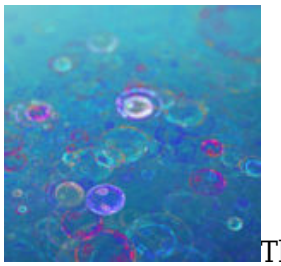
FDA Announces Total Product Life Cycle Advisory Program (TAP) Pilot

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 The CDS Guidance follows the Agency's September 2019 draft guidance of the same name (the "Draft Guidance") and seeks to clarify several key concepts for determining whether clinical decision support ("CDS") software is a medical device.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**.

Visit the **Goodwin on Medtech hub** to stay informed on important developments affecting medtech innovators and investors.

USPTO Doubles Down Calling Out Pharmaceutical Industry

The new Director of the U.S. Patent and Trademark Office (USPTO), Katherine Vidal, published a stern reminder regarding the duties of disclosure and reasonable inquiry during examination of a patent application, including reexamination, reissue, and proceedings before the Patent Trial and Appeal Board (PTAB) (87 FR 45764 (July 29, 2022)). The justification was to provide examiners and judges with all the material information needed to decide on patentability of a claimed invention. According to the USPTO, more robust and reliable patents should result, which is better for the public. **See** *USPTO Publishes Notice Calling Out Pharmaceutical Industry*, Goodwin Life Sciences Perspective blog, August 1, 2022.

The USPTO now published a Request for Comments (RFC) (87 FR 60130 (October 4, 2022)) on USPTO initiatives to ensure "robustness and reliability" of patent rights, the new buzz words for increased patent quality. Again, the pharmaceutical industry appears to be the main target of the new initiatives. In the background section is President Biden's Competition Executive Order (EO) that calls for action "to help ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic drug or biosimilar competition beyond that reasonably contemplated by applicable law." The RFC also references the Food and Drug Administration and USPTO interactions and communications to help promote the EO.

In particular, the new initiatives for "robust and reliable" patents are primarily directed to preventing what's been termed, "patent thickets," which has been defined by Senators Leahy, Blumenthal, Klobuchar, Cornyn, Collins and Braun as a "large number of patents that cover a single product or minor variations on a single product." According to the Senators, patent thickets impede the generic drug industry to the detriment of the U.S. public.

Included in the new USPTO initiatives to execute the EO are more time and resources to examine patent applications, enhanced processes for information disclosure statements and the identification of key prior art, consideration of applying greater scrutiny to continuation patent applications and use of declaratory evidence during patent prosecution, revisiting terminal disclaimer practice and procedures for third party input during prosecution, and a comparative analysis of the prosecution and grant of "pharmaceutical and biological patents" in the United States versus other countries.

The stated primary purpose of this RFC is to solicit comments from the public on these initiatives, the latter of which is specific to the pharmaceutical industry. Of note, though, the specific topics and initiatives currently being addressed in the RFC are prior art searching, e.g., databases of non-patent literature, support for patent claims in continuation patent applications including priority dates, request for continued examination (RCE) practice, and restriction, divisional, and terminal disclaimer practices.

The RFC includes a list of eleven questions. The first five, some with many subparts, address the USPTO topics and initiatives discussed immediately above. The final six questions are directly from a letter from the Senators to the USPTO. These latter questions are quite enlightening as to what's in the minds of the Senators and their possible solutions to their perceived problems with the U.S. patent system.

More specifically, the Senators question terminal disclaimer practice, suggesting eliminating it to

prohibit patents that are obvious variants. Another question suggests that patents terminally disclaimed over each other should stand or fall together with respect to their validity because they are all obvious variants of each other. Other questions lean towards higher scrutiny and examination of continuation patent applications including limiting the time frame when such applications can be filed and increasing the fees for such filings.

Although the specific questions posed do not single out patents of the pharmaceutical industry nor include a comparison of such patents to non-U.S. counterpart patents, the incentive for the RFC, which typically precedes a notice of proposed rulemaking, seems to signal an attempt to change the current patent practices of the pharmaceutical industry.

