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USA | Biotechnology

Equity Research
June 9, 2025

SLIDES Operation MFN - Webcast TODAY, 6/9 @ 11am ET

Most Favored Nation (MFN) remains one of the big 3 regulatory overhangs, along with disruption at the FDA and Tariffs, for the Healthcare Sector

Join Jefferies Biotech & Pharma analyst Akash Tewari & HC Specialist Will Sevush **TODAY, 6/9/25 @ 11AM ET** as we go over different scenarios (Legislation, CMMI, IRA, etc.) + mitigation steps, backed with analysis.

CLICK HERE TO REGISTER FOR THE WEBCAST & SEE ATTACHED FOR OUR SLIDES*

Additionally, please see HERE for our proprietary Excel with the top 50 Medicare Part D/B drugs and price spreads between US and ex-US markets + our deep dive on Tariffs HERE.

Thanks,

Akash & Team

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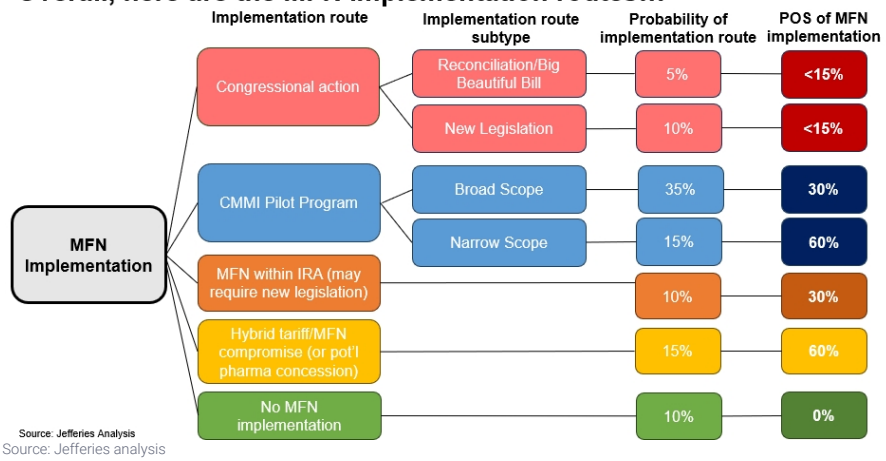
Overall, here are the MFN implementation routes…



Source: Jefferies analysis

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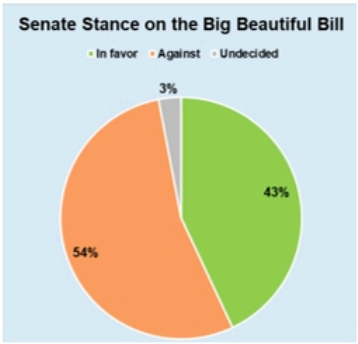
= = Teaser Images = =

That said, we collected all public statements that the Senate members have made on the One Big Beautiful Bill…in its current state, there is a chance that OBBBA won't pass the Senate given concerns re: Medicaid & debt – only 3 Republicans need to vote 'no' for the bill not to be passed

Last Name	Senator's Name	State	Party	Stance	Quote
Abrecrooks	Abrecrooks, Angela D.	Maryland	Democratic	Against	"The largest cuts to Medicaid and SNAP in American history – and Trump is calling it the "Big, Beautiful" bill. Well beautiful for whom? Certainly not the millions of Americans who rely on SNAP to feed their children and on Medicaid to
Baldwin	Baldwin, Tammy	Wisconsin	Democratic	Against	"Mo Wisconsinite should be forced to forgo the medication they need to stay healthy because of cost."
Banks	Banks, Jim	Indiana	Republican	In favor	One Big, Beautiful Bill will make America affordable again.
Barrasso	Barrasso, John	Wyoming	Republican	In favor	I am for whatever can get 218 votes in the House, 51 votes in the Senate and get signed by the president
Bennet	Bennet, Michael F.	Colorado	Democratic	Against	Trump likes to call it "one big, beautiful bill" -- but for middle-class families and workers, this bill is nothing but a nightmare
Blackburn	Blackburn, Marsha	Tennessee	Republican	In favor	Priority number one: passing the "one big, beautiful bill."
Blumenthal	Blumenthal, Richard	Connecticut	Democratic	Against	Introduced the Medicare Beneficiary Co-Pay Fairness Act of 2025 to make Medicare's co-pay structure more affordable.
Blunt Rochester	Blunt Rochester, Lisa	Delaware	Democratic	Against	"House Republicans' "Big Beautiful Bill" is nothing more than a big ugly tax give-away for the ultra-wealthy while everyday Americans pick up the tab."
Booker	Booker, Cory A.	New Jersey	Democratic	Against	"We cannot let Trump hide behind his Big Budget Bill. We must fight each and every provision that threatens democracy and American lives."
Boozman	Boozman, John	Arkansas	Republican	In favor	I'd like to get the risk management tools -- that's the real expense of the Farm Bill -- I'd like to get that included in reconciliation.
Britt	Britt, Katie Boyd	Alabama	Republican	In favor	The American people are firmly behind us in this effort, and they're counting on us to deliver relief in our one, big beautiful bill.
Budd	Budd, Ted	North Carolina	Republican	In favor	"I think he's caring for seniors, and all of the cuts that you see they're not cuts on Social Security. They are things we're doing to shore up our federal spending so that we have the money to pay for Social Security and Medicare. You're
Cantwell	Cantwell, Maria	Washington	Democratic	Against	Announced bill to spare physicians from cut in Medicare reimbursements.
Capito	Capito, Shelley Moore	West Virginia	Republican	In favor	"Unless we bend the curve on it future generations) are really going to suffer here." Capito said of the national debt. "One of the ways we can really do this through reconciliation is to look at mandatory spending, and Medicaid is one of
Cassidy	Cassidy, Bill	Louisiana	Republican	In favor	U.S. Senator Bill Cassidy, M.D. (R-LA) penned an op-ed in the Washington Examiner highlighting his Education Choice for Children Act (ECCA), a bill to expand education freedom for students and empower parents to make the best d
Collins	Collins, Susan M.	Maine	Republican	In favor	Sen. Susan Collins, R-Maine, said she's "inclined" to support the bill's work requirements, but worries that "the way provider taxes are treated would be very harmful to Maine's hospitals."
Coons	Coons, Christopher A.	Delaware	Democratic	Against	Maybe because it's a bad bill.
Cornyn	Cornyn, John	Texas	Republican	In favor	John Cornyn joined Hugh to discuss the need to press forward with the "One Big, Beautiful Bill".
Cortez Masto	Cortez Masto, Catherine	Nevada	Democratic	Against	"This plan could cut health care coverage for nearly 190,000 Nevadans on Medicaid or marketplace insurance plans and could threaten health care providers across our state." Senator Jacky Rosen criticized the bill as a "partisan" me
Cotton	Cotton, Tom	Arkansas	Republican	In favor	"A little bit more savings in Medicaid. Medicaid is a critical program for many Arkansans, for elderly, for pregnant women, for poor children, for the blind, the disabled. It shouldn't be providing health insurance, though, to freeloaders are
Cramer	Cramer, Kevin	North Dakota	Republican	In favor	ND Senator Cramer argues 'big beautiful bill' before Congress is "better to pass than not pass"
Crapo	Crapo, Mike	Idaho	Republican	In favor	If we can get this done, it will probably be the most significant thing that we do in our service in Congress. That's how strongly I feel about it.
Cruz	Cruz, Ted	Texas	Republican	In favor	Sen. Ted Cruz is confident Trump's 'big, beautiful bill' will pass, but warns of 'rhetoric and turns' along the way.
Curtis	Curtis, John R.	Utah	Republican	Undecide	Curtis, who has said he wants some serious changes to President Trump's "big, beautiful bill,
Daines	Daines, Steve	Montana	Republican	In favor	Once we receive the Big Beautiful Bill from the House, we've got some ideas in the Senate that's going to make it even more beautiful.
Duckworth	Duckworth, Tammy	Illinois	Democratic	Against	Trump's "one big beautiful bill" greenlights Republicans gutting Medicaid and SNAP to fund billionaires' tax cuts. That's an ugly bill imo.
Durbin	Durbin, Richard J.	Illinois	Democratic	Against	[Republicans' reconciliation bill] dismantles the American Dream and strips our institutions of essential services that help the most vulnerable people in our country. All so the ultimate goal can be served... to give major tax breaks to
Ernst	Ernst, Joni	Iowa	Republican	Against	Ernst has criticized the bill's potential effects on Medicaid spending, suggesting that targeting the working poor is unjust and could be politically damaging.
Fetterman	Fetterman, John	Pennsylvania	Democratic	Against	I will never support a bill that cuts Medicare, Medicaid or SNAP outs to pay for tax cuts for billionaires.
Fischer	Fischer, Deb	Nebraska	Republican	In favor	Senator Fischer hopes to get some, if not all, of her priorities included in the reconciliation pack age
Gallego	Gallego, Ruben	Arizona	Democratic	Against	"Republicans' "Big Beautiful Bill" puts thousands of good-paying union jobs on the chopping block and threatens the livelihoods of families across the country."
Gillibrand	Gillibrand, Kirsten E.	New York	Democratic	Against	"This proposal would be a catastrophic for the millions of Americans who rely on Medicaid," said Senator Gillibrand. "Republicans should be focused on bringing down the cost of essentials; instead, they are making health care harder f
Graham	Graham, Lindsey	South Carolina	Republican	In favor	I prefer "one big beautiful bill" that provides funding to implement the Trump border security agenda and a boost in military spending
Grassley	Grassley, Chuck	Iowa	Republican	In favor	Grassley says while the reconciliation bill is just touching base on a few key points that would be considered in the farm bill doesn't mean the rest will just be forgotten.
Hagerty	Hagerty, Bill	Tennessee	Republican	In favor	The "Big, Beautiful Bill" will lead to more investment in the United States, more jobs for the American people, tax relief and increased wages, and economic prosperity. All of this is going to be very positive.
Hassan	Hassan, Margaret Wood	New Hampshire	Democratic	Against	"Republicans' so-called 'Big, Beautiful Bill' will hurt America's families by giving tax cuts to billionaires."
Hawley	Hawley, Josh	Missouri	Republican	Against	Against Medicaid cuts - "slashing health care for the working poor "is both morally wrong and politically suicidal."
Heinrich	Heinrich, Martin	New Mexico	Democratic	Against	According to Donald Trump, a "big, beautiful bill" is one that leaves almost 14 million people uninsured and drives up families' energy bills. No Thanks.
Hickenlooper	Hickenlooper, John W.	Colorado	Democratic	Against	"The Republicans' budget is a nightmare for working Americans. We're game to make government more cost-effective and lower taxes for working families – this does the opposite. Higher costs from the grocery store to the gas tank

We collected comments that Senators have publicly made on X, their websites, conferences, etc. and the stances tend to skew quite negatively *caveat*: some senators noted they would vote 'no' if certain adjustments re: Medicare and debt were not made – there is a chance that the bill is edited in Congress such that they agree to vote on it



Currently, only 3 Republicans need to vote no to strike down the bill – recently, Senate Finance Committee Chair Mike Crapo (R-Idaho) warned colleagues that there are two likely "no" votes against the bill within the Senate Republicans

- "the One Big Beautiful Bill will almost certainly add to our deficits and debt. That's why I can't support this bill as it's currently being discussed and doubt that it will pass the Senate" – Ron Johnson, R-WY
- "I will not vote to raise the debt ceiling by $5 trillion" – Rand Paul, R-KY
- Other Republicans to watch out for include Lisa Murkowski, Susan Collins (concerns re: cutting Medicaid), Mike Lee, Rick Scott (deficit concerns)

Source: Jefferies Analysis, US Congress

Source: Jefferies analysis

We've seen that prior CMMI models could be narrow or broader in scope – for example, we're seeing that models with more narrow geographic focus could be easier to implement likely due to lower cost & ease of scaling

While there is no set definition for what makes a CMMI model broad vs narrow, we've seen that relatively speaking broader models affect large segments of the population vs narrow models are limited to a specific disease/specialty (often smaller populations). The type of population being targeted could also be relevant to the scope of the model. For example, there were 93 sites for the KCC model (close to ACO REACH model) & they were limited to pts with kidney disease so the scope for expansion in CMMI Phase 2 would still be limited

Model Name	Reason for Classification	Implementation Outcome
ACO REACH	Targets population-level care delivery across providers with a focus on full-risk capitation and sites participating in ~25 states and 103 sites	Implemented (ongoing, as of 2025)
Comprehensive Primary Care Plus (CPC+)	Multi-state, multi-payer model focused on transforming primary care across ~14 states and 2610 sites	Ended in 2021
Bundled Payments for Care Improvement (BPCI) Advanced	Applies broadly across dozens of clinical episodes and provider types in many regions. ~29 states 170 sites	Implemented (ongoing – finishes Dec 2025)
Kidney Care Choices (KCC)	Targets specific population (CKD/ESRD) and nephrologists with focused interventions. ~93 total sites across US (kidney treatment only)	Implemented (ongoing, voluntary participation)
Independence at Home Demonstration	Limited to 1 participating site. In-home care to frail elderly with narrow eligibility criteria.	Implemented (ended in 2020)
Vermont All-Payer ACO Model	Applies only to 1 site in Vermont with state-specific governance and narrow geographic reach.	Implemented (ongoing, state-level model)

Looking at a few precedent CMMI pilot programs with disclosed geographic impacts, we're seeing a higher implementation rate for more narrow models (eg, lower # of sites and/or states, defined population). **We're seeing that the CPC+ model included a larger # of sites (eg, 2610) – it's no longer active due to mixed patient care quality improvement and large cost**

While specific results from individual models determine whether they are implemented in Ph.2, we noted that narrow models have a could have better chance of being implemented vs broad model given:

1) **Ease of scaling vs broad models** (inc. less scrutiny based on narrow population).
2) **Less funding needed to implement at larger scale.**
3) **Narrow models having a specific target population that limits the scope** (e.g. KCC model only for pts with kidney disease), whereas broad models are usually for a type of generic care delivery model that affects a larger population (e.g. CPC is for primary care)

Source: Jefferies analysis, CMS.gov

Source: Jefferies analysis

Overall, assuming Co.'s implement mitigation strategies, the EPS impact could be more blunted –

			Non-GAAP EPS Impact												DCF	
			2025		2026		2027		2028		2029		2030			
Company	Assumption - with mitigation	Drug Selection	EPS	% change	EPS	% change	EPS	% change	EPS	% change					JEF Est	% change
BMY	Co phase in R&D and SG&A cuts over 4 years each by ~10% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$6.32	-2%	$5.88	-9%	$4.77	-22%	$4.52	-23%	$4.99	-11%	$5.21	-12%	$65	-5%
LLY	Co phase in R&D and SG&A cuts over 4 years each by ~15% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$21.04	0%	$32.12	0%	$40.54	-5%	$47.14	-9%	$53.18	-10%	$59.66	-12%	$974	-8%
MRK	Co phase in R&D and SG&A cuts over 4 years each by ~10% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$8.80	-1%	$9.27	-7%	$10.25	-13%	$10.53	-17%	$10.54	-12%	$9.29	-16%	$122	-12%
PFE	Co phase in R&D and SG&A cuts over 4 years each by ~10% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$2.72	-4%	$2.55	-8%	$2.45	-16%	$2.37	-18%	$2.61	-10%	$2.71	-12%	$29	-14%
REGN	Co phase in R&D and SG&A cuts over 4 years each by ~20% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$32.74	0%	$37.39	-3%	$42.66	-22%	$45.57	-28%	$56.25	-21%	$54.35	-30%	$649	-19%
ARGX	Co phase in R&D and SG&A cuts over 4 years each by ~10% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$14.02	0%	$15.62	0%	$26.43	-2%	$34.29	-2%	$45.42	-9%	$51.71	-15%	$626	-19%

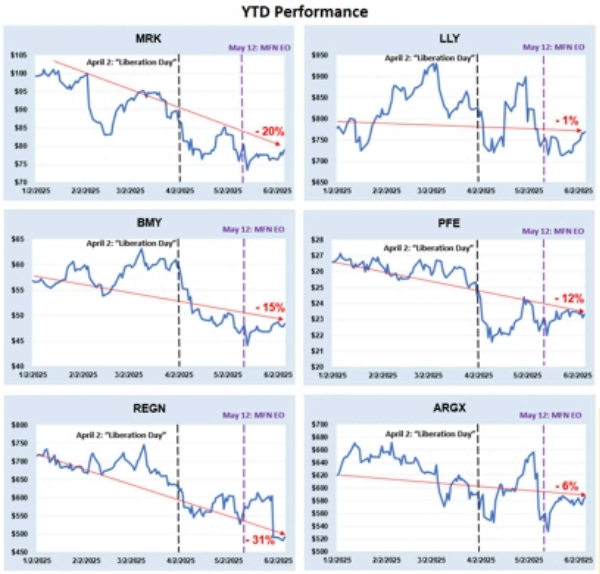
Note that our analysis does not incorporate potential tax benefits from the 'Big Beautiful Bill' (e.g., 100% deduction of qualified property and domestic R&D, and the extensions of FDII, GILTI, and BEAT provisions).

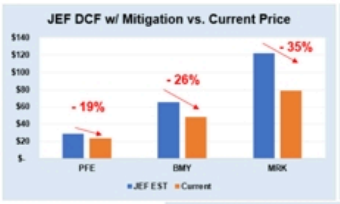
For REGN, we assumed a higher phased-in reduction of 20% for both R&D and SG&A, since both Eylea HD and Dupixent, made up a significant portion of the co's revenue, were selected under out Top 50 Medicare lists.

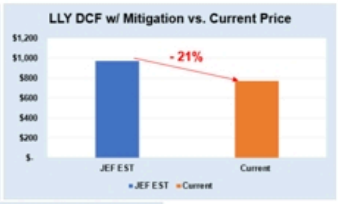
Source: Jefferies Analysis

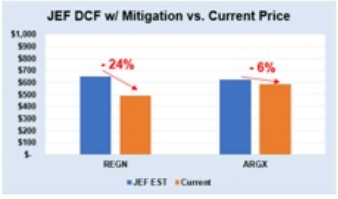
Source: Jefferies analysis

Further, our illustrative scenario analysis re: mitigated MFN impact suggests that valuation still remains above where the stock is currently trading









Therapeutic stocks have traded down since the beginning of the year, with MRK -20%, LLY -1%, BMY -15%, PFE -12%, REGN -31%, and ARGX -6%. **We saw notable declines following key events – April 2nd (Liberation Day) and May 12th (when Trump signed MFN EO).** Based on our analysis of each co's mitigated scenario, we believe the recent sell-off is overdone. Our valuation estimates remain above the current market levels, **with share price currently trading at 6%-35% discounts to our DCF valuations.**

Source: Jefferies Analysis

Source: Jefferies analysis

Operation MFN

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PM Summary –

#1. MFN remains a headline risk & there's still a fair amount of uncertainty particularly around the implementation framework & scope (eg, Medicare Part B/D, Medicaid) - that said, we're skeptical MFN ultimately gets implemented

- We see several distinct outcomes re: MFN implementation – what seems to be most likely at this point is CMMI pilot program & we think the Administration will likely try to implement a broad MFN model
- That said, we don't think MFN ultimately gets implemented as: a) CMMI pilot programs cannot cause patient harm, which will be difficult to avoid as MFN may limit access to drugs for Medicare and/or Medicaid patients, b) we see a negative impact in R&D and innovation long-term

#2. Our analysis suggests US pharma stocks are more exposed to the impact of MFN given larger delta between ex-US prices vs US prices & co's overall portfolio having ~higher Medicare exposure - we ran a few illustrative scenario analyses (in combination with our 25% tariff w/ mitigation model) to understand the impact

- Without mitigation, our LC Pharma coverage could see a 20~30% impact to EPS, assuming MFN-selected drugs include Top 50 Medicare Part D & B drugs (with ~15% price reduction to commercial) That said, assuming pharma employs mitigation measures (eg, cutting OPEX, pulling out/raising prices of select ex-US geographies, commercial taking more volume from Medicare over time) we think MFN's impact to earnings drops to mid-teens for LC Pharma
- Notably, our MFN & 25% tariff-adjusted DCF (with mitigation) for our LC Pharma names still comes out above where the stock is currently trading

#3. Given the uncertainty on how the tariffs will be imposed, we recommend names that largely have US manufacturing & US sales (we prefer Mid cap biotech)

- Overall, we see co's like MDGL, EXEL, ALKS, JAZZ, BMRN & ARGX as relatively better positioned for MFN because they either have de minimis ex-US revs, and/or low Medicare exposure, or a relatively low delta between US vs ex-US pricing...but even companies like MDGL would have to rethink whether entering Ex Us mkts is worth it going forward

Source: Jefferies Analysis

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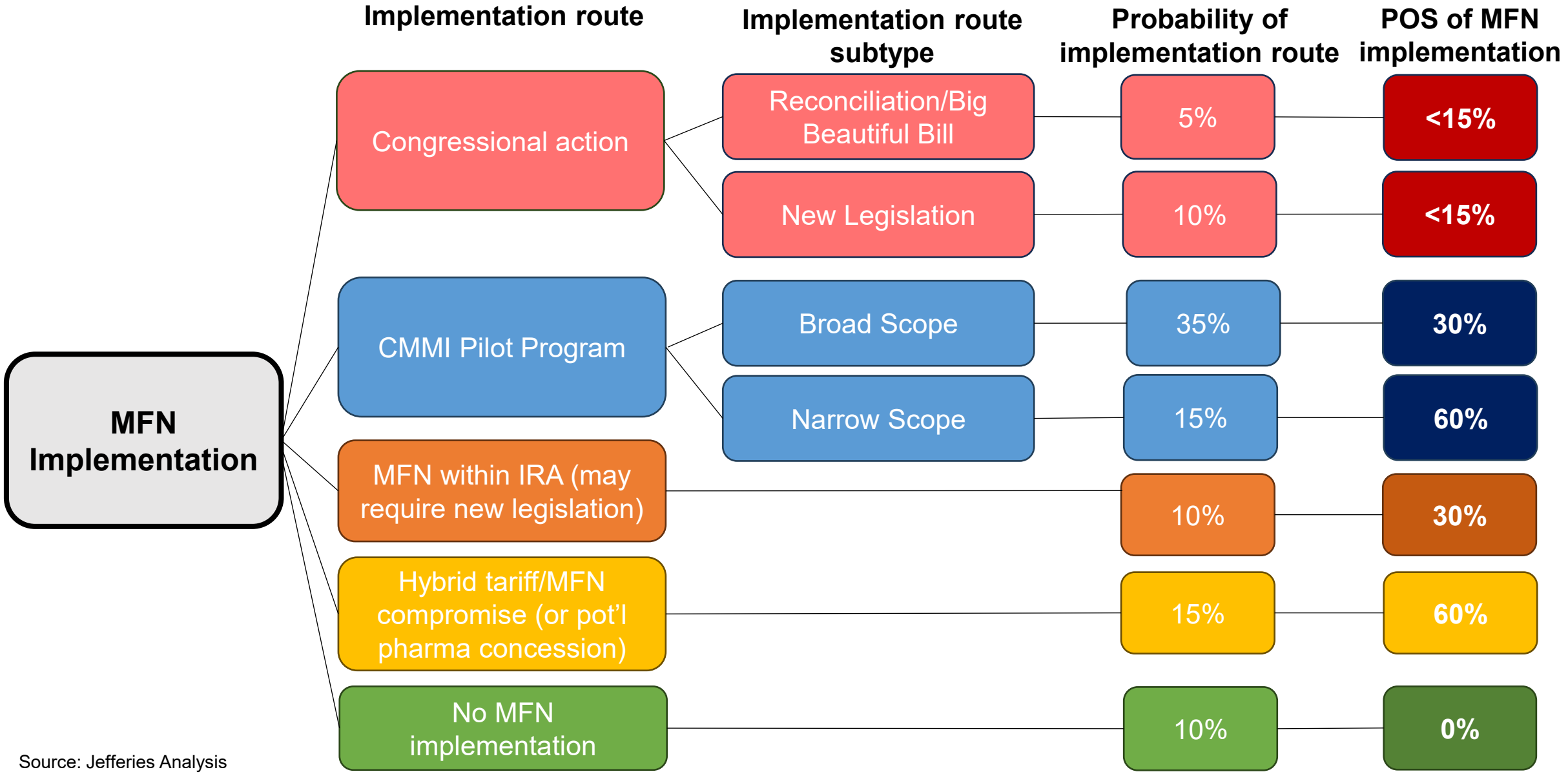
Overall, here are the MFN implementation routes…



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Let's start with an overview of the MFN Policy & recent updates

Background: Trump's Most Favored Nation's Drug Price Proposal

- Overview of MFN Pricing Policy and major historical events
- Thoughts on recent MFN Executive Order & HHS Press Release – what we know & major remaining Q's

Legal Analysis: How likely will MFN get implemented?

- Summary of ways MFN could get implemented including via: a) Congressional Action (eg, Reconciliation or new Legislation), b) CMMI pilot program, c) IRA, d) hybrid tariff/MFN compromise (or potential pharma concession)
- Our diligence re: probability of success that MFN gets implemented through these routes

Impact Analysis: What is the impact to our coverage if MFN does get implemented?

- We considered multiple different scenarios (in combination with our 25% tariff w/ mitigation model) for our LC Pharma & Biotech:
  1. Full impact MFN (top 50 Medicare Part B/D or IRA only or all Medicare)
  2. MFN (top 50 Medicare Part B/D) with pharma employing mitigation parameters
- Overall, we believe certain mid biotechs (eg, those that have de minimis ex-US revs, and/or low Medicare exposure, or a relatively low delta between US vs ex-US pricing) are generally winners here

Macro & Potential Downstream Effects of MFN Policy

- Thoughts on potential long-term/downstream impact of MFN if it gets implemented
- Our MFN/tariff-adjusted earnings relative to the S&P500 still seem to trade at a discount into a recession

Source: Jefferies Analysis

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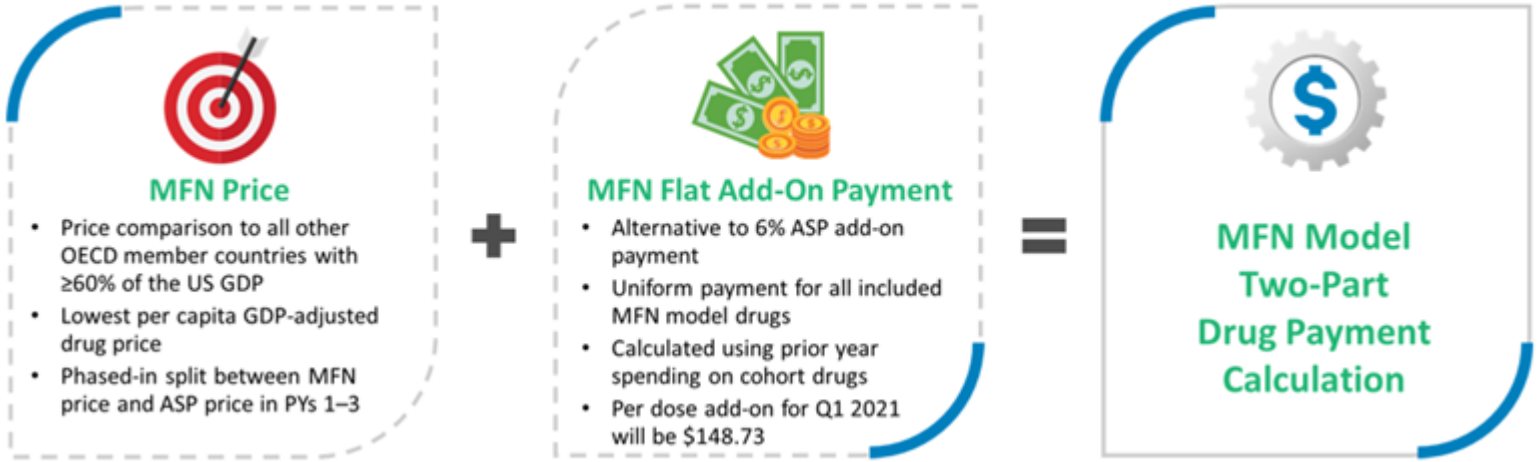
As a background, the Most Favored Nation (MFN) policy aims to align US drug prices/payments with the lowest international drug price (from a set of economic peer countries)…Trump had tried to implement MFN at the end of his first term in 2020 targeting the top 50 Medicare Part B drugs



Summary of MFN policy from Trump's prior 2020 proposal:

- Currently, Medicare Part B drugs are reimbursed at average sales price (ASP) + 6%
- Under Trump's previously proposed MFN pricing model, rather than reimbursing providers a percentage of each drug's cost, the MFN model would have included a two-part payment: one based on the MFN price and the second being a flat add-on payment for each drug dose. Providers would be responsible for negotiating with pharmaceutical manufacturers to sell them drugs at prices at or near the MFN price. Pharmaceutical manufacturers will not be directly obligated to discount their drugs.
- The MFN model would have initially applied to a set of roughly 50 Medicare Part B drugs that make up an estimated 73% of the total Medicare Part B drug spending. CMS identified the top 50 Medicare Part B separately payable drugs with the highest aggregated Medicare Part B total allowed charges in the baseline period, after some exclusions, to create the initial set of drugs to be included in PY1.

Source: Jefferies analysis, CMS

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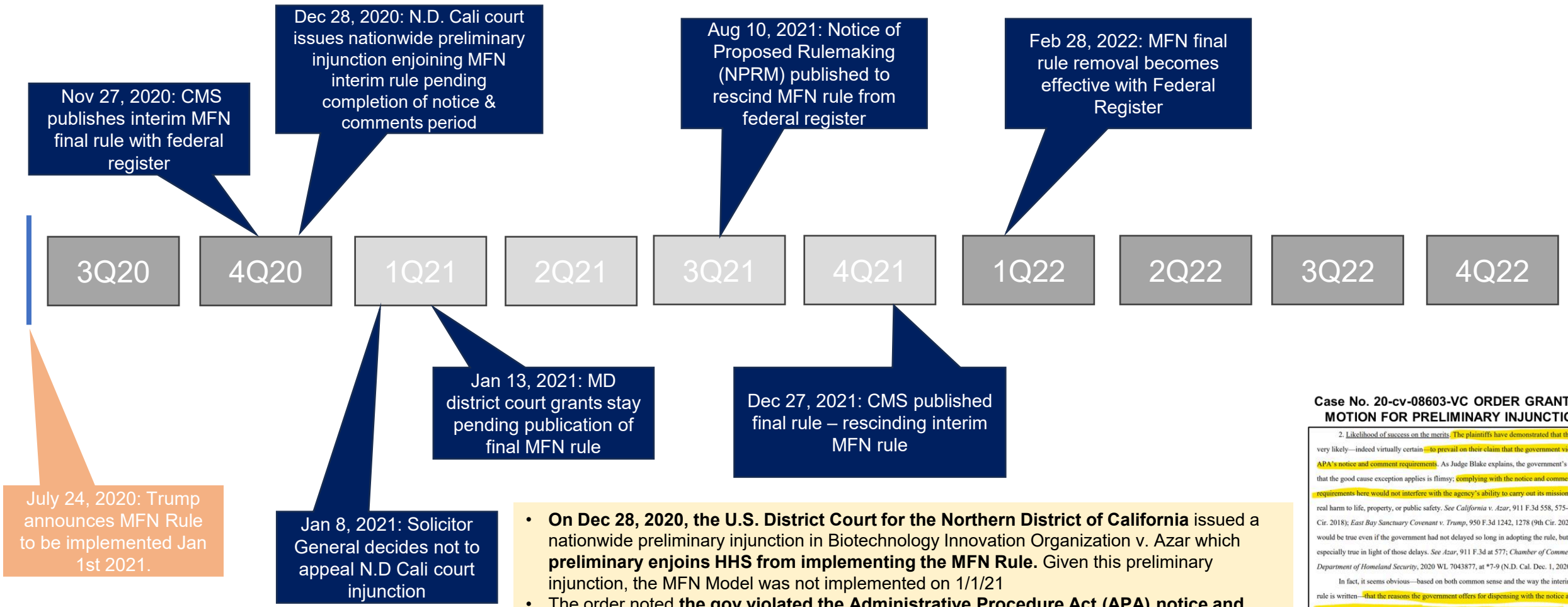
That said, the initial policy faced legal challenges and was ultimately blocked as it violated the APA by skipping the notice period requirement



- **On Dec 28, 2020, the U.S. District Court for the Northern District of California** issued a nationwide preliminary injunction in Biotechnology Innovation Organization v. Azar which **preliminary enjoins HHS from implementing the MFN Rule.** Given this preliminary injunction, the MFN Model was not implemented on 1/1/21
- The order noted **the gov violated the Administrative Procedure Act (APA) notice and comment req, because the Trump administration had limited days**

Case No. 20-cv-08603-VC ORDER GRANTING MOTION FOR PRELIMINARY INJUNCTION

2. Likelihood of success on the merits. The plaintiffs have demonstrated that they are very likely—indeed virtually certain—to prevail on their claim that the government violated the APA's notice and comment requirements. As Judge Blake explains, the government's argument that the good cause exception applies is flimsy; complying with the notice and comment requirements here would not interfere with the agency's ability to carry out its mission, or cause real harm to life, property, or public safety. *See California v. Azar*, 911 F.3d 558, 575-77 (9th Cir. 2018); *East Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1278 (9th Cir. 2020). This would be true even if the government had not delayed so long in adopting the rule, but it is especially true in light of those delays. *See Azar*, 911 F.3d at 577; *Chamber of Commerce v. Department of Homeland Security*, 2020 WL 7043877, at *7-9 (N.D. Cal. Dec. 1, 2020).

In fact, it seems obvious—based on both common sense and the way the interim final rule is written—that the reasons the government offers for dispensing with the notice and comment requirements are contrived. The real reason is that the current presidential administration is in its waning days and would not have time to enact the policy if it adhered to these requirements. While there's nothing unlawful per se about rushing to enact policy in the final days of a presidential administration (indeed, it's a time-honored tradition), executive

Source: Jefferies analysis, Federal Register

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During his current term, Trump is reintroducing the MFN policy, with a formal Executive Order issued on 5/12 & an HHS press release following on 5/20

MFN Executive Order (EO) - May 12, 2025

DELIVERING MOST-FAVORED-NATION PRESCRIPTION DRUG PRICING TO AMERICAN PATIENTS

Executive Orders | May 12, 2025

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. The United States has less than five percent of the world's population and yet funds around three quarters of global pharmaceutical profits. This egregious imbalance is orchestrated through a purposeful scheme in which drug manufacturers deeply discount their products to access foreign markets, and subsidize that decrease through enormously high prices in the United States.

The United States has for too long turned its back on Americans, who unwittingly sponsor both drug manufacturers and other countries. These entities today rely on price markups on American consumers, generous public subsidies for research and development primarily through the National Institutes of Health, and robust public financing of prescription drug consumption through Federal and State healthcare programs. Drug manufacturers, rather than seeking to equalize evident price discrimination, agree to other countries' demands for low prices, and simultaneously fight against the ability for public and private payers in the United States to negotiate the best prices for patients. The inflated prices in the United States fuel global innovation while foreign health systems get a free ride.

This abuse of Americans' generosity, who deserve low-cost pharmaceuticals on the same terms as other developed nations, must end. Americans will no longer be forced to pay almost three times more for the exact same medicines, often made in the exact same factories. As the largest purchaser of pharmaceuticals, Americans should get the best deal.

Sec. 2. Policy. Americans should not be forced to subsidize low-cost prescription drugs and biologics in other developed countries, and face overcharges for the same products in the United States. Americans must therefore have access to the most-favored-nation price for these products.

My Administration will take immediate steps to end global freeloading and, should drug manufacturers fail to offer American consumers the most-favored-nation lowest price, my Administration will take additional aggressive action.

Sec. 3. Addressing Foreign Nations Freeloading on American-Financed Innovation. The Secretary of Commerce and the United States Trade Representative shall take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security and that has the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries.

Sec. 4. Enabling Direct-to-Consumer Sales to American Patients at the Most-Favored-Nation Price. To the extent consistent with law, the Secretary of Health and Human Services (Secretary) shall facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers that sell their products to American patients at the most-favored-nation price.

Sec. 5. Establishing Most-Favored-Nation Pricing. (a) Within 30 days of the date of this order, the Secretary shall, in coordination with the Assistant to the President for Domestic Policy, the Administrator for the Centers for Medicare and Medicaid Services, and other relevant executive department and agency (agency) officials, communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations.

(b) If, following the action described in subsection (a) of this section, significant progress towards most-favored-nation pricing for American patients is not delivered, to the extent consistent with law:

(i) the Secretary shall propose a rulemaking plan to impose most-favored-nation pricing;

(ii) the Secretary shall consider certification to the Congress that importation under section 804(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of prescription drugs to the American consumer; and if the Secretary so certifies, then the Commissioner of Food and Drugs shall take action under section 804(j)(2)(B) of the FDCA to describe circumstances under which waivers will be consistently granted to import prescription drugs on a case-by-case basis from developed nations with low-cost prescription drugs;

(iii) following the report issued under section 13 of Executive Order 14273 of April 15, 2025 (Lowering Drug Prices by Once Again Putting Americans First), the Attorney General and the Chairman of the Federal Trade Commission shall, to the extent consistent with law, undertake enforcement action against any anti-competitive practices identified within such report, including through use of sections 1 and 2 of the Sherman Antitrust Act and section 5 of the Federal Trade Commission Act, as appropriate;

(iv) the Secretary of Commerce, and the heads of other relevant agencies as necessary, shall review and consider all necessary action regarding the export of pharmaceutical drugs or precursor material that may be fueling the global price discrimination;

(v) the Commissioner of Food and Drugs shall review and potentially modify or revoke approvals granted for drugs, for those drugs that maybe be unsafe, ineffective, or improperly marketed; and

(vi) the heads of agencies shall take all action available, in coordination with the Assistant to the President for Domestic Policy, to address global freeloading and price discrimination against American patients.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii.) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Department of Health and Human Services shall provide funding for publication of this order in the *Federal Register*.

DONALD J. TRUMP

HHS Press Release (PR) - May 20, 2025

FOR IMMEDIATE RELEASE
May 20, 2025

Contact: CMS Press Office
202-690-6343
Submit a Request for Comment

HHS, CMS Set Most-Favored-Nation Pricing Targets to End Global Freeloading on American Patients

Most-Favored-Nation policy builds on President Trump's broader reforms to eliminate global freeloading and ensure every American has access to affordable, life-saving treatments.

Washington, DC—MAY 20, 2025— The U.S. Department of Health and Human Services announced today that it is taking immediate steps to implement President Trump's Executive Order "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," a central component of the Administration's strategy to lower health care costs in the United States.

Under the leadership of President Donald J. Trump, HHS Secretary Robert F. Kennedy Jr., and CMS Administrator Dr. Mehmet Oz, the Department has identified specific targets pharmaceutical manufacturers are expected to meet to satisfy the requirements of the Executive Order. President Trump and Secretary Kennedy look forward to highlighting commitments in the coming weeks. These commitments will ensure Americans no longer pay more for medications than patients in other economically comparable countries, relieving the unfair burden placed on hard-working Americans.

"For too long, Americans have been forced to pay exorbitant prices for the same drugs that are sold overseas for far less," **said Secretary Kennedy**. "That ends today. We expect pharmaceutical manufacturers to fulfill their commitment to lower prices for American patients, or we will take action to ensure they do."

HHS expects each manufacturer to commit to aligning US pricing for all brand products across all markets that do not currently have generic or biosimilar competition with the lowest price of a set of economic peer countries. The MFN target price is the lowest price in an OECD country with a GDP per capita of at least 60 percent of the U.S. GDP per capita. These targets will drastically bring down U.S. drug prices, which are often three to five times higher than prices abroad, while preserving innovation by simply ensuring that Americans bear no greater burden than patients receiving the same drugs in other countries.

Source: Jefferies Analysis, whitehouse.gov, hhs.gov

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Here's what stood out: a) MFN target price will be lowest price of OECD countries w/ ≥60% US GDP per capita, b) drugs w/ current gx/biosimilar competition may be exempt, c) language re: this being a "commitment"

MFN Executive Order (EO) & Trump Press Conference

- HHS Secretary will (in coordination w/ Assistant to the President for Domestic Policy & CMS Administrator), **within 30 days of EO, communicate MFN price targets to pharma mfg**
- The initial draft of the EO **gave pharma co's 180 days to come up with solutions – this was REMOVED from the final EO**
- **There's clearly no mechanism for implementing any MFN model and a CMMI model is NOT directly referenced**
- **There's no clarification on if the program will apply to Medicare Part D, Part B, or Medicaid**
- EO offered **DTC purchasing program incentive** for mfg's selling at MFN price
- **EO said MFN policy would be enforced using section 804(j) of the Food Drug & Cosmetic Act (regulates imports of drugs from countries like Canada to the US).** We looked at the language & saw that **"eligible prescription drugs do not include... a biologic product and intravenously injected drugs"**
- In the press conference, **Trump seems supportive of US pharma Cos & more antagonistic towards the EU & PBMs** — Trump thinks EU gov. forces US pharmas to charge very low prices while in the US middlemen (aka PBMs) driveprices higher. As such, the administration will likely help US pharma negotiate w/ int'l govts using trade and cut out the middlemen to facilitate direct sale of drugs to American citizens (+ accelerate price reductions)...almost as if trade/MFN negotiations could be done holistically

HHS Press Release (PR)

- MFN target price will be the **lowest price of OECD countries w/ ≥60% of US GDP per capita** (similar to 2020 MFN model)
- Drugs that **currently have generic or biosimilar competition may be exempt**
- PR cited US drug prices being 3~5x higher than prices abroad
- **What's most curious is the language re: this being a commitment** - ie, *"we expect pharmaceutical manufacturers to fulfill their commitment to lower prices for American patients, or we will take action to ensure they do."*
- The PR **still did not give any color on the scope (eg, Medicare Part B/D, Medicaid) or how MFN will be implemented**

Source: Jefferies Analysis

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While it's unclear how the Administration will enforce MFN pricing, we've seen some hints that: 1) FDA could theoretically go after mfg's that don't comply – Dr. Makary's recent comments at JEF HC Conference suggest FDA could indirectly impact drug prices via streamlining approvals & the MFN EO also references FDA's ability to "modify or revoke approvals"

MFN Executive Order (EO) - May 12, 2025

(b) If, following the action described in subsection (a) of this section, significant progress towards most-favored-nation pricing for American patients is not delivered, to the extent consistent with law:
(i) the Secretary shall propose a rulemaking plan to impose most-favored-nation pricing;
(ii) the Secretary shall consider certification to the Congress that importation under section 804(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of prescription drugs to the American consumer; and if the Secretary so certifies, then the Commissioner of Food and Drugs shall take action under section 804(j)(2)(B) of the FDCA to describe circumstances under which waivers will be consistently granted to import prescription drugs on a case-by-case basis from developed nations with low-cost prescription drugs;
(iii) following the report issued under section 13 of Executive Order 14273 of April 15, 2025 (Lowering Drug Prices by Once Again Putting Americans First), the Attorney General and the Chairman of the Federal Trade Commission shall, to the extent consistent with law, undertake enforcement action against any anti-competitive practices identified within such report, including through use of sections 1 and 2 of the Sherman Antitrust Act and section 5 of the Federal Trade Commission Act, as appropriate;
(iv) the Secretary of Commerce, and the heads of other relevant agencies as necessary, shall review and consider all necessary action regarding the export of pharmaceutical drugs or precursor material that may be fueling the global price discrimination;
(v) the Commissioner of Food and Drugs shall review and potentially modify or revoke approvals granted for drugs, for those drugs that maybe be unsafe, ineffective, or improperly marketed; and
(vi) the heads of agencies shall take all action available, in coordination with the Assistant to the President for Domestic Policy, to address global freeloading and price discrimination against American patients.

Comments from FDA Commissioner Dr. Marty Makary at JEF NY HC Conference

- Drug pricing is outside the FDA's domain - that said, Dr. Makary indicated FDA could indirectly impact prices by: **a)** encouraging competition, **b)** streamlining the regulatory approval process, **c)** reducing "red tape" w/ approvals of biosimilars
- Dr. Makary believes that the best way to make drugs more affordable is to "stop taking drugs we don't need" (he's focusing on food & preventing chronic diseases)
- On MFN, he said that the President isn't putting blame squarely on pharma co's, but also on ex-US countries not paying their "fair share" into R&D - Dr. Makary sees the President's approach to MFN as no different from his approach on NATO fees, WHO membership fees, etc

(v) the Commissioner of Food and Drugs shall review and potentially modify or revoke approvals granted for drugs, for those drugs that maybe be unsafe, ineffective, or improperly marketed; and

Source: Jefferies Analysis, whitehouse.gov

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2) EO also called out that HHS Secretary RFK Jr. has rulemaking ability (potentially via CMMI pilot program – we'll talk about this later) & 3) direct importation of drugs from ex-US (via FDCA) could be used as punishment, although this may not be applicable for all tx

MFN Executive Order (EO) - May 12, 2025

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(iii) following the report issued under section 13 of Executive Order 14273 of April 15, 2025 (Lowering Drug Prices by Once Again Putting Americans First), the Attorney General and the Chairman of the Federal Trade Commission shall, to the extent consistent with law, undertake enforcement action against any anti-competitive practices identified within such report, including through use of sections 1 and 2 of the Sherman Antitrust Act and section 5 of the Federal Trade Commission Act, as appropriate;

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(v) the Commissioner of Food and Drugs shall review and potentially modify or revoke approvals granted for drugs, for those drugs that maybe be unsafe, ineffective, or improperly marketed; and

(vi) the heads of agencies shall take all action available, in coordination with the Assistant to the President for Domestic Policy, to address global freeloading and price discrimination against American patients.

The MFN EO included a provision that **HHS Sec. RFK Jr. could propose rulemaking plan to impose MFN pricing** (we think one way is via CMMI pilot program - we'll talk about this later).

