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Client Alert

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# Price Negotiation, Medicare Rebates, and Benefit Reform

## Key Drug Pricing Implications of the Inflation Reduction Act of 2022

### I. Introduction

On Sunday, August 7, 2022, the United States Senate passed the most consequential drug and biologics pricing legislation in almost two decades. The Inflation Reduction Act ("IRA"), which was passed by the House of Representatives on August 12th and is expected to be signed by President Biden this week, will dramatically affect pharmaceutical pricing and Medicare rebating in the United States.

For the first time in history, the Secretary of Health and Human Services will be empowered—indeed required—to negotiate certain drug prices with manufacturers. Similarly, drug manufacturers will be required to pay rebates to the Medicare program if their drug prices increase faster than inflation, potentially portending higher launch prices. Finally, the Medicare Part D program will be fundamentally restructured, shifting coverage responsibility away from the federal government and onto Prescription Drug Plans ("PDPs") and drug manufacturers across new layers of the benefit, and for the first time capping beneficiary out-of-pocket costs at $2,000 per year.

The IRA promises to impact all drug and biologics manufacturers, including branded, generic and biosimilar manufacturers, and to require them to rethink business models and pricing strategies. While many manufacturers appreciate that this legislation could have been far more aggressive, the IRA will still exact a significant bite from the industry, estimated by the Congressional Budget Office at over $200 billion over ten years from the negotiation and inflation rebate provisions alone. We highlight below some of the details of the IRA, how it will work, and what stakeholders can expect in the coming months and years.

## II. Medicare Negotiation of Prices for "High Priced" Single Source Drugs

### a. Background

For decades, Congress has prohibited the federal government from directly negotiating drug and biologic prices. Since 2003, Congress set reimbursement in the Part B program based on the market rate for drugs and biologics, setting reimbursement at 106% of the "Average Sales Price" of a product—a true market measure of the drug price. In the Part D program, Congress relied on PDPs and Pharmacy Benefit Managers ("PBMs") to negotiate drug prices with manufacturers. Congress felt so strongly about keeping the government out of the negotiations that it enacted the "non-interference clause" explicitly prohibiting the government from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and … requir[ing] a particular formulary or institut[ing] a price structure for the reimbursement of covered part D drugs."[1] At least for "negotiation-eligible drugs," as described below, those days are no more.

### b. Drugs Subject to Negotiation

Starting in September 2023 (and February 1 of each following year), the new law requires the Secretary of Health and Human Services to publish a list of the top 100 most expensive drugs (50 from Part B and 50 from Part D), known as "negotiation-eligible drugs," as measured by total federal spend. From that list, the Secretary will then select 10 Part D (but not Part B) drugs for 2026, 15 Part D (but not Part B) drugs for 2027, 15 B or D drugs for 2028, 20 B or D drugs for 2029, and 20 B or D drugs for each year following 2029, to "negotiate" a new drug price. But as explained in more detail below, this is not a true negotiation where both parties come to the table with equal bargaining power. Here, the law limits the "maximum fair price" a manufacturer may charge, and the negotiation only goes down from there. While the negotiation provision will affect relatively few products, the impact on manufacturers of those products will likely be very significant.

There are several qualifications for a drug to be included on the lists, and several exceptions as well. First, a drug can be negotiation-eligible only if it has been approved by FDA for at least seven years and it is not the reference listed drug for any approved and marketed generic competitor. A biologic can be eligible only if it has been licensed for at least 11 years and is not the reference product for any licensed and marketed biosimilar competitor. Notably, authorized generics are specifically excluded from the definition of generic competition, as are unbranded biologics, which are equated with authorized generics for this purpose. Second, there are special rules for "small biotech drugs" (a defined term in the law) for the first several years of the program. Third, exemptions from negotiation apply both to drugs with federal spend under $200 million per year (starting in 2025, and indexed to inflation thereafter) and drugs that are approved only for a single orphan disease or condition. Fourth, starting in 2028 the drug or biologic has to be from the top of the list of 50 highest gross Medicare spend drugs in Part B, or starting in 2026 from top 50 in Part D (except in 2026 and 2027, when the selected drugs will come only from the Part D program), with packaged or bundled units excluded from the calculation.

### c. Impact on Biologics and the Biosimilars Special Rule

A large number of impacted drugs are expected to be biologics, as evidenced in the list shown below. Perhaps recognizing this, the IRA includes a number of provisions directed at biologics specifically.

