VitalTransformation

The impact of health technology made simple

Medicare Part B and D International Reference Pricing

What Will be the Impact on Patients, Outcomes, and Innovation

October 23, 2019

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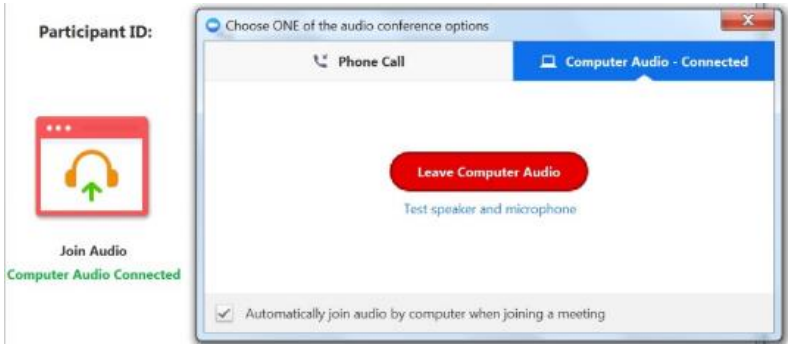

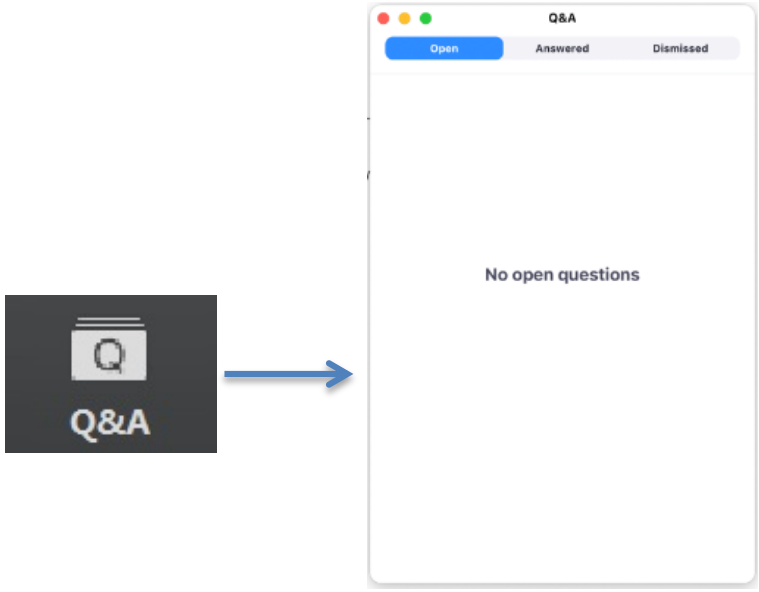

The final 30 min of the webinar will be for audience Q&A, please use the question bar in the control panel

Part B Reference Pricing? HHS says the following...

- Medicare Part B drug cost is 1.8 times higher when compared to an international average of countries
- Medicare Part B drugs will be reimbursed based on their average cost in a basket of other countries, plus a mark-up (i.e. 1.26 times the average basket price in the initial HHS case study)
- Would initially focus on Part B drugs that encompass a high percentage of utilization and spending
- HHS will test this model under section 1115A of the Social Security Act – i.e. does not require congressional approval
- The model would operate for five years, from Spring 2020 to Spring 2025, starting in 50% of the Medicare Part B market
- Model will only impact R&D by 1%
- "The pharmaceutical industry will be pressured to fairly allocate the burden of funding innovation across wealthy countries" (i.e. raise prices in Europe, Japan)

What Countries Were Benchmarked?

"The HHS analysis compared United States drug acquisition costs for a set of Medicare Part B physician-administered drugs to acquisition costs in 16other developed economies Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and the United Kingdom(UK)."

The Situation in Europe – Raising Prices in Europe?