The EO also called out using section 804(j) of the FDCA. As a background, the FDCA (Food, Drug & Cosmetic Act mainly regulates the import of drugs from Canada to the US. If applied, it could provide an alternative avenue for drugs to enter the US at lower prices, therefore force price decreases.

We looked at section 804(j) of the FDCA and we saw that **"eligible prescription drugs do not include…a biologic product and intravenously injected drugs".**

Source: Jefferies Analysis, whitehouse.gov

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That said, there are still some major unanswered Q's on a potential MFN implementation framework & the scope of drugs impacted

Questions on MFN Implementation Framework

- CMMI pilot model?
- Congressional Action? Included in Reconciliation/Big Beautiful Bill? New Legislation?
- Included in IRA?

Questions on scope of drugs impacted

- Medicare Part B/D and/or Medicaid?
- Top 50 drugs by spend or all drugs?
- IRA-negotiated drugs?
- Any commercial spillover?

Source: Jefferies Analysis

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Finally, we could get an update by this Wednesday June 11th re: MFN price targets set by CMS (30 days from May 12th EO)

MFN Executive Order (EO) - May 12, 2025

Sec. 5. Establishing Most-Favored-Nation Pricing. (a) Within 30 days of the date of this order, the Secretary shall, in coordination with the Assistant to the President for Domestic Policy, the Administrator for the Centers for Medicare and Medicaid Services, and other relevant executive department and agency (agency) officials, communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations.

(b) If, following the action described in subsection (a) of this section, significant progress towards most-favored-nation pricing for American patients is not delivered, to the extent consistent with law:

We'll call out that we could see an update on the EO by **June 11th 2025** disclosing the MFN targets to Pharma co's. *(caveat: we don't know whether it would be publicly disclosed)*

HHS Press Release (PR) - May 20, 2025

Under the leadership of President Donald J. Trump, HHS Secretary Robert F. Kennedy Jr., and CMS Administrator Dr. Mehmet Oz, the Department has identified specific targets pharmaceutical manufacturers are expected to meet to satisfy the requirements of the Executive Order. President Trump and Secretary Kennedy look forward to highlighting commitments in the coming weeks. These commitments will ensure Americans no longer pay more for medications than patients in other economically comparable countries, relieving the unfair burden placed on hard-working Americans.

Likewise, we saw the HHS press release mention an **update over the "coming weeks"**

Source: Jefferies Analysis, whitehouse.gov, hhs.gov

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Now we'll discuss the potential MFN implementation routes & the probability that this policy successfully goes through

Background: Trump's Most Favored Nation's Drug Price Proposal

- Overview of MFN Pricing Policy and major historical events
- Thoughts on recent MFN Executive Order & HHS Press Release – what we know & major remaining Q's

Legal Analysis: How likely will MFN get implemented?

- Summary of ways MFN could get implemented including via: a) Congressional Action (eg, Reconciliation or new Legislation), b) CMMI pilot program, c) IRA, d) hybrid tariff/MFN compromise (or potential pharma concession)
- Our diligence re: probability of success that MFN gets implemented through these routes

Impact Analysis: What is the impact to our coverage if MFN does get implemented?

- We considered multiple different scenarios (in combination with our 25% tariff w/ mitigation model) for our LC Pharma & Biotech:
  1. Full impact MFN (top 50 Medicare Part B/D or IRA only or all Medicare)
  2. MFN (top 50 Medicare Part B/D) with pharma employing mitigation parameters
- Overall, we believe certain mid biotechs (eg, those that have de minimis ex-US revs, and/or low Medicare exposure, or a relatively low delta between US vs ex-US pricing) are generally winners here

Macro & Potential Downstream Effects of MFN Policy

- Thoughts on potential long-term/downstream impact of MFN if it gets implemented
- Our MFN/tariff-adjusted earnings relative to the S&P500 still seem to trade at a discount into a recession

Source: Jefferies Analysis

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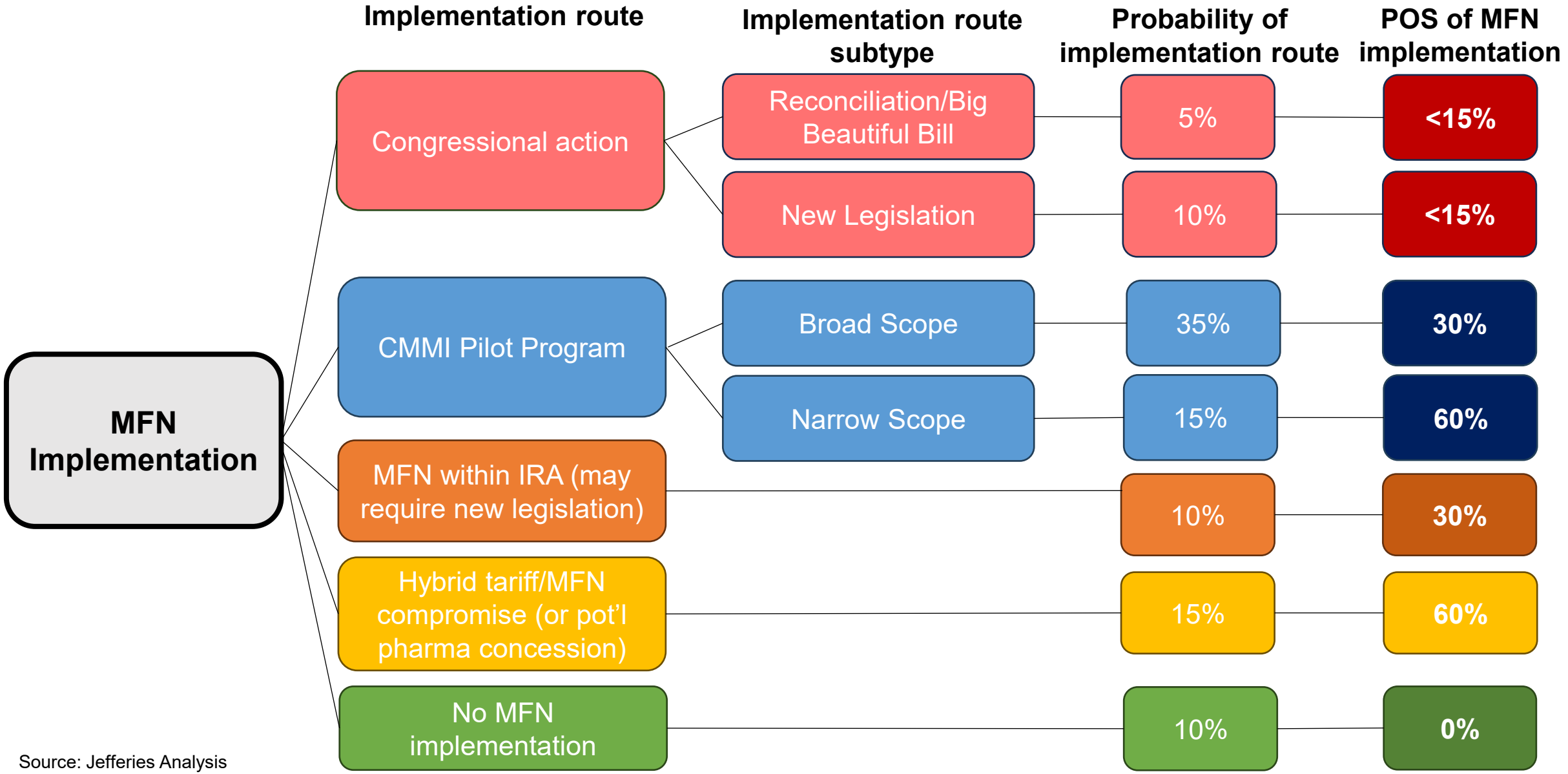
Overall, here are the MFN implementation routes…



Source: Jefferies Analysis

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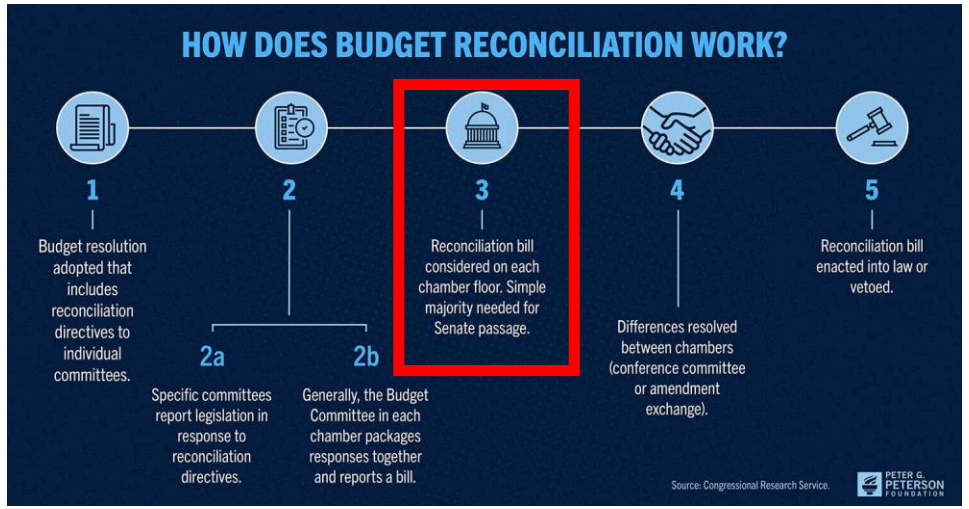
1) Congressional Action:

As a background, the Reconciliation Bill is passed yearly and only requires a simple majority vote to pass in the House & Senate

As a background, the Congressional Budget Act of 1974 allows for bills related to the budget to pass the Senate with a simple majority (51 votes) as opposed to the typical vote threshold of 60 votes under the Byrd rule (Section 313 of the Congressional Budget Act of 1974 (2 U.S.C. 644)). This is because congress adopts a budget resolution every year that directs specific committees to make changes to the spending, revenues, or debt limits for congressional activates. The committees are then required to draft legislation that meets those budget goals.



Byrd Rule Classification Criteria:

A provision is considered to be extraneous if it falls under one or more of the following six definitions:

- it does not produce a change in outlays or revenues or a change in the terms and conditions under which outlays are made or revenues are collected;
- it produces an outlay increase or revenue decrease when the instructed committee is not in compliance with its instructions;
- it is outside of the jurisdiction of the committee that submitted the title or provision for inclusion in the reconciliation measure;
- it produces a change in outlays or revenues which is merely incidental to the non-budgetary components of the provision;
- it would increase the deficit for a fiscal year beyond the "budget window" covered by the reconciliation measure;[12] and
- it recommends changes in Social Security.

Based on the Byrd Rule, we think the OBBBA would fit under the reconciliation process because it does not fit the extraneous criteria.

Past precedence of healthcare reconciliation: Deficit Reduction Act (2005)

Deficit Reduction Act of 2005 is an example of legislation that was passed which affected healthcare (Medicaid) pricing in the US.
Goal: 1) Allowed states to charge premiums and higher copays for Medicaid, 2) Allowed stated to offer reduced benefit packages, 3) Tightened rules to prevent individuals from transferring assets to qualifying Medicaid nursing home services.
Outcome: Passed the senate with a single vote (51 – 50; VP - Dick Cheney breaking the tie).

We'll flag the key advantages for the administration to use reconciliation are:

1) **Limits debate on the law (20 hours)**
2) **Avoids a filibuster – which could delay proceedings**
3) **Reduces the threshold of votes needed to pass legislation (simple majority)**

Source: Jefferies Analysis, US Congress

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The One Big Beautiful Bill Act (OBBBA) is a budget reconciliation bill that has passed the House (215-214 votes) and currently sits with the Senate

As a background, on May 22nd 2025, the One Big Beautiful Bill Act (OBBBA) was narrowly passed the house in **a 215-214 vote**. It was framed as a continuation of the Trump-era economic agenda and bill seeks to permanently extend the 2017 tax cuts, dramatically cut federal spending, and enact changes to Medicaid, Medicare, and the Affordable Care Act (ACA). The act aims to save $1.6 trillion in mandatory spending. Since it was introduced through budget reconciliation process, the bill avoids the Senate filibuster and can pass with a simple majority—though key provisions must survive scrutiny under the Byrd Rule to ensure they are primarily budgetary in nature.

CBO report to Speaker Jeffries summarizing effect of the 2025 reconciliation bill:

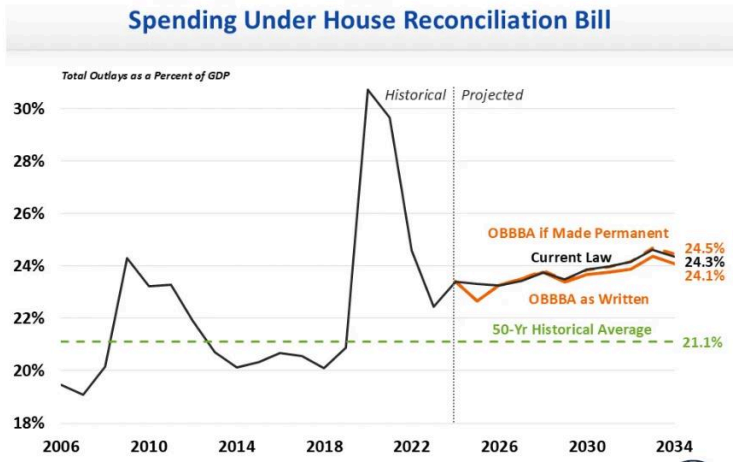
The total effects reported in this analysis for the 2026–2034 period include the following:

- An increase in the federal deficit of $3.8 trillion attributable to tax changes, including extending provisions of the 2017 tax act, which includes revenues and outlays for refundable credits.
- $698 billion less in federal subsidies from changes to the Medicaid program.
- $267 billion less in federal spending for SNAP.
- $64 billion less in spending, on net, for all other purposes. That includes increases in outlays for defense, immigration enforcement, and homeland security. Those are offset by reductions in federal pensions, receipts from spectrum auctions, and changes in receipts and outlays associated with changes to emissions regulations.
- $78 billion in additional state spending, on net, accounting for changes in state contributions to SNAP and Medicaid and for state tax and spending policies necessary to finance additional spending.

As it stands, the OBBBA would decrease spending to 24.1% growth by 2034 vs 24.3% with current law. Overall, this administration has intended to decrease spending and we're seeing the reflect into the OBBBA

*"I was just telling the speaker, it's going to be hard for the Democrats to vote against the one big beautiful bill, the greatest tax cuts in history, but **now you have the big drug prices because that's going to be included**" – Donald Trump, MFN EO Speech, May 12th 2025*

We'll flag that **currently there is no MFN policy in the reconciliation bill as it stands, however Trumps' comments from the EO signing suggest that it was the intention of the administration** to include it in the OBBBA. Additionally, it sounds like the inclusion of MFN in OBBBA is also designed to sweeten the deal for senate democrats to vote for the bill.



While it has not officially been announced whether the bill has passed the Byrd rule in the senate yet, but if we assume it does, here's a breakdown of what would happen:

1) **There would only be a 20h debate period** in the senate (since it would be filibuster proof)
2) **There would be a vote-a-rama**: this is a period that allows senators to propose an unlimited number of amendments and a rapid succession of voting occurs. Typically, debate is limited to ~2mins before voted on.

Caveat: Not all amendments proposed in the vote-a-rama are intended to become law. *Past precedence: Senate republicans introduced an amendment to block undocumented immigrants receiving stimulus checks during the Biden COVID-19 Bill vote to put democrats on record supporting this legislation, however undocumented immigrants were not eligible based on the rules anyway.* **We'll call out that even if MFN is introduced as an amendment, it may be symbolic.**

Source: Jefferies Analysis, US Congress

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Current OBBBA doesn't include MFN - we're watching Sen. Josh Hawley (R-MO) in particular to see if he brings MFN as an amendment to OBBBA in the vote-a-rama

Despite MFN not being included in the current OBBBA, we're still watching to see if any amendments get proposed to include it in the senate during the vote-a-rama. We'll flag that Josh Hawley (R-MO) is a prominent republican senator who breaks from traditional republican values anti-government price control and is in favor of MFN because he has expressed the opinion that pharma co's have too high margins on drugs.

Past precedence of MFN policy support: *S.1218 - Fair Prescription Drug Prices for Americans Act*

Hawley has shown past precedence for MFN support by co-sponsoring the Fair Prescription Drug Prices for Americans Act (currently under consideration by Senate)

Shown Here:
Introduced in Senate (04/19/2023)
Fair Prescription Drug Prices for Americans Act

This bill caps the price of drugs and biologics at the average price among certain countries.

Specifically, the retail list price of a drug or biologic in the United States may not exceed the average retail list price among Canada, France, Germany, Italy, Japan, and the United Kingdom. The Department of Health and Human Services (HHS) must calculate the average price in these countries based on data that is submitted by manufacturers directly to HHS and on publicly filed materials from manufacturers.

Manufacturers who violate the bill's price cap are subject to civil penalties.

*Josh Hawley (R-MO): "For too long, Americans have subsided **prescription drug cost for foreigners while paying outrageous prices for their own medication**. President Trump previously advanced major reforms to ensure that **American patients pay the same prices as consumers abroad**. This bipartisan legislation [Fair Prescription Drug Prices for Americans Act] would continue that work to end a drug market that favors big pharma, **make prescription prices affordable again**, and empower Americans to get the care they need."*

We'll flag following the signing of the MFN EO on May 12th, Hawley posted on X that he 1) supports the bill, 2) wants to see it made permanent.
We think a potential path MFN policy could be introduced is via a vote-a-rama to the OBBBA. *Caveat: Hawley has not explicitly stated he would do this.*

Our KOL thinks that if the senate were to make changes, they would have to send the bill back to the house for another vote and, given the narrow margins, this may be a risky strategy because it could lead to delays if not passed. He thinks the more likely scenario is that a conference committee of key leaders from the house and senate will hammer out a compromised bill – one that can be passed by nearly a full house and senate as opposed that the senate dictates and the house merely accepts.

Source: Jefferies Analysis, US Congress, X

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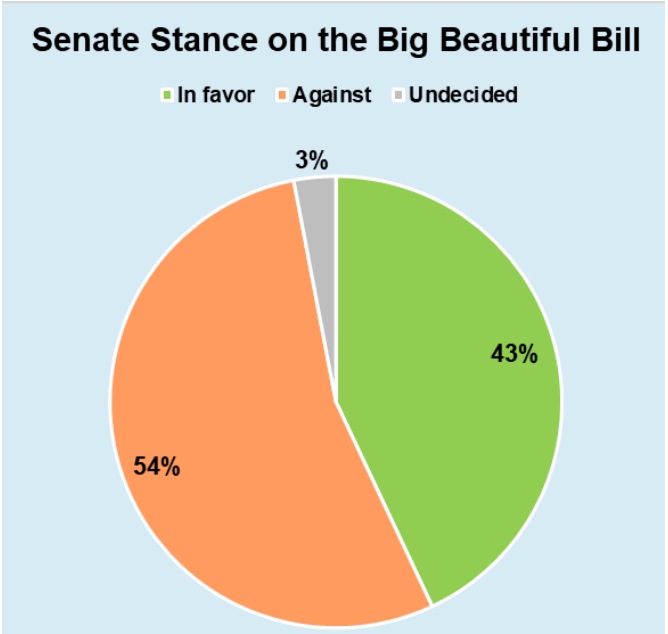
That said, we collected all public statements that the Senate members have made on the One Big Beautiful Bill…in its current state, there is a chance that OBBBA won't pass the Senate given concerns re: Medicaid & debt – only 3 Republicans need to vote 'no' for the bill not to be passed

Last Nam	Senator's Name	State	Party	Stance	Quote
Alsobrooks	Alsobrooks, Angela D.	Maryland	Democratic	Against	"The largest cuts to Medicaid and SNAP in American history – and Trump is calling it the 'Big, Beautiful' bill. Well beautiful for whom? Certainly not the millions of Americans who rely on SNAP to feed their children and on Medicaid to
Baldwin	Baldwin, Tammy	Wisconsin	Democratic	Against	"No Wisconsinite should be forced to forgo the medication they need to stay healthy because of cost."
Banks	Banks, Jim	Indiana	Republican	In favor	One Big, Beautiful Bill will make America affordable again.
Barrasso	Barrasso, John	Wyoming	Republican	In favor	I am for whatever can get 218 votes in the House, 51 votes in the Senate and get signed by the president
Bennet	Bennet, Michael F.	Colorado	Democratic	Against	Trump likes to call it "one big, beautiful bill" — but for middle-class families and workers, this bill is nothing but a nightmare
Blackburn	Blackburn, Marsha	Tennessee	Republican	In favor	Priority number one: passing the "one big, beautiful bill."
Blumenthal	Blumenthal, Richard	Connecticut	Democratic	Against	Introduced the Medicare Beneficiary Co-Pay Fairness Act of 2025 to make Medicare's co-pay structure more affordable.
Blunt Roche	Blunt Rochester, Lisa	Delaware	Democratic	Against	"House Republicans' 'Big Beautiful Bill' is nothing more than a big ugly tax giveaway for the ultrawealthy while everyday Americans pick up the tab."
Booker	Booker, Cory A.	New Jersey	Democratic	Against	"We cannot let Trump hide behind his Big Budget Bill. We must fight each and every provision that threatens democracy and American lives."
Boozman	Boozman, John	Arkansas	Republican	In favor	I'd like to get the risk management tools — that's the real expense of the Farm Bill — I'd like to get that included in reconciliation
Britt	Britt, Katie Boyd	Alabama	Republican	In favor	The American people are firmly behind us in this effort, and they're counting on us to deliver relief in our one, big beautiful bill
Budd	Budd, Ted	North Carolina	Republican	In favor	"I think he's caring for seniors, and all of the cuts that you see they're not cuts on Social Security. They are things we're doing to shore up our federal spending so that we have the money to pay for Social Security and Medicare. You've
Cantwell	Cantwell, Maria	Washington	Democratic	Against	Announced bill to spare physicians from cut in Medicare reimbursements.
Capito	Capito, Shelley Moore	West Virginia	Republican	In favor	"Unless we bend the curve on it future generations are really going to suffer here," Capito said of the national debt. "One of the ways we can really do this through reconciliation is to look at mandatory spending, and Medicaid is one of
Cassidy	Cassidy, Bill	Louisiana	Republican	In favor	U.S. Senator Bill Cassidy, M.D. (R-LA) penned an op-ed in the Washington Examiner highlighting his Education Choice for Children Act (ECCA), a bill to expand education freedom for students and empower parents to make the best d
Collins	Collins, Susan M.	Maine	Republican	In favor	Sen. Susan Collins, R-Maine, said she's "inclined" to support the bill's work requirements, but worries that "the way provider taxes are treated would be very harmful to Maine's hospitals."
Coons	Coons, Christopher A.	Delaware	Democratic	Against	Maybe because it's a bad bill.
Cornyn	Cornyn, John	Texas	Republican	In favor	John Cornyn joined Hugh to discuss the need to press forward with the "One Big, Beautiful Bill".
Cortez Mast	Cortez Masto, Catherine	Nevada	Democratic	Against	"This plan could cut health care coverage for nearly 100,000 Nevadans on Medicaid or marketplace insurance plans and could threaten health care providers across our state." Senator Jacky Rosen criticized the bill as a "partisan" me
Cotton	Cotton, Tom	Arkansas	Republican	In favor	"A little bit more savings in Medicaid. Medicaid is a critical program for many Arkansans, for elderly, for pregnant women, for poor children, for the blind, the disabled. It shouldn't be providing health insurance, though, to freeloaders and
Cramer	Cramer, Kevin	North Dakota	Republican	In favor	ND Senator Cramer argues 'big beautiful bill' before Congress is "better to pass than not pass"
Crapo	Crapo, Mike	Idaho	Republican	In favor	If we can get this done, it will probably be the most significant thing that we do in our service in Congress. That's how strongly I feel about it.
Cruz	Cruz, Ted	Texas	Republican	In favor	Sen. Ted Cruz is confident Trump's 'big, beautiful bill' will pass, but warns of 'twists and turns' along the way.
Curtis	Curtis, John R.	Utah	Republican	Undecide	Curtis, who has said he wants some serious changes to President Trump's "big, beautiful bill,
Daines	Daines, Steve	Montana	Republican	In favor	Once we receive the Big Beautiful Bill from the House, we've got some ideas in the Senate that's going to make it even more beautiful.
Duckworth	Duckworth, Tammy	Illinois	Democratic	Against	Trump's "one big beautiful bill" greenlights Republicans gutting Medicaid and SNAP to fund billionaires' tax cuts. That's an ugly bill imo.
Durbin	Durbin, Richard J.	Illinois	Democratic	Against	[Republicans' reconciliation bill] dismantles the American Dream and strips our institutions of essential services that help the most vulnerable people in our country. All so the ultimate goal can be served... to give major tax breaks to
Ernst	Ernst, Joni	Iowa	Republican	Against	Ernst has criticized the bill's potential effects on Medicaid spending, suggesting that targeting the working poor is unjust and could be politically damaging.
Fetterman	Fetterman, John	Pennsylvania	Democratic	Against	I will never support a bill that uses Medicare, Medicaid or SNAP cuts to pay for tax cuts for billionaires.
Fischer	Fischer, Deb	Nebraska	Republican	In favor	Senator Fischer hopes to get some, if not all, of her priorities included in the reconciliation package
Gallego	Gallego, Ruben	Arizona	Democratic	Against	"Republicans' "Big Beautiful Bill" puts thousands of good-paying union jobs on the chopping block and threatens the livelihoods of families across the country."
Gillibrand	Gillibrand, Kirsten E.	New York	Democratic	Against	"This proposal would be catastrophic for the millions of Americans who rely on Medicaid," said Senator Gillibrand. "Republicans should be focused on bringing down the cost of essentials; instead, they are making health care harder
Graham	Graham, Lindsey	South Carolina	Republican	In favor	I prefer "one big beautiful bill" that provides funding to implement the Trump border security agenda and a boost in military spending
Grassley	Grassley, Chuck	Iowa	Republican	In favor	Grassley says while the reconciliation bill is just touching base on a few key points that would be considered in the farm bill doesn't mean the rest will just be forgotten.
Hagerty	Hagerty, Bill	Tennessee	Republican	In favor	The "Big, Beautiful Bill" will lead to more investment in the United States, more jobs for the American people, tax relief and increased wages, and economic prosperity. All of this is going to be very positive.
Hassan	Hassan, Margaret Wood	New Hampshire	Democratic	Against	"Republicans' so-called 'Big, Beautiful Bill' will hurt American families by giving tax cuts to billionaires."
Hawley	Hawley, Josh	Missouri	Republican	Against	Against Medicaid cuts - "slashing health care for the working poor "is both morally wrong and politically suicidal."
Heinrich	Heinrich, Martin	New Mexico	Democratic	Against	According to Donald Trump, a "big, beautiful bill" is one that leaves almost 14 million people uninsured and drives up families' energy bills. No Thanks.
Hickenloope	Hickenlooper, John W.	Colorado	Democratic	Against	"The Republicans' budget is a nightmare for working Americans. We're game to make government more cost-effective and lower taxes for working families – this does the opposite. Higher costs from the grocery store to the gas tanl

We collected comments that Senators have publicly made on X, their websites, conferences, etc. and the stances tend to skew quite negatively *caveat*: some senators noted they would vote 'no' if certain adjustments re: Medicare and debt were not made – there is a chance that the bill is edited in Congress such that they agree to vote on it



Currently, only 3 Republicans need to vote no to strike down the bill – recently, Senate Finance Committee Chair Mike Crapo (R-Idaho) warned colleagues that there are two likely "no" votes against the bill within the Senate Republicans

- "the One Big Beautiful Bill will almost certainly add to our deficits and debt. That's why I can't support this bill as it's currently being discussed and doubt that it will pass the Senate" – Ron Johnson, R-WY
- "I will not vote to raise the debt ceiling by $5 trillion" – Rand Paul, R-KY
- Other Republicans to watch out for include Lisa Murkowski, Susan Collins (concerns re: cutting Medicaid), Mike Lee, Rick Scott (deficit concerns)

Source: Jefferies Analysis, US Congress

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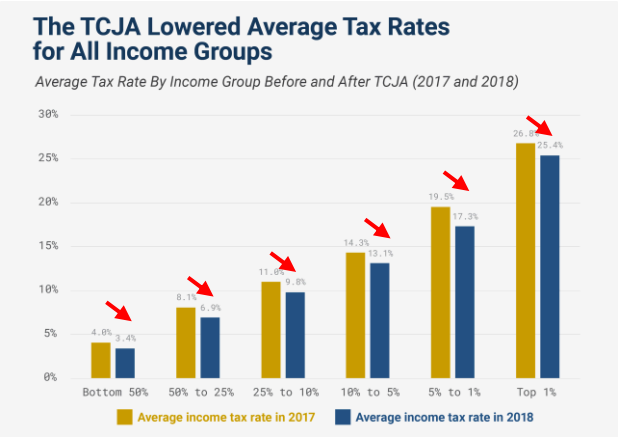
However, we will note that the Tax Cuts and Jobs Act (TCJA 2017) is set to expire in 2025, which could potentially be an incentive for Republicans to pass the OBBBA quickly to prevent lapsing

Provision	Original Expiration (TCJA)	OBBBA Action	New Expiration (if applicable)
Individual Income Tax Rates	End of 2025	Make permanent; maintains the 37% top rate instead of reverting to 39.6%.	N/A
Standard Deduction	End of 2025	Make permanent; includes an additional $1,000 for single filers, $1,500 for heads of household, and $2,000 for married couples filing jointly through 2028.	Additional amounts expire after 2028
Child Tax Credit (CTC)	End of 2025	Make permanent at $2,000 per child; temporarily increased to $2,500 per child for tax years 2025 through 2028.	Temporary increase expires after 2028
Personal Exemption Deduction	End of 2025	Permanently repealed.	N/A
Pass-Through Business Deduction (Section 199A)	End of 2025	Make permanent; increases deduction from 20% to 23% for tax years beginning after 2025.	N/A
Bonus Depreciation	Phased out by 2027	Resets to 100% deduction for eligible property acquired and placed in service after Jan 1, 2025, and before Jan 1, 2030.	Expires after 2029
Alternative Minimum Tax (AMT) Relief	End of 2025	Make permanent; retains higher exemption amounts and phase-out thresholds.	N/A
Estate Tax Exemption	End of 2025	Make permanent; retains the doubled exemption amount, adjusted annually for inflation.	N/A
State and Local Tax (SALT) Deduction Cap	End of 2025	Increases cap from $10,000 to $40,000 for tax year 2025; phases out at incomes over $500,000.	Cap increases by 1% annually through 2033
Research and Development (R&D) Expensing	End of 2025	Suspends required capitalization of domestic R&D expenditures for tax years 2025 through 2029.	Expires after 2029

"We're seeking permanent income tax cuts all across the board" – Pres. Donald Trump; March 4th 2025 Address to Congress

We'll call out that the 39.6% → 37% tax rate decrease is a key reason that Trump wanted the OBBBA to pass –mentioned in his address to congress. That said, we think this is an additional incentive for senate republican not to make significant changes to the OBBBA because it will then get sent back to the house and potentially lead to delays that may lapse the tax cuts. Currently, congress has 6mo to pass the OBBBA before expiry on Dec 31 2025.



Btw 2017 and 2018, there was an across-the-board tax cut for all tax brackets. We suspect that Trump views this as something that boosts his favorability ratings which may be why he is hopes to extend this policy forward.

Source: Jefferies Analysis, US Congress

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In the circumstance that a version of the OBBBA *does* pass the Senate, we're still skeptical that a changed version could get passed by the House based on House Congressmen comments…

House Republicans have a majority of 220 to 212, meaning they can only spare three "no" votes in their ranks to pass the bill when the Senate sends back its revised version.
Five House Republicans originally opposed the bill: Ralph Norman of South Carolina, Chip Roy of Texas, Josh Brecheen of Oklahoma, Andrew Clyde of Georgia and Lloyd Smucker of Pennsylvania.

House Speaker Mike Johnson noted that he **"encouraged Senators to make as few modifications as possible, remembering that I have a very delicate balance on our very diverse Republican caucus over in the House"** – to us, this suggests that certain changes could make some House Republicans who may have initially voted in favor of the bill might vote against it if too many changes are enacted by the Senate

Here are the key changes we're tracking that could make or break passage of an edited bill in the House

*"While we were proud to have worked to ensure that the bill did not include a full repeal of the clean energy tax credits, **we remain deeply concerned by several provisions…**the House-passed bill includes a phase out schedule for credits that would cause **significant disruption to projects under development and stop investments needed to win the global energy race.**"* - Jen Kiggans, R-Va.

Bill changes that would lead House Republicans to vote for the bill	Bill changes that would lead House Republicans to vote against the bill
Sen. Thom Tillis, R-N.C - willing to undo some of the clean energy funding, but wants to make sure existing business investments aren't harmed by the bill.	Cuts to clean energy funding under the 2022 Inflation Reduction Act were part of a House agreement to win the votes of conservative hard-liners who want to reduce deficit
Sen. Shelley Moore Capito, R-W.Va. stated that her version of the bill will probably relax some of the deadlines to cut off funding, "I imagine it's going to track fairly similarly, but I think some of the deadlines are pretty tight in terms of when you have to have construction and those things"	"You backslide one inch on those IRA subsidies and I'm voting against this bill…So you do what you want to do in the Senate, House of Lords, have your fun. **But if you mess up the Inflation Reduction Act, Green New Scam subsidies, I ain't voting for that bill.**" -Rep. Chip Roy, R-Texas

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…and given how close the initial House vote was, we see low PoS of MFN being added in last minute through the Senate version of the OBBBA, given it's too much of a liability AND could cause harm - we think a standalone bill is more likely

Reasons for introducing MFN via reconciliation	Reasons against introducing MFN in reconciliation bill
1) Reconciliation process is favorable to passage (limited debate, no filibuster, 50% vote threshold for passage) 2) Fastest route of implementation	1) Delay in passage of OBBA (pot'ly affecting the TJCA extension end 2025) 2) Potential reversal of Republican congressmembers to a 'no' vote once it is sent back to the house (narrow majority the first time around) might tank the whole bill given pot'l to cause harm 3) Not all republicans are in favor of MFN concept based on previous comments

We're seeing more risk to the administration to introduce MFN into OBBBA given its progression past the house. **We think if MFN were to be done legislatively, it would be easier for the government to introduce a separate piece of legislation, thereby separating the liability from the must-pass reconciliation bill**

Source: Jefferies Analysis, US Congress

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In fact, we'll note that Speaker Mike Johnson has alluded to splitting up the agenda into two or even multiple reconciliation bills to get this version (OBBBA) through the door…thus we may not even see MFN get enacted in FY26 given it doesn't seem to be a priority of current Republicans in Congress

> "We're going to have another reconciliation bill that follows this one, possibly a third one before this Congress is up, because you can have a reconciliation bill for each budget year, each fiscal year. So that's ahead of us…We're also doing rescissions packages. We got the first one delivered this week from the White House, and that will codify many of the DOGE cuts."
>
> –Mike Johnson (R-LA)

- That said, Republicans also noted that they would not know what a second budget reconciliation would entail and it would be dependent on what gets passed first
- We think that even if MFN is not included in the OBBBA and tried to be implemented as a separate legislation, there wouldn't be a lot of support given 1) not a lot of Congress members are speaking about what MFN implementation would look like, 2) there would be hqrm to the system, which we think makes it harder to pass given current contention, even among Republicans, on the potential harm to pts from proposed Medicaid cuts

Source: Jefferies Analysis, US Congress

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IMPT Regardless if MFN gets included in Reconciliation or proposed as new legislation, we're skeptical MFN gets through the Senate based on previous comments from Republican Senators

We'll note that while Trump tried to put pressure on the Senate republicans to initially include MFN in the OBBBA, not all Republicans were on board. We noticed 2 themes from Republican senators that led them to disagree with the idea of MFN:

Government price-setting:

Mitch McConnell (R-KY): "***Socialist price controls*** *will do a lot of left-wing damage to the healthcare system. And of course we're not going to be calling up a bill like that."*

Pat Toomey (R-PA): "Simply put, the MFN proposal **amounts to nothing more than price controls and could severely undermine investment in life science research and development**"

Mike Lee (R-UT): "***Price controls never work****. Instead they exacerbate the problems they seek to resolve.* ***Mandating fixed prescription drug prices will ultimately result in the shortening of American lives****."*

Pharmaceutical innovation:

Bob Latta (R-OH): *"We want to make sure in this country that we* ***always lead the world*** *and our Americans have* ***every option that's available for treatment****,"*

Sen. Majority Leader John Thune (R-SC): *"The US leads the world in* ***prescription drug innovation*** *and a big reason for that is because the* ***US government doesn't dictate drug prices."***

Bill Cassidy (R-LA): "***Research decisions should be driven by evidence****, not top-down price controls"*

Our conclusion? Based on previous comments, not all Republicans may be on board with MFN in the OBBBA. Given the narrow majority republicans hold in the senate (53 Rep, 45 Dem), even with the introduction of MFN policy into the OBBBA through the vote-a-rama we'll flag that MFN may still not pass a majority vote.

Source: Jefferies Analysis, Congress comments

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2) CMMI pilot program:

Centers for Medicare and Medicaid Innovation (CMMI) is part of the CMS & can pilot (Phase 1) as well as nationally implement (Phase 2) new payer models

CMMI's mission is to **design, test, and implement new ways of paying for and delivering healthcare through Medicare and Medicaid.** Its purpose is to **improve patient care, lower costs, and align payment systems.** The aim of model testing is to **gain evidence** that a model is better than the current standard and that the model should be **expanded nationally.**

The Center for Medicare and Medicaid Innovation, also known as the CMS Innovation Center, develops and tests new healthcare payment and service delivery models to:

- Improve patient care.
- Lower costs.
- Better align payment systems to promote patient-centered practices.

Section 1115A (est. under Social Security Act of Affordable Care Act – 2010) **established CMMI** as a center to evaluate new healthcare payment delivery models.

SEC. 1115A. [42 U.S.C. 1315a] (a) CENTER FOR MEDICARE AND MEDICAID INNOVATION ESTABLISHED.—

(1) IN GENERAL.—There is created within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Innovation (in this section referred to as the "CMI") to carry out the duties described in this section. The purpose of the CMI is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).

There are 2 phases to implementing a model nationally through CMMI – Phase I is a pilot program to collect data. Phase II is expansion of a successful phase I nationwide

CMMI Phase Goals	
Phase 1:	**Design and pilot** model in selected areas to assess feasibility, gather initial data, and make adjustments. **Focus on operationally feasible. Gather data on how providers and beneficiaries respond to the model. Identify potential areas of improvement before scaling the model to a broader group of participants**
Phase 2:	**Wider implementation** and further evaluation. Confirm the model's effectiveness, assess broader impacts, **and determine national implementation**

Source: Jefferies analysis, CMS

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CMMI has the authority to do this through section 1115A of the Social Security Act (added by the Affordable Care Act, 2010) – models within section 1115A are aimed at reducing spend and/or improving quality of care & aren't explicitly limited by factors like geography

1) Geographical limit: **Not strictly defined**. Arguments *against* geographical limit center around the word '**may**' **- not 'must'** for phase 1.

(5) TESTING WITHIN CERTAIN GEOGRAPHIC AREAS.—For purposes of testing payment and service delivery models under this section, the Secretary may elect to limit testing of a model to certain geographic areas.

2) Limit of model purpose: List of examples defined in section 1115A. Overarching themes are: **reduce program costs** and **enhance quality of care**

(2) SELECTION OF MODELS TO BE TESTED.—

(A) IN GENERAL.—The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title. The models selected under this subparagraph may include, but are not limited to, the models described in subparagraph (B).

(A) INITIAL PERIOD.—The Secretary shall not require, as a condition for testing a model under paragraph (1), that the design of such model ensure that such model is budget neutral initially with respect to expenditures under the applicable title.

(B) TERMINATION OR MODIFICATION.—The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to—

(i) improve the quality of care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under the applicable title;

(ii) reduce spending under the applicable title without reducing the quality of care; or

(iii) improve the quality of care and reduce spending.

Such termination may occur at any time after such testing has begun and before completion of the testing

3) Limit of funding: defined budgets for all models

(f) FUNDING.—

(1) IN GENERAL.—There are appropriated, from amounts in the Treasury not otherwise appropriated—

(A) $5,000,000 for the design, implementation, and evaluation of models under subsection (b) for fiscal year 2010;

(B) $10,000,000,000 for the activities initiated under this section for the period of fiscal years 2011 through 2019; and

(C) the amount described in subparagraph (B) for the activities initiated under this section for each subsequent 10-year fiscal period (beginning with the 10-year fiscal period beginning with fiscal year 2020).

Amounts appropriated under the preceding sentence shall remain available until expended.

(2) USE OF CERTAIN FUNDS.—Out of amounts appropriated under subparagraphs (B) and (C) of paragraph (1), not less than $25,000,000 shall be made available each such fiscal year to design, implement, and evaluate models under subsection (b).

Source: Jefferies analysis, Section 1115A

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Additionally, HHS seems to have full discretion what it tests…Congress oversees but cannot alter models

4) Limit of model review: **No outside forces can determine which models are tested or expanded – HHS has full discretion here**

(2) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

(A) the selection of models for testing or expansion under this section;

(B) the selection of organizations, sites, or participants to test those models selected;

(C) the elements, parameters, scope, and duration of such models for testing or dissemination;

(D) determinations regarding budget neutrality under subsection (b)(3);

(E) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and

(F) determinations about expansion of the duration and scope of a model under subsection (c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

5) Limit of national expansion: **Provided model reduces spending or improves quality of care, discretion is with HHS Secretary**

(c) EXPANSION OF MODELS (PHASE II).—Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if—

(1) the Secretary determines that such expansion is expected to—

(A) reduce spending under applicable title without reducing the quality of care; or

(B) improve the quality of patient care without increasing spending;

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and

(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

6) Limit of congressional oversight: CMMI must report & justify models to Congress**, but Congress does not have authority to alter models**

(g) REPORT TO CONGRESS.—Beginning in 2012, and not less than once every other year thereafter, the Secretary shall submit to Congress a report on activities under this section. Each such report shall describe the models tested under subsection (b), including the number of individuals described in subsection (a)(4)(A)(i) and of individuals described in subsection (a)(4)(A)(ii) participating in such models and payments made under applicable titles for services on behalf of such individuals, any models chosen for expansion under subsection (c), and the results from evaluations under subsection (b)(4). In addition, each such report shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.

- Altogether, we think CMMI has broad power to test and implement models.
- This is driven by **vague language in section 1115A** defining limits on what can be tested and **could prevent legal challenges** to **content** of models.
- In future, we think we could see CMMI being used to trial (phase I) and expand (phase II) MFN policy nationally, but it will be slow due to the required testing phase.

Source: Jefferies analysis, Section 1115A

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We've seen that prior CMMI models could be narrow or broader in scope – for example, we're seeing that models with more narrow geographic focus could be easier to implement likely due to lower cost & ease of scaling

While there is no set definition for what makes a CMMI model broad vs narrow, we've seen that relatively speaking broader models affect large segments of the population vs narrow models are limited to a specific disease/specialty (often smaller populations). The type of population being targeted could also be relevant to the scope of the model. For example, there were 93 sites for the KCC model (close to ACO REACH model) & they were limited to pts with kidney disease so the scope for expansion in CMMI Phase 2 would still be limited

Model Name	Reason for Classification	Implementation Outcome
ACO REACH	Targets population-level care delivery across providers with a focus on full-risk capitation and sites participating **in ~25 states and 103 sites**	**Implemented (ongoing, as of 2025)**
Comprehensive Primary Care Plus (CPC+)	Multi-state, multi-payer model focused on transforming primary care across **~14 states and 2610 sites**	**Ended in 2021**
Bundled Payments for Care Improvement (BPCI) Advanced	Applies broadly across dozens of clinical episodes and provider types in many regions. **~29 states 170 sites**	**Implemented (ongoing – finishes Dec 2025)**
Kidney Care Choices (KCC)	Targets specific population (CKD/ESRD) and nephrologists with focused interventions**. ~93 total sites across US (kidney treatment only)**	**Implemented (ongoing, voluntary participation)**
Independence at Home Demonstration	Limited to **1 participating site**. In-home care to frail elderly with narrow eligibility criteria.	**Implemented (ended in 2020)**
Vermont All-Payer ACO Model	Applies only to **1 site in Vermont** with state-specific governance and narrow geographic reach.	**Implemented (ongoing, state-level model)**

Looking at a few precedent CMMI pilot programs with disclosed geographic impacts, we're seeing a higher implementation rate for more narrow models (eg, lower # of sites and/or states, defined population). **We're seeing that the CPC+ model included a larger # of sites (eg, 2610) – it's no longer active due to mixed patient care quality improvement and large cost**

While specific results from individual models determine whether they are implemented in Ph.2, we noted that narrow models have a could have better chance of being implemented vs broad model given:

1) **Ease of scaling vs broad models** (inc. less scrutiny based on narrow population).
2) **Less funding needed to implement at larger scale.**
3) **Narrow models having a specific target population that limits the scope** (e.g. KCC model only for pts with kidney disease), whereas broad models are usually for a type of generic care delivery model that affects a larger population (e.g. CPC is for primary care)

Source: Jefferies analysis, CMS.gov

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Similarly, we're seeing that CMMI pilot programs with more narrow scope re: impacted drugs could have an easier chance of getting implemented

Model Name	Drug Focus	Status	Approx. Number of Drugs Involved	Medicare Part	Drug Selection Criteria
Medicare $2 Drug List Model	Low-cost generics for chronic conditions	Withdrawn (Mar 12, 2025)	90 different drug names	Part D	Generic, chronic use, low acquisition cost
Accelerating Clinical Evidence (ACE) Model	Drugs approved under FDA Accelerated Approval	Withdrawn (Mar 12, 2025)	Accelerated Approval drugs (APP_- mostly oncology)	Part B	FDA accelerated approval with pending confirmatory trials
Cell and Gene Therapy Access (CGTA) Model	High-cost cell and gene therapies	Planned for 2025	2 gene therapies (targeted high-cost therapies)	Medicaid	High-cost, curative potential, Medicaid eligibility
International Pricing Index (IPI) Model	High-cost Medicare Part B drugs	Withdrawn (2020)	~26 drugs on prelim list	Part B	Top Part B drugs by spending vs. international prices
Part D Senior Savings Model	Insulin products	Implemented (2021–2023)	5 manufactures providing 1 vial and 1 pen dose of rapid, short, intermediate, long-acting insulin.	Part D	Insulins offered under voluntary manufacturer plans
Part D Payment Modernization (PDM) Model	High-cost Part D drugs (e.g., specialty, branded)	Ended Dec 2021	All covered Part D drugs	Part D	Based on spending patterns and risk-sharing eligibility

We'll call out that there is a precedence of CMMI models that were not based on geography, but on therapy type. We noted a trend with **models having broad criteria for drug inclusion were all discontinued and narrow models remain active/planned (e.g. CGTA, Part D Senior savings).**

Source: Jefferies analysis, CMS.gov

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We think Trump could likely try to implement MFN via a broad CMMI pilot program – stepping back, Trump's prior 2020 MFN model was via CMMI pilot program & was broad in nature (targeted top 50 Medicare Part B drugs & covered all of US)

MFN Model – 85 FR 76250 (Nov 27th, 2010) – Trump's 2020 MFN plan

§ 513.120 MFN Model geographic area.

