

# The Inflation Reduction Act: A boon for the generic and biosimilar industry

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## Abstract

**What is Known and Objective:** After more than a year of negotiation, a \$740 billion climate and health care bill known as The Inflation Reduction Act (IRA) became law on 16 August 2022. In addition to its impact on the environment, job creation and reducing inflation, a key focus is to reduce the burden of Medicare by over \$100B per year and other benefits to 65 million Medicare patients. A fixed number of top expenditures drugs that have stayed as single-source chemical products for 8 years and the biologicals for 12 years; 2 years more are allowed if the approval of a generic or biosimilar is imminent. Once a second source appears, as a generic or biosimilar, the price reduction is removed. The number of products negotiated for price reduction goes from 10 to 20 over the years and stays fixed at this number. Reaching any significant number out of the 14,000 reimbursed will take forever if biosimilars and generics keep entering. The IRA does not apply to private markets.

**Methods:** The IRA legislation and related statutes were analysed in consultation with legal teams; the spending data were derived from the CMS portals and the FDA databases to rank the most likely products selected when the selection process is initiated.

**Results and Discussion:** The savings to Medicare will come from reducing the price of only a few products, primarily with \$1B and upward spending; when Plan B product scheduling enters, these will be at the bottom of the selection because of their lower expenditure. The total number of products subject to price reduction may be negligible if generics and biosimilars are introduced after the exclusivity period of the listed drug or reference product. The private market with an 80% share may benefit due to price spillover but mainly by the expedited entry of generics and biosimilars.

**What is New and the Conclusion:** The entry of generics and biosimilars will now be encouraged by brand-name product companies, reducing the intellectual property hurdles like the “patent dance” for biosimilars. The IRA includes restrictions to prevent the brand name companies from exploiting the entry of generics and biosimilars to assure their independence.

## KEYWORDS

AAM, biosimilars, Biosimilars Council, BPCIA, CMS, FDA, Medicare, the Inflation Reduction Act

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## 1 | INTRODUCTION

The US has a per capita cost of \$1200 per capita and total healthcare expenses of \$4 trillion-plus. This is an untenable situation. However, unlike the rest of the world, there are no price controls in the US. This is the right strategy to promote competition.

The prohibition against the federal government negotiating drug prices was a contentious provision of the Medicare Modernization Act of 2003,<sup>1</sup> the law that established the Medicare Part D program. Lifting this prohibition has been a longstanding goal for many Democratic policymakers. On 16 August 2022, President Biden signed into law the Inflation Reduction Act of 2022 (IRA), enacting the most significant reform for the payment of drugs and biologicals.

The lower the out-of-pocket healthcare cost of seniors while saving over the 10 years between 2022 and 2031, through prescription drug negotiation and the Medicare inflationary rebates, approximately \$101 billion and \$71 billion, respectively. In addition, a significant saving is achieved by prohibiting the Secretary from implementing the drug rebate rule adopted by the Trump Administration until 1 January 2032.

The H. R. 5376 or IRA<sup>2</sup> incorporates many of the drug pricing concepts, and its most important health care provisions include:

- Establishing a new program for Medicare to directly negotiate prices with pharmaceutical manufacturers for certain high-spend Medicare drugs, with stiff penalties for companies that refuse;
- Requiring manufacturers to pay rebates on drugs reimbursed under Medicare Parts B or D for which average (i.e. net) prices increase faster than inflation;
- Revamping the Medicare Part D benefit, including establishing an annual out-of-pocket cap for beneficiary cost-sharing on prescription drugs and eliminating patient cost-sharing in the catastrophic phase;
- Delaying the effective date of the November 2020 Anti-Kickback Statute final rule removing safe harbour protection for prescription drug rebates until 2032; and
- Extending the temporarily expanded health insurance subsidies for the ACA plans through 2025.

The first two provisions are the main topic of discussion in this article. This article clarifies the Bill, removes every misconception related to the impact on biosimilar products, and demonstrates how generic and biosimilar manufacturers should take advantage of these new opportunities. Other benefits are well-defined in detail in the Bill.

## 2 | UNDERSTANDING THE IRA

The objectives of the IRA will be achieved through a complex financing plan, as shown in Table 1.

The IRA:

- **Expands Medicare benefits:** free vaccines (2023), \$35/month insulin (2023) and caps out-of-pocket drug costs to an estimated \$4000 or less in 2024 and settling at \$2000 in 2025.

- **Lowers energy bills:** cuts energy bills by \$500–\$1000 per year.
- **Makes historic climate investment:** reduces carbon emissions by roughly 40% by 2030.
- **Lowers health care costs:** saves the average enrollee \$800/year in the ACA marketplace, allows Medicare to negotiate 100 drugs over the next decade, and requires drug companies to rebate back price increases higher than inflation.
- **Creates manufacturing jobs:** more than \$60 billion investment will create millions of new domestic clean manufacturing jobs.
- **Invests in disadvantaged communities:** cleaning up pollution and taking steps to reduce environmental injustice with \$60 billion for environmental justice.
- **Closes tax loopholes used by the wealthy:** a 15% corporate minimum tax, a 1% fee on stock buybacks and enhanced IRS enforcement.
- Protects families and small businesses making \$400,000 or less.
- **It helps 13 million people** save an average of \$800 a year on health insurance premiums.
- **Add insurance to 3 million more people** will have health insurance than otherwise would without the law, according to the White House summary.<sup>4</sup> It does not affect private insurance or drug markets. It is also not a free insurance program as widely misrepresented.
- The current CBO score<sup>5</sup> reports even the legislation would reduce deficits by \$305 billion through 2031—including over \$100 billion of net scoreable savings and another \$200 billion of gross revenue from stronger tax compliance. Because the prescription drug savings would be larger than new spending, CBO finds the legislation would modestly reduce net spending by almost \$15 billion through 2031, including nearly \$40 billion in 2031. The legislation would generate almost \$300 billion of net revenue over a decade, mostly from improved tax compliance and the spillover effects of higher wages as a result of lower health premiums—neither of which are tax increases—along with early revenue collection as corporations shift the timing of certain payments. Overall, CBO estimates the

**TABLE 1** IRS financing<sup>3</sup>

Total revenue raised	\$737 billion
15% Corporate minimum tax	222 billion
Prescription drug pricing reform	265 billion <sup>a</sup>
IRS Tax enforcement	124 billion <sup>b</sup>
1% Stock buybacks fee	74 billion <sup>a</sup>
Loss limitation extension	52 billion <sup>a</sup>
Total investments	\$437 billion
Energy security and climate change	369 billion <sup>a</sup>
Affordable Care Act extension	64 billion <sup>b</sup>
Western drought resiliency	4 billion <sup>c</sup>
Total deficit reduction	\$300+ billion

<sup>a</sup>Joint Committee on Taxation estimate.

<sup>b</sup>Congressional Budget Office estimate.

<sup>c</sup>Senate estimate, awaiting final CBO score.

legislation includes \$790 billion of offsets to fund roughly \$485 billion of new spending and tax breaks as negotiators account for the policies, it includes \$739 billion of offsets and \$433 billion of investments.

To better understand how the IRA will transform American society, we need to look at the current state of healthcare in America.

The US has the highest national health expenditure (NHE) than other wealthy countries, reaching more than \$4 trillion in 2020, or about \$12,000 a person, according to the Centers for Medicare & Medicaid Services.<sup>6</sup> However, other wealthiest countries have a much lower cost,<sup>7</sup> and the cost in developing countries is less than \$200 per person.<sup>8</sup>

One reason for the high cost of healthcare in the US is the cost of medication, which averages around \$1200 per capita,<sup>9</sup> which is almost 20% of the GDP. To reduce the burden of drug costs, the US introduced the Hatch-Waxman Bill<sup>10</sup> in 1984 to introduce generic drugs, and now 90% of all drugs dispensed are generics.<sup>11</sup> Yet they only constitute about 15% of the expenditure, the balance going to branded drugs. It is important to remember that the Hatch-Waxman Act was not a cost-fixing Bill; it allowed competition that brought the cost down. Without this Bill, we will be paying hundreds of billions more for drugs in the US.