PHARMALOT

STAT+

U.K. lawmaker challenges the government to issue a compulsory license for Vertex drug

By ED SILVERMAN @Pharmalot / FEBRUARY 1, 2019

pharmaphorum™
bringing healthcare together

Fury as NHS rejects cystic fibrosis drug price offer

July 5, 2018

HOSPITAL EXEMPTION FOR ATMPS: PERSPECTIVES & REGULATORY TRENDS UNDER DISCUSSION

ATMP, Regulatory Affairs

IPI By The Numbers - Methodology

- We used HHS' own IPI model to calculate the balance sheet impact of companies with products under Medicare Part B's revised pricing
- We take all financial corporate data from FY 2017
- Financials are taken from audited corporate annual reports and Medtrack by Informa
- Our analysis is limited to those medications where the price is above the calculated IPI 1.26 (126%) threshold (i.e. 20 products)
- Assumes impact is limited to the Medicare Part B Market, does not impact the commercial market

But… What About the Non - Medicare Part B Market?

- Medicare Part B is less than half of product revenue
- HHS assumes these price ceilings will be contained to Medicare Part B
- The insurers, public and PBMs will certainly know the lower price

IPI By The Numbers

Impact on Total Product Sales – 100% Target Price

$USD Millions

Company	Number of Therapies	Total 2017 US Sales IPI Impacted Products	Total New Revenue (Multiple 1.26)	Total Change in Revenue ($US Mil)	Current R&D Budget ($US Mil)	Potential R&D Impact	20% R&D Impact
Company A	3	6,308	2,498	-3,810	3,737	-102%	-20%
Company B	6	13,426	7,063	-6,362	10,529	-60%	-12%
Company D	1	918	386	-532	1,057	-50%	-10%
Company C	1	642	117	-525	1,213	-43%	-9%
Company G	1	1,114	484	-630	2,250	-28%	-6%
Company F	3	5,714	4,488	-1,226	4,894	-25%	-5%
Company E	1	4,080	3,024	-1,056	5,200	-20%	-4%
Company H	1	1,034	651	-383	5,357	-7%	-1%
Company I	1	832	388	-444	8,510	-5%	-1%
Company J	1	726	704	-22	10,329	0%	0%
Company K	1	10	7	-3	5,894	0%	0%
TOTAL	**20**	**34,804**	**19,811**	**-14,993**	**58,970**	**-25.4%**	**-5%**

Methodology: Ways And Means Study

"Using External Reference Pricing In Medicare Part D To Reduce Drug Price Differentials With Other Countries"

So-Yeon Kang et al, : 10.1377/hlthaff.2018.05207 HEALTH AFFAIRS 38, NO. 5 (2019): 804–811 ©2019 Project HOPE— The People-to-People Health Foundation, Inc

- Study compared the price differentials in the US and the UK, Japan, and Ontario (Canada) for 79 single-source brand-name drugs that had been on the market for at least three years, and consumed 70% of Part D spending.
- US prices averaged 3.2–4.1 times higher after rebates were considered. The price differential for individual drugs varied from 1.3 to 70.1.
- The estimated cost reduction to Medicare Part D of adopting the average price of drugs in the reference countries was $72.9 billion in 2018.

Study Summary Overview

Medicare Part D International Reference Pricing

- 2017 Medicare total drug spend and per dose pricing taken directly from Medicare Part D Spending Dashboard
- Corporate product revenue taken from 2017 audited annual reports, and cross referenced with Medtack “Pharma Intelligence” and US Government Bureau of Labor Statistics.
- Reference pricing for 79 assets (69 in this analysis after the removal of diagnostics and consolidation of insulin platforms) taken directly from House Ways and Means study, “Using External Reference Pricing In Medicare Part D To Reduce Drug Price Differentials With Other Countries”, So-Yeon Kang et al, 2019
- Reference pricing 1.2x ‘margin’ taken from “H.R. 3 - Drug Price Negotiation Bill Summary” and applied directly to House Ways and Means reference pricing
- Our modeling predicts an annual reduction in revenue for the impacted firms of $71.6 bil (five year impact of $358 bil), compared to CBO analysis of $334 over 5 years. Our financial impact is for the entire market, and is likely underestimated as we look at only the 79 assets in the Ways and Means study, not the 125 drugs included in the CBO analysis. However, given the results, we feel the impact will be clear to all readers.
- We do not agree with the CBO's assessment of market reduction of 8-15 drugs over 10 years as they do not fully analyze and depict anticipated investment behavior under H.R. 3. The data in our study shows a much greater impact: the number of new medicines developed by California-based companies supported by revenue generated by Medicare Part D products would fall from 25 to 3 over the next 10 years, an 88% reduction.

