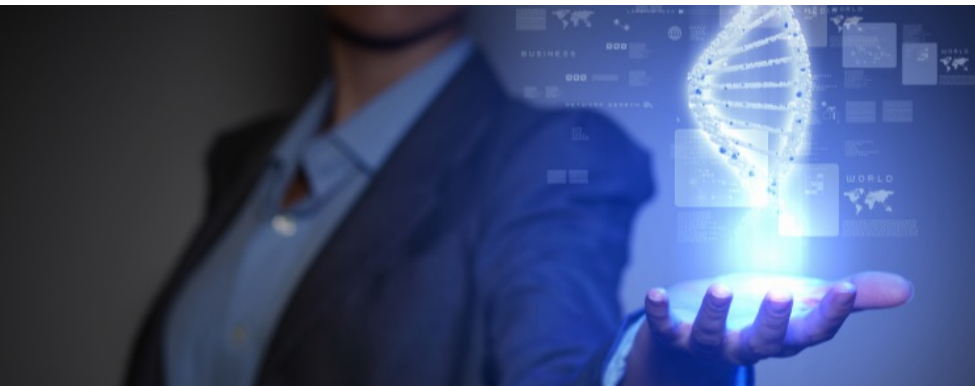




**VitalTransformation**

The impact of health technology made simple



## Build Back Better

Total market Impact of price controls  
in Medicare parts D and B.

July 28, 2022

Prepared by

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# Executive Summary

- We model and estimate the impacts of BBBA price reductions for 20 therapies collectively produced by 12 biopharmaceutical companies.
- We find that BBBA mandated price reductions impact all 12 companies, causing an average decline in net earnings (EBIT) of 55% :
  - The 25% most negatively impacted companies see reductions in their net earnings in excess of 100%;
  - Six of the 12 companies see earnings reductions in excess of 70%.
- These EBIT reductions would substantially reduce cashflows available for R&D partnerships and pipeline investments into drug discovery and development.
  - With an average 55% drop in EBIT, our model estimates that - under BBBA - only 6 of 110 approved therapies would be considered “not at risk” of cancelled development.
- In the last 20 years, drug prices in Europe declined 75% relative to the United States. We believe that, under BBBA, the US would see similar price declines, and thus declines far exceeding the initial, pre-negotiation, BBBA price reductions (depending on “age” of a therapy) of between 25% and 60%
- Importantly, BBBA does not address the increasing challenges posed by higher rebates demanded by PBMs, currently estimated to be at least 50% of companies’ gross revenues.
- This study was funded by BIO.

# Overview: What does BBBA Do?

- Includes a Price Negotiation Program for Single Source Drugs beginning in 2026:
  - 10 therapies in '26
  - 15 therapies in '27 + '28
  - 20 therapies in '29 and beyond
- Small molecule therapies without generic competition enter pricing negotiations at 7 years, with regulated prices being implemented in year 9.
- Biologics without generic competition enter pricing negotiations at 11 years, with regulated prices being implemented in year 13.
- Establishes a "ceiling price" to start the negotiation, based upon the following criteria:
  - Short Monopoly: 9-12 years after approval, 75% of Non-Federal Average Manufacturers Price (non-FAMP)
  - Extended Monopoly: 12-15 years after approval, 65% of non-FAMP
  - Long Monopoly: 16+ years, 40% of non-FAMP
- Implements mandatory inflation-based rebates in Medicare Parts B and D that extend to the commercial market beginning October 2022 (Part D) and January 2023 (Part B).
- In 2025, implements a \$2,000 out-of-pocket cap in Medicare Part D and alters manufacturers discounts

## Study Objectives:

- Vital Transformation (VT) developed a model that measures the impact of BBBA on the biopharmaceutical industry assuming several scenarios:
  - We assume the “Maximum Fair Price”, or ceiling price, is a best-case scenario for the cohort of drugs price controlled each year.
  - We estimate a further reduction of 10% below this ceiling price, based upon the evolution of pricing controls in the EU.
  - We compare the projected global revenues through 2031 at average market growth rates which are far below the current rate of inflation, to the revised revenues after the implementation of BBBA.
  - We use the PCE price index to measure all values in constant 2022 \$USD.
- We model BBBA’s impacts for the entire commercial market:
  - 340B prices are increasingly flowing into the commercial market and will be reset by the new ceiling price.
  - BBBA states clearly that the “Maximum Fair Price”, or ceiling price, will be “announced”; there is no provision for “announced” price reductions to be confidential, inviting political pressures to apply reductions to commercial prices.
  - The experience in the EU shows that prices have continued in a downward spiral once the EMA centralized procedure was put in place, we see no reason to doubt the same political pressures on pricing will be seen in the US.
- We calculated the impacts of BBBA on the investment ecosystem and drug development under the above scenarios.

# BBBA Methodology

- Current ASP, WAC and Non-FAMP drug prices were obtained by agreement with [SSR Health](#).
- BBBA revenue reductions were modeled at the drug level based upon per dose data obtained from the [Medicare Part D & B Drug Spending Dashboard](#), audited SEC financial statements, Pitchbook, Biomedtracker by Informa, and BioCentury.
- A historical average growth rate of CMS spending was derived from a 10-year cohort of 125 Medicare Part D and B drugs. The computed growth rate was then used to project forward current sales through the year 2034, by which time all our 2022 based drug cohort had entered the BBBA pricing model.
- Audited sales of the top 20 drugs from Medicare Parts D and B were projected forward to simulate the impact of pricing reductions under BBBA, which is based upon the actual 2021 earnings of companies net of PBM rebates listed in their 10-K audited SEC reports
- We opted to maintain a static 2022 drug cohort for our analysis with the understanding that many of these drugs may not meet the BBBA criteria after 2022. However, we feel the top 20 drugs included in the 2022 cohort are representative of the level of impact that will occur under the BBBA pricing framework.
- Data on the previous 10 years of investment/partnering activity by our BBBA impacted companies were obtained from Biomedtracker and BioCentury databases. This activity was statistically reduced based on the calculated BBBA impacts on available free cashflows of each company.
- The impact of revenue losses caused by BBBA was statistically modeled to determine the revised probability of approved products entering the market from 2012-2021.
- The impact on employment was calculated using the 2017 IMPLAN U.S. 2017 Model by TEconomy.

