August 21, 2023

Getting Ready for the List

New Legal Challenges as Top 10 List for Rx Negotiation Comes By Sept. 1

Relevant Companies

The top ten drug list for Part D negotiation in '26 is expected to be released by -- and could come before -- September 1. i.e., in late August. As a reminder, to be selected, a drug must fall within the (1) top 50 drugs with highest total gross spending for Part D and (2) it must be past 7 years since FDA approval for small molecule drugs and 11 years for biologics with no "bona fide" generic or biosimilar (coming). Drugs that are considered small biotech drugs, plasma-derived drugs, and those with 1 orphan designation will be excluded.

Our Take & Next Up

If a preliminary injunction (Oct 1) or summary judgment is granted for any cases the law is halted/delayed for now. Those two decisions would halt the entire program, delay implementation for months-years while the cases take time to resolve. However, most in Washington believe that the program will move forward and our take on the Top 10 are below. In addition, we have created a tracker with companies that have announced discontinuation of clinical programs due to the IRA (9 total clinical programs, big & small manufacturers). We recap the legal arguments in the 6 main cases challenging the IRA below.

Key Points

Based on CMS spending data, we expect the following drugs to be eligible for negotiations in 2026. Companies impacted include PFE and BMY as Eliquis tops CMS Part D spend, Xarelto (Bayer AG, JNJ), Januvia (MRK), Imbruvica (ABBV, JNJ), Enbrel (AMGN), Jardiance (Boehringer Ingelheim, LLY), Ibrance (PFE), Symbicort (AZN), Xtandi (Astellas, PFE), Breo Ellipta (GSK), Myrbetriq (Astellas).

Final CMS negotiation rules (June 30) were friendlier to industry, and addressed some of the lawsuit arguments (gag clauses). The injunction request was submitted less than 2 weeks after the final negotiation guidance was released. While the

rules were friendlier to industry on transparency, it did not materially improve the parameters for manufacturers reiterating their stance on orphan drug and small biotech exclusions and “bona fide” marketing requirement for generics.

IRA passage has already impacted investments in small molecules (13 companies with public commentary to date, per Capitol Street analysis). We have compiled a running list of companies (*AZN, LLY, NVS, Roche*) who have discontinued or may discontinue assets due to the *Inflation Reduction Act*. Therapeutic areas that face the biggest impact going forward will be oncology, neuroscience, and likely rare diseases. Oncology pipelines may become much narrower and additional oncology indications may not be pursued by manufacturers. Contact us for access to this analysis.

Manufacturer legal challenges could delay the law. The law could be halted this Fall via preliminary injunction. A request was filed by the Dayton Chamber of Commerce that seeks relief by October 1. The request will be reviewed by Judge Thomas M. Rose (a Bush nominee) who may rule in the Chamber’s favor if he agrees with the Sixth Circuit precedence, presented by the Chamber, that the government must afford procedural safeguards to ensure just and reasonable prices and a fair return on investment and constitutional harm is “certain and impending” as ABBV (manufacturer of Imbruvica), a member, is expected to be harmed by the first year of negotiations. In the same case, HHS has filed a motion to dismiss arguing that the Chamber has no standing to sue as it is alleging harm that has not occurred yet and has not identified any members that currently have the standing to sue.

A preliminary injunction (by October 1) is relevant because that date reflects the deadline by which manufacturers must to agree to negotiation terms (for the first year, or 2026). The preliminary injunction aims to halt implementation before the program goes into effect. While the list is expected to be released on September 1, it will be rendered moot if manufacturers are not required to sign negotiation agreements by October 1.

LAWSUIT UPDATE

To date, six lawsuits have been filed. They include MRK’s lawsuit filed in the District Court for DC, BMY’s lawsuit filed in a District Court for New Jersey, the Chamber of Commerce’s lawsuit filed in a District Court for Ohio, PhRMA’s lawsuit filed in District Court for the Western District of Texas, JNJ’s lawsuit filed in a District Court for New Jersey, and Astellas’ lawsuit filed in a District Court in Illinois. Note all of the filings have been in different states with different regional Circuits for appeals. The number of cases in different Circuit courts increases odds of Supreme Court review as the high court may step in to harmonize conflicting decisions.