Part D – Reference Price H.R. 3 Impact with Commercial Market

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Company	Number of Drugs	Reference Discount	US Total Sales 2017	Revised Total Sales	Revised Total Sales H.R. 3 1.2 Margin	Change In Revenue	Total R&D Spend 2017	Reduction as a % of R&D	Reduction as 20% R&D ratio
Company R	2	73%	$14,505	$3,965	$4,758	-$9,747	$5,007	-195%	-39%
Company D	5	77%	$8,719	$2,016	$2,419	-$6,300	$3,925	-161%	-32%
Company F	3	83%	$6,479	$1,129	$1,355	-$5,124	$2,254	-227%	-45%
Company H	2	73%	$6,580	$1,801	$2,161	-$4,419	$3,562	-124%	-25%
Company G	6	57%	$9,032	$3,883	$4,659	-$4,373	$3,734	-117%	-23%
Company Q	6	69%	$6,563	$2,025	$2,429	-$4,134	$9,143	-45%	-9%
Company E	2	70%	$6,434	$1,942	$2,331	-$4,103	$3,274	-125%	-25%
Company L	5	78%	$5,518	$1,200	$1,440	-$4,078	$5,357	-76%	-15%
Company I	4	73%	$6,023	$1,654	$1,985	-$4,038	$4,894	-83%	-17%
Company C	4	83%	$4,711	$779	$935	-$3,776	$3,078	-123%	-25%
Company S	3	74%	$4,879	$1,254	$1,505	-$3,374	$7,645	-44%	-9%
Company M	4	84%	$3,790	$590	$708	-$3,082	$9,818	-31%	-6%
Company P	3	56%	$5,655	$2,506	$3,008	-$2,647	$14,014	-19%	-4%
Company K	2	79%	$3,400	$708	$850	-$2,550	$4,482	-57%	-11%
Company U	3	76%	$3,448	$844	$1,012	-$2,436	$8,510	-29%	-6%
Company J	4	57%	$4,834	$2,057	$2,468	-$2,366	$5,472	-43%	-9%
Company N	1	65%	$1,331	$470	$564	-$768	$1,957	-39%	-8%
Company A	1	71%	$1,133	$329	$394	-$739	$260	-284%	-57%
Company W	1	71%	$1,120	$327	$392	-$728	$2,108	-35%	-7%
Company X	2	78%	$829	$186	$223	-$606	$5,455	-11%	-2%
Company T	2	85%	$733	$109	$130	-$602	$2,930	-21%	-4%
Company O	1	71%	$826	$239	$287	-$538	$1,161	-46%	-9%
Company Y	1	74%	$662	$171	$205	-$457	$10,529	-4%	-1%
Company B	1	71%	$666	$193	$232	-$434	$361	-120%	-24%
Company V	1	71%	$377	$109	$131	-$246	$1,991	-12%	-2%
TOTAL	**69**	**72%**	**$108,246**	**$30,484**	**$36,581**	**-$71,665**	**$120,920**	**-59%**	**-12%**

Industry Impact % of Total Annual Earnings (EBIT), 2017 Base

Company	2017 Total Annual EBIT ($Mil Base)
Company Q	17,673
Company G	13,529
Company S	12,304
Company Y	12,287
Company H	9,597
Company R	9,314
Company U	8,999
Company P	7,194
Company M	6,521
Company J	6,201
Company I	5,131
Company F	5,129
Company D	4,453
Company E	4,314
Company N	2,602
Company K	2,559
Company W	2,352
Company L	2,197
Company X	2,186
Company T	1,324
Company O	1,091
Company C	-246
Company A	-312
Company B	-1,741
Company V	-10,386
Total	**$ 124,272**

	Revenue Impact	% Reduction
Medicare D Reduction Ways and Means	-41,546	33%
Part D H.R. 3 1.2 Multiple	-38,141	31%
Part D H.R. 3 1.2 Full Market	-71,665	58%