The developers justify the high cost of new drugs to pay for developing new drugs that run around a billion dollars<sup>12</sup>; it is evident that the US brings the highest number of new drugs<sup>13</sup> spending hundreds of billions of dollars annually. Despite the cost constraints, the US has the best healthcare system that should continue as an uncontrolled system, unlike the rest of the world; the social medicine system, as applied in many jurisdictions, has never worked well; Canada<sup>14</sup> and the UK<sup>15</sup> are just two examples. The US system works well and needs fine-tuning, which the IRA aptly provides.

Since the US never had any price control contrary to such policies worldwide, including in the wealthiest countries that also partake in developing new drugs. The campaigns to control drug prices in the US have failed for various reasons, including the lobby efforts of the big pharma. In addition, the high cost of drugs brings a tremendous burden to the US government through the CMS Medicare and Medicaid plans. Some relief was provided to private insurance through the Affordable Care Act,<sup>16</sup> yet the US government obligations remained high; now, there is hope that the IRA will reduce these costs.

The primary source for these changes will come from the CMS, responsible for Medicare and Medicaid. Therefore, the IRA is mainly focused on the scope and activities of the CMS and its budget<sup>17</sup>:

- In 2022, CMS will reimburse over \$110B for Part D<sup>18</sup> and \$50B for Part B drugs.<sup>19</sup>
- Medicare spending grew 3.5% to \$829.5 billion in 2020 or 20% of total NHE.
- Medicaid spending grew 9.2% to \$671.2 billion in 2020 or 16% of total NHE.
- Private health insurance spending declined 1.2% to \$1151.4 billion in 2020 or 28% of total NHE.

- Out-of-pocket spending declined 3.7% to \$388.6 billion in 2020 or 9% of total NHE.
- Federal government spending for health care grew 36.0% in 2020, significantly faster than the 5.9% growth in 2019. This faster growth was largely in response to the COVID-19 pandemic.
- Hospital expenditures grew 6.4% to \$1270.1 billion in 2020, slightly faster than the 6.3% growth in 2019.
- Physician and clinical services expenditures grew 5.4% to \$809.5 billion in 2020, faster than the 4.2% in 2019.
- Prescription drug spending increased 3.0% to \$348.4 billion in 2020, slower than the 4.3% growth in 2019.
- The federal government sponsored the most significant share of total health spending (36.3%) and the households (26.1%). The need for reducing this burden is evident as the NHE is projected to grow at an average annual rate of 5.4% to reach \$6.2 trillion by 2028.
- The total expenditure for both Part D and B was \$435.6B in 2020 (the most recent data available):
  - For Part B drugs, the amount was \$38.52B; seven drugs with \$1B+ expenditure accounted for \$13.16B. Total drugs reimbursed are 600.
  - For Part D drugs, the amount was \$397.3B, with 40 drugs with billing of \$1B+, and the total amount of these drugs was \$78.6B. Total drugs reimbursed 13,570.
  - Part D and B total for drugs over \$1B was \$91.75B for 45 drugs.

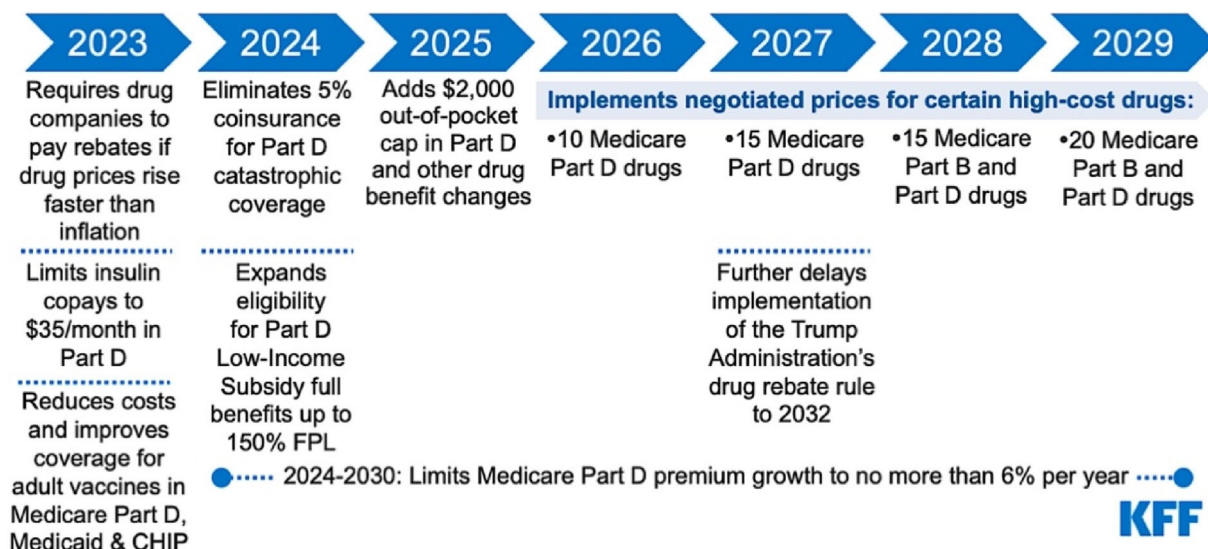
### 3 | THE NEW PROGRAM FOR MEDICARE

The IRA requires negotiating and renegotiating the prices that will commence in 2026 based on a tiered schedule (Figure 1). It is noteworthy that biologicals are primarily included in Part B unless it is a dispensed product such as adalimumab that is included in Part D. Most concerns about biosimilars related to Part B where the price negotiation starts in 2027, provided the entries in Part B drugs are higher than the entries in Part B, as it would be a combined selection.

Table 2 list the top 74 drugs for 2020 spending drugs of CMS on Part D and Part B<sup>20</sup>—the most likely drugs to be selected in the first round of the price negotiation in 2026 for Part D and 2028 for Part B, subject to the exclusivity, the change of current spending and availability of generics of biosimilars or being part of another reimbursement program such as the Social Security or the plan for insulins.

No biological product will enter price reduction for 5 years as most of them are Part B drugs unless they are dispensed directly to patients like adalimumab. The chemical drugs have a particular concession for up to 8 years, while the NCE exclusivity is only 5 years. Since the product selection does not mandate that products from Part B must be chosen—it is all rank ordered, the likelihood of selecting biological products remains remote (Table 2). The products listed in Table 2 should be the imminent choice for biosimilar developers.

The total number of products with price reduction will increase by a fixed number per year, but the total number of price-controlled



**FIGURE 1** Implementation timeline of the prescription drug provisions in the IRA (<https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/>). It is anticipated that by 2031, up to 100 drugs could be subject to price negotiation.

products will decrease as there is no replacement for those removed from the list if they are no longer single-source products. As a result, this list may stay short forever, hailing the entry of generics and biosimilars.

The inclusion criteria for products subject to price negotiation include a single source drug or under Medicare Part B and D:

- In addition, having the highest expenditures for a given year, manufactured by a single source, for example, a company making both brand name and generic or biosimilar, will count as one.
- Approved or licensed (as applicable) under section 505(j) or section 351(a), and it is not listed as the reference product for a 351(k) product or application.
- Drugs or biologics have been on the market for at least 7 years for branded drugs or 11 years for biologics. It is noteworthy that the exclusivity of a new chemical entity is 5 years.<sup>21</sup> The biological drugs have a 12-year exclusivity.<sup>22</sup> Two years are added if requested if a generic or biosimilar product is expected to be registered within 2 years. If a biosimilar is not approved within 2 years, the reference product will have to pay rebates from the date of selection listing. These rebates are likely lower than the negotiated price difference, giving the reference product manufacturer to invoke this exclusivity, even if a biosimilar entry is not imminent.
- Among the 50 qualifying products with the highest total expenditures during the most recent 12-month period.
- The exclusion criteria for products subject to price negotiation include:
  - Biologics are named reference products for a product approved or under approval in the 351(k) filing.
  - Change status due to entry until a generic or biosimilar enters the market. This exclusion applies to a biological that is an extended-monopoly drug approved for 12 and 16 years; this is

an automatic classification since biological products have 12-year exclusivity; the negotiations begin past 11 years.