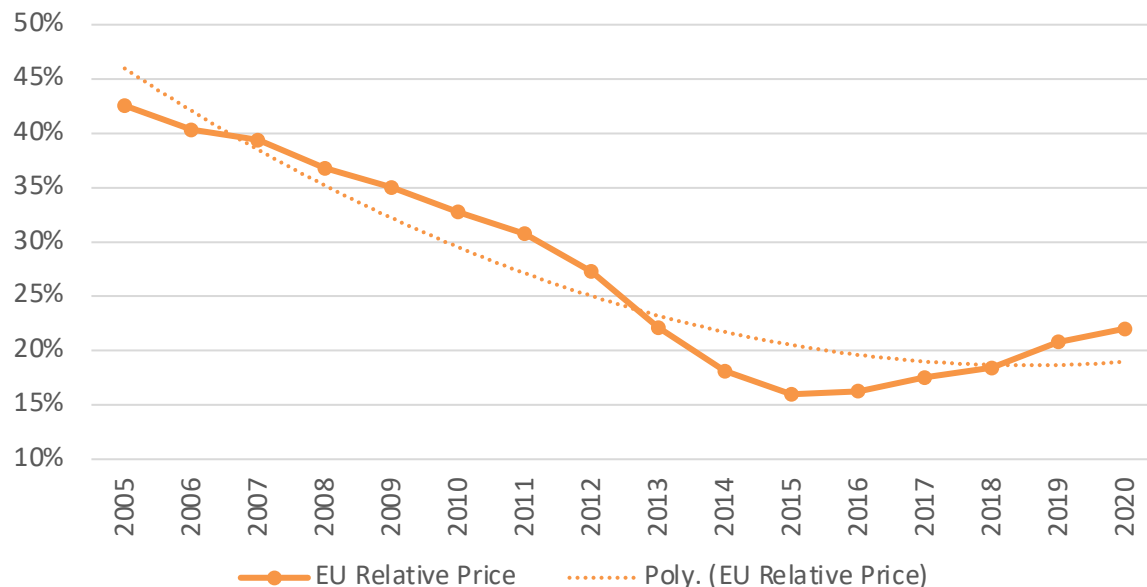
# Price Controls

**Negative impact on the EU innovation ecosystem**

# Price Controls in the EU Indicate How BBBA Will Evolve

## Average EU Price Relative to the US

3 year moving avg

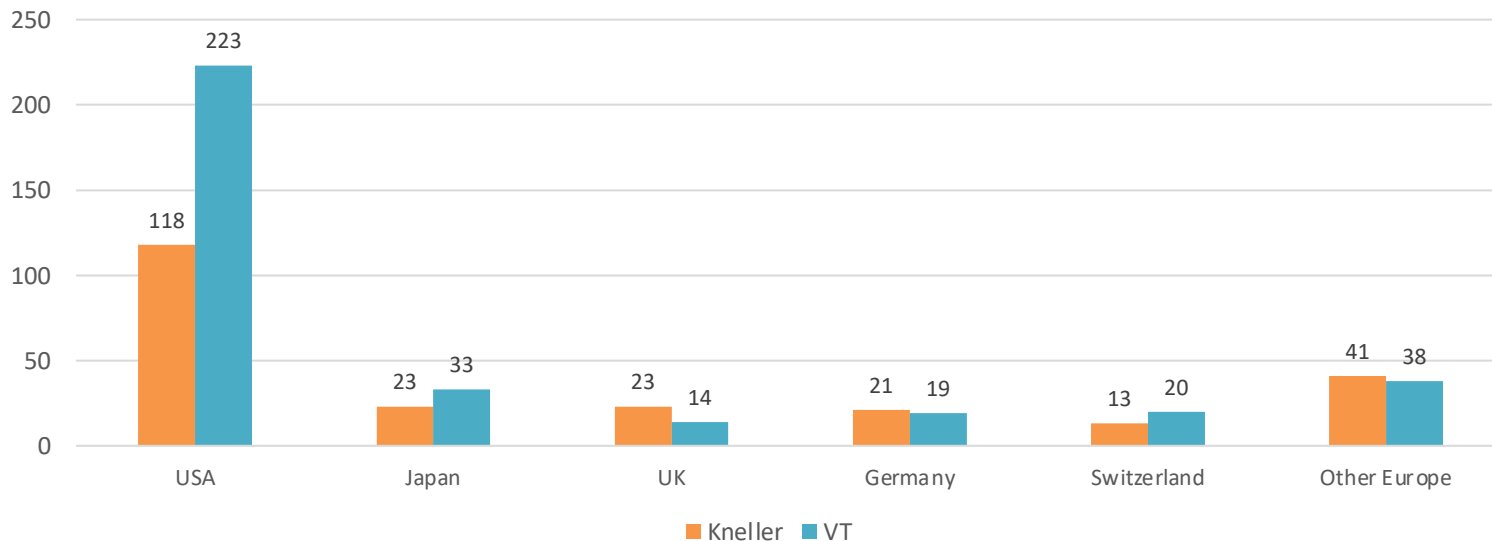


- EU price controls have led to a marked drop in pricing when compared to the US.
- Given the experience of the EU, VT assumes the negotiated final price will be at least -10% below the “ceiling price”, landing at least 70% below the current non-FAMP price at the final price control stage.

Sample countries are Belgium, France, Germany, Ireland, Italy, Spain, Sweden, United Kingdom, and United States

# US vs Rest of World Biopharmaceutical Developments

Total FDA Approvals by Geographic Origination of IP  
Kneller 1998 - 2007 vs. VT 2011-2020

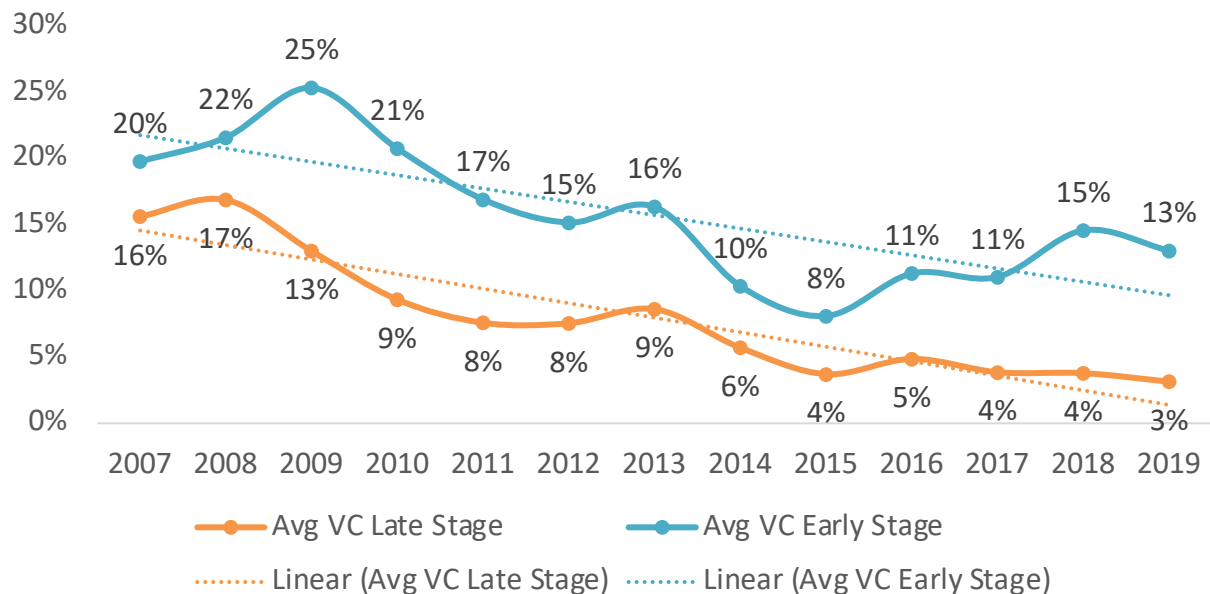


The USA alone was responsible for 95% of the increase of 111 total FDA approvals in the 11 years between [Kneller's 2010](#) groundbreaking publication and this research.