Under H.R. 3, the model anticipates a -$71.6 Bil revenue impact, or a 58% reduction in Total Annual Earnings under the House Ways and Means International Reference Pricing methodology

H.R. 3 International Reference Pricing – Impact on CA Biopharma Investment

Methodology

- From October 2009 – 2019, firms potentially impacted by Medicare Part D Reference Pricing invested a total $621 billion into Biopharma partnerships, licensing agreements, and acquisitions in the U.S.
- This funding was taken primarily from free cash flow from operations.
- From October 2009 – 2019, 85 California Biopharma firms received $178 bil of the $621 bil invested in the U.S., nearly 30% of the total invested
- Of the 85 firms receiving investment above, 25 received marketing authorization for a new product
- With this data, we ran several statistical tests modeling the potential impact for both market access for new medicines and investor behavior/willingness to invest with reductions in revenue due to reference pricing.

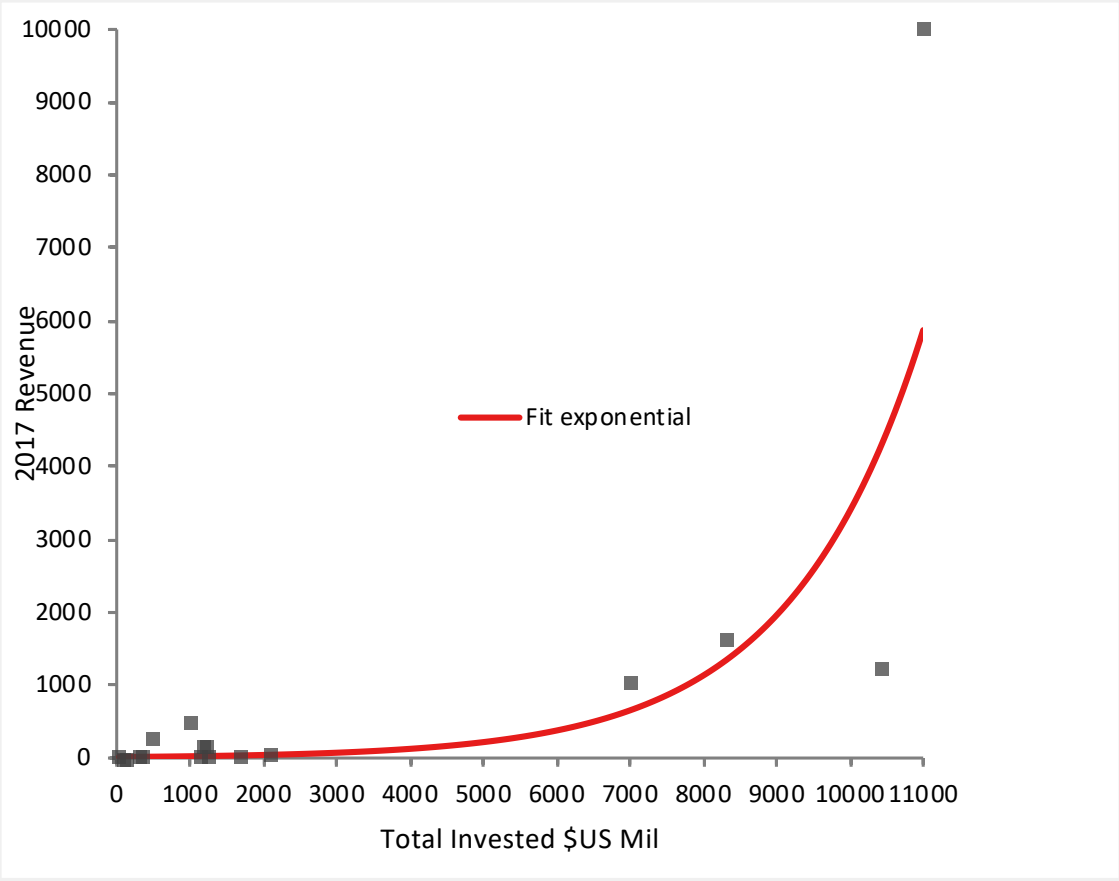
Biopharma Investors – Relationship to Revenue

