# China Closer to Granting Patent Term Extensions?


A new draft amendment to Chinese Patent Law was submitted to the National People's Congress Standing Committee on June 28, 2020. Key provisions include the establishment of patent term adjustment (PTA) caused by delays in the patent office and patent term extension (PTE). Under the new draft amendment, a Patentee could receive up to 5 years of PTE, as long as the overall patent term does not extend beyond 14 years after approval of the drug, similar to PTE available in the United States

The proposed amendments in the draft also address many other weaknesses in biopharma IP protection in China. For example, these changes include litigation reform, including stronger and more efficient patent enforcement, an increase in the statutory limit on damages (up to CNY 5,000,000), and a 6-month grace period for public disclosures made for the benefit of the public during a national emergency.

Notably, the draft also provides for a delay of marketing approval of a new drug, if that new drug is subject to patent dispute. If a lawsuit is filed by an owner of a patent listed in China's "drug patent information registration platform" within 30 days of publication of a marketing approval application, the application is stayed for up to 9 months.

If implemented, these changes would make China a more attractive jurisdiction for life science innovators and biopharmaceutical investment opportunities from around the world.

This new draft is currently available for public comment until August 16, 2020.

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# Real-World Evidence: Challenges and Opportunities During COVID-19

The urgent needs of the COVID-19 pandemic have more squarely brought into focus the role real-world evidence (RWE) can play in analyzing and informing product development and clinical and public health decisions. Specifically, the U.S. Food and Drug Administration (FDA) is participating in the COVID-19 **Evidence Accelerator**, in partnership with Friends of Cancer Research and the Reagan-Udall Foundation, to bring leading experts together to share insights and use RWE to help answer the most pressing research questions raised by the pandemic.

The FDA believes that RWE can play an informative role in analyzing potential therapies, vaccines, and diagnostics for COVID-19. At the recent "Establishing a High-Quality Real-World Data Ecosystem" **workshop** hosted by the Duke Margolis Center for Health Policy, Amy Abernethy, the Principal Deputy Commissioner of Food and Drugs and Acting Chief Information Officer at the FDA, highlighted the work of the Evidence Accelerator initiative, noting that RWE allows the FDA to constantly update its understanding of COVID-19 and recurrently analyze data to address changing needs. Amongst the other presenters, the general discussion focused on the many hurdles industry needs to address to establish a robust and more accurate RWE data ecosystem, including efficient capture of reliable data at the source. While internet access, smartphones, and wearable technology enable consumers and patients to keep meticulous records of their biometric data, the vast amount of collected data does not necessarily lead to efficient or fruitful analysis currently. FDA noted during the workshop that, to be more insightful, RWE stakeholders must narrowly tailor their collection to what is actually useful and relevant to clinical endpoints, fit for purpose, rather than merely what is easily accessible. Eric Perakslis, a Rubenstein Fellow at Duke University, noted that stakeholders must balance the usefulness of RWE collection against the risk of over-surveillance for each data point collected. While not discussed during the workshop, collecting massive data sets must also be weighed against the ever-present risk of data breach. Finally, speakers also discussed patient-generated health data (PGHD) and the need for aligned stakeholders who are motivated to collect this data and understand the process for doing so, including a plan for handling outlier data which is unavoidable with PGHD.

In the context of the COVID-19 pandemic, RWE presents an opportunity for real-time learnings toward quicker identification and development of treatments and vaccines. As a result, the pandemic has only strengthened the importance of RWE in product development and, if deployed well, could help support more efficient and expedited product development plans.

*Emily Tribulski, a 2020 summer associate in Goodwin's Washington, D.C. office, contributed to this post.

# Life Science Companies Participate in Convertible Bond Surge

Life science companies have been among the biggest users of convertible debt financing in the first half of 2020.  As highlighted in our recent **Client Insight article**, life science, technology and other traditional high-yield debt issuers were the biggest participants in the record issuance of convertible bonds.  Through June 30, 2020, U.S. companies raised over $64 billion in 114 convertible bond offerings with most of the surge occurring in the second quarter. May 2020 saw a record $20.7 billion of convertible debt issued. The previous record monthly high for convertible issuance was $19.2 billion in May 2001.

