

June 6, 2023

## MRK Litigates Rx Negotiation (5th and 1st Amendment)

More to Come, Injunction Sought in DC Court, Final HHS Guidance Impacts

Relevant Companies



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Today, Merck (MRK) formally sued HHS and CMS to stop IRA drug negotiation implementation that is set to start in 2026. The link to the Court filing is [here](#). The lawsuit precedes the release of final drug negotiation guidance this summer as well as the release of the first list of drugs in September 2023.

### »» Our Take & Next Up

**The bellicose wording is noteworthy, as Merck attacks the constitutionality of the *Inflation Reduction Act's* Rx negotiation clause.** (1) We should see an injunction decision in the coming weeks/months (2) Lawsuits are never quick – and easily take months, and often years (3) We have seen past HHS guidances impacted by legislation. In this case, we could see more industry-friendly language in the final rule around secrecy provisions by the manufacturers (4) This is the first in a series of lawsuits that are expected on the IRA's drug negotiation program. As a reminder, the IRA bars administrative or judicial review of which drugs Medicare determines as negotiation-eligible and the "maximum fair price." (5) PhRMA, BIO, and individual drug manufacturers are openly discussing eyeing litigation options and we expect other lawsuits to follow MRK's in the near future – today's action may accelerate other litigation. (6) We may also see other stakeholders engage in litigation as negotiations negatively impact small molecule development, including oncologic treatments and rare disease medicine development, as well as pharmacies, specialty pharmacy, PBMs, health plans and others.

### »» Key Points

**Filed in the federal court in Washington DC, the 1st IRA lawsuit (of many) alleges that the drug negotiation program is neither “genuine negotiations nor real agreement.”** MRK alleges that once HHS unilaterally selects a drug, its manufacturer will be compelled to sign an agreement to sell the drug at “a fraction of their value.” The two main arguments of unconstitutionality are described below. The documents describe the drug negotiation program, part of the Inflation Reduction Act, as a “dystopian parody of ‘negotiation’” with the discounts CMS will negotiate to be 25-60%.

**(1) Merck challenges penalties for not participating in negotiation (violation of 5th Amendment).** The company argues that the requirement to negotiate violates the Fifth amendment as the government is forcing manufactures to sell their property to the government without “just compensation.” The lawsuit takes issue with the heavy penalties that manufacturers could face if they do not cooperate with negotiations which MRK points to as forcing manufacturer compliance. As a reminder, CMS will be allowed to charge an excise tax that starts at 65% of a product’s sales in the U.S. and increases by 10% every quarter to a maximum of 95%.

**(2) MRK also alleges violation of 1st Amendment rights from HHS’s public misrepresentation of the negotiation program.** The lawsuit alleges that HHS is operating through “a façade of “negotiations” and “agreements” that present the appearance that manufacturers have “agreed” to HHS’s prices. MRK has alleged this public appearance of the drug negotiation program has “conscripted companies to legitimize government extortion” which is compelled-speech.

**MRK’s pugnacious lawsuit predates final CMS guidance that is expected to be released later this summer (June/July).** Lawsuits takes months, not years, and MRK has asked for an injunction to stop the rules from going into effect.

**Lawsuits influence policy, as we have seen before, and we could see industry-friendly modifications to the final rules.** MRK filed its lawsuit with an argument that has nothing to do with guidances or anything related to procedural grounds. We could still see the final Negotiation guidance released this summer, per CMS’s timeline, but potentially friendlier to industry than the draft guidance due to this lawsuit, future litigation (unless of course an injunction is granted, which halts the new law).

**One change we could see in the final rules.** Recall that secrecy of all negotiation details were required by manufacturers -- .companies couldn’t even say what the original price was. This could be moderated. “The IRA uses severe penalties to requisition medicines while refusing to pay their fair value — and then coerces manufacturers to smile, play along, and pretend it is all part of a ‘fair’ and voluntary exchange,” the suit states.

**The “list” ...** MRK is one of several companies (PFE, LLY, JNJ, BMY, NVO, among others) that are likely to be impacted in the first year of negotiations in 2026. Based on most recent CMS data, these drugs are likely to be eligible for negotiation. Eliquis (*BMY, PFE*), Xarelto (*Bayer AG, JNJ*), Januvia (*MRK*), Imbruvica (*ABBV, JNJ*), Enbrel (*AMGN*), Jardiance (*Boehringer Ingelheim, LLY*), Ibrance (*PFE*), Symbicort (*AZN*), Xtandi (*Astellas, PFE*), Ozempic (*NVO*), Myrbetriq (*Astellas*).

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