

YEAR-END EARNINGS: FOR PHARMA COMPANIES IN IRA PRICE NEGOTIATIONS, A MOMENT TO HEDGE



OVERVIEW

The Inflation Reduction Act is on everyone's radar – and the drug price negotiation aspect is the legislative centerpiece for the pharma industry, as it is poised to potentially reshape the pharma landscape. As we approach the September 1 deadline for final price setting of the first 10 drugs under the IRA, stakeholders are observing how companies involved maneuver through these uncharted waters; in particular, we expect more questions from investors that companies will need to address around the potential impact on their business, pipelines, development plans and growth prospects. With price negotiations in progress, DGA analyzes the corporate response, examining which companies are addressing the IRA, and how, in their most recent earnings calls.

THE IRA & DRUG PRICE NEGOTIATIONS – HOW WE GOT HERE

When drug price negotiations were included in the Inflation Reduction Act (“IRA”) signed into law in August 2022, reactions were swift and strong. While the negotiations would be limited to the price Medicare pays for them, companies with drugs that were likely to be targeted were tracking closely and legal, commercial and communications teams moved quickly to understand the potential impact. Several filed lawsuits just as the Centers for Medicare and Medicaid (CMS) named the first 10 drugs for price negotiations last August.

By September 2023, AstraZeneca, Novo Nordisk, Merck, Johnson & Johnson, Boehringer Ingelheim, Bristol Myers Squibb and the industry trade group PhRMA all filed complaints against the Department of Health and Human Services, with arguments ranging from unconstitutionality (violations against freedom of speech, taking private property for public use without just compensation), to “price controls” and government overreach, all of which were underscored by the industry's main argument that forcing lower prices would stifle innovation and hamper access to lifesaving drugs, ultimately harming patients.

The conversation around the IRA and its impact seemed to stall at this year's J.P. Morgan Healthcare Conference, with nary a mention. But, as we gear up for US presidential elections, the political and polemic around the IRA will be in full effect. With some lawsuits still in play and 2023 year-end earnings now complete for the 12 companies in the IRA, DGA looked at how these organizations are talking about the IRA and the questions investors are (and aren't) asking now that price negotiations are finally underway.

DGA'S KEY TAKEAWAYS

1

Companies and investors, following the lead from this year's JPMorgan Conference, are still somewhat reticent about the IRA – although that will certainly change as we approach the September 1st final pricing date.

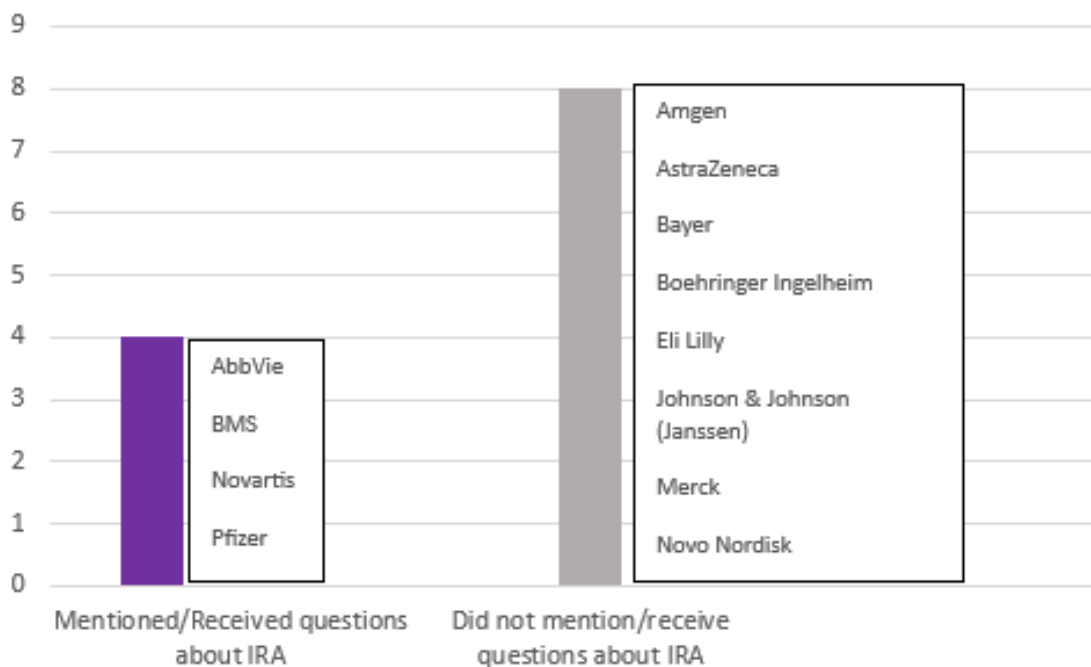
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The process is new and uncertain for everyone and, unsurprisingly, companies are reluctant to risk saying too much about how negotiations are proceeding and where prices might end up.