The strength of the convertible bond market was due in part to high share price volatility in equity markets and wide credit spreads above comparable U.S. Treasuries in debt markets.  These market conditions make convertible debt an attractive source of capital versus equity follow-ons and high-yield debt offerings.  One notable life science transaction in the first half of 2020 was BridgeBio Pharma Inc.'s (BBIO) pricing of an upsized $550 million (from $375 million) convertible debt offering that featured a 2.50% coupon.  Additionally, BBIO entered into capped call transactions to raise the effective conversion prices of the notes and hedge risk of equity dilution upon conversion.  The strength of the convertible debt market enabled BBIO and other life science companies to raise capital at attractive levels.  In the first half of 2020, the average coupon rate for all convertible debt offerings was 1.25% with an average conversion premium of 37%.

Given that share price volatility and credit spreads are still at historically high levels, convertible bond offerings are expected to remain a popular source of financing for life science issuers in the second half of 2020.

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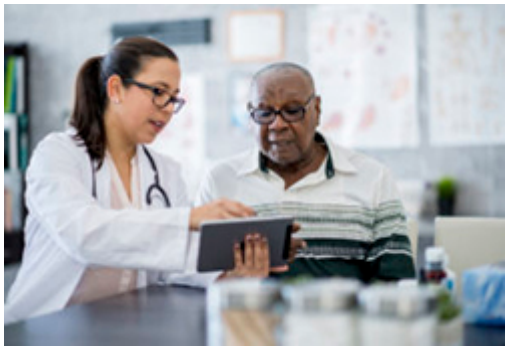
# What are Clinical Outcome Assessments (COAs) and Can They be Used to Support Approval and/or Labeling Claims?



The patient voice is recognized as one of the most critical sources of data in drug development, and patients play an increasingly important role in these efforts by teaching us about their experience with their condition and its impact. A common way sponsors can leverage the patient experience is by utilizing a clinical outcome assessment (COA). A COA is an assessment that describes or reflects how a patient feels, functions, or survives. Such an assessment can be a patient-reported outcome (PRO) measure, observer-reported outcome (ObsRO) measure, clinician-reported outcome (ClinRO) measure, or a performance outcome (PerfO) measure. **Alexander Varond** chaired a session on this topic in June 2020 at the Drug Information Association's Annual Meeting. Slides from his presentation can be found **here**.

FDA plans to issue a guidance that will provide patient-focused approaches and methods to consider in the selection and/or development of COAs. This future guidance, known as Patient-Focused Drug Development (PFDD) Guidance 3, is one piece of FDA's plan to develop a series of four PFDD-specific guidances for stakeholders on how to collect and utilize patient experience data in drug development. We initially discussed this plan and background on patient experience data **here**. In the meantime, FDA has described a "roadmap to COA selection/development for clinical trials" **here**. This roadmap sets forth how to obtain an understanding of the disease or condition, conceptualize clinical benefit (i.e., how a patient feels, functions and survives), and how to select, develop and modify a COA. In Guidance 4, FDA will discuss how to incorporate COAs into endpoints for regulatory decision-making. FDA issued a discussion document related to the forthcoming Guidance 4 **here**.

As background, a COA may support approval of a product if it is a "well-defined and reliable" assessment (21 CFR § 314.126). FDA interprets this to mean that the COA must have content validity, construct validity, reliability, and the ability to detect change. But COAs can do much more. For example, COAs can be included in labeling claims, as with CRYSVITA (burosumab-twza) for X-linked hypophosphatemia linked **here**, which incorporates both PRO and ClinRO measures. COAs can even lead to a regulatory change in thinking about a particular disease or condition. For example, just over two months after hearing directly from patients with epidermolysis bullosa (EB), a rare disorder that results in serious cutaneous manifestations, at an externally-led PFDD meeting, FDA published a draft guidance for sponsors developing therapies for EB that outlined specific examples of efficacy endpoints that would show the drug provides a clinically meaningful improvement. The finalized guidance can be found **here**.

