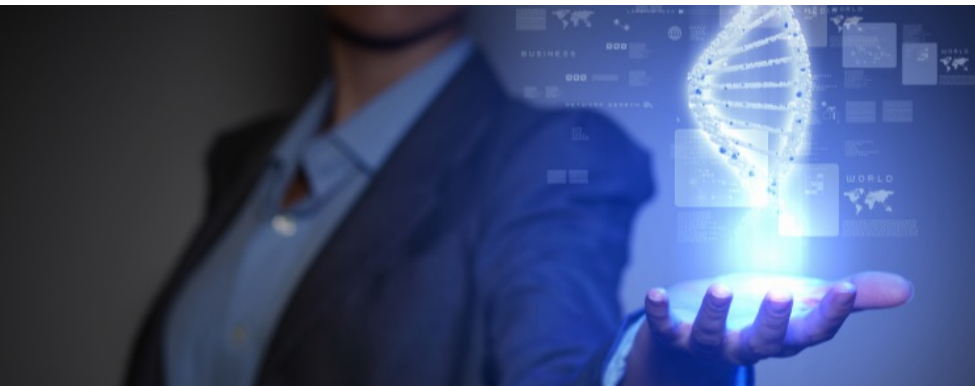# Vital Transformation
The impact of health technology made simple

The Impact of IRA Policy Expansion Proposals on the US Biopharma Ecosystem

June 15, 2023

Prepared by

Daniel Gassull
Research Partner

Harry Bowen
Consulting Economist

Duane Schulthess
CEO

Executive Summary

- Vital Transformation (VT) modeled the impacts of the drug pricing provisions of President Biden's 2024 Budget, now proposed by Senator Baldwin as the "Smart Prices Act (SPA)", which would impose government price setting for selected Medicare drugs at only 5 years after initial FDA approval.

- We modeled the impacts on industry revenues and future R&D investments and estimated future lost innovation impacts including the impact on industry jobs.

- We estimate a loss of between 146,000 – 223,000 direct biopharmaceutical industry jobs and a total of 730,000 – 1,100,000 U.S. jobs across the economy if the proposed IRA expansion were to be implemented.

- Looking forward, we estimate that the expanded government price setting could result in roughly 230 fewer FDA approvals of new medicines over a ten-year period, once the impacts are fully reflected in the pipeline.

  o Impacts will be felt most heavily in many areas of unmet need, including in rare disease, oncology, neurology, and infectious disease.

  o The most significant ecosystem impacts would be concentrated primarily in CA, MA, and NY.

- Had the drug pricing provisions of the SPA been in place prior to the development of today's top-selling medicines, we estimate that 82 of the 121 therapies we identified as selected for price setting would likely have not been developed.

Study Objectives:

- Model the impact of the SPA on the biopharmaceutical industry:

  o We assume that the, "Maximum Fair Price", or ceiling price, is a best-case scenario for the cohort of drugs price controlled each year.

  o We compare the projected global revenues from 2026 through 2035 at average market growth rates which are far below the current rate of inflation, to the revised revenues after the implementation of the SPA.

  o All revenues are adjusted to 2023 USD (CPI-U).

- We model the SPA's impacts for the entire commercial market:

  o The IRA 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.

  o We assume a two-year delay for the impacts of the Biden Budget to impact commercial pricing.

- We calculated the impact of the SPA on the investment ecosystem, drug development, and orphan therapies, jobs, and future patient access under the above scenarios.

Overview: Modeling the Smart Prices Act

- Based on the 30 largest selling products over the last 10 years, we generated two baseline average US revenue curves over the life of a product (pre- and post- loss-of-exclusivity), one for small molecule medicines and one for biologics.

- We then modelled baseline revenues for the 216 top-selling Part B and D drugs, applying the average lifetime revenue curves to project revenues from 2023 to 2040. All values were adjusted to 2023 constant dollars. We assigned revenues to the commercial or Medicare markets using SEC filings data to determine the prevalence, by disease group, of those over 65 versus rest of population.

- Impacts from price setting begin in 2026 for single source small molecules and large molecules.

- The SPA would impose price setting beginning at year 5 for both small and large (biologic) molecules. We modeled the "negotiated ceiling price" based upon the following criteria:
  - Short Monopoly: 5-7 years after approval, 75% of Non-Federal Average Manufacturers Price (non-FAMP),
  - Extended Monopoly: 8-12 years after approval, 65% of non-FAMP,
  - Long Monopoly: 12+ years, 40% of non-FAMP.

- As outlined in the SPA, we modelled price-setting for 20 drugs in year one, 30 drugs in year two and three, and 40 drugs in year four and beyond.

- The stated IRA exemptions for single source orphan therapies, and small market drugs under $200 mil were maintained for our SPA analysis.

- We model impacts in two ways:
  - Identifying products selected for price setting that would likely not have been developed had the SPA been in place prior to investment decisions
  - Estimating the number of fewer products developed over a ten0-year period, once the full impacts of price setting were reflected in the pipeline.