A biological product is considered a qualifying single source drug—and hence potentially included on the list of negotiation-eligible drugs—if it meets three conditions. First, it must have been licensed under section 351(a) of the Public Health Service Act ("PHS Act"). Second, at least 11 years must have elapsed since licensure, as of the publication date of the list of negotiation-eligible drugs; this is one year shy of the 12-year period of regulatory exclusivity for a new biologic under the PHS Act. Third, there must be no approved and marketed biosimilars referencing that biological product.

If a biological product meets these criteria, and if it meets the other criteria mentioned above, it will be selected for the list of "negotiation-eligible drugs" published by the Secretary each year and referred to a "selected drug list" with respect to that year. That "selected drug list" is required to be published by February 1 of the year that begins two years before each "initial price applicability year," *i.e.*, two years before the negotiated price would be in effect (although there are special provisions governing the first initial price applicability year, 2026). For example, the selected drug list for the 2035 initial price applicability year would be published by February 1, 2033.

Under this framework, the price negotiation occurs relatively late in the lifecycle of a negotiation-eligible biological product, coming one year *before* the 12-year reference product exclusivity ends[2] and biosimilars can be approved by FDA (though maybe not before the end of patent life). Since biosimilar competition may already be brewing by this point in the reference product lifecycle, the IRA includes a "Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry" ("Biosimilars Special Rule") which sets forth a series of complicated rules and determinations for delaying the inclusion of a reference product on the selected drug list.

Under the Biosimilars Special Rule, inclusion of a biological product on the list of negotiation-eligible drugs can be delayed for up to two years—broken down into two, one-year periods. A biosimilar applicant must request the delay, and the Secretary must determine that there is a "high likelihood" that the biosimilar will be both licensed and marketed by FDA within two years of the selected drug publication date for the relevant initial price applicability year. This initial "high likelihood" determination is predicated on information submitted by the biosimilar applicant that demonstrates both that the biosimilar biologics license application ("BLA") has been filed or approved by FDA and, through "clear and convincing evidence," that the biosimilar will be marketed within the relevant timeframe. If a "high likelihood" is shown, inclusion of the reference product on the selected drug list is delayed for 1 year.

If the biosimilar is not approved and marketed during this first one-year period, a second one-year delay may be provided. This second bite at the apple comes with a higher bar, though—the second one-year delay requires that biosimilar applicant again request the delay and that the Secretary again determine a "high likelihood" of licensure and marketing, and it *also* depends on clear and convincing evidence that the biosimilar "has made a significant amount of progress" towards both licensure and marketing. If the Secretary so determines, inclusion of the reference product on the published negotiation-eligible drug list will be delayed for a second year.

The IRA goes to lengths to build guardrails around use of the Biosimilars Special Rule, including:

- Any further delays are prohibited, as is any delay if a biosimilar has been approved but not launched.
- The Special Rule is available only to so-called extended monopoly drugs, *i.e.*, those 12-16 years post-approval. Biologics that transition to "long-monopoly" drugs cannot be further delayed.

- Reference product manufacturers acting as biosimilar applicants cannot take advantage of the Special Rule. Similarly, a delay cannot be provided under the Special Rule if the biosimilar applicant has been required or incentivized by a reference product manufacturer to request a delay, or if an agreement between the two "restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time." Notably, there is not a similar restriction on agreements between reference biologics and biosimilars separate and apart from the Special Rule, even though at baseline a biological product will not qualify as "negotiation-eligible" if there is a licensed and marketed biosimilar.

If the biosimilar is not approved and launched within the one-year or two-year delay, the reference product license-holder will be subject to a rebate with respect to the negotiated price for the previous year. Once a biosimilar has been approved and marketed for 9 months, whether with or without a delay under the Special Rule, the reference product will be spared from inclusion in the selected drug list for the next publication year.

At the end of the day, whether the Biosimilars Special Rule is helpful (and to whom) will be a fact-specific inquiry involving a number of competing considerations on both sides. The Rule's utility may end up trapped between the rigidity of the Act's timing provisions, on the one hand, and the timing of BLA approvals and reference product exclusivity, on the other. Or it may end up shifting the balance between innovation and competition again, just as the BPCI Act did 12 years ago when it created the biosimilars pathway.

d. Negotiation Ceiling and Determining the Maximum Fair Price ("MFP")

As noted above, there is not a true "negotiation" between the Secretary and a manufacturer, because Section 1194(c) places a ceiling on the start of the negotiations. That ceiling will be 75%-40% of the product's Non-Federal Average Manufacturer Price ("Non-FAMP"), depending how long the product has been in the market. As manufacturers are aware, Non-FAMP is a measurement of the average price to merchant middlemen (wholesalers and distributors), net of wholesaler discounts and chargebacks relating to commercial sales. The metric is reported quarterly and annually, and is used in calculating the Federal Ceiling Price, the price enjoyed by the Department of Defense, Veterans Administration facilities, and other federal purchasers.