The MFN Model geographic area is all states and U.S. territories.

→ We saw Trump's 2020 MFN rule had **no geographical restriction – under 1115A we noted this is not a mandated requirement**

The MFN Model will focus on a select cohort of separately payable Medicare Part B drugs. This cohort will initially include 50 single source drugs and biologicals (including biosimilar biological products) that encompass a high percentage of Medicare Part B drug spending. The MFN Model will require mandatory participation. Participants in the MFN Model will include all providers and suppliers that

→ We note the model's scope was **Medicare Part B (50 single source drugs and biologics)**

§ 513.400 Quality measures.

(2) If during the MFN Model CMS determines that the quality measures specified in paragraph (b) of this section are not sufficient to adequately monitor the quality of care that MFN beneficiaries are receiving from MFN participants or that MFN participants are providing, CMS may specify additional measures. CMS applies the following criteria when specifying additional quality measures:

(i) Additional measures are among one or more of the following categories:

(A) Patient experience of care.
(B) Patient activation
(C) Shared decision making.
(D) Adherence.
(E) Utilization.
(F) Process measures.

→ 1) Collected data on patient **quality of care.**
2) Collected data on process measures to show **improved efficiency** – in line with goals of CMMI.

§ 513.410 Beneficiary protections.

(a) *Beneficiary choice.*

(1) MFN participants must not restrict beneficiaries' ability to choose to receive care from any Medicare participating provider or supplier or any provider or supplier who has opted out of Medicare.

→ We note it does not restrict participants to Medicare exclusively

Source: Jefferies analysis, MFN Model 2020

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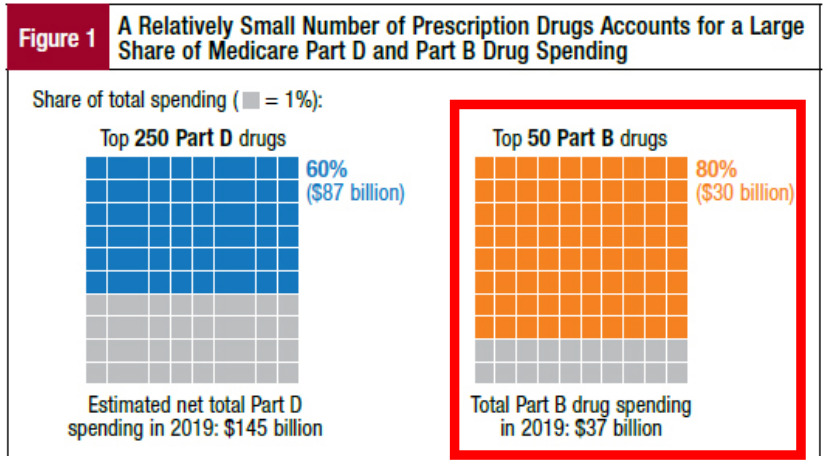
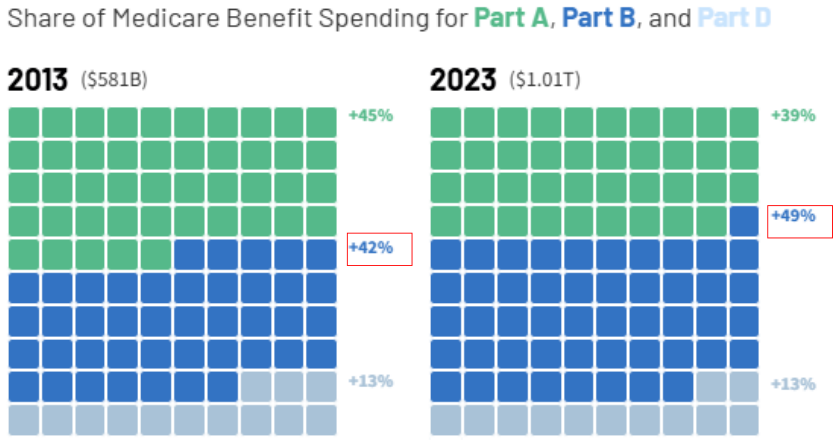
While 2020 MFN model was limited to top 50 Medicare Part B, this still makes up ~80% of Part B spending

Based on past precedence of the 2020 MFN model including top 50-part B Medicare drugs, **we think a pot'l MFN model would include the same (and pot'l even more) – therefore making it a broad model**. We'll flag that **between 2013 and 2023, Medicare part B spending increased from 42% to 49%,** turning it into the largest section of Medicare part spending. Also, the top 50 Medicare part B spending accounted ~$30B (80%) of Part B spending. We'll flag that the ramifications of including top-50 part B would **be larger than any previous CMMI model that had a selection criteria based on drugs**

MFN Model (2020) inclusion criteria

The MFN Model will focus on a select cohort of separately payable Medicare Part B drugs. This cohort will initially include 50 single source drugs and biologicals (including biosimilar biological products) that encompass a high percentage of Medicare Part B drug spending. The MFN Model will require mandatory participation. Participants in the MFN Model will include all providers and suppliers that





Source: Jefferies analysis, CMS.gov

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We don't know if the current MFN proposal will include Medicare Part B and/or Part D and/or Medicaid, KOL feedback + our diligence suggests that Part B could be easier to include, followed by Part D & Medicaid

Takeaways from Our Call with Policy Expert

- **On the use of CMMI,** our KOL thinks MFN will end up as CMMI because White House doesn't have authority in other ways. He flagged that if it is CMMI, it would have to be limited in scope and geography – a mandatory nationwide model would be extremely tenuous legally.
  - **Part B is nearly guaranteed because it can be implicated in a CMMI model**
  - **Our KOL think it may be more difficult for Part D to be included** and cited the SSA non-interference rule and IRA carveouts for Part D. However, **he acknowledged there is a debate.** He felt if you want to get MFN with part D it needs to be in the IRA and that is not a likely for this admin.
  - Finally, our KOL reminded us that the legislative intent of CMMI is to experiment, and Republicans have raised concerns that board mandatory models look like legislative reform. Best way to implement MFN in a legally defensible way is to narrowly tailor it.
- **On Medicaid being included in a CMMI model,** our KOL states must opt-in. In past, Republicans opposed MFN because it was seen as gov't price control, but new-age Republicans are more populist. **It stands to reason that both Republican and Democratic states would opt-in and the largest hurdle would be the hoops to jump through procedurally**
- **On commercial spillover,** our KOL believes this problem is not specific to MFN and he also doesn't think it will be significant. He flagged the current system is balanced with PBMs, insurance co's, and pharma co's all profiting he does not expect that there will be an automatic change
- **On being stopped during the pilot phase,** even in 1 year, they can still abandon the model after it starts (KOL cited that FDA does this frequently). Pharma may want to hand Trump a victory so he can have good headline going into the midterms and then get him to drop the model.

Takeaways from Our Call with PBM KOL (HERE)

- On operational complexity across payer types - according to our KOL, **from a payer perspective, implementing reimbursement changes is relatively feasible under Part D, particularly in PDP and MAPD, since the payers bear most of the risk and retain more control over the pricing**
- Part B can be more challenging since the risk is shared & payer has less control
- **Medicaid has the greatest difficulty since changes require state approvals and often involve other pricing models such as NADAC Plus, COST Plus, and 340B**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA amended section 1144 of the SSA) includes ***a "noninterference clause," which prohibits the gov't from engaging in price negotiations, requiring formularies, or setting prices for Medicare Part D drugs.*** *However, we'll flag there are exclusion criteria for select critical drugs (e.g. anticonvulsants, antineoplastics)*

42 U.S.C. Section 1395w-111(i): Non-interference clause

(i) NONINTERFERENCE

In order to promote competition under this part and in carrying out this part, the Secretary—

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors;

(2) may not require a particular formulary, except as provided under section 1395w–104(b)(3)(I)[4] of this title; and

(3) may not institute a price structure for the reimbursement of covered part D drugs, except as provided under part E of subchapter XI.

42 U.S. Code § 1395w-104 G(iv): Exclusion Criteria

(iv) Requirement for certain categories and classes until criteria established

Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):

(I) Anticonvulsants.

(II) Antidepressants.

(III) Antineoplastics.

(IV) Antipsychotics.

(V) Antiretrovirals.

(VI) Immunosuppressants for the treatment of transplant rejection.

Source: Jefferies analysis, CMS.gov, KOL

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Notably, CMS previously suggested the only way for an MFN model to work is for it to be broad in both geography and # of drugs included

MFN 2020 Comment: disparities in geographical/provider inclusion

Comment:

In the October 2018 ANPRM, CMS anticipated the geographic area included in a potential IPI Model would encompass 50 percent of Medicare Part B drug spending. Several commenters expressed concern that having model participants subjected to multiple payment methodologies for included drugs based on having some but not all of their locations within the model's geographic area would be administratively burdensome. Additionally, some commenters expressed concern at the idea of requiring participation in some geographic areas but not others, noting that this approach would disproportionately affect some providers and suppliers and not others. Multiple commenters noted that reduced cost-sharing for patients in the model compared to those outside of the model would create potential differences in access for beneficiaries. One commenter noted that there would be a risk of patient steering if the model created a financial incentive for providers and suppliers to provide care at sites outside of the model geographic area rather than at sites in the model geographic area.

We'll flag that comments were received that providers not included in the model (either by geography, or by type of provider) would have different prices/patient outcomes and that this could lead to **patient steering based on financial incentives to provide care outside of the MFN model**

CMS response:

Due to the administrative complexity and risk to model integrity associated with a limited scope, CMS believes that the MFN Model cannot realize its full potential in spending reductions for Medicare and its beneficiaries and improvement in quality of care without broad participation of Medicare participating providers and suppliers through a nationwide scope. Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the scope of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. It follows that the Secretary could similarly elect not to limit testing to certain geographic areas, and instead test a nationwide model.

The MFN Model requires mandatory, nationwide participation of Medicare participating providers and suppliers (with limited exclusions) to be able to successfully test the model for the reasons described later in this section. First, a nationwide scope avoids additional administrative burden on MFN participants with some service locations inside the MFN Model geographic area and others outside of the MFN Model geographic area, which could lead to such MFN participants needing to track and follow separate requirements for how drugs are acquired, furnished, and billed, depending on the service location. Second, a nationwide model geographic area eliminates the potential for MFN participants with service locations both inside and outside the MFN Model's geographic area to seek to influence beneficiaries' choice of treatment location in response to the differences between non-model payments

In our KOL conversation, he indicated that for an MFN model to have the highest POS, it would have to be narrow in scope and geography and that a mandatory nationwide model would be extremely tenuous legally. Based on CMS response, we think CMMI's aim is for a broad model which would decrease their POS

Importantly, we'll note CMS' response suggests they believe an MFN model cannot realize it's full potential unless **it is broad in scope.** They cited 2 reasons:

1) **Administratively easier**
2) **Prevents providers that have both included and excluded services to funnel pts to the excluded sites**

Read across to pot'l future MFN model: We think that the same reasoning will hold if the intention is to lower drug prices across the board. As such, we think that CMMI will select the broad model route for both # of drugs and geography

Source: Jefferies analysis, Federal Register

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In the case of the 2020 MFN model, it didn't go through due to APA violations re: lack of the typical 30-60-day notice-and-comments period (rather than model content)

Taking a step back, the **Administrative Procedure Act (APA) (5 U.S.C. §§ 551–559 & §§ 701–706)** is the statute that governs how federal administrative agencies propose and establish regulations. It ensures agencies provide **notice-and-comment rulemaking – typically 30 to 60 days -** (5 U.S.C. § 553), allows for **judicial review of agency actions** (5 U.S.C. § 702), and sets standards for fairness and transparency in administrative processes.

Typical pathway for estab. CMMI model under APA

1 Agency Issues Notice of Proposed Rulemaking (NPRM)

The agency initiates the notice-and-comment rulemaking process by publishing an NPRM in the *Federal Register* (see IIB-001). The NPRM must describe the proposed rule, the legal authority for the rule, and opportunities for public participation. Many agencies also use their websites, social media, and other means to notify the public of rulemakings (see ACUS Recs. 2013-5, 2011-8).

2 Agency Provides Opportunity for Public Comment

The agency must provide the public an opportunity to participate in the rulemaking through electronic or paper submission of written comments. Public comment periods often last at least 30–60 days from publication of the NPRM (see ACUS Rec. 2011-2). Many agencies have also adopted additional methods to engage with and elicit input from the public (see ACUS Rec. 2018-7). Agencies make comments, along with the NPRM and supporting materials, publicly available in an online docket (see ACUS Rec. 2013-4, IIB-005).

3 Agency Considers Comments and Develops Final Rule

After the comment period, the agency must consider all relevant, timely-submitted comments. If it decides to issue a final rule, the agency develops the regulatory text along with a preamble explaining the rule's basis and purpose and responding to all significant issues raised in the comments.

4 Agency Publishes Final Rule

The agency concludes the rulemaking by publishing the final rule and preamble in the *Federal Register* (see IIB-001). The notice must specify the rule's effective date, which must be at least 30 days after publication in the *Federal Register* (and at least 60 days after publication for "major" rules, as defined in the Congressional Review Act, 5 U.S.C. § 801).

The typical 30–60-day notice-and-comment period was omitted in the 2020 MFN model, which was the primary reason HHS lost its lawsuits

Agencies must respond to key comments, but we'll flag they are not mandated to incorporate them

ACCC vs HHS – Judge's comments

THE COURT: Before you move on to jurisdiction, though, let's assume, hypothetically, that is properly adopted new method of payment that cut costs and tied those costs more to what other countries are paying might be a good idea somewhere down the road. Can you explain to me, and can you point to the evidence in the rule itself, that justifies the good cause exception. As I understand that, it's a burden on the government, and the burden's got to show how allowing this comment would harm the public interest.

I'm not, you know, going to debate with you whether ultimately a rule like this might or might not be a good thing. But what we're talking about right now, I have a hard time seeing how, as I say, dispensing with notice-and-comment is going to harm the public interest. And that is my

We noted the judge focused on the mandatory **notice-and-comment period outline in the APA**. She was skeptical that the government's argument of COVID-19 and the cost of high drug prices in the US were sufficient to warrant dispensing of the notice period. Our view is this is an easy fix in the future, making CMMI a potential avenue to implement MFN

Critically, we noted the judge **decided not to comment on the content of the MFN rule – rather only focused on the APA procedural violation. This is in line with Section 1115A(2) that prevents the judicial review of CMMI models based on content, scope, and budget**

Section 1115A(2)

(2) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

(A) the selection of models for testing or expansion under this section;

(B) the selection of organizations, sites, or participants to test those models selected;

(C) the elements, parameters, scope, and duration of such models for testing or dissemination;

(D) determinations regarding budget neutrality under subsection (b)(3);

(E) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and

(F) determinations about expansion of the duration and scope of a model under subsection (c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

Source: Jefferies analysis, Pacer

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There were 5 main lawsuits filed against HHS to block it – 4 out of 5 were successful in stopping MFN based on APA violations & 1 was dismissed on lack of subject matter jurisdiction by the court

Plaintiff	Summary of Arguments
REGN	**1) Insufficient notice period per APA** (5 U.S.C. §§553(b)-(c)); lack of good cause violation of 60-day notice period (42 U.S.C. §1395hh(b)(1)); 2) Excessive transformative changes from CMMI under section 1115A 3) MFN Rule is arbitrary (5 U.S.C. §706(2)(A)); 4) Violates separation of powers (.U.S. Const. art. I, §1, §7, cl. 2- 3.); 5) Violates first amendment (Buckley v. Valeo, 424 U.S. 1, 14 (1976)); 6) Irreparable harm to company (5 U.S.C. §702)
ACCC	**1) Insufficient notice period per APA** (5 U.S.C. §§553(b)-(c)); lack of good cause violation of 60-day notice period (42 U.S.C. §1395hh(b)(1)) 2) Excessive transformation changes from CMMI under section 1115A; 3) irreparable harm to patients and company (85 Fed. Reg. at 76,236–37.)
PhRMA	**1) Insufficient notice period per APA** (5 U.S.C. §§553(b)-(c) & rule is arbitrary 5 U.S.C. § 706(2)(A) 2) Final rule creates closed drug distribution system (21 C.F.R. § 314.50); 3) Lack of experience to handle public health threat (21 C.F.R. § 314.50); 4) MFN rule undermines DSCSA safeguards (21 C.F.R. § 251.14(c)(4)(ii)); 5) Compromises trade secrets (21 C.F.R. § 251.16(g)). 6) Violates first amendment free speech rights (U.S.C. Amendment 1)
BIO	**1) Insufficient notice period per APA** (5 U.S.C. §§553(b)-(c)); lack of good cause violation of 60-day notice period (42 U.S.C. §1395hh(b)(1)); 2) Exceeds CMS statutory authority under 42 U.S.C. 3) irreparable harm to trade organization companies (42 U.S.C. § 1396r–8(b)(3)(A)(iii)).
COA	**1) Insufficient notice period per APA** (5 U.S.C. §§553(b)-(c)); 2) Exceeds CMS statutory authority under 42 U.S.C. §1315a; 3) Rule is unconstitutional under separation of powers (.U.S. Const. art. I, §1, §7, cl. 2- 3.); & non-delegation doctrine

Source: Jefferies analysis, Pacer

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We did want to flag one interesting point from the court cases…while courts didn't comment on the content of the 2020 MFN, they did rule against REGN's & BIO's CMMI overreach argument on a point of technicality (the co's conflated subchapters 1315a & 1395)

REGN, ACCC & BIO argued CMMI overreach under Section 1315(a)(1)

REGN:

The first clue that the government is way over its skis in its reliance on Section 1115A is that the provision grants authority to CMMI, an ACA-created entity authorized to experiment with innovative "models." It is not a grant to CMS itself to make "transformative" changes on the most important issues that CMS addresses. Further, although the statute does not define "model," it describes the characteristics of a qualifying "model," repeatedly referencing "payment and service delivery models," *id.* §1315(a)(1), (a)(5), (b)(1), and providing that such models must "address[] a defined population for which there are deficits in care" leading to "poor clinical outcomes or potentially avoidable expenditures," *id.* §1315a(b)(2)(A). But the MFN Rule goes far beyond how payments or services are delivered; it changes *substantive* reimbursement law, and it applies to

ACCC:

The MFN Rule Exceeds CMS's Statutory Authority

77. The authority invoked by the MFN Rule, Social Security Act Section 1115A, authorizes CMMI "to test innovative payment and service delivery models." 42 U.S.C. § 1315a(a)(1). That testing authority is subject to narrow and strict requirements about what may be tested, how a test is evaluated, and under what circumstances a test can be expanded.

BIO:

48, § 3021, 124 Stat. 119, 389 (2010) (codified at 42 U.S.C. § 1315a). The purpose of CMMI is to test innovative payment and service delivery models to reduce program expenditures under Medicare and/or Medicaid] while preserving or enhancing the quality of care furnished to individuals under such subchapters." 42 U.S.C. § 1315a(a)(1).

62. Under this provision, HHS has limited authority to waive or amend certain Medicare provisions "solely" for purpose of running "tests" on "payment and service delivery models." 42 U.S.C. § 1315a(b)(1). The results of Phase I tests must be evaluated and, if certain requirements are

- **Plaintiffs argued that CMMI overstepped its authority conducting a nationwide MFN model**
- HHS rebuttal was always that Section 1115A stated it 'may elect to limit testing of a model to a certain geographic area' (but that it was not a requirement).
- That said, the courts ruled the argument was not accurate **due to conflation of the application of subchapters of 1315a & 1395 to this scenario**. We'll flag argument were stopped on this technicality, but also Section 1115A does not mandate models are limited in geography, therefore we think the argument would not work even if argued correctly

REGN vs HHS: Court Ruling

discussed, the last sentence of § 405(h) bars federal courts' jurisdiction only for "any claim arising under this subchapter." 42 U.S.C. § 405(h). And § 1395ii applies this provision only "with respect to this subchapter." 42 U.S.C. § 1395ii. Section 1395ii also is located in Subchapter XVIII. By contrast, Section 1115A and the Secretary's source of rulemaking authority under Section 1115A are both located in Subchapter XI. *See* 42 U.S.C. §§ 1302, 1315a. Neither section incorporates § 405(h), *id.*, but other provisions of Subchapter XI do, *see*

15

Case 7:20-cv-10488-KMK Document 45 Filed 12/30/20 Page 16 of 30

e.g., 42 U.S.C. § 1320a-7(f)(3), suggesting that Congress did not intend § 405(h) to apply to §§ 1302 or 1315a.

BIO vs HHS: Court Ruling

1. Judicial review. As Judge Blake explains, the bars on judicial review contained in 42 U.S.C. §§ 405(g), (h) do not apply to this case. The defendants cite 42 U.S.C. § 1395ff(b), which incorporates the bars in section 405 into the Medicare statute, but that provision applies to appeals of initial determinations of benefits under part A and part B of subchapter XVIII ("Health Insurance for Aged and Disabled"). Section 1395ii similarly incorporates section 405(h into the Medicare statute, but only "with respect to this subchapter"—subchapter XVIII. *See* 42 U.S.C. § 1395ii. Here, the plaintiffs challenge the government's implementation of a model

Case 3:20-cv-08603-VC Document 50 Filed 12/28/20 Page 2 of 4

under 42 U.S.C. § 1315a, which is in subchapter XI ("General Provisions, Peer Review, and Administrative Simplification"). Section 1320a-7 applies the bars on judicial review in section 405(h) to parts of subchapter XI, but not to section 1315a. *See* 42 U.S.C. § 1320a-7(f). Because the plaintiffs' claims do not "arise under" any of the subchapters or sections subject to section

Source: Jefferies analysis, Pacer

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Overall, we believe a broad CMMI pilot would be difficult to implement due to patient harm – importantly, Section 1115A explicitly states the CMMI model CANNOT reduce the quality of care, even if it reduces spend

Section 1115A: (b) (2) (A) & (3) (B) (1)

(2) SELECTION OF MODELS TO BE TESTED.—

(A) IN GENERAL.—The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title. The models selected under this subparagraph may include, but are not limited to, the models described in subparagraph (B).

(A) INITIAL PERIOD.—The Secretary shall not require, as a condition for testing a model under paragraph (1), that the design of such model ensure that such model is budget neutral initially with respect to expenditures under the applicable title.

(B) TERMINATION OR MODIFICATION.—The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to—

(i) improve the quality of care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under the applicable title;

(ii) reduce spending under the applicable title without reducing the quality of care; or

(iii) improve the quality of care and reduce spending.

We noted that in **section 1115A (b) (2) (A), "preserving or enhancing the quality of care" is a key factor in the selection of models for implementation.** Likewise in **section 1115A (3) (B) (1), "improve quality of care" is a key measure for a successful CMMI model**. That said, we think if a model poses a risk of patient harm, it could worsen outcomes/ decrease quality of care and therefore face valid legal challenges requiring the secretary to remove the model.

We split our CMMI model analysis into 2 groups to determine the read across based on precedence for a pot'l future MFN model

1) Models that received significant pushback during the notice-and-comment period based on patient harm/access/care quality concerns and did not enter the pilot phase (Ph.1)

2) Broad models that DID enter the pilot phase, but DID NOT show significant improvement in patient care/quality/access. For these, we performed an analysis of using the following criteria for CMMI models:

1) At least two years of model performance published through evaluation reports on CMMI's website (to evaluate outcomes related to patient harm/access/care quality)
2) Broad models with more than 5 different sites (we suspect an MFN CMMI model would be broad)

Source: Jefferies analysis, Section 1115A

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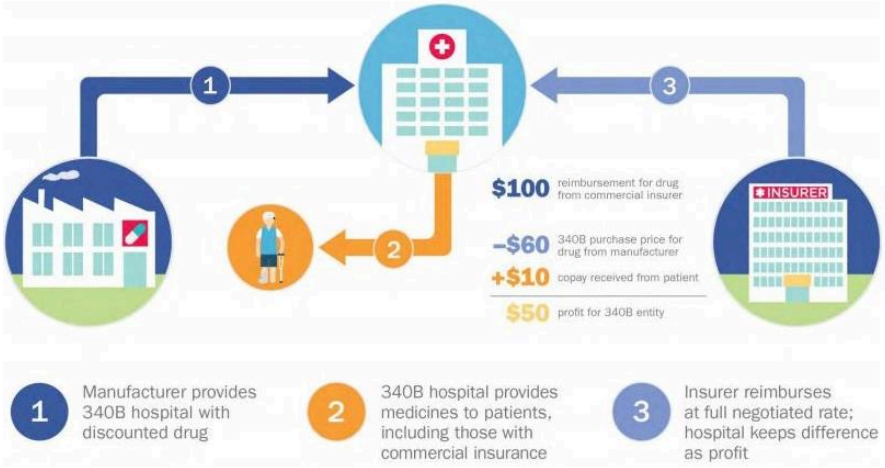
We think an MFN model could theoretically reduce patient quality of care by limiting the access of drugs – our KOL calls suggest that if economics/reimbursement for certain drugs worsen (via either MFN pricing or other avenues of price negotiation) then hospitals & pharmacies may no longer make it available to pts over time

KOL Call #1 HERE :

- Our KOL highlighted that a CMMI model **cannot deliver lower quality of care or harm patients. He noted the big litmus test would be if patient access is affected, which is critical in determining if a model is successful and can be moved forward. If patient access is impeded, programs will be scaled back, as historically seen (e.g.** with Part B Drug Payment model).
- He believes it will face significant opposition from providers and hospitals based on drug access concerns for patients and having to renegotiate contracts with wholesalers of drugs
- KOL believes if Medicare is included broadly in MFN, **it would face tremendous opposition from providers - particularly community oncologists.**
- He believes **it will face significant opposition from providers and hospitals based on drug access concerns for patients** and **having to renegotiate contracts with wholesalers of drugs** (as was seen with Part B Drug Payment Model stopped in 2016).

KOL Call #2 HERE:

- **Our KOL (payer) flagged that pharmacies may not be incentivized to buy highly rebated drugs (eg, Januvia) for less than its AWP price since payers will only reimburse that amount. Otherwise, the pharmacy loses money to sell the product. Further, our KOL stated that for some IRA negotiated drugs, he as a payer would push patients to a branded competitor product (eg Januvia vs Jardiance) because 1) payer gets rebates & 2) pharmacies still make money (or at least won't lose money) + while he would cover Januvia given it's federally mandated, he would likely promote elsewhere**
- Our KOL mentioned that during the Obama administration's 2016 proposal to tweak Medicare reimbursement from ASP +6% to ASP +2.5% + $16, the operational hurdle was high. **Particularly, hospital revenue cycle processes and claims systems were fundamentally built around the ASP +6% structure and workflows were hardwired into the infrastructure.** Changing the reimbursement will lead to large-scale changes in the operating system.



Example of MFN impact to US HC system – 340B hospital:

- Keep in mind that the 2020 MFN model didn't directly lower prices, but lowered reimbursement for providers
- Through 340B, hospitals receive drugs at a discounted price and reimburse them at list price, leading to a price difference between the discounted price and list price to generate savings.
- According to a report from the Office of the Inspector General, most 340B discounts range from 25% to 75% of the amount Medicare pays for physician-administered drugs and apply to all drugs purchased by the safety-net provider, not just drugs for patients who are uninsured or low income

Source: Jefferies analysis

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We looked at 2 categories of precedents to understand how harm/quality of care is determined: 1) we collected prior CMMI models that were stopped after/during the notice-and-comment period & think that the IPI, RO, and Part B Drug Payment Models have potential read-across

Model Name	Status	Date Withdrawn/ Delayed	Reason for Withdrawal/ Delay
Most Favored Nation (MFN) Model	Withdrawn	February 28, 2022	Legal challenges for APA violations; CMS officially rescinded the model via final rule.
Radiation Oncology (RO) Model	Earliest legal start Jan 1 2023, but new start date not proposed	2022	Implementation delayed multiple times due to Protecting Medicare and American Farmers From Sequestering Cuts Act; CMS suspended the model indefinitely.
International Pricing Index (IPI) Model	Withdrawn	2020	Proposed to align Medicare Part B drug payments with international prices; faced opposition and was withdrawn to become MFN 2020 model
Part B Drug Payment Model	Withdrawn	Oct 4th 2017	Concerns 1350 comments expressing concern over lowering ASP to 2.5%
Medicare $2 Drug List Model	Withdrawn	March 12, 2025	Withdrawn following the rescission of Executive Order 14087.
Accelerating Clinical Evidence (ACE) Model	Withdrawn	March 12, 2025	Withdrawn following the rescission of Executive Order 14087.

We noted MFN (2020), RO, IPI, and Part B were stopped/delayed before entering the pilot phase, so we looked at these further to determine the read across to a pot'l future MFN model

We noted **the Medicare $2 and the ACE were terminated due to recession of EO 14087** – a Biden era EO aimed at reducing drug prices that Trump stopped on his first day in office. We felt this circumstance would not read across to a future MFN model, since we don't expect Trump to rescind his MFN EO from May 12, 2025.

Source: Jefferies analysis, CMS.gov

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a) Part B Drug Payment Model (change Part B to ASP 2.5% + $16.80) is a good precedent – it was withdrawn post pushback in notice & comment period from medical community & Congress which highlighted concerns re: reduced drug access, higher physician/hospital purchasing costs & lower quality/disruption of care in the sickest seniors

As a background, the Part B Drug Payment Model was Obama Admin's proposal to change the ASP + 6% model established under Medicare Part B into ASP 2.5% + $16.80 to decrease Medicare costs while improving the quality of care. In the **first phase, the model proposed altering the current 6 percent add-on to the Average Sales Price (ASP) used for Part B drug payments to 2.5 percent plus a flat fee, ensuring budget neutrality. The second phase would introduce value-based purchasing strategies akin to those used by commercial health plans, pharmacy benefit managers, hospitals etc.**

In <1 year of the proposal, CMS ultimately decided not to implement that program, **citing the "complexity of the [stakeholder] issues and the limited time available led to the decision not to finalize the rule."**

Medicare Program; Part B Drug Payment Model:
2016-05459 (81 FR 13230)

TABLE 1: Summary of the Proposed Model

Phase 1 – ASP+X (no earlier than 60 days after display of final rule, Fall 2016)	Phase 2 – VBP (no earlier than January 2017)
ASP+6% (control)	ASP+6% (control)
	ASP+6% with VBP Tools
ASP+2.5% and Flat Fee Drug Payment	ASP+2.5% and Flat Fee Drug Payment
	ASP+2.5% + Flat Fee Drug Payment with VBP Tools

Community Oncology Alliance (COA) to CMMI director

the Part B Proposal. Please understand that it is not hyperbole when we say that we are pursuing every possible avenue to stop this dangerous experiment on cancer care, including legal action. Otherwise, the Part B Proposal will adversely impact the cancer care provided to Medicare patients and effectively treat them as second-class citizens by diminishing the highest quality medical treatment to which they are entitled under Medicare.

Alliance of Community Health Plans (ACHP) to CMMI director

price means that some providers (and health plans) are paying more than ASP, some are paying less. Price negotiations with manufacturers are likely to be affected by the volume of drugs purchased by the provider or plan. Those with less purchasing clout may pay above average prices for drugs. Given that these provider groups already have to absorb the effects of sequestration, the payment changes called for by phase I of the proposed model may force them to re-evaluate how they continue to practice. It is not unreasonable to anticipate that some would refer patients to other providers (shifting many to outpatient hospital departments, for example) and some may decline to accept Medicare patients, outcomes which would create disruptions in care and potential access problems. We urge CMS to monitor for this potential effect to ensure beneficiaries are receiving timely and appropriate care.

Congress to CMMI director

Dear Acting Administrator Slavitt:

We write to express our deep concerns regarding the Centers for Medicare & Medicaid Services (CMS) "Part B Drug Payment Model" proposed rule, published in the *Federal Register* on March 11, 2016. CMS's proposed Medicare drug experiment would unnecessarily disrupt care for the sickest seniors who depend on Medicare, including those with cancer, macular degeneration, rheumatoid arthritis, neurological disorders, rare diseases and primary immunodeficiency diseases. Given these concerns outlined here, we ask that CMS withdraw this proposed rule that could endanger access to care for America's most vulnerable seniors.

Immune Deficiency Foundation to CMMI director

Many patients lost access to Ig in the physician's office as well as in the home. As a result of the MMA cuts, intravenous immunoglobulin (IVIG) therapy (the only Ig therapy at the time) in the physician's office was nearly eliminated because physicians could not afford to administer infusions. Even though Medicare covered home infusions, the

Org's lobbied against CMMI director Slavitt. We'll flag pts harm & drug access were common themes:

COA said it was lowering standard of care because acquisition of the ideal cancer drugs will be difficult using existing contracts and this would adversely impact care for pts. Congress flagged in its letter that the model **would "severely harm patient access to drugs" and "make it harder for patients to receive the drugs they need"** – which implies there would be patient harm if implemented. **IDF commented against the model citing patient access to critical therapies as their concern, as well as adequate reimbursement for providers. ACHP also made a comment about patient access concerns, as well as their member providers being able to get adequate reimbursement for their prescribed drugs.**

Read across to MFN? Arguments of: 1) patient harm, 2) critical drug shortage, 3) financial harm to providers has been shown effective to stop a CMMI model *(caveat: CMS must voluntarily withdraw model - no external party stopped them*). We speculate a large public pushback to MFN would decrease the public approval and increases PoS for voluntary withdrawal by CMS.

Source: Jefferies analysis, CMS.gov

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b) Similarly, the IPI model (came before the MFN 2020 model) for Medicare Part B drugs which wasn't implemented also had significant pushback medical & pt care orgs expressing concerns around patient access and lack of safeguards for patients

As a background, the International Pricing Index (IPI) Model, aimed to reduce Medicare Part B drug spending by aligning U.S. prices by using average international prices from 14 OECD countries to benchmark payments for a subset of physician-administered drugs representing approximately 50% of Part B drug spending. Providers in selected geographic areas would no longer purchase drugs directly; instead, Medicare-selected private vendors would buy and distribute the drugs, assume the financial risk, and bill Medicare. Providers would receive a fixed add-on payment per drug administration, replacing the existing 6% add-on, while CMS reimbursed vendors based on the new international reference prices.

Feature	International Pricing Index (IPI) Model	Most Favored Nation (MFN) Model
Announcement Date	October 30, 2018 (ANPRM only)	November 20, 2020 (Interim Final Rule)
Implementation Status	Never implemented (no proposed/final rule)	Blocked by courts (APA procedural violation)
Participation	Mandatory for selected geographic areas (not specified before model abandoned	Mandatory nationwide for providers billing Part B (excl. applied)
Scope	Limited set of Medicare Part B drugs (based on top spend)	Top 50 Medicare Part B drugs by spending
Drug Payment Reform	Based on average international prices from select countries	Based on lowest international price among selected countries
Vendor Involvement	Introduced vendors to purchase and distribute drugs	No vendors; Medicare paid providers directly
Provider Payment	Fixed add-on payment per drug (replacing % add-on)	Included administrative add-on payment per dose

Organization	Key concerns raised
American Association for Respiratory Care (AARC) + 338 add'l orgs	Foreign price controls; vendor disruptions; restrict drug access short-term, and reduce incentives for medical advancement in the long-term, **ultimately posing serious risks to vulnerable Medicare beneficiaries**.
American Society of Health-System Pharmacists (ASHP)	**Could limit access to care for patients**; complexity in drug distribution; DSCSA compliance concerns
National Pharmaceutical Council (NPC)	**Impedes patients access to healthcare services and products**; Uncertainty whether there will be cost savings
Partnership to Improve Patient Care (PIPC)	**Scale of model removes safeguards for patients**; Use of QALYs is discriminatory against seniors for drug access
American Medical Association (AMA)	**No mechanism to safeguard patients**; concerns over timely access to treatments; **concerns for biologic access leading to pot'l patient harm**; inability to opt-out if supplier is not reliable; **single-source drug limits will raise access issue**

Source: Jefferies analysis, CMS.gov

We noted that key themes in lobbying letters were **drug access concern, patient harm concerns, and removal of patient safeguards**. We'll flag we continue to see during the notice-and-comments section, these arguments remain effective in preventing CMMI models from progressing (like with the Part B Drug payment model). ***Read across to MFN? We think highlighting access to care and safeguarding issues are effective (caveat: it's tough to say if IPI was dropped by CMS because MFN was coming out or for genuine concern over these comments).***

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c) We'll also call out that the Radiation Oncology (RO) model which targeted bundled Medicare payments for radiation tx received pushback/concerns around pt access to high-quality radiation tx & financial harm…Congress delayed implementation (to Jan 1 '23 at the earliest – although this has still not been implemented)

As a background, the Radiation Oncology (RO) CMMI model (**July 10, 2019)**, was a mandatory, 90-day episode-based payment model designed to test whether bundled payments for radiation therapy could reduce Medicare costs while maintaining care quality. It covered **16 cancer types** and targeting Physician Group Practice (PGP), (inc. freestanding radiation therapy centers) and Hospital Outpatient Departments (HOPDs), it included separate bundled payments for professional and technical services, quality reporting requirements, and performance-based adjustments. **It was set to launch on January 1, 2021** and the model aimed to shift radiation therapy from fee-for-service to value-based care but was delayed until January 1, 2023 by the 'Protecting Medicare and American Farmers from Sequester Cuts Act' (Section 5**). No official start date has been set.**

The AHA wrote a letter to the CMS director to **express financial concerns about the model's TC and PC discount rate,** but more importantly, **the pot'l patient access issue to radiation therapy services.** Likewise, ASTRO released a statement along similar lines expressing **concern for patient access to high quality radiation oncology.** We'll flag that there were **also concerns over the proposed discount rates and the implementation during the COVID-19 pandemic**. As such, there was sufficient concern over the model such that Congress delayed it.

We think this is important for 2 reasons:

1) This sets a precedence that **patient access concerns are a valid argument to take to Congress to delay the implementation of a CMMI model.**
2) Section 1115A(g) does not give authority to Congress to change the content of a CMMI model. It only mandates that the HHS sec. reports & justifies what becomes national in scale. **However, as evidenced here, Congress does in fact have power to delay models without an explicit mandate in section 1115A**. We think this could be a pot'l avenue for pharma co's, healthcare associations, and patient access groups to delay an MFN rule if it were to get implemented under CMMI.

AHA complaint to CMS director (2021)

and mandatory nature of the model. **We also remain extremely puzzled as to why the TC discount factor was higher than the PC discount factor.** This was quite concerning to us given that hospital TC providers have little ability to impact the treatment plan/episode cost and make all the capital investments for radiation therapy. Yet at the same time, they could not earn a 5% advanced APM bonus under the Quality Payment Program through participation in this model, unlike PC providers. **We continue to believe that lower TC and PC discounts at 3% or less are much more appropriate and would help ensure all patients retain access to radiation therapy services.**

Stop-loss Policy. CMS's stop-loss policy was also of concern because it applied only to participants with 60 or fewer episodes during the baseline period. We do not understand this limitation — the number of episodes a participant performs is unrelated to case complexity, for which stop-loss policies are designed to account. We are worried that under this policy, outlier patients could have lost access to services either at their home facility or at highly specialized locations to which they travel for care. **As such, we urge CMS to apply future stop-loss policies to all participants.**

ASTRO statement against RO

"ASTRO is still reviewing the minor changes, but we are disappointed that CMS's radiation oncology model continues to emphasize significant payment cuts on practices that have no choice but to participate," Adler said. "Unfortunately, the RO Model reductions today and massive Medicare physician payment cuts to radiation oncology will risk access to high quality radiation therapy for patients."

(g) REPORT TO CONGRESS.—Beginning in 2012, and not less than once every other year thereafter, the Secretary shall submit to Congress a report on activities under this section. Each such report shall describe the models tested under subsection (b), including the number of individuals described in subsection (a)(4)(A)(i) and of individuals described in subsection (a)(4)(A)(ii) participating in such models and payments made under applicable titles for services on behalf of such individuals, any models chosen for expansion under subsection (c), and the results from evaluations under subsection (b)(4). In addition, each such report shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.

Source: Jefferies analysis, CMS.gov

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Interestingly, while CMS didn't specifically address the concerns around patient "harm" for the RO model, they did acknowledge them & stated they'll "evaluate how best to proceed"

RO Model Comment: patient access concerns

Comment: Some commenters requested that the RO Model as it is currently designed be cancelled altogether. These commenters noted that they believe that the Model as currently designed does not align with the Biden Administration's Cancer Moonshot goal of increasing access to innovative and appropriate cancer care. Specifically, commenters were concerned the Model would impact equitable access to proton therapy and future innovation in radiation oncology. Some commenters stated that CMS should work with interested parties to redesign the Model with respect to, for example, the discounts, mandatory participation, billing requirements, quality and clinical reporting, included modalities, and the Advanced Alternative Payment Model (APM) bonus. (printed page 52701)

Response: We appreciate these comments. However, we do not agree with the comments that the RO Model should be cancelled. As noted previously, we continue to believe that the RO Model will address long-standing concerns related to delivery and payment of RT services and benefit RT providers and RT suppliers as well as beneficiaries, because of the RO Model's focus on financial predictability through prospective, site-neutral, episode-based payment and care improvement by linking payment to quality. The RO Model is designed to test an innovative approach to payment and service delivery in the field of radiation oncology. We welcome further dialogue with interested parties and RO participants about the design of the RO Model.

We'll call out this comment raised concerns about **patient access to proton therapy and radiation oncology** – thereby suggesting that if the model were to be implemented there would be patient harm. CMS responded saying they do not agree because the RO model links payment to quality. **We noted that CMS did not specifically address the concerns about patient access.**

RO Model Comment: health equity and health disparity

Comment: Many commenters provided feedback not directly related to our proposal to delay the start date of the RO Model to a date to be determined through future rulemaking. These comments concerned a range of issues, including participation requirements and criteria, the geographic size of the Model, included modalities, Advanced APM incentive payment under the Quality Payment Program (QPP), and the Model's pricing methodology (for example, the national base rates, trend factor, case mix and historical experience adjustments, blend, and discount rates). Commenters also provided feedback related to the RO Model's potential impact on rural practices, health equity, and health disparities, as well as the burden of collecting and reporting the clinical data elements and the quality measures, and the burden of the RO Model's billing requirements. Commenters also discussed patient navigation tools, the beneficiary notification letter, and how the RO Model does or does not align with the goals of the Biden Administration's cancer agenda and the Cancer Moonshot.

Response: We appreciate these additional comments, which we may further consider as we evaluate how best to proceed with the RO Model going forward. As noted previously, we continue to welcome further feedback and dialogue with interested parties and RO participants on the design of the RO Model.