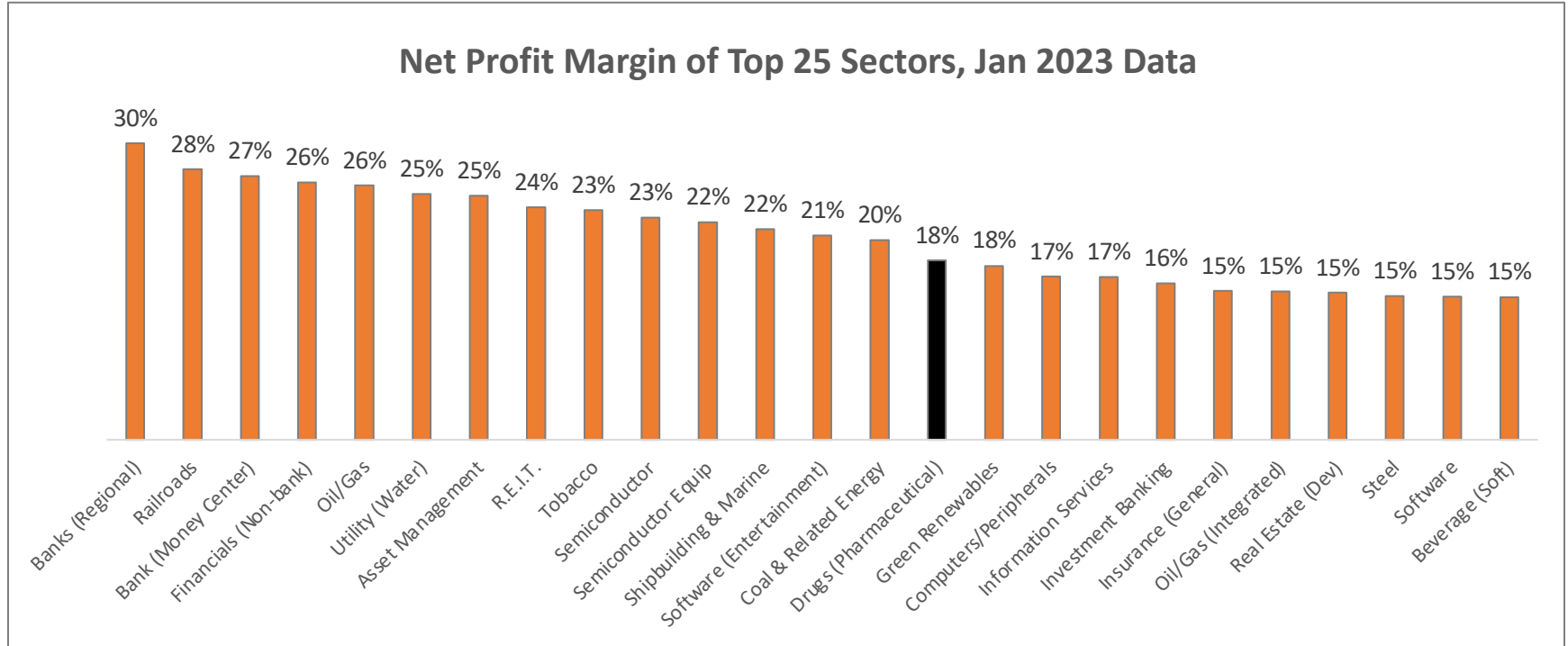SPA's Impact on Drug Discovery

To estimate future revenues of drugs approved by CMS and FDA, we modeled the performance of the top selling 30 drugs over the last 10 years from market entry through to generic competition.

Average US sales of top 30 products by year since FDA approval
(Excluding Peak Sales Outliers)
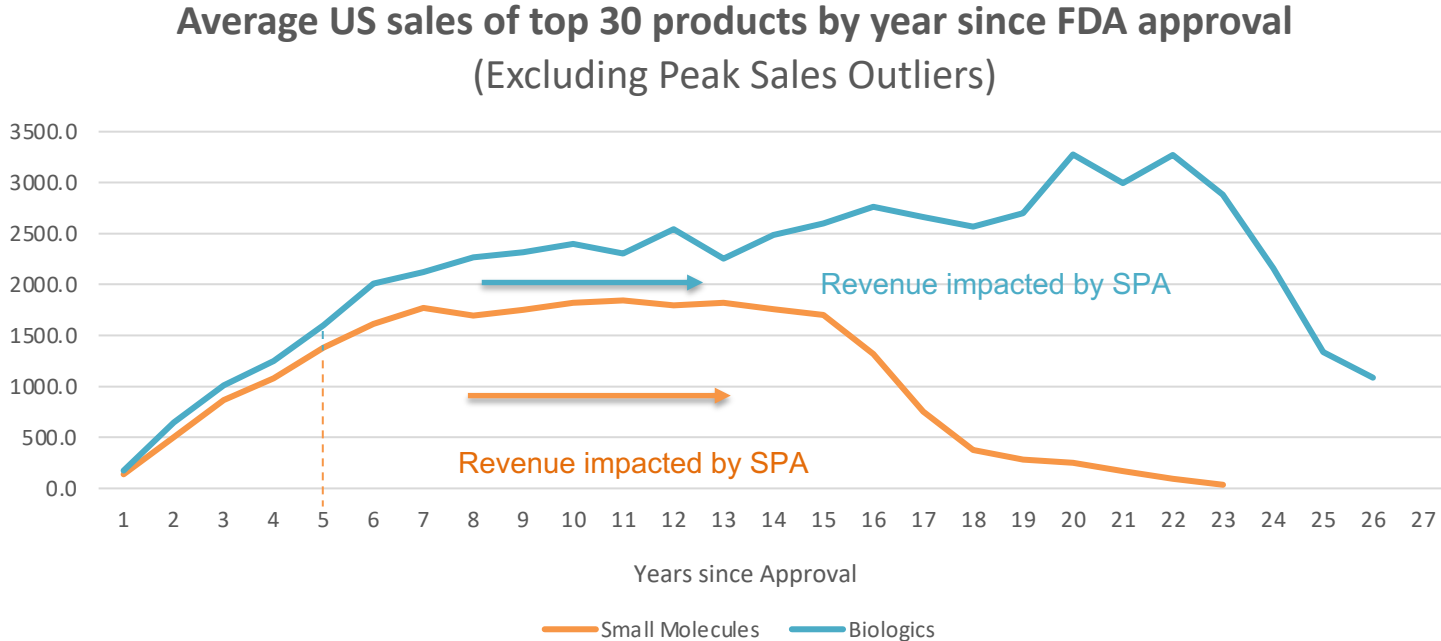
Arrows indicate where SPA will put revenues at risk for negotiation after years 5 years

Despite the rhetoric, the biopharmaceutical sector is not overly profitable
Biotechnology is excluded as it is ranked 92nd