The ceiling for drugs in the market fewer than 12 years will be 75% of Non-FAMP, 12-16 years will be 65% of Non-FAMP, and more than 16 years will be 40% of Non-FAMP. In each case, the 2021 Non-FAMP (adjusted for inflation) will serve as the benchmark.

The Secretary is then encouraged to negotiate even steeper discounts, based upon the company's R&D cost recovery, receipt of federal financial support in the drug's development, dead net unit production cost, and other factors. The IRA also directs the Secretary to consider whether alternative treatments are available, and comparative effectiveness criteria (with limits prohibiting the Secretary from considering research that treats the life of a senior or elderly person as less than a younger person). Renegotiation is allowed if a drug receives a new indication, or for other reasons to be defined by the Secretary in rulemaking. The result of this negotiation is known as the "maximum fair price," and dictates the discount affected manufacturers must extend to eligible purchasers.

e. Process and Timing of Negotiation

Within four weeks of a drug being selected and published on the list of most expensive drugs (by February 1 of each year), the Secretary and the manufacturer must enter into an agreement to negotiate the MFP. The agreement will require the manufacturer to negotiate the MFP, to make the drug or biologic available to Part D beneficiaries and pharmacies at the MFP and to Part B hospitals and physicians at the MFP (unless the 340B price is lower), and by March 1 to provide all data required by the Secretary to negotiate the price. The Secretary will then have until June 1 to make a written offer, and 30 days after the Secretary's offer, the manufacturer must accept or counter. The negotiations must end prior to November 1, with the Secretary publishing the price that November 30 (and publishing an explanation of the price the following March).

Numerous analysts and publications have published lists of the drugs and biologics anticipated to be subject to negotiation in the coming years.[3] We expect the lists will change in the coming years as manufacturers develop strategies to navigate the MFP.

f. Enforcement and Penalties

There are two enforcement regimes in the MFP provisions. First, if a manufacturer agrees to an MFP and does not adhere to it, the manufacturer must pay a civil monetary penalty equal to ten times the difference between the MFP and the price at which the drug was actually sold in the Medicare program. Second, the legislation includes an excise tax on all sales of an applicable drug for each day that the manufacturer of a selected drug does not negotiate with the Secretary. The excise tax starts at 65% of the sales of the manufacturer's drug for the first 90 days, 75% for the next 90 days, 85% for the next 90 days, and 95% thereafter. Generously, Congress has allowed manufacturers to pull all their drugs (not just the select drug) out of the Medicare and Medicaid programs to avoid this tax, but that will be unrealistic for many manufacturers.

## III. Inflation Rebates for Single-Source Part B and D Drugs

The IRA obligates drug manufacturers to calculate and pay rebates to the federal government on Medicare utilization of drugs that increase in price faster than inflation. Manufacturers are familiar with the inflation penalty rebate in the Medicaid context. The new Medicare rebate obligations work in much the same way, but apply to units reimbursed by Parts B and D, rather than Medicaid and 340B. Shortly before passage of the bill, the Senate parliamentarian forced drafters to reduce the reach of these provisions by excluding commercial utilization. Nevertheless, these are the first federal price concession obligations in Medicare (other than coverage gap obligations), and are certain to impact the pricing strategies and gross-to-net calculations of medicines that serve older Americans.

Both the Part B and Part D inflation rebate amounts are affirmatively excluded from Average Sales Price, Best Price, and Average Manufacturer Price. As such, they will not directly impact provider reimbursement, Medicaid rebates or 340B prices.

Manufacturers that fail to comply with the rebate requirements set out below are subject to civil monetary penalties of 125 percent of the amount owed for the applicable period (potentially more under Part B).

a. Part B Drugs

Beginning January 1, 2023, manufacturers of single-source Part B drugs approved before December 1, 2020 will be required to pay a quarterly rebate to the Medicare Trust Fund if the prices of their drugs have increased faster than inflation. The obligation for Part B drugs approved after December 1, 2020 begins six quarters after approval (or January 2023, whichever is later). Part B beneficiary coinsurance will be adjusted downward to reflect the post-rebate net price to Medicare.