If you are considering developing or utilizing in your clinical development program a COA, or if have questions about other PFDD initiatives such as PFDD meetings, we encourage you to contact your Goodwin life sciences lawyer for assistance on how to incorporate the patient voice–the real experts on their disease or condition—in drug development.

# Goodwin Webinar – Healthcare Issues + Trends: The False Claims Act and Other Government Enforcement

Healthcare companies are facing unprecedented challenges as a result of the COVID-19 crisis. This includes heightened enforcement risks. A key area of risk is the federal False Claims Act (FCA), a powerful tool for the DOJ to seek substantial penalties including three times the amount of money a company received in federal funds.

Join members of Goodwin's Healthcare team as they discuss recent enforcement developments and ways to mitigate risk from a panel of Goodwin lawyers with experience helping healthcare companies, their executives and medical professionals navigate enforcement investigations.

To register for this event, please visit the registration page **here**.

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# USPTO Announces COVID-19 Prioritized Examination Pilot Program for Small or Micro Entities

The United States Patent and Trademark Office (USPTO) is accepting requests for prioritized examination or "fast track" of patent applications that claim a product or process subject to FDA approval for COVID-19 use, without the payment of additional fees. The USPTO will advance accepted patent applications out of turn, aiming to reach a final disposition within one year of granting prioritized status. Up to 500 patent applications will be accepted under the pilot program. As of July 9, 2020, 66 requests had been granted, with 434 acceptances still available.

Details regarding the pilot program were published in the Federal Register (**85 Fed. Reg. 28932**). The Federal Register Notice indicates that FDA approvals may include, but are not limited to, an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA).

To qualify for consideration under the pilot program, a **request** for prioritized examination must be made with the filing of a new utility or plant nonprovisional application or with the filing of a utility or plant nonprovisional application claiming priority to only one prior nonprovisional or international patent application. In addition, a request for prioritized examination may be filed with or after filing a Request for Continued Examination (RCE) of an existing utility or plant nonprovisional application, but only one such request may be granted in an application. The Applicant also must certify that they qualify for small or micro entity status. Other requirements include the submission of an Application Data Sheet with the application, and limiting the number of claims to 4 independent claims and 30 total claims.

The USPTO has announced that it will periodically evaluate whether the program should be expanded.

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# Think Your Drug is Safe and Effective? Not So, Says the SEC

For life sciences companies who are or are looking to become publicly traded in the U.S., one of the most frequent comments that we see from the SEC as part of their review process is the following:

You make several assertions regarding the safety and efficacy of certain of your product candidates. Safety and efficacy determinations are solely within the authority of the FDA (or applicable foreign regulators). Please revise these statements to remove statements/inferences that your product candidates are safe and/or effective. We will not object to a discussion of whether your product candidates were well-tolerated or discussion of whether trial endpoints were met.

Given the frequency with which verbiage such as “safety data” or “efficacy data” is used among drug developers, investors and even the FDA itself, this position by the SEC often catches companies by surprise. However, the SEC has consistently taken the view that such references are not appropriate in companies’ SEC disclosures. Importantly, even oblique references to “safety” or “efficacy” (for instance, forward-looking statements regarding the expected safety profile of a product candidate) will often draw an SEC comment.

Fortunately, there are typically relatively straightforward ways to resolve this comment. For instance, rather than referring to a drug's efficacy, companies can instead refer to whether it met trial endpoints or demonstrated activity. Similarly, in lieu of referring to a drug's safety, companies can refer to its tolerability or its adverse event profile observed to date.

While this topic is typically a point of emphasis in the IPO process, we often find that companies become less vigilant about avoiding "safety" and "efficacy" references in their subsequent Exchange Act periodic reports (not to mention their press releases and investor presentations). However, we frequently see this comment come up in SEC reviews of public company periodic reports, and proactively steering away from references to "safety" and "efficacy" can be a useful way to remove some low-hanging fruit that might otherwise draw an SEC comment.

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# Capital Markets in the Time of Pandemic – Second Quarter Biotech Update


As we reach the mid-point of 2020, the second quarter was the busiest quarter for biotech equity to date, and we continue to see an active IPO market with issuers pushing to expeditiously get on file and take advantage of the continued investor receptiveness to biotech equity offerings. The ongoing effect of COVID-19 has brought about some interesting trends during the 2020 IPO frenzy. Although many were at first hesitant to launch a road show in light of COVID-19, "early canaries in the coal mine" Zentalis Pharmaceuticals and Keros Therapeutics successfully launched and priced their upsized offerings at the top of the range.