# Early & late-stage VC have declined significantly in the EU relative to the US

## AVG EU VC Funding Per Capita Relative to US by %

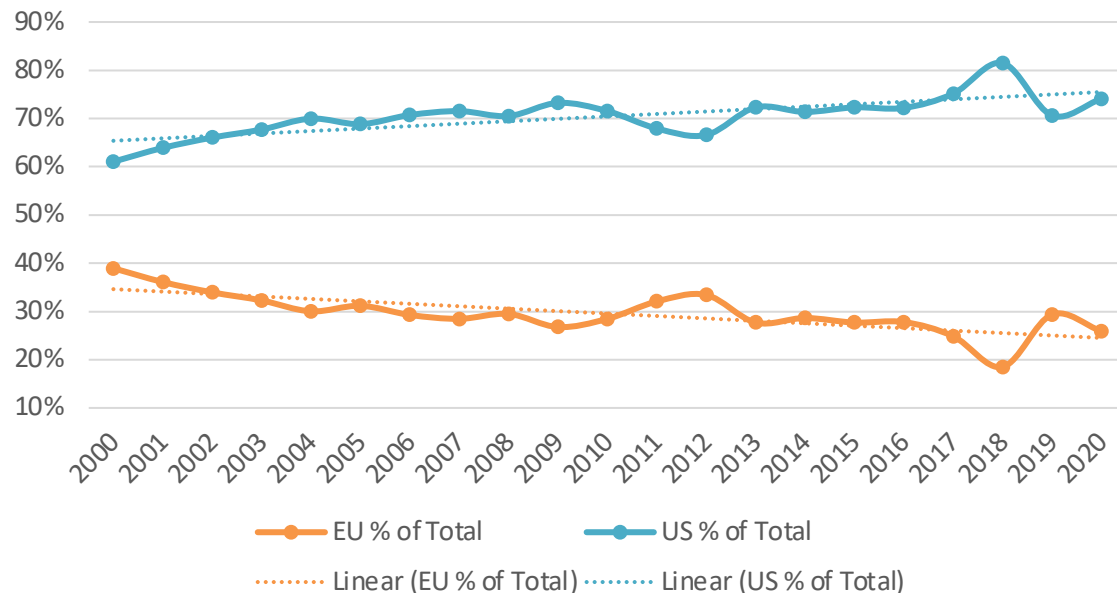


- By 2019, EU Late-Stage VC was just 3% of US Late-Stage VC.
- Our [estimates](#) demonstrate that each 10% drop in drug prices in a given market led to a 14% decrease in total VC funding;
  - 10% early-stage VC funding,
  - 17% late-stage VC funding.

Sample countries are Belgium, France, Germany, Ireland, Italy, Spain, Sweden, United Kingdom, and United States

## The US share of total biotech startups has grown, the EU share has declined

EU and US % Total Annual Share of Startups



Lower drug prices caused by price controls in the EU statistically predict the decline of EU biotechnology startups.

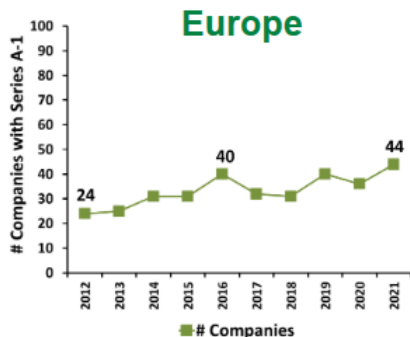
For every 10% difference in pricing between the EU and the US, we see a 9% change in the number of biotech start ups.

In 2020, the US share of total annual biotech startups was roughly three times greater than the EU share.

Sample countries are Belgium, France, Germany, Ireland, Italy, Spain, Sweden, United Kingdom, and United States.

# Global Early Stage Venture Backed Biopharma Start-ups

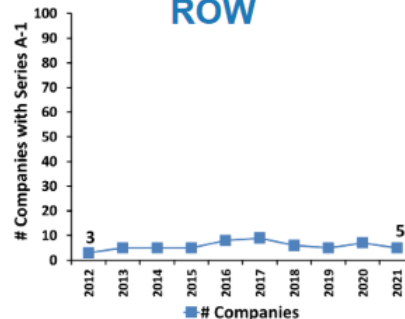
2021 = barely a record



2021 = record #,  
by 2x vs 2020



ROW



- In 2021, Asia (primarily China) had 93 venture backed start-ups, this is roughly equal to the annual US total.
- EU is flat with limited innovative early-stage growth.
- It would be naïve to assume that price controls in the US will not have similar impacts to what we've analyzed in the EU.
- VC will move to markets where they obtain a reliable ROI, BBBA could exacerbate a transition to China for innovative biopharma.

Primary Databases used: Primary: Cortellis/TR, EvaluatePharma, Informa, Biocentury BCiQ

[www.bio.org/iaareports](http://www.bio.org/iaareports), BIO Industry Analysis, 2022



