Congress Expands Pathway for Drug & Device Manufacturers' Pre-Approval Communication of Health Care Economic Information to Payors, Formularies, & Similar Entities

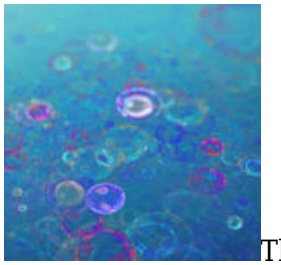
The legislation previously introduced as the **Pre-Approval Information Exchange Act of 2022** ("PIE Act") was passed as part of Congress's December 23, 2022 omnibus spending bill. Once signed into law, this legislation will amend the Federal Food, Drug, and Cosmetic Act's (FDCA's) provisions on misbranded drugs and devices to formally allow drug and medical device manufacturers to proactively share investigational drug and device information, including health care economic information, with payors, health plans, formulary committees, and other similar entities *prior* to the clearance or approval of the drug or device or new use of the drug or device but with now-statutory strings attached.

The US Food and Drug Administration (FDA) has long had the authority to enforce against pre-approval *promotional* communications, and a pathway for pre-approval communication of health care economic information regarding the selection of drugs for coverage and reimbursement was enacted under the Food and Drug Administration Modernization Act of 1997. **Current guidance from FDA**, finalized in 2018, expressly permits drug and device companies to provide some details about investigational products or investigational uses of marketed products to payors, formulary committees, and similar entities prior to approval or clearance of the product or its new use; however, for device companies this has come in the form of non-binding guidance that lacks a formal anchor in the statutory language. The inclusion of the legislation previously known as the PIE Act in the omnibus spending bill formally establishes a statutory pathway built on FDA's 2018 final guidance for both drug and medical device companies to engage in pre-market communications about health care economic information with payors, formulary committees, and similar entities.

Read the client alert **here**.

FDA Announces Total Product Life Cycle

Advisory Program (TAP) Pilot

 The U.S. Food and Drug Administration's ("FDA" or "the Agency") Center for Devices and Radiological Health ("CDRH") recently announced the launch of its Total Product Life Cycle Advisory Program ("TAP") Pilot. The first phase of this voluntary initiative, called TAP Pilot Soft Launch, will be conducted during fiscal year ("FY") 2023 with enrollment beginning on January 1, 2023.

The Agency committed to establishing the TAP Pilot as part of the MDUFA V reauthorization, and the Agency's long-term vision for TAP is "to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance." As part of the TAP Pilot, the FDA will provide strategic engagement for such devices by:

- Improving participants' experiences with the FDA by providing for more timely premarket interactions
- Enhancing the experience of all participants throughout the device development and review process, including FDA staff
- Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk
- Facilitating regular and solutions-focused engagement early in device development between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers
- Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process

Read client alert **here**.

FDA Issues Final Clinical Decision Support Software Guidance

 On September 28, 2022, the U.S. Food and Drug Administration ("FDA" or

"the Agency") issued its long-awaited final guidance, "Clinical Decision Support Software" (the "CDS Guidance"). The CDS Guidance follows the Agency's September 2019 draft guidance of the same name (the "Draft Guidance") and seeks to clarify several key concepts for determining whether clinical decision support ("CDS") software is a medical device.

Specifically, the CDS Guidance provides the Agency's interpretation of the four criteria established by the 21st Century Cures Act for determining whether a decision support software function is excluded from the definition of a device (i.e., is considered "Non-Device CDS"). A software function must meet all of the following four criteria to be considered Non-Device CDS:

1. Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device ("IVD") or a pattern or signal from a signal acquisition system
2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
3. Intended for the purpose of supporting or providing recommendations to a health care professional ("HCP") about prevention, diagnosis, or treatment of a disease or condition
4. Intended for the purpose of enabling such HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Software functions that *do not* meet all four criteria are considered device functions subject to FDA oversight. Notable updates to FDA's interpretation of the four criteria include the following.

Read the Goodwin insight **here**.

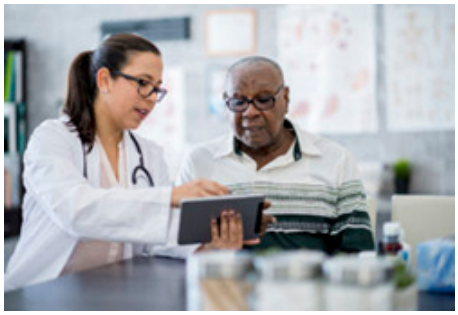
Brian Burgess to Speak on Emerging Legal Issues and Trends for Interchangeable Biosimilars at FDLI Annual Conference

The annual Food & Drug Law (FDLI) conference will be held on June 14-15, bringing together experts from the federal government, industry, the private bar, non-profit, patient and consumer advocates, consulting organizations, and academia to address complex legal, regulatory, compliance, and policy issues facing the FDA-regulated industry. Goodwin is a proud sponsor of the conference and partner **Brian Burgess** is a featured speaker on the panel, ***Interchangeable Biosimilars –***

Emerging Legal Issues and Trends. During this session, the speakers will discuss what can be learned from the first interchangeable approvals and what it tells us about FDA's interchangeability framework. The speakers will also address what the competitive landscape for biologics looks like, how the statutory standard regarding "any given patient" may play out, and whether applicants will be able to use real world evidence to support interchangeable licensure.