In sum, similar to the USPTO Notice on disclosure requirements, although all technologies are included, the RFC appears to be directed most specifically to brand name pharmaceutical companies. Is the RFC another a shot over the bow of the brand name pharmaceutical companies' patent filing and prosecution strategies? Is this more signaling of the beginning of higher scrutiny for their patent applications and the "patent thickets" they create? If so, will such scrutiny permit generics to enter the marketplace earlier, to meet the Administration's objectives? Again, only time will tell.

Significant Drug Pricing Reform Measures in the Inflation Reduction Act of 2022

On August 16, President Biden signed the Inflation Reduction Act of 2022 into law,[1] which includes some of the most significant drug pricing-related changes since the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

The healthcare-related portions of the law introduce many important changes, most notably allowing the Medicare program to negotiate with pharmaceutical companies for reduced prescription drug prices under Medicare Part B and Medicare Part D (commonly known as the Prescription Drug Benefit for America's senior population) for certain single-source drugs, or rather those drugs and biologicals without generic or biosimilar competitors. The law will also require drug makers to pay the government a rebate for any drug whose price increases faster than the pace of inflation. It also modifies several aspects of the Part D benefit to cap Medicare beneficiaries' out-of-pocket costs.

Heath Ingram, **Matt Wetzel** and **Roger Cohen** provide a high-level summary of these provisions and other important considerations in this **client alert**.

USPTO Publishes Notice Calling Out Pharmaceutical Industry



President Biden's *Executive Order on Promoting Competition in the American Economy*, 86 FR 36987 (2021), expressed concerns about the patent system being misused to unnecessarily inhibit or delay entry of generic drugs or biologics to the marketplace for years, denying Americans access to lower cost drugs. The President called for action "to help ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic drug or biosimilar competition beyond that reasonably contemplated by applicable law."

The Food and Drug Administration (FDA) was charged with the task of identifying any concerns with the patent system being used in such an unjustified way. To this end, the FDA reached out to the U.S. Patent and Trademark Office (USPTO) in a cooperative spirit to promote further interactions to better understand their overlap in work and information, particularly where inconsistent statements might be made to each agency.

In response to the President and the FDA's outreach, the new Director of the USPTO, Katherine Vidal, published in the Federal Register (87 FR 45764 (July 29, 2022)) a stern reminder regarding the duties of disclosure and reasonable inquiry during examination of a patent application, including reexamination, reissue, and proceedings before the Patent Trial and Appeal Board (PTAB). The justification is to provide examiners and judges with all the material information needed to decide on patentability of a claimed invention. Consequently, more robust and reliable patents should result, which is better for the public.

The Notice reminds us of who has duty to disclose material information and what material information needs to be disclosed. In essence, anyone associated with the prosecution of a patent application or involved in the examination of a patent before the USPTO or PTAB is required to disclose to the patent examiner or administrative law judge information that would be material to the patentability of the claimed invention. Material information could include communications from other government agencies, for example, from the FDA.

The Notice also details what is the duty of reasonable inquiry. For example, a party filing a paper with the USPTO has a duty to perform an inquiry as reasonable under the circumstances, which may include reviewing documents received from another government agency, for example, the FDA. If the document is material to patentability, then the document must be appropriately submitted to the USPTO.

The final section of the Notice is under the heading, "When the Duties of Disclosure and Reasonable

Inquiry Arise in Dealings With Other Government Agencies," which section emphasizes the consistency of statements made to different agencies and the need to correct statements later learned to be incorrect at the time they were made. Activities and publications associated with testing, marketing, and commercialization by a patentee or patent applicant can also be material to patentability and must be disclosed. Examples also include information learned from a generic company filing an Abbreviated New Drug Application (ANDA) and namely, a paragraph IV certification alleging that the patent(s) covering the brand name drug product are invalid. The prior art cited in the ANDA certification must be cited to the USPTO unless cumulative to publications already cited.