This comment raised **concerns of geographic size, impact on rural activities and health equity/patient care access**, however we'll note **CMS response did not directly address these**. **Our read is, while CMS is required to respond to major comments, it would not appear that the response has to be substantive in addressing them.**

Read across to pot'l MFN model (from CMS' perspective): We expect in a pot'l MFN model comments on the same subject of patient access/quality would be raised. Based on our analysis of RO model comments, **it appears CMS can choose to not directly address concerns of patient access. That said, as we noted earlier, these same concerns can be used by Congress to delay a model. We think that if Trump were to implement MFN through a CMMI program, an effective way to stop it would be to highlight patient access concerns both to CMS and to Congress.**

Source: Jefferies analysis, CMS.gov

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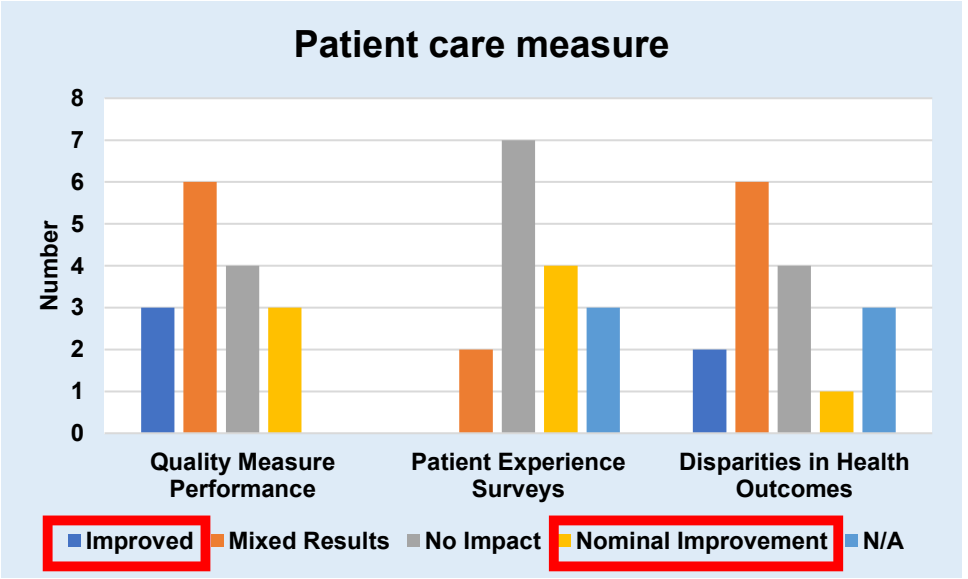
2) Our illustrative analysis of broad CMMI models that made it past the notice & comment period and into Phase 1 (pilot) suggests that a lack of pt care/quality improvement & high cost can prevent model from moving into Phase 2 (wide/national implementation)

Model	Number of Participants	Quality Measure Performance	Patient Experience Surveys	Disparities in Health Outcomes	Model Outcome Summary
Accountable Health Communities (AHC)	28	Mixed Results	No Impact	Mixed Results	Not Active; Mixed results in quality and disparities; increased readmissions
Bundled Payments for Care Improvement Advanced (BPCI-A)	170 participants, 208 Episode Initiators	No Impact	No Impact	Mixed Results	Active; No impact on quality or patient experience; mixed disparities
Bundled Payments for Care Improvement (BPCI)	N/A	No Impact	No Impact	No Impact	Not Active; No improvement in outcomes; negative patient experience
Comprehensive Care for Joint Replacement (CJR)	324 hospitals in 34 MSAs	Nominal Improvement	Mixed Results	Mixed Results	Active; Nominal improvement in care quality; mixed disparities
Comprehensive ESRD Care (CEC)	33	Improved	No Impact	Improved	Not Active; Improved quality and disparities; no change in experience
Comprehensive Primary Care Initiative (CPC)	442	Mixed Results	Nominal Improvement	N/A	Not Active; Mixed quality outcomes; nominal patient experience improvement
Comprehensive Primary Care Plus (CPC+)	2610	Mixed Results	No Impact	No Impact	Not Active; Mixed quality; no patient experience or disparities improvement; large cost
ESRD Treatment Choices (ETC)	N/A	No Impact	No Impact	No Impact	Terminating early (2025); No improvement across all domains
Maryland Total Cost of Care (TCOC)	550	Improved	No Impact	Improved	Active; Improved quality and disparities; no impact on experience
Medicare Advantage Value-Based Insurance Design (MA VBID)	65 (2025 only)	Improved	Nominal Improvement	No Impact	Terminating 2025; High costs, nominal experience improvement, no disparity impact
Million Hearts: CVD Risk Reduction	319	Mixed Results	N/A	Nominal Improvement	Not active; Mixed quality; increased hospitalizations; nominal disparity improvement
Next Generation ACO Model	35	No Impact	N/A	Mixed Results	Not Active; No quality improvement; mixed disparities
Oncology Care Model (OCM)	122 practices, 5 payers	Nominal Improvement	Mixed Results	Mixed Results	Not active; Nominal quality gains; mixed patient experience and disparities
Part D Enhanced Medication Therapy Management (Enhanced MTM)	6	Mixed Results	Nominal Improvement	N/A	Not Active; Mixed results; some nominal improvement in experience
Primary Care First (PCF)	1752	Mixed Results	N/A	N/A	Terminating 2025; Mixed results, poor cost performance



We collected a list of broad CMMI pilot programs that made it into Phase 1 - our analysis showed most broad CMMI models did not show an improvement/nominal improvement in patient care/quality measures, however when combined with high costs, models that reported either no improvement, or mixed results, CMS chose to discontinue/not renew them

Caveat: While we have data on model outcomes, the exact reason why some of these models were terminated/not-renewed by CMS oftentimes is not disclosed

Source: Jefferies analysis, CMS.gov

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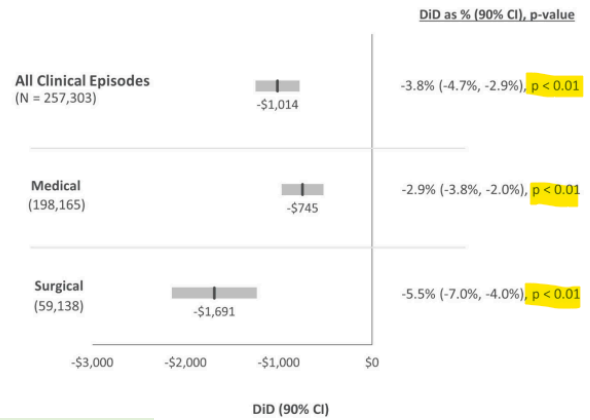
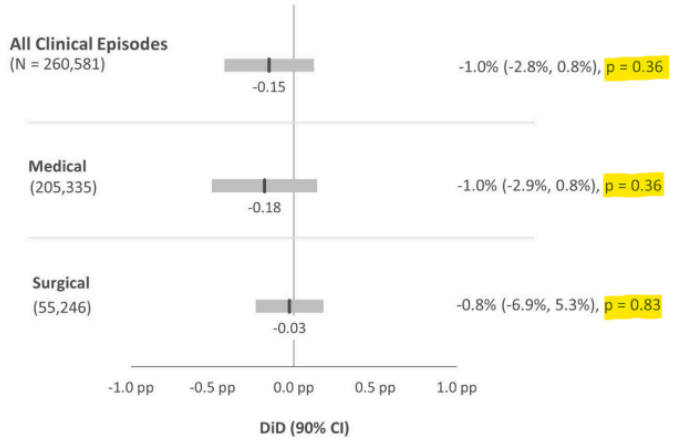
Looking at a few specific examples: a) We'll call out that the BPCI-A model demonstrated that cost-saving alone is enough to keep a model active as long as there's no decrease in pt care standards

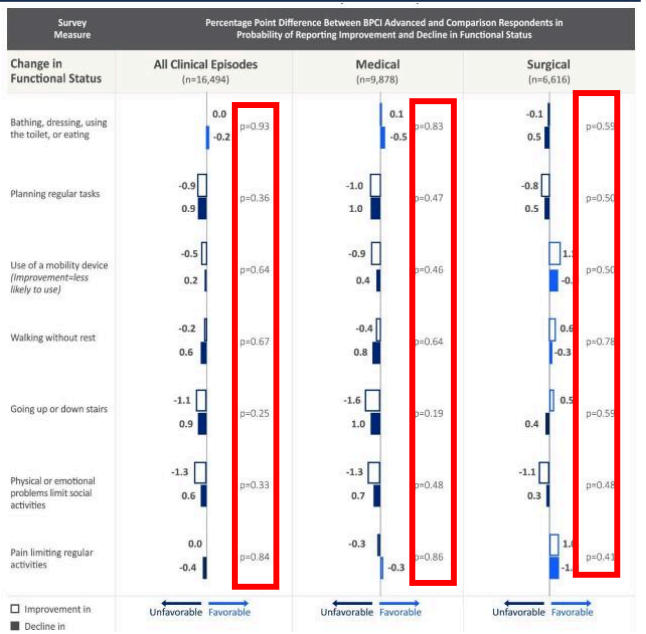
As a background, the BPCI Advanced Model aims to facilitate coordination among the health care teams and provide patients high-quality care, support a successful recovery, and **reduce the frequency and length of preventable hospital stays and emergency department use.**

BPCI-A model: Cost savings were stat. sig.



BPCI-A model: Care outcomes were not stat. sig





We noted that the BPCI-A model **showed statistical significance in cost savings (p<0.01) for all clinical episodes**, however, **medical and surgical care outcomes were not stat. sig (p=0.36 and p=0.83 respectively). Furthermore, changes in functional status was not stat. sig for any outcome reported (p>0.05). We'll also flag most were trending to unfavorable outcomes.**

Read across to pot'l MFN model? From the BPCI-A model, we observed that cost savings alone are sufficient to justify retaining a CMMI model, so long as there is no decrease in patient care outcomes. We anticipate that an MFN model would successfully be able to show cost savings for the gov't given drug prices would decline, however the big question would be whether there would be a non-stat. sig decrease in patient outcome measures. Given the pushback to the previous MFN model based on patient harm/access concerns, we don't think this would be the case and therefore an MFN model would not stand under CMMI Section 1115A.

Source: Jefferies analysis, CMS.gov

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b) Additionally, CPC model showed pt care improvement on certain metrics (M-PCMH-A), but other metrics weren't positive (eg, ED visits, continuity of care metrics, Medicare savings) so the model wasn't continued

As a background, the **Comprehensive Primary Care (CPC) Initiative** aimed to strengthen primary care. It focused on five key functions: **risk-stratified care management, access and continuity, planned care for chronic conditions and preventive care, patient and caregiver engagement, and coordination of care across the medical neighborhood**. The initiative aimed to improve patient care and reduce Medicare part B costs. It was not renewed in 2017 after running for 4 years.

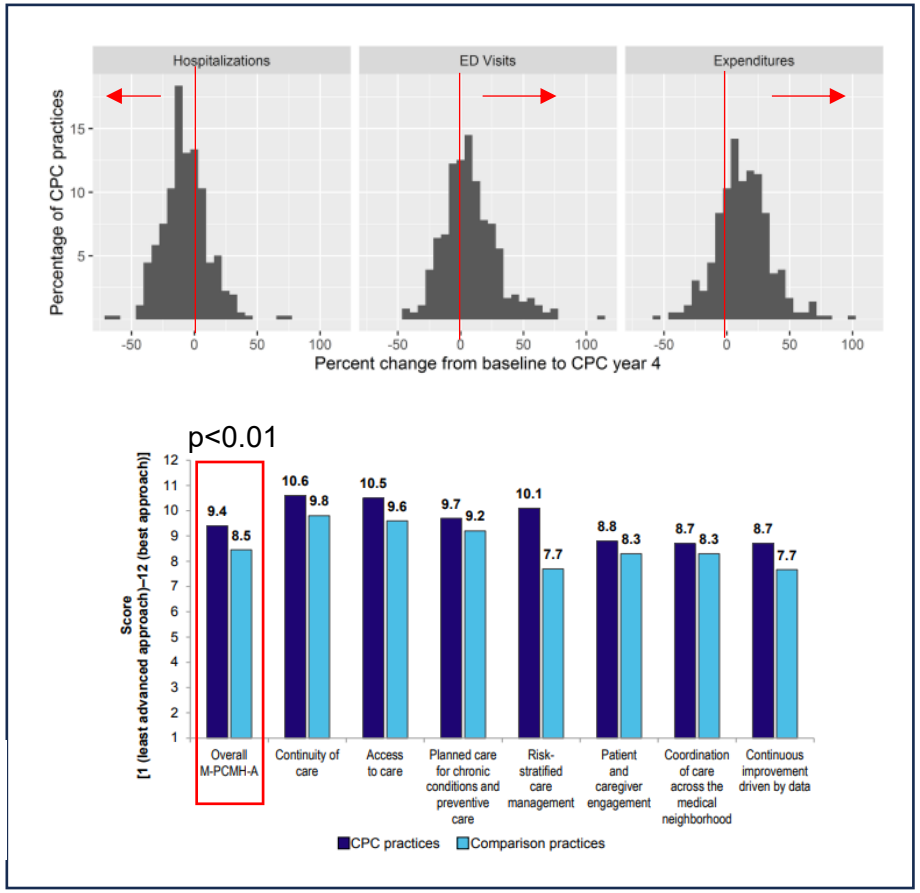
We'll call out that the CPC model is no longer active. It showed a stat sig increase in overall M-PCMH-A from 9.4 to 8.5 (p<0.01) (caveat: stat sig was not achieved for all measures) furthermore, there was no stat sig improvement in continuity-of-care measures and ED visits and expenditures trended towards increase. **Furthermore, there was no stat sig Medicare savings seen (p=0.16)**

Read across to pot'l MFN model? We noted that while there were some improvements to care quality, the increase in ED visits, ED revisits, and ED expenditures coupled with the non-stat sig savings meant the model did not make sense to continue, however the select positive results led to the creation of CPC+ (not active now). **Our read is that even with improvements in pt care, the net-net improvement must be overall positive to warrant transitioning a model to nationwide scale**. We think a pot'l MFN model would be able to show cost savings, but would show a net–negative patient care/access/quality result that overall makes the model detrimental, which could prevent continuation

- **CPC did not lead to statistically significant changes in total Medicare expenditures (excluding care management fees).** Over the course of the initiative, Medicare expenditures without care management fees increased by 1 percent (or $9 PBPM) less for the CPC practices than the comparison practices, but the difference was not statistically significant ($p = 0.16$, 90 percent confidence interval [CI] -$19, $2) (Table ES.2). Lower growth in inpatient expenditures, expenditures on skilled nursing facilities, and outpatient services drove the lower growth in total expenditures for the CPC group.

There were no statistically significant effects on any of the continuity-of-care measures. For all four measures—the percentage of primary care visits at the beneficiary's attributed practice, the percentage of all primary and specialty care visits at the attributed practice, the Bice-Boxerman index based on primary care visits, and the Bice-Boxerman index based on all visits—continuity declined similarly for both the CPC and comparison groups by 4 to 14

CPC led to a slower increase in the likelihood of an ED revisit within 30 days of an outpatient ED visit, but had no discernible effect on other quality-of-care outcome measures. For the quality-of-care outcome measures, there were no statistically significant effects on either ACSC admissions or the likelihood of an unplanned 30-day readmission among



Source: Jefferies analysis, CMS.gov

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c) More importantly, while CJR started as a fully mandatory model, comments questioning CMMI's authority mandate this led to implementation being more lenient (eg, half of the initially planned sites became voluntary)

CJR Model Comment: mandatory model authority
Comment: A commenter stated that the extension of the CJR model continues to raise concerns about CMS' authority to implement a mandatory model, contending that it is an unconstitutional delegation of legislative authority and unfairly targets one-fifth of hospitals and one type of procedure and medical specialty. Another commenter stated that after 5 years of mandatory participation in the CJR model, the extension provides CMS the opportunity to transition CJR to a voluntary model for PYs 6-8. The commenter contended that a mandatory requirement violates the Innovation Center's authority. *Response:* For the reasons we discussed in the CJR model's November 2015 and the December 2017 final rules, we continue to believe that section 1115A of the Act and the Health and Human Services (HHS) Secretary's existing authority to operate the Medicare program authorize the CJR model, including an extension of its duration as well as its mandatory nature. Specifically, sections 1102 and 1871 of the Act give the Secretary the authority to implement regulations as necessary to administer Medicare, including testing these Medicare payment and service delivery models as was done in the November 2015 and the December 2017 final rules.

We'll call out that a comment against the CJR raised concerns of the mandatory nature of the model. CMS response was that the secretary had authority under sections 1102 and 1871 of the ACA. We investigated those sections and suspect they are referring to the following passages:

Section 1871: "The secretary shall prescribe such regulations as may be necessary to carry out the administration insurance programs under this title"

Section 1102: Gives authority to secretary to implement provisions of the ACA

We'll flag that **there is no explicit mention of Section 1115A, Section 1871, or Section 1102 allowing for CMMI models to be mandatory. While CMS does not elaborate further, we'll also flag that during conception the model had 67 sites with mandatory participation, however after launch, they allowed 34 sites to voluntarily participate.**

Read across to Pot'l MFN model: Based on the mandatory part B top 50 drug inclusion in the 2020 MFN mode, if an MFN model were to be implemented by CMMI, **we suspect the admin would try a mandatory model otherwise pharma co's could work around it.** Specifically, we think the drugs included and the national scope would be mandatory. From the CJR model, we concluded CMMI **1) has justified they have the authority to create mandatory model and there has been successful implementation of the CJR as having a mandatory component, 2) referenced sections 1102 and 1871 as their authority to do so.** We expect comments against a mandatory MFN model would question CMMI's authority to create one. **We expect a similar response as in the CJR model, as well as citing past precedence of mandatory models such as CJR. Nonetheless, we think these comments may only partially dilute the mandatory nature of the model, but not outright stop it.**

Source: Jefferies analysis, CMS.gov

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That said, here's how Trump may respond to pt harm concerns: a) MFN 2020 model excluded children's hospitals, cancer hospitals, and rural health hospitals which are key at-risk pop sensitive to access/quality issues…we could see similar carveouts (although we'll note it's difficult to completely carve-out impact while maintaining volume)

We'll flag that children's hospitals, cancer hospitals, critical access hospitals, rural health clinics, and acute care hospitals (year 1) were excluded in the 2020 MFN model. We see one interpretation for this exclusion to be to show that this is a pilot model that does not encompass all healthcare facilities, but another interpretation is they excluded critical hospitals so as to not show a reduced quality of care

We think this is important for 2 reasons:

1) **It prevents hospitals that are most vulnerable to financial harm from an MFN model having to reduce their standards of patient care – reminder: Section 1115A prohibits a reduction in patient quality of care.**
2) **It circumvents the arguments seen in the notice-and-comment period/lobbying efforts for the RO and IPI models that cancer/critical access/rural care will be affected.**

That said, there is a precedence of cancer hospitals and children's hospital being excluded in the AHEAD model nationwide and the model remains active, however, while the RO did exclude critical access & PPS-exempt cancer hospitals, it excluded RT in only a select few states, therefore still leading to patient access concerns being raised.

Comp. Model name	Exclusion Criteria	Outcome
AHEAD (2023)	**Cancer Hospitals; Children's Hospitals;** Long-Term Care Facilities; Psychiatric Hospitals (free standing and distinct part units); Rehabilitation Hospitals (free standing and distinct part units); Transplant Hospitals; Veterans' Hospitals	**Active (6 participants)**
Radiation Oncology Model (2022)	Ambulatory Surgical Centers; **Critical Access Hospitals; PPS exempt Cancer Hospitals;** Furnishes RT services only in Maryland; Furnishes RT services only in Vermont; Furnishes RT services only in U.S. Territories; or Participates in the Pennsylvania Rural Health Model; or Participates in the Community **Transformation Track of the Community Health Access and Rural Transformation (CHART)** Model as a participating hospital.	**Delayed indefinitely**

Read across to pot'l MFN model? Based on precedence, we'll flag that exclusion of key care facilities can work to deter comments about patient access/care quality in the notice-and-comment period, but it looks like they must be nationwide and include: Cancer hospitals, Children's hospitals, rural health hospitals/clinics. Additional exclusions further increase PoS of an MFN model. **We think it's near-impossible to carve out the devastating impact entirely while maintaining MFN as intended, which is why we give a low PoS on a pot'l MFN model because insufficient carveouts will increase risk of comments that stop the model before pilot phase.**

Source: Jefferies analysis, Federal Register

Exclusion criteria: MFN model (2020)

(c) *Excluded providers and suppliers.* The following are excluded from participation in the MFN Model:

(1) Children's hospitals (defined under section 1886(d)(1)(B)(iii) of the Act).

(2) PPS-exempt cancer hospitals (defined under section 1886(d)(1)(B)(v) of the Act).

(3) Critical access hospitals (CAHs) (defined under section 1820 of the Act).

(4) Indian Health Service (IHS) facilities (as described in section 1880 of the Act)), except when MFN Model drugs are furnished and such service is described in section 1880(e)(2)(B) of the Act.

(5) Federally Qualified Health Centers (FQHCs) (defined under section 1861(aa)(4) of the Act).

(6) Rural Health Clinics (RHCs) (defined under section 1861(aa)(2) of the Act).

(7) Hospitals that are not subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act) and are paid on the basis of reasonable costs subject to a ceiling under section 1886(b) of the Act.

(8) Extended neoplastic disease care hospitals (defined in section 1886(d)(1)(B)(vi) of the Act).

(9) For the first quarter and second quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act.

(10) Beginning with the third quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of

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b) CMS could select to use data collection methods that minimize patient quality/access detection to maintain that an MFN model is not leading to patient harm and justify its existence

MFN model (2020) comment: may impact access to care and care experience

topic. Several commenters expressed concern that testing alternative payments for Part B drugs in general may impact beneficiaries' access to care and may impact the overall patient experience of care. Some commenters requested that any quality measurement not add burden to model participants. Some commenters also discussed the importance of adherence to nationally recognized clinical guidelines in treatment decisions, stating that adherence to nationally recognized clinical guidelines would reduce drug spending while also maintaining and possibly increasing quality of care.

We appreciate the public feedback on ways we could structure a model to enhance and monitor quality of care. In the MFN Model, we will implement robust monitoring activities, such as analyzing claims data, using patient survey data, and site visits, to identify any unintended consequences and ensure that MFN beneficiaries' access to medications is not impeded and that quality of care is preserved or enhanced. Further, we believe the following principles are appropriate for a quality measurement approach for the MFN Model: (1) Use quality measures for the purpose of monitoring quality of care and beneficiary access to treatment and experience with care; (2) avoid unnecessary participant reporting burden as many providers and suppliers are currently reporting quality measures to other programs and payers, for example, the MFN Model should use claims-based measures where appropriate; and (3) establish standards for adding quality measures, if necessary, during the model. We believe that this approach will allow CMS to test the MFN Model's alternative drug payment methodology, while creating a safeguard for beneficiary access and quality of care, as well as a means to monitor patient access and quality of care. We are also sensitive to concerns regarding adding administrative burden to MFN participants and beneficiaries and, thus, seek to minimize burden on them. As such, in § 513.400(b)(1) we will collect only one quality measure, focused on patient experience, to help better understand the impact of the MFN Model on beneficiary access and quality of care. This survey will be fielded by CMS to avoid any quality measure reporting burden for MFN participants, although there will be reporting burden on beneficiaries. CMS will also monitor for quality as outlined in section III.I.4. of this IFC, including monitoring access to medications through rapid analysis of claims data, using monthly claims extracts that will provide frequent assessments of beneficiary access to MFN Model drugs and that complement existing methods to receive, assess, and respond to beneficiary and health care provider feedback on the MFN Model.

We believe patient access and care experience may be raised as concerns in a future MFN model and we'll flag they were also raised in the 2020 MFN model. Notably, CMS response to these comments in 2020 highlighted:

1) Patient quality of care is a priority for CMS.

2) CMS would monitor it by conducting surveys/ pulling data themselves (to not burden the model participants).

3) They will only collect data for 1 quality measure patient experience (to reduce administrative burden).

<u>We'll flag several key things about this method:</u>

1) **Only collecting patient experience as a quality measure will omit other critical measures to the benefit of CMS not showing patient care issues.**
2) **Only using claims data will not highlight how many times a patient needed a specific drug covered under MFN but could no longer get access.**
3) **CMS collecting their own surveys could introduce bias that benefits CMS.**
4) **Even still…we don't think patient experience would show improvements if there are issues with drug access/reduced services.**

<u>Read across to pot'l MFN model:</u> We think CMS might try a similar approach to collecting data on patient care quality/access because it will underplay any detrimental patient access/care quality findings that might warrant stopping the model prematurely. That said, we think the omission of key data collection would be challenged.

Source: Jefferies analysis, CMS.gov

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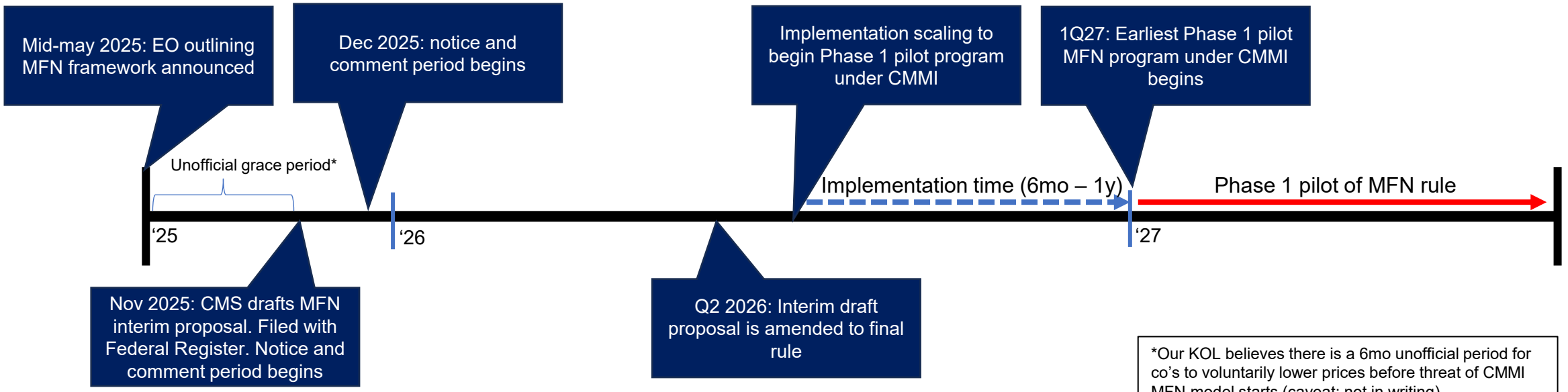
In terms of timelines with a CMMI pilot program, our expert discussions suggest that the earliest we'd see it is 2027 (& it may not hold for long as the political environment changes)



*Our KOL believes there is a 6mo unofficial period for co's to voluntarily lower prices before threat of CMMI MFN model starts (caveat: not in writing)

Our KOL flagged:

1) **Any faster than this timeline, the admin. would likely be skirting laws and run into procedural legal challenges**
2) **With earliest implementation in 2027, it would be after the midterms, so a different Congress may not uphold/block the model**
3) **Even if it holds past 2027, the 2028 presidential election may still lead to the model ending and prices would revert to where they currently stand**

Source: Jefferies analysis

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3) IRA:

Another possible MFN implementation route could be to focus only on IRA selected drugs since: a) there's already a statute in place w/ an established process to select high spend drugs and negotiate lower prices (see below for key terms)

The secretary negotiates prices between February 28 and November 1, and publishes the list on February 1, two years before the price applicability year

- **For 2026**, 10 negotiation-eligible drugs will be selected
- **For 2027, as well as 2028**, 15 negotiation-eligible drugs will be selected
- **For 2029, and each subsequent year**, 20 negotiation-eligible drugs will be selected

The drugs will be selected in the following manner:

1. Rank negotiation-eligible drugs based on the 50 highest Medicare Part B and 50 highest Part D combined expenditures from the past 12 months of the selected drug publication date

2. Select the highest-ranked drugs with respect to each year from the ranked list

(A) Short-monopoly drugs and vaccines

- For **small-molecule short-monopoly drugs**, it would be defined as one that is between **9 to 12 years after its approval, with respect to the price applicability year**
- The maximum fair price **shall not exceed 75% of its non-federal average manufacturer price**

(B) Extended-monopoly drugs

- An **extended-monopoly drug** is defined as one that is between **12 and 16 years after its approval**, with respect to the price applicability year
- The maximum fair price **shall not exceed 65% of its non-federal average manufacturer price**
- ***Excludes vaccines approved under 351*** *(vaccines to protect against global infectious diseases + diseases endemic in areas outside the U.S. as well as diseases endemic in the U.S.) and selected drugs where the mfg has an agreement under his part w/ the secretary w/ initial price applicability year before 2030.*

(C) Long-monopoly drugs

- An extended-monopoly drug is defined as one that has been **approved for more than 16 years**, with respect to the price applicability year
- The maximum fair price shall **not exceed 40%** of its non-federal average manufacturer price
- ***Excludes vaccines approved under 351***

Source: Jefferies analysis, Inflation Reduction Act

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b) the IRA includes an exception to Medicare's non-interference clause – as a reminder, this clause typically prevents HHS from negotiating Medicare drug prices

Importantly, the noninterference clause in section 42 U.S.C. § 1395w-111(i) of the Social Security Act explicitly states that HHS Secretary cannot interfere w/ negotiations between drug mfg, pharmacies, & PDP sponsors or set a formulary/price structure to reimburse covered Part D drugs

That said, we'll flag that the IRA created the first ever exception to the Part D non-interference clause –

Going forward, we think this could make it easier to either 1) add MFN to the IRA provisions via CMS or statute amendment, and/or 2) introduce new legislation that also creates an exception to the Part D non-interference clause

42 U.S.C. Section 1395w-111(i): Non-interference clause

(i) NONINTERFERENCE

In order to promote competition under this part and in carrying out this part, the Secretary—

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors;

(2) may not require a particular formulary, except as provided under section 1395w–104(b)(3)(I)[4] of this title; and

(3) may not institute a price structure for the reimbursement of covered part D drugs, except as provided under part E of subchapter XI.

CONFORMING AMENDMENTS.—

(1) UNDER MEDICARE.—

(C) EXCEPTION TO PART D NON-INTERFERENCE.—Section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) is amended—

(i) in paragraph (1), by striking "and" at the end;

(ii) in paragraph (2), by striking the period at the end and inserting ", except as provided under section 1860D–4(b)(3)(I); and"; and

(iii) by adding at the end the following new paragraph:

"(3) may not institute a price structure for the reimbursement of covered part D drugs, except as provided under part E of title XI.".

Source: Jefferies analysis, Social Security Act, Inflation Reduction Act

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And c) we hosted a KOL HERE who suspects that if Part D is included in an MFN model, it would likely only apply to IRA selected drugs

Jeromie Ballreich, Ph.D., is currently an Associate Research Professor and Director of MHS in Health Economics at John Hopkins University (05/2017-Present). He is a health economist specializing in pharmaceutical economics and policy; economic evaluations alongside clinical studies; and high-cost/high-needs patient populations + he has advised CMMI on several pharmaceutical policy issues including the gene therapy CMMI program. In the pharmaceutical economics and policy space, Dr. Ballreich has been involved in a number of major U.S. policy discussions with key stakeholders including Congress, the U.S. Food and Drug Administration, Centers for Medicare and Medicaid services, and industry.

Key Takes from our KOL Jeromie Ballreich (former director at CMS) re: IRA & MFN implementation –

- Our KOL thinks Part D inclusion chances are **< 25%. However, he sees 50-50 between Medicaid or Medicare Part B.** He also anticipates a very limited scope (i.e. top 10 drugs in Part B)
- Importantly, our KOL suspects that if **Part D is included in an MFN model, it would primarily focus on IRA-selected drugs.** He noted that Part D has a different reimbursement model compared to part B on account of PBMs and premiums from beneficiaries.
    - Caveat: While IRA lends itself better to implementing MFN through part D, the IRA is already being legally challenged
- **Our KOL believes that, overall, MFN under the IRA is not legal.** Price setting under the IRA is subject to judicial review using a pre-defined formula, but determination of 'Maximum Fair Price' is subject to negotiations.
- **Interestingly, our KOL also thinks adjusting the pill penalty in the IRA is another way to implement MFN**

Source: Jefferies analysis

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On the flipside, we'll flag that it may be difficult to implement MFN pricing since the statute already has an explicit process for determining MFP prices & price ceilings – changing it without legislation could lead to an APA lawsuit re: exceeding authority & failure to follow rulemaking procedures

Inflation Reduction Act – H.R.536 – 117th Congress

"(i) INITIAL PRICE APPLICABILITY YEAR 2026.—In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug

"(3) APPLICABLE PERCENT DESCRIBED.—For purposes of this subsection, the applicable percent described in this paragraph is the following:

"(A) SHORT-MONOPOLY DRUGS AND VACCINES.—With respect to a selected drug (other than an extended-monopoly drug and a long-monopoly drug), 75 percent.

"(B) EXTENDED-MONOPOLY DRUGS.—With respect to an extended-monopoly drug, 65 percent.

"(C) LONG-MONOPOLY DRUGS.—With respect to a long-monopoly drug, 40 percent.

Administrative Procedures Act – 5 U.S.C. §551-559 and §701-706

§706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall-

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be-

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

§553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved-

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include-

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

Source: Jefferies analysis, Inflation Reduction Act, Administrative Procedures Act

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4) Hybrid tariff/MFN compromise (or other pharma concession):

From our discussions, Trump could be looking for a headline “win” against pharma ahead of midterms & we think there could be room for pharma to negotiate

Comments from call with Policy Expert(s)

- KOL believes that pressure is tied to 2026 elections (resolution is expected in 2025)
- Pharma co’s may want to hand Trump a victory so he can have good headline going into the midterms and then get him to drop/be more lenient on the model
- Additionally, **Pharma co’s could offer flexibility on issues such as PBM reform, 340B or ACA subsidies**
- **KOL indicated that while tariffs alone may not satisfy Trump, they could be part of a broader negotiation**

Comments from FDA Commissioner Dr. Marty Makary at JEF NY HC Conference

- On MFN, he said that the President isn't putting blame squarely on pharma co’s, but also on ex-US countries not paying their "fair share" into R&D - **Dr. Makary sees the President’s approach to MFN as no different from his approach on NATO fees, WHO membership fees, etc**
- Dr. Makary thinks active communication is important & **has been speaking with pharma leadership/developers** to understand their challenges

Comments from Trump during Press Conference re: MFN EO

- In the press conference, Trump seems supportive of US pharma Cos & more antagonistic towards the EU & PBMs — **Trump thinks EU gov. forces US pharmas to charge very low prices while in the US middlemen (aka PBMs) drive prices higher. As such, the administration will likely help US pharma negotiate w/ int'l govts using trade** and cut out the middlemen to facilitate direct sale of drugs to American citizens (+ accelerate price reductions)...almost as if trade/MFN negotiations could be done holistically

Source: Jefferies analysis

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One example of something we could see is hybrid country-specific tariff/trade deals (combined w/ MFN but with less aggressive price reductions) – the US-UK trade deal seemed to push UK to improve the environment for pharma co's to operate in

As a background, The US-UK reached a bilateral trade agreement on May 8th 2025 to carve out individual exemptions to the tariffs. It was a broad, but did include language regarding pharma. **After the agreement, the UK would pay ~1 billion pounds extra for drugs (therefore increase drug prices in the UK)**

Fact Sheet: U.S.-UK Reach Historic Trade Deal

The White House | May 8, 2025

- It creates a secure supply chain for pharmaceutical products.

We'll call out that prior to the trade agreement signing, **on April 7th 2025, David Ricks (LLY CEO) attended the UK ABPI meeting with Keir Starmer where we think it is possible they discussed drug innovation in the UK and LLY investments in addition to avoiding tariffs**

The pharmaceutical sector was carved out in the official Trump tariff announcements but industry consensus is that this exemption will be brief before a further forthcoming planned sector-focused announcement from the US Administration. Eli Lilly's Dave Rick's summed up US CEO sentiment by saying these tariffs are "hard to come back from".

The Sunday Times (May 28th 2025)

NHS and Treasury clash over medicine bill to placate Trump

The prime minister promised the US president that Britain would pay £1 billion more for drugs but it is not clear which government body will pick up the bill

General Terms from US-UK Economic Prosperity Deal:

(iii) Contingent on the findings of the U.S. Section 232 investigation on pharmaceuticals and pharmaceutical ingredients, and consistent with the United Kingdom's compliance with the supply chains security requirements described in subparagraph (ii), the United States and the United Kingdom intend to promptly negotiate significantly preferential treatment outcomes on pharmaceuticals and pharmaceutical ingredients. The United Kingdom confirms that it will endeavor to improve the overall environment for pharmaceutical companies operating in the United Kingdom.

We noted that the language from the UK release was vague in implementation methodology, but still **showed an intention to "improve the overall environment for pharmaceutical companies".**

We'll flag this information is important because:

1) **It happened before the MFN EO was announced. We think this means that Trump is ultimately looking to make country specific deals because if MFN were the true goal, there would not be a need to include pharma investment by the UK to make the deal happen. We'll also flag that pharma tariffs get linked to trade leverage whereas MFN would be pure price setting.**
2) **Since this is already in place before MFN is implemented, we think it could be a legacy deal that could pot'l partially exempy the UK from MFN. That said, we think pharma co's may lobby ex-US govm'ts to make deals with the US to pot'l keep them off MFN inclusion lists.**

Source: Jefferies analysis, The Times, Gov.uk

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We see similar policy pieces being laid for other countries (e.g. South Korea, Japan) to make a deal with the US (similar to the UK's)… Trump could potentially be levering their auto industry to push them towards the negotiating table

BioWorld: South Korea Lobbying to prevent pharma tarriffs

South Korean government and biopharmaceutical industry representatives urged American policymakers May 7 to refrain from imposing tariffs on pharmaceutical imports, and to spare allies if pharma tariffs are deemed necessary. Both Korea's Ministry of Health and Welfare on May 4 and the Korea Biotechnology Industry Organization on May 6 submitted comments to the U.S. Department of Commerce in response to its ongoing investigation of pharmaceutical imports.

We've seen South Korea attempt to lobby the administration to prevent any pharma specific tariffs, however, we'll flag that no trade deal like the UK has been reached.

Hudson Institute: Negotiations with Japan

Tariffs and Negotiations

In summary, Japan is at risk of seeing new tariffs through several White House initiatives on trade. These include, but are not limited to, the following:

- 25 percent tariffs on auto and auto parts imports
- 25 percent tariffs on steel
- Tariffs on other national security-related goods, such as copper, lumber, semiconductors, and pharmaceuticals
- 10-20 percent tariffs on all imports from Japan because of the goods deficit
- Tariffs on specific commodities with high tariff schedule rates and NTBs

Of these possible tariffs, a 25 percent tariff on auto and auto part imports from Japan is the most consequential.

Likewise, there have been suggestions from the White House that pharmaceutical tariffs will be implemented on Japan and again no trade deal like the UK has been reached.

Trump MFN EO speech (May 12th 2025)

The biggest thing we're going to do is we're going to tell those countries, like those represented by the European Union, that they -- you know, that game is up, sorry. And if they want to get cute, then they don't have to sell cars into the United States anymore. It's a very big subject. And they won't get queued (ph) because I'll defend the drug companies from that standpoint.

Without reading too far into Trump's comments, it seems like an argument could be made that Trump wants to tie pharma investment (through EU prices) to trade leverage. If this were to happen, the admin. would effectively be raising drug prices ex-US and this would undermine an MFN rule. The admin. is likely aware of this and could be using the threat of MFN as a method to encourage negotiation to help US co's abroad not suffer negative financial consequences.

Source: Jefferies analysis, BioWorld, Hudson Institute, CNN archives

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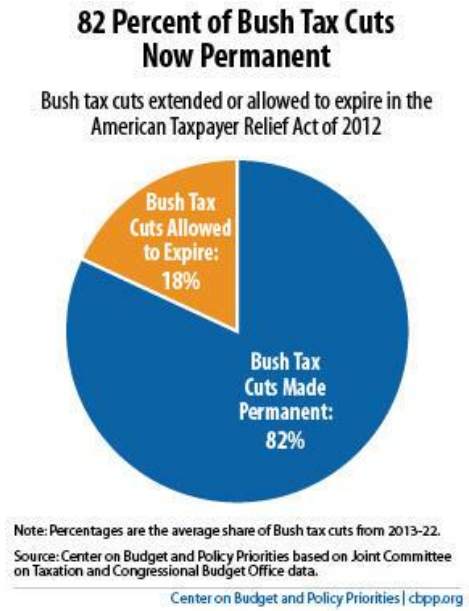
Additionally, we noticed broad policy interventions can have narrower impact in reality vs the scope of their headlines when first introduced – we've seen this previously for a) tax proposals…

Looking at examples of tax proposals, we've seen that the actual impact was generally narrower in scope vs the initial headlines. We wouldn't be surprised if MFN went through a similar process of softening relative to initial headlines (via carve outs, exceptions, or other means of mitigation)

1) 2012 Fiscal-Cliff Tax Hikes & American Taxpayer Relief Act (ATRA)

- There was a headline threat that letting every Bush-era cut expire was projected to raise ~$3.4T over 10 yrs; top ordinary tax rate from 35% to 39.6 %, capital gains rate from 15% to 20% (+3.8 % NIIT), payroll-tax holiday ends, estate-tax exemption drops.
- In reality, ATRA (Jan 2013) made ~82% of those cuts permanent, delivering an estimated ~$620B of revenue (~1/5 of the headline figures)

	Actual, 2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Total 2013-2017	Total 2013-2022
	In Billions of Dollars													
Revenues														
Individual income taxes	1,091	1,123	1,425	1,543	1,719	1,886	2,069	2,234	2,387	2,542	2,704	2,870	8,642	21,379
Social insurance taxes	819	851	958	1,020	1,074	1,143	1,217	1,289	1,351	1,412	1,474	1,539	5,411	12,476
Corporate income taxes	181	235	298	363	440	482	491	488	475	473	478	489	2,074	4,477
Other	212	225	232	283	308	307	305	317	338	363	382	398	1,434	3,232
Total	**2,303**	**2,435**	**2,913**	**3,208**	**3,541**	**3,817**	**4,083**	**4,328**	**4,551**	**4,790**	**5,039**	**5,295**	**17,562**	**41,565**
On-budget	1,738	1,863	2,240	2,479	2,772	2,998	3,209	3,401	3,577	3,771	3,975	4,187	13,699	32,608
Off-budget[a]	566	572	673	729	768	819	874	927	974	1,019	1,064	1,108	3,863	8,957
Outlays														
Mandatory	2,027	2,053	2,105	2,174	2,311	2,499	2,617	2,738	2,926	3,104	3,296	3,555	11,705	27,324
Discretionary	1,346	1,289	1,231	1,194	1,199	1,220	1,236	1,253	1,286	1,316	1,346	1,384	6,079	12,664
Net interest	230	220	218	227	244	284	354	416	470	512	541	570	1,327	3,835
Total	**3,603**	**3,563**	**3,554**	**3,595**	**3,754**	**4,003**	**4,206**	**4,407**	**4,681**	**4,932**	**5,183**	**5,509**	**19,111**	**43,823**
On-budget	3,104	3,055	2,919	2,885	2,993	3,191	3,341	3,489	3,707	3,897	4,083	4,341	15,328	34,844
Off-budget[a]	499	507	635	710	761	812	865	919	974	1,035	1,099	1,168	3,783	8,979
Deficit (-) or Surplus	**-1,300**	**-1,128**	**-641**	**-387**	**-213**	**-186**	**-123**	**-79**	**-130**	**-142**	**-144**	**-213**	**-1,549**	**-2,258**
On-budget	-1,367	-1,192	-679	-405	-220	-193	-132	-88	-130	-126	-109	-154	-1,629	-2,236
Off-budget[a]	67	64	38	19	7	7	9	9	*	-16	-36	-59	80	-22
Debt Held by the Public	10,128	11,318	12,064	12,545	12,861	13,144	13,371	13,536	13,746	13,964	14,181	14,464	n.a.	n.a.



2) Build Back Better Corporate-Tax Hike & Inflation Reduction Act (IRA)

- There was a headline threat of the White House opened bid which proposed raising the statutory rate from 21% to 28% & stricter GILTI rules which would generate estimate ~$1.0-1.3 T revs over 10 yrs.
- The House Ways & Means draft (Sep 2021) replaced the flat rate w/ graduated structure (max 26.5%) which would generate $873Bn at 28% and $540Bn at 26.5%
- The Final IRA (Aug 2022) showed the statutory rate remained 15%, & a 15% corporate book-income minimum tax (CAMT) was added onto ~150 firms with ≥$1B average profits (adding est ~$222B rev for FY'22-23), and a 1% stock buy-back excise tax (~74Bn over 10yrs).

How President Biden's Minimum Tax Could Claw Back the Proposed "Made in America" Tax Credit

	Current Law	Biden Proposal
A U.S. book income	$100 million	$100 million
B Excess of tax depreciation over book depreciation	$30 million	$30 million
C U.S. taxable income	$70 million (A- B = C)	$70 million (A -B = C)
D Corporate Tax Rate	21%	28%
E U.S. tax on U.S. income before credits	$14.7 million (C * D = E)	$19.6 million (C * D = E)
F R&D tax credit	$5 million	$5 million
G Made in America Tax Credit	$0	$0.48 million (see note)
H U.S. tax on U.S. income after credits	$9.7 million (E – F - G = H)	$14.12 million (E – F - G = H)
I 15 Percent Minimum Book Tax	$0	$0.88 million [(A * 15%) – H = I)]
J Total tax liability	$9.7 million (H +I = J)	$15 million (H +I = J)

Source: Jefferies analysis, CBO, Tax Foundation

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& b) in examples of how automakers have circumvented CAFE efficiency standards using different loopholes, we saw the cost of compliance in practice ended up being relatively cheap vs expectations

We've seen through the implementation of CAFE in the auto industry that companies can adapt to burdensome laws using economic incentives embedded in the law itself.