3

Most investors don't appear to be too concerned about the IRA impact yet; a handful want more visibility into potential impact for current drugs under negotiation but also those that may be targeted in the future – namely, will patient need and volume make up in any way for price erosion?

IRA MENTIONS/QUESTIONS IN 2023 YE EARNINGS CALLS



THE SPECIFICS

During year-end earnings, only 4 companies received questions about the IRA and its impact, and only 1 (BMS) proactively addressed the IRA in prepared remarks. But a few insights emerged:

- **Potential for spillover:** AbbVie and BMS received questions about “spillover” onto their commercial books of business, or the non-Medicare portion of patients. While AbbVie indicated the impact will be “contained” to Medicare products, BMS was more conservative, noting they always look at multiple planning scenarios, including the risk of spillover to commercial.
- **We don’t know what we don’t know:** AbbVie, BMS, and Pfizer all referenced the newness and uncertainty of the process and weren’t willing to comment on ongoing negotiations.
- **Pricing and volume:** AbbVie and BMS indicated that price erosion could be partially offset by increased volume; it’s important to note that only BMS stressed patient affordability in its messaging points.
- **What about generics?:** For Novartis only, the question focused on how the IRA would be applied to its heart failure treatment Entresto in 2026 if a generic were to launch in 2025. According to Novartis’s interpretation of the current IRA guidance, a generic option in 2025 would render Entresto ineligible for price negotiations the following year, but did acknowledge without a generic, Entresto would be IRA eligible in 2026 – indicating the company is anticipating impact one way or another. Importantly, Novartis noted its confidence in growing Entresto well beyond its loss of exclusivity and the IRA.
- **Future products:** Once again for Novartis only, a question about when breast cancer treatment Kisqali might become eligible for price negotiation. The measured response from CEO Vas Narasimhan was that while it’s “not a precise science to predict IRA for these patients” because they’re typically younger and not in the Medicare population,” he sees this as a topic for Kisqali toward the end of the decade and only in the Medicare population of patients. Vas also promised to keep investors updated “as we learn more and understand better how the program will unfold.”



LOOKING AHEAD

As negotiations continue and lawsuits play out (including the dismissal of AstraZeneca's on March 4 and the joint oral arguments from Novartis, Merck, J&J and Novo Nordisk delivered on March 7) and we move closer toward the September 1 deadline for final pricing, DGA will follow the IRA discussion in subsequent earnings calls, including questions that may come up and how companies are addressing them. As the year progresses, we expect different scenarios to emerge that companies need to prepare for, such as: what would Medicare price negotiations look like under a Trump presidency, or what's the possibility of rolling them back completely? What drugs will be listed – and when – for next year and the subsequent years? Will the process look the same every year? Will commercial payors want the same price discounts that Medicare negotiated? Is this the beginning of a single payer system?

UPCOMING MILESTONES

We'll be tracking to see what changes in the next quarter, and every quarter throughout 2024, as the key milestones in the IRA approach:

- **April 1:** Deadline for CMS to respond to manufacturers' (optional) maximum fair price (MFP) counteroffer; if CMS accepts the counteroffer, negotiations end; if CMS rejects the counteroffer, up to 3 meetings between CMS and manufacturers can occur to discuss offers and counteroffers
- **June 28:** Deadline to complete up to 3 negotiation meetings between CMS and manufacturers (if needed)
- **July 15:** Deadline for CMS to make a final written MFP offer to manufacturers
- **July 31:** Deadline for manufacturers to accept or reject CMS's final offer for MFP
- **August 1:** Deadline to complete price negotiation process between CMS and manufacturers
- **September 1:** Negotiated MFPs for selected drugs published

SOURCES

[KFF FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program](#)

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