Of particular note is the discussion of inequitable conduct when inconsistent positions were taken before the USPTO and the FDA. The Notice details a number of examples of where inconsistent statements led to detrimental effects for the malfeasance. The Notice further warns that attempts to wall off patent practitioners from the FDA lawyers to prevent learning of possible material information are inappropriate and likely will have dire consequences. "By following the guidance in this notice, it is expected that patent applicants can obtain more reliable patent protection and avoid the findings of inequitable conduct and sanctions noted [herein]."

In sum, although all technologies are included, the Notice appears to be directed most specifically to brand name pharmaceutical companies and their dealings with the USPTO and FDA. Is the Notice a shot over the bow of the brand name pharmaceutical companies' patent filing and prosecution strategies? Is this signaling the beginning of higher scrutiny for their patent applications and the "patent thickets" they create? If so, will such scrutiny permit generics to enter the marketplace earlier, which ultimately could mean cheaper medicines sooner, meeting the Administration's objectives? Only time will tell.

The Potential Impact of State Abortion Laws on Reproductive Health Apps

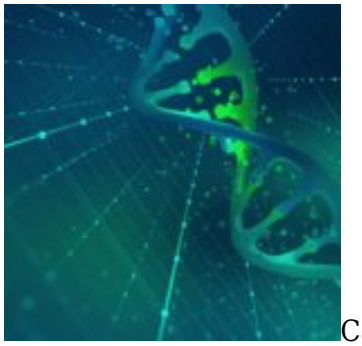


Millions of women use reproductive health applications (or "apps") to track menstrual cycles, ovulation, and pregnancy. These apps provide women that use the rhythm method for birth control and women seeking to become pregnant access to more accurate information about their reproductive systems. To accurately track a user's reproductive cycles, many health apps need the users to share highly sensitive and personal health data. This sensitive data is generally stored and may include dates of ovulation, conception, pregnancy start, and pregnancy end, if applicable. Needless to say, reproductive health app developers manage and maintain a data platform that contains some of the most sensitive and private information about their customers.

The highly sensitive and private customer information contained in reproductive health apps has been thrust to the forefront of the evolving landscape of abortion laws in the United States. The U.S. Supreme Court ("SCOTUS") **decision** to overturn ***Roe v. Wade*** authorizes states to limit, restrict, and criminalize abortion. **As many as half of all U.S. states have some form of an abortion ban in effect, or one that is expected to take effect in the near future**, due to the SCOTUS decision. These abortion ban laws are frequently referred to as "trigger laws." State laws that criminalize abortion could have an immediate impact on how reproductive health apps implement and enforce personal health data security measures (*i.e.*, privacy policies and procedures).

Read the alert **here**.

Taking Security Interests In Human Reproductive Tissue: Clarifying Lender Options Under Federal And State Law



Can human reproductive tissue ("HRT") held by a fertility clinic serve as collateral for a loan to (or investment in) the fertility clinic? In short, the scope and extent of governmental regulation addressing the sale of or transfer of ownership interests in HRT held by a fertility clinic varies from state to state; however, most state laws would likely prohibit the sale of HRT except in very specified cases. As an extension of this concept, most state laws would also prohibit taking a security interest in the HRT, as would ethical and religious-based concerns triggered by the concept of third-party ownership interests in another person's HRT. Read the alert **here**.

New OIG Advisory Opinion Impacts Pharmaceutical & Medical Device Company Funding of Continuing Education Programs



OIG Advisory Opinion 22-14 (June 29, 2022) could have significant implications for how life sciences companies (pharmaceutical, medical device, and diagnostics test makers) contribute towards continuing education ("**CE**") programs for healthcare providers ("**HCPs**"). Specifically, in AO 22-14, the U.S. Department of Health & Human Services Office of Inspector General ("**OIG**") rejects a Requestor's proposal to permit pharmaceutical and medical device industry sponsorship of a CE program for HCPs, noting that it could generate prohibited remuneration under the Federal Anti-Kickback Statute.

Read the full Washington legal Foundation's Legal pulse blog post **here**.