We saw a study by Anderson & Sallee (2011) that looked at how automakers have used regulatory loopholes in CAFE (Corporate Average Fuel Economy) standards to avoid the full burden of compliance for making fuel efficient vehicles. Here's what we've noticed:

- Flex-fuel credit inflated reported fleet MPG by ~67 % without any real-world CO2 savings (seemed moreso like an accounting maneuver)
- Co's took the cheapest path to compliance by spending $100~$200 to retrofit cars (ethanol-capable fuel lines + sensor) to deliver the same regulatory benefit as more costly engine redesign
- Domestic OEMs (GM/Ford/Chrysler) retrofitted a few high-volume, low-MPG models; most foreign brands either ignored the credit or simply paid fines—evidence of targeted, not universal, exploitation.
- **True cost of tightening CAFE by 1 mpg ran just $9~$27 per vehicle - well below the $55 statutory fine and far below prior structural models ($150+).**
- Despite documented ineffectiveness, the loophole survived 1993-2014

TABLE 8—MARGINAL COMPLIANCE COST PER VEHICLE OF TIGHTENING FUEL-ECONOMY STANDARDS

	Chrysler domestic cars	Chrysler trucks	Ford domestic cars	Ford trucks	GM domestic cars	GM trucks	Nissan trucks
1996			$11–$23				
1997			$9–$18				
1998		$14–$28	$8–$17				
1999		$14–$27	$9–$17	$13–$25			
2000		$13–$26	$8–$16	$12–$25		$15–$31	
2001		$14–$28	$8–$17	$13–$26		($15–$29)	
2002		($13–$26)	$9–$17	$12–$24		($10–$21)	
2003	$8–$16	$13–$25	$8–$17	($11–$22)		($10–$20)	
2004	$8–$16	$10–$19	$9–$19	($11–$23)		($10–$20)	
2005	$8–$17	$13–$26	$8–$17	$11–$21		$10–$20	$10–$19
2006	$13–$26	$12–$24	$8–$15	$10–$20	($8–$16)	$9–$19	$10–$19
Average	$9–$18	$13–$27	$9–$17	$12–$24		$11–$21	$10–$19
CAFE fine	$55	$55	$55	$55	$55	$55	$55
Jacobsen	$373	$157	$52	$251	$438	$264	na
Gramlich	$347	$347	$347	$347	$347	$347	na

Notes: The table shows estimates of marginal compliance costs per vehicle based on equation (8). Ranges assume an

Our takeaway from this example is that, just as automakers seemed to take the cheapest compliance path, pharma co's might prefer rebate schemes, country-specific negotiations, or marketing exceptions to circumvent MFN pressure

Source: Jefferies analysis, Company Publications

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& c) coming back to pharma, we saw last month in the new Medicare Part B & D draft guidance that bona fide marketing looks more lenient vs our previous expectations (HERE)

- Under prior Medicare draft guidance, branded drugs could still be subject to IRA negotiation upon gx/biosimilar entry if the CMS determined there wasn't "bona fide marketing". In basic terms this meant ex. Eylea could still be selected for negotiation EVEN post biosimilar entry if the CMS determines there wasn't enough generic uptake. This directly conflicted with the text of IRA which clearly stated that if a biosimilar was set to launch, the branded drug was ineligible for selection under the IRA price negotiation program.
- We have long felt the "bona fide marketing" element, introduced only under the CMS draft guidance was vulnerable to legal challenge under the APA/post Chevron because it directly contradicted with the original law (HERE/HERE/HERE).
- **The new draft guidance changes that. In fact, it explicitly states low utilization/sales WON'T disqualify a gx/biosimilar from being considered bona fide as long as there's no restricted distribution (ex volume gated authorized Gx).**

	FINAL PART D GUIDANCE [October 2024]	DRAFT GUIDANCE FOR PART B & D [May 2025]
Bona Fide Marketing	**"The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be a holistic inquiry,** but these sources of data over the specified intervals will be informative for that determination.	"...As another example, a potential qualifying single source drug might have a newly or recently approved generic or licensed biosimilar and the **product has relatively low PDE utilization, AMP sales, and/or ASP sales**. In this example, if CMS finds in additional review of public information that the generic or biosimilar manufacturer has successfully launched their product, **and there is no evidence of agreements limiting distribution of the generic or biosimilar product, then CMS will consider the generic or biosimilar product of the potential qualifying single source drug as bona fide marketed."**

Source: Jefferies analysis, Company Publications

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We noticed several tax incentives in The One Big Beautiful Bill, including immediate expensing & extension of int'l tax benefits – our illustrative analysis (on MRK) suggests that this + mitigation could potentially lead to accretive impact

Subtitle B – Make Rural America and Main Street Grow Again

Part 1 – Extension of Tax Cuts and Jobs Act Reforms for Rural America and Main Street

Sec. 111001. Extension of special depreciation allowance for certain property.
Current Law: Under current law, taxpayers are generally required to deduct the cost of property used in a trade or business over a period of time. However, in the case of certain "qualified property" (including most equipment and machinery), a taxpayer is permitted to deduct a percentage of the cost in the first year that the property is placed in service ("immediate expensing"). For qualified property placed in service in 2025, a taxpayer is generally permitted to immediately expense 40 percent of the cost. For qualified property placed in service in 2026, a taxpayer is generally permitted to immediately expense 20 percent of the cost.

Provision: This provision allows taxpayers to immediately expense 100 percent of the cost of qualified property acquired on or after January 20, 2025, and before January 1, 2030.

Sec. 111002. Deduction of domestic research and experimental expenditures.
Current Law: Under current law, taxpayers are required to deduct research or experimental expenditures over a five-year period. Research or experimental expenditures that are attributable to research conducted outside the U.S. are required to be deducted over a 15-year period.

Provision: This provision allows taxpayers to immediately deduct domestic research or experimental expenditures paid or incurred in taxable years beginning after December 31, 2024, and before January 1, 2030.

This provision includes rules to coordinate the immediate deductibility of domestic research or experimental expenditures with the research credit, rules clarifying the treatment of foreign research or experimental expenditures, and other coordinating changes.

Sec. 111003. Modified calculation of adjusted taxable income for purposes of business interest deduction.
Current Law: Under current law, the deduction for business interest expense for a taxable year is generally limited to the sum of (1) the taxpayer's business interest income for the taxable year, (2) 30 percent of the taxpayer's "adjusted taxable income" for the taxable year, and (3) the taxpayer's "floor plan financing interest" for the taxable year. "Adjusted taxable income" corresponds with the financial accounting concept of earnings before interest and taxes (EBIT).

"Floor plan financing interest" refers to interest paid or accrued on indebtedness used to finance the acquisition of motor vehicles held for sale or lease to retail customers and secured by the inventory so acquired. A "motor vehicle" means a motor vehicle that is: (1) any self-propelled vehicle designed for transporting person or property on a public street, highway, or road; (2) a boat; or (3) farm machinery or equipment.

Provision: This provision increases the cap on the deductibility of business interest expense for taxable years beginning after December 31, 2024, and before January 1, 2030. Specifically, it provides that "adjusted taxable income" is computed without taking into account deductions for depreciation, amortization, or depletion. As a result, "adjusted taxable income" corresponds with the financial accounting concept of earnings before interest, taxes, depreciation, and amortization (EBITDA).

Trump has alluded support for offering tax incentives to pharma that bring manufacturing back to the US (HERE). The One Big Beautiful Bill reinforced this direction, **proposing 100% immediate expense of qualified property and domestic R&D costs along with permanent extensions of FDII, GILTI, and BEAT.** Note that the immediate expensing provision applies only to the business activities between Jan '25 to Dec '29.

In our illustrative analysis, on top of our tariff scenarios, we assumed a 15% effective tax rate for the 2025-2029 period to reflect the impact of the proposed deductions. We found that **the overall effect on companies could be accretive when combined with mitigation strategies.** In addition to the previously outline mitigations, **we also assumed a limited tariff impact for 2026, given the Q1 Co commentary re: stockpiling efforts and the availability of unused manufacturing capacity** (HERE). We want to caveat that this legislation has passed the House of Representative but not yet been enacted into law, and the final version of the bill may be different.

Sec. 111004. Extension of deduction for foreign-derived intangible income and global intangible low-taxed income.

Provision: This provision permanently increases the deduction amount for foreign-derived intangible income from 21.875 percent to 37.5 percent and increases the deduction for global intangible low-taxed income from 37.5 percent to 50 percent for taxable years beginning after December 31, 2025.

Sec. 111005. Extension of base erosion minimum tax amount.

Provision: This provision permanently reduces the rate from 12.5 percent to 10 percent beginning January 1, 2026. The provision also permanently retains the current treatment of ta credits for taxable years beginning after December 31, 2025.

MRK Diluted EPS	2025	2026	2027	2028	2029
JEF Estimate	$ 8.86	$ 9.97	$ 11.80	$ 12.73	$ 11.97
Impact	$ 8.96	$ 10.15	$ 11.76	$ 12.89	$ 12.19
delta	*1%*	*2%*	*0%*	*1%*	*2%*
DCF					
JEF Estimate	138				
Impact	139				
delta	*0.3%*				

Source: Jefferies Analysis, The One, Big, Beautiful Bill

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& while we don't know what the obvious workarounds are if MFN gets implemented, we could see pharma co's responding to MFN by introducing a gross and net bubble within Europe (mentioned in a CBO report)

We could see pharma co's responding to MFN by introducing a gross net price bubble within Europe – we saw this method explicitly mentioned in a 2021 CBO working paper:

- The CBO flagged that manufacturers can "*adjust the availability and price of the drug in foreign markets to affect the international price data on which the negotiations are based*," i.e., lift EU list prices to raise the MFN ceiling.
- CBO's model shows that negotiated U.S. prices cluster "close to the specified upper bound of ~120 % of the avg intl price (AIM), so every €1 hike in an EU list price effectively boosts the U.S. cap by €1.20.
- The AIM index relies on publicly reported list prices, not confidential rebates; CBO details how it builds AIM from country-level list-to-U.S. price ratios, leaving undiscounted "gross" prices as the reference point
- The CBO's sensitivity analysis shows that raising the upper bound (or,, inflating the AIM denominator) erodes the predicted savings – the average MFP climbs from 32% to 78% of today's price as the cap moves from 120% to 360% of AIM.
- CBO mentions that "*if firms managed to distort the AIM price by changing their behavior in foreign markets*," MFN would still cut prices, but by substantially less; so there does seem to be a real-world incentive to create a gross vs net spread in Europe.

Figure 4: Effect of the MFP Upper Bound on Average MFPs Relative to Current Prices

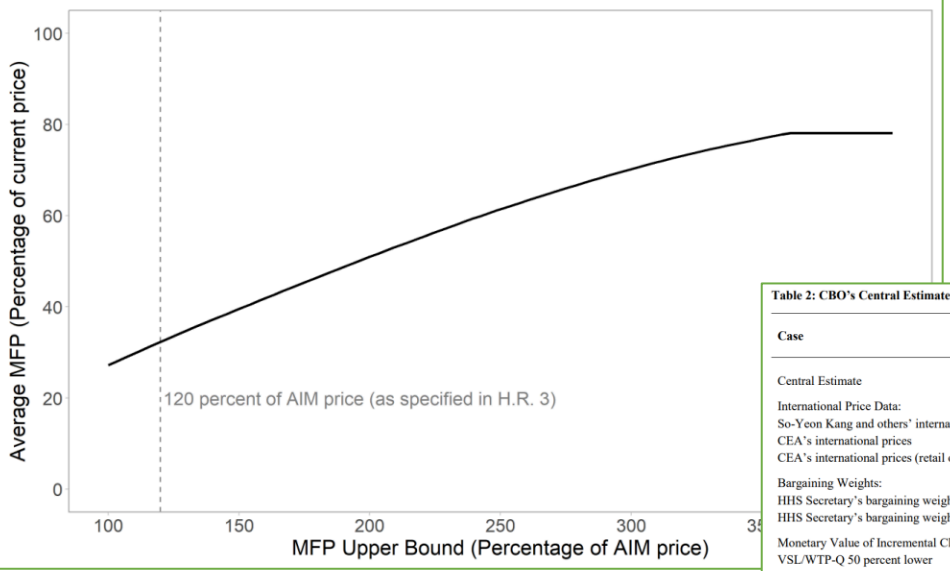

Table 2: CBO's Central Estimate and Its Sensitivity to Parameters

Case	MFP Index (Percentage of AIM price)	Average Price Reduction (Percentage of current price)
Central Estimate	116	68
International Price Data:		
So-Yeon Kang and others' international prices	117	71
CEA's international prices	116	58
CEA's international prices (retail only)	117	71
Bargaining Weights:		
HHS Secretary's bargaining weight = 0.25	118	67
HHS Secretary's bargaining weight = 0.75	109	70
Monetary Value of Incremental Clinical Benefit:		
VSL/WTP-Q 50 percent lower	114	68
VSL/WTP-Q 50 percent higher	117	67
Alternative Treatment If Negotiation Fails:		
All beneficiaries receive highest-spending alternative if one is available	117	67
All beneficiaries receive SOC, even if an alternative is available	116	68
Beneficiaries receive an alternative proportional to Medicare shares	117	67
Half of beneficiaries receive an alternative proportional to Medicare shares, half receive SOC	116	68
Legislative Details:		
MFP lower bound is zero	115	68
MFP upper bound is the current price	281	22
MFP lower bound is zero and upper bound is the current price	280	22

Data source: Congressional Budget Office.

AIM = average international market; CEA = Council of Economic Advisers; HHS = Department of Health and Human Services; MFP = maximum fair price; SOC = standard of care; VSL = value of statistical life; WTP-Q = willingness to pay for an additional quality-adjusted life year.

Source: Jefferies analysis, Company Publications

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Moving on, if MFN does happen, we ran a few scenarios looking at the potential impact to our large cap pharma and biotech stocks

Background: Trump's Most Favored Nation's Drug Price Proposal

- Overview of MFN Pricing Policy and major historical events
- Thoughts on recent MFN Executive Order & HHS Press Release – what we know & major remaining Q's

Legal Analysis: How likely will MFN get implemented?

- Summary of ways MFN could get implemented including via: a) Congressional Action (eg, Reconciliation or new Legislation), b) CMMI pilot program, c) IRA, d) hybrid tariff/MFN compromise (or potential pharma concession)
- Our diligence re: probability of success that MFN gets implemented through these routes

Impact Analysis: What is the impact to our coverage if MFN does get implemented?

- We considered multiple different scenarios (in combination with our 25% tariff w/ mitigation model) for our LC Pharma & Biotech:
  1. Full impact MFN (top 50 Medicare Part B/D or IRA only or all Medicare)
  2. MFN (top 50 Medicare Part B/D) with pharma employing mitigation parameters
- Overall, we believe certain mid biotechs (eg, those that have de minimis ex-US revs, and/or low Medicare exposure, or a relatively low delta between US vs ex-US pricing) are generally winners here

Macro & Potential Downstream Effects of MFN Policy

- Thoughts on potential long-term/downstream impact of MFN if it gets implemented
- Our MFN/tariff-adjusted earnings relative to the S&P500 still seem to trade at a discount into a recession

Source: Jefferies Analysis

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As a reminder, Trump released a prior MFN model in 2020 + here are the key provisions that we incorporated into our analysis –

1) MFN Price

- Instead of paying solely based on manufacturers' average sales price (ASP), Medicare would have paid based on a blending formula that includes the lowest adjusted international price, (the "MFN Price") for the drug
- This price is based on the **lowest GDP-adjusted price paid by an OECD member country with a GDP per capita (based on purchasing power parity) that is at least 60 percent of the U.S. GDP per capita, and the ASP**.
- The formula would not allow the model payment amount for a drug (before the per-dose add-on) to exceed the ASP.

2) 4 year phase in – 7 year model (we ran ours indefinitely to be conservative)

- **The MFN Price would have been phased-in over the first 4 years of the 7-year model, phasing in 25% per year for years 1-4, and would have been 100 percent of the MFN Price for years 4-7.**
- For example, for the first year the phase-in calculation would use 75 percent of the ASP and 25 percent of the MFN Price. In years 4-7, the MFN Price would be fully phased-in.
- However, CMS would have accelerated the blending formula for a drug in years 1-4, if U.S. prices rose faster than inflation and the MFN Price.

3) Alternative to ASP Add-on Payments for Medicare Part B drugs

- The current add-on payment based on 6 percent of ASP for the individual drug would be replaced with a **flat payment per dose that is uniform for all included drugs in the MFN Model.**
- The per-dose add-on was calculated using 6.1224% of 2019 historic spending for the cohort of drugs included in the first year of the model. CMS bumped up the 6% add-on from 2019, to equal 6% post-sequestration prior to calculating the per-dose add-on and applying an inflationary factor for the model start and quarterly thereafter.
- The MFN Model was a mandatory, nationwide model that required participation from Medicare-participating providers and suppliers that receive separate Medicare Part B fee-for-service payment for the model's included drugs, with certain exceptions.

Source: Jefferies analysis, CMS

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1) We started off by selecting drugs that could be impacted by MFN – here's what Co's have said (1/2):

Ticker	Mgmt Comments
BMY	*"With respect to ex-US net prices, we actually agree with the administration.* ***Countries outside of the US need to be allocating more healthcare spending to innovative medicines****. So, we're engaging directly with the administration, working with our pharma partners, of course, and supporting the administration's efforts here to leverage whatever tools they can to get ex-US countries to allocate more of their healthcare spending to the types of innovative medicines that we develop at BMS." - Apr. '25*
	"The good news is that when you talk to the administration, when you talk to members of Congress, there's a recognition that this is a critically important industry....this is an industry where you have China is investing heavily. And so, how we think about the next set of policy moves is important because policy moves can make this ecosystem that we have here more robust and it can also work in the other direction. And I think that discussion is setting a good context for what happens next. I think people in the ***administration recognize this is an industry that's important and we need to make sure that, at the end of the day, it continues to thrive.I think there is a focus on what do we do to bridge the gap between what's paid for medicines in the US and what's paid outside of the US, and I think there are ways we're going to have to engage with the administration on what can we do to bring prices up outside of the US and what are reasonable steps that we can take in the US that don't distort the overall dynamics of the industry****. And that's going to be the needle that has to be threaded." - May '25*
PFE	*"Thank you very much for both questions. Look, on the MFN, first of all, I can't speak about what would be the intentions of the government, but I can comment on what I have seen so far...* ***MFN was not mentioned over there. On the contrary, what was mentioned over there was the pill panel that he instructed so that we will find ways to resolve it. What was mentioned over there was PBM reform and transferring of rebates to the patient. What was mentioning over there was 340B reform****." - Apr. '25*
MRK	*"And a lot of it depends on the reimbursement mechanism as well. If it's rebates, et cetera, like instead in Medicaid, you can kind of ring fence this earlier if the conversation was, if you do something in Medicaid, it could bleed into 340B, right, which then becomes a much broader exposure beyond just Medicaid itself. So, can you ring fence some of these? I think on the medical benefit products,* ***when your product is ASP braced in terms of reimbursement, the ASP does bleed into other segments in the market. And I think that's where companies are saying that, you might well see the price in Medicare ultimately impacting your ASP and that ASP affects your commercial business because the reimbursement is ASP based****. So, it might take a bit of time, but ultimately the ASP is going to catch up across all your segments." - May '25*
LLY	*"In terms of the affordability and then this type of referencing to OUS pricing,* ***we don't feel that actually the comparison versus OUS pricing is the right way to start. I think some of these actions do actually address some of the disconnections in the US system****. In particular, when you think about the gross to net component,* ***all the companies are talking about gross to net of 50%, 60%. That's not even close to anything OUS****. You don't have those intermediaries OUS. So, that's, in my eyes, how we can start addressing that affordability objective that the administration has.....we don't have clarity about the Executive Order yet, but thinking about it, studied on Medicare, on Medicaid,* ***we have proven, over time, that the firewall that we have with commercial has very limited spillover****. So, we still believe that is going to be the case even with this new Executive Order." May '25*
JNJ	*"We had announcement this morning about MFN and kind of building on the executive order, I believe, of last week. We hear a lot from the administration about middlemen, which again too, I do want to compliment, because we have not heard that before. And so, we take our opportunities to educate.* ***If you think about the pricing problem in the US, patients go to the pharmacy counter and they're experiencing not only higher insurance premiums, but a co-pay of $100 on a chronic monthly med that maybe five years ago was $10 or $15.*** *" - May '25*
	"...We invest in our products and in getting the right endpoints and the right data. So, we've got the right value dossiers and can go in and can argue very, very compellingly for getting the right value back, for bringing those innovations to patients. And so, because of that, we are very disciplined throughout the world. We both have speed to market in terms of gaining access, but we also have very, very good discipline as it relates to pricing and value throughout the world. And so, ***we think regardless of any pricing dynamics in the other markets and changes in political parties and things like that, we think that we're in a very good position to be able to continue to advance our innovation and to continue to grow our business at above-market rates.*** *" June '24*

Source: Jefferies Analysis

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Here's what companies have said on MFN (2/2):

Ticker	Mgmt Comments
NVS	*"Clearly, prices in Europe have continued to decline, no longer reflecting the innovation that we deliver. It's a combination of capping market growth, penalizing new indications,* ***low prices at launch have really led to 30% of medicines not being launched in Europe or being delayed in Europe****."- Apr. '25*
	*"****MFN if it's – as previously conceived, is limited to Part B drugs, for Novartis, highly manageable. If MFN in Medicare Part B and Part D but we no longer have to pay rebates and a number of other discounts disappear, manageable. If it's Medicare Part B, Part D with the spillover into Medicaid, the spillover into 340B pricing and all of the other problems, definitely painful. If it spills over into the private market, devastating.*** *So, I think all of this, of course, is something to look at. And here I speak about the industry, I think, broadly as well. Of course, for Novartis,* ***given our relative exposure to the US and relative exposure to Medicare, if this policy ultimately were to come into place, we're well positioned relatively speaking****. But that still doesn't mean that we would, in any way, want this to happen given – obviously, given the damage it would do to our ability to invest in R&D, invest in manufacturing, invest in future pipeline of medicines for patients around the globe, it would definitely have a significant impact. But, certainly, it depends on the details of what ultimately is conceived."- Apr. '25*
AZN	*"The reality, I think, is that there has to be a rebalancing. And in fact, the US has been funding innovation for our industry for a long time.* ***And we believe that Europe has to invest a greater share of their health care expenses and that share has been declining steadily over the last number of years,*** *down to 7% of health care budget being allocated to innovative medicines in the UK."- Apr. '25*
SNY	*'the executive order from last week was reasonably explicit in its intensity. It stepped back a little bit from most favored nation, stepped forward a little bit into what it means for patients and what it could mean for out-of-pocket, and importantly, brought in 340B and PBMs into that narrative. So, I would imagine there'll be a pay-for because clearly, if you move them from 9 to 13 we'd be delighted as an industry because I think some small molecule innovation was lost in that mistake first time around. I think it looks to me, at least from the executive order and subsequent conversations, that it may be a shared responsibility in how we get there to do that and I would hope that's the case. Again, with the administration, we take nothing for granted. We read the executive order, we reflect on it, and we'll see what it means in practical application"- Apr. '25*
REGN	*"And I don't think it'd be appropriate to get into discussions of pricing differential.* ***Even we have pricing strategies as of Regeneron that we consider to be confidential for our brands****. I'd also note that in some situations, we've had partnerships with other companies for international marketplaces, and I respect that confidentiality and the information they need to operate their businesses. I think Regeneron is a great partner in science and business to all of those that we work with and that's what's most important to us."- May '25*
ARGX	*"..what we really try to do at argenx is to build the company for the long haul. So I think we are very thoughtful when it comes to organizing the business with the long-term in mind, the way we organize supply chain, the way we disciplined in the global rollout and pricing of the products.* ***So I think in general, this company is very well-positioned to navigate the current environment, because we have been organizing it in a thoughtful way for the long haul.*** *That means that from a pricing point of view, if you think like, a product like VYVGART,* ***we have been pricing internationally in a pretty tight price band****, that's what you do in the type of product category where we play. If you look at it from a supply chain point of view the tariffs, we have actually already since COVID been organizing the supply chain, such that we produce in the market for that market and that's also paying dividend today. So in general,* ***I would say, in absence of all the details, the carrots and stick is in favor of a company like argenx.*** *"- May '25*
ALKS	*'With respect to potential tariffs and foreign reference pricing,* ***we are in an advantageous position because we manufacture all of our proprietary products in the US, in the state of Ohio, and we do not commercialize them in markets outside the US.*** *"- May '25*
JAZZ	In our post Q1 call, Mgmt also flagged Epidiolex's price in Europe is roughly **70–80% of the U.S. price, which narrows the risk from MFN.** - May '25
NBIX	*'We're also seeing the setup of the President to allow a health team within the administration to set in place or in motion the terms and the communication to manufacturers on most favored nation targets. HSS then would have the ability to define rules and implement those between this team and the manufacturers that have medicines that are outside the US. And ultimately, if there's not significant process, again, this is kind of referring to the language in the executive order,* ***the government could potentially import the lowest priced medicines within this most favored nation basket and bring those to the US at a lower price.*** *.... What we're going to try to focus on are those things that we can control, which is building Neurocrine into a strong, resilient business and doing best for our shareholders and our patients. And we'll continue to evolve this, keep an eye on this evolving situation. Where there are things that we see impact the business, we'll be sure to let everyone know."- May '25*

Source: Jefferies Analysis

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Jefferies

Since Co. comments have been relatively unclear re: scope & whether Medicare Part D, Part B, Medicaid, we decided to look at the Top 50 Medicare drugs for both Part B and Part D

In the original 2020 MFN model, 50 Medicare Part B Top spend drugs were included based on the annual Medicare Part B spend in 2019 (price one year prior) after excluding certain claims (i.e. at home oral medications) and drugs (vaccines, oral drugs, multiple source, IVIG, etc.). Although language around MFN has still been relatively unclear re: scope & whether Medicare Part D, Part B, Medicaid, or some combination of these government pay drugs are included, we decided to take a look at the Top 50 Medicare drugs for both Part B and Part D.

We identified **the Top 50 Part B and Part D Drugs based on 2025 consensus revs & adjusted for Medicare exposure based on company commentary, therapeutic class, or our backed-out impact from Part D redesign disclosures/total company Medicare exposures**. Similar to our Part D work (HERE), Medicare exposure is assumed to be ~50% for Oncology, ~56% for cardiovascular, ~40% for Neurology, ~50% for autoimmune, ~20% for HIV, ~30% for GI, ~35% for psychiatry. We use the same % for each drug class unless otherwise specified (i.e. company disclosures or indication with majority 65y+ uptake such as COVID vaccine)

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Large Cap Pharma

	Medicare Part B	Medicare Part D	Commercial	Medicaid	Others	Ex-US Exposure
LLY		20%	50%	8%	22% including Part B	30%
BMY	10%-15%	45%-50%	35%-40%	<1% of 2024 Sales	< 5%	30%
Eliquis		60-65%	35-40%			26%
Cobenfy		40%	15%	45%		5%
PFE	<5%	30%-35%	30%-40%	<5%	15%-20%	41%
MRK	38%	5%	45%	12%		45%

Spec Pharma

ALKS	Medicare Part B	Medicare Part D	Medicaid	Commercial	Others	Ex-US Exposure
Lybalvi		30%	45%	20%	5%	
Aristada		33%	47%	5%	15%	0%
Vivitrol		6%	51%	22%	22%	
JAZZ	Medicare Part B	Medicare Part D	Medicaid	Commercial	Others	Ex-US Exposure
Epidiolex			50%	40%	10%	19%
Zepzelca		64%		32%	4%	0%
Rylaze			minority	majority		4%
Oxybate	small portion			vast majority		<1%

Biotech >$10Bn Market Cap

REGN	Medicare Part B	Medicare Part D	Medicaid	Commercial	Others	Ex-US Exposure
Eylea	40%		<5%	25%	30% Medicare Advantage <5% Other/Federal	43%
Eylea HD	50%		<5%	20%	25% Medicare Advantage <5% Other/Federal	
Dupixent		10%	10%	75%	<5% Other/Federal	22%
Libtayo	25%		5%	25%	40% Medicare Advantage <5% Other/Federal	34%
Evkeeza	15%	10%	15%	55%	5% Medicare Advantage <5% Other/Federal	0%
NBIX	Medicare Part B	Medicare Part D	Medicaid	Commercial	Others	Ex-US Exposure
Ingrezza		60-70%	30-40%			22%
Crenessity		30-40%		60-70%		0%
ARGX	50%			50%		24%
BMRN	2%		30%	68%		76%
EXEL	Medicare Part B	Medicare Part D	Medicaid	Commercial	Others	Ex-US Exposure
Cabometyx		40%		60%		9%

Biotech <$10Bn Market Cap

	Medicare Part B	Medicare Part D	Commercial	Medicaid	Others	Ex-US Exposure
MDGL	30%-35%		50%-55%	10%-15%		0%
APLS	Medicare Part B	Medicare Part D	Medicaid	Commercial	Others	Ex-US Exposure
Syfovre	Majority Medicare/Med Advantage			remainder		0%
Empaveli	~evenly distributed					39%
IONS	Medicare Part B	Medicare Part D	Medicaid	Commercial	Others	Ex-US Exposure
Tryngolza	<40% government pay			<60% commercial		22%

Source: Jefferies Analysis, Company comments

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Here are full lists of our estimated Top 50 Part B and Part D drugs:

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Company	Product	2025 Est Sales	Medicare Exposure	Medicare Sales	Medicare Part	Spending ranking
Merck & Co	Keytruda	19,337.92	65%	12,569.65	B	1
Johnson & Johnson	Darzalex	7,547.89	50%	3,773.94	B	2
Bristol Myers Squibb	Opdivo	5,166.73	50%	2,583.36	B	3
Roche	Hemlibra	3,072.16	65%	1,996.91	B	4
Roche	Ocrevus	5,985.45	30%	1,795.64	B	5
Roche	Vabysmo	4,285.64	40%	1,714.26	B	6
Pfizer	Prevnar 13	4,185.57	40%	1,674.23	B	7
AstraZeneca	Imfinzi	2,886.56	50%	1,443.28	B	8
Daiichi Sankyo	Enhertu	2,815.43	50%	1,407.71	B	9
Takeda	Entyvio	4,581.76	30%	1,374.53	B	10
Regeneron Pharmaceuticals	Eylea HD	2,407.57	50%	1,203.79	B	11
AbbVie	Botox	2,894.00	40%	1,157.60	B	12
Bristol Myers Squibb	Reblozyl	1,818.99	60%	1,091.40	B	13
Pfizer	Comirnaty	2,411.15	40%	964.46	B	14
Amgen	Evenity	1,323.03	69%	912.89	B	15
GSK	Benlysta	1,695.57	50%	847.78	B	16
argenx	Vyvgart	1,694.92	50%	847.46	B	17
Bristol Myers Squibb	Yervoy	1,671.57	50%	835.78	B	18
Roche	Tecentriq	2,015.59	40%	806.24	B	19
Exelixis	Cabometyx	1,993.07	40%	797.23	B	20
Eisai	Lenvima	1,538.75	50%	769.37	B	21
Bristol Myers Squibb	Orencia	1,446.96	50%	723.48	B	22
Johnson & Johnson	Carvykti	1,416.04	50%	708.02	B	23
Pfizer	Padcev	1,691.13	41%	693.36	B	24
UCB	Cimzia	1,333.35	50%	666.67	B	25
GSK	Nucala	1,322.45	50%	661.23	B	26
Sanofi	Fluzone	1,636.71	40%	654.69	B	27
Amgen	Kyprolis	1,002.88	61%	611.75	B	28
Roche	Perjeta	1,222.11	50%	611.06	B	29
Merck & Co	Bridion	1,518.79	40%	607.52	B	30
Johnson & Johnson	Tremfya	2,918.38	20%	583.68	B	31
Moderna	Spikevax	1,431.18	40%	572.47	B	32
AstraZeneca	Fasenra	1,093.45	50%	546.72	B	33
Novartis	Kesimpta	2,732.50	20%	546.50	B	34
Johnson & Johnson	Simponi	1,020.52	50%	510.26	B	35
Gilead Sciences	Trodelvy	1,017.92	50%	508.96	B	36
Amgen	Nplate	897.77	54%	484.80	B	37
Pfizer	Adcetris	1,162.85	41%	476.77	B	38
Amgen	Krystexxa	1,340.60	35%	469.21	B	39
Apellis Pharmaceuticals	SYFOVRE	669.77	60%	401.86	B	40
Roche	Phesgo	776.52	50%	388.26	B	41
Merck & Co	Gardasil 9	2,587.53	15%	388.13	B	42
CSL	Fluad	634.23	60%	380.54	B	43
Novo Nordisk	NovoSeven	616.52	60%	369.91	B	44
Biogen	Tysabri	718.66	50%	359.33	B	45
Novartis	Sandostatin LAR De	686.95	50%	343.48	B	46
Astellas Pharma	Izervay	568.81	60%	341.29	B	47
GSK	Jemperli	681.39	50%	340.70	B	48
AbbVie	Elahere	662.12	50%	331.06	B	49
Gilead Sciences	Yescarta	625.14	50%	312.57	B	50

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Company	Product	2025 Est Sales	Medicare Exposure	Medicare Sales	Medicare Part	Spending ranking
Bristol Myers Squibb	Eliquis	10,615.10	63%	6,634.44	D	1
Novo Nordisk	Ozempic	14,854.32	40%	5,941.73	D	2
Eli Lilly	Mounjaro	12,896.46	30%	3,868.94	D	3
Pfizer	Vyndaqel	3,999.65	77%	3,079.73	D	4
Gilead Sciences	Biktarvy	11,115.04	25%	2,778.76	D	5
Boehringer Ingelheim	Jardiance	6,619.53	40%	2,647.81	D	6
Novo Nordisk	Wegovy	9,655.34	25%	2,413.83	D	7
GSK	Trelegy Ellipta	2,786.20	70%	1,950.34	D	8
Incyte	Jakafi	2,960.30	60%	1,776.18	D	9
Novartis	Entresto	3,195.86	55%	1,757.72	D	10
Neurocrine Biosciences	Ingrezza	2,614.51	65%	1,699.43	D	11
Bristol Myers Squibb	Pomalyst	2,277.81	68%	1,548.91	D	12
AstraZeneca	Tagrisso	3,014.26	45%	1,356.42	D	13
AbbVie	Skyrizi	13,443.43	10%	1,344.34	D	14
AstraZeneca	Ultomiris	2,627.39	50%	1,313.69	D	15
AbbVie	Vraylar	3,618.92	35%	1,266.62	D	16
Sanofi	Dupixent	12,316.97	10%	1,231.70	D	17
Novartis	Kisqali	2,436.98	50%	1,218.49	D	18
AbbVie	Imbruvica	1,921.85	60%	1,153.11	D	19
AbbVie	Rinvoq	5,616.56	20%	1,123.31	D	20
Teva Pharmaceutical Industries	Austedo	1,803.39	60%	1,082.04	D	21
Eli Lilly	Verzenio	4,028.49	26%	1,047.41	D	22
Novartis	Cosentyx SC	4,127.94	25%	1,031.99	D	23
Bausch Health Companies	Xifaxan 550	2,031.47	50%	1,015.74	D	24
Boehringer Ingelheim	Ofev	2,403.27	40%	961.31	D	25
AstraZeneca	Calquence	2,374.15	40%	949.66	D	26
Amgen	Tepezza	2,044.97	45%	920.24	D	27
Johnson & Johnson	Uptravi	1,628.27	56%	911.83	D	28
BeiGene	Brukinsa	1,795.18	50%	897.59	D	29
Eli Lilly	Trulicity	2,970.78	30%	891.23	D	30
Johnson & Johnson	Opsumit	1,585.85	56%	888.07	D	31
Pfizer	Paxlovid	2,955.45	30%	886.63	D	32
Merck & Co	Winrevair	1,156.92	71%	821.41	D	33
AbbVie	Creon	1,403.65	55%	772.01	D	34
Pfizer	Ibrance	2,290.72	33%	755.94	D	35
Roche	Activase	1,345.48	56%	753.47	D	36
Johnson & Johnson	Erleada	1,471.24	50%	735.62	D	37
Bayer	Nubeqa	1,455.01	50%	727.50	D	38
Amgen	Repatha	1,297.25	56%	726.46	D	39
United Therapeutics	Tyvaso DPI	1,283.10	56%	718.54	D	40
Pfizer	Abrysvo	807.20	85%	686.12	D	41
GSK	Shingrix	1,623.28	40%	649.31	D	42
Otsuka Holdings	Rexulti	1,821.01	35%	637.35	D	43
AbbVie	Ubrelvy	1,106.11	55%	608.36	D	44
Eli Lilly	Zepbound	10,708.71	5%	535.44	D	45
Vertex Pharmaceuticals	Trikafta	5,300.27	10%	530.03	D	46
AbbVie	Venclexta	1,259.80	40%	503.92	D	47
AstraZeneca	Lynparza	1,399.26	35%	489.74	D	48
Pfizer	Nurtec ODT	1,393.58	34%	473.82	D	49
Boehringer Ingelheim	Tradjenta	1,140.54	40%	456.22	D	50

Source: Jefferies Analysis

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+ our list of potential Top 50 drugs for both Medicare Part B and D includes 31 total drugs for stocks under our coverage, including ARGX, REGN, BMY, LLY, PFE, and MRK

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Product	Medicare Part	Company	Dose
Vyvgart	B	ARGX	400 MG/20ML
Opdivo	B	BMY	40 mg/4 mL
Yervoy	B	BMY	50 mg/10 mL IV
Orencia	B	BMY	250 mg IV
Eliquis	D	BMY	5 mg 60/bottle
Pomalyst	D	BMY	1 mg oral capsule 21/bottle
Reblozyl	B	BMY	25 mg subQ
Cabometyx	B	EXEL	40 MG/30 tablets
Jardiance	D	LLY	10mg/30 tablets
Mounjaro	D	LLY	10mg 4 weeks
Verzenio	D	LLY	150mg/28 tablets
Trulicity	D	LLY	1.5mg/0.5ml 4 weeks
Zepbound	D	LLY	10mg 4 weeks
Tradjenta	D	LLY	5mg/30 tablets
Keytruda	B	MRK	100 MG/4ML
Lenvima	B	MRK	10mg capsule/30 pieces
Bridion	B	MRK	200 MG/2ML
Gardasil 9	B	MRK	1 vial
Winrevair	D	MRK	45mg 1 piece
Lynparza	D	MRK	150mg, 56 pieces
Ingrezza	D	NBIX	40 MG/ 30 tablets
Prevnar	B	PFE	0.5ML
Comirnaty	B	PFE	1-dose-adult
Padcev	B	PFE	20mg(1-dose-adult)
Adcetris	B	PFE	50mg
Vyndaqel	D	PFE	20mg/1 tablet
Paxlovid	D	PFE	Pack 20 x 150 MG & 10 x 100MG
Ibrance	D	PFE	100mg/21 tablets
Nurtec ODT	D	PFE	75mg/8 tablets
Abrysvo	D	PFE	120 MCG/0.5ML(1-dose-adult)
Eylea HD	B	REGN	8 MG/0.07ML
Dupixent	D	REGN	300 MG/2ML

Although the original 2020 MFN model had various exclusions, including vaccines, radiopharma, certain oral medication, IVIG, etc., we took a look at the reasoning laid out in the federal registrar and decided to include vaccines, oral medication, and previous EUA products (assuming they wouldn't get excluded in a new MFN model) given **1) vaccines make up a large part of Part B spend & paid under AWP, which made it difficult to reconcile with the 2020 MFN model method of calculation (ASP + alternative add-on payment); 2) certain oral medications were excluded due to being administered at home; 3) EUA products at the time like COVID vaccines were excluded due to the pandemic.** That said, we still exclude radiopharmaceuticals and IVIG due to the nature of their susceptibility to being in short supply. We also get to the Top 50 Part D list using a similar approach.

In total, our Top 50 lists from Medicare Part B and D include 31 drugs under our coverage

Source: Jefferies Analysis

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2) Next, we determined the MFN price for 1) drugs within our top 50 lists under our coverage & 2) all drugs under our coverage + here are our key steps –

A

Determine the qualified MFN countries and adjust for Economic Capacity
- Compute the GDP adjuster for each country and determine the qualified list (GDP adjuster > 0.6)

B

Gather and Standardize International Pricing Data:
- Identify publicly available international drug price

C

Determine the MFN Price
- Select the lowest GDP-adjusted price across countries as the MFN price for the drug

D

Compare to Domestic Price
- Identify the applicable domestic drug price + calculate the domestic and MFN spread

Note that we considered 2 scenarios – 1) Full impact MFN (top 50 Medicare Part B/D or IRA only or all Medicare) & 2) MFN (top 50 Medicare Part B/D) with pharma employing mitigation parameters

Source: Jefferies Analysis

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A) We selected OECD countries that were at least 60% of the US GDP per capita GDP-adjusted on a purchasing power parity basis, which we think should adjust for economic capacity on a country-by-country level

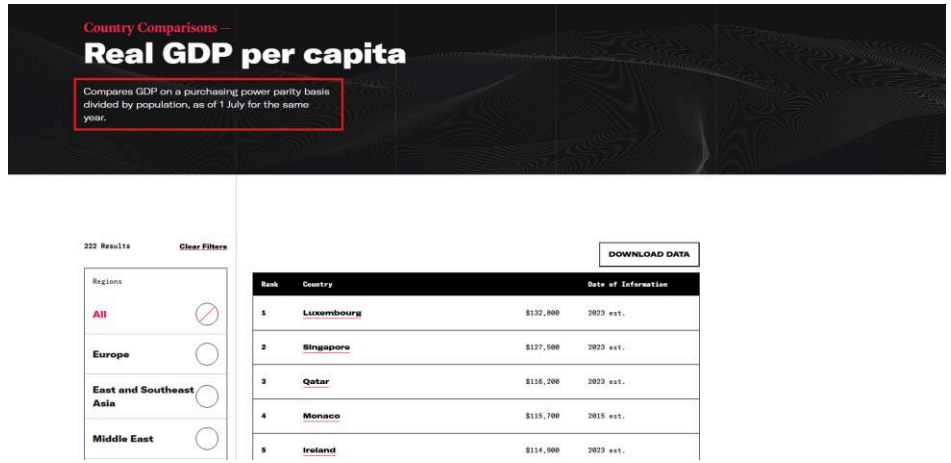
Trump's original 2020 model laid out a framework around implementation + we followed this method to reidentify the countries and lowest drug prices assuming similar criteria:
1) We selected the **OECD countries that were at least 60% percent of the US GDP per capita**.

2) Our adjustment is calculated by **dividing a non-U.S. OECD country's GDP per capita by the U.S. GDP per capita on a purchasing power parity basis**, which allows us to adjust country-level prices to reflect relative purchasing power.

3) **We capped the GDP adjustment at 1.0, given CMS guidance which ensures that countries with higher GDP per capita than the U.S. do not receive additional discounts**

Overall, we identified 25 OECD countries that may be used for MFN reference pricing. These countries are **Luxembourg, Ireland, Norway, Switzerland, Netherlands, Iceland, Denmark, Australia, Austria, Germany, Belgium, Sweden, Canada, Finland, France, United Kingdom, Italy, Israel, Slovenia, New Zealand, Spain, Czechia, South Korea, Lithuania, and Japan.**

There are several existing sources for GDP data, including the Central Intelligence Agency (CIA) World Factbook,[51] the World Bank,[52] and the International Monetary Fund.[53] Upon examining these sources, we noted that the GDP data across these sources are highly associated with one another. We will use the CIA World Factbook as our source for GDP data as it is issued by a U.S. government agency and includes estimates for all OECD member countries. We will use the following process to determine the countries that were non-U.S. OECD member countries as of October 1, 2020, with a GDP per capita that is at least 60 percent of the U.S. GDP per capita. For each country, we will assess the GDP per capita based on purchasing power parity that is available in the CIA World Factbook at the end of the applicable ASP calendar quarter. The CIA World Factbook contains the most recent estimate of GDP per capita based on purchasing power parity for a country as well as historical data. We will identify whether a country has a GDP per capita that is at least 60 percent of the U.S. GDP per capita by dividing the most recent estimate of GDP per capita based on purchasing power parity for a country by the U.S. GDP per capita, using data for the same year, and assessing the results. We will use the GDP per capita from the same year as the international drug pricing information that is used to calculate the unadjusted country-level price, if available, or the most recent prior year.