Vital Transformation

Net Profit Margin of Top 25 Sectors, Jan 2023 Data

Banks (Regional) 30%, Railroads 28%, Bank (Money Center) 27%, Financials (Non-bank) 26%, Oil/Gas 26%, Utility (Water) 25%, Asset Management 25%, R.E.I.T. 24%, Tobacco 23%, Semiconductor 23%, Semiconductor Equip 22%, Shipbuilding & Marine 22%, Software (Entertainment) 21%, Coal & Related Energy 20%, Drugs (Pharmaceutical) 18%, Green Renewables 18%, Computers/Peripherals 17%, Information Services 17%, Investment Banking 16%, Insurance (General) 15%, Oil/Gas (Integrated) 15%, Real Estate (Dev) 15%, Steel 15%, Software 15%, Beverage (Soft) 15%
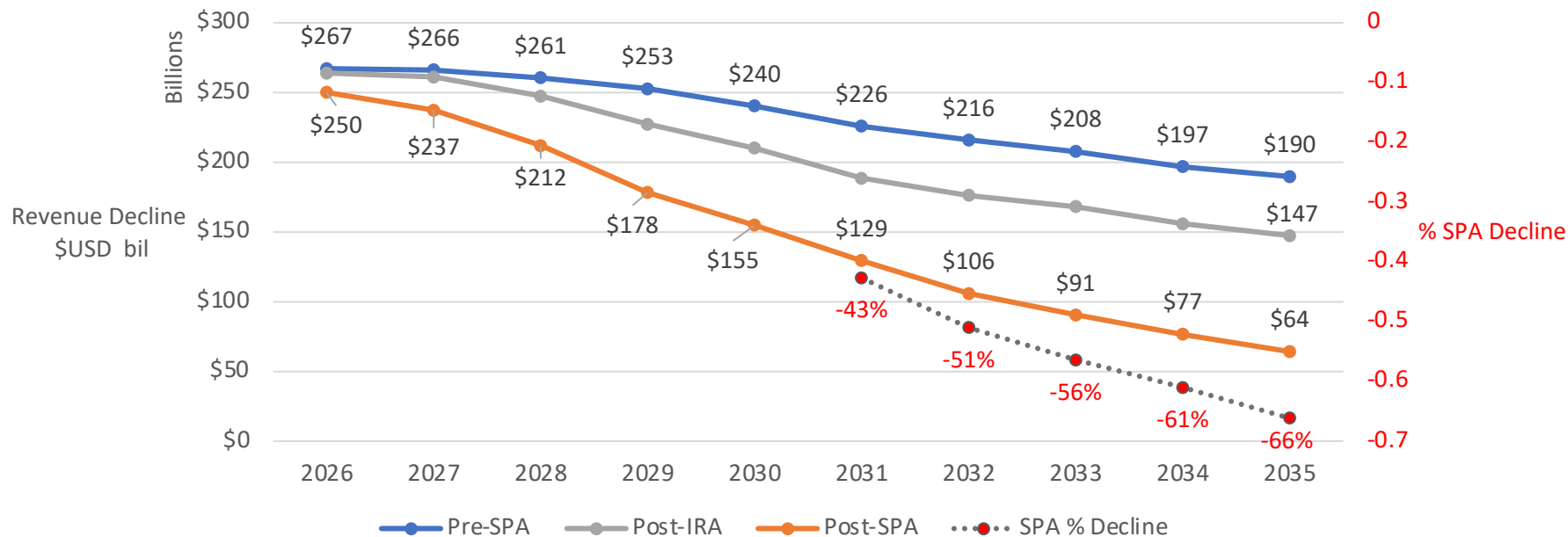
Source: https://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/margin.html

SPA has a substantial impact on biopharma sector revenues far beyond IRA
44 firms, 121 therapies*, 2023 constant dollars

SPA Impact on Revenues, 2026 - 2035

Billions

Revenue Decline $USD bil

% SPA Decline

Pre-SPA values: $267, $266, $261, $253, $240, $226, $216, $208, $197, $190

Post-IRA values: $250, $237, $212, $178, $155, $129, $106, $91, $77, $64 (grey line labels: $250, $237, $212, $178, $155... with lower labels $147)

Post-SPA values: $250, $237, $212, $178, $155, $129, $106, $91, $77, $64

SPA % Decline: -43%, -51%, -56%, -61%, -66%

Legend: Pre-SPA, Post-IRA, Post-SPA, SPA % Decline
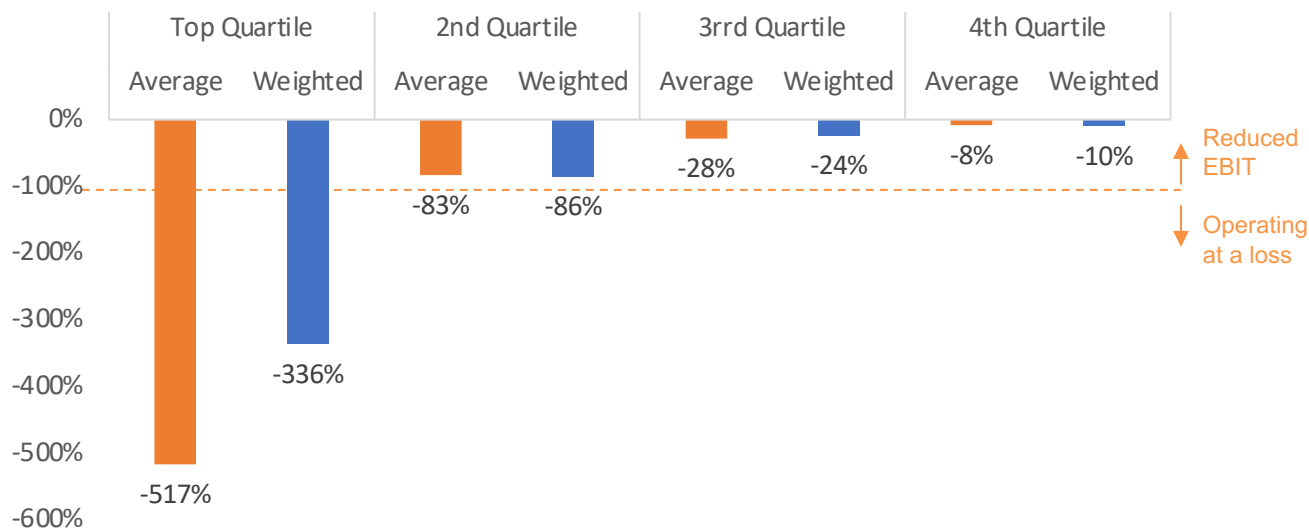
*IRA Impact is upon 92 therapies

© Vital Transformation, LLC 2023

SPA's impact on available cash for investments/pipelines 2026 - 2035

Impact of SPA on Firm EBIT by Quartile
2023 constant dollars

Top Quartile		2nd Quartile		3rrd Quartile		4th Quartile	
Average	Weighted	Average	Weighted	Average	Weighted	Average	Weighted

Chart values:
- Top Quartile Average: -517%
- Top Quartile Weighted: -336%
- 2nd Quartile Average: -83%
- 2nd Quartile Weighted: -86%
- 3rrd Quartile Average: -28%
- 3rrd Quartile Weighted: -24%
- 4th Quartile Average: -8%
- 4th Quartile Weighted: -10%

Reduced EBIT
Operating at a loss

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

- SPA reduces the ability of companies to reinvest their free cashflow into their pipelines as they lose on average 37% of their net earnings (EBIT).

- Had SPA been in place from 2018-2022, the 25% most impacted firms would have incurred annual earnings losses exceeding -500%.

- SPA primarily impacts the most successful and innovative therapies, which fund a majority of the R&D in the biopharma ecosystem.