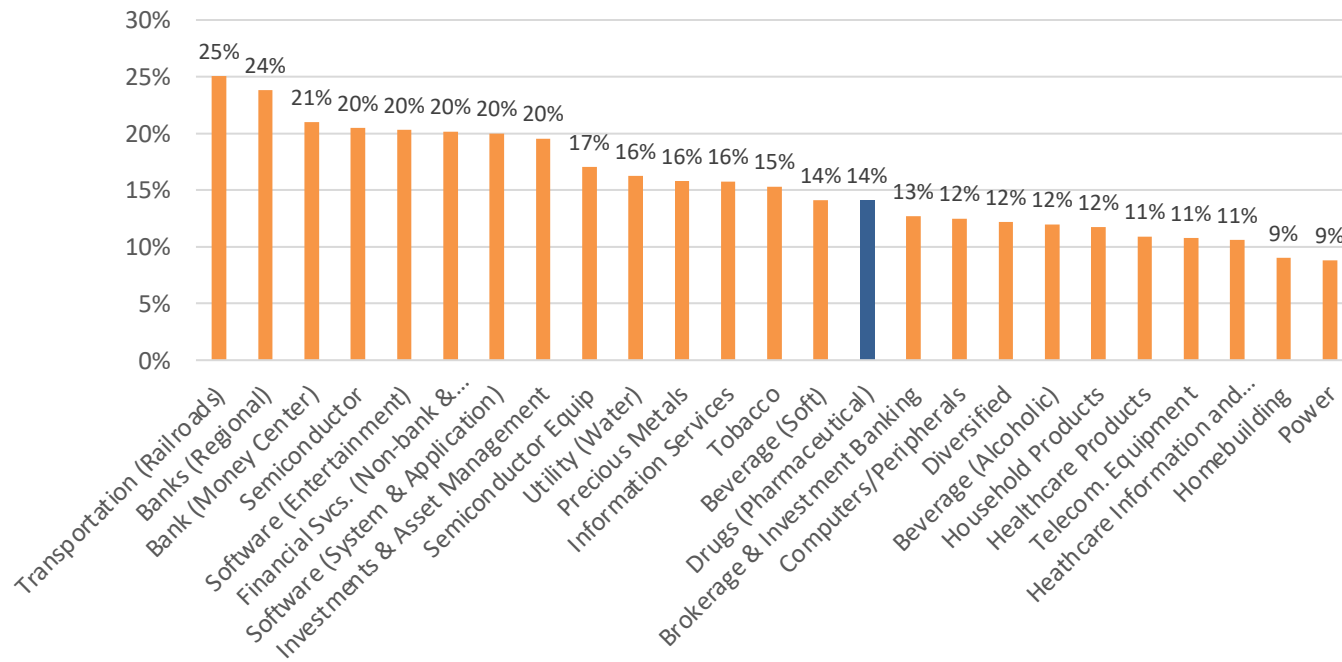
# Modeling the impact

## BBBA in Practice

# Actual Profitability of the Biopharma Sector in Context

## Net Margin by Industry

NYU Stern January 2021 data of the 25 most profitable sectors by net margin



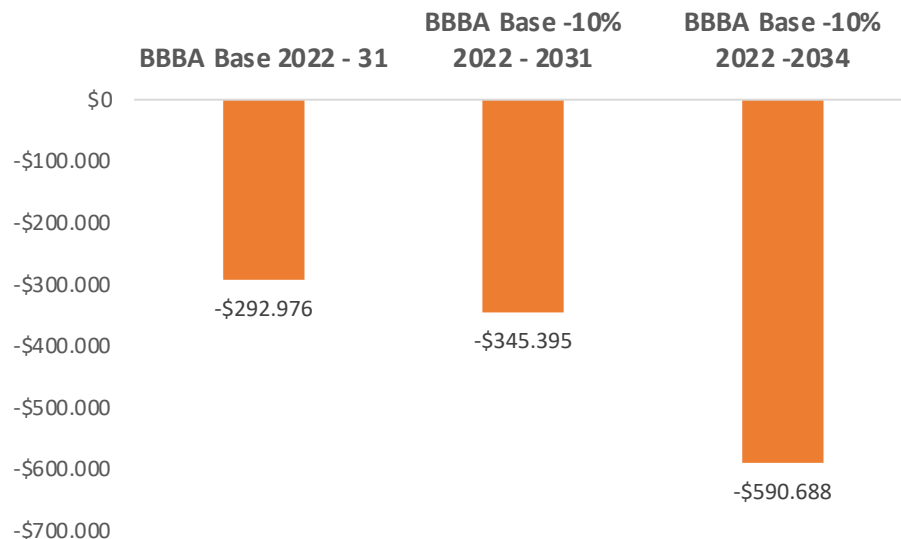
The Biopharma industry's net profitability is decidedly average when compared to other US sectors.

Given the industry has enormous up-front development costs and failure rates in excess of 90%, cash control is a key aspect of decision making in bringing new therapies to market to treat patients.

[http://pages.stern.nyu.edu/~adamodar/New\\_Home\\_Page/datafile/margin.html](http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/margin.html)

# BBBA negotiation impacts on 20 therapies in our cohort

## Impact Assessments of BBBA, Base Case and Further 10% Reduction



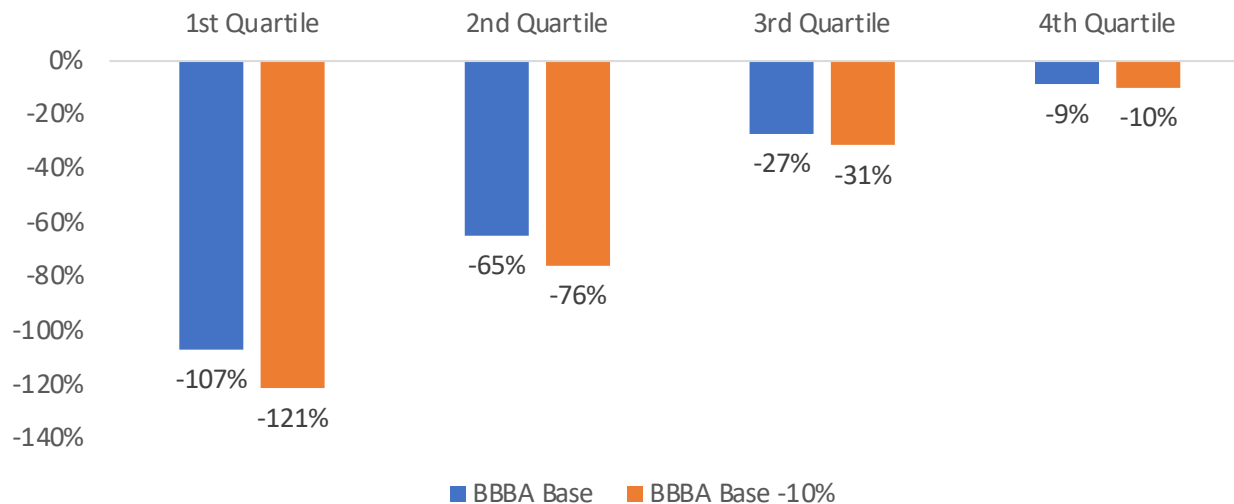
- VT modeled the impact on the top 20 drugs in Medicare by spending, manufactured by 12 companies.
- We find the BBBA criteria for negotiation will lower revenue for the 20 drugs in our cohort by \$293 bil USD.
- BBBA states, “the Secretary shall publish the Maximum Fair Price”, this is a loud market signal that will impact commercial prices as well.
- VT believes price controls will lead to pricing declines for the entire market below the -60% included as the BBBA price ceiling.
- When the full impact is realized in our 20-drug cohort in 2034, the revenue declines to the 12 impacted companies are extremely large, exceeding their 2022 net earnings by more than 4x.

# BBBA impact on available cash for investments/pipelines

## 2022 - 2031

### EBIT reductions on 12 BBBA impacted companies by quartiles

2022 Constant Dollars, 2022-2031



EBIT = earnings before interest expense and tax, i.e. net cash available to a firm at year end