Source: Jefferies Analysis, cia.gov, worldbank.org

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Here are our full GDP adjustments + we project GDP using a historical 10-yr avg and apply this going forward to determine if countries are still eligible

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OECD Countries		GDP per capita, based on purchasing power parity - 2023	GDP adjuster
United States	$	74,600	1.00
Luxembourg	$	132,800	1.00
Ireland	$	114,900	1.00
Norway	$	90,500	1.00
Switzerland	$	82,600	1.00
Netherlands	$	71,400	0.96
Iceland	$	67,300	0.90
Denmark	$	72,100	0.97
Australia	$	59,600	0.80
Austria	$	65,000	0.87
Germany	$	63,600	0.85
Belgium	$	64,200	0.86
Sweden	$	63,100	0.85
Canada	$	55,900	0.75
Finland	$	57,100	0.77
France	$	55,400	0.74
United Kingdom	$	54,500	0.73
Italy	$	53,300	0.71
Israel	$	48,400	0.65
Slovenia	$	48,200	0.65
New Zealand	$	48,800	0.65
Spain	$	47,100	0.63
Czechia	$	49,700	0.67
Korea, South	$	50,600	0.68
Lithuania	$	46,700	0.63
Japan	$	46,200	0.62
Portugal	$	41,800	0.56
Estonia	$	42,500	0.57
Poland	$	44,400	0.60
Hungary	$	40,500	0.54
Slovakia	$	39,300	0.53
Turkey (Turkiye)	$	34,600	0.46
Latvia	$	37,000	0.50
Greece	$	36,900	0.49
Chile	$	29,500	0.40
Costa Rica	$	26,300	0.35
Mexico	$	22,100	0.30
Colombia	$	18,700	0.25

10yr GDP per capita avg Growth%	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
1.87%	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
0.12%	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
6.98%	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
0.72%	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
0.84%	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.99	0.98	0.97	0.96	0.95	0.94	0.93
1.47%	0.95	0.95	0.94	0.94	0.93	0.93	0.93	0.92	0.92	0.92	0.91	0.91	0.91	0.90	0.90	0.89
1.57%	0.90	0.89	0.89	0.89	0.89	0.88	0.88	0.88	0.88	0.87	0.87	0.87	0.87	0.86	0.86	0.86
1.69%	0.96	0.96	0.96	0.96	0.96	0.95	0.95	0.95	0.95	0.95	0.95	0.94	0.94	0.94	0.94	0.94
1.01%	0.79	0.78	0.77	0.77	0.76	0.75	0.75	0.74	0.73	0.73	0.72	0.72	0.71	0.70	0.70	0.69
0.60%	0.85	0.84	0.83	0.82	0.81	0.80	0.79	0.78	0.77	0.76	0.75	0.74	0.73	0.72	0.71	0.70
0.83%	0.84	0.83	0.82	0.81	0.80	0.79	0.79	0.78	0.77	0.76	0.75	0.75	0.74	0.73	0.72	0.72
1.16%	0.85	0.84	0.84	0.83	0.83	0.82	0.81	0.81	0.80	0.80	0.79	0.79	0.78	0.77	0.77	0.76
1.10%	0.83	0.83	0.82	0.81	0.81	0.80	0.80	0.79	0.78	0.78	0.77	0.77	0.76	0.75	0.75	0.74
0.41%	0.73	0.72	0.71	0.70	0.69	0.68	0.67	0.66	0.65	0.64	0.63	0.62	0.61	0.60		
0.63%	0.75	0.74	0.73	0.72	0.71	0.70	0.69	0.69	0.68	0.67	0.66	0.65	0.64	0.64	0.63	0.62
0.82%	0.73	0.72	0.71	0.71	0.70	0.69	0.68	0.68	0.67	0.66	0.66	0.65	0.64	0.64	0.63	0.62
1.00%	0.72	0.71	0.71	0.70	0.69	0.69	0.68	0.68	0.67	0.66	0.66	0.65	0.65	0.64	0.64	0.63
1.25%	0.71	0.70	0.70	0.69	0.69	0.68	0.68	0.68	0.67	0.67	0.66	0.66	0.66	0.65	0.65	0.64
1.98%	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.66	0.66	0.66	0.66	0.66	0.66	0.66	0.66	0.66
2.74%	0.66	0.66	0.67	0.67	0.68	0.69	0.69	0.70	0.70	0.71	0.72	0.72	0.73	0.73	0.74	0.75
1.17%	0.65	0.64	0.64	0.63	0.63	0.62	0.62	0.61	0.61	0.61	0.60					
1.67%	0.63	0.63	0.63	0.63	0.62	0.62	0.62	0.62	0.62	0.62	0.62	0.62	0.61	0.61	0.61	0.61
1.96%	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.68	0.68	0.68
2.23%	0.68	0.69	0.69	0.69	0.69	0.70	0.70	0.70	0.70	0.70	0.71	0.71	0.71	0.71	0.72	0.72
3.60%	0.65	0.66	0.67	0.68	0.69	0.70	0.72	0.73	0.74	0.75	0.77	0.78	0.79	0.81	0.82	0.83
0.79%	0.61															
1.90%																
1.88%																
4.15%	0.62	0.64	0.65	0.66	0.68	0.69	0.71	0.73	0.74	0.76	0.78	0.79	0.81	0.83	0.85	0.87
3.41%						0.60	0.61	0.62	0.63	0.64	0.65	0.66	0.67	0.68	0.69	0.70
2.38%																
3.78%													0.60	0.61	0.62	0.64
3.10%															0.60	0.61
1.93%																
0.85%																
2.58%																
0.57%																
1.54%																

We then projected the GDP adjustment through 2040 to forecast future GDP by applying the average annual GDP per capita growth rate over the past 10 years for each country(data from worldbank.org). **We will caveat that we used flat rate for 10-year avg growth in our projection. For the countries with projected rates falling below 0.6 in the future years (e.g., Japan, New Zealand, and Canada), we conservatively assumed a flat rate of 0.6 for the remainder of the period.**

Source: Jefferies Analysis, cia.gov, worldbank.org

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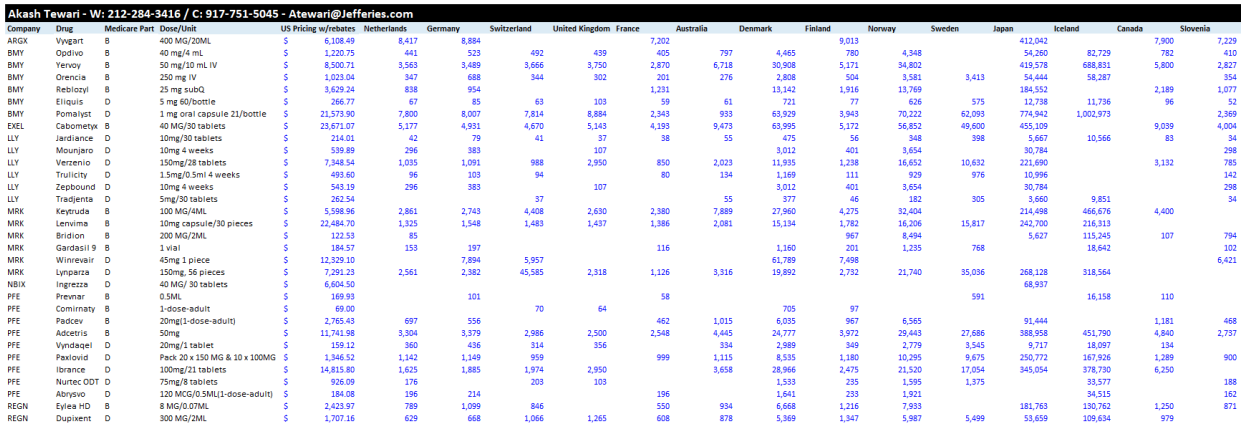
B) We then collected international drug pricing data per drug using publicly available sources as per MFN 2020 guidelines. Caveat here that sources do not disclose details re: rebates or discounts

Commenters also noted that one potential adverse reaction to the model described in the October 2018 ANPRM may be a shift internationally to a high price and high rebate pricing strategy. Specifically, commenters expressed concern that if the international drug pricing information used to establish payment under a model relied on the list prices in the included countries, then manufacturers would restructure their pricing arrangements to increase the list prices of the model's drugs in those countries, and offer higher rebates to offset the increased list price. CMS appreciates this concern, and we will prioritize use of available international drug pricing information that incorporate discounts and rebates to the extent possible, rather than just the list prices.



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Company	Drug	Medicare Part	Dose/Unit	US Pricing w/rebates	Netherlands	Germany	Switzerland	United Kingdom	France	Australia	Denmark	Finland	Norway	Sweden	Japan	Iceland	Canada	Slovenia
ARGX	Vyvgart	B	400 MG/20ML	$ 6,108.49	8,417	8,884			7,202			9,013			412,042		7,900	7,229
BMY	Opdivo	B	40 mg/4 mL	$ 1,220.75	441	523	492	439	405	797	4,465	780	4,348		54,260	82,729	782	410
BMY	Yervoy	B	50 mg/10 mL IV	$ 8,500.71	3,563	3,489	3,666	3,750	2,870	6,718	30,908	5,171	34,802		419,578	688,831	5,800	2,827
BMY	Orencia	B	250 mg IV	$ 1,023.04	347	688	344	302	201	276	2,808	504	3,581	3,413	54,444	58,287		354
BMY	Reblozyl	B	25 mg subQ	$ 3,629.24	838	954			1,231		13,142	1,916	13,769		184,552		2,189	1,077
BMY	Eliquis	D	5 mg 60/bottle	$ 266.77	67	85	63	103	59	61	721	77	626	575	12,738	11,736	96	52
BMY	Pomalyst	D	1 mg oral capsule 21/bottle	$ 21,573.90	7,800	8,007	7,814	8,884	2,343	933	63,929	3,943	70,222	62,093	774,942	1,002,973		2,369
EXEL	Cabometyx	D	40 MG/30 tablets	$ 23,671.07	5,177	4,931	4,670	5,143	4,193	9,473	63,995	5,172	56,852	49,600	455,109		9,039	4,004
LLY	Jardiance	D	10mg/30 tablets	$ 214.01	42	79	41	37	38	55	475	56	348	398	5,667	10,566	83	34
LLY	Mounjaro	D	10mg 4 weeks	$ 539.89	296	383		107			3,012	401	3,654		30,784			298
LLY	Verzenio	D	150mg/28 tablets	$ 7,348.54	1,035	1,091	988	2,950	850	2,023	11,935	1,238	16,652	10,632	221,690		3,132	785
LLY	Trulicity	D	1.5mg/0.5ml 4 weeks	$ 493.60	96	103	94		80	134	1,169	111	929	976	10,996			142
LLY	Zepbound	D	10mg 4 weeks	$ 543.19	296	383		107			3,012	401	3,654		30,784			298
LLY	Tradjenta	D	5mg/30 tablets	$ 262.54			37			55	377	46	182	305	3,660	9,851		34
MRK	Keytruda	B	100 MG/4ML	$ 5,598.96	2,861	2,743	4,408	2,630	2,380	7,889	27,960	4,275	32,404		214,498	466,676	4,400	
MRK	Lenvima	B	10mg capsule/30 pieces	$ 22,484.70	1,325	1,548	1,483	1,437	1,386	2,081	15,134	1,782	16,206	15,817	242,700	216,313		
MRK	Bridion	B	200 MG/2ML	$ 122.53	85							967	8,494		5,627	115,245	107	794
MRK	Gardasil 9	B	1 vial	$ 184.57	153	197			116		1,160	201	1,235	768		18,642		102
MRK	Winrevair	D	45mg 1 piece	$ 12,329.10		7,894	5,957				61,789	7,498						6,421
MRK	Lynparza	D	150mg, 56 pieces	$ 7,291.23	2,561	2,382	45,585	2,318	1,126	3,316	19,892	2,732	21,740	35,036	268,128	318,564		
NBIX	Ingrezza	D	40 MG/ 30 tablets	$ 6,604.50											68,937			
PFE	Prevnar	B	0.5ML	$ 169.93		101			58					591		16,158	110	
PFE	Comirnaty	B	1-dose-adult	$ 69.00			70	64			705	97						
PFE	Paxlev	B	20mg(1-dose-adult)	$ 2,765.43	697	556			462	1,015	6,035	967	6,565		91,444		1,181	468
PFE	Adcetris	B	50mg	$ 11,741.98	3,304	3,379	2,986	2,500	2,548	4,445	24,777	3,972	29,443	27,686	388,958	451,790	4,840	2,737
PFE	Vyndaqel	D	20mg/1 tablet	$ 159.12	360	436	314	356		334	2,989	349	2,779	3,545	9,717	18,097	134	
PFE	Paxlovid	D	Pack 20 x 150 MG & 10 x 100MG	$ 1,346.52	1,142	1,149	959		999	1,115	8,535	1,180	10,295	9,675	250,772	167,926	1,289	900
PFE	Ibrance	D	100mg/21 tablets	$ 14,815.80	1,625	1,885	1,974	2,950		3,658	28,966	2,475	21,520	17,054	345,054	378,730	6,250	
PFE	Nurtec ODT	D	75mg/8 tablets	$ 926.09	176		203	103			1,533	235	1,595	1,375		33,577		188
PFE	Abrysvo	D	120 MCG/0.5ML(1-dose-adult)	$ 184.08	196	214			196		1,641	233	1,921			34,515		162
REGN	Eylea HD	B	8 MG/0.07ML	$ 2,423.97	789	1,099	846		550	934	6,668	1,216	7,933		181,763	130,762	1,250	871
REGN	Dupixent	D	300 MG/2ML	$ 1,707.16	629	668	1,066	1,265	608	878	5,369	1,347	5,987	5,499	53,659	109,634	979	

Source: Jefferies Analysis

In response to its October 2018 ANPRM, CMS considered requiring manufacturers to report international drug sales data but received feedback that this would be too burdensome and complex**. Instead, CMS will use existing data sources to calculate MFN Drug Payment Amounts, which they believe are sufficient.** Commenters also flagged that the model could incentivize manufacturers to raise list prices abroad while increasing rebates. CMS acknowledged the risk and will prioritize using international pricing data that accounts for discounts and rebates as available.

In our analysis, we gathered international drug prices from publicly available government drug databases. Note that the prices listed in the table are in local currency. **We want to caveat that these sources generally do not disclose details related to confidential rebates or discounts, thus may overstate the actual prices.**

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C) Next, we collected domestic prices using I) ASP for U.S. prices for Part B drugs & II) US net price using MedPAC data and the IRA published price list for Part D drugs

H. COMPARE THE MFN PRICE TO THE APPLICABLE ASP

As a safeguard for beneficiaries, we will compare the MFN Price to the applicable ASP in order to ensure that beneficiaries are always paying the lowest amount of coinsurance available. If the applicable ASP is less than the MFN Price, we will establish the MFN Price as equal to the applicable ASP.

Chart 10-22 **Top 15 therapeutic classes of drugs covered under Part D, by spending, 2022**

	Gross spending		Negotiated rebates as a share of gross spending	Coverage-ga discount (billions)
	Billions	Percent		
Diabetic therapy	$46.9	19.5%	≥50%	$6.2
Antineoplastics	32.1	13.4	<10%	0.9
Anticoagulants	21.7	9.0	40% to 49%	3.5
Asthma/COPD therapy agents	16.6	6.9	40% to 49%	1.4
Disease-modifying anti-rheumatoid drugs	11.9	4.9	20% to 29%	0.4
Antipsychotics (neuroleptics)	8.4	3.5	10% to 19%	0.1
Antiretrovirals	7.9	3.3	<10%	0.2
Antihypertensive therapy agents	7.6	3.2	10% to 19%	0.5
Ophthalmic agents	5.9	2.5	30% to 39%	0.4
Antihyperlipidemics	5.4	2.3	10% to 19%	0.3
Dermatological (antipsoriatics)	5.2	2.2	10% to 19%	0.1
Anticonvulsants	4.1	1.7	<10%	0.1
Multiple sclerosis agents	3.9	1.6	10% to 19%	0.1
Antidepressants	3.0	1.3	<10%	0.1
Urinary incontinence treatment agents	3.0	1.3	40% to 49%	0.3
Subtotal, top 15 drug classes	183.9	76.5	28%	14.6
Total, all drug classes	240.5	100.0	24%	16.4

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price	Total Part D Gross Covered Prescription Drug Costs, CY 2023	Number of Medicare Part D Enrollees Who Used the Drug, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	$113.00	$527.00	79%	$4,091,399,000	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	$119.00	$495.00	76%	$2,612,719,000	785,000
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	$178.50	$556.00	68%	$4,342,594,000	994,000
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,355.00	$7,106.00	67%	$2,951,778,000	48,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	$197.00	$573.00	66%	$8,840,947,000	1,883,000
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$4,695.00	$13,836.00	66%	$2,988,560,000	23,000
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$197.00	$517.00	62%	$6,309,766,000	1,324,000
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	$231.00	$521.00	56%	$18,275,108,000	3,928,000
Entresto	Novartis Pharms Corp	Heart failure	$295.00	$628.00	53%	$3,430,753,000	664,000
Imbruvica	Pharmacyclics LLC	Blood cancers	$9,319.00	$14,934.00	38%	$2,371,858,000	17,000

Source: Jefferies Analysis, MedPAC, CMS

In the published MFN model, CMS selected the top 50 Medicare Part B drugs by spending. **For the US price component, CMS used the Average Sales Price (ASP) to reflect the lowest available net price, inclusive of discounts and rebates. We want to flag that MFN Model should apply to US net price.**

To match their assumptions, we adopted the following for US net price:

- We used the Average Sales Price (ASP) for Medicare Part B drugs.
- **For Part D, we estimated discounts based on historical rebate levels within each drug's therapeutic class using MedPAC published report**(HERE).
- We used the **CMS published discount of the 2023 list price as a proxy for the US price for the drugs that were IRA negotiated**(HERE).

After converting the intl prices to USD and applying the GDP adjusters, we used the lowest price as our MFN price and MFN country. We then compared the MFN price with US price to get the spread.

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D) After, we converted all prices to USD and applied GDP adjusters to normalize price across countries – we used the lowest GDP adjusted price as the MFN price and found the spread between US and MFN Price

Difference%	Drug	US Pricing w/rebates	MFN Price - in $	*FX	Netherlands	Germany	Switzerland	United Kingdom	France	Australia	Denmark	Finland	Norway	Sweden	Japan	Iceland	Canada	Slovenia
				Country	1.14	1.14	1.21	1.33	1.14	0.64	0.15	1.14	0.095	0.10	0.007	0.0079	0.72	1.14
-22%	Vyvgart	$ 6,108	$ 4,758	Japan	$ 10,105	$ 12,125			$ 11,288			$ 13,757			$ 4,758		$ 7,814	$ 12,539
-66%	Opdivo	$ 1,221	$ 413	Norway	$ 530	$ 714	$ 596	$ 813	$ 635	$ 649	$ 696	$ 1,191	$ 413		$ 627	$ 729	$ 774	$ 711
-61%	Yervoy	$ 8,501	$ 3,306	Norway	$ 4,277	$ 4,762	$ 4,436	$ 6,945	$ 4,498	$ 5,474	$ 4,814	$ 7,893	$ 3,306		$ 4,845	$ 6,068	$ 5,737	$ 4,904
-78%	Orencia	$ 1,023	$ 225	Australia	$ 417	$ 938	$ 416	$ 560	$ 315	$ 225	$ 437	$ 769	$ 340	$ 410	$ 629	$ 513		$ 613
-72%	Reblozyl	$ 3,629	$ 1,006	Netherlands	$ 1,006	$ 1,302			$ 1,929		$ 2,047	$ 2,925	$ 1,308		$ 2,131		$ 2,165	$ 1,869
-81%	Eliquis	$ 267	$ 50	Australia	$ 81	$ 117	$ 76	$ 191	$ 92	$ 50	$ 112	$ 117	$ 59	$ 69	$ 147	$ 103	$ 95	$ 90
-96%	Pomalyst	$ 21,574	$ 760	Australia	$ 9,364	$ 10,928	$ 9,455	$ 16,453	$ 3,672	$ 760	$ 9,958	$ 6,018	$ 6,671	$ 7,454	$ 8,948	$ 8,835		$ 4,110
-78%	Cabometyx	$ 23,671	$ 5,255	Japan	$ 6,216	$ 6,730	$ 5,651	$ 9,524	$ 6,571	$ 7,718	$ 9,968	$ 7,894	$ 5,401	$ 5,954	$ 5,255		$ 8,940	$ 6,945
-85%	Jardiance	$ 214	$ 33	Norway	$ 51	$ 108	$ 49	$ 68	$ 60	$ 45	$ 74	$ 86	$ 33	$ 48	$ 65	$ 93	$ 82	$ 59
-63%	Mounjaro	$ 540	$ 198	United Kingdom	$ 355	$ 523		$ 198			$ 469	$ 613	$ 347		$ 355			$ 516
-84%	Verzenio	$ 7,349	$ 1,195	Switzerland	$ 1,243	$ 1,489	$ 1,195	$ 5,463	$ 1,332	$ 1,648	$ 1,859	$ 1,889	$ 1,582	$ 1,276	$ 2,560		$ 3,098	$ 1,362
-82%	Trulicity	$ 494	$ 88	Norway	$ 115	$ 141	$ 113		$ 126	$ 109	$ 182	$ 170	$ 88	$ 117	$ 127			$ 247
-64%	Zepbound	$ 543	$ 198	United Kingdom	$ 355	$ 523		$ 198			$ 469	$ 613	$ 347		$ 355			$ 516
-93%	Tradjenta	$ 263	$ 17	Norway			$ 45			$ 45	$ 59	$ 70	$ 17	$ 37	$ 42	$ 87		$ 60
-56%	Keytruda	$ 5,599	$ 2,477	Japan	$ 3,434	$ 3,744	$ 5,333	$ 4,871	$ 3,730	$ 6,428	$ 4,355	$ 6,525	$ 3,078		$ 2,477	$ 4,111	$ 4,352	
-93%	Lenvima	$ 22,485	$ 1,540	Norway	$ 1,591	$ 2,113	$ 1,794	$ 2,661	$ 2,172	$ 1,696	$ 2,357	$ 2,720	$ 1,540	$ 1,899	$ 2,802	$ 1,905		
-47%	Bridion	$ 123	$ 65	Japan	$ 102							$ 1,475	$ 807		$ 65	$ 1,015	$ 106	$ 1,377
-50%	Gardasil 9	$ 185	$ 92	Sweden	$ 183	$ 269			$ 182		$ 181	$ 306	$ 117	$ 92		$ 164		$ 177
-42%	Winrevair	$ 12,329	$ 7,208	Switzerland		$ 10,773	$ 7,208				$ 9,625	$ 11,444						$ 11,137
-76%	Lynparza	$ 7,291	$ 1,765	France	$ 3,074	$ 3,250	$ 55,158	$ 4,292	$ 1,765	$ 2,702	$ 3,098	$ 4,170	$ 2,065	$ 4,206	$ 3,096	$ 2,806		
-88%	Ingrezza	$ 6,605	$ 796	Japan											$ 796			
-58%	Prevnar	$ 170	$ 71	Sweden		$ 138			$ 91					$ 71		$ 142	$ 109	
0%	Comirnaty	$ 69	$ 85	Switzerland			$ 85	$ 119			$ 110	$ 149						
-77%	Padcev	$ 2,765	$ 624	Norway	$ 837	$ 758			$ 724	$ 827	$ 940	$ 1,476	$ 624		$ 1,056		$ 1,168	$ 811
-76%	Adcetris	$ 11,742	$ 2,797	Norway	$ 3,967	$ 4,611	$ 3,613	$ 4,630	$ 3,993	$ 3,622	$ 3,859	$ 6,062	$ 2,797	$ 3,324	$ 4,491	$ 3,980	$ 4,787	$ 4,747
-29%	Vyndaqel	$ 159	$ 112	Japan	$ 432	$ 595	$ 380	$ 660		$ 272	$ 466	$ 533	$ 264	$ 426	$ 112	$ 159	$ 132	
-33%	Paxlovid	$ 1,347	$ 909	Australia	$ 1,371	$ 1,568	$ 1,160		$ 1,566	$ 909	$ 1,329	$ 1,801	$ 978	$ 1,161	$ 2,895	$ 1,479	$ 1,275	$ 1,562
-87%	Ibrance	$ 14,816	$ 1,951	Netherlands	$ 1,951	$ 2,572	$ 2,388	$ 5,463		$ 2,980	$ 4,512	$ 3,778	$ 2,044	$ 2,047	$ 3,984	$ 3,336	$ 6,182	
-84%	Nurtec ODT	$ 926	$ 152	Norway	$ 211		$ 245	$ 191			$ 239	$ 359	$ 152	$ 165		$ 296		$ 327
-1%	Abrysvo	$ 184	$ 182	Norway	$ 236	$ 292			$ 307		$ 256	$ 356	$ 182			$ 304		$ 282
-69%	Eylea HD	$ 2,424	$ 754	Norway	$ 947	$ 1,500	$ 1,024		$ 862	$ 761	$ 1,039	$ 1,856	$ 754		$ 2,099	$ 1,152	$ 1,236	$ 1,510
-67%	Dupixent	$ 1,707	$ 569	Norway	$ 755	$ 911	$ 1,289	$ 2,342	$ 953	$ 715	$ 836	$ 2,057	$ 569	$ 660	$ 620	$ 966	$ 968	

After converting international prices to USD and adjusting GDP, we identified the MFN price for the Top 50 Medicare Part B and Part D drugs in our coverage. The difference between US net price and MFN price ranged from 0% to 96%. And some of the frequently represented countries included Norway, Australia, Japan, and Switzerland.

Source: Jefferies Analysis, Government Drug Database

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3) Lastly, we built an illustrative model to run scenarios re: MFN impact –

Here are our key assumptions:

1. We used the US net price and assumed an increase of 3% YoY
2. For international prices, we assumed a 1-time increase of 10% for the countries that is > 80% of US GDP per capita
3. We then applied the MFN spread to the US revenue * the Medicare exposure. We also assumed a 15% commercial spillover.
4. We then assumed co's will shift from Government channel to commercial to about ~20% over 10 years.
5. Companies increase prices across their portfolio by 3% for Medicare/Medicaid (assuming inflation at 3%), and 7% for commercial for unselected drugs
6. Companies opt-out of some markets with high MFN spread and low revenue

Non-GAAP PNL	2025	2026	2027	2028	2029	2030
MFN Impact						
Commercial Spillover	15%	15%	15%	15%	15%	15%
Mounjaro	-	-	(1,081)	(2,348)	(3,690)	(5,249)
Zepbound	-	-	(611)	(1,457)	(2,446)	(3,621)
Verzenio	-	-	(326)	(690)	(1,060)	(1,338)
Trulicity	-	-	(146)	(227)	(271)	(288)
Humalog	-	-	(48)	(91)	(130)	(166)
Emgality	-	-	(19)	(41)	(65)	(82)
Humulin	-	-	(24)	(46)	(66)	(84)
Basaglar	-	-	(18)	(34)	(49)	(63)
Erbitux	-	-	(20)	(37)	(51)	(65)
Cialis	-	-	(1)	(2)	(3)	(4)
Ebglyss	-	-	(60)	(157)	(321)	(485)
Forteo	-	-	(7)	(12)	(17)	(22)
Cymbalta	-	-	(1)	(2)	(3)	(4)
Orforglipron	-	-	-	-	-	-
Taltz	-	-	(152)	(308)	(421)	(425)
Jardiance	-	-	(161)	(231)	(201)	(187)
Olumiant	-	-	(20)	(41)	(64)	(87)
Cyramza	-	-	(11)	(17)	(22)	(25)
Jaypirca	-	-	(62)	(153)	(268)	(385)
Retevmo	-	-	(24)	(52)	(75)	(107)
Omvoh	-	-	(38)	(94)	(174)	(266)
Tradjenta	-	-	(4)	(8)	(12)	(15)
Kisunla	-	-	-	-	-	-
Zyprexa	-	-	-	-	-	-
Alimta	-	-	-	-	-	-
Reyvow	-	-	(3)	(6)	(9)	(13)
MFN Impact	-	-	**(2,328)**	**(4,961)**	**(7,680)**	**(10,698)**

Source: Jefferies Analysis

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Importantly, our illustrative model captures the four-year phase-in period from Trump's 2020 MFN guidance – post the 4-year phase-in period, we maintain impact at 100% (we conservatively assume MFN impact long term)

Table 5—Phase-In of MFN Prices by Performance Year

Performance year	Blend of the ASP and MFN price for an MFN model drug at the HCPCS code level
Year 1	75 percent applicable ASP and 25 percent MFN Price.
Year 2	50 percent applicable ASP and 50 percent MFN Price.
Year 3	25 percent applicable ASP and 75 percent MFN Price.
Year 4	100 percent MFN Price.
Year 5	100 percent MFN Price.
Year 6	100 percent MFN Price.
Year 7	100 percent MFN Price.

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Camzyos	1,370	1,370	1,370	1,370	1,370	1,370	1,370	1,370	1,370	1,370	1,370
Empliciti	806	806	806	806	806	806	806	806	806	806	806
Abecma	273,600	273,600	273,600	273,600	273,600	273,600	273,600	273,600	273,600	273,600	273,600
Sprycel	890	890	890	890	890	890	890	890	890	890	890
Cobenfy	-	-	-	-	-	-	-	-	-	-	-
Revlimid	1,325	1,325	1,325	1,325	1,325	1,325	1,325	1,325	1,325	1,325	1,325
Abraxane	242	266	266	266	266	266	266	266	266	266	266
Sotyktu	532	532	532	532	532	532	532	532	532	532	532
Onureg	8,580	9,439	9,439	9,439	9,439	9,439	9,439	9,439	9,439	9,439	9,439
Zeposia	1,268	1,394	1,394	1,394	1,394	1,394	1,394	1,394	1,394	1,394	1,394
Krazati	-	-	-	-	-	-	-	-	-	-	-
Augtyro	1,456.69	1,457	1,457	1,457	1,457	1,457	1,457	1,457	1,457	1,457	1,457
Fedratinib	3,645	4,010	4,010	4,010	4,010	4,010	4,010	4,010	4,010	4,010	4,010
Phase-In Rate	-	-	25%	50%	75%	100%	100%	100%	100%	100%	100%
%impact on Sales											
Pomalyst/Imnovid	0%	0%	-21%	-42%	-63%	-85%	-85%	-85%	-85%	-86%	-86%
Eliquis	0%	0%	-17%	-34%	-51%	-69%	-69%	-70%	-70%	-71%	-71%
Opdivo	0%	0%	-13%	-26%	-40%	-55%	-57%	-58%	-59%	-60%	-61%
Orencia	0%	0%	-18%	-35%	-54%	-72%	-73%	-73%	-74%	-74%	-75%
Yervoy	0%	0%	-12%	-24%	-38%	-51%	-53%	-54%	-55%	-56%	-57%
Reblozyl	0%	0%	-16%	-31%	-48%	-64%	-65%	-66%	-66%	-67%	-67%
Opdualag/ Relatlimab	0%	0%	-16%	-32%	-48%	-65%	-65%	-66%	-67%	-67%	-68%
Breyanzi	0%	0%	-5%	-12%	-19%	-28%	-30%	-32%	-34%	-36%	-37%
Camzyos	0%	0%	-20%	-40%	-60%	-80%	-81%	-81%	-82%	-83%	-83%
Empliciti	0%	0%	-14%	-28%	-43%	-58%	-59%	-60%	-60%	-61%	-62%
Abecma	0%	0%	-7%	-14%	-23%	-31%	-33%	-34%	-35%	-36%	-38%
Sprycel	0%	0%	-24%	-47%	-71%	-94%	-95%	-95%	-95%	-95%	-95%
Cobenfy	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Revlimid	0%	0%	-23%	-46%	-68%	-92%	-92%	-92%	-92%	-92%	-93%
Abraxane	0%	0%	-20%	-40%	-61%	-81%	-82%	-82%	-83%	-83%	-84%
Sotyktu	0%	0%	-21%	-42%	-64%	-85%	-86%	-86%	-86%	-87%	-87%
Onureg	0%	0%	-13%	-27%	-42%	-57%	-58%	-60%	-61%	-62%	-63%
Zeposia	0%	0%	-19%	-39%	-59%	-79%	-79%	-80%	-80%	-80%	-81%
Krazati	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Augtyro	0%	0%	-17%	-34%	-52%	-70%	-71%	-71%	-72%	-73%	-74%
Fedratinib	0%	0%	-20%	-41%	-62%	-83%	-83%	-83%	-84%	-84%	-84%

Source: Jefferies Analysis

The MFN Price would have been phased-in over the first 4 years of the 7-year model, **phasing in 25% per year for years 1-4**, and would have been 100 percent of the MFN Price for years 4-7.

As stated in the CMS model, for the first year the phase-in calculation would use 75 percent of the ASP and 25 percent of the MFN Price. In years 4-7, the MFN Price would be fully phased-in. **We also assumed that MFN would remain in effect indefinitely, rather than being limited to the 7-year period,**

However, we will flag that in the 2020 published MFN model, CMS would have accelerated the blending formula for a drug in years 1-4, if U.S. prices rose faster than inflation and the MFN Price.

As previously noted, our **KOL believes the CMMI pilot program will be implemented no earlier than 2027.** Thus, we assume an initial phase-in starting in 2027 in our analysis.

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Stepping back, we'll flag that our MFN analysis is in addition to a 25% tariff scenario (HERE), with impact mitigated assuming Co's can use the following strategies –

1. • Companies **stockpile drug** ahead of tariffs coming in to cover them for 2Q's (tariff impact kicks in next year)
2. • Companies **raise drug prices by 3% for Medicare/Medicaid (assuming inflation at 3%) & 7% for commercial** during the period of the tariffs
3. • Companies **gradually move manufacturing back into the US** (how long it takes to move manufacturing is dependent on company & existing manufacturing infrastructure)
4. • Companies reduce **OpEx (eg, R&D and SG&A) by ~10% - we assume less OpEx cuts for companies like ARGX and ALKS** who we think can move manufacturing over quicker & have less exposure to tariffs

Source: Jefferies Analysis

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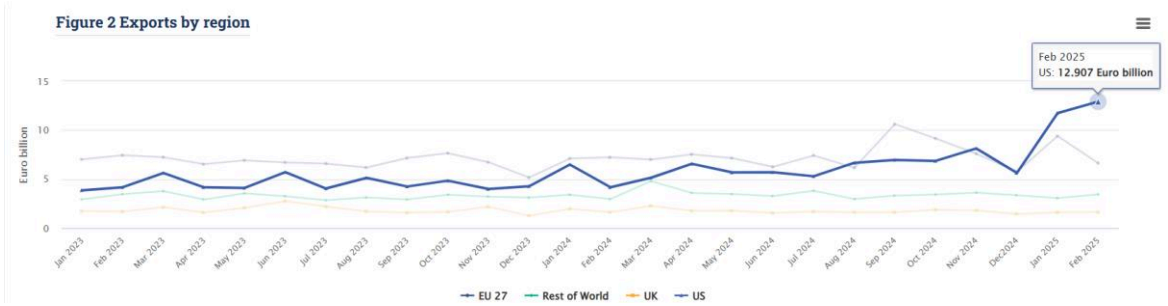
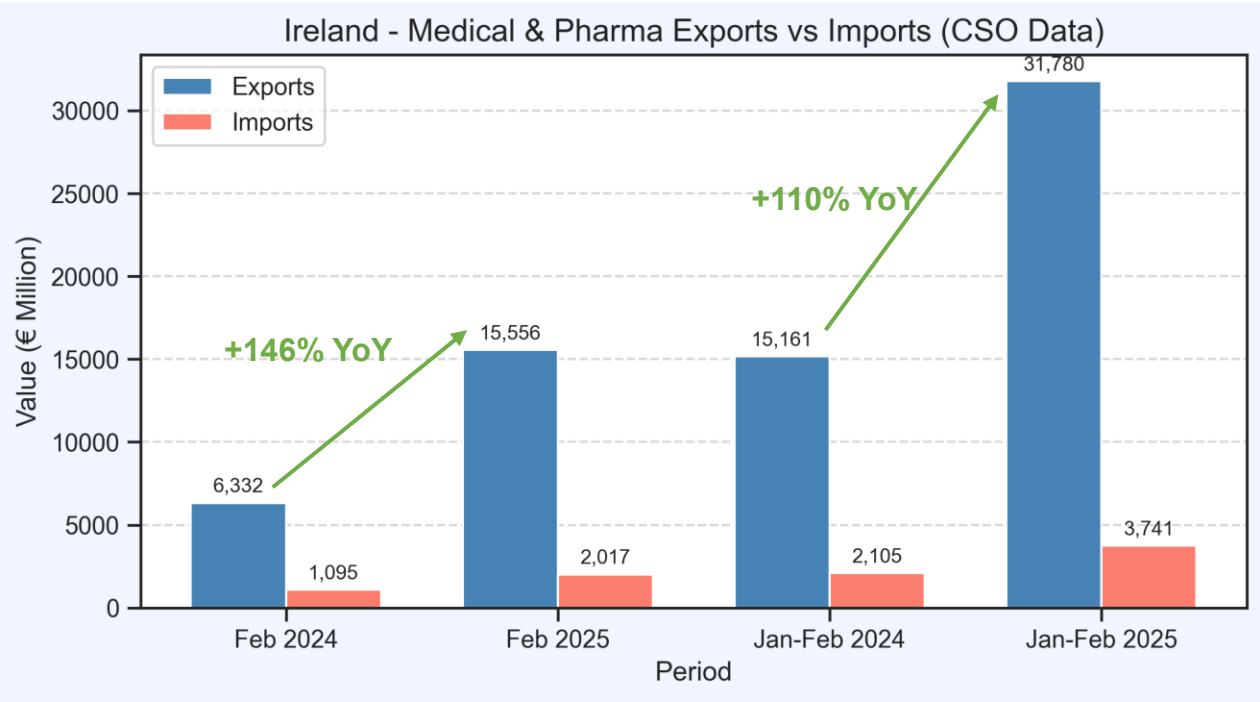
MRK has flagged to us that they could stockpile drug inventory ahead of any potential tariffs…interestingly, we're also seeing an increase in pharma exports from Ireland in Feb'25 (+146% YoY)

When we caught up w/ MRK mgmt. ahead of Q1 EPS, they indicated that they could potentially stockpile inventory/finished goods in certain markets ahead of any potential tariffs being enacted… interestingly, we also saw recent data from Ireland's CSO showing a sharp increase in medical & pharma exports from Ireland in Feb'25 (+146% YoY)

The CSO report data suggests a sudden spike in pharma exports from Ireland to the US :

- **Medical & pharma products made up 91% of Irish exports to the US in Feb'25**
- **In Feb'25, there was a +146% YoY spike in Irish pharma exports**
- **Chemical products (mostly medical/pharma) exports to US were up +279% YoY in Feb'25, whereas exports to EU27 were down -10%**





Source: Jefferies Analysis, CSO.ie

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Additionally, we think companies can raise drug prices to offset tariffs - we assume this is 3% YoY for Medicare/Medicaid (assuming inflation at 3%) & 7% for commercial during the period of the tariffs (no price increase on LOE or close to LOE drugs)

- We assume co.'s will increase price increases of 3% for Medicare/Medicaid, in line w/ inflation as there's a maximum allowed inflation rate before triggering IRA penalties on price growth (co's would owe govt excess in the form of rebate)
- For the commercial channel, we assume 7% price increases during the tariff period as we expect greater pricing flexibility in the private market.
- Our assumptions exclude off-patent products or drugs near LOE, where price leverage is likely limited, or drugs that haven't had recent price increases
- E.g. for MRK, we model ~3% price increase for Medicare/Medicaid and ~7% for commercial channel

(In millions, except per share amounts)	Q425	2025	2026	2027	2028	2029	2030	2031	2032	2033
eries Non-GAAP Total Revenues	$ 16,724	$ 64,934	$ 71,081	$ 73,530	$ 74,748	$ 71,861	$ 67,576	$ 68,163	$ 71,076	$ 68,718
Non GAAP Diluted EPS	$ 2.17	$ 8.80	$ 9.27	$ 10.25	$ 10.53	$ 10.54	$ 9.29	$ 9.61	$ 10.63	$ 10.34
Price Increase Build -- US										
Keytruda Part B exposure	65%	65%	64%	63%	62%	61%	60%	59%	59%	58%
Bridion Part B exposure	40%	40%	39%	39%	38%	38%	37%	37%	36%	36%
Gardasil 9 Part B exposure	15%	15%	15%	15%	14%	14%	14%	14%	14%	13%
Winrevair Part D exposure	71%	71%	70%	69%	68%	67%	66%	65%	64%	63%
Medicaid exposure	6%	6%	6%	6%	6%	6%	6%	6%	6%	6%
Medicare Part B exposure	38%	38%	37%	37%	36%	36%	35%	35%	34%	34%
Medicare Part D exposure	5%	5%	5%	5%	5%	5%	5%	5%	5%	4%
Medicare exposure	43%	43%	42%	42%	41%	41%	40%	39%	39%	38%
Medicare Price Inc. - cap at Inflation	1%	3%	3%	3%	3%	3%	3%	3%	3%	3%
Commercial exposure	51%	51%	52%	52%	53%	53%	54%	55%	55%	56%
Commercial Price Increase	2%	7%	7%	7%	7%	7%	7%	7%	7%	7%
			*price increase starts 2026 with tariff							
Keytruda	-	-	434	473	456	-	-	-	-	-
Gardasil 9	-	-	-	-	-	-	-	-	-	-
ProQuad M M R II and Varivax	-	-	132	136	139	141	144	147	150	152
Lynparza	-	-	39	-	-	-	-	-	-	-
Reblozyl	-	-	15	16	23	25	27	-	-	-
Zerbaxa	-	-	9	8	-	-	-	-	-	-
Winrevair	-	-	33	44	62	81	101	230	-	-
Januvia	-	-	-	-	-	-	-	-	-	-
Lenvima	-	-	-	-	-	-	-	-	-	-
Prevymis	-	-	29	29	26	-	-	-	-	-
Janumet	-	-	-	-	-	-	-	-	-	-
Adempas	-	-	-	-	-	-	-	-	-	-
Welireg	-	-	-	-	-	-	-	-	-	-
Lagevrio	-	-	4	4	3	3	3	3	3	3
Verquvo	-	-	26	22	22	21	20	-	-	-
Dificid	-	-	21	21	-	-	-	-	-	-

We'll also note some additional considerations:

- Medicare Part B and D seem to have an inflationary cap but commercial may not (although there could be restrictions from health insurances on how much premiums can be raised by)
- Additionally the type of drug (branded drugs in beginning/mid life span probably will be able to raise prices more than drugs near/post LOE or generic drugs)

Source: Jefferies Analysis, CMS.gov

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We assume that Co's start to move manufacturing back to the US – we estimate that the speed at which they can do this could generally be 3~4 yrs (caveat this depends on location, size, type of facility, etc)…that said, ARGX and LLY could likely move mfg back quicker

- We aggregated examples of different types of facilities (e.g. small molecule vs biologics) and how long each took to become operational from first construction to production of drug products – overall, on average, our examples suggest that it takes facilities ~3.5 yrs to be built and become operational (+ an added 6mo to a year re: early planning)
- We'll flag here that **MRK and LLY already announced plans to develop in US ergo they may be able to ramp up faster generally + ARGX would theoretically only need to move their fill/finish facility (mgmt thinks this is relatively quick).** Addtl, we'll flag that some products are easier to move vs others e.g. PFE covid vaccines & tirzepatide LLY since they are either already mfg in US or Co. has announced mfg plans to increase capacity & can do so easily
- **We assume ARGX takes 1 year to move fill/finish to US & LLY takes 1~2 to move Tzp manufacturing to US**

Size	Type of Facility	Example	Timeframe	
420K sq feet	Small molecule mfg	PFE - MI	~3-4 yrs	
31m sq feet	Biologics mfg	Samsung biologics - SK	~3 yrs	
100K sq feet	Vaccine mfg	Moderna mRNA - AU	~3 yrs	
50K sq feet	Cell & Gene Therapy mfg	Novartis - IL	~2 yrs	
296K sq feet	Fill-finish facility	Lonza - CH	~2-3 yrs	***includes foundations*
1.4M sq feet	Fill-finish facility	Novo Nordis - NC	~3-5 yrs	***includes foundations*
		Final Yrs Assumption	***3.5***	***assume an additional half year for planning*

Facility	Low end	High end	
Small molecule mfg	3	4	
Biologics mfg	3	3	
Vaccine mfg	3	3	
Cell & Gene Therapy mfg	2	2	
Fill-finish facility	2	3	
Fill-finish facility	3	5	
Average	**2.7**	**3.3**	
Average + 6mo	**3.2**	**3.8**	***assume an additional half year for planning*

Source: Jefferies Analysis

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Notably, LLY and MRK have already announced large manufacturing expansions in US this year – moving mfg could be easier for certain pharma/ biotech companies w/ existing US infrastructure & rich balance sheet

Lilly plans to more than double U.S. manufacturing investment since 2020 exceeding $50 billion

February 26, 2025

Company expects to begin building four more domestic manufacturing sites this year and add 13,000 high-wage manufacturing and construction jobs in America

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The company's plans represent the largest pharmaceutical manufacturing investment in U.S. history

INDIANAPOLIS, Feb. 26, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced at a press conference in Washington, D.C., plans to bolster its domestic medicine production across therapeutic areas by building four new pharmaceutical manufacturing sites in the United States. This brings the company's total U.S. capital expansion commitments to more than $50 billion since 2020.

Three of the future U.S. sites announced today will focus on manufacturing active pharmaceutical ingredients (API), reshoring critical capabilities of small molecule chemical synthesis and further strengthening Lilly's supply chain. The fourth location will extend the company's global parenteral manufacturing network for future injectable therapies.

"Lilly's optimism about the potential of our pipeline across therapeutic areas – cardiometabolic health, oncology, immunology and neuroscience – drives our unprecedented commitment to our domestic manufacturing build-out. Our confidence positions us to help reinvigorate domestic manufacturing, which will benefit hard-working American families and increase exports of medicines made in the U.S.A.," said David A. Ricks, Lilly chair and CEO. "This bold move reflects our commitment to stay ahead of anticipated demand for safe, high-quality, FDA-approved medicines of the future."

At these four new sites, Lilly expects to create more than 3,000 jobs for highly skilled workers, including engineers, scientists, operations personnel and lab technicians. Additionally, the company anticipates that it could create nearly 10,000 construction jobs during the development of the sites.

"To deliver on our big bets on next-generation modalities like small molecules, biologics and nucleic acid therapies, Lilly is investing in the state-of-the-art manufacturing infrastructure needed to deliver tomorrow's safe and reliable medicines," said Edgardo Hernandez, executive vice president and president of Lilly Manufacturing Operations. "We are not just building facilities. We are creating a future where American innovation leads the world in pharmaceutical manufacturing, requiring a highly skilled workforce prepared to shape the future of health care. This is a significant step for our company, our communities and the patients we serve."

From MRK Q4'24 Earnings Presentation

Capital investments
2024 to 2028

~$20B

Over 5 years, including expanding manufacturing capacity for Oncology, Vaccines, and Animal Health. Includes >$11B in the U.S.

"This expansion of our Durham plant is a crucial component of the more than $12 billion Merck has invested toward U.S. capital investment since 2018 focused on expanding domestic manufacturing and research and development capabilities and creating new jobs in the U.S., with another $8 billion of U.S. capital investment expected by 2028."

–MRK Q4'24

Source: Jefferies Analysis, Company website

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Jefferies

Given the shift in manufacturing back to the US, we illustratively assume that tax rate could go up to ~19-19.5% over the 4-year time frame

Although we expect tax rate to rise when mfg & IP are brought back to the US, we'll flag here that we don't anticipate CO.'s will get hit with the full corporate tax rate given credits etc. Some examples include –

- Federal and state R&D credits
- FDII rate for US based IP ~13%
- deductible income/credits
- Strategic charitable donations
- Cost-sharing agreements

Overall, we conservatively assume ~19-19.5% for tax rate phased in over a few yrs

2024 profitability US vs ex-US for our large cap pharma coverage

(in millions)	2024 Earnings Breakdown			
Company	**MRK**	**BMY**	**LLY**	**PFE**
US EBIT	(1,849)	(14,893)	2,536	(637)
Ex. US EBIT	21,785	6,514	10,144	8,660
Total EBIT	**19,936**	**(8,379)**	**12,680**	**8,023**
US Rev	32,277	34,105	30,375	38,691
Ex. US Rev	31,891	14,195	14,668	24,936
Total Rev	**64,168**	**48,300**	**45,043**	**63,627**
US Tax	(532)	(906)	1,133	(1,717)
Ex. US Tax	3,335	1,460	957	1,688
Total Tax	**2,803**	**554**	**2,090**	**(29)**
Effective tax%	*14.1%*	*-6.6%*	*16.5%*	*-0.4%*

Source: Jefferies Analysis

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Jefferies

Additionally, we think Co's will likely cut OPEX (we assume ~10% for most companies in our mitigation scenarios) – LLY's CEO has alluded that they'll cut down on R&D

Tariffs 'hard to come back from', says US pharma boss

7 days ago

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Simon Jack
Business editor

David Ricks said he was doubtful whether tariffs would succeed in bringing jobs and money to the US

The boss of US pharmaceutical giant Eli Lilly has told the BBC there is no looking back from Donald Trump's decision to impose sweeping tariffs on imports from the rest of the world.

In an exclusive interview, David Ricks described it as a watershed moment in US economic history, "I think it's a pivot in US policy and it feels like it'll be hard to come back from here."