- Small biotech drugs. Expenditure is less than 1% of Medicare Part D or B spending. Therefore, the maximum fair price (MFP) negotiated may not be less than 66% of the average non-Federal average manufacturer price (AMP) for 2021. In addition, for the minor volume biotech drugs, the MFP is not subject to an MFP less than 34% off the non-FAMP.
- Drugs of a manufacturer acquired by a certain manufacturer after 2021.
- Orphan drugs for only one rare disease or condition for which there is only one indication.
- Drugs or biologics with Part B and D spend less than \$200,000,000 per year (increased annually by inflation).
- Plasma-derived products.
- Products of the manufacturer are acquired after 2021 by another manufacturer or, in the case of an acquisition, before 2025.
- New formulations include extended-release, higher concentration and change of route of administration of a qualifying drug.
- Drugs for a single rare disease or condition.
- Drug or biological product that is a selected drug in special Social Security Plan for which 106% of the MFP will be applicable for such drug and a year during such period.
- If the drug or biological constitutes 80% of the manufacturer's revenue and expenditure is not more than 1% of the total Part B or Part D, as the case may be.
- Part B reimbursement for a selected drug is not average sales price (ASP) plus 6%, but the maximum price plus 6%.
- Renegotiation.
  - Renegotiation is mandatory if selected drug graduates to extended-monopoly have 75% market for at least 11 years but

TABLE 2 Part D and Part B drugs 2020 spending

No.	Part	Brand	Generic	Approved	2020 Spending	Qualified	Eligible
1	D	Eliquis	Apixaban	2014	9,936,069,814	Yes	2021
2	D	Revlimid	Lenalidomide	2017	5,356,050,275	Yes	2024
3	D	Xarelto	Rivaroxaban	2011	4,701,314,805	Yes	2018
4	D	Januvia	Sitagliptin Phosphate	2006	3,865,087,773	Yes	2013
5	B	Keytruda	Pembrolizumab	2016	\$3,500,947,569	No*	2027
6	D	Trulicity	Dulaglutide	2014	3,284,873,062	Yes	2021
7	B	Eylea	Aflibercept	2011	\$3,013,081,886	No*	2022
8	D	Imbruvica	Ibrutinib	2017	2,962,909,304	Yes	2024
9	D	Lantus Solostar	Insulin Glargine	2000	2,663,360,232	No*	2011
10	D	Jardiance	Empagliflozin	2016	2,376,166,292	Yes	2023
11	D	Humira(Cf) Pen	Adalimumab	2002	2,169,430,424	No*	2009
12	D	Ibrance	Palbociclib	2017	2,108,937,188	Yes	2024
13	D	Symbicort	Budesonide/Formoterol Fumarate	2006	1,979,983,682	Yes	2013
14	D	Xtandi	Enzalutamide	2019	1,968,567,948	Yes	2026
15	D	Novolog Flexpen	Insulin Aspart	2000	1,844,084,368	Yes	2007
16	D	Biktarvy	Bictegrav/Emtricit/Tenofovir Ala	2018	1,775,846,507	Yes	2025
17	D	Myrbetriq	Mirabegron	2012	1,749,232,347	Yes	2019
18	B	Prolia	Denosumab	2010	\$1,626,844,122	Yes	2021
19	B	Opdivo	Nivolumab	2014	\$1,586,591,103	Yes	2025
20	D	Levemir Flextouch	Insulin Detemir	2005	1,554,791,325	Yes	2012
21	D	Victoza 3-Pak	Liraglutide	2010	1,545,815,415	Yes	2017
22	D	Breo Ellipta	Fluticasone/Vilanterol	2013	1,504,155,910	Yes	2020
23	D	Trelegy Ellipta	Fluticasone/Umeclidin/Vilanter	2020	1,487,802,308	No	2027
24	D	Ozempic	Semaglutide	2020	1,455,812,267	No	2027
25	D	Pomalyst	Pomalidomide	2013	1,453,860,767	Yes	2020
26	D	Restasis	Cyclosporine	2003	1,451,534,384	Yes	2010
27	D	Ivega Sustenna	Paliperidone Palmitate	2009	1,372,610,289	Yes	2016
28	D	Enbrel Sureclick	Etanercept	2003	1,371,059,068	No	2007
29	D	Latuda	Lurasidone HCl	2017	1,317,919,887	Yes	2024
30	D	Jakafi	Ruxolitinib Phosphate	2021	1,296,674,522	No	2028
31	B	Rituxan	Rituximab	1997	\$1,295,821,132	Yes	2008
32	D	Tradjenta	Linagliptin	2011	1,288,663,293	Yes	2018
33	D	Humira Pen	Adalimumab	2008	1,215,774,159	No*	2019
34	D	Entresto	Sacubitril/Valsartan	2015	1,203,043,540	Yes	2022
35	D	Advair Diskus	Fluticasone Propion/Salmeterol	2000	1,160,474,903	Yes	2007
36	D	Ofev	Nintedanib Esylate	2020	1,157,563,828	No	2027
37	D	Spiriva	Tiotropium Bromide	2004	1,153,453,863	Yes	2011
38	D	Linzess	Linacotide	2012	1,144,468,128	Yes	2019
39	B	Lucentis	Ranibizumab	2006	\$1,113,026,179	Yes	2017
40	D	Stelara	Ustekinumab	2020	1,106,356,248	No	2027
41	D	Lantus	Insulin Glargine	2000	1,055,722,607	No*	2011
42	D	Tecfidera	Dimethyl Fumarate	2013	1,054,984,601	Yes	2020
43	D	Humalog KPen U-100	Insulin Lispro	2017	1,053,915,810	Yes	2024
44	B	Orencia	Abatacept	2005	\$1,023,001,524	Yes	2016
45	D	Anoro Ellipta	Umeclidinium Brm/Vilanterol Tr	2013	1,002,343,776	Yes	2020
46	B	Neulasta	Pegfilgrastim	2002	\$899,790,554	Yes	2013



TABLE 2 (Continued)

No.	Part	Brand	Generic	Approved	2020 Spending	Qualified	Eligible
47	B	Darzalex	Daratumumab	2015	\$837,400,701	Yes	2026
48	B	Avastin	Bevacizumab	2004	\$680,539,026	No*	2015
49	B	Remicade	Infliximab	1998	\$663,412,142	No*	2009
50	B	Tecentriq	Atezolizumab	2021	\$624,194,083	Yes	2032
51	B	Ocrevus	Ocrelizumab	2017	\$618,708,735	Yes	2028
52	B	Soliris	Eculizumab	2007	\$610,425,467	Yes	2018
53	B	Cimzia	Certolizumab Pegol	2008	\$508,504,399	Yes	2019
54	B	Imfinzi	Durvalumab	2017	\$505,845,757	Yes	2028
55	B	Alimta	Pemetrexed Disodium	2004	\$498,501,786	Yes	2015
56	B	Herceptin	Trastuzumab	1998	\$461,732,465	No*	2009
57	B	Sandostatin Lar Depot	Octreotide Acetate, mi-Spheres	1998	\$445,226,506	Yes	2009
58	B	Entyvio	Vedolizumab	2014	\$434,481,708	Yes	2025
59	B	Xolair	Omalizumab	2013	\$399,757,988	No*	2024
60	B	Gammagard Liquid	Immun Glob G(Igg)/Gly/Iga Ov50	2005	\$389,369,090	Yes	2016
61	B	Gammaked	Immune Globulin G/Gly/Iga Avg 46	2005	\$385,877,482	Yes	2016
62	B	Velcade	Bortezomib	2003	\$381,241,268	Yes	2010
63	B	Yervoy	Ipilimumab	2011	\$365,961,395	Yes	2022
64	B	Simponi Aria	Golimumab	2009	\$359,631,479	Yes	2020
65	B	Somatuline Depot	Lanreotide Acetate	2007	\$340,276,002	Yes	2014
66	B	Abraxane	Paclitaxel Protein-Bound	2005	\$339,486,064	Yes	2016
67	B	Privigen	Immun Glob G(Igg)/Pro/Iga 0-50	2007	\$334,425,289	Yes	2018
68	B	Botox	OnabotulinumtoxinA	2002	\$330,554,707	Yes	2013
69	B	Perjeta	Pertuzumab	2012	\$303,275,857	Yes	2023
70	B	Stelara (J3357)	Ustekinumab	2016	\$302,454,069	Yes	2027
71	B	Kyprolis	Carfilzomib	2016	\$293,472,937	Yes	2027
72	B	Eligard	Leuprolide Acetate	2004	\$285,196,045	Yes	2011
73	B	Actemra	Tocilizumab	2010	\$282,144,470	Yes	2021
74	B	NPlate	Romiplostim	2008	\$232,040,247	Yes	2015