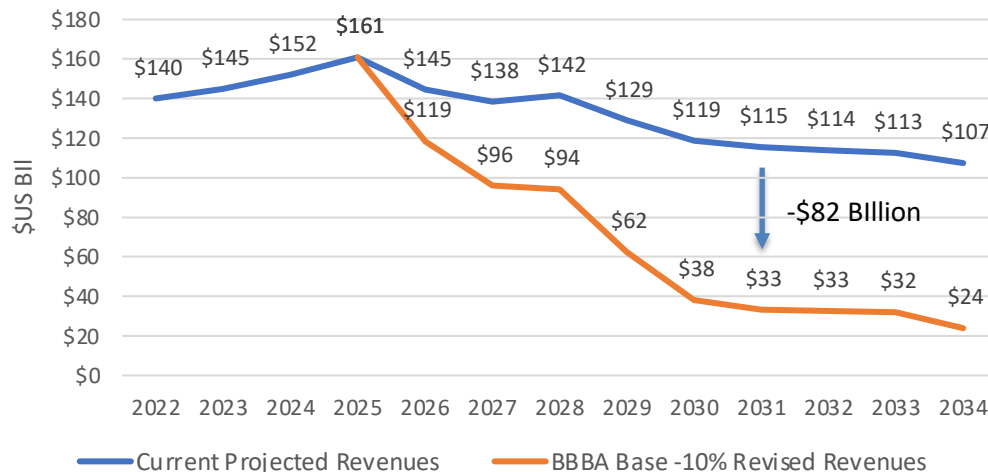
- BBBA reduces a company's ability to reinvest their free cash flow into their future pipelines.
- The most impacted 25% of companies in the year of 2031 show average annual revenue **reductions of 121%, exceeding their current 2022 net annual earnings (EBIT)**.
- Taking the single year of 2031 projected BBBA revenue reductions, the total revenue losses across all 12 impacted firms equals 55% (range of 51% - 58%) of their 2022 EBIT.

# Projected revenues with and without BBBA

## 20 therapy cohort

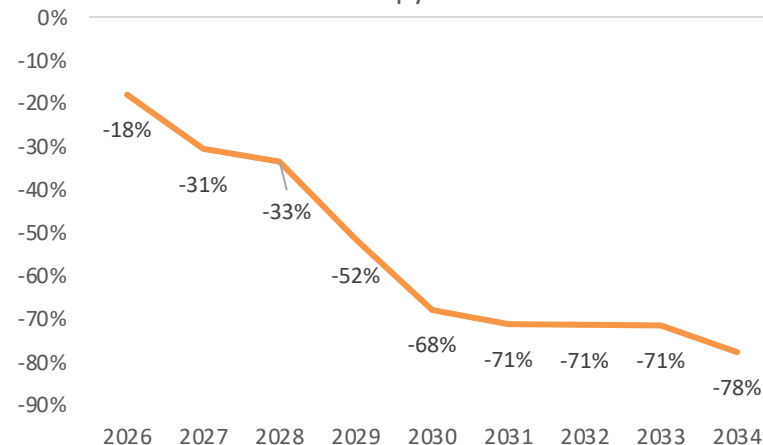
### Impact of BBBA on Revenues for 20 Therapy Cohort

2022 Constant \$US Bil



### BBBA Revenue Declines as a %

20 Therapy Cohort



- In 2031, the final year of the CBO estimate, the revenue reduction impact of BBBA in our cohort of 20 therapies is **-\$82 billion**.
- Our analysis restricts the cohort to a total of 20 therapies: 10 in 2026, 15 in 2027-2028, and 20 from 2029 forward.
- If the cohort instead grew over time, bringing in 15 additional drugs in 2027 & 2028 (30 total), and a further 20 drugs in 2029 and each year after, the 2034 annual impact would be similar to our [H.R.3. analysis](#), roughly **-\$125 billion** a year.



# BBBA Direct and Total Supported Annual Job Losses

## Total US and Puerto Rico by State/District/Region

### Jobs Impact - 2031 -\$82.3 Billion Reduction in Revenue \$US Mil

State	Direct Biopharma Jobs Impact	Total Biopharma Supported Jobs Impact	Biopharma Supported Output Impact (\$M)	State	Direct Biopharma Jobs Impact	Total Biopharma Supported Jobs Impact	Biopharma Supported Output Impact (\$M)
<b>Totals, U.S. &amp; PR</b>	<b>-118,950</b>	<b>-592,290</b>	<b>(\$168,568)</b>				
California	-20,479	-111,415	(\$33,789)	South Carolina	-753	-3,620	(\$1,000)
New Jersey	-8,903	-44,764	(\$12,236)	Maine	-666	-3,392	(\$757)
Massachusetts	-8,907	-41,699	(\$10,396)	West Virginia	-687	-3,331	(\$1,105)
Pennsylvania	-6,868	-37,230	(\$9,870)	Iowa	-820	-3,199	(\$865)
North Carolina	-6,595	-36,815	(\$10,920)	Kentucky	-775	-2,816	(\$644)
Illinois	-5,978	-36,184	(\$10,704)	Oregon	-614	-2,538	(\$565)
New York	-8,089	-33,849	(\$9,840)	Delaware	-728	-2,519	(\$560)
Texas	-5,578	-28,779	(\$7,889)	Nebraska	-457	-2,146	(\$609)
Indiana	-3,616	-20,522	(\$8,157)	Alabama	-514	-2,110	(\$592)
Florida	-3,777	-19,196	(\$4,257)	Rhode Island	-283	-1,944	(\$535)
Maryland	-4,480	-19,033	(\$4,958)	New Mexico	-524	-1,831	(\$383)
Ohio	-3,064	-13,317	(\$3,236)	New Hampshire	-353	-1,647	(\$397)
Michigan	-2,344	-12,682	(\$3,341)	Oklahoma	-406	-1,597	(\$375)
Puerto Rico	-2,625	-11,439	(\$8,453)	Nevada	-314	-1,449	(\$351)
Utah	-1,808	-10,738	(\$2,539)	Louisiana	-403	-1,367	(\$309)
Missouri	-1,799	-9,687	(\$2,367)	Mississippi	-264	-1,174	(\$332)
Washington	-2,258	-8,361	(\$1,978)	Vermont	-169	-688	(\$165)
Georgia	-1,703	-8,356	(\$1,958)	Idaho	-137	-567	(\$133)
Wisconsin	-1,603	-7,555	(\$1,765)	Arkansas	-121	-561	(\$149)
Tennessee	-1,781	-6,809	(\$1,532)	Montana	-124	-413	(\$84)
Colorado	-1,264	-6,706	(\$1,645)	Hawaii	-132	-379	(\$71)
Arizona	-1,233	-6,090	(\$1,341)	DC	-94	-218	(\$64)
Virginia	-1,423	-5,956	(\$1,452)	Wyoming	-44	-160	(\$58)
Minnesota	-1,115	-5,882	(\$1,435)	South Dakota	-47	-145	(\$26)
Connecticut	-1,314	-5,196	(\$1,322)	North Dakota	-41	-119	(\$30)
Kansas	-851	-4,046	(\$1,014)	Alaska	-24	-53	(\$11)

Source: TEconomy analysis; IMPLAN U.S. 2017 Model, VT adjusted for estimated annual reduction of revenues associated to BBBA