- It's worth noting that even a 8% drop in EBIT will have substantial negative impacts at the firm level, requiring major cuts in personnel and operations.

R&D programs will be cut when revenues are reduced under SPA

Vital Health Podcast
John LaMattina, Defending Pharma & Profits

John LaMattina, Defending Pharma & Profits

View description | Share

Published Jan 25, 2023, 3:47 PM

00:00   59:14

"The pharmaceutical industry invests 25% of total sales into R&D. . . what is a company going to do with less revenues? When Lipitor went off patent . . we closed research sites around the globe. Fewer researchers, and fewer research programs. Is this really what we want to do?"
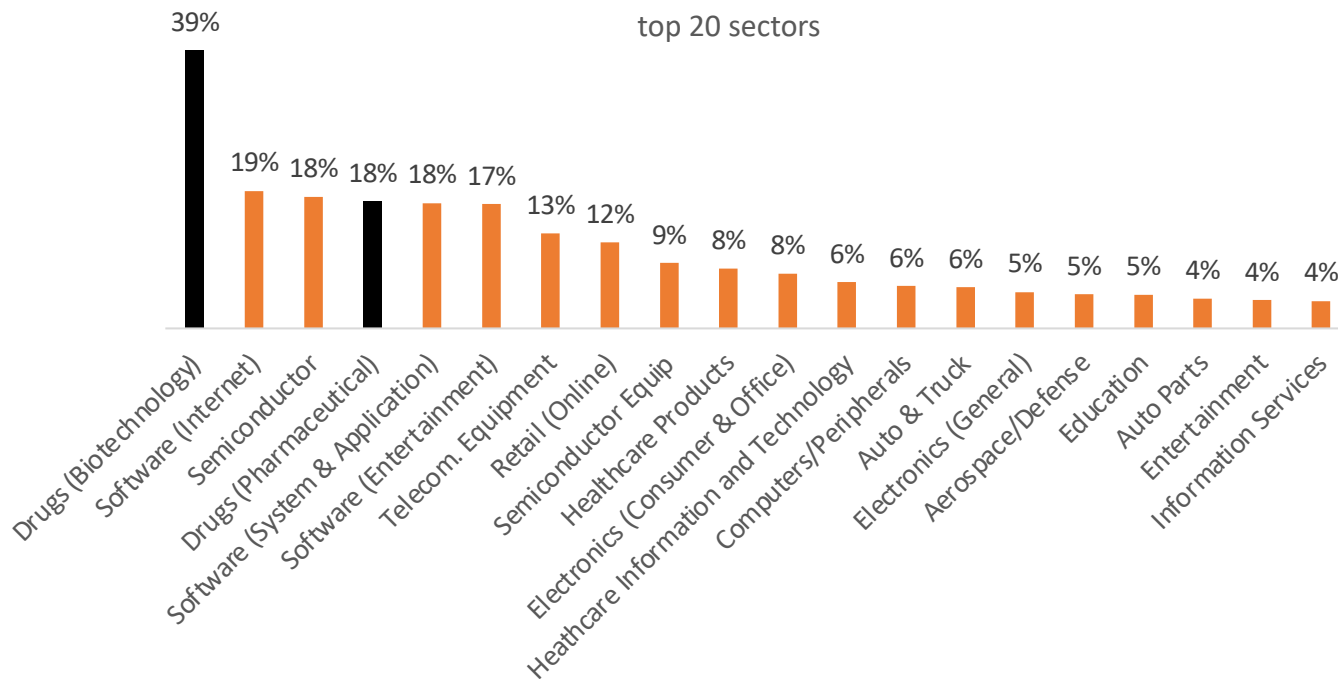
John LaMattina, former President of Pfizer Global Research and Development, Forbes contributor.

Biopharma allocated, on average, 28% of revenues toward R&D in 2022
Biotech allocated 39%, Pharma allocated 18%

R&D as a % of sales – Jan 2023
top 20 sectors

- The biopharma sector, on average, allocates 50% more of it's revenues to R&D than the next closest sector (Software and Internet companies).

- Given projected revenue reductions from SPA, we can model the subsequent impact on R&D spending assuming that 20%, 30%, or 40% of revenue is allocated to R&D.

- The impacts on R&D spending allows one to determine the impact of SPA on the drug development ecosystem.

Sources of the cost basis of our analysis

Research | Open Access | Published: 10 January 2019

Estimating the clinical cost of drug development for orphan versus non-orphan drugs

Kavisha Jayasundara ✉, Aidan Hollis, Murray Krahn, Muhammad Mamdani, Jeffrey S. Hoch & Paul Grootendorst

Orphanet Journal of Rare Diseases **14**, Article number: 12 (2019) | Cite this article

28k Accesses | **48** Citations | **51** Altmetric | Metrics

Journal of Health Economics
Volume 47, May 2016, Pages 20-33

Innovation in the pharmaceutical industry: New estimates of R&D costs ☆

Joseph A. DiMasi [a] ✉, Henry G. Grabowski [b], Ronald W. Hansen [c]

Show more ⌄

+ Add to Mendeley   ⤳ Share   ❞ Cite

https://doi.org/10.1016/j.jhealeco.2016.01.012   Get rights and content

Impact of SPA Revenue Reductions FDA Approvals

| Cost Impact (USD 2022)	Drugs Lost by R&D Revenue Allocation		
	20%	30%	40%
DIMasi ($2 bil)	-37	-55	-74
Jayasundara/Prasad ($1 bil)	-73	-110	-146
Average	**-55**	**-82**	**-110**

- Using the risk weighted cash cost estimates of DiMasi and Jayasundara/Prasad for developing a new therapy, we can calculate the impact of SPA on future FDA approvals on our cohort.

- On average, between 55 and 110 new therapies would not come to market; our revenue analysis indicates these lost therapies will be concentrated in a few firms that are highly impacted by SPA.

- The above estimates of therapies lost implies that, on average, there will be 82 fewer new FDA approved therapies over a 10 year period once SPA's impacts are felt at the firm level.