Certain vaccines are excluded, as are drugs that cost beneficiaries less than $100 per year, drugs that are reimbursed as part of a bundle or package, and qualifying biosimilars. The Secretary may waive inflation rebates for drugs in shortage, or in the event of supply chain disruption.

The rebate per unit of Part B drug equals the amount by which (a) 106% of the Average Sales Price of the drug in the quarter exceeds (b) the payment amount for the billing and payment code for the drug in the benchmark quarter, times the percentage by which the rebate period Consumer Price Index for all Urban Consumers ("CPI-U") exceeds the benchmark period CPI-U. The benchmark quarter for drugs approved before December 1, 2020 is third quarter of 2021; the benchmark CPI-U for such drugs is that for January 2021. For Part B drugs approved after December 1, 2020, the third full quarter after launch is the benchmark quarter; the benchmark CPI-U will be that for the first month of the first quarter after launch.

The inflation rebate per Part B unit is multiplied by eligible units to determine the quarterly rebate. Eligible units are the total number of units for the billing and payment code "furnished" by Part B during the quarter. Commercial units are not included, nor are units on which a 340B discount is provided or a Medicaid rebate is paid. Units not separately payable by Part B are also excluded from eligible utilization.

There are no new price or data reporting obligations for manufacturers in this provision of the IRA. CMS will be required to calculate the rebate per unit, determine the number of eligible units, and invoice manufacturers within six months of the end of each quarter. Therefore, manufacturers should expect to see their first Part B rebate demands by the end of September 2023 (although the IRA permits the Secretary to take up to a two-year extension at the start of the program). Manufacturers will have 30 days from the date they receive the Medicare invoice in which to pay it. There is no mechanism in the IRA for manufacturers to dispute the data or amounts in the rebate invoices; indeed, administrative and judicial review of the units, rebate amount, and other elements is affirmatively barred.

b. Part D Drugs

Beginning October 1, 2022, manufacturers of single-source Part D drugs will be required to pay an annual rebate to the Medicare Trust Fund if the prices of their drugs have increased faster than inflation. Part D enrollees will benefit from these rebates indirectly, through the Part D benefit redesign described below.

Part D rebatable drugs include products approved via NDA, BLA (including biosimilar BLA), or ANDA that are covered by Part D. A generic drug will be rebatable only if (1) the 505(c) reference listed drug (including any authorized generic) is not being marketed, (2) no other 505(j)-approved therapeutically equivalent drug is marketed, (3) the ANDA holder is not a "first applicant" during a relevant period of 180-day exclusivity, and (4) the ANDA holder is not a "first approved applicant" for a competitive generic therapy. Drugs that cost beneficiaries less than $100 per year also are excluded. The Secretary may waive inflation rebates for drugs in shortage, or in the event of supply chain disruption.

The rebate per unit of Part D drug equals the amount by which (a) the annual manufacturer price ("AnMP") of the dosage form and strength of the drug exceeds (b) the benchmark period manufacturer price, times the percentage by which the applicable period CPI-U exceeds the benchmark period CPI-U. The benchmark period for drugs approved before October 1, 2021 is the first through third quarters of 2021; the benchmark CPI-U for such drugs is that for January 2021. For Part D drugs approved after October 1, 2021, the first calendar year after launch is the benchmark period; the benchmark CPI-U will be that for January of the first year beginning after launch. Note that for older drugs, the benchmark period is only three quarters long – the rest of the calculations are annual.

AnMP is the weighted average AMP of the following four quarters: 4QYEAR1, 1QYEAR2, 2QYEAR2, and 3QYEAR2. The benchmark period manufacturer price is similarly calculated, in that it is the weighted average AMP of the applicable benchmark quarters. There is no mechanism in the IRA for revision of AnMP or benchmark period manufacturer price if a manufacturer restates its AMP, as is not uncommon. Perhaps this will be clarified in forthcoming guidance from CMS.

The IRA instructs HHS to determine an appropriate formula for calculation of rebates to be applied to line extensions, consistent with the provisions in the MDRP statute on new formulations (§1927(c)(2)(C)). One wonders how this punt to the agency will be received, and executed upon.

The inflation rebate per Part D unit is multiplied by eligible units to determine the annual rebate. Eligible units are the total number of units for the dosage form and strength "dispensed under" Part D during each 4QYEAR1-3QYEAR2 period. Commercial units are not included, nor (beginning in 2026) are units on which a 340B discount is provided. There is no exception for units on which a Medicaid rebate is paid, subjecting Part D drugs to a duplicate (and until 2026 a *triplicate*) discount. The IRA permits HHS to revise manufacturer invoice amounts if revised data from the PDPs or Medicare Advantage plans are received after invoices have been issued.