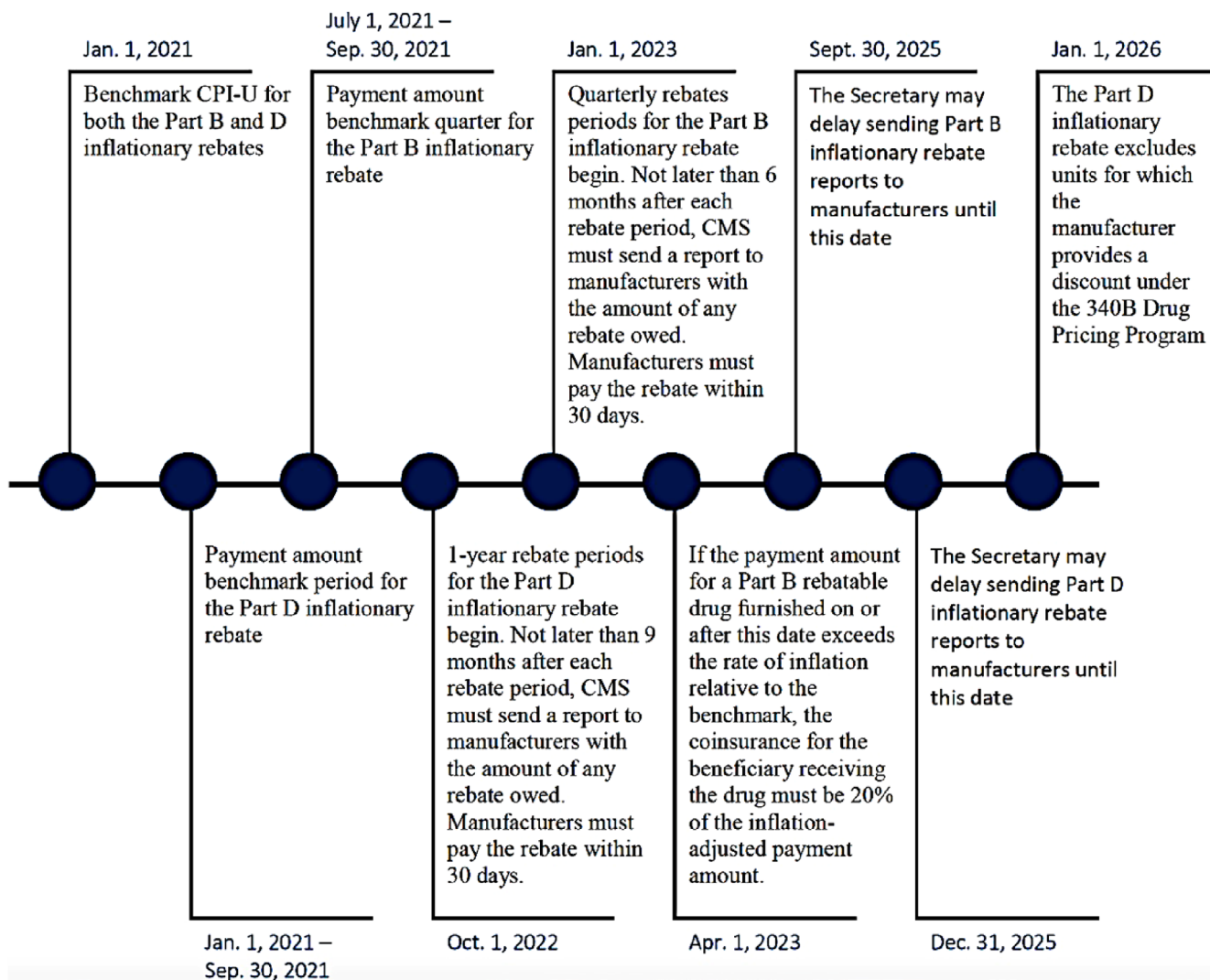
Note: Eligibility for drugs in the first round in 2026 and biologicals first round in 2027. Asterisk entries are disqualified because of the presence of a generic or biosimilar or imminent before the first date of selection.

less than 16 years; long-monopoly drugs have 65% market for 16 years or more. Standard monopoly drugs have a 40% market. It excludes vaccines.

- If a selected drug receives a new indication or there is a material change in the factors considered by the Secretary in setting the initial negotiated price.
- A selected drug's negotiated price (or as renegotiated when applicable) will remain in place until a generic or biosimilar is launched, in which case the selected drug's MFP would terminate at the start of the first year that begins 9 months after the generic or biosimilar has entered the market.
- The MFP is based on:
  - The statute includes specific minimum discounts based on categories of products to serve as a ceiling to the MFP, which is the lesser of: (1) 25% of the non-federal AMP for short-monopoly drugs, 35% off the non-federal AMP for extended monopoly drugs, and 60% of the non-federal AMP for long-monopoly

drugs; or (2) the sum of the plan-specific enrolment weighted amounts (for Part D selected drugs), or the drug's Part B payment amount for the year before the year of the selected drug publication date concerning the initial price applicability year for the drug or biological product (for Part B selected drugs).

- Research and development costs;
- Current unit costs of production and distribution of the drug;
- Prior Federal financial support for novel therapeutic discovery and development;
- Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under sections 505(c) or 351(a);
- Market data and revenue and sales volume data for the drug in the United States; The extent to which such drug represents a therapeutic advance as compared with existing therapeutic alternatives and the costs of such existing therapeutic alternatives; comparative clinical effectiveness research evidence that treats extending



**FIGURE 2** Timeline: Medicare Parts B and D Drug Inflationary Rebates<sup>23</sup>

the life of an elderly, disabled or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled or not terminally ill.

#### 4 | PRESCRIPTION DRUG INFLATION REBATES

The Act requires manufacturers to pay rebates for certain drugs under Medicare Parts B or D if their average prices increase faster than inflation. (Figure 2). Beginning on 1 January 2023, the Part B inflationary rebate applies to single-source drugs and biologics (including biosimilars) for which payment is made under Medicare Part B. Drugs and biologics excluded from the inflationary rebate include those with annual price changes of less than \$100 per individual, certain specified Part B vaccines, and qualifying biosimilar biological products with ASPs that do not exceed the reference biological's ASP during the quarter for

5 years. Part B inflationary rebates may also be waived or reduced in the case of drug shortages and severe supply chain disruptions.

Exclusion includes qualifying biosimilars within 5 years—a biosimilar with an ASP for the quarter that is not greater than the ASP for the reference drug.

#### 5 | ENFORCEMENT

Manufacturers that do not agree to an MFP with HHS will be subject to a tax of 65%–95% of Medicare utilization based on the prior year. In addition, manufacturers that agree on an MFP, but do not honour it, will be subject to civil monetary penalties equal to 10 times the amount of the product dispensed or administered that year, as well as the difference between the reimbursed price and the MFP.

Manufacturers will be subject to civil monetary penalties of 125% of the rebate amounts for untimely payments.



The Act precludes administrative and judicial review of the Secretary's selection of drugs subject to the Program, determining MFPs, and choosing renegotiation-eligible drugs.

## 6 | SUMMARY

The US legislative system is complex and not ideal and thus subject to criticism, the IRA being no exception. The same happened with the Affordable Healthcare Act<sup>24</sup> that quietly embedded in the BPCIA<sup>25</sup> to allow entry of biosimilars. The BPCIA had been on the table at the Senate for a decade; when it became part of a much larger Bill, many deniers did not even pay attention to it and signed off without realizing that it had only 7 years of exclusivity for biological products. An uproar post-approval made President Obama concede to 12 years of exclusivity.

The IRA is similar to the AHA in many ways. While bringing extreme comfort to Medicare patients by removing the famous “donut hole,” it capped the cost for the elderly. It also brought support to the direly needed environmental control. Unfortunately, the cost of \$780 billion had to be paid somehow. The Act added a minimum tax of 15% on corporations and taxed the purchase of own equity by the companies. However, it does not force additional tax and removes the already unavailable clause that is already not available to individuals.

The IRA does not restrict the pricing of biosimilars as commonly practiced in the EU.<sup>26</sup> A reference product selected towards the end of the exclusivity period will likely be subject to a 35% price reduction since it will be considered an extended monopoly drug, notwithstanding other considerations that might reduce this margin. This is not a “precipitous” drop in the price that a biosimilar could not match. But that scenario does not even arrive since the approval of a biosimilar removes this price reduction. If the reference product decides to keep the lower price, this has little to do with the IRS, and it is market play.