Number of price-controlled therapies retrospectively at risk, by firm

Had SPA been in place prior to initial investment decisions, 82 of the 121 price-controlled medicines in our cohort may not have been developed

SPA Drugs Loses Based on % Revenue Dedicated to R&D
Average DiMasi and Jayasundara/Prasad
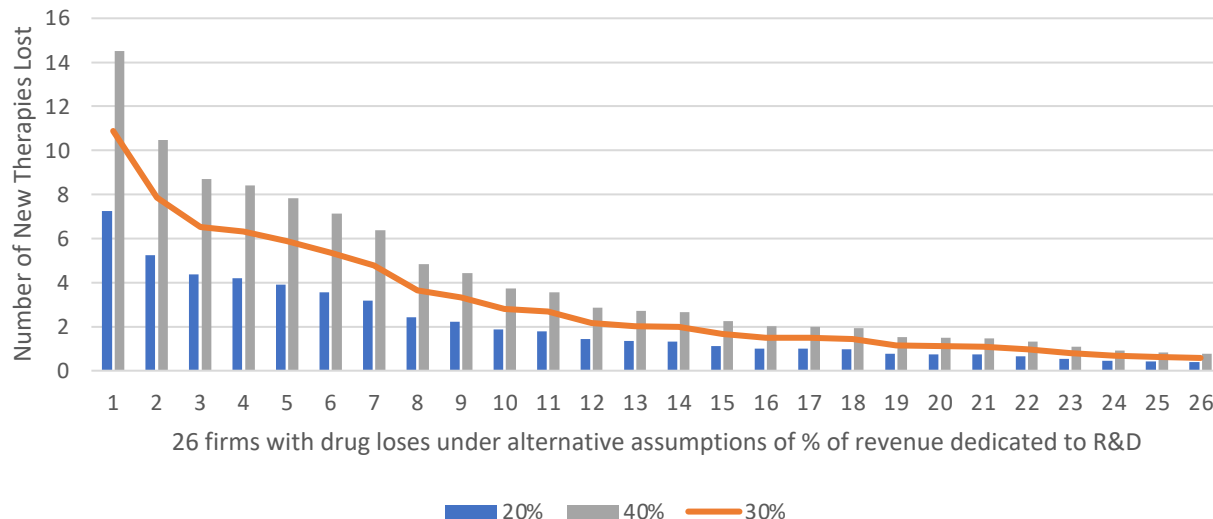
- The revenue reductions for 26 of 44 firms in our cohort imply a loss of 82 new FDA approved therapies.

- The 44 firms in our cohort have 121 FDA approved therapies that are price controlled by SPA; a loss of 82 of these developed therapies represents 68% of the total.

- Losses of more than one new approved medicine per firm on average are concentrated in 16 of the 44 companies in our cohort.

Price-controlled therapies retrospectively at risk, by type

Had SPA been in place prior to investment decisions, companies may have forgone development of 82 medicines in many areas of continued unmet need

Indication	Current		Post SPA		# Lost	
	Non-Orphan	Orphan	Non-Orphan	Orphan	Non-Orphan	Orphan
Oncology	21	22	7	7	14	15
Neurology	12	3	4	1	8	2
Endocrine	10	1	3	0	7	1
Infectious Disease	8	3	3	1	5	2
Autoimmune/immunology	7	5	2	2	5	3
Respiratory	5	1	2	0	3	1
Psychiatry	5		2	0	3	0
Cardiovascular	3	2	1	1	2	1
Allergy	2		1	0	1	0
Hematology	2	2	1	1	1	1
Ophthalmology	2	2	1	1	1	1
Gastroenterology	2		1	0	1	0
Metabolic		1	0	0	0	1
Sub Total	**79**	**42**	**25**	**14**	**54**	**28**
Total	**121**		**39**		**82**	

SPA's Potential Impact on Future Drug Discovery:

Once the impacts of price controls are fully reflected in the pipeline, SPA could see reductions of up to 237 new FDA approvals over a decade

Number of Novel New FDA Approvals Per Year	Rate of SPA Losses	10 Year Losses of New Therapies
35	67.8%	237

- The challenge with any analysis of SPA is that we can only calculate its impacts upon a fixed CMS dataset at one point in time (2022).

- However, the FDA approves, on average, 35 novel new therapies per year.

- As new therapies will enter the CMS cohort each year, if we assume the current impact rates remain constant, all things being equal, we could see declines of up to 237 approvals over the next 10 years.

SPA's impact on investments in US start-ups by state

SPA's impact on Future Pipeline Investments
2023, constant dollars

SPA EBIT Impact on 26* firms with highest development losses
$US Mil
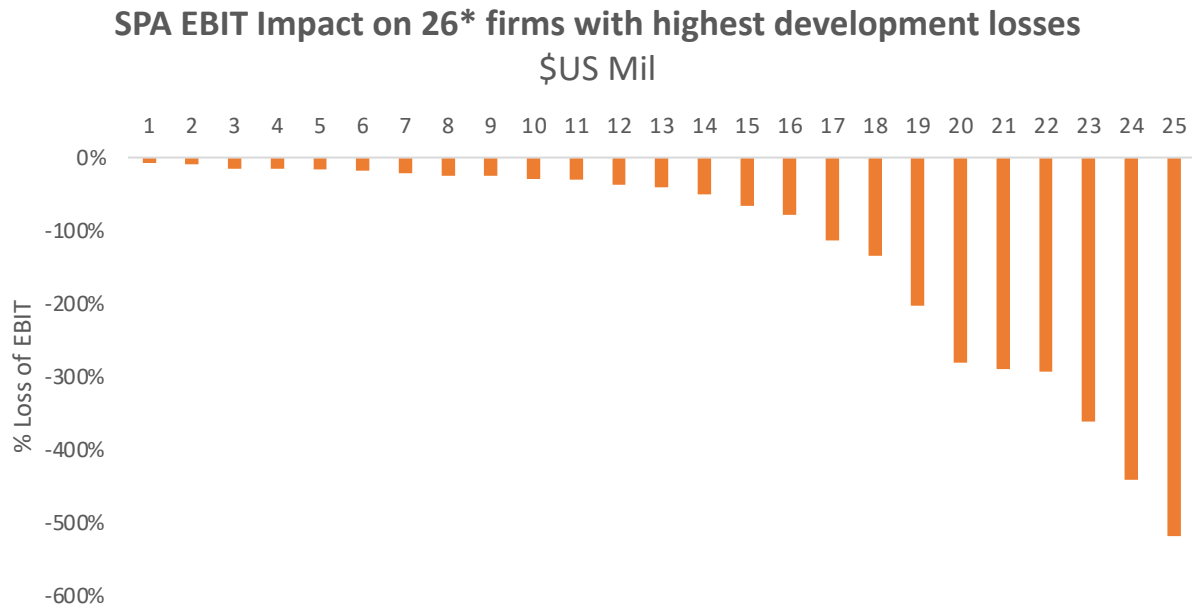
- The 26 firms which we project to be most likely to lose new approved therapies due to SPA see an average weighted annual loss of free cash flow (EBIT) by 39%.