There are no new price or data reporting obligations for manufacturers in this provision of the IRA. CMS will be required to calculate the rebate per unit, determine the number of eligible units, and invoice manufacturers within nine months of the end of each Part D inflation rebate year. Therefore, manufacturers should expect to see their first Part D rebate demands by the end of June 2024 (although the IRA permits HHS to take up to a two-year extension at the start of the program). Manufacturers will have 30 days from the date they receive the Part D invoice in which to pay it. There is no mechanism in the IRA for manufacturers to dispute the data or amounts in the rebate invoices; indeed, administrative and judicial review of the units, rebate amount, and other elements is affirmatively barred.

## IV. Part D Program Changes

### a. Benefit Redesign

From its inception in 2006, the Part D program has had four "layers" in the benefit: a deductible layer (today around $450) for which the beneficiary was fully responsible, then a coverage layer (ranging from around $450 of spend to around $2,750 of spend) for which the PDP was 75% responsible and the enrollee 25% responsible, then a "coverage gap" known as the donut hole" (ranging from around $2,750 to around $4,500 of spend) for which the enrollee was 100% responsible, and then the "catastrophic" layer for which the enrollee was 5% responsible, the plan 15%, with the federal government picking up the remaining 80%. Many enrollees were deeply unhappy to learn when they hit the donut hole

that they had no coverage in the gap even though they were paying monthly premiums to their PDP. In response, in 2010 the Affordable Care Act closed the coverage gap by making enrollees responsible for 25%, plans responsible for 25%, and manufacturers responsible for 50% of the gap (this was changed to 70% for manufacturers and 5% for plans in 2018). Starting after the ACA, manufacturers had to sign "Medicare Coverage Gap Discount Agreements" with the government. Still, many were unhappy there was any "donut hole" in the program (even it was almost closed).

The IRA restructures the benefit design again and eliminates the donut hole altogether. In its place, the deductible will remain as is, followed by a coverage layer with the enrollee still bearing 25%, the plan bearing 65%, and manufacturers now bearing 10% of the drug cost. Following the coverage layer, a "catastrophic" layer will apply, with enrollees paying nothing (other than per drug co-pays), plans paying 60%, manufacturers paying 20% and the federal government share going to 20%. This will provide the government significant savings, will incentivize PDPs to slow the rate of enrollee progression through the coverage layers, and affect manufacturers in a multitude of different ways, depending on their drug portfolio and the typical spending patterns of Medicare beneficiaries consuming their drugs. Generally, however, manufacturers' 10%/20% responsibility in the coverage and catastrophic layers will be less than or around their current spend on 70% of the donut hole obligation. Medicare beneficiaries are the true winners of the restructuring, for the reasons set out below. Either way, manufacturers will have to enter into new drug discount agreements with the government starting in 2025.

b. Maximum Out-of-Pocket Cap

As noted above, the previous structure of the Part D program required enrollees to bear a 5% co-payment for drugs even at the "catastrophic" spending level (when the enrollee already needed over $6,000 of drugs in a year). For certain high-cost Part D drugs, even that 5% share of cost could be devastating for many Medicare beneficiaries. Thus, to provide the promise of real insurance, and to solve for this significant problem, Congress has now set an out-of-pocket limit of $2,000 per enrollee per year in the Part D program. Ironically, the number of Part D enrollees who exceed the $2,000 out-of-pocket limit is remarkably small. In 2019, only about 3% of nearly 45 million Medicare beneficiaries in the Part D program, around 1.5 million, had out-of-pocket spending above the catastrophic coverage threshold.[4] Yet, the point of prescription drug coverage is to provide comfort to Medicare beneficiaries about what they may not have to pay, as much as it is to provide actual payment for the drugs they take. Thus, although relatively few enrollees will actually be affected, the greater peace of mind will be felt across the entire Part D population.

c. Maximum Monthly Cost-Sharing Cap

Congress was also sensitive to the fact that enrollees could not afford to use the Part D benefit for some high-cost drugs (for example, a specialty drug costing $25,000 per dose) because they could not afford the deductible, cost-sharing and co-pay that would all be due in January of each year upon purchase of the first dose. To address that concern, Congress adopted a "smoothing" process where, at the election of the enrollee, a PDP can charge equal increments of anticipated enrollee cost sharing across each month of the plan year following the election. As noted, PDPs do not have to utilize the smoothing process unless an enrollee elects to do so. The math is not simple, and it is not obvious how many Part D enrollees will ever understand that they have this option or make the selection to their benefit.