The IRA only applies to Medicare, and the price negotiation applies only to chemical drugs after 7 years of market monopoly and the past 11 years to biological drugs when the negotiations begin. Two additional years are added if the arrival of a generic or biosimilar is imminent.

Over a decade, there will be about 10 drugs put into price reduction out of 14,000 that the CMS reimburses. The cumulative number will keep reducing as generics and biosimilars are approved. The Act will reduce the cost of drugs to 63 million patients on Medicare and 3.5 million on Medicaid,<sup>27</sup> compared with 177 million patients receiving drugs through private insurance.<sup>28</sup> The negotiated price will benefit everyone if it spills over to the private market.

The argument is fallacious; if the price of brand name products is reduced, it will reduce the incentive for generics and biosimilars to enter the market. The entry of biosimilars will remove the price reduction, incentivizing reference product manufacturers to encourage biosimilars entry. If the reference product manufacturer decides to keep its price lower after the restrictions are removed, this can happen to any drug and has little to do with the IRA.

Medicare Part B reimbursement for biosimilars will be temporarily increased to ASP +8% (8% is calculated on the ASP of the reference product) for 5 years. For biosimilars currently on the market, the increase will be effective through 31 December 2027. In addition, new biosimilars launched before 31 December 2027, will experience a temporary increase in reimbursement from their launch date to the end of the 5 years. Biosimilars launched after 31 December 2027, will be reimbursed as ASP +6% (6% is calculated on the ASP of the reference product). This is a benefit included in the IRA.

The IRA not only reduces the burden of the CMS by \$100 billion; it also reduces the cost burden of millions of patients, improves the environment and holds corporations responsible for their contribution to the welfare of society. The clear beneficiaries are the 60+ million Americans who will no longer have to deal with the notorious “donut hole” and now have a ceiling of \$2000 for their Part D and B contribution.

As the list of price-negotiated drugs shrinks over time, the Medicare saving will shift from reimbursing the reference product to the biosimilar, as it is doing now. So, in essence, the entire purpose of the price-reduction exercise is to prompt the entry of generics and biosimilars.

The proposition of negotiating the price is not new or uncommon; more than half of the EU countries now fix the pricing with a tender system, and others require significant price reductions for biosimilars.<sup>26</sup> The IRA is much less aggressive than it was supposed to be; it is based on fairness that chooses biological drugs after 11 years of marketing and 7 years for chemical drugs, regardless of the patent status. This period should be enough to secure a profitable return on the investment when we look at the prices charged by the reference product companies. For example, according to WHO,<sup>29</sup> the cost of producing an antibody ranges from \$95 to 150 per gram; these are sold at 100–1000 times the COGs during the exclusivity periods. There is enough allowance for the reference product to recoup its billion-dollar investment. This is the same argument offered in patent rights; when a patent expires, humanity should be able to benefit.

The drug negotiation provisions of the IRA do not extend to the private market. However, the negotiation agreement requires manufacturers to make the MFP available to MFP-eligible individuals who are enrolled in a prescription drug plan under either Part C or D and are dispensed a selected drug, but also those who are furnished or administered a selected drug for which payment is made under Part B. However, there is no penalty if offering MFP to an individual who is not an MFP-eligible individual.

While the IRA pertains only to Medicare, the inflation rebates based on Medicare utilization could have spillover effects in other market segments. However, it is not likely to happen since there is already in place a rebate program managed by the Pharmacy Benefit Managers (PBMs). The Federal Trade Commission (FTC) recently began an inquiry into how these drug rebates block patient access to cheaper pharmaceuticals.<sup>30</sup> The FTC has charged that rebates could be driving up prices of vital drugs such as insulin, the list price of which has increased by more than 300% in recent decades. The “exclusionary” rebates cut off competition from a less expensive



alternative like a generic or a biosimilar. The PBMs, as the “drug middlemen,” have placed higher-priced drugs on formularies instead of “lower-cost alternatives” in a manner that shifts costs to payers and patients. In addition to other factors, some have suggested that high rebates and fees to PBMs and other intermediaries may incentivize higher list prices for drugs and discourage coverage of the lowest-cost products.

A new Senate bill aims to empower FTC to crack down on PBMs.<sup>31</sup>

Major supporters of IRA include the Commonwealth Fund,<sup>32</sup> The American Pharmaceutical Association,<sup>33</sup> which also pointed out the need to fix the PBM's role in drug distribution. Surprisingly, the opponents of the IRA are going to be the biggest beneficiary, the associations representing the generic and biosimilar industry,<sup>34</sup> as well as the big pharma groups like the BIO, while accepting it as good news for agricultural biotechnology.<sup>35</sup> While many scholars and leaders support the Bill, many have opposed it due mainly to their misconceptions and misunderstanding of the Bill, as explained below.

## 7 | MISCONCEPTIONS AND MISUNDERSTANDINGS

The statements and pleadings made by prominent scholars and heads of associations responsible for promoting generics and biosimilars are presented below, along with a detailed explanation to remove these misconceptions and misunderstandings. The numerical parenthesis is added to focus on the underlined comments.

Association for Affordable Medicines<sup>36</sup> states: “Senate has chosen to replace competition – the only proven way to provide patients relief from high brand drug prices – with a flawed framework for (1) government price setting that will (2) chill the development of, and (3) reduce patient access to, lower-cost generic and biosimilar medicines. While the bill's ill-advised price setting scheme (4) will harm Medicare and seniors, its negative impact will (5) extend to employers and patients that rely on generic and biosimilar medicines to keep costs down.” Dan Leonard, President & Chief Executive Office, Association for Accessible Medicines [parentheses added]

- (1) There is no “price setting”; it is a price reduction of about 25% for chemical drugs after 8 years and 35% for biological drugs after 12 years of monopoly, provided no generic or biosimilars become available.
- (2) This statement is incorrect and misleading.<sup>37</sup> The correct number is 15 out of 1300,<sup>38</sup> or about 1%, over 20 year period, assuming that no biosimilar or the generic product arrives and the price reduction of the single-source product stays at 65% after 16 years of exclusivity. All the while, the CMS had saved over \$2–3 trillion. A major misunderstanding comes from thinking that once a reference product has been subjected to price-reduction, it will remain so; chances are that most of product brought into price negotiation will soon leave the classification, significantly reducing the number of products in this category. Products removed are not replaced by

additional products, except 20 per year; faster removal of drugs from price negotiation may leave the number of such drugs to no more than those selected each year.

- (3) The entry of 15 fewer drugs over 20 year period applies to new chemical or biological drugs; it has no impact on the affordable generics and biosimilars. If it is asserted that the price reduction of single-source products will hamper the entry of generics and biosimilars is welcomed, the single-source product is faced with price reduction.
- (4) It is impossible to give credence to this statement; how would Medicare patients and seniors suffer? They are even getting a cap on their out-of-pocket expense, the “donut hole” is leaving, and no change will come to their medical supplies. They will receive their reimbursement as before; only private patients might see a difference, which is in their favour with the lowered cost of single-source drugs.
- (5) How could there be a negative impact on employers and patients? If it refers to employers paying for insurance, it will reduce the burden, not increase, if the price spillover comes to the private market. If the employers are referred to generic and biosimilar companies, they are here to get the biggest benefits.

Robert E. Moffit, Ph.D., Senior Research Fellow, Center for Health and Welfare Policy,<sup>39</sup> has also stated: “(6) the so-called Medicare prescription drug ‘negotiation’ plan has nothing to do with negotiation and everything to do with government price setting. For the record, when CBO issued its 2021 report on the impact of the Lower Drug Costs Now Act, last year's Democratic congressional proposal, it concluded that that bill, (7) if enacted, would have ‘reduced global revenue for new drugs by 19 percent’, resulting in the 30 fewer drugs over a 20-year period.”

- (6) The price reduction applies only to a single-source drug, whether a brand-name drug, generic or biosimilar, and if their expenditure is the highest, likely above \$1B per year; the reduced price goes away once the product is no longer a single-source product.
- (7) This is also misrepresenting the data from the CBO, as shown above.