Summary judgments are also on deck that could halt implementation. A summary judgment is a decision made by a judge based on statements and evidence without going to trial. A summary judgment is awarded if the undisputed facts and the law make it clear that one party would prevail if the matter were to proceed to trial.

- **On July 11, MRK filed a motion for summary judgment in its favor**. MRK argues that the ongoing case creates “untenable uncertainty” for the company and for the government. MRK refers to their needs to know IRA impact on their R&D plans and the federal government’s needs to know if lower prices are going to be “boomerang” back in compensatory awards to companies. MRK also notes there is uncertainty around the “Government’s obligation to pay monetary compensation for its below-market seizures” and there is a public policy perspective where “declaration would serve the public interest by clarifying the legality of the program”. A summary judgment, if granted to MRK, can be appealed but the government is expected to halt the negotiations during the appeal process.
- **On August 10, PhRMA files a motion for summary judgment based on all three of its arguments**. PhRMA references various court precedence that supports their arguments for violations of separation of powers and the nondelegation doctrine, the Eight Amendment’s Excessive Fines clause, and Fifth Amendment’s Due Process Clause.
- **BMY & JNJ filed motions for summary judgment as well (August 16).** Both companies have agreed to consolidate their cases against the government as they present similar legal arguments. A combined case is expected to allow for a

more efficient resolution as the government will be able to respond to arguments from the different plaintiffs simultaneously.

The constitutional challenges to IRA's drug negotiation remain relatively consistent (1st, 5th, & 8th amendment violation), but PhRMA and Chamber of Commerce are making broader arguments on the legality of the Congress to confer these negotiation powers (separation of power). Multiple lawsuits in separate District Courts have been filed to increase the odds of Supreme Court review as conflicting decisions are likely to arise. PhRMA and other litigation is aiming for Supreme Court review as any decision striking down the Medicare price negotiations would have to be made by the justices.

LEGAL RECAP

All suits filed to date consistently argue the violation of the 5th Amendment from the Rx negotiations. PhRMA alleges that negotiations violate the 5th Amendment but frame it in a "due process" argument like the Chamber of Commerce suit, rather than a "just compensation" argument by drug manufacturers (BMY, MRK, JNJ, Astellas). The companies stated the negotiations by the government are forcing manufacturers to sell their property to the government without "just compensation" as the government unilaterally can determine price and they point to the heavy penalties that manufacturers could face if they do not cooperate. Notably, Astellas uses both "just compensation" and "due process" arguments under the Fifth Amendment in their suit.

The 5th Amendment arguments are expected to be consistent in future litigation and be critical in terms of having the negotiation program declared unconstitutional. PhRMA accuses the Drug Negotiation program of denying manufacturers their protected property interest without constitutional adequate procedures. The lawsuit points to the (1) limited number of meetings between manufacturer and agency during the negotiation process, (2) the gag order on manufacturers, (3) the lack of public notice-and-comment procedures and (4) the exemption from judicial or administrative review.

Most of the lawsuits (MRK, BMY, JNJ, Astellas, Chamber of Commerce) also allege violation of the 1st Amendment or "compelled speech" from negotiation implementation. The lawsuits allege that companies will be forced to communicate that they have "agreed" and endorse HHS's "fair price" even when they do not agree with this characterization.

PhRMA and the Chamber of Commerce lawsuit share similar arguments in violation of the 8th Amendment's excessive fines clause. PhRMA states, "by design, this tax functions as a penalty" and argues that the penalty over-punishes pharmaceutical companies compared to the offense ("unwillingness to agree to a government-mandated price"). PhRMA and the Chamber of Commerce also allege an additional violation of "separation-of-powers" clause as HHS has nearly unfettered discretion in setting drug prices and compelling pharmaceutical manufacturers.

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