Drug Category	Status	Total Invested $US Mil	2017 Revenue $US Mil
Respiratory	Marketed	30	12.91
Infectious Diseases	Marketed	46	0
Endocrine, Metabolic and Genetic Disorders	Marketed	75	0.47
Infectious Diseases	Marketed	133.4	1.2
Endocrine, Metabolic and Genetic Disorders	Marketed	315	31
Respiratory	Post Marketing	342.4	34.4
Oncology	Marketed	465	0
Ophthalmology	Marketed	487.5	281
Oncology	Marketed	510	0
Central Nervous System	Marketed	680	0
Oncology	Post Marketing	1000	500
Oncology	Marketed	1000	0
Respiratory	Marketed	1150	16
Oncology	Marketed	1160	175
Oncology	Marketed	1200	149
Hematology	Marketed	1200	0
Musculoskeletal	Marketed	1260	2.4
Endocrine, Metabolic and Genetic Disorders	Post Marketing	1695	5.69
Endocrine, Metabolic and Genetic Disorders	Marketed	2100	56
Endocrine, Metabolic and Genetic Disorders	Approved	2755	0
Endocrine, Metabolic and Genetic Disorders	Marketed	7000	1042
Musculoskeletal	Marketed	8300	1647
Oncology	Marketed	10400	1211
Infectious Diseases	Marketed	11000	10000

- For 25 therapies, we were able to accurately track specific investments to a specific product's market access and revenue generation.
- In general, products that gain market access require a minimum investment between $100 mil and $1 bil, this is the 'ante' needed to sit at the pharma table. Many products that come to market with this 'minimum' investment level do not generate meaningful revenue nor ROI.
- The relationship shows conclusively that investors seem to accurately predict and anticipate revenue, i.e. the smaller the investments, the lower the revenue potential of the asset.
- This relationship is highly statistically significant, in that the amount of potential revenue accurately predicts the amount of investment that is made.

Biopharma Investors – Relationship to Revenue

Statistical Significance of Investor Prediction of Annual Revenue



Effect of Model

Source	SS	DF	MS	F	p-value
Difference	68.645	1	68.645	19.07	0.0006 [1]
Error	53.994	15	3.600		
Null model	122.640	16	7.665		