Biosimilars Council<sup>40</sup> states: “Contrary to its name, the Inflation Reduction Act would increase prescription costs by (8) stifling biosimilar competition and innovation,” said Craig Burton, Executive Director of the Biosimilars Council. “The price control proposals would actively (9) harm millions of patients by rewarding brand drug manufacturers with a perpetual monopoly. Congress should reject this proposal and support solutions that sustainably lower drug prices by (10) encouraging generic and biosimilar adoption.”

- (8) Biosimilar competition is fostered by the IRA as it makes the entry of biosimilars a condition to remove the price reduction of the reference product. There is no impact on innovation as these products will have exclusivity. If the intent is to state that the price reduction will reduce the entry of new drugs, then it is the same misconceived statement discussed above.



- (9) There is no monopoly awarded; it is instead punished. For example, when a biosimilar product comes out of exclusivity, the price reduction will be 35%, and if no competitor arrives until 16 years, the price reduction goes to 65%. Suppose the statement intends that the price reduction of a single-source product will deter the entry of generics and biosimilars. In that case, the statement is misconceived since the price cap for reference products goes away once a generic or biosimilar enters the market.
- (10) No legislation or effort has done more to promote generics and biosimilars than the IRA. It is straightforward. Unless a generic or biosimilar is available, the brand name product must sell at a lower price. Can there be a better incentive for generic and biosimilar industries?

Craig Burton<sup>41</sup> responding to the opinion of the author<sup>42</sup>: “...threatens to undermine (11) biosimilar competition by creating unprecedented price controls. In addition, this misguided provision could (12) compromise future biosimilar development and inadvertently leave patients with costlier brand-name treatment options.”

- (11) Since there has never been a price control, there cannot be a precedence. The reference product manufacturer will prefer to have biosimilars enter the market to remove their price reduction after their exclusivity period. Medicare is already reimbursing all licensed biosimilars and waiting to remove the reimbursement of reference products once the biosimilars arrive.
- (12) On the contrary, it will speed up the entry of biosimilars; if the intent is to say that since there are price reductions for a single-source product, no competition will arrive even though its arrival removes the price reduction, then this is entirely unrealistic. Furthermore, to assume that the costlier brand-name products with a 65% reduction will stay expensive and continue to sell is also misleading. If the brand-name product decides to keep its price lower of its own volition, then the assumption that a biosimilar product cannot sell at less than the price of the brand-name product it should be in the market.

“(13) If the reference biologic is selected for negotiations near the end of its exclusivity period, its product's price will (14) drop precipitously. This would then require the biosimilar competitors to price themselves (15) even lower than the point of economic viability and out of the market entirely.”

- (13) There is no “if,” all products will be selected at the end of their exclusivity.
- (14) A 35% reduction in price after 12 years of exclusivity of biological drugs and 25% price reduction of single-source chemical drug after 8 years is not “precipitous.”
- (15) This statement has two misconceptions. First, a biosimilar product cannot sell at a price lower than the reference product; second, a 35% price reduction will make biosimilar unviable. Most biosimilars sell at much more than 35% and remain economically viable.

“significantly reduce the competitive edge (16) just as the market considers which potential competitors to bring to market.”

- (16) The choice of competitors shall remain the same; the highest value products are most likely to be selected for the price reduction. The CMS listing of spending is an open database that anyone can use to determine which drug or biological product will be subject to price negotiation (see Tables 2–4).

“Biosimilar manufacturers have (17) no role in the negotiation process and would instead have to (18) gamble on whether or not a reference biologic becomes 1 of the 100 negotiated drugs.”

- (17) Negotiations are held with the product manufacturer; if a biosimilar is a one-source product (say, if the innovator leaves the market), then it will be subject to a price reduction as well if it spends on it more than a billion dollars. So why would they be part of any negotiation for another product?
- (18) It will be 2033 when the total number of drugs negotiated will reach 100. Given that only the top 50 drugs in Part D and B are eligible for price negotiation with no preference for Plan D or B, it is improbable that any biological product will be added to the list (see Tables 2–4). The total count of price-reduced drugs will likely be no larger than 20, the newly introduced drugs for the year as the entry of generics and biosimilars for these lucrative market drugs will reduce the count of single-source products.

“(19) ...too risky for would-be biosimilar manufacturers to invest the decades and hundreds of millions of dollars required to produce lower-cost alternatives. This would (20) give costly brand-name medicines a de facto monopoly at a price likely higher than what patients would have paid in (21) a traditionally functioning market with multiple biosimilar competitors.”

- (19) Unlike chemical drugs, biologicals have almost perpetual life; one of the earliest products, erythropoietin, is now projected to become the #1 product in 2025 (Table 4). The only risk to biosimilars is the competition from other biosimilars, and if that is the case, then it is a business decision with little to do with the IRA.
- (20) De facto monopoly assumes that the reference product stays the single-source product after its exclusivity expires. The price will be reduced eventually by 65%, but all of it applies to Medicare, not the private market. Not realized here is that the price reduction plan penalizes monopoly.
- (21) Nothing in the IRA impacts the market, it only reduces the price of a few drugs reimbursed by Medicare. 80% of the private market is not included in the IRA. If there is any impact on the private market, it will be positive, not negative.
- (22) “Biologic brands often file non-innovative patents that, in this case, would delay biosimilars past the point of the negotiation window – effectively rendering this safeguard provision useless.”
- (22) The IRA motivates reference product manufacturers to let go of the Patent Dance and let the biosimilars arrive sooner, so they

**TABLE 3** Biosimilar candidates as Part B reimbursed biologicals (biosimilars in bold) with only one drug (\*) with \$1B+ expenditure

*Abatacept	Abobotulinumtoxina	Ado-Trastuzumab Emtrastine	*Aflibercept	Agalsidase Beta
Albumin Human	Alemtuzumab	Alglucosidase Alfa	Alpha-1-Proteinase Inhibitor	Alteplase
Anti-Inhibitor Coagulant Comp.	Anti-Thymocyte Globulin, rabbit	Antihem. FVIII, several types	Antihemophilic Factor/VWF	Antithrombin III (Hum Plas)
Antivenin, crotalidae Fab(Ovin)	Asparaginase (Erwinia Chrysan)	Atezolizumab	Avelumab	Basiliximab
Belatacept	Belimumab	Bendamustine HCL	Benralizumab	<b>Bevacizumab</b>
Bezlotoxumab	Blinatumomab	Bortezomib	Brentuximab Vedotin	Brolucizumab-Dbll
Burosumab-Twza	C1 Esterase Inhibitor, Recomb	Canakinumab/PF	Carfilzomib	Cemiplimab-Rwlc
Certolizumab Pegol	Cetuximab	Chorionic Gonadotropin, Human	Coagulation Factor VIIA, recomb	Coagulation Factor X
Crizanlizumab-Tmca	Daratumumab	<b>Darbepoetin Alfa In Polysorbat</b>	*Denosumab	Digoxin Immune Fab
Dornase Alfa	Durvalumab	Eculizumab	Elotuzumab	Emicizumab-Kxwh
Enfortumab Vedotin-Ejfv	<b>Epoetin Alfa</b>	Factors IX several types	Factor XIII several types	Fam-Trastuzumab DeruxtecN-Nxki
<b>Filgrastim</b>	Gemtuzumab Ozogamicin	Glucagon, human Recombinant	Golimumab	Ibalizumab-Uiyk
Idursulfase	Imiglucerase	Imm Glob G (Igg)/Sorb/Iga 0-50	Incobotulinumtoxina	<b>Infliximab</b>
Inotuzumab Ozogamicin	Insulin Aspart	Insulin Lispro	Interferon Alfa-2b, recomb.	Interferon Beta-1a
Ipilimumab	Isatuximab-Irfc	Mepolizumab	Methoxy Peg-Epoetin Beta	Mogamulizumab-Kpkc
Moxetumomab Pasudotox-Tdfk	Natalizumab	Necitumumab	*Nivolumab	Obinutuzumab
Ocrelizumab	Ocriplasmin/PF	Ofatumumab	Olaratumab	Omalizumab
Onabotulinumtoxina	Panitumumab	Pegaspargase	<b>Pegfilgrastim</b>	Pegloticase
*Pembrolizumab	Pertuzumab	Polatuzumab Vedotin-Piiq	Ramucirumab	*Ranibizumab
Ravulizumab-Cwvz	Reslizumab	Rho(D) Immune Globulin	Rimabotulinumtoxinb	<b>*Rituximab</b>
<b>Rituximab/Hyaluronidase, human</b>	Romozosumab-Aqqg	Sargramostim	Siltuximab	Tagraxofusp-Erzs
Taliglucerase Alfa	Teprotumumab-Trbw	Thyrotropin Alfa	Tildrakizumab-Asmn	Tocilizumab
<b>Trastuzumab</b>	Trastuzumab-Hyaluronidase-Oysk	Treprostinil	Ustekinumab	Vedolizumab
Velaglucerase Alfa	Von Willebrand Factor	Ziv-Aflibercept		

Note: Adalimumab is classified under Part D.

may not be subject to price negotiation. It will expedite, not delay, the entry of biosimilars. It is time for first-time biosimilar entries to work with reference product manufacturers to reduce the cost burden of patent litigation—it is an unprecedented opportunity.