# BBBA and Distributed R&D Ecosystem

**Impact of cash reductions on pipeline investments**

## Ecosystem Impacts of BBBA

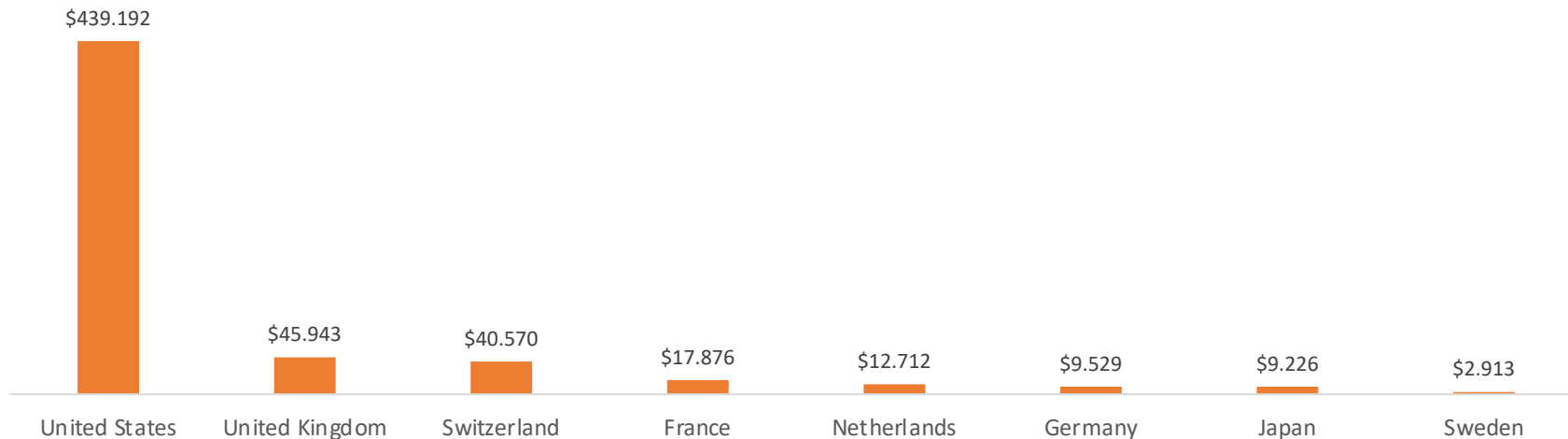
- The 12 companies in our cohort we identified as being impacted by BBBA, invested \$588 billion into 364 venture pipeline investments identifiable by location from 2012-2021.
- 75% of these global investments were made in the US, leading to 110 approved therapies.
- BBBA would reduce the cashflow available for pipeline investments by 55% in the 12 impacted firms.
- Partnerships are not just driven by US companies; all global companies are developing assets in the US.
- According to VT research, over 60% of therapies now originate in the US, and 62% of global biopharma therapies are commercialized in the US regardless of the location of the parent company.
- We have found that BBBA will disproportionately impact small/emerging companies in California, New Jersey, New York, and Massachusetts where 80% of all US investments were made.

## Global Pipeline Investments made by BBBA Impacted Companies in our Cohort

75% of their global investments are made into the US

### Value of 364 Pipeline Investments by Location of Seller 2012-2021

\$US Mil – Top 8 Countries – \$588 Billion Total



Source BioCentury BCIQ database <https://www.biocentury.com/home>

# Total value of 229 US pipeline investments made by cohort of 12 BBA impacted companies

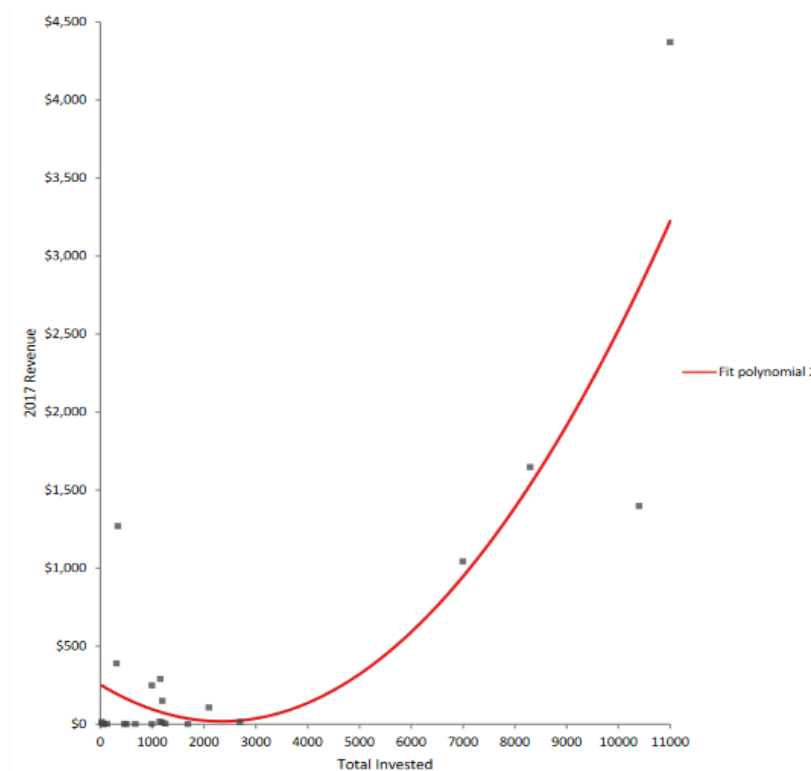
CA, MA, NJ, & NY = 80%

State	Total Pipeline Investments	# of Deals
California	\$148,042,390,000	53
Massachusetts	\$78,059,700,000	32
New Jersey	\$74,776,100,000	49
New York	\$52,224,000,000	42
Illinois	\$32,445,500,000	17
Connecticut	\$21,272,190,000	5
Colorado	\$11,400,000,000	1
Indiana	\$7,063,600,000	11
Maryland	\$5,245,000,000	2
Texas	\$3,656,500,000	3
North Carolina	\$3,506,000,000	5
Washington	\$948,000,000	3
Minnesota	\$386,500,000	2
Pennsylvania	\$68,100,000	1
Michigan	\$65,600,000	1
Ohio	\$22,500,000	1
Delaware	\$10,000,000	1
<b>United States</b>	<b>\$439,191,680,000</b>	<b>229</b>

These pipeline investments made by our 12 BBBA impacted companies would have been at risk of not being developed had BBBA been in effect when these investments were made.