- We now investigate the firm's investing behavior over the previous 10 years to see how their partnering activities would have been reduced if the SPA had been in place.

*One firm removed from chart as a significant outlier

State investments by 26 SPA impacted firms with the most projected lost therapies
4/1/2014 - 3/31/2023

State	Deals	Total Value	State	Deals	Total Value
California	85	$61,222,599,996	Virginia	1	$500,000,000
Massachusetts	84	$48,782,800,000	Wisconsin	2	$456,500,000
New York	15	$18,193,999,990	Pennsylvania	5	$445,000,000
Maryland	8	$2,968,500,000	Arizona	1	$345,000,000
New Jersey	8	$2,857,991,211	Texas	4	$294,500,000
Washington	5	$2,744,000,000	Florida	3	$275,000,000
Connecticut	3	$2,117,498,451	Delaware	1	$245,000,000
North Carolina	2	$1,888,000,000	Indiana	1	$225,000,000
Wisconsin	3	$1,556,500,000	Iowa	1	$20,000,000
New Hampshire	2	$1,065,000,000	Nevada	1	$19,500,000
			Total Deals		235
			Value of Deals		$146,222,389,648
			Avg Per Deal		$622,222,935

- Our 26 firm cohort invested $146 billion into 235 deals identifiable by indication, for an average of $622 million per deal.

- SPA reduces this available capital by 39%, which will impact a firm's deal selection.

Projected lost investments by 26 SPA impacted firms with a 39% reduction in EBIT in CA

4/1/2014 - 3/31/2023

California Lost Investments 4/1/2014 - 3/31/2023			
Indication	**Investments by Indication**	**Indication**	**Loses by Indication**
Solid Tumors	$11,995,766,667	Gastroenteritis	$800,000,000
Cancer	$5,402,000,000	Multiple Sclerosis (MS)	$765,000,000
Hemophilia	$3,560,000,000	Alpha-1 Antitrypsin Deficiency (A1AD or AATD)	$740,000,000
Hepatitis B (HBV)	$3,535,000,000	Influenza (excluding vaccines)	$695,000,000
Inflammatory Disorders	$3,460,000,000	Dry Age-Related Macular Degeneration (Dry AMD)	$630,000,000
Amyloidosis	$3,385,000,000	NSCLC	$603,666,667
Crohn's Disease	$3,330,000,000	Diabetic Retinopathy	$586,500,000
Alzheimer's Disease (AD)	$2,507,500,000	Anemia Due to Chronic Kidney Disease	$492,000,000
Indication	**Loses by Indication**	Melanoma	$380,499,996
Undisclosed	$2,500,000,000	Venous Thromboembolism (VTE)	$350,000,000
DLBCL	$2,392,500,000	Contraception	$310,000,000
Multiple Myeloma (MM)	$2,121,000,000	Systemic Lupus Erythematosus (SLE)	$250,000,000
Non-Alcoholic Steatohepatitis (NASH)	$1,945,000,000	Thyroid Cancer	$228,000,000
Pancreatic Cancer	$1,867,500,000	Colorectal Cancer (CRC)	$166,666,667
Ulcerative Colitis (UC)	$1,390,000,000	Hypertrophic Cardiomyopathy (HCM)	$100,000,000
Chronic Myelogenous Leukemia (CML)	$1,205,000,000	Chronic Heart Failure	$100,000,000
Rheumatoid Arthritis (RA)	$1,170,000,000	Erectile Dysfunction (ED)	$61,000,000
Amyotrophic Lateral Sclerosis (ALS)	$1,095,000,000	Hypercholesterolemia	$55,000,000
Autoimmune Disorders	$1,025,000,000	Congenital Adrenal Hyperplasia (CAH)	$23,000,000
		SPA EBIT Impact - 39% loss of investments	**-$23,876,813,998**

We base our selection of indications by cumulative investment size as a proxy for demand

Projected lost investments by 26 SPA impacted firms with a 39% reduction in EBIT in MA
4/1/2014 - 3/31/2023

Massachusetts Lost Investments 4/1/2014 - 3/31/2023			
Indication	**Investments by Indication**	**Indication**	**Loses by Indication**
Cancer	$6,790,000,000	Non-Alcoholic Steatohepatitis (NASH)	$824,000,000
Parkinson's Disease (PD)	$6,705,000,000	Undisclosed	$684,000,000
Solid Tumors	$5,448,000,000	Hematologic Cancer	$608,000,000
Muscular Dystrophy	$5,190,000,000	Pruritus	$600,000,000
Hypercholesterolemia	$2,737,500,000	Urinary Tract Infections	$525,000,000
Cystic Fibrosis (CF)	$2,357,500,000	GVHD	$450,000,000
Indication	**Loses by Indication**	Diabetes Mellitus, Type I	$410,000,000
Asthma	$2,100,000,000	Metabolic - General	$357,500,000
Psoriasis	$2,000,000,000	Inflammatory Disorders	$270,000,000
Autoimmune Disorders	$2,000,000,000	Hereditary Angioedema (HAE)	$195,500,000
Sickle Cell Anemia	$1,977,500,000	Crohn's Disease	$100,000,000
Infectious Disease	$1,940,000,000	Non-Hodgkin's Lymphoma (NHL)	$47,000,000
Cardiovascular Diseases	$1,757,500,000	Pulmonary Fibrosis	$25,000,000
Pain Indications	$950,000,000	Influenza (excluding vaccines)	$25,000,000
Epstein Barr Virus (EBV)	$872,500,000	Chronic Pain	$10,000,000
Amyloidosis	$825,000,000	Metachromatic Leukodystrophy	$1,300,000
		SPA EBIT Impact - 39% loss of investments	**-$19,025,292,000**

We base our selection of indications by cumulative investment size as a proxy for demand

NY, MD Lost Investments 4/1/2014 - 3/31/2023					
State	Indication	Investments by Indication	State	Indication	Loses by Indication
NY	Psoriasis	$13,400,000,000	MD	Wet AMD	$1,380,000,000
			NY	Solid Tumors	$1,350,000,000
			NY	Renal Cell Cancer (RCC)	$1,350,000,000
			MD	Colorectal Cancer (CRC)	$750,000,000
			MD	Solid Tumors	$665,000,000
			NY	Seizure Disorders (Epilepsy)	$660,000,000
			NY	Melanoma	$625,000,000
			NY	Prostate Cancer	$179,000,000
			NY	Retinitis Pigmentosa (RP)	$170,000,000
			NY	Color Blindness	$170,000,000
			NY	Undisclosed	$170,000,000
			MD	Gout	$153,500,000
			NY	Myopia	$80,000,000
			NY	DLBCL	$39,999,990
			MD	Major Depressive Disorder (MDD)	$20,000,000
			SPA EBIT Impact - 39% loss of investments		-$8,253,374,996