Biopharma Investors – Impact of Modeling

Drug Category	Status	Total Invested $US Mil	2017 Revenue $US Mil
Respiratory	Marketed	30	12.91
Infectious Diseases	Marketed	46	0
Endocrine, Metabolic and Genetic Disorders	Marketed	75	0.47
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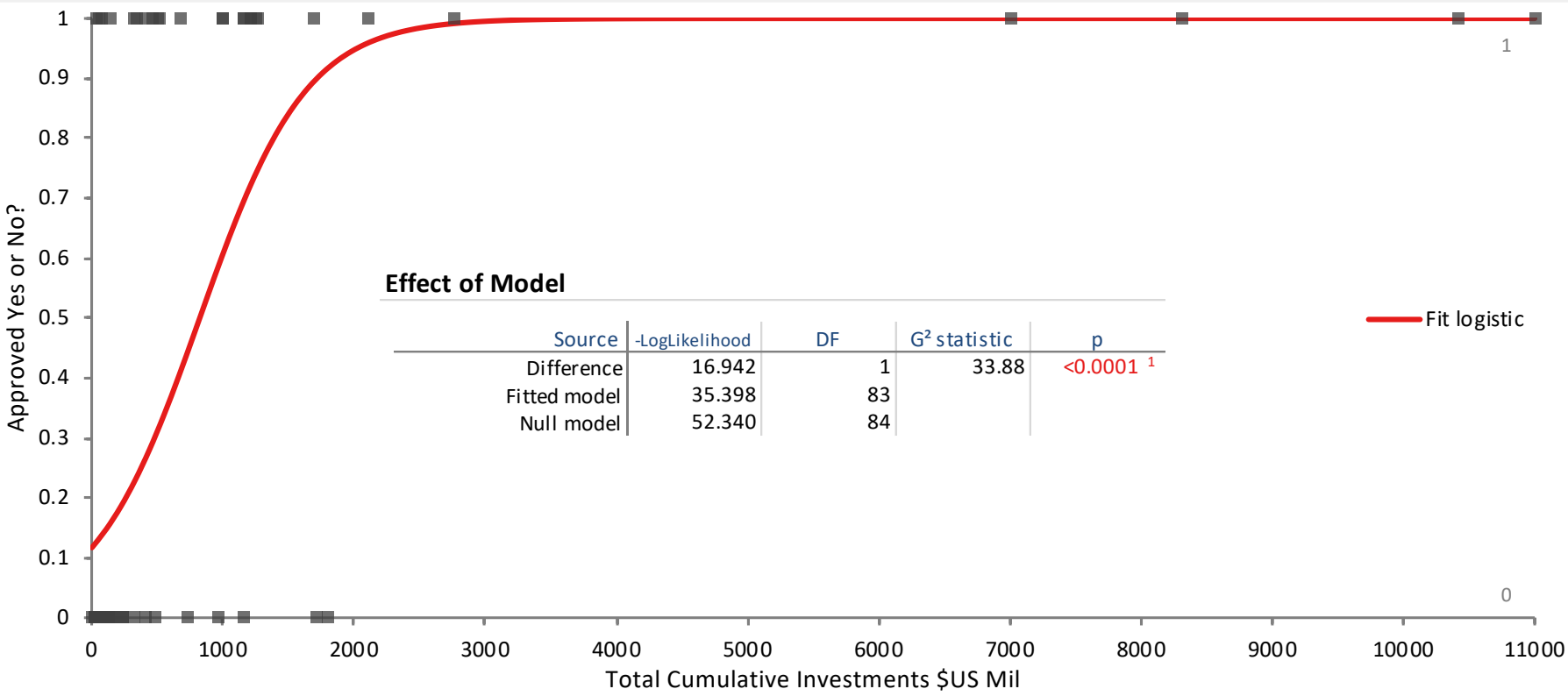
Infectious Diseases	Marketed	11000	10000

- Based on our model, large revenue reductions will influence which assets classes are ‘investible’.
- Small market indications, early stage platforms with lower revenue potential, or products that risk not breaking even after making the initial ‘ante’, will not be brought to market (i.e. Alzheimer’s and neurological disorders may further be hindered, as will research requiring long-term outcomes [CVD] as well as targeted therapies in smaller indications).
- Investors will dedicate their reduced available capital to those assets with the largest market potential.
- However, investors will still need to ‘ante’ to know which assets have potential. It will still cost hundreds of millions of dollars to fail, so there will be substantially fewer drugs coming to market given the loss of revenue.

Investments Predicting Market Entry

Amount of Cumulative Investments is a Statistically Significant Predictor of Successful Market Entry of New California Biotech Products



Effect of Model

Source	-LogLikelihood	DF	G^2 statistic	p
Difference	16.942	1	33.88	<0.0001 [1]
Fitted model	35.398	83		
Null model	52.340	84		

Investments Predicting Market Entry

- Given the rate of success in biopharma market entry is a constant, 8% success, 92% failure, any reduction in revenue will mean that a firm will need to make fewer investments in proportion to their drop of free cashflow.
- We have modeled the revised investment decision of market entry (i.e. the amount of drugs entering the market) based on our market probability modeling in our logistic regression.
- H.R. 3 will reduce market entry from 25 products from emerging companies and technologies to 3, all things being equal and with a 58% drop in free cashflow.