The inability to have the traditional 10-day in-person road show meetings has resulted in truncated four-day virtual road meetings, which was utilized by both Zentalis and Keros and the biotech IPOs that followed. This shortened book building process has shifted priority and significance to testing-the-water meetings, resulting in more robust and fulsome meetings to allow issuers and underwriters to assess market interest.  Additionally, with the XBI outperforming the S&P, we've seen more generalist investors shifting their investments to biotech. This increase in demand has, in turn, resulted in larger than usual IPOs pricing, with several issuers raising in excess of $200 million after upsizing their offering and pricing at the top of, or above, their initial offering range.  Importantly, the completed IPOs have generally traded well, opening sharply up on the first day of trading, which in turn fuels the pipeline of issuers and demand.

Another interesting development in 2020 is the traditional lack of disclosure regarding insider participation on the cover of S-1s to show support for the IPO,  which was the norm in 2019 and previous years.  In 2019, banks typically looked to have insiders fully cover the IPO with insider demand before launching the deal and expressly signaled the insider support by having prominent

disclosure on the cover of the S-1. In 2020, we've seen banks move away from this express disclosure and marketing angle in order to signal to new investors that meaningful allocations will be available as the company looks to diversify its inventor base. As we look forward into the back half of the year, July is shaping up to be another busy month with several companies having publicly filed their S-1s to commence the 15-day waiting period before beginning their road shows. The desire for companies to commence their IPO process with organizational meetings and bake-offs continues, and if the market holds,  the third quarter, and even the fourth, could continue to the trends we've seen to date.

**Read the Insight >>**

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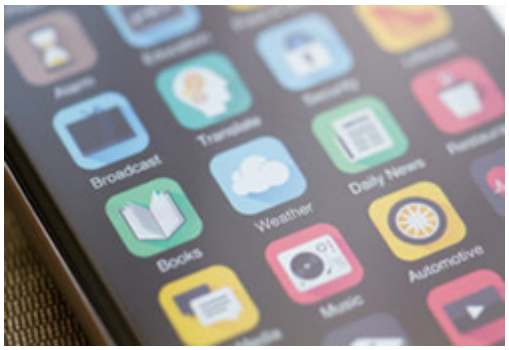
# FDA's COVID-19 Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders




Developers of certain digital health devices for treating psychiatric disorders may be able to take advantage of an FDA **enforcement policy**, which remains in effect for the duration of the COVID-19 public health emergency.  The policy applies to certain prescription computerized behavioral therapy (CBT) devices for psychiatric disorders, digital health therapeutic devices for psychiatric disorders that operate using a different fundamental technology than CBT, other variations of CBT devices, such as non-prescription devices, and low-risk general wellness and digital health products for mental health or psychiatric conditions.

Relevant psychiatric conditions include Obsessive Compulsive Disorder, Generalized Anxiety Disorder, Insomnia Disorder, Major Depressive Disorder, Substance Use Disorder, Post-traumatic Stress Disorder, Autism Spectrum Disorder, and Attention Deficit Hyperactivity Disorder. The enforcement policy's goal is "to help expand the availability" of these devices to aid those with these conditions "while reducing user and healthcare provider contact and potential exposure to COVID-19."

Under this policy, these devices may be distributed and used without complying with the following regulatory requirements, where such devices do not create an undue risk in light of the public health emergency: 510(k) submission, correction and removal reports, registration and listing requirements, and Unique Device Identification requirements. For those software products with low-risk general wellness indications or functionality, FDA does not intend to enforce regulatory requirements consistent with the agency's existing policies, which were in effect prior to the

pandemic. Finally, FDA’s enforcement policy sets forth certain recommendations regarding the performance and labeling elements for these devices, such as user instructions that direct the patient to contact a physician before using the device. This enforcement policy highlights FDA’s regulatory flexibility for software and app developers in this therapeutic area during the COVID-19 pandemic.