We base our selection of indications by cumulative investment size as a proxy for demand

AZ, CT, DE, IA, IL, IN, NC, NH, NJ, NV, PA, TN, TX, VA, WA, WI Lost Investments 4/1/2014 - 3/31/2023

State	Indication	Investments by Indication	State	Indication	Loses by Indication
NJ	Multiple Myeloma (MM)	$1,350,000,000	VA	Inflammatory Disorders	$500,000,000
WA	Breast Cancer	$1,125,000,000	NJ	Solid Tumors	$480,000,000
WI	Undisclosed	$1,100,000,000	WI	Cancer	$456,500,000
NC	Cystic Fibrosis (CF)	$1,090,000,000	IL	Celiac Disease	$420,000,000
CT	Solid Tumors	$917,500,000	WA	Neuropathic Pain	$359,000,000
NC	Antibacterial	$798,000,000	AZ	Breast Cancer	$345,000,000
WA	Systemic Lupus Erythematosus (SLE)	$730,000,000	TX	Myelofibrosis (MF)	$294,500,000
CT	Multiple Myeloma (MM)	$624,998,451	NJ	Obesity	$250,000,000
TX	Atopic Dermatitis (Eczema)	$600,000,000	DE	Desmoid Tumors	$245,000,000
NJ	Fungal Infections - Systemic	$593,000,000	IN	Sarcoma - Imaging	$225,000,000
CT	Breast Cancer	$575,000,000	PA	Retinal Dystrophy	$170,000,000
State	**Indication**	**Loses by Indication**	NJ	Celiac Disease	$150,000,000
NH	Autoimmune Disorders	$565,000,000	NJ	Diabetes Mellitus, Type I	$34,991,211
WA	Cancer	$530,000,000	IA	Ebola	$20,000,000
TN	Neurology - Other	$515,000,000	NV	Melanoma	$19,500,000
NH	Multiple Sclerosis (MS)	$500,000,000	**SPA EBIT Impact - 39% loss of investments**		**-$6,077,365,968**

We base our selection of indications by cumulative investment size as a proxy for demand

SPA's impact on patients with unmet medical needs

US disease prevalence of therapies in our cohort projected to see the largest investment reductions

Analysis of investing activity before SPA implementation, if 39 % of free cash flow was lost by firms impacted by R&D pipeline losses:
4/1/2014 - 3/31/2023

Indications Lost	Prevalence	Indications Lost	Prevalence	Indications Lost	Prevalence
Epstein Barr Virus (EBV)	297,000,000	Neuropathic Pain	3,300,000	Retinal Dystrophy	184,048
Obesity	138,600,000	Desmoid Tumors	3,000,000	Multiple Myeloma (MM)	144,922
Chronic Pain	50,200,000	Celiac Disease	2,481,203	DLBCL	143,000
Autoimmune Disorders	50,000,000	Diabetes Mellitus, Type I	2,100,000	Antitrypsin Deficiency (A1AD or AATD)	100,000
Pruritus	44,550,000	Crohn's Disease	1,950,000	Pulmonary Fibrosis	100,000
NASH	39,600,000	Hematologic Cancer	1,650,000	Sickle Cell Anemia	100,000
Chronic Kidney Disease	37,000,000	Colorectal Cancer (CRC)	1,369,005	Pancreatic Cancer	89,248
Rheumatoid Arthritis (RA)	32,500,000	Melanoma	1,361,282	Non-Hodgkin's Lymphoma (NHL)	80,550
Hypercholesterolemia	28,000,000	Ulcerative Colitis (UC)	1,050,000	Leukemia (CML)	62,895
Asthma	26,000,000	Multiple Sclerosis (MS)	1,000,000	ALS	24,821
Dry AMD	18,340,000	Sarcoma	970,588	Myelofibrosis (MF)	16,500
Solid Tumors	18,200,000	Thyroid Cancer	915,664	GVHD	14,000
Erectile Dysfunction (ED)	15,000,000	Venous Thromboembolism (VTE)	900,000	Hereditary Angioedema (HAE)	6,000
Psoriasis	7,500,000	Hypertrophic Cardiomyopathy (HCM)	600,000	Amyloidosis	3,300
Chronic Heart Failure (Chronic HFrEF)	5,280,000	NSCLC	576,924	Congenital Adrenal Hyperplasia (CAH)	2,200
Diabetic Retinopathy	4,000,000	Systemic Lupus Erythematosus (SLE)	345,000	Ebola	11
Breast Cancer	3,771,794	Metachromatic Leukodystrophy	330,000		

SPA's impact on Jobs

SPA Direct and Total Supported Annual Job Losses by Avg Cohort Impact

Total US and Puerto Rico by State/District/Region

	Jobs Impact SPA: 2026 - 2035 $82 Billion Average Annual Revenue Reductions (Cohort)						
State	**Direct Biopharma Jobs Impact**	**Total Biopharma Supported Jobs Impact**	**Biopharma Supported Output Impact ($M)**	**State (Cont)**	**Direct Biopharma Jobs Impact (Cont)**	**Total Biopharma Supported Jobs Impact (Cont)**	**Biopharma Supported Output Impact ($M)**
Totals, U.S. & Puerto Rico	**-146,791**	**-730,916**	**($208,021)**				
California	-25,272	-137,492	($41,697)	South Carolina	-930	-4467	($1,234)
New Jersey	-10,987	-55,241	($15,100)	Maine	-822	-4186	($934)
Massachusetts	-10,991	-51,459	($12,830)	West Virginia	-848	-4110	($1,363)
Pennsylvania	-8,475	-45,943	($12,180)	Iowa	-1012	-3948	($1,067)
North Carolina	-8,138	-45,432	($13,475)	Kentucky	-956	-3476	($795)
Illinois	-7,377	-44,653	($13,209)	Oregon	-757	-3132	($697)
New York	-9,982	-41,771	($12,144)	Delaware	-898	-3108	($691)
Texas	-6,883	-35,515	($9,736)	Nebraska	-564	-2648	($751)
Indiana	-4,462	-25,326	($10,066)	Alabama	-634	-2604	($731)
Florida	-4,661	-23,689	($5,253)	Rhode Island	-349	-2399	($661)
Maryland	-5,528	-23,487	($6,119)	New Mexico	-647	-2260	($473)
Ohio	-3,781	-16,434	($3,993)	New Hampshire	-435	-2032	($490)
Michigan	-2,892	-15,651	($4,123)	Oklahoma	-501	-1970	($463)
Puerto Rico	-3,239	-14,116	($10,431)	Nevada	-388	-1788	($433)
Utah	-2,231	-13,251	($3,134)	Louisiana	-497	-1687	($382)
Missouri	-2,220	-11,954	($2,921)	Mississippi	-326	-1449	($410)
Washington	-2,786	-10,318	($2,441)	Vermont	-209	-849	($204)
Georgia	-2,101	-10,312	($2,416)	Idaho	-170	-699	($164)
Wisconsin	-1,978	-9,324	($2,178)	Arkansas	-149	-692	($184)
Tennessee	-2,198	-8,403	($1,891)	Montana	-153	-510	($104)
Colorado	-1,560	-8,276	($2,030)	Hawaii	-163	-468	($87)
Arizona	-1,522	-7,516	($1,655)	DC	-116	-269	($79)
Virginia	-1,756	-7,350	($1,792)	Wyoming	-55	-198	($71)
Minnesota	-1,375	-7,259	($1,771)	South Dakota	-58	-179	($32)
Connecticut	-1,622	-6,412	($1,631)	North Dakota	-51	-147	($38)
Kansas	-1,051	-4,993	($1,252)	Alaska	-29	-65	($13)