But Mr Ricks seemed in little doubt that tariffs will eventually hit and that this will have damaging consequences for investment in new medicines.

He explained drug prices were essentially capped in Europe and the US, which meant the impact of tariffs would be felt elsewhere.

"We can't breach those agreements so we have to eat the cost of the tariffs and make trade offs within our own companies," he said.

"Typically that will be in reduction of staff or research and development (R&D) and I predict R&D will come first. That's a disappointing outcome."

Mr Ricks said he did not support the imposition of tariffs but understood its intention and respected President Trump's political mandate.

"We don't support tariffs, to be clear. In pharma, about 70% of global R&D takes place in the United States. So we're creating the next generation of breakthroughs and cures.

"But the production is heavily weighted outside the US. And that's not unique to our industry. It happened with electronics and software and other things".

"So I think what this administration is saying is we want both. We want the means of production and we want the research and development intellectual property generation."

Eli Lilly are in the process of building a new additional $800m facility in Ireland, where they employ more than 3,000 people. Mr Ricks said that development would proceed.

Source: Jefferies Analysis, BBC

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Jefferies

Overall, in our unmitigated scenarios where the tariff and MFN impacts are fully realized, our illustrative scenarios suggest peak EPS impacts of: 1) ~18-47% if MFN applies to our est. top 50 Part D/B drugs & 2) ~21-55% if MFN applies to all drugs

		Non-GAAP EPS Impact												DCF	
		2025		2026		2027		2028		2029		2030			
Company	Assumption - on top of mitigated 25% tariff + no MFN mitigation	EPS	% change	EPS	% change	EPS	% change	EPS	% change	EPS	% change	EPS	% change	JEF Est	% change
BMY	Top 50 Medicare Part B/D drugs	$ 6.32	-2%	$ 6.06	-6%	$ 4.68	-23%	$ 4.12	-30%	$ 4.24	-25%	$ 4.16	-30%	$58	-15%
	All drugs	$ 6.32	-2%	$ 6.06	-6%	$ 4.45	-27%	$ 3.69	-37%	$ 3.60	-36%	$ 3.30	-44%	$52	-23%
LLY	Top 50 Medicare Part B/D drugs	$ 21.09	0%	$ 31.79	-1%	$ 40.81	-4%	$ 46.73	-10%	$ 51.45	-13%	$ 55.59	-18%	$913	-14%
	All drugs	$ 21.09	0%	$ 31.79	-1%	$ 40.33	-5%	$ 45.71	-12%	$ 49.83	-16%	$ 53.45	-21%	$889	-16%
MRK	Top 50 Medicare Part B/D drugs	$ 8.80	-1%	$ 9.52	-5%	$ 10.26	-13%	$ 10.26	-19%	$ 9.76	-18%	$ 8.09	-27%	$112	-19%
	All drugs	$ 8.80	-1%	$ 9.52	-5%	$ 10.20	-14%	$ 10.15	-20%	$ 9.59	-20%	$ 7.86	-29%	$110	-21%
PFE	Top 50 Medicare Part B/D drugs	$ 2.72	-4%	$ 2.65	-5%	$ 2.47	-15%	$ 2.29	-21%	$ 2.35	-19%	$ 2.32	-25%	$27	-19%
	All drugs	$ 2.72	-4%	$ 2.65	-5%	$ 2.41	-17%	$ 2.17	-25%	$ 2.16	-25%	$ 2.10	-32%	$25	-24%
REGN	Top 50 Medicare Part B/D drugs	$ 32.74	0%	$ 37.74	-2%	$ 40.34	-26%	$ 40.08	-37%	$ 46.01	-36%	$ 41.21	-47%	$498	-38%
	All drugs	$ 32.74	0%	$ 37.74	-2%	$ 38.68	-29%	$ 37.05	-42%	$ 41.41	-42%	$ 35.16	-55%	$451	-44%
ARGX	Top 50 Medicare Part B/D drugs	$ 14.02	0%	$ 15.60	0%	$ 24.83	-8%	$ 29.49	-16%	$ 38.87	-22%	$ 43.26	-29%	$536	-31%
	All drugs	$ 14.02	0%	$ 15.60	0%	$ 24.83	-8%	$ 29.49	-16%	$ 38.87	-22%	$ 43.26	-29%	$536	-31%

*We assumed 25% tariff with mitigation – moving back mfg to US; co's increase prices between 2026-2028; OpEx cut for 2026-2028.

*We will caveat that our analysis does not include potential impact from upcoming or pipeline products, such as Ofro for LLY, which could contribute to additional downside.

We built our scenario analysis on top of our tariff impact assumptions. For tariffs, we assume companies will stockpile to offset any impact through the remainder of 2025, and that the tariff-related impact would last only four years, aligned with a Trump's 4-year term. We then layered in the full, unmitigated MFN impact to assess the full impact. **When the MFN impact fully phases in by 2023, the EPS impact is ~21%-55% for all drugs; ~18%-47% if only applies to top 50 Part B and Part D drugs; and ~5%-23% if MFN is implemented through IRA.**
While not shown, ALKS has limited exposure to MFN - mgmt. noted that the company do not commercialize outside of US, and they do not expect any exposure to MFN related pricing changes. JAZZ's primary market is the US, the company does have sales in ex.US countries. However, based on our analysis, none of the JAZZ's products appear on the Top 50 Part B and Part D lists.

Source: Jefferies Analysis

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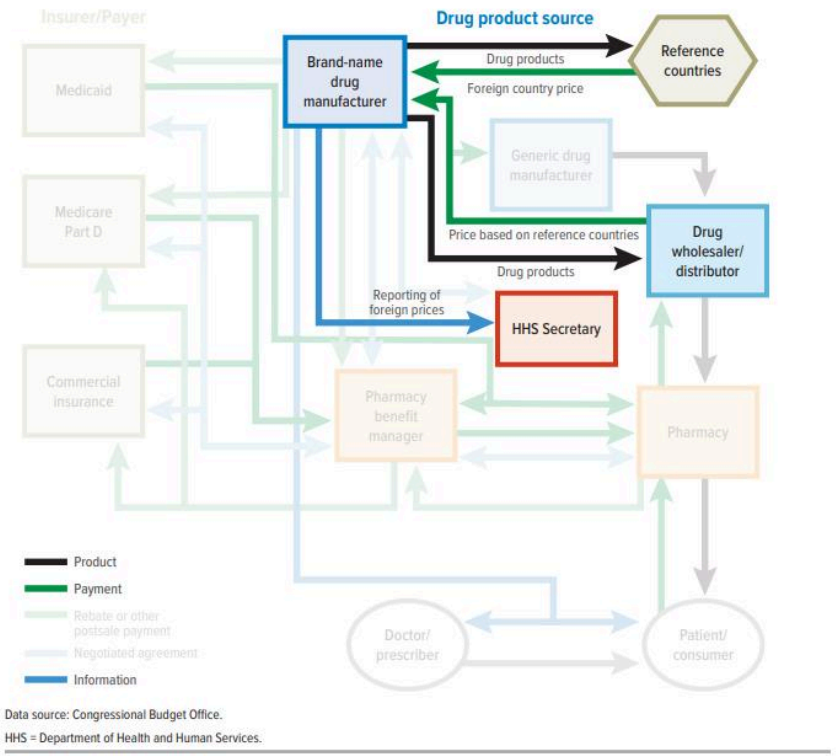
Moving on, we'll go over our scenarios assuming Co's can mitigate impact:

Starting off, CBO's Oct '24 report (HERE) on lowering U.S. drug prices noted that companies could work around international reference pricing by delaying launches, exiting smaller markets, altering drugs, or using hidden discounts to maintain the report prices –

Figure 2-1.

Set Maximum Allowed Prices Based on Prices Outside the United States



Data source: Congressional Budget Office.
HHS = Department of Health and Human Services.

Source: Jefferies Analysis, CBO

In its October 2024 report, the CBO highlighted international reference pricing as one potential approach to reducing U.S. prescription drug costs. Under this framework, U.S. drug prices would be capped based on the observed prices among the reference countries.

CBO also noted that pharma co's have workarounds to mitigate the policy's impact.

1) **Co's might delay launching new drugs in lower-priced foreign markets, avoiding the creation of reference prices that could impact US pricing. Co's might also withdraw products from smaller markets entirely to avoid be used as benchmark prices.**

2) Another tactic would involve **modifying the products sold ex.US** to make it less comparable to the U.S. version which might make it not referable.

3) **Co's could also threat to withdrawal from the markets to negotiate higher prices in foreign countries.** While this method may be limited by strict price regulations in most EU markets, raising foreign prices would help narrow the price gap and preserve the higher prices in the U.S.

4)**Pharma may lower the net cost of drugs ex.US without reducing the official list price. These could include providing rebates or making donations to hospitals, reducing the net cost while keeping reported list prices high for referencing.**

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We assume that companies can use the following strategies to mitigate the impact of MFN:

1	• Companies opt-out of some markets with high MFN spread and low revenue
2	• Medicare volume decrease by 20% and the volume shifts to commercial over 10 years
3	• Companies reduce OpEx (e.g. R&D and SG&A) by ~10% each
4	• Companies increase prices across their portfolio **by 3% for Medicare/Medicaid (assuming inflation at 3%), and 7% for commercial for unselected drugs**
5	• Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level

Source: Jefferies Analysis

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1) We modeled manufacturer opt-outs from select MFN countries by identifying low-revenue markets (<2% of ex-U.S. sales + MFN impact > 50%) with disproportionately high MFN pricing exposure

MFN Countries	Revenue - 2023	% WW Rev	% Ex.US Rev
Luxembourg	263	0.02%	0.05%
Ireland	2,166	0.20%	0.44%
Norway	3,207	0.29%	0.65%
Switzerland	6,454	0.59%	1.30%
Netherlands	5,721	0.52%	1.15%
Iceland	218	0.02%	0.04%
Denmark	2,689	0.25%	0.54%
Australia	9,622	0.88%	1.94%
Austria	3,554	0.32%	0.72%
Germany	37,414	3.42%	7.53%
Belgium	5,235	0.48%	1.05%
Sweden	4,777	0.44%	0.96%
Canada	19,251	1.76%	3.88%
Finland	1,974	0.18%	0.40%
France	26,164	2.39%	5.27%
United Kingdo	29,200	2.67%	5.88%
Italy	16,363	1.50%	3.30%
Israel	2,899	0.26%	0.58%
Slovenia	455	0.04%	0.09%
New Zealand	1,308	0.12%	0.26%
Spain	15,051	1.38%	3.03%
Czechia	2,045	0.19%	0.41%
Korea, South	12,652	1.16%	2.55%
Lithuania	379	0.03%	0.08%
Japan	45,882	4.19%	9.24%
United States	597,915	54.63%	
WW Rev	1,094,512	100.00%	

Opt-Out criteria	
%Ex. US	<2%
MFN Impact	<-50%

Product	Company	Country	GDP Adjuster	MFN Price	Estimated US	Reduction %	% Ex.US Rev	Opt-Out
Vyvgart	ARGX	Japan	0.61	$ 4,758	$ 6,108	-22%	9.2%	No
Opdivo	BMY	Norway	1.00	$ 413	$ 1,221	-66%	0.6%	Yes
Yervoy	BMY	Norway	1.00	$ 3,306	$ 8,501	-61%	0.6%	Yes
Orencia	BMY	Australia	0.79	$ 225	$ 1,023	-78%	1.9%	Yes
Eliquis	BMY	Australia	0.79	$ 50	$ 267	-81%	1.9%	Yes
Pomalyst	BMY	Australia	0.79	$ 760	$ 21,574	-96%	1.9%	Yes
Reblozyl	BMY	Netherlands	0.95	$ 1,006	$ 3,629	-72%	1.2%	Yes
Cabometyx	EXEL	Japan	0.61	$ 5,255	$ 23,671	-78%	9.2%	No
Jardiance	LLY	Norway	1.00	$ 33	$ 214	-85%	0.6%	Yes
Mounjaro	LLY	United Kingdom	0.72	$ 198	$ 540	-63%	5.9%	No
Verzenio	LLY	Switzerland	1.00	$ 1,195	$ 7,349	-84%	1.3%	Yes
Trulicity	LLY	Norway	1.00	$ 88	$ 494	-82%	0.6%	Yes
Zepbound	LLY	United Kingdom	0.72	$ 198	$ 543	-64%	5.9%	No
Tradjenta	LLY	Norway	1.00	$ 17	$ 263	-93%	0.6%	Yes
Keytruda	MRK	Japan	0.61	$ 2,477	$ 5,599	-56%	9.2%	No
Lenvima	MRK	Norway	1.00	$ 1,540	$ 22,485	-93%	0.6%	Yes
Bridion	MRK	Japan	0.61	$ 65	$ 123	-47%	9.2%	No
Gardasil 9	MRK	Sweden	0.83	$ 92	$ 185	-50%	1.0%	Yes
Winrevair	MRK	Switzerland	1.00	$ 7,208	$ 12,329	-42%	1.3%	No
Lynparza	MRK	France	0.73	$ 1,765	$ 7,291	-76%	5.3%	No
Ingrezza	NBIX	Japan	0.61	$ 796	$ 6,605	-88%	9.2%	No
Prevnar	PFE	Sweden	0.83	$ 71	$ 170	-58%	1.0%	Yes
Comirnaty	PFE	Switzerland	1.00	$ 85	$ 69	0%	1.3%	No
Padcev	PFE	Norway	1.00	$ 624	$ 2,765	-77%	0.6%	Yes
Adcetris	PFE	Norway	1.00	$ 2,797	$ 11,742	-76%	0.6%	Yes
Vyndaqel	PFE	Japan	0.61	$ 112	$ 159	-29%	9.2%	No
Paxlovid	PFE	Australia	0.79	$ 909	$ 1,347	-33%	1.9%	No
Ibrance	PFE	Netherlands	0.95	$ 1,951	$ 14,816	-87%	1.2%	Yes
Nurtec ODT	PFE	Norway	1.00	$ 152	$ 926	-84%	0.6%	Yes
Abrysvo	PFE	Norway	1.00	$ 182	$ 184	-1%	0.6%	No
Eylea HD	REGN	Norway	1.00	$ 754	$ 2,424	-69%	0.6%	Yes
Dupixent	REGN	Norway	1.00	$ 569	$ 1,707	-67%	0.6%	Yes

Row Labels	Sum of % Ex.US Rev
⊟ Bristol Myers Squibb	14.9%
Eliquis	6.1%
Opdivo	3.1%
Orencia	1.9%
Pomalyst	1.9%
Reblozyl	1.2%
Yervoy	0.6%
⊟ Eli Lilly	17.1%
Jardiance	6.1%
Trulicity	6.0%
Verzenio	3.4%
Tradjenta	1.6%
⊟ Merck & Co	7.0%
Gardasil 9	1.0%
Lenvima	6.0%
⊟ Pfizer	14.8%
Adcetris	6.6%
Ibrance	4.1%
Padcev	0.6%
Prevnar	1.0%
Xtandi	2.6%
⊟ Regeneron Pharmaceuticals	3.2%
Dupixent	0.6%
Eylea HD	2.6%
Grand Total	57.0%

We gathered a breakdown of global pharmaceutical revenues by country for 2023 and found that the United States accounted for approximately 55% of total global revenue. We also calculated each country's share of global revenue for the 25 qualified OECD countries. We then derived the relative share of global ex-U.S. revenue and aligned these percentages with the countries included on the drug list within our coverage.

In our assumptions, **we assumed opt-out countries that 1) contribute less than 2% of global ex-U.S. revenue and 2) have MFN discount greater than 50%**, under the rationale that companies may opt out of markets where revenue exposure is insignificant, but MFN impact is significant. Under these assumptions, some of the countries we opt-out on a drug level are **Australia, Norway, Sweden, Switzerland, Netherlands, Slovenia, Iceland, Denmark**.

Source: Jefferies Analysis

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2) We think there could be commercial spillover – in fact, we recently hosted a KOL who flagged commercial pricing might face pressure (HERE). Addtl, he noted that while plans may not adopt full discounts, they could adopt partial reductions (~10%-20%) to maintain competitiveness

We assume Medicare exposure decreases by 20% over time and the volume shifts to commercial

-20%

(In millions, except per share amounts)	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
eries Non-GAAP Total Revenues	$ 64,934	$ 71,196	$ 74,454	$ 75,959	$ 72,726	$ 68,585	$ 69,311	$ 72,241	$ 69,892	$ 67,860	$ 65,868	$ 63,066	$ 60,623	$ 57,635	$ 53,836	$ 51,989
Non GAAP Diluted EPS	$ 8.80	$ 9.31	$ 10.56	$ 10.94	$ 10.83	$ 9.63	$ 10.00	$ 11.03	$ 10.74	$ 10.62	$ 10.42	$ 10.16	$ 9.95	$ 9.66	$ 9.21	$ 9.05
Price Increase Build -- US																
Keytruda Part B exposure	65%	64%	63%	62%	61%	60%	59%	58%	58%	57%	56%	55%	54%	53%	53%	52%
Bridion Part B exposure	40%	39%	39%	38%	38%	37%	37%	36%	35%	35%	34%	34%	33%	33%	32%	32%
Gardasil 9 Part B exposure	15%	15%	15%	14%	14%	14%	14%	13%	13%	13%	13%	13%	13%	12%	12%	12%
Winrevair Part D exposure	71%	70%	69%	68%	67%	66%	65%	64%	63%	62%	61%	60%	59%	58%	57%	57%
Medicaid exposure	12%	12%	12%	11%	11%	11%	11%	11%	11%	10%	10%	10%	10%	10%	10%	10%
Medicare Part B exposure	38%	37%	37%	36%	36%	35%	35%	34%	34%	33%	33%	32%	32%	31%	31%	30%
Medicare Part D exposure	5%	5%	5%	5%	5%	5%	5%	4%	4%	4%	4%	4%	4%	4%	4%	4%

Our KOL mentioned that from pharma's perspective, **there is a clear incentive to deprioritize Medicare and Medicaid due to their low margins and target populations**. While this shift may make sense from a financial perspective, it raises clinical concerns. He would picture a shift of ~50% Medicare and Medicaid population towards commercial. It will hurt Medicare and Medicaid since they will have less choice and less innovation. This could likely end up with ~70% of volume going through commercials, resulting in Medicare and Medicaid ending up being a truly bare-bone safety-net program.

Source: Jefferies Analysis

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3) Additionally, we think companies can raise drug prices to offset tariffs and MFN - we assume this is 3% YoY for Medicare/Medicaid (assuming inflation at 3%) & 7% for commercial during the period of the tariffs (no price increase on LOE or close to LOE drugs)

- **We broke down the Medicare exposure for major drugs (for the drugs on our top 50 Part B and Part D lists).** For the remaining products, we used company-level exposure, as disclosed by the management, as a proxy.
- We assume co.'s will increase price increases of 3% for Medicare/Medicaid, in line w/ inflation as there's a maximum allowed inflation rate before triggering IRA penalties on price growth (co's would owe govt excess in the form of rebate) + **according to the previously published MFN model, CMS would have accelerated the phase in for a drug in years 1-4, if U.S. prices rose faster than inflation**
- For the commercial channel, we assume 7% price increases during the tariff period as we expect greater pricing flexibility in the private market.
- Our assumptions exclude off-patent products or drugs near LOE, where price leverage is likely limited, or drugs that haven't had recent price increases

(In millions, except per share amounts)	024	Q125	Q225	Q325	Q425	2025	2026
eries *Non-GAAP Total Revenues*	68	$ 15,529	$ 15,804	$ 16,876	$ 16,724	$ 64,934	$ 71,196
Non GAAP Diluted EPS	65	$ 2.22	$ 2.01	$ 2.40	$ 2.17	$ 8.80	$ 9.31
Price Increase Build -- US							
Keytruda Part B exposure		65%	65%	65%	65%	65%	64%
Bridion Part B exposure		40%	40%	40%	40%	40%	39%
Gardasil 9 Part B exposure		15%	15%	15%	15%	15%	15%
Winrevair Part D exposure		71%	71%	71%	71%	71%	70%
Medicaid exposure		12%	12%	12%	12%	12%	12%
Medicare Part B exposure		38%	38%	38%	38%	38%	37%
Medicare Part D exposure		5%	5%	5%	5%	5%	5%
Medicare/Medicaid exposure		55%	55%	55%	55%	55%	54%
Medicare/Medicaid Price Inc. - cap at Inflation		1%	1%	1%	1%	3%	3%
Commercial exposure		45%	45%	45%	45%	45%	46%
Commercial Price Increase		2%	2%	2%	2%	3%	7%
Keytruda		-	-	-	-	-	495
Gardasil 9		-	-	-	-	-	-
ProQuad M M R II and Varivax		-	-	-	-	-	141
Lynparza		-	-	-	-	-	39
Reblozyl		-	-	-	-	-	16
Zerbaxa		-	-	-	-	-	9
Winrevair		-	-	-	-	-	38
Januvia		-	-	-	-	-	27
Lenvima		-	-	-	-	-	-
Prevymis		-	-	-	-	-	31
Janumet		-	-	-	-	-	4

Source: Jefferies Analysis, CMS.gov

We'll also note some additional considerations:

- Medicare Part B and D seem to have an inflationary cap but commercial may not (although there could be restrictions from health insurances on how much premiums can be raised by)
- Additionally, the type of drug (branded drugs in beginning/mid life span probably will be able to raise prices more than drugs near/post LOE or generic drugs)

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4) Similar to our approach with tariff mitigations, given the potentially greater impact of the MFN, we assume Co's will increase OpEx reductions. We model a 10% reduction in both R&D and SG&A, phased in over time to align with the anticipated rollout of MFN impacts.

"Here are a few advertising expenses that are usually deductible:

- *Reasonable advertising expenses that are directly related to the business activities.*
- *An expense for the cost of institutional or goodwill advertising to keep the business name before the public if it relates to a reasonable expectation to gain business in the future."*

- IRS

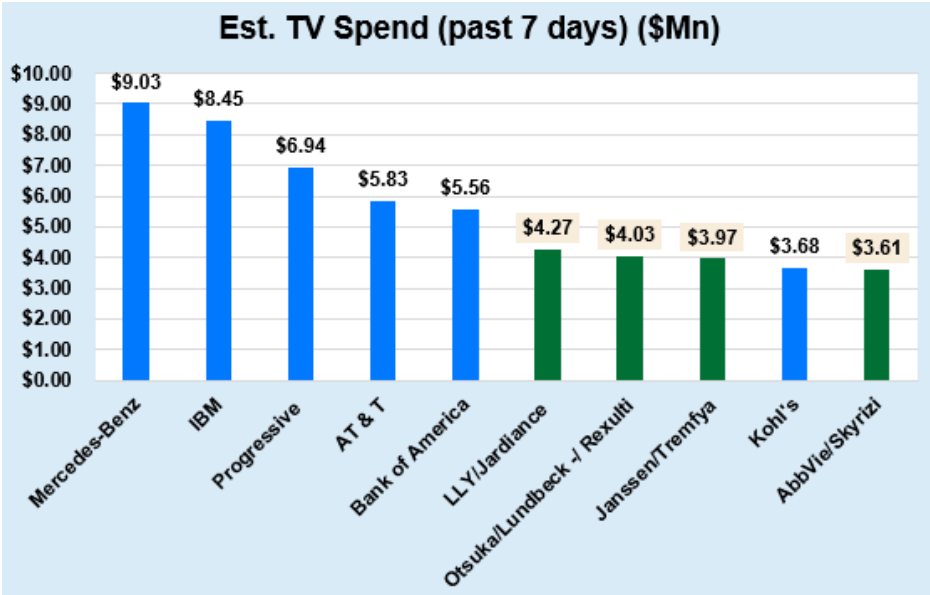
Drug	Medicare Part B or D spending 2018 ($)	DTC spend 2018 ($)	DTC spend as % of total Medicare Spend
Humira	2,388,794,497	502,669,516	21.04%
Lyrica	2,950,257,661	245,401,444	8.32%
Trulicity	1,360,642,452	243,636,695	17.91%
Keytruda	1,813,727,267	179,812,336	9.91%
Eliquis	4,992,184,164	173,836,505	3.48%
Ibrance	1,507,730,890	148,897,381	9.88%
Xarelto	3,358,810,708	141,467,580	4.21%
Botox	348,391,516	133,021,371	38.18%

Looking at some of the top spenders, the DTC spend appeared to be ~10% (range 4-38%) of the total Medicare spending. Among the top 10 drugs with the highest cost to Medicare, four were also in the top 10 for advertising spending (Humira, Eliquis, Keytruda, Lyrica)

Table 1: Topline financial data, 2023 (millions)

Company	WW Revenue	EBIT	Global Tax Paid	US Tax Paid	Effective Global Tax Rate	SG&A	A&P Spend	A&P as % of SG&A	A&P as a % of WW Revenue
Pfizer	$58,496	$1,058	-$1,115	-$1,605	-105.40%	$14,771	$3,700	25.00%	6.30%
J&J	$54,759	$15,062	$1,736	-$690	11.50%	$21,512	$500	21.90%	4.30%
AbbVie	$54,318	$6,250	$1,377	$948	22.00%	$12,872	$2,200	17.10%	4.10%
Merck	$53,583	$1,889	$1,512	-$690	80.00%	$10,504	$2,300	18.00%	3.10%
BMS	$45,006	$8,440	$400	$406	4.70%	$7,772	$1,400	15.10%	3.30%
GSK	$37,772	$7,543	$940	N/A[1]	12.50%	$11,673	$1,039	8.90%	2.80%
Eli Lilly	$34,124	$6,555	$1,314	$667	20.10%	$7,403	$1,120	13.60%	3.00%
Amgen	$28,190	$7,855	$1,138	$418	14.50%	$6,179	$647	10.50%	2.30%
Gilead	$27,116	$6,859	$1,247	$905	18.20%	$6,090	$826	2.30%	0.90%
Biogen	$9,835	$1,297	$135	-$207	10.40%	$2,549	$71	2.80%	0.70%
Total	**$403,199**	**$62,808**	**$8,684**	**$152**	**13.83%**	**$101,325**	**$13,803**	**13.62%**	**3.42%**

EBIT: Earnings before interest and taxes; A&P: Advertising and Promotion; SG&A: selling, general, and administrative expenses; WW: worldwide.



Source: Jefferies Analysis, Company data

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5) Although we believe raising ex. US price, particularly in the US, face high hurdles, we assume Co's may still implement a one-time 10% price increase in countries with economic capacity, we define as those with GDP per capita at lease 80% of the US level

As previously discussed, increasing drug prices outside the U.S. has significant challenges due to stringent regulatory frameworks, particularly in EU, which involves preapproval, strong justification, strict timelines, and etc.

Despite these hurdles, we assumed that co's still pursue price increases in ex-U.S. markets to mitigate the impact of MFN. Given the regulatory burdens and the complexity of price adjustments in the EU, it is reasonable for companies to limit the frequency of increases. In our analysis, we assume that **1)companies will implement a one-time 10% price increase in countries with the economic capacity to absorb the increase in drug costs; 2)We define those countries as with a GDP per capita exceeding 80% of that of the U.S.**
The countries are **Luxembourg, Ireland, Norway, Switzerland, Netherlands, Iceland, Denmark, Austria, Germany, Belgium, and Sweden.**

Country	% US GDP Per capita
Australia	0.79
Austria	0.85
Belgium	0.85
Canada	0.73
Denmark	0.96
Finland	0.75
France	0.73
Germany	0.84
Iceland	0.90
Ireland	1.00
Israel	0.65
Italy	0.71
Japan	0.61
Korea, South	0.68
Luxembourg	1.00
Netherlands	0.95
New Zealand	0.65
Norway	1.00
Spain	0.63
Sweden	0.83
Slovenia	0.66
Lithuania	0.65
Switzerland	1.00
Czechia	0.67
United Kingdom	0.72

Source: Jefferies Analysis

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Specifically, EU drug price increases face high regulatory hurdles because they impose strict pre-approval processes, strong justifications, and limited exceptions, discouraging manufacturers from seeking price increases

Article 3

Without prejudice to Article 4, the following provisions shall apply if an increase in the price of a medicinal product is permitted only after prior approval has been obtained from the competent authorities:

1. Member States shall ensure that a decision is adopted on an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorization to increase the price of a medicinal product and communicated to the applicant within 90 days of its receipt. The applicant shall furnish the competent authorities with adequate information including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information.

In case of an exceptional number of applications, the period may be extended once only for a further 60 days. The applicant shall be notified of such extension before the expiry of the period.

In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to apply in full the price increase requested.

2. Should the competent authorities decide not to permit the whole or part of the price increase requested, the decision shall contain a statement of reasons based on objective and verifiable criteria and the applicant shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

3. At least once a year, the competent authorities shall publish in an appropriate publication and communicate to the Commission, a list of the medicinal products for which price increases have been granted during the relevant period, together with the new price which may be charged for such products.

2. In exceptional cases, a person who is the holder of a marketing authorization for a medicinal product may apply for a derogation from a price freeze if this is justified by particular reasons. The application shall contain an adequate statement of these reasons. Member States shall ensure that a reasoned decision on any such application is adopted and communicated to the applicant within 90 days. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information. Should the derogation be granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Raising drug prices in the EU has a high hurdle for manufacturers due to the regulatory hurdles imposed by Directive 89/105/EEC, particularly Articles 3 and 4.

National authorities needs to grant pre-approval for price increases and may ask for strong justification based on the objective, verifiable criteria, with decisions subject to strict timelines that can be extended.

Under article 4, if prices are frozen, exemptions are only granted in exceptional cases and must be supported by detailed evidence. These procedural requirements, combined with the risk of delays, rejections, and lack of transparency, create a disincentive for companies to pursue price increases.

Source: Council Directive 89/105/EEC of 21 December 1988

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That said, we have seen the Co's actively urging reforms, warning that the unsustainable low drug price will cause long-term harm, and suggested benchmark with US net price

Recent data shows that over 30 per cent of medicines approved in the US were not available in Europe after two years. Over time it is inevitable that clinical trials and R&D will further shift to the US and China.

So what should Europe do? First, the EU should implement a Europe-wide list price that fully values a medicine or "new indications", setting a benchmark for member states, within range of US net prices and adjusted via rebates to member states.

Second, the EU should set a Europe-wide spend target for innovative medicines and vaccines so that member states increase support for new medicines and fairly reward innovation.

Third, individual countries should end artificially capping biopharma market growth and reducing prices for new indications. This creates a clear disincentive for innovators.

Europe has leading universities, talent and hospitals. With deregulation and an attractive market for innovation, it can succeed. However, it must act decisively and urgently or decline will set in and departure of companies will accelerate.

Vas Narasimhan
CEO, Novartis, Basel, Switzerland

Paul Hudson
CEO, Sanofi, Paris, France

Source: Financial Times

Although the challenge of raising drug prices in EU remains significant due to stringent regulatory framework, pharma companies are actively seeking opportunities to address this issue**. In Apr '25, CEOs from NVS and SNY published a letter in the Financial Times and advocated for an EU pricing system change, which will benchmark within the range of US net prices and adjusted via rebates.** They argued that the current pricing system in EU is undermining EU's attractiveness for R&D, development and innovation.

The CEO of AZN also highlighted the urgency of address the pricing issue on the Q1 earnings call, noting that EU spends far less on innovative medicines relative to GDP than US, and warned that this could threat the long-term health sovereignty for the European region.

"It's a question of sovereignty and sovereignty of the – health sovereignty for the European citizens. It's not only a question of price. People think it's a question of price sometimes. No, it's also a question of delay. I mean, in many countries in Europe, patients have to wait two years, three years to get access or it's very restrictive.

So, I think with a reasonably modest increase of the share of GDP allocated to innovative medicines a lot of these things could be addressed and disappear." – Apr '25 Pascal Soriot, AZN CEO

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Overall, assuming Co.'s implement mitigation strategies, the EPS impact could be more blunted –

			Non-GAAP EPS Impact												DCF	
			2025		2026		2027		2028		2029		2030			
Company	Assumption - with mitigation	Drug Selection	EPS	% change	EPS	% change	EPS	% change	EPS	% change					JEF Est	% change
BMY	Co phase in R&D and SG&A cuts over 4 years each by ~10% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$6.32	-2%	$5.88	-9%	$4.77	-22%	$4.52	-23%	$4.99	-11%	$5.21	-12%	$65	-5%
LLY	Co phase in R&D and SG&A cuts over 4 years each by ~15% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$21.04	0%	$32.12	0%	$40.54	-5%	$47.14	-9%	$53.18	-10%	$59.66	-12%	$974	-8%
MRK	Co phase in R&D and SG&A cuts over 4 years each by ~10% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$8.80	-1%	$9.27	-7%	$10.25	-13%	$10.53	-17%	$10.54	-12%	$9.29	-16%	$122	-12%
PFE	Co phase in R&D and SG&A cuts over 4 years each by ~10% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$2.72	-4%	$2.55	-8%	$2.45	-16%	$2.37	-18%	$2.61	-10%	$2.71	-12%	$29	-14%
REGN	Co phase in R&D and SG&A cuts over 4 years each by ~20% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$32.74	0%	$37.39	-3%	$42.66	-22%	$45.57	-28%	$56.25	-21%	$54.35	-30%	$649	-19%
ARGX	Co phase in R&D and SG&A cuts over 4 years each by ~10% and last for the remainder of the period. Increase prices to offset (~3% for govt channel & ~7% commercial) for unselected drugs. Increase ex.US price by 10% for the countries that has GDP per capita at lease 80% of the US level. Medicare volume decrease by 20% over time and shift to commercial. Co opt out drugs in countries w/ MFN impact > 50% + < 2% of ROW revenue.	Top 50 Medicare Part B + Part D	$14.02	0%	$15.62	0%	$26.43	-2%	$34.29	-2%	$45.42	-9%	$51.71	-15%	$626	-19%

Note that our analysis does not incorporate potential tax benefits from the 'Big Beautiful Bill' (e.g., 100% deduction of qualified property and domestic R&D, and the extensions of FDII, GILTI, and BEAT provisions).

For REGN, we assumed a higher phased-in reduction of 20% for both R&D and SG&A, since both Eylea HD and Dupixent, made up a significant portion of the co's revenue, were selected under out Top 50 Medicare lists.

Source: Jefferies Analysis

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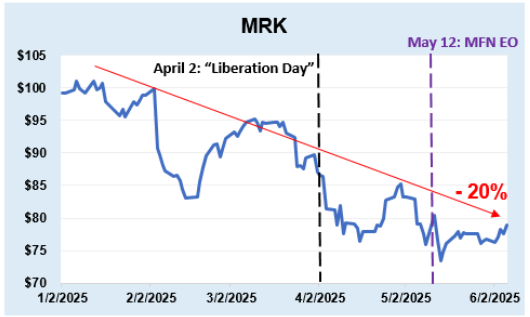
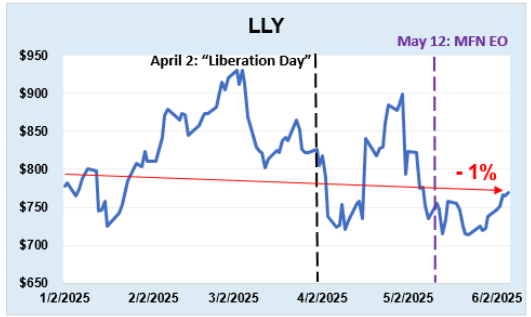
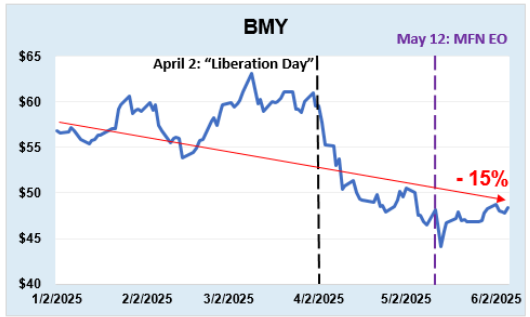
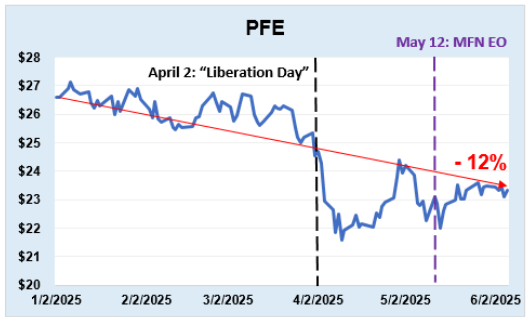
Further, our illustrative scenario analysis re: mitigated MFN impact suggests that valuation still remains above where the stock is currently trading

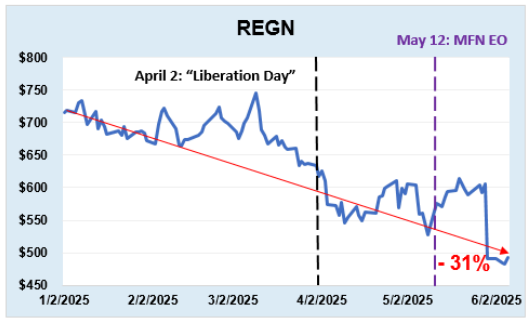
YTD Performance

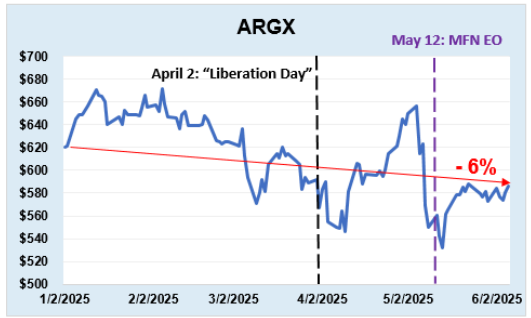


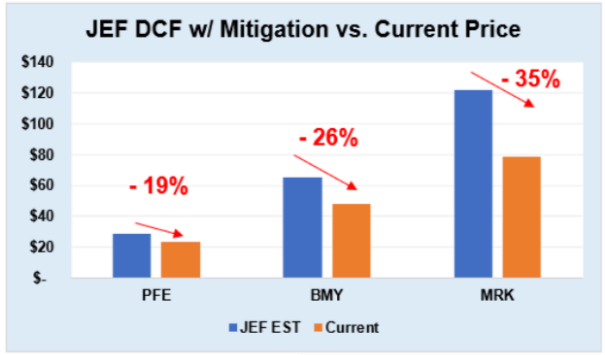


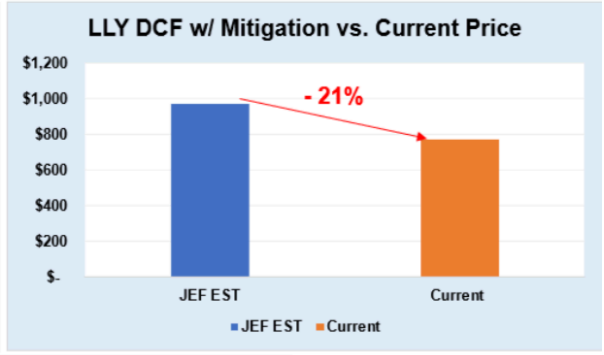


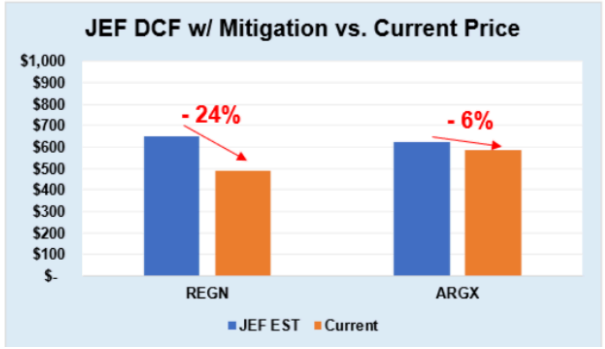












Therapeutic stocks have traded down since the beginning of the year, with MRK -20%, LLY -1%, BMY -15%, PFE -12%, REGN -31%, and ARGX -6%. **We saw notable declines following key events – April 2nd (Liberation Day) and May 12th (when Trump signed MFN EO).** Based on our analysis of each co's mitigated scenario, we believe the recent sell-off is overdone. Our valuation estimates remain above the current market levels, **with share price currently trading at 6%-35% discounts to our DCF valuations.**

Source: Jefferies Analysis

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Overall, we see Mid cap biotech's like MDGL, EXEL, ALKS, JAZZ, BMRN & ARGX are relatively better positioned for MFN because they either have de minimis ex-US revs, and/or low Medicare exposure, or a relatively low delta between US vs ex-US pricing...but even companies like MDGL would have to rethink whether entering Ex Us mkts is worth it going forward

Ticker	Rationale
NBIX	We think A) FY'25 Ingrezza guide is doable, B) tariff & MFN impact is minimal, C) NBIX could generate its EV by the end of the decade, & D) lead products won't go off patent for the next 13 years
EXEL	This is a profitable US centric biotech w/ the potential for beat and raise near-term setup & majority of cabo sales are in the US
MDGL	We think this name looks particularly attractive here given the strong commercial growth on Rezdiffra, limited regulatory/tariff risk, and sales that are largely/currently all in the US
BMRN	Although the co has some manufacturing ex-US, ~2/3 of revenue is ex-US
ALKS & JAZZ	De minimis ex-US exposure

Source: Jefferies Analysis

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Wrapping up, we'll discuss the potential long-term downstream impact that a broad/ nationwide MFN policy could have as well as current macro considerations

Background: Trump's Most Favored Nation's Drug Price Proposal

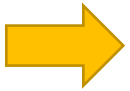
- Overview of MFN Pricing Policy and major historical events
- Thoughts on recent MFN Executive Order & HHS Press Release – what we know & major remaining Q's

Legal Analysis: How likely will MFN get implemented?

- Summary of ways MFN could get implemented including via: a) Congressional Action (eg, Reconciliation or new Legislation), b) CMMI pilot program, c) IRA, d) hybrid tariff/MFN compromise (or potential pharma concession)
- Our diligence re: probability of success that MFN gets implemented through these routes

Impact Analysis: What is the impact to our coverage if MFN does get implemented?

- We considered multiple different scenarios (in combination with our 25% tariff w/ mitigation model) for our LC Pharma & Biotech:
  1. Full impact MFN (top 50 Medicare Part B/D or IRA only or all Medicare)
  2. MFN (top 50 Medicare Part B/D) with pharma employing mitigation parameters
- Overall, we believe certain mid biotechs (eg, those that have de minimis ex-US revs, and/or low Medicare exposure, or a relatively low delta between US vs ex-US pricing) are generally winners here



Macro & Potential Downstream Effects of MFN Policy

- Thoughts on potential long-term/downstream impact of MFN if it gets implemented
- Our MFN/tariff-adjusted earnings relative to the S&P500 still seem to trade at a discount into a recession

Source: Jefferies Analysis

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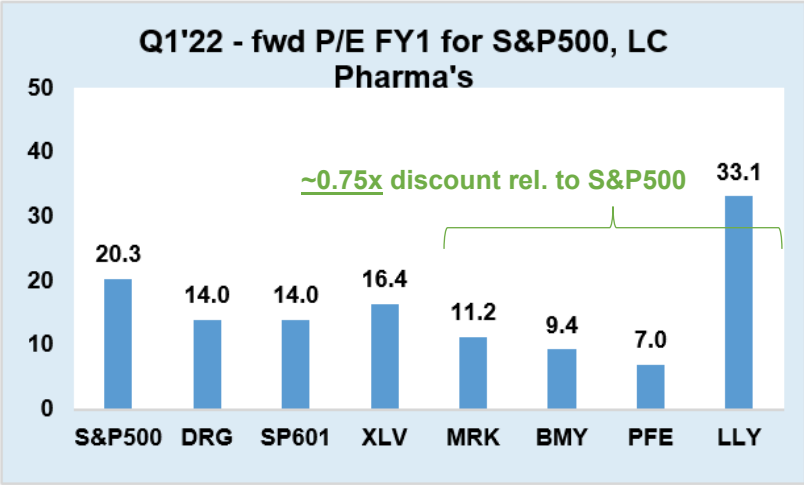
Starting off, our MFN/tariff-adjusted earnings for our LC pharma's still seem to trade at a discount relative to the S&P500 (~0.67x) which looks in-line/even more discounted vs early 2022 (~0.75x) right before pharma traded up in a defensive tape

A major takeaway we laid out in our tariffs deep dive (HERE) is that EVEN if 25% tariffs get announced on transfer price, the impact w/ reasonable mitigation steps should be manageable (single digit % EPS impact)… in fact we've argued Pharma is trading at a discount to S&P500 similar/even more so than it was in 2022 (another time it traded up in a defensive tape) – we see a similar situation here:

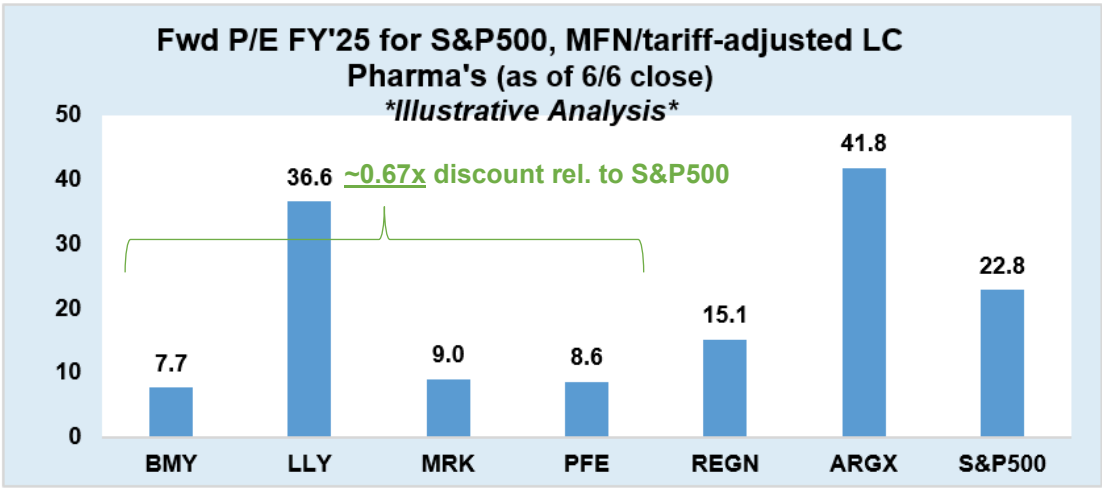
- In Q1'22, our LC Pharma's (MRK, BMY, PFE, LLY) were trading at a mean ~0.75x discount to S&P500 on the basis of fwd P/E
- When we applied MFN/tariffs from our scenarios analysis that we outlined earlier (25% tariff for all countries + top 50 Part B + Part D drugs) to our FY'25 EPS estimates for our LC Pharma's, our fwd $P/E_{FY'25}$ estimates came in at ~0.67x discount to S&P500 which looks in-line/slightly numerically lower vs where pharma was trading at in Q1'22

If we're headed for a recession, we think it could actually be a relatively bullish sign that our tariff-adjusted fwd P/E looks similar to the levels we saw in Q1'22 and we could see value in owning HC names due to their defensive nature

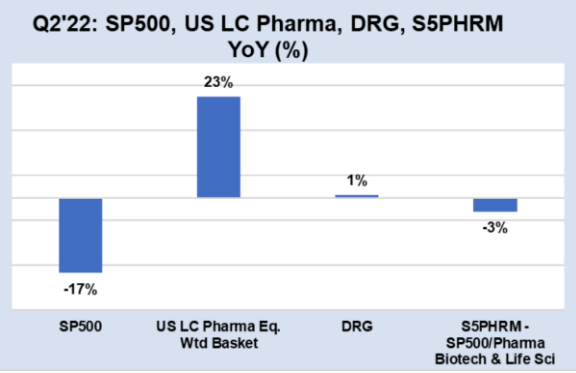
- **As reminder, in 2H'21/Q1'22, we saw US LC pharma trade at a discount of 0.64-0.72x relative fwd P/E vs S&P500** – in Q4'21 in particular, S&P500 was at ~22x fwd P/E vs ~14x for US large cap pharma on avg (~12x if we remove LLY)
- **In Q2'22, the US was reported to be in a "technical recession" & interestingly, we saw SP500 down -17% YoY vs pharma was up +23% for US LC Pharma (eq. wtd basket),** +1% for DRG, and slightly down -3% for S5PHRM.