(23) “Under the bill, the Department of Health and Human Services would be required to negotiate prices for over 100 drugs—many of which would be reference biologics subject to biosimilar competition.”

- (23) It will take a decade before 100 out of 14,000 drugs are put to price negotiation and only those that make the top 50 list of

Medicare expenditure. No reference biological product qualifies for at least a decade (Table 2). Given the historical difference in the expenditure between Plan D and Plan B drugs, it is improbable that any biological product will ever be subject to price negotiation. The cumulative number will remain very small as most of the drugs in the price-control category will be removed with the arrival of generics and biosimilars.

“(24) Essentially, biosimilars are forced to accept the outcome of the negotiation process, and they would be in no position to establish any incentives for themselves.”

**TABLE 4** Top market-share biosimilar opportunities

Product	Category	Global (\$B) Market, 2025	Biosimilar approval US/EU; *interchangeable
Erythropoietin (Epoetin), Amgen	Haematopoietic	18	1/3
Pembrolizumab (Keytruda), Merck	HER2	16	0/0
Nivolumab (Opdivo), BMS	PD-1	14	0/0
Adalimumab (Humira) AbbVie	TNF-alfa	11	7/10
Etanercept (Enbrel), Amgen	TNF-alfa	8	2/3
Infliximab (Remicade), Janssen	TNF-alfa	8	4/4
Ustekinumab (Stelara), Janssen	IL-12, IL-23	8	0/0
Bevacizumab (Avastin), Roche	VEGF-A	7	3*/9
Ocrelizumab (Ocrevis), Genentech	CD-20	7	0/0
Pertuzumab (Perjeta), Roche	HER-2	7	0/0
Secukinumab (Cosentyx), Novartis	PD-1	6	0/0
Aflibercept (Eyelea), Regeneron	VEGF	4	0/0
Darbepoetin alfa (Aranesp), Amgen	Haematopoietic	4	0/0
Peg-filgrastim (Neulasta), Amgen	Neutropenic	4	5/7
Ranibizumab (Lucentis), Novartis	VEGF	4	2*/1
Trastuzumab (Herceptin), Genentech	HER-2/neu	4	5/6
Rituximab (Rituxan), Genentech	CD-20	3	3/5
Cetuximab (Erbix), Lilly/Merck	EGF	1	0/0
Eculizumab (Soliris), Alexion	Complement C5	1	0/0
Filgrastim (Neupogen), Amgen	Neutropenic	1	3/9

- (24) This statement conjectures that the biosimilars will sell at a lower price than the reduced price of the reference product, even if there is no reduced price.

“(25) *What’s ironic about the Inflation Reduction Act is that artificially setting prices ignores the proven benefits of competition established by the Hatch-Waxman Act. Further, (26) it bypasses bipartisan legislative solutions that would nurture future competition and sustainably lower prices.*”

- (25) There is no arbitrary price setting; a biological product that has passed beyond its 12-year exclusivity will be subject to a 35% price reduction or less if it qualifies for many circumstantial waivers. The BPCIA has done what the Hatch-Waxman Act did to chemical drugs. Both the BPCIA and the IRA operate with no price controls.
- (26) This statement may be showing the slip. The IRA was rejected by 100% of Republicans in both the Senate and the House. Dreamers can think of a bipartisan resolution to anything in America. The IRA has many humanitarian and environmental benefits besides the budget reduction of Medicare. But none of these were countable when the decision came to partisanship.

Amitabh Chandra,<sup>43</sup> director of health policy research at the Harvard Kennedy School of Government, stated: “*there could also be ‘strong incentives’ for the brand manufacturer to (27) introduce its biosimilar and forestall negotiations through this channel.*”

- (27) The IRA already prevents such practice. The imminent biosimilar cannot be owned directly or indirectly by the reference product

company, or if the product company incentivizes the biosimilar developer, that is defined under the Aggregation Rule. The IRA further prohibits tactics from using biosimilar entries to remove the reference production selection for price negotiation. The statement is misconceived.

## 8 | PERSPECTIVE

The future of biosimilars depends on the efficiency of their development cost, enabling the offering of affordable products.<sup>44</sup> However, the current \$100–300 million price for each biosimilar is untenable.<sup>45</sup> Therefore, the onus to reduce the development cost lies as much on the developers<sup>46</sup> and the regulatory agencies.<sup>47</sup> The associations representing generic and biosimilar companies should focus on achieving this goal instead of politicizing the efforts intended to help the generic and biosimilar industry if they disagree with the legislature due to their partisan views.

The US FDA has approved more than 130 recombinant proteins for clinical use. However, and more than 170 recombinant proteins are available.<sup>48</sup> Yet, only nine molecules in the US and 14 in the EU are available as biosimilars. The opportunities for biosimilars are boundless (Table 3).

The IRA’s impact on biosimilars will help bring more biosimilars sooner and reduce legal hurdles like the “patent dance.” In addition, the IRA offers many concessions to biosimilars.

The developers and promoters of biosimilars should realize that eventually, the biosimilars will become fully adopted when the price

drops by 60%–70%, regardless of the current efforts to change the opinions of prescribers, patients and other stakeholders. Once the payors come into play, biosimilars will turn no different than generics.

Table 3 lists the biological drugs reimbursed under Plan B, all of which make an excellent choice for the biosimilar developers to choose from since these have an established market through Medicare.

Table 4 lists the biosimilar candidates with the anticipated market of over \$135B in 2025. None of these would be subject to price reduction, including the 10 single-source products for which the arrival of biosimilars. In addition, none of these drugs are likely to make it to the top 15–20 drugs in expenditure to be selected.

Significant changes coming to the regulatory guidelines will reduce the burden of testing as the analytical assessment becomes more sophisticated and reliable. For example, the FDA has recently funded a grant of \$2 million<sup>49</sup> to create strategies to reduce the testing burden to establish biosimilarity. In addition, the MHRA<sup>50</sup> has already declared that animal testing<sup>51</sup> and comparative efficacy testing may not be required,<sup>52</sup> as suggested by the author.

## 9 | CONCLUSION

The IRA is the law now; there is no perfect law, but it can be made perfect by those who choose to practice it diligently. The law relating to drug price reduction applies only to Medicare, which serves 20% of patients; it has little to do with the 80% of the private market. The IRA does not control (meaning capping) the price of drugs; it forces the reduction of specific products that meet limited criteria of the highest expenditure to Medicare and time on the market as a single-source product. The price reduction is 25% for generics and 35% for biologics when they become eligible for a price reduction; staying as a single source beyond 16 years will increase the reduction to 65%; thus, the IRA promotes the generic and biosimilar industry to remove the single-source status of drugs.

Any projections of impact on the industry, the patients and other stakeholders based on the number of price-reduced single-source products are overblown, not realizing that most of these products will be removed and replaced with other products; it should not surprise if the total number is not more than 10–20, the first entrants, throughout the life of the practice of the IRA.

Associations promoting generics and biosimilars need to rethink their opposition to IRA; the challenge is the high development cost, not the temporary price reduction of the reference product that will positively impact generics and biosimilars. They should work to educate the developers and the regulatory agencies<sup>47</sup> instead of focusing on advertising the value of generics and biosimilars. The FDA has already approved them. Once the cost of goods goes down, the biosimilars, as do the generics, will become adopted, forced by the payors. A significant hurdle in the accessibility of affordable biosimilars is the presence of PBMs.<sup>53</sup> Getting out of this trap alone can reduce the cost of all drugs by 50%.

Despite the partisan politics, the generics and biosimilars have a great future, now brightened by the IRA.