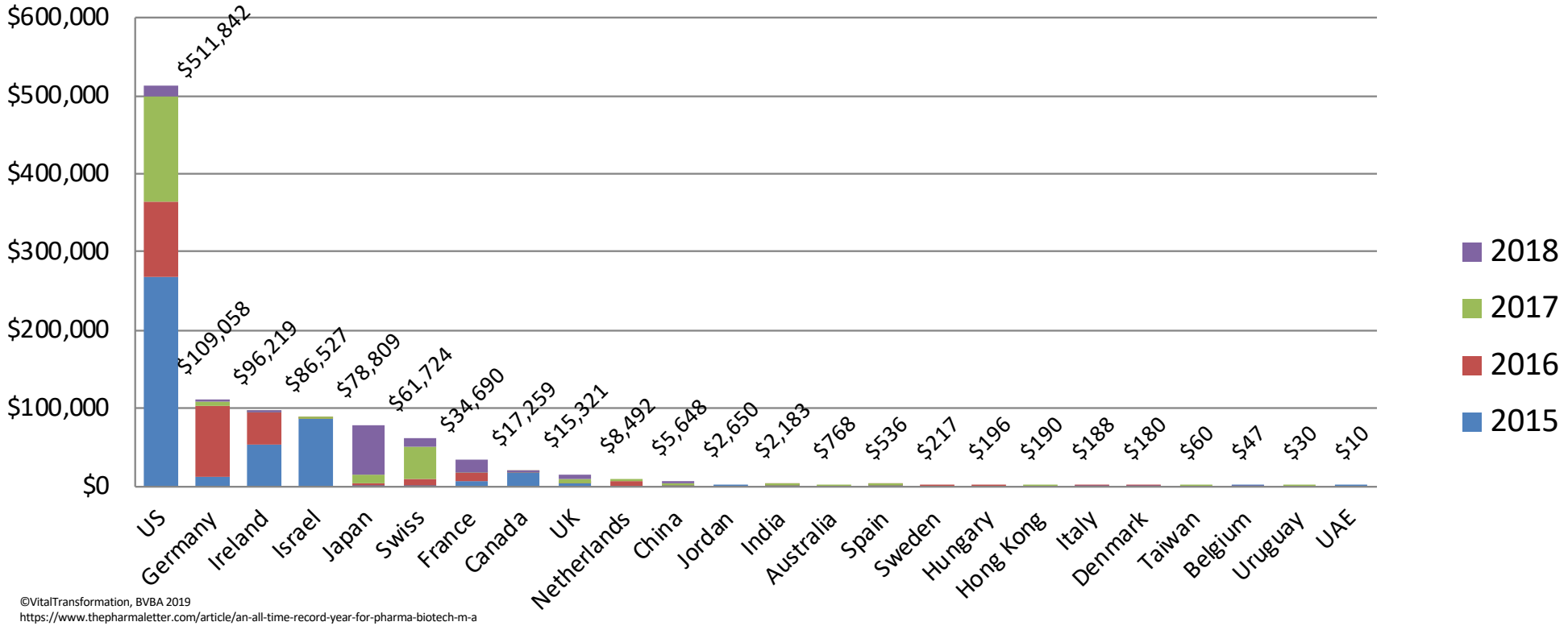
Asset Type	Total Investment ($56 bil)	Current Probablity	Ways and Means Revised Revenue ($36 bil Available Capital)	H.R. 3 Revised Revenue ($23 bil Available Captial)
Infectious Diseases	$11,000	100.00%	100.00%	99.99%
Oncology	$10,400	100.00%	100.00%	99.98%
Musculoskeletal	$8,300	100.00%	100.00%	99.87%
Metabolic and Genetic Disorders	$7,000	100.00%	99.99%	99.48%
Endocrine, Metabolic and Genetic Disorders	$2,755	99.14%	92.31%	69.90%
Endocrine, Metabolic and Genetic Disorders	$2,100	95.85%	80.42%	54.01%
Endocrine, Metabolic and Genetic Disorders	$1,695	89.51%	67.91%	43.51%
Musculoskeletal	$1,260	74.52%	50.93%	32.87%
Cardiovascular	$1,240	73.58%	50.11%	32.41%
Oncology	$1,200	71.62%	48.47%	31.51%
Hematology	$1,200	71.62%	48.47%	31.51%
Oncology	$1,160	69.58%	46.84%	30.61%
Respiratory	$1,150	69.06%	46.43%	30.39%
Oncology	$1,000	60.68%	40.41%	27.19%
Oncology	$1,000	60.68%	40.41%	27.19%
Central Nervous System	$680	41.26%	28.65%	21.11%
Hematology	$510	31.61%	23.31%	18.32%
Oncology	$465	29.27%	22.02%	17.63%
Oncology	$415	26.79%	20.64%	16.88%
Respiratory	$342	23.44%	18.76%	15.85%
Endocrine, Metabolic and Genetic Disorders	$315	22.25%	18.09%	15.47%
Infectious Diseases	$133	15.47%	14.09%	13.16%
Endocrine, Metabolic and Genetic Disorders	$75	13.69%	12.97%	12.48%
Infectious Diseases	$46	12.86%	12.45%	12.15%
Respiratory	$30	12.43%	12.16%	11.97%