Let our Goodwin team **know** if you will be attending the FDLI Annual Conference. For additional information about the conference, please click **here**.

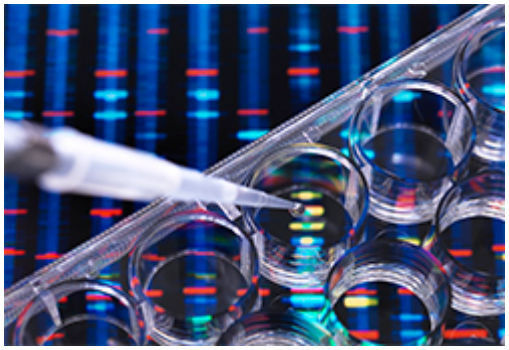
Clinical Trial Diversity Planning for Sponsors: What to Know About FDA's Recent Draft Guidance



On April 13, 2022, the U.S. Food and Drug Administration ("FDA") issued a **draft guidance** providing specific recommendations to the industry on how to improve diversity in clinical trials. The FDA's focus on increasing racial and ethnic diversity in clinical trials is not new, with the agency issuing several guidances since 2016 on this topic.[1] However, the recent draft guidance sets out new expectations for sponsors conducting clinical trials intended to support marketing authorization of drugs, biologics, and medical devices.

Read the **client alert** by FDA Senior Associate **Elizabeth Mulkey** and Partner **Alexander Varond**.

Goodwin's Clinical Trials Service Offering



Given the breadth of clinical-stage companies that the Goodwin FDA and Healthcare teams advise, our regulatory attorneys together with our commercial contracting, products liability and insurance attorneys play an integral role in counseling clinical-stage companies on matters related to the conduct of clinical trials.

Learn more about our clinical trials service offering **here**.

Congress Enacts Amendments Affecting The Regulation Of Generic Drugs And Biosimilars

 On December 27, 2020, the President signed into law the "Consolidated Appropriations Act, 2021" (the "Act"). Included within this omnibus legislation are several provisions (in Division BB, Title III, Subtitle C) that affect the regulation of generic drugs and biosimilar medicines by the U.S. Food and Drug Administration (FDA).

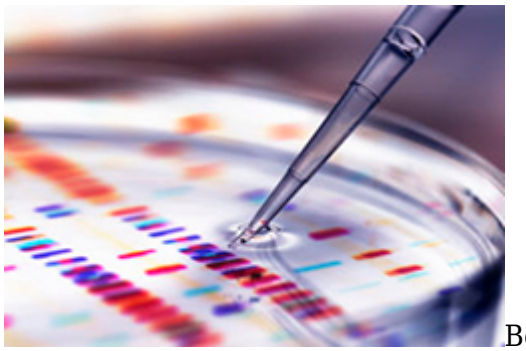
Read the Alert >>

Conduct of Clinical Trials During the COVID-19 Pandemic: Recommendations from FDA

 As the COVID-19 pandemic unfolds, our drug, biologic, and medical device clients conducting or planning to conduct clinical trials may be faced with challenges related to quarantines, travel limitations, site closures or access restrictions, infection transmission concerns of site research personnel and study subjects, and supply chain interruptions. Nonetheless, it remains critical during the COVID-19 pandemic to continue to assure the safety of trial participants, comply with good clinical practice (GCP) requirements, and minimize risks to trial integrity. In this client alert which follows our earlier article on product development considerations for COVID-19 and article on FDA scrutiny of COVID-19 medical product marketing, we briefly discuss the impact the COVID-19 pandemic may have on our life sciences clients, and we provide an overview of FDA's "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic" issued on March 18, 2020.

Read the Alert >>

Clinical Holds: Tips for Handling FDA's Call and What to Do Next

 Because life sciences companies hope to never end up on clinical hold, preparing for such a call from the U.S. Food and Drug Administration (FDA) is often not on the to-do list. But there can be significant advantages to advance preparation. Our Goodwin Insight shares some tips for life sciences companies on navigating that first call with FDA and the actions that follow.

Read the Insight >>

Developing Medical Products for Public Health Emergencies

 The 2019 novel coronavirus (coined COVID-19 by the World Health Organization) is the latest in a series of public health emergencies in recent years to challenge product developers in the life sciences community. With every challenge comes an opportunity, in this case to leverage product development plans and technologies to be first-to-market with products useful in remediating some aspect of COVID-19 and its spread. Earlier this year, the U.S. Food and Drug Administration (FDA) announced its commitment to extend all available resources to help expedite the development and availability of medical countermeasures (MCMs) to prevent, treat, or diagnose COVID-19 and, in fact, issued the first emergency use authorization (EUA) shortly thereafter. For life sciences companies exploring potential opportunities to leverage their programs to help treat, detect, or address some aspect of COVID-19, a number of regulatory mechanisms may be available to facilitate and advance product development plans.

Read the Alert >>