What the Bipartisan Budget Agreement Means for the Healthcare Industry and Life Sciences Companies

December 23, 2019

On December 20, 2019, President Trump signed into law an appropriations bill containing a number of provisions that will significantly impact the healthcare industry and life sciences companies. Among other things, this law repeals certain taxes imposed by the Affordable Care Act ("ACA"); requires innovator pharmaceutical companies to make samples of their drugs available to "eligible product developers" who request them; adds "chemically synthesized polypeptides" to the FDA-regulated category of "biologics"; and provides additional funding for cancer and Alzheimer's research. Noticeably absent from the bill are controversial proposals governing drug pricing and provider billing practices. We address the impact of these provisions, and what they mean for the healthcare industry, life sciences companies and investors, below.

ACA Taxes to Be Repealed

The law repeals the following three taxes that were originally included in the ACA but have either never been implemented or are currently suspended:

Medical device surtax. The ACA included a 2.3% surtax on medical devices. The tax was in place from 2013 through 2015.

Cadillac tax. The ACA included a 40% excise tax on the cost of employer-sponsored healthcare plans that exceeded a statutory threshold. This tax was supposed to be implemented starting in 2018 but has never gone into effect.

Health insurance tax. The ACA included a tax on the cost of health insurance plans, which was estimated to add 3% to the cost of health insurance premiums. This tax was in place from 2013 to 2016, and then again in 2018. It has subsequently been suspended.

What is the impact of the repeal of these taxes? All three taxes were opposed by the impacted industries and many other stakeholders for a wide range of reasons. In particular, the Cadillac tax would have been highly disruptive because premiums above the statutory threshold would likely have become unaffordable for many policyholders.

Had the Cadillac tax gone into effect, insurers would have needed to substantially restructure plans to lower premiums—with corresponding large increases in consumer cost sharing or reductions in the scope of coverage. By finally eliminating these taxes, Congress has ended longstanding uncertainty surrounding when and whether these taxes would be revived.

The "CREATES Act"

The law includes language from a stand-alone bill known as the "Creating and Restoring Equal Access to Equivalent Samples Act" (the "CREATES Act"). These provisions were designed to address allegations made by generic drug companies ("generics") and their supporters that innovator pharmaceutical companies ("innovators") are using improper tactics to extend the marketing exclusivity of branded drugs beyond what is allowed by law.[1]

After patents and marketing exclusivity for an innovator drug expire, lower-cost generic drugs are typically introduced into the market. To receive approval from the Food and Drug Administration ("FDA") to sell a generic drug, a manufacturer must ordinarily submit an Abbreviated New Drug Application ("ANDA") demonstrating, among other things, that the generic drug is bioequivalent to the innovator drug. To conduct bioequivalence studies, however, a generic needs to obtain samples of the innovator drug. In certain circumstances, innovators may face legal impediments to making samples available. For instance, limitations on distribution are sometimes imposed by the FDA as part of a Risk Evaluation and Mitigation Strategy ("REMS") with elements to assure safe use ("ETASU"). Innovators also have concerns that they may be sued if generics mishandle the samples. That said, generics claim that innovators are refusing to provide samples in order to preclude generics from conducting the bioequivalence studies that are prerequisites for ANDAs.

This law addresses such allegations by allowing an "eligible product developer"—typically a generic—to file suit against an innovator in federal district court if the innovator does not make available sufficient quantities of needed samples "on commercially reasonable, market-based terms."

These "commercially reasonable" terms are defined as follows:

---

[1] Although we use the terms "innovators" and "generics," many companies market and develop both innovator and generic drugs. Such companies may be on both sides of this issue at various points in time and therefore should develop policies reflecting the potential for disparate positions regarding this issue.

- The price must be "nondiscriminatory" and must be at or below the drug's wholesale acquisition cost.

- The innovator may not impose any conditions on the sale of samples.

- For a drug that is not covered by REMS with ETASU, an innovator must provide the samples within 31 days after a demand is made for them. For a drug that is covered by REMS with ETASU, the samples must be provided within 31 days following the later of: (i) the date of the demand for the product or (ii) the date under which FDA provides authorization for release of the samples (if certain conditions are met).

The law provides that an innovator is not subject to liability if it can prove that (i) the innovator is not manufacturing the drug and does not have inventory access; (ii) the drug is available to purchase from wholesalers or distributors; and (iii) the innovator made an offer to sell sufficient quantities of the product at commercially reasonable terms.[2]

If an "eligible product developer" prevails in a lawsuit, it can obtain three remedies (which are not mutually exclusive):

- A court order requiring the innovator to provide the samples "without delay";

- A court order requiring the innovator to pay reasonable attorney fees and court costs; and

- In certain circumstances, a monetary award that is "sufficient to deter" future refusal to provide samples. The award would be capped at the amount of revenue earned on the drug at issue from the original deadline for providing the samples (which can be substantial) to the time the samples were actually provided.