d. Takeaways for Manufacturers

Different manufacturers will be affected differently by the Part D restructuring. For example, manufacturers with a product portfolio or pipeline focusing on drugs taken by the Low Income Subsidy ("LIS") population (such as AIDS, mental health, epilepsy or certain cancer drugs) will likely owe a greater manufacturer discount liability than in the past, because Congress has eliminated the historic exemption for drugs sold to LIS beneficiaries from the manufacturer discount program. (Congress did phase in the LIS liability for certain manufacturers which have LIS drugs in the market as of 2021).

Similarly, the PDPs now have far greater liability (80% vs. the previous 15%) for drug costs above the "catastrophic" coverage layer (approximately $6,500 of drug spend per enrollee); it is likely that the PDPs will develop a new series of tactics to slow drug spending and prevent enrollees from hitting the catastrophic level in the first instance. This may affect rebate agreements, enrollee utilization patterns, and other aspects of the Part D program. Further, many PDP rebate agreements have so-called "hold harmless" provisions and it is unclear whether those provisions will be overtaken by events or enforced by the PDPs.

Finally, PDPs are obligated to include on formulary all MFP drugs subject to price negotiation and pass-through the government-negotiated price to the beneficiary at the point of sale, Manufacturers of those drugs are required to make the drugs available to pharmacies at the government-negotiated price, meaning that manufacturers are highly unlikely to offer any rebates to PDPs (or others) for these drugs. It is unclear how and from where the PDPs will attempt to recover that lost rebate revenue, but it may come from higher beneficiary premiums (subsidized by the government), increased manufacturer rebate requirements, pharmacy DIR fees, or elsewhere.

## V. Expected Reactions

Given the amount of money and market disruption at stake, it is inevitable that numerous provisions of the IRA will be subject to challenge. PhRMA has already made clear that it is gearing up to challenge the law, with its CEO, Steve Ubl, noting that "[f]ew associations have all the tools of modern political advocacy at their disposal in the way that PhRMA does."[5] Mr. Ubl has made clear that PhRMA will continue to pursue political action, noting "[t]hose members who vote for this bill will not get a free pass. We'll do whatever we can to hold them accountable." The Association for Accessible Medicines ("AAM"), the generic drug association, has similarly condemned the bill (an ironic alignment of branded and generic manufacturers), noting "[t]he Senate has chosen to replace competition—the only proven way to provide patients relief from high brand drug prices—with a flawed framework for government price setting that will chill the development of, and reduce patient access to, lower-cost generic and biosimilar medicines."[6]

Potential litigation may include challenges to the price negotiation process and the inflation penalty regime. Given the severity of the MFP price reductions and the lack of procedures for evenhanded negotiations, a party may bring a challenge under the Fifth Amendment Takings or Due Process clauses taking that has caused a significant diminution in value or deprivation of an economical use of property, a challenge that the excise tax and inflation provisions amount to excessive fines and penalties, efforts to eliminate some of the mandatory manufacturer disclosures as compelled speech in violation of the First Amendment, and other similar challenges. Even if some of the IRA's substantive provisions are barred from judicial review, if a court strikes the penalty provisions, the law may become toothless, similar to some provisions of the Affordable Care Act.

Beyond the courts, there may be political activity in the coming Congress to either reverse aspects of the law (not the Part D changes, but others), or block HHS from implementing the law. Depending on the mid-term election outcome, if the Republicans are later able to regain control of both Congress and the White House, they may able to repeal some of the provisions. Further, depending on how industry responds, and whether drugs are withdrawn from the Medicare and Medicaid programs as a result of the IRA or innovation suffers as many predict, Congress may rethink the wisdom of having chosen to empower the government to mandate radical price reductions and reverse itself. Even if the Republicans are not in control, there may be opportunities through the appropriation process to deprive HHS of any funds to implement the negotiation and inflation provisions, effectively staying the law through appropriation "riders." Time will tell.

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[1] 42 U.S.C. § 1395w-111(i).
[2] Compare section 1192(e)(1)(B)(ii) with section 351(k)(7)(A) of the Public Health Service Act.
[3] BiopharmaDive Wire, Pharma CEOs press case against drug price negotiation as bill gains support, August 4, 2022, *available at* https://www.biopharmadive.com/news/pharma-drug-pricing-negotiation-bill-ceo-response/628872/
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