# Analysis of biopharma investments

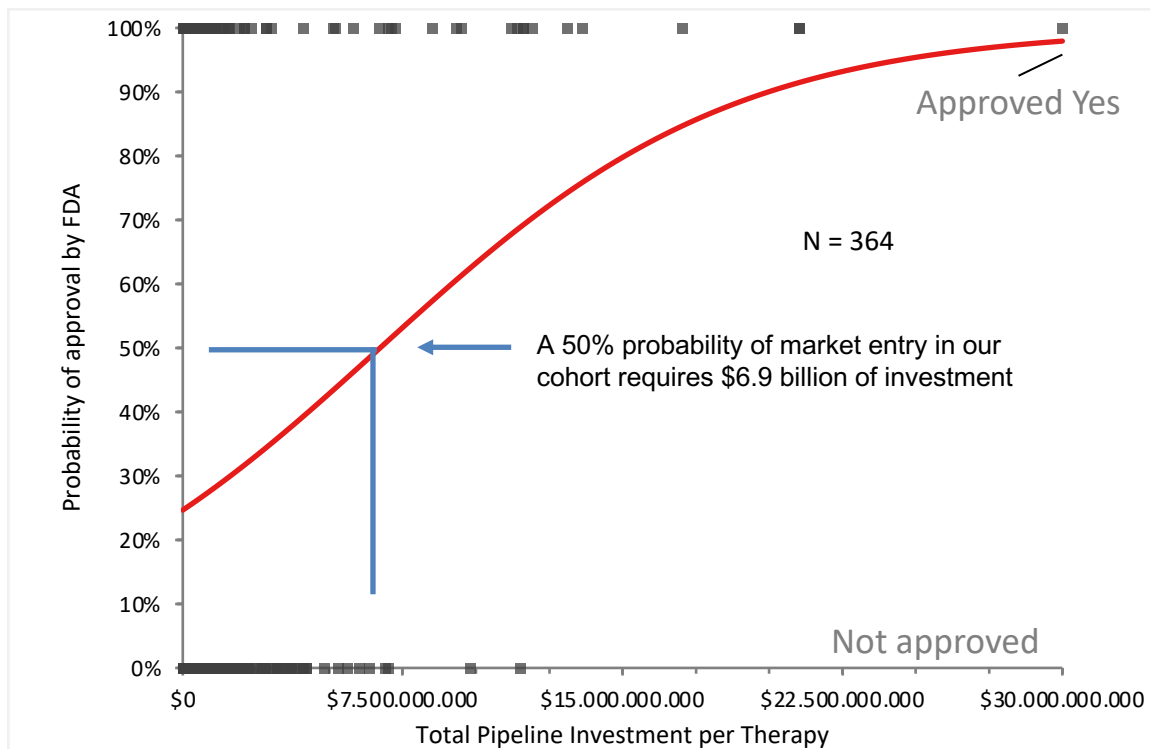
## Total Investments Accurately Predict Future Revenues



- Our previous peer reviewed [study](#) showed that the total amount invested is a reliable predictor of future revenues.
- The relationship between investments and future annual revenues is statistically significant ( $p < 0.0001$ ), and accounts for 77% of the model's variability ( $R^2 = 0.773$ ).
- Those assets with the greatest probability of generating large revenues generate the higher investment levels.
- A future 55% average cut in net revenues from free cash flows due to BBBA would have substantial implications for the 12 BBBA impacted companies in our cohort, and their willingness to invest in higher-risk, lower margin products.

# Size of total pipeline investments by 12 BBBA impacted companies predicts FDA approval

Total Investments Accurately Predict Market Entry



- This chart shows the total amount invested into each of the 364 pipeline therapies by the 12 impacted BBBA companies predicts FDA approval with high statistical certainty – the more investment there is into a therapy, the more likely it is to be approved by the FDA.
- The p-value of the model,  $p < 0.0001$  means that there is less than a 1 in 10,000 probability that this relationship arises by random chance.
- In our cohort of therapies, a 50% probability of market entry requires a cash commitment of \$6.9 billion.
- Cutting revenues by 55%, and greater that 70% in half of the 12 companies in our cohort, statistically reduces the likelihood of FDA approval, lowers potential returns for investors, and increases the risks of those investments.

# -55% EBIT reduction alters the benefit risk for pipeline investments made by 12 company cohort

BBBA leads to a substantial increase in risk for 104 of our 110 approved therapies

## BBBA Impact on FDA probability of approval with 55% EBIT Reductions

Many previously approved therapies are unlikely to come to market with reduced probability of market entry

Indication	Probability of market entry	Indication	Probability of market entry	Indication	Probability of market entry	Indication	Probability of market entry	Indication	Probability of market entry
Brain cancer	83%	Lupus	30%	Influenza virus	26%	Migraine	25%	Anthrax	25%
Cancer (unspecified)	69%	Skin cancer	30%	Dermatitis	26%	Angina	25%	Diarrhea (infectious)	25%
ITP	69%	NSCLC	30%	Fungal infection	26%	Thyroid cancer	25%	Emesis	25%
Cancer (unspecified)	61%	RSV	29%	COPD	26%	Herpes virus (HSV)	25%	Hypertension	25%
B cell lymphoma	53%	Hypertension	28%	Ophthalmic	26%	GERD	25%	Constipation	25%
Cardiomyopathy	52%	Asthma	28%	ADD	26%	COPD	25%	Gaucher disease	25%
ALL	49%	Psoriasis	28%	Encephalitis	26%	Migraine	25%	Fungal infection	25%
Sinusitis	49%	Bacterial infection	27%	B cell lymphoma	26%	Hyperuricemia/gout	25%	Erectile (ED)	25%
Anemia	49%	Anesthesia	27%	Asthma	26%	AML	25%	Diabetes	25%
Breast cancer	48%	Anesthesia	27%	Schizophrenia	26%	Depression	25%	Conjunctivitis	25%
HCV	48%	Diabetes	27%	Bacterial infection	26%	Sarcoma	25%	Cholera	25%
Post-operative ileus	44%	Migraine	27%	Conjunctivitis	25%	Angina	25%	Psoriasis	25%
B cell lymphoma	43%	COVID-19	27%	Acne	25%	Crohn's disease	25%	Breast cancer	25%
Cancer (unspecified)	42%	Dermatitis	27%	Hypertension	25%	Heart failure (CHF)	25%	Breast cancer	25%
Lung cancer	39%	Neuropathy	27%	Hypertension	25%	Endocrine	25%	Lymphoma	25%
Infectious (unspecified)	38%	Thrombosis	27%	Crohn's disease	25%	Hepatitis C (HCV)	25%	Bipolar disorder	25%
Lipodystrophy	38%	Encephalitis	27%	Diarrhea (infectious)	25%	Clostridium	25%	Ankylosing spondylitis	25%
IBD	38%	COVID-19	26%	Asthma	25%	Meningitis	25%	Erectile (ED)	25%
Cancer (unspecified)	36%	Diabetes	26%	Hypertension	25%	Migraine	25%	(GvHD)	25%
Psoriasis	34%	Gastric ulcers	26%	Lipodystrophy	25%	Smallpox	25%	Arterial thrombosis	25%
Lymphoma	34%	Arthritis (RA)	26%	Prostate cancer	25%	Bleeding	25%	Cancer (unspecified)	25%
Diabetes	32%	Constipation	26%	Hypertension	25%	Cancer (unspecified)	25%	Burns	25%
<b>Bring to Market</b>	<b>At Risk</b>	<b>Bring to Market</b>	<b>At Risk</b>	<b>Bring to Market</b>	<b>At Risk</b>	<b>Bring to Market</b>	<b>At Risk</b>	<b>Bring to Market</b>	<b>At Risk</b>

- Many previously approved therapies would be 'at risk' due to price controls implemented in BBBA.
- With 6 of our 12 companies losing in excess of 70% of their free cash flow, there will be a reduction in the 12 impacted company's ability to invest in small and less certain therapeutic areas.
- BBBA will force companies to focus on only those assets with the highest probability of market entry and largest indications.
- Those therapies with probabilities below 50% after the implementation of BBBA would be at risk for not being developed.