MRK/BMY/PFE/LLY rel. fwd P/E ~0.75x



MRK/BMY/PFE/LLY rel. fwd P/E ~0.67x



Source: Jefferies analysis, FactSet

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Additionally, we think MFN could have sig. negative downstream effects:

1) MFN could pose a risk to the US healthcare system – as an example, let's look at 340B, which is a discounted drug program hospitals use to generate savings (makes up ~20-50% of Medicare Part B sales in hospitals)

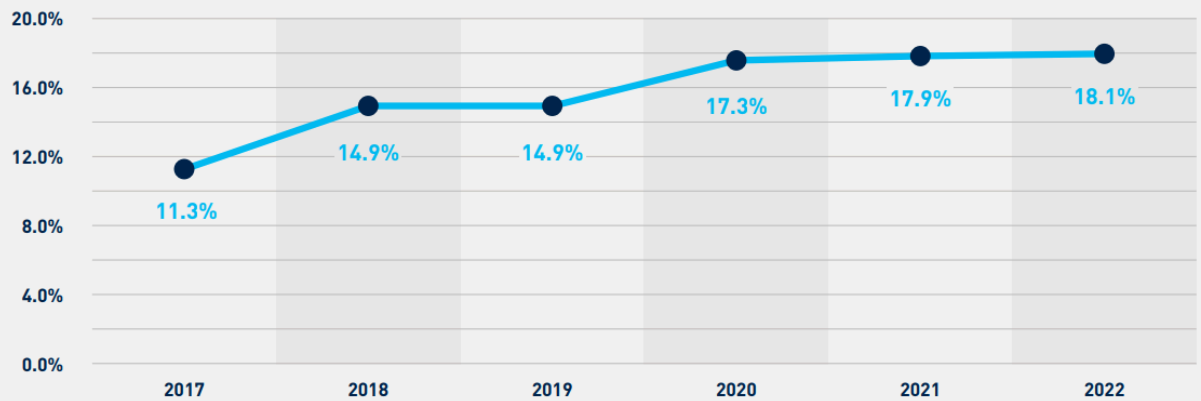
- Keep in mind that the 2020 MFN model didn't directly lower prices, but lowered reimbursement for providers
- Through 340B, hospitals receive drugs at a discounted price and reimburse them at list price, leading to a price difference between the discounted price and list price to generate savings.
- According to a report from the Office of the Inspector General, most 340B discounts range from 25% to 75% of the amount Medicare pays for physician-administered drugs and apply to all drugs purchased by the safety-net provider, not just drugs for patients who are uninsured or low income.

FIGURE 5

	2022
Total Branded 340B Purchases at WAC Price	$113.7
Total Outpatient Branded Drug Sales at WAC Price	$629.6
340B Purchases as % of Outpatient Branded Drug Sales	18.1%

Note: amount in billions

FIGURE 6: 340B PURCHASES AS PERCENTAGE OF OUTPATIENT BRANDED DRUG SALES



- According to a JAMA study + Medicare Advisory Payment Commission Report, 340B makes up ~20-50% of Medicare Part B sales in hospitals
- 340B sales accounted for 18.1% of total US branded outpatient drug sales in 2022, 60 percent above what they represented in 2017

Source: Jefferies Analysis, PhRMA, IQVIA

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MFN could potentially drive 340B hospitals towards bankruptcy given that the margin between 340B discount and reimbursement could be entirely eliminated

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs:				
Annualized Monetized ($million/year)	-29.4	2018	7	January 2021-December 2028.
	-27.1	2018	3	January 2021-December 2028.
To Whom	Hospital/physicians.			

- In fact, CMS published a report post the initial MFN model & estimates a **16% discount from ASP of MFN drugs in the first year and up to a 65% discount from ASP in the fourth through seventh years.** The MFN Model would ultimately mean Medicare would never pay providers or suppliers more than this MFN Price for applicable drugs**, which means the margin between the price hospitals receive through 340B and what they're reimbursed could diminish or be entirely eliminated (caveat: 340B reimbursement changed from ASP minus 22.5% to ASP+6% post the initial MFN model in 2020)**

- Further, this approach would significantly reduce hospital reimbursement for Part B drugs, making the program less attractive to manufacturers and potentially leading to a reduction in the availability of discounted drugs.
- This could further mean that hospitals and clinics participating in 340B get a smaller rebate...hospitals typically reinvest these savings to provide free care for uninsured patients, free vaccines, services in mental health clinics, and medication management and community health programs - as such, limiting the amount of savings they get from the discounted vs list price differential means hospitals may be forced to cut back on access and affordability for outpatient services
- A cross-sectional study found that the estimated profits that hospitals derived from administering 340B-discounted drugs to Medicare patients are small compared with operating budgets yet substantial compared with uncompensated care costs for many hospitals.

Source: Jefferies Analysis, CMS

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For example, MetroHealth, a major hospital network in Ohio disclosed that they are reimbursed at 77.5% ASP w/ many of the initial Part B list's drugs being bought at a discount of ASP minus 90% - profit margins remain quite thin at ~3% in 2024 and ~21% in 2023, thus MFN could further reduce profits and close programs, creating patient harm

			Prior Year	Current Year
Revenue	8	Contributions and grants (Part VIII, line 1h)	12,171,468	7,842,025
	9	Program service revenue (Part VIII, line 2g)	176,549	0
	10	Investment income (Part VIII, column (A), lines 3, 4, and 7d)	1,235,683	1,652,594
	11	Other revenue (Part VIII, column (A), lines 5, 6d, 8c, 9c, 10c, and 11e)	-367,071	-26,361
	12	Total revenue—add lines 8 through 11 (must equal Part VIII, column (A), line 12)	13,216,629	9,468,258
Expenses	13	Grants and similar amounts paid (Part IX, column (A), lines 1–3)	8,985,549	8,497,591
	14	Benefits paid to or for members (Part IX, column (A), line 4)	0	0
	15	Salaries, other compensation, employee benefits (Part IX, column (A), lines 5–10)	0	0
	16a	Professional fundraising fees (Part IX, column (A), line 11e)	0	0
	b	Total fundraising expenses (Part IX, column (D), line 25) 336,269		
	17	Other expenses (Part IX, column (A), lines 11a–11d, 11f–24e)	1,486,721	658,401
	18	Total expenses. Add lines 13–17 (must equal Part IX, column (A), line 25)	10,472,270	9,155,992
	19	Revenue less expenses. Subtract line 18 from line 12	2,744,359	312,266

- In Metrohealth's comments post-CMS' redaction of the 2020 MFN rule, they noted savings from the 340B program have allowed them to offer HIV and diabetes management programs, which combined served at least 2,000 patients in 2019. The savings have also helped them embed clinical pharmacists in our HIV, Oncology, Pulmonary, and endocrinology clinics.
- Even the CMS acknowledges that 340B hospitals may have "fewer resources available for their 340B program activities" and "will face the same or increased burden from model participation.
- Further, CMS estimates that the MFN Model will lead to "reduced beneficiary access through 340B providers" and predicts nearly $143 billion worth of drugs will simply be forgone by patients.
- Under MFN, if reimbursement for drugs is lower, then the profit margin would decline even more, potentially facing a profit loss

Source: Jefferies Analysis, HRSA

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MFN pricing could potentially harm 340B pharmacies by deepening 340B discounts, potentially creating duplicate discounts, and forcing manufacturers to choose between lower prices and market exits

Drug price: $1500 → MFN Drug price: $300

Margin: $500

Margin post-MFN: $300

Drug reimbursement due to ASP: $2000 → Under MFN ASP reflection: $600

- Although the Executive Order does not directly address the 340B program, it could impact how covered entities take advantage of the 340B discount on MFN-priced drugs. The implementation of the direct-to-consumer purchasing could impact covered entities: 1) patients of covered entities could buy tx directly from manufacturers and 2) payments to many 340B covered entities could decrease as drug costs decrease
- For provider-administered drugs, the reduced prices might result in a lower "average sales price" used to determine Medicare reimbursement. Commercial payers, Medicare drug plans, and managed Medicaid plans might reduce reimbursement to account for the lower acquisition costs available to pharmacies. For example, a drug that was $1,500 and reimbursed for $2,000 might become $500 and reimbursed at $625, leading to a 75% reduction in the savings available for the covered entity to reinvest in care for vulnerable and underserved populations.

Source: Jefferies Analysis, HRSA

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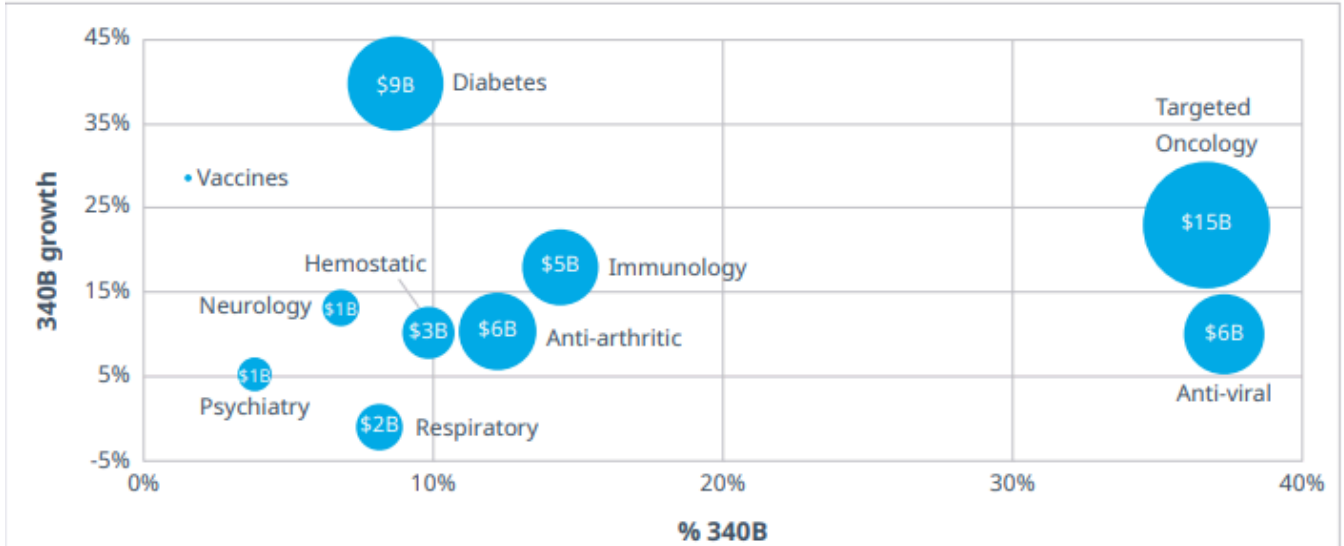
On drug spend, if we look specifically at Oncology drugs, these make up a large part of 340B drug spend, w/ MRK disclosing to us that Keytruda is ~1/2 within the 340B segment & IQVIA finding an avg discount of 40%



- High-cost pharmaceuticals purchased through specialty distribution channels represent an increasing proportion of the amount of spending in the 340B Program.
- While representing only 36% of all 340B units purchased, these high-cost pharmaceuticals purchased through specialty channels accounted for 60.6% ($40 billion) of reported 340B purchases – illustrating the significant impact that the relatively smaller numbers of specialty units purchased has on overall 340B purchases.
- In 2023, the top 10 drugs in terms of 340B purchases represented approximately one third of the total spending in the 340B Program.
- Targeted oncology and anti-viral products have high 340B exposure of 35-36%, and moderate to high 340B growth of 10-23%. Their average 340B discount was 40-41% (not shown), and their combined 340B revenue in 2023 was $21.5B

Brand Name	Primary Indications	2023 Total 340B Sales
Keytruda	Oncology	$6,905,377,755
Biktarvy	HIV	$3,577,083,273
Opdivo	Oncology	$1,953,824,181
Darzalex Faspro	Oncology	$1,891,559,523
Ocrevus	Oncology	$1,850,213,455
Trikafta	Cystic Fibrosis	$1,817,226,143
Humira (CF) Pen	Immunology	$998,809,804
Descovy	HIV	$969,510,516
Entyvio	Immunology	$949,744,300
Durvalumab	Oncology	$889,594,527

Source: Jefferies Analysis, IQVIA

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As a case study, Keytruda is ~1/2 within the 340B segment & IQVIA finds oncology drugs to have an avg discount of 40% via 340B – under our illustrative analysis, we see savings across 340B hospitals from Keytruda alone of $2.76Bn…which would become 0 given our MFN price for Keytruda is at a 56% discount to original US price

Brand Name	Primary Indications	2023 Total 340B Sales
Keytruda	Oncology	$6,905,377,755

Average oncology 340B discount: 40%
Assumed Price Bought at = $6.9Bn * (1-40%) = $4.14Bn
Savings from Keytruda 340B Margin = $2.76Bn

Product	Medicare Part	Company	Dose	Country	MFN Price	Estimated US Price post Rebate/Discount	Reduction %
Keytruda	B	MRK	100 MG/4ML	Japan	$ 2,477	$ 5,599	-56%

- MRK disclosed to us that Keytruda is ½ within the 340B segment
- Targeted oncology and anti-viral products have an average 340B discount was 40-41%, and their combined 340B revenue in 2023 was $21.5B – our analysis based on 2023 total 340B sales suggests 340B hospitals collectively get $2.76Bn in savings from Keytruda alone, which realizes to $0 upon MFN pricing implementation

Source: Jefferies Analysis, HRSA

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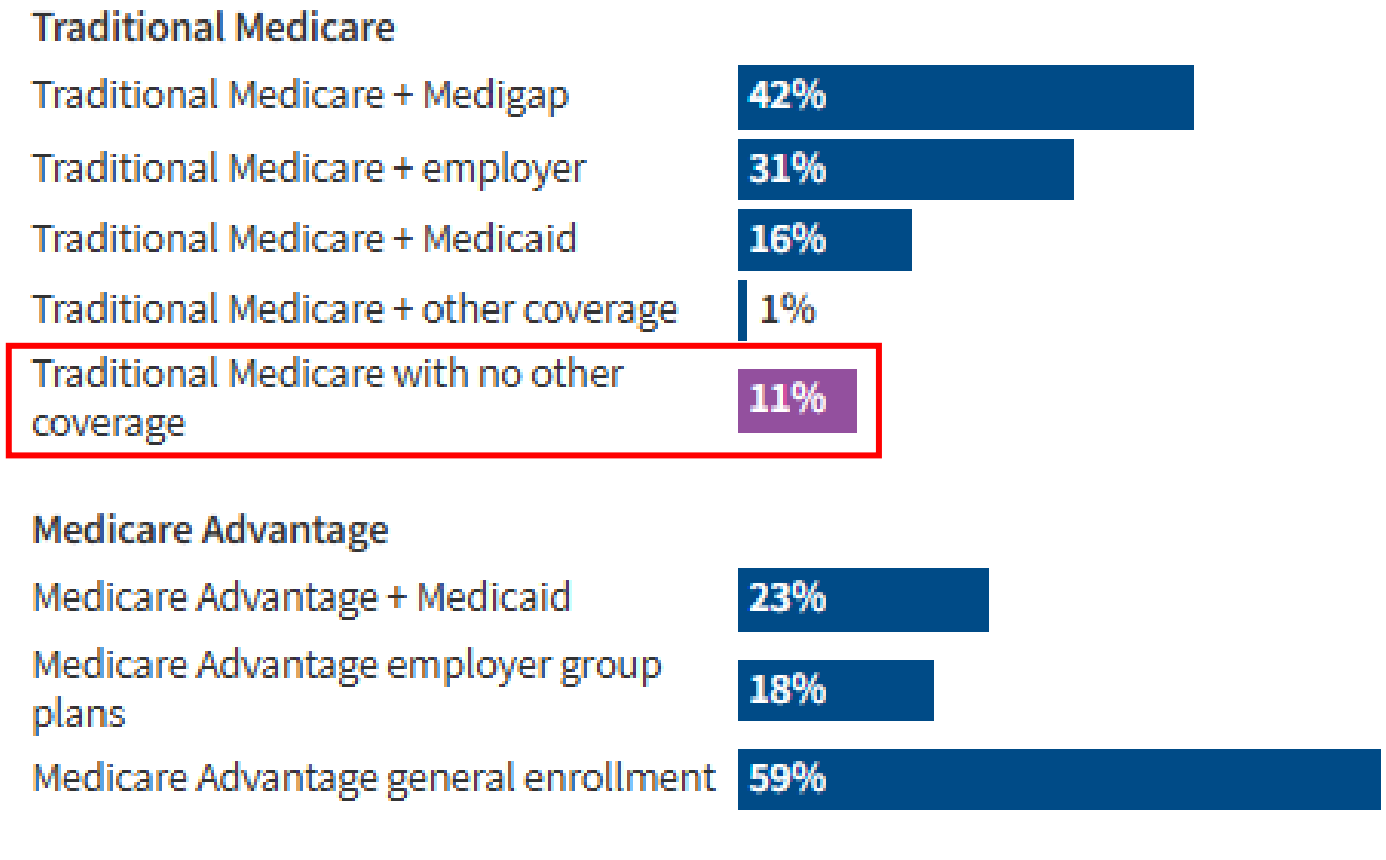
Further, while MFN would create substantial barriers to access for patients through disruptions to the 340B hospital and pharmacy systems, it would yield little benefit on patient affordability given >94% FFS Part B beneficiaries have supplemental coverage



Note: Total excludes beneficiaries with Part A only or Part B only for most of the year (n=5.0 million) or Medicare as a Secondary Payer (n=1.6 million).

- An analysis by Avalere found that very few Medicare fee-for-service beneficiaries would experience a substantial reduction in their out-of-pocket costs under the MFN Model. Further, less than 1 percent of beneficiaries would see reduced out-of-pocket costs (in a given year) if the 2020 MFN Model included the 50 drugs listed.
- This is largely because more than 94 percent of fee-for-service Part B beneficiaries using MFN drugs have supplemental coverage (e.g., Medigap, employer sponsored insurance, Medicaid) that covers some or all of their cost-sharing for Part B drugs.

Source: Jefferies Analysis, Avalere, KFF

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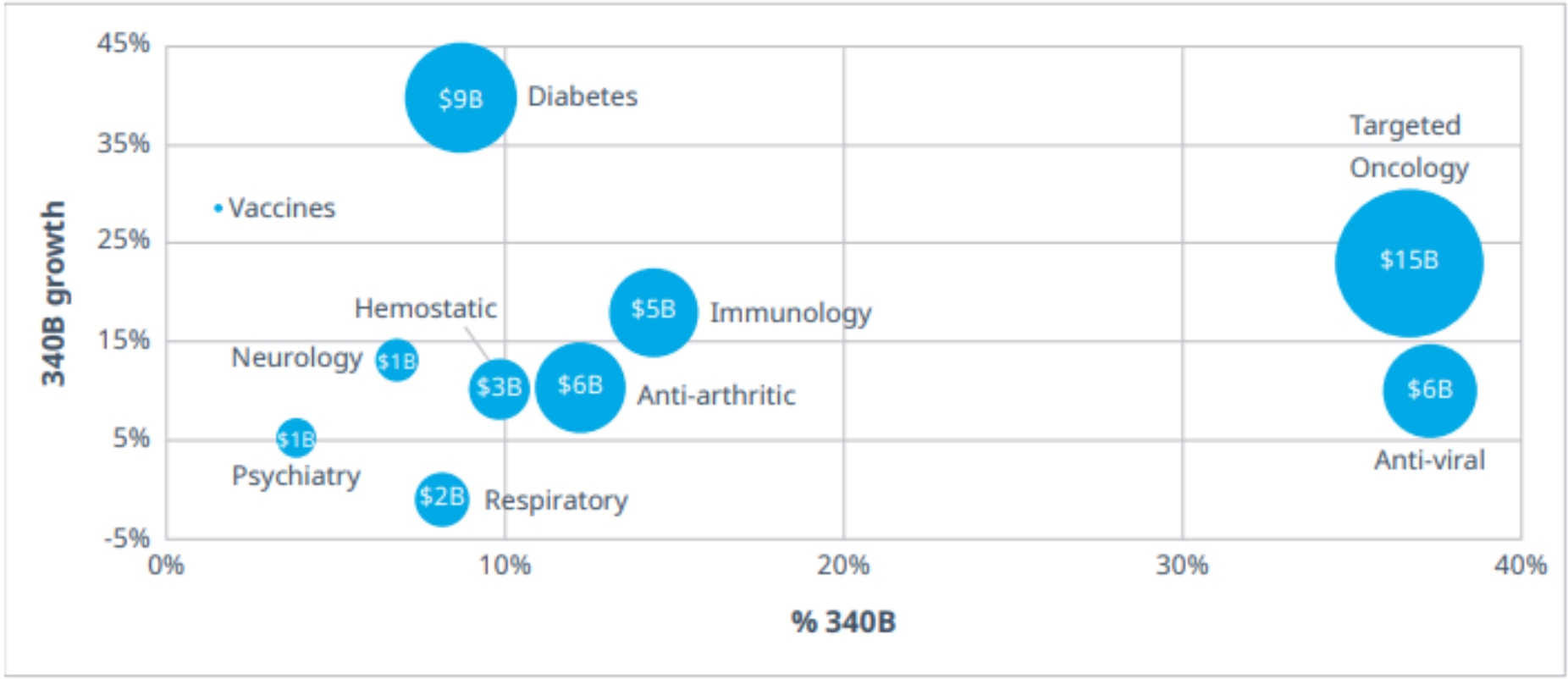
Additionally, to stay competitive vs biosimilars or competitors after being subject to MFN prices, companies may meaningfully decrease prices, which could force drugs down an 'ASP spiral', such that drug pricing declines to the point of unprofitability



- Since diabetes has a large number of drugs and very high total sales, despite its relatively low 340B exposure, its high 340B growth of 40%, and very high average 340B discount of 82%, the 340B program alone is having a growing impact on its gross to net, which could get greater with MFN

Source: Jefferies Analysis, IQVIA

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Remember discounts are reflected in ASP ~6mo later, so aggressive discounting will force drugs to discount even further down the line – as a reminder, we believe this is what led to manufacturing of Cimerli (Lucentis biosimilar) to be discontinued as it recently took aggressive 20% & 16% discounts

ASP *preliminary

HCPCS Code	Brand Name	Name	Q3'22	Q4'22	Q1'23	Q2'23	Q3'23	Q4'23	Q1'24	Q2'24	Q3'24	Q4'24	Q1'25	Q2'25
J0178	Eylea	aflibercept	$ 913	$ 903	$ 898	$ 894	$ 876	$ 868	$ 862	$ 841	$ 835	$ 822	$ 801	$ 796
J0177	HD Eylea	aflibercept									$ 336	$ 334	$ 329	$ 321
J2777	Vabysmo	faricimab	$ -	$ 38	$ 38	$ 37	$ 37	$ 37	$ 36	$ 35	$ 35	$ 34	$ 35	$ 35
J9035	Avastin	bevacizumab	$ 69	$ 70	$ 71	$ 71	$ 74	$ 74	$ 74	$ 74	$ 72	$ 73	$ 73	$ 73
J2778	Lucentis	ranibizumab	$ 275	$ 258	$ 237	$ 248	$ 237	$ 197	$ 188	$ 173	$ 138	$ 137	$ 124	$ 90
Q5124	Byooviz	ranibizumab-nuna			$ 236	$ 223	$ 221	$ 200	$ 188	$ 175	$ 158	$ 171	$ 169	$ 86
Q5128	Cimerli	ranibizumab-eqrn					$ 279	$ 273	$ 262	$ 256	$ 205	$ 201	$ 169	$ 147
Q5147	Pavblu	aflibercept-ayyh												$ 796

ASP changes QoQ

HCPCS Code	Brand Name	Name	Q3'22	Q4'22	Q1'23	Q2'23	Q3'23	Q4'23	Q1'24	Q2'24	Q3'24	Q4'24	Q1'25	Q2'25
J0178	Eylea	aflibercept		(1.1)%	(0.5)%	(0.5)%	(2.0)%	(0.8)%	(0.7)%	(2.5)%	(0.7)%	(1.6)%	(2.5)%	(0.6)%
J0177	HD Eylea	aflibercept		-	-	-	-	-	-	-	-	(0.6)%	(1.4)%	(2.4)%
J2777	Vabysmo	faricimab		-	(1.0)%	(0.7)%	(0.9)%	(1.4)%	(1.3)%	(1.8)%	(1.7)%	(1.7)%	2.9%	(1.5)%
J9035	Avastin	bevacizumab		0.7%	1.5%	0.9%	3.1%	0.3%	0.4%	0.1%	(2.3)%	0.3%	0.7%	(0.6)%
J2778	Lucentis	ranibizumab		(6.1)%	(8.2)%	4.4%	(4.5)%	(16.6)%	(5.0)%	(7.6)%	(20.6)%	(0.4)%	(9.6)%	(27.1)%
Q5124	Byooviz	ranibizumab-nuna		-	-	(5.4)%	(1.0)%	(9.6)%	(6.0)%	(6.6)%	(9.9)%	8.3%	(0.9)%	(49.4)%
Q5128	Cimerli	ranibizumab-eqrn		-	-	-	-	(2.2)%	(4.1)%	(2.3)%	(20.1)%	(1.7)%	(16.1)%	(13.0)%
Q5147	Pavblu	aflibercept-ayyh		-	-	-	-	-	-	-	-	-	-	-

	Brand Name	Name	Q4'22	Q1'23	Q2'23	Q3'23	Q4'23	Q1'24	Q2'24	Q3'24	Q4'24	Q1'25	Q2'25
ASP Price	Cimerli	ranibizumab-eqrn				$ 279	$ 273	$ 262	$ 256	$ 205	$ 201	$ 169	$ 147
QoQ ASP % decline	Cimerli	ranibizumab-eqrn					(2.2)%	(4.1)%	(2.3)%	(20.1)%	(1.7)%	(16.1)%	(13.0)%

	Brand Name	Name	Q4'22	Q1'23	Q2'23	Q3'23	Q4'23	Jan/Feb	Mar	Q2-Q4'24	Q1'25	Q2'25
Revenues	Cimerli	ranibizumab-eqrn	$ 6,900	$ 6,174	$ 26,728	$ 40,037	$ 52,449	$ 28,194		$ 115,000		
QoQ revs % decline	Cimerli	ranibizumab-eqrn				49.8%	31.0%		(24.3)%		-	-
									Implied ~$11,500 per month/$34,500 per Q			

- Over time, ASP could decline rapidly as more biosimilars enter the market. With biosimilar Lucentis, there was 16% drop in ASP for Cimerli in Q4'24 – we believe this is what likely caused Cimerli to stop being manufactured. We looked at Cimerli revs and noticed that it took a 20% discount in Q3'24 (vs 10% Byooviz), lowering avg revs per Q to be less than previous Qs
- Thus, providers may need to negotiate further discounts w/ co's to ensure adequate reimbursement, or choose alternative, less expensive treatments.
- Another method manufacturers may take to mitigate the effect of ASP decline could be price increases ex-US (though there are measures in place penalizing this activity) or increasing Medicare Advantage/commercial prices to inflate ASP

Source: Jefferies analysis, CMS

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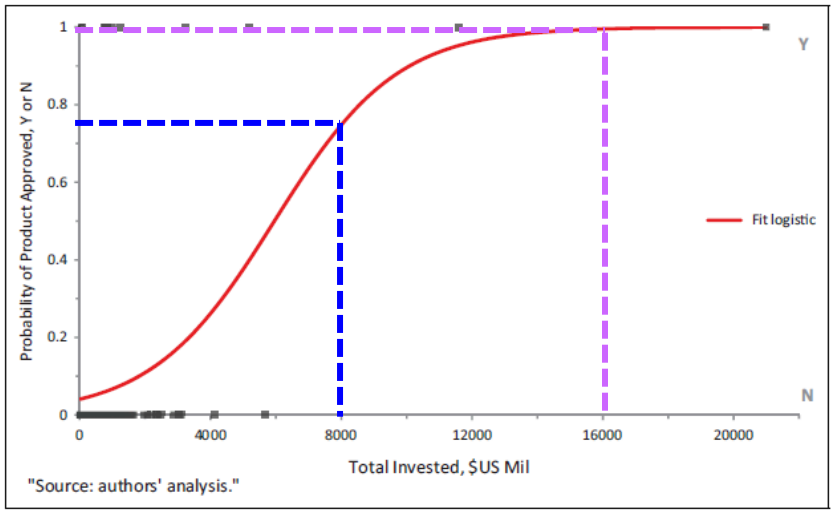
2) MFN could also lead to a reduction of US R&D innovation - Vital Transformation Group analysis suggests that a broad MFN model would decrease R&D investment → decreased probability of product approval (even with products going through the clinical pipeline)

'Tying Medicare Part B Drug prices to International reference prices will devastate R&D' – Schulthess et at. 2019 (Vital Transformation Consulting)

- Schulthess et al. 2019 **estimated a revenue losses** for 20 medicines included in the **Reference Pricing Model** using manufacturers'
- Secretary Azar claimed the **IPI pricing plan** would only reduce **R&D budgets by 1%** but assumed **only the 50% test group** is affected. However, we noted when implemented across **all of Medicare Part B**, the **actual impact is 2% on average**.
- On **firm-level effects, vital transformation stated they** are even more severe, **reaching up to 10% of R&D budgets** for companies with **multiple referenced products**.



Illustrative Analysis:

Current R&D investment levels lead to high chances of product approval

If IPI were to be implemented, R&D investment would drop, so drugs have a decreased PoS of getting approved even if still going through dev. pipeline.

Re: long-term consequences, Schulthess et at. 2019 highlighted:

- **Reduced Incentive for Innovation** – Pharmaceutical companies may **avoid developing new Medicare Part B physician-administered drugs** if the plan takes effect.
- **Market Access Limitations** – To maintain **higher U.S. prices**, companies may **withdraw from benchmarked European countries** with lower drug prices, depriving patients in **Greece, Italy, Slovakia, Spain, Ireland,** and others of **new treatments**.
- **Unrealistic Price Adjustments** – The assumption that companies can **raise prices in Europe** is refuted by **past attempts (e.g. Vertex' dispute with the UK government** over cystic fibrosis drug pricing increase).

We also noted **Amitabh Chandra**, professor of social policy and director of health policy research at the Harvard Kennedy School echo Schulthess et at. 2019 saying, **"fundamentally at odds with the U.S. approach for determining healthcare prices," and pharma co's will "exit, or not to launch their medications, in countries with small markets where a low government-imposed price could lead to a reduced price in the U.S."**

Read across to MFN? We anticipate these same arguments coming up for a pot'l future MFN model and we'll flag that reports such as these can be used by pharma co's in lawsuits to substantiate their claims of reduced R&D leading to fewer drugs for pts.

Source: Jefferies analysis, Schulthess et al. 2019 (Vital Transformation Consulting)

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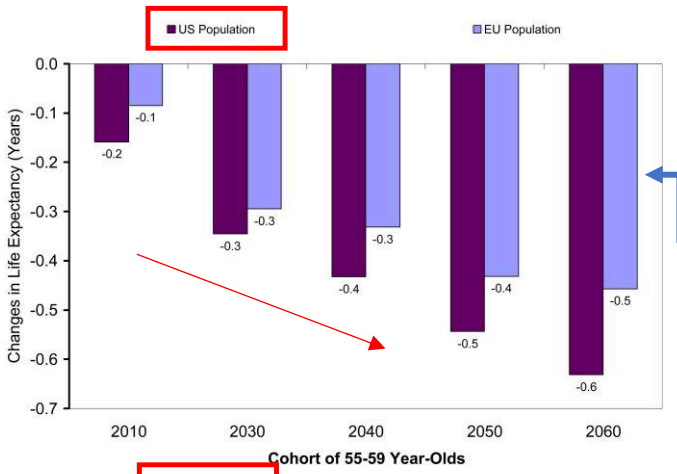
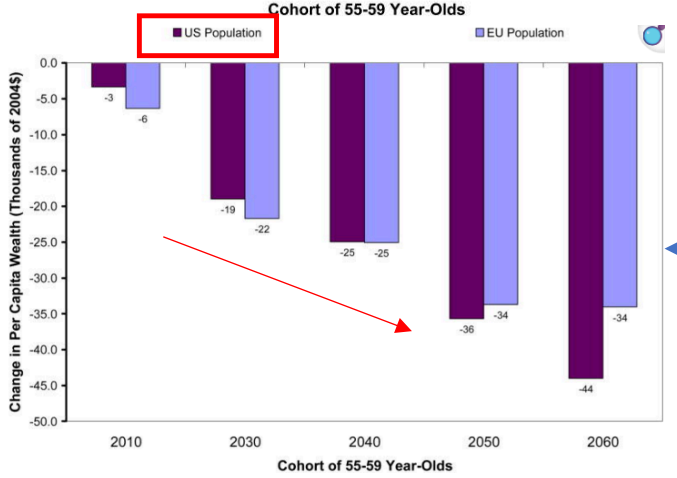
& another analysis showed that US price controls (eg, MFN) would decrease pharma innovation which would lead to lower health and wealth for the US and EU

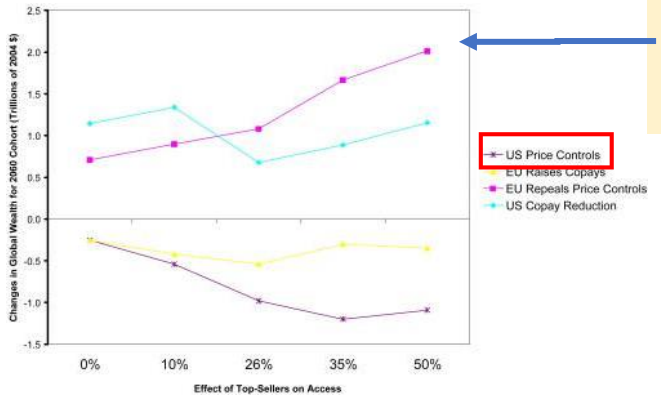
RAND Corporation research: Life exp. & per capita wealth under US price control





A RAND corporation research report cited that **there would be a decrease in life expectancy by from reduced pharmaceutical innovation that would affect both US and EU, but predominantly US over next ~5 decades (-0.6y by 2060).**

There would also be **a decrease in per capital wealth attributed to less innovation spending by pharma co's that would initially hit the EU harder, but transition to affect the US more by 2050**



A research report from the RAND corporation cited that the "***US adoption of European-style price controls would harm consumers in the US and Europe; over a 50-year period, it would cost $8 trillion in the US, and $5 trillion in Europe.*** *Similarly, repealing European price controls would add $10 trillion to the wealth of US society, and $6 trillion to wealth in Europe. Even under the most conservative assumptions,* ***adopting price controls generates at best a small benefit, but risks a large cost".***

On innovation price control, the same report cited *"When innovation-responsiveness is relatively low, US price controls may create small but positive benefits for consumers.* ***When it is high, however, the same policies are extremely costly for consumers. As such, price controls represent a risky policy strategy that may have modest pay-offs, or large costs, depending on the responsiveness of innovation***".

We'll flag they reported under different simulations, US drug price controls (e.g. MFN) would lead to the most reduction in global wealth and worldwide knock-on effect in drug innovation

Read across to MFN? 1) We expect pharma co's to use reports such as this in lawsuits/lobbying to show MFN would lead to lack of innovation → harms US patients health and wealth. 2) This outcome is difficult to avoid with MFN and not easily reversible.

Source: Jefferies analysis, RAND Corporation

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3) Lastly, we think MFN could potentially open the door for China to compete directly with the US drug development model

Di Tommaso et al. 2018: pharma patents and imports

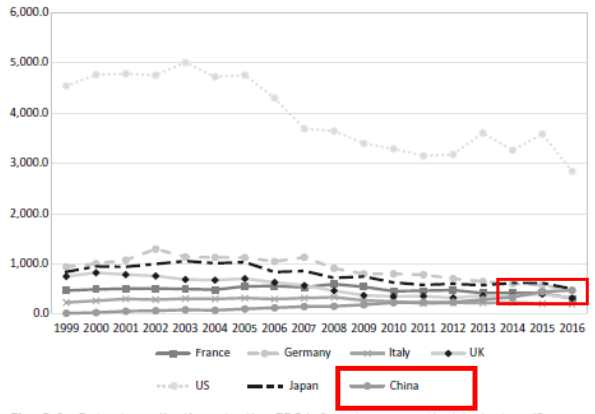


Fig. 2.4 Patent applications to the EPO* for pharmaceutical industry. (Source: Author's elaboration on OECD https://stats.oecd.org/. *based on Inventor(s)'s country(ies) of residence, priority date, year 2017)

Di Tommaso et al. 2018 reported that **China is the only country studied that showed an increase in pharma patent applications** (though still below US) and has now surpassed Germany, Italy, and the UK.

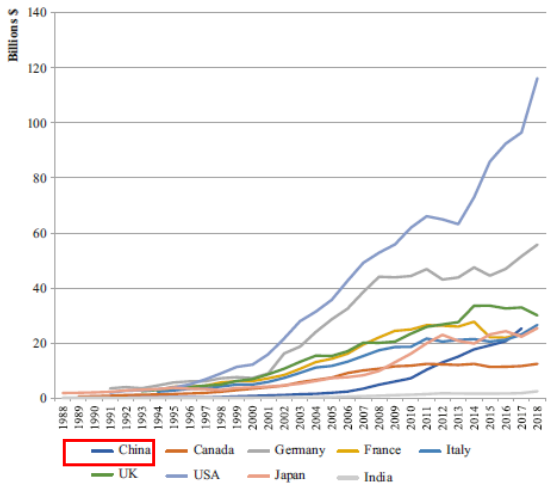
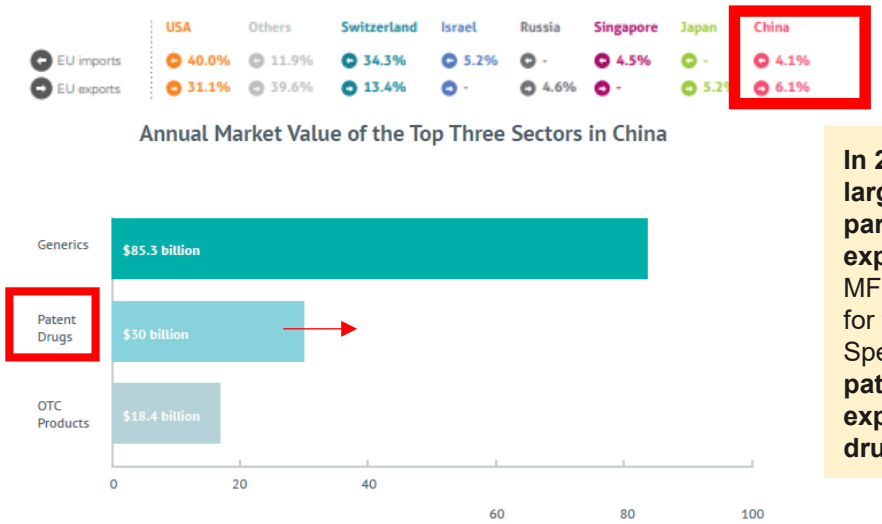


Fig. 2.2 Pharmaceutical products: import—trade value US$. (Source: Author's elaboration on UnComTrade data base)

We'll also flag that **China surpassed India, Canada, Japan, and France in pharma imports and is on track to beat the UK.** We think this shows that demand is increasing therefore EU partnerships would be of greater importance to the country.

- Assuming MFN gets implemented & US biotechs go to EU and demand a higher price, we think EU Co's can also go directly to a Chinese biotech and ask to purchase its drugs at a lower cost
- Chinese patient data can already be a part of an EU regulatory approval package & as we've seen in the amount of in-licensing deals over the last 3 years, US pharma/biotechs clearly think science from China and the regulatory environment is stable/reliable enough to justify sig. investment - we've also seen larger EU/China license deals vs US in '24 (EU closed 23 deals [$4.6B] vs US closed 22 deals [$3.5B])
- We wouldn't be surprised if Chinese biotechs (which have been struggling given fundraising environment & lack of price incentives in China) turn to other developed countries that may not be able to afford the price for drugs that US pays

Prescient Research: China partnerships can grow



In 2017, China was the 5th largest pharma trading partner w/ EU (6.1% exports). We think under MFN a market gap will open for this to increase. Specifically, **we think the patented drug market will expand from $30B as US drug innovation declines.**

Interview w/ Dr. Aviral Maheshwari: *"The other advantage that we have in the West is marketing. So **far, Chinese companies have not been investing in marketing or creating value for their medicines. We should expect this to change. Partnerships have a good track record of bringing the best of both sides together. Chinese companies will bring their market knowledge while Western companies will bring their brands, and when those brands say quality, it is very powerful.***

Source: Jefferies analysis, Di Tommaso et al. 2018, Prescient Research

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Company Valuation/Risks

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Investment Recommendation Record

(Article 3(1)e and Article 7 of MAR)

Recommendation Published	June 9, 2025 10:29 A.M.
Recommendation Distributed	June 9, 2025 10:29 A.M.

Company Specific Disclosures

Jefferies is acting as Financial Advisor to Landos Biopharma on the proposed acquisition by AbbVie.
Steven DeSanctis owns shares of Bank of America common shares.
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- Argenx SE (ARGX: $585.93, BUY)
- Astellas Pharma (4503 JP: ¥1,396, HOLD)
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- Eisai (4523 JP: ¥3,948, HOLD)
- Eli Lilly & Co (LLY: $769.88, BUY)
- Exelixis, Inc. (EXEL: $43.03, BUY)
- Ford Motor Co. (F: $10.26, UNDERPERFORM)
- GSK Plc (GSK LN: p1,513.00, HOLD)
- General Electric Company (GE: $255.63, BUY)
- General Motors Company (GM: $47.47, HOLD)
- Gilead Sciences, Inc. (GILD: $112.46, BUY)
- Incyte Corporation (INCY: $68.77, BUY)
- International Business Machines Corporation (IBM: $268.87, HOLD)
- Ionis Pharmaceuticals, Inc. (IONS: $35.29, BUY)
- Jazz Pharmaceuticals plc (JAZZ: $111.13, BUY)
- Kohl's Corporation (KSS: $8.75, HOLD)
- Madrigal Pharmaceuticals Inc (MDGL: $278.23, BUY)
- Mercedes-Benz Group AG (MBG GR: €51.35, HOLD)
- Merck & Co Inc (MRK: $78.97, BUY)
- Merck KGaA (MRK GR: €115.20, BUY)
- Moderna, Inc. (MRNA: $27.46, HOLD)
- Neurocrine Biosciences (NBIX: $125.39, BUY)
- Novartis AG (NVS: $118.02, HOLD)
- Novo Nordisk (NOVOB DC: DKK490.35, UNDERPERFORM)
- Otsuka Corporation (4768 JP: ¥2,932, BUY)
- Pfizer Inc (PFE: $23.35, BUY)
- Progressive Corporation (PGR: $279.32, BUY)
- Regeneron Pharmaceuticals, Inc. (REGN: $493.22, BUY)
- Roche (ROG SW: CHF268.20, HOLD)
- Sanofi (SNY: $50.47, BUY)
- Sanofi (SAN FP: €88.41, BUY)
- Takeda Pharmaceutical Co. (4502 JP: ¥4,295, BUY)
- Teva Pharmaceutical Industries Ltd (TEVA: $17.77, BUY)
- UCB (UCB BB: €162.75, BUY)
- United Therapeutics (UTHR: $325.82, BUY)
- Vertex, Inc. (VERX: $41.07, BUY)

Distribution of Ratings

			IB Serv./Past12 Mos.		JIL Mkt Serv./Past12 Mos.	
	Count	Percent	Count	Percent	Count	Percent
BUY	2107	60.51%	373	17.70%	121	5.74%
HOLD	1224	35.15%	112	9.15%	22	1.80%
UNDERPERFORM	151	4.34%	4	2.65%	3	1.99%

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