Source: TEConomy analysis; IMPLAN U.S. 2017 Model, VT adjusted for average annual reduction of SPA cohort revenue, 2023 constant dollars.

SPA Direct and Total Supported Annual Job Losses by Peak Year Sales Impact
Total US and Puerto Rico by State/District/Region

Jobs Impact SPA: 2026 - 2035 $126 Billion Avg Annual Revenue Reductions (Projection from Peak Sales Impact)						
State	Direct Biopharma Jobs Impact	Total Biopharma Supported Jobs Impact	Biopharma Supported Output Impact ($M)	State (Cont)	Direct Biopharma Jobs Impact (Cont)	Total Biopharma Supported Jobs Impact (Cont)	Biopharma Supported Output Impact ($M)
Totals, U.S. & Puerto Rico	-223,687	-1,113,805	($316,993)				
California	-38,510	-209,517	($63,540)	South Carolina	-1417	-6807	($1,881)
New Jersey	-16,743	-84,180	($23,010)	Maine	-1253	-6380	($1,423)
Massachusetts	-16,749	-78,416	($19,551)	West Virginia	-1292	-6263	($2,077)
Pennsylvania	-12,914	-70,010	($18,561)	Iowa	-1542	-6016	($1,625)
North Carolina	-12,401	-69,232	($20,534)	Kentucky	-1457	-5297	($1,211)
Illinois	-11,241	-68,045	($20,130)	Oregon	-1154	-4773	($1,063)
New York	-15,212	-63,653	($18,505)	Delaware	-1368	-4736	($1,054)
Texas	-10,490	-54,120	($14,835)	Nebraska	-860	-4035	($1,145)
Indiana	-6,800	-38,592	($15,339)	Alabama	-967	-3968	($1,114)
Florida	-7,103	-36,098	($8,004)	Rhode Island	-532	-3655	($1,008)
Maryland	-8,424	-35,791	($9,323)	New Mexico	-986	-3442	($721)
Ohio	-5,762	-25,044	($6,085)	New Hampshire	-663	-3096	($747)
Michigan	-4,407	-23,849	($6,283)	Oklahoma	-764	-3003	($705)
Puerto Rico	-4,937	-21,510	($15,896)	Nevada	-592	-2725	($660)
Utah	-3,401	-20,193	($4,775)	Louisiana	-759	-2571	($582)
Missouri	-3,383	-18,216	($4,451)	Mississippi	-496	-2208	($624)
Washington	-4,247	-15,723	($3,721)	Vermont	-319	-1293	($311)
Georgia	-3,202	-15,714	($3,680)	Idaho	-259	-1066	($251)
Wisconsin	-3,014	-14,207	($3,320)	Arkansas	-227	-1055	($280)
Tennessee	-3,348	-12,805	($2,882)	Montana	-233	-777	($158)
Colorado	-2,377	-12,611	($3,094)	Hawaii	-249	-714	($133)
Arizona	-2,318	-11,454	($2,520)	DC	-175	-409	($121)
Virginia	-2,677	-11,200	($2,731)	Wyoming	-84	-301	($109)
Minnesota	-2,095	-11,061	($2,700)	South Dakota	-89	-272	($49)
Connecticut	-2,472	-9,771	($2,485)	North Dakota	-78	-225	($57)
Kansas	-1,600	-7,609	($1,908)	Alaska	-44	-99	($21)

Source: TEConomy analysis; IMPLAN U.S. 2017 Model, VT adjusted for projected reductions in peak sales, 2023 constant dollars.

Conclusions

Implications of SPA

Conlusions and Implications of SPA

- SPA reduces net earnings for a 44 company cohort by 37%, but these impacts are highly concentrated in a few firms representing a substantial loss of their free cashflow for pipeline investments.

- As measured by EBIT (annual net earning):
  - The SPA induced revenue reductions exceed 500% of the annual earnings for a quarter of the 44 companies in our cohort.
  - The SPA penalizes the most innovative, successful therapies which fund an outsized amount innovation in the U.S. biopharma ecosystem.
  - The SPA penalizes successful biopharma companies.

- At the firm level, the revenue reductions caused by the SPA imply a 68% reduction in future FDA approvals within our cohort.

- Impact are most concentrated in a few firms. For each of the most impacted companies, between 8 and 14 of the medicines selected for price setting would likely not have been developed if SPA had been in place prior to those investment decisions.

- SPA will reduce investments into 50 different indications; these indications range from micro orphan conditions such as Ebola, to large anti-infective therapies targeting Epstein Barr virus and chronic pain (300 million and 50 million disease prevalence respectively).

- We model losses of between 146,000 – 223,000 direct biopharmaceutical industry jobs and 730,000 – 1,100,000 total jobs across the U.S. economy.

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 SPA, on the biopharmaceutical innovation ecosystem.

- We investigated SPA's impacts on investments and small company capital formation.

- Our focus was new drug pipeline developments in small molecule and biological products, as well as the SPA's impact on the U.S. biopharma ecosystem writ large.

- 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 We Work for Health.

- The opinions included in this work are those of Vital Transformation LLC, and not necessarily those of the project's sponsors.

- The raw data behind this study is being held in preparation for peer review; questions are taken about the data on request.