These provisions are highly favorable to generics because innovators have limited defenses if they turn down a request to purchase samples and are subject to large damage awards (in the form of attorney fees and potentially large "deterrence" penalties). It will therefore be imperative for innovators to develop processes—overseen by skilled litigation and FDA counsel—to ensure that demands for samples are addressed appropriately.[3]

---

[2] This law precludes suits against innovators under federal or state law as a result of a generic manufacturer improperly using or handling the samples.

[3] The definition of "eligible product developer" is broad and not limited to generic drug companies. Innovators should carefully assess litigation risk before turning down any sample requests.

From a diligence perspective, investors should consider inquiring whether generics have made requests for samples that have been denied or whether the innovator has taken other steps that could be construed as attempts to preserve marketing exclusivity beyond the period prescribed by law. Although every situation is different, conduct that is intended to delay generic drug entry after the end of the exclusivity period may violate not only this new law but also the antitrust laws.

Inclusion of Chemically Synthesized Polypeptides Within the "Biologics" Definition

Chemically synthesized polypeptides are a category of pharmaceutical compounds used to treat diseases including diabetes, osteoporosis and cancer. There are currently at least 60 such products on the market and many more under development. These products can be lucrative: the manufacturer of one of these products reported $1.5 billion in revenue for 2018.

Previously, the biologic definition statutorily excluded chemically synthesized polypeptides, which led such products to be regulated as "drugs" (rather than "biologics"). The law removes that exclusion, meaning that chemically synthesized polypeptides will now be regulated as "biologics." As a result, newly approved chemically synthesized polypeptides will be granted 12 years of marketing exclusivity (for biologics)—instead of five years of exclusivity (for certain drugs). Depending on the size of the market, the extra seven years of exclusivity could result in substantial additional revenue.

In the Biologics Price Competition and Innovation Act of 2009 ("BPCI Act"), Congress mandated that certain protein products previously approved as "drugs" pursuant to "new drug applications" would be "deemed" to have a biologics license ("BLA") as of March 23, 2020. FDA has issued multiple guidance documents addressing the transition of such products from drugs to biologics, but chemically synthesized polypeptides were excluded. Based upon the statutory change described above, chemically synthesized polypeptides that were previously approved as drugs are also expected to be converted to biologics on March 23, 2020. Further, according to FDA, as of March 2020, pharmaceutical compounds containing chemically synthesized polypeptides will be subject to competition under the regulatory framework governing biosimilar or interchangeable products.

Additional Funding on Disease Research

The law provides for $11.6 billion in funding for the National Institutes of Health ("NIH"), which is a 38.6% increase. That funding includes: (i) a $350 million increase in funding for Alzheimer's research; (ii) $50 million for the Childhood Cancer Data Initiative; and (iii) $212.5 million in increased funding for cancer research. NIH funding is typically directed to research institutions. Studies suggest that NIH funding in specific therapeutic areas is often correlated with future drug approvals and biopharmaceutical investment priorities.

What Is Not in the Appropriations Bill?

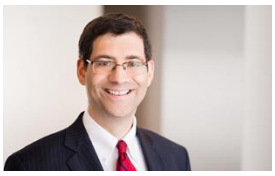
For some healthcare and life sciences sectors, the most significant development is what the law does not include. In recent weeks, Congress has been considering legislation to address two controversial issues: (i) drug pricing; and (ii) a practice often termed "surprise billing," which typically occurs when a patient is treated at a hospital that is in-network, but a provider is out of network or a patient receives care at an out-of-network emergency room facility.[4] Such bills were opposed by a wide range of interests, and would have adversely affected pharmacy benefit managers (in the case of drug pricing bills) and hospitals, physician staffing companies, and potentially air ambulances (in the case of "surprise billing"). It is now much more uncertain whether a divided Congress will reach consensus on either or both issues.

* * *

Please do not hesitate to contact us with any questions.

[4] We wrote a client update that can be found here regarding the "surprise billing" issue.

NEW YORK


Andrew L. Bab
albab@debevoise.com


Jennifer L. Chu
jlchu@debevoise.com


Mark P. Goodman
mpgoodman@debevoise.com


Maura Kathleen Monaghan
mkmonaghan@debevoise.com

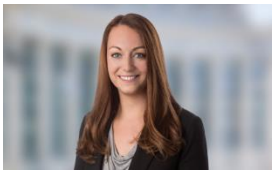

Kevin Rinker
karinker@debevoise.com


Jacob W. Stahl
jwstahl@debevoise.com

WASHINGTON, D.C.


Ted Hassi
thassi@debevoise.com


Paul D. Rubin
pdrubin@debevoise.com


Leah S. Martin
lmartin@debevoise.com