## CONFLICT OF INTEREST

The author has served as an advisor to Vice President Kamala Harris on drafting the IRA. The author is also a US patent law practitioner.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

## DISCLAIMER

The views expressed in this article are entirely author's and do not necessarily represent any institution, association, or company.

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## REFERENCES

- <https://www.nytimes.com/2003/11/24/us/medicare-debate-turns-to-pricing-of-drug-benefits.html>
- The Inflation Reduction Act. <https://www.congress.gov/bill/117th-congress/house-bill/5376/text?q=%7B%22search%22%3A%5B%22inflation+reduction+act%22%2C%22inflation%22%2C%22reduction%22%2C%22act%22%5D%7D&r=1&s=1>
- [https://www.democrats.senate.gov/imo/media/doc/inflation\\_reduction\\_act\\_one\\_page\\_summary.pdf](https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_one_page_summary.pdf)
- <https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/15/by-the-numbers-the-inflation-reduction-act/>
- <https://www.cbo.gov/publication/58366>
- <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet>
- <https://data.oecd.org/healthres/health-spending.htm>
- [https://www.pgpf.org/blog/2022/07/how-does-the-us-healthcare-system-compare-to-other-countries?utm\\_term=per%20capita%20healthcare%20spending%20by%20country&utm\\_campaign=Healthcare+General&utm\\_source=adwords&utm\\_medium=ppc](https://www.pgpf.org/blog/2022/07/how-does-the-us-healthcare-system-compare-to-other-countries?utm_term=per%20capita%20healthcare%20spending%20by%20country&utm_campaign=Healthcare+General&utm_source=adwords&utm_medium=ppc)
- <https://www.healthsystemtracker.org/chart-collection/how-do-prescription-drug-costs-in-the-united-states-compare-to-other-countries/#Per%20capita%20prescribed%20medicine%20spending%20U.S.%20dollars%202004-2019g>
- <https://www.govinfo.gov/content/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf>
- <https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2021-annual-report>
- Wouters OJ, McKee M, Luyten J. Estimated Research and Development investment needed to bring a new medicine to market 2009–2018. *JAMA*. 2020;323(9):844–853. doi:10.1001/jama.2020.1166
- <https://www.science.org/content/blog-post/where-drugs-come-country>
- <https://www.fraserinstitute.org/article/canada-not-a-good-example-of-universal-health-care#:~:text=The%20reality%20of%20Canadian%20health,any%20country%20should%20consider%20replicating.>
- <https://www.nationalreview.com/2021/01/the-deadly-failures-of-britains-national-health-service/>
- <https://www.healthcare.gov/where-can-i-read-the-affordable-care-act/>
- <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet#:~:text=Historical%20NHE%2C%202020%3A&text=Medicaid%20spending%20grew%209.2%25%20to%209%20percent%20of%20total%20NHE.>
- <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>
- <https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending/#:~:text=Part>



- %20B%20covers%20a%20substantially,drugs%20are%20relatively%20costly%20medicationsy.
20. <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug/data>
  21. [https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What\\_is\\_the\\_difference\\_between\\_patents\\_a](https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a)
  22. <https://www.fda.gov/drugs/biosimilars/background-information-list-licensed-biological-products-reference-product-exclusivity-and>
  23. <https://foleyhoag.com/-/media/files/foley%20hoag/publications/white%20papers/foley%20hoag%20llp%20-%20summary%20of%20inflation%20reduction%20act%20of%202022%20-%20key%20drug%20pricing%20provisions%20and%20implementation%20timeline.ashx?la=en>
  24. <https://www.congress.gov/bill/111th-congress/house-bill/3590>
  25. <https://www.congress.gov/bill/117th-congress/senate-bill/1428/text>
  26. Vogler S, Schneider P, Zuba M, Busse R, Panteli D. Policies to encourage the use of biosimilars in European countries and their potential impact on pharmaceutical expenditure. *Front Pharmacol*. 2021;25(12):625296. doi:10.3389/fphar.2021.625296
  27. <https://www.cms.gov/newsroom/news-alert/cms-releases-latest-enrollment-figures-medicare-medicaid-and-childrens-health-insurance-program-chip#:~:text=As%20of%20October%202021%2C%20the%20total%20Medicare%20enrollment%20is%2063%2C964%2C675>
  28. <https://sgp.fas.org/crs/misc/IF10830.pdf>
  29. WHO. Call for consultant on monoclonal antibodies for infectious diseases. Accessed March 23, 2022. <https://www.who.int/news-room/articles-detail/call-for-consultant-on-mono-clonal-antibodies-for-infectious-diseases>
  30. <https://www.fiercehealthcare.com/payers/ftc-puts-pbms-notice-enforce-ment-policy-surrounding-drug-rebates>
  31. <https://www.fiercehealthcare.com/payers/senate-bill-aims-ban-pbm-practices-such-spread-pricing-and-boost-ftc-enforcement-powers>
  32. <https://www.commonwealthfund.org/publications/issue-briefs/2020/apr/lower-drug-costs-now-act-hr3-how-it-would-work>
  33. <https://www.pharmacist.com/APhA-Press-Releases/apha-reminds-policy-makers-to-fix-broken-pbm-marketplace-to-compliment-new-drug-pricing-law>
  34. <https://khn.org/news/article/big-pharma-oppose-drug-pricing-negotiations-history/>
  35. <https://www.bio.org/gooddaybio-archive/good-day-bio-inflation-reduction-act-and-ag-biotech>
  36. <https://accessiblemeds.org/resources/press-releases/aam-statement-senate-passage-inflation-reduction-act>
  37. Cookson G, Hitch J. Limitations of CBO's simulation model of new drug development as a tool for policymakers. OHE Consulting Report; 2021. <https://www.ohe.org/publications/limitations-cbo%E2%80%99s-simulation>
  38. [https://www.cbo.gov/system/files/2022-07/senSubtitle1\\_Finance.pdf](https://www.cbo.gov/system/files/2022-07/senSubtitle1_Finance.pdf)
  39. <https://www.heritage.org/medicare/commentary/reducing-patient-access-new-medications-the-lefts-latest-medicare-price-fixing>
  40. <https://biosimilarscouncil.org/news/inflation-reduction-act-would-stifle-biosimilar-competition-and-savings/>
  41. Burton C. Opinion: the Inflation Reduction Act is a step backward for biosimilar competition. August 18, 2022. <https://www.centerforbiosimilars.com/view/opinion-the-inflation-reduction-act-is-a-step-backward-for-biosimilar-competition>
  42. Niazi S. Impact of Inflation Reduction Act 2022; Addressing Critics. <https://www.centerforbiosimilars.com/view/opinion-impact-of-inflation-reduction-act-2022-addressing-critics>
  43. <https://news.bloomberglaw.com/ip-law/drug-negotiations-will-drive-biosimilars-as-patent-tactics-shift>
  44. Niazi SK. The coming of age of biosimilars: a personal perspective. *Biol Theory*. 2022;2(2):107-127. doi:10.3390/biologics2020009
  45. Chen Y, Monnard A, Jorge Santos DS. An inflection point for biosimilars, McKinsey & Co. June 8 2022. <https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars>
  46. Niazi S. Biosimilars: a futuristic fast-to-market advice to developers. *Expert Opin Biol Ther*. 2022;22(2):1-7. doi:10.1080/14712598.2022.2020241
  47. Niazi SK. Biosimilars: harmonizing the approval guidelines. *Biol Theory*. 2022;2(3):171-195. doi:10.3390/biologics2030014
  48. <https://www.sciencedirect.com/topics/neuroscience/recombinant-proteins>
  49. NIH Grant 1U01FD007763-01. Anna Schwendemen (PI) and Sarfaraz Niazi (CoPI). <https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-22-026.html>
  50. MHRA. Biosimilar guidance. June 8, 2022. <https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products>
  51. Niazi S. End animal testing for biosimilar approval. *Science*. 2022;377(6602):162-163. doi:10.1126/science.add4664
  52. Niazi S. Scientific rationale for waiving clinical efficacy testing of biosimilars. *Drug Des Devel Ther*. 2022;16:2803-2815. doi:10.2147/DDDT.S378813
  53. <https://phma.org/resource-center/Topics/Access-to-Medicines/New-Report-Finds-Largest-PBMs-Restrict-Access-to-More-Than-1150-Medicines>

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