.

See the full list **here**.

On Remote Control: FDA Issues Draft Guidance to Facilitate Use of Digital Health Technologies for Remote Data Acquisition in Clinical Trials

 During the COVID-19 pandemic, decentralized clinical trials and remote patient monitoring and data acquisition became a necessity, accelerating the use of digital health technologies in clinical trials. Acknowledging that technological advances "have revolutionized the ability to remotely obtain and analyze clinically relevant information from individuals" and that "DHTs [ ] are playing a growing role in health care and offer important opportunities in clinical research," the FDA issued during the last week of December 2021 a draft guidance, ***Digital Health Technologies for Remote Data Acquisition in Clinical Investigations***, which provides recommendations for sponsors, investigators and other stakeholders to facilitate the use of DHTs for remote data acquisition in clinical trials, including clinical trials that will be submitted to the FDA in a marketing application for a medical product.

The draft guidance defines a digital health technology (DHT) as a system that uses computing platforms (such as a mobile phone, tablet, or smart watch), connectivity, software, and/or sensors for healthcare and related uses. Some DHTs may meet the definition of "device" under the Federal Food, Drug and Cosmetic Act, but the draft guidance specifically does not address the circumstances under which a DHT would meet the statutory definition of a device and notes that DHTs used in clinical investigations generally are exempt from premarket clearance or approval requirements, as long as the clinical investigation is compliant with 21 CFR Part 812.

The draft guidance explains that sponsors must foremost ensure that a DHT is "**fit-for-purpose**" for its proposed use in a specific clinical investigation. In essence, the level of verification and validation associated with the DHT must be sufficient to support its use and interpretability in the clinical investigation. This may require sponsors to work with the developer or manufacturer of the DHT, patients, caregivers, and other technical and clinical experts to assure that the DHT is suitable for its intended purpose in the clinical investigation. The draft guidance advises sponsors to select a DHT that corresponds to the clinical outcome to be assessed, and that considers the clinical trial population and the design/operating characteristics of the DHT that may affect trial participants' use of the DHT.

Sponsors should also be prepared to describe how they will analyze data collected from DHTs in their statistical analysis plan, including prespecifying "**intercurrent events**" (defined as events that occur after treatment initiation that result in missing or erroneous data associated with the clinical

outcome of interest) that may be related to the DHT and/or the general purpose computing platform, and how these events will be accounted for in the analysis. To maintain data integrity, FDA recommends that the output of the DHT and associated metadata be transmitted to a **durable electronic data repository** that is protected from alterations and maintained until the end of the record retention period. FDA generally will consider data in such a repository to constitute the source data and should be made available for inspection and to reconstruct and evaluate the clinical investigation.

FDA further notes that "unique privacy risks" may arise when DHTs are used in a clinical trial. Sponsors are advised to evaluate the risk of potential disclosures of personally identifiable information through breaches of the DHT, the general computing platform on which the DHT runs, and/or the durable electronic repository, assure appropriate security safeguards are in place, and consider including such information in the informed consent documents for the clinical trial.

The draft guidance recommends that sponsors:

- train trial participants and trial personnel on the use of DHTs and develop a plan to provide technical assistance to trial participants and study personnel;
- develop a risk management plan to address potential problems with the DHT (e.g., interference between mobile applications, or loss, damage and replacement);
- develop a safety monitoring plan that addresses how abnormal measurements related to participants' safety measured by DHTs will be reviewed and managed; and
- develop a contingency plan for any changes to the DHT (e.g., discontinuation of a specific model, operating system updates)

The draft guidance includes appendices with specific examples of how different types of DHTs could be incorporated into a clinical investigation. Given the particular circumstances of each DHT and clinical investigation, the draft guidance encourages sponsors to engage early with the appropriate FDA Center responsible for the medical product under development to discuss the proposed use of DHT(s) in a clinical investigation and, for DHTs or DHT-collected endpoints that require qualification, engage with an appropriate FDA qualification program, such as the **Medical Device Development Tool Qualification Program**.

Comments on the draft guidance are due March 23, 2022.