Whistleblower Lawyers Use False Claims Act to Target Private Equity Firms Invested In Healthcare and Life Sciences



Recent developments demonstrate that the health care industry – including life sciences companies – continues to be subject to heightened regulatory scrutiny and enforcement risk. This alert addresses the U.S. Department of Justice ("DOJ") use of the False Claims Act ("FCA") to pursue private equity investors and their portfolio companies, including life sciences companies. While DOJ has been actively investigating private equity portfolio companies, the driver behind the majority of DOJ's investigations are whistleblower plaintiff lawyers who file *qui tam* suits alleging FCA violations. These lawyers have found a receptive audience in both legislative and executive branches of the federal government and are bringing pressure on DOJ to ramp up its focus on the private equity industry, a perceived deep-pocket in FCA cases. Our lawyers **Kirk Ogrosky**, **Anne Railton**, **John LeClaire** and **Chris Wilson** examine the issue in this **client alert**.

Common Bioresearch Monitoring Violations: Updates from FY 2021 to Now



The Bioresearch Monitoring Program (BIMO), run by the U.S. Food and Drug Administration (FDA), oversees the conduct of on-site inspections and data audits of FDA-regulated research in support of new product development and marketing approvals. As a follow up to our **July 2021 post**, we highlight here the most common violations FDA's BIMO identified in Fiscal Year (FY) 2021 along with those we have seen so far in FY 2022. Our review focuses on BIMO's clinical investigator, sponsor, and contract research organization (CRO) inspection outcomes across 516 inspections conducted in FY 2021, as these comprised nearly 85 percent of all BIMO inspections.

Amongst these, 81 percent did not result in any findings of noncompliance. Eighteen percent resulted in findings of noncompliance but without recommending regulatory action, and about one percent resulted in findings of noncompliance recommending official regulatory action. In FY 2021, the most common violations leading FDA to issue a Form FDA 483, FDA's official form for documenting noncompliant inspection findings, included:

- **Failure to submit an IND application.** For example, FDA issued several Warning Letters for investigations of dietary supplements or foods determined by the FDA to be drugs. FDA found that the study designs demonstrated the investigational products were intended to cure, mitigate, and/or treat a disease or condition, triggering application of FDA's drug authorities and requiring an Investigational New Drug (IND) application to be in place before conducting the research.

- **Failure to follow the investigational plan and implement corrective or preventive action plans.** For example, in one **Warning Letter** resulting from a BIMO inspection, the FDA noted that the investigator failed to exclude subjects according to the study's exclusion criteria and did not identify any procedures in place to prevent future violations.

- **Inadequate or inaccurate recordkeeping (including case histories, study records, and drug disposition records).** For example, in one recent **Warning Letter** following a BIMO inspection, the FDA noted that a study site failed to retain necessary documents for 2 years following marketing approval when it could not locate informed consent forms and case report forms, amongst others, from a study for which a Biologics License Application was pending.

Of note, these continue to be the most frequently cited violations in BIMO Warning Letters issued to date in 2022. To avoid these missteps and better understand the scope of their respective

responsibilities before, during, and after a clinical trial, sponsors, CROs and investigators should review **FDA's BIMO Compliance Program Guidance Manuals** and ensure adoption of standard operating procedures (SOPs) that provide an infrastructure for regulatory compliance. Sponsors and investigators should also ensure that they understand when an IND application is required, and review the requirements for appropriate recordkeeping during and after a clinical trial. Finally, sponsors and CROs should have mechanisms in place to both promote protocol adherence and promptly respond to any deviations when they inevitably occur. Sponsors receiving BIMO Form FDA 483s should respond with a detailed explanation of their root cause findings, corrective actions, and their plan to prevent similar missteps in the future. The Goodwin FDA team works closely with sponsors to apply FDA's Good Clinical Practice requirements and to resolve BIMO inspection findings when they occur.

Connect with our Goodwin FDA team to learn more.

*Maura Friedlander, a 2022 summer associate in Goodwin's Washington, D.C. office, contributed to this post.