# Pipeline retrospectively at risk for abandonment due to BBBA

Clinical Area	At Risk
Infectious Disease	22
Cancer	19
Neurology	11
Cardiovascular	11
Autoimmune	9
Endocrine/Metabolic	8
Gastrointestinal	8
Dermatology	4
Inflammation	3
Hematology	2
Pulmonary	2
Genitourinary	2
Ophthalmic	1
Transplant	1
Diagnostic	1

- Our previous approved pipeline cohort includes many therapies that have since cured hepatitis C, and effectively caused many types of cancers to be treated as chronic conditions.
- Science evolves, and products don't always launch for the exact indications for which they were investigated, however BBBA will force pipeline investment decisions to be made that will have real impacts upon patients with unmet medical needs.

# BBBA and Price Reductions

## PBM Revenue Capture

# PBMs and Insulin – who actually benefits from rising prices?

PBMs use rebates for insurance premium reductions

FIRST OPINION

## Insulin prices and pharmacy benefit manager rebates: pin the tail on the patient

By Duane Schulthess March 19, 2020

R

Company	Insulin Drug	Medicare Part D Spending 2017	Total Reported U.S. Sales 2017	Difference
Sanofi	Lantus	\$4.184 billion	\$2.813 billion	-\$1.371 billion
Sanofi	Toujeo	\$541 million	\$503 million	-\$38 million
Novo Nordisk	Novolog	\$2.235 billion	\$1.629 billion	-\$606 million
Novo Nordisk	Levemir	\$1.404 billion	\$1.429 billion	+\$25 million
Eli Lilly	Humalog	\$1.535 billion	\$1.717 billion	+\$182 million
Eli Lilly	Humulin	\$172 million	\$884 million	+\$712 million

- In 2020, VT published an analysis in [STAT](#) comparing the estimated total Federal spending on insulin in the CMS database to audited revenues included in corporate 10-k reports.
- We found that, “unallocated insulin sales .. in Medicare Part D ... total a bit over \$2 billion...How could \$2 billion in sales simply vanish into thin air?”
- According to [Prof Gary Branning of Rutgers University](#), this revenue is used as rebates and, “what this translates to is affordable premiums”.
- According to former [FDA Director Scott Gottlieb](#), “Sick people aren’t supposed to be subsidizing the healthy.”

# Companies aren't capturing drug price increases

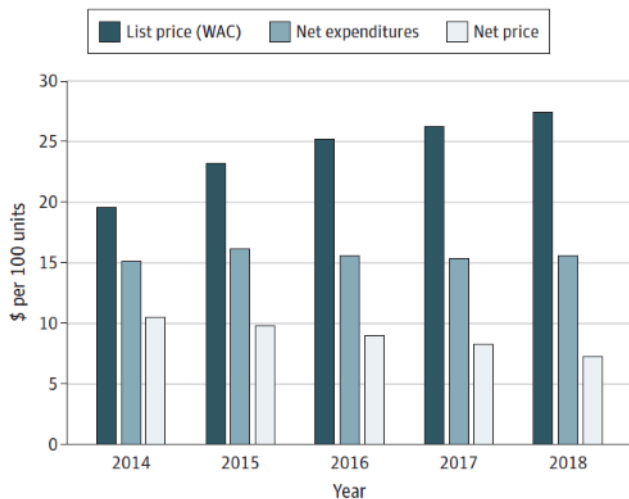
60%+ of insulin revenues are transferred to PBMs as rebates

## JAMA Health Forum™

Original Investigation

### Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018

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- According to a [recent study in JAMA](#), manufacturers on average receive only 40% of the total out of pocket patient cost of insulin (i.e. the net price).
- The difference between list (WAC) and net prices for insulin increased by 122.5% since 2014.
- BBBA initially included large provisions to manage insulin pricing, those provisions have been removed from the July 2022 revision of the bill.
- BBBA assumes, we feel mistakenly, that the 60% non-FAMP pricing reductions will be proportional to current price and revenue distributions between PBMs and the manufacturers.
- As the PBM's clients are, ultimately, the policy holders who seek the lowest premiums via rebate reductions, BBBA completely ignores the fact that PBMs will likely insist on the same cash rebate levels, regardless of drug prices being forced lower – this will have devastating impacts on US Innovation.

# Conclusions

## Implications of BBBA

# Conclusions and Implications of BBBA

- BBBA reduces net earnings for a 12 company cohort by 55%, which will likely lead to a large reduction in the value of all US biopharmaceutical companies and a substantial loss of free cashflow for pipeline investments.
- As measured by EBIT (Net annual Earning):
  - The BBBA reductions exceed the annual earnings of a quarter of the 12 companies in our cohort;
  - half of all companies in our cohort see a reduction of their earnings greater than -70%
- The loss of revenues, coupled with rising inflation and the enormous recent drops in global equity markets is likely to cause an exodus of investors whom are no longer willing to assume the risks of biopharma development; in 3-5 years, there would be a sharp reduction in needed new drugs entering the FDA approval pipeline.
- The 55% drop in available cashflow is likely to have large negative unintended consequences on the innovation ecosystem, seeing substantial reductions in the number of new drugs being created and originated in the United States.
- BBBA does not address the increasing challenges posed by rebates demanded by PBMs, these are unlikely to be reduced in light of lower prices – to quote Scott Gottlieb, “Sick people aren’t supposed to be subsidizing the healthy.”
- Price controls have had a demonstrably negative impact on the EU biopharma sector, we would anticipate that BBBA will have similar negative impacts in the US – the Biopharma sector will likely be forced to seek out marketing opportunities and developments in China, where VC is currently investing heavily in biopharma startups.

# Disclosure

- Vital Transformation, an international health economics and strategy consultancy, was asked to conduct an analysis of the impact of price controls as proposed in BBBA, on the biopharmaceutical innovation ecosystem, and specifically the impact on investment and small company capital formation and new drug pipeline development.
- The opinions included in this work are those of Vital Transformation LLC, and not necessarily those of the project sponsors.
- The analysis was performed by Vital Transformation's Consulting Economist Dr Harry Bowen, Research Manager Dr Daniel Gassull, and CEO Duane Schulthess
- This study was funded by the Biotechnology Innovation Organization, BIO.

# Appendix 1 – Regression Table

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Equation |  $\text{logit}(\text{Approved}) = -1.117 + 1.659\text{e-}10 \text{ total\_deal\_value}$

Parameter	Estimate	95% CI	SE
Constant	-1.117	-1.385 to -0.8485	0.13688
total_deal_value	1.659E-10	7.933E-11 to 2.526E-10	4.4191E-11

$\beta = \log \Phi_{\text{Yes}}$

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Source	-log Likelihood	DF	G <sup>2</sup> statistic	p
Difference	9.3603	1	18.72	<0.0001
Fitted model	213.67	362		
Null model	223.03	363		

H0:  $g(x) = \beta_0$   
The model is no better than a null model  $Y=\pi$ .  
H1:  $g(x) = \beta_0 + \beta x$   
The model is better than the null model.