BRING TO MARKET | **DO NOT BRING TO MARKET**

BIOTECH M&A BY BUYING COUNTRY, 2015 - 2018

$US Millions

In order to commercialize, international biotech is locating to the US. This chart shows, over the last 4 years, that 70% of all global biotech companies are being acquired by US interests.



https://www.thepharmaletter.com/article/an-all-time-record-year-for-pharma-biotech-m-a
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https://www.thepharmaletter.com/article/pharmaceutical-m-a-deals-in-2018

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BIOCOM 2019 California Impact Assessment

Industry Competitiveness – California
(The larger the Regional Share compared to Expected Change, the more competitive the industry)

	2013 Jobs	2018 Jobs	% Change	Expected Change	Regional Share
Total - All Industries	17,598,587	19,568,418	11.19%		
BioRenewables	31,429	31,060	-1.18%	-467	98
Biopharmaceutical Manufacturing	45,650	49,942	9.4%	2,497	1,795
Medical Devices & Diagnostic Equip	78,233	77,819	-0.53%	4,270	3,502
Life Science Wholesale	24,090	27,159	12.74%	4,223	-1,154
Research & Lab Services	216,814	242,303	11.76%	13,835	11,655
All Life Sciences	396,216	428,284	8.09%	15,896	11,724

Source: EMSI, TClower & Assoc.

Life Science Industry Economic Impacts (Direct, Indirect, Induced) **California 2018**

Industry	Output	Value Added	Labor Income	Employment
BioRenewables	$45,457,635,219	$16,927,057,541	$10,203,590,199	174,851
Biopharmaceutical Manufacturing	$133,728,677,745	$78,773,084,989	$30,267,453,451	311,244
Medical Devices & Diagnostic Equip	$61,718,832,890	$32,705,152,201	$19,419,853,650	229,060
Life Science Wholesale	$12,492,977,918	$8,141,172,704	$4,370,229,833	60,637
Research & Lab Services	$92,763,069,655	$59,231,912,129	$40,414,575,741	518,066
All Life Sciences	$346,161,193,427	$195,778,379,564	$104,675,702,874	1,293,858

Source: EMSI, IMPLAN, TClower & Assoc.

Conclusions on International Reference Pricing

- Ignores the cumulative impact on companies that have multiple products
- Reduces revenues of innovative companies at a rate higher than 1% of R&D
- Penalizes innovation, targets companies with the most advanced, newest products in the market for what are often the most challenging diseases
- Assumes companies will be able to raise prices in Europe; this is highly unlikely, and could lead to compulsory licenses against US products given the current EU political climate
- Attacks the amount of liquidity available for investments into new products, mergers, partnerships etc., negatively impacting market entry of new medicines
- Believes reducing Medicare prices will not impact innovation, this is wrong.
- Ignores the reality that the US is currently buying and 'owning' 70% of mature biotech and late stage value creation (and job creation).

Speakers

Sue Peschin
President and CEO
Alliance for Aging Research (US)

Patrick Kilbride
Vice President of international intellectual property for the Global Innovation Policy Center (GIPC)
U.S. Chamber of Commerce.

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Director of Content
Medtrack – Strategic Transactions

Joe Damond
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Biotechnology Innovation Organization
(BIO)

Pharma Intelligence
Informa

Medtrack

About Medtrack

Medtrack provides a comprehensive view of the biopharmaceutical business landscape – companies, investments, partnerships, pipelines, patents, sales and forecasts

Coverage includes:
48,000 **Companies**
>193,000 **Drugs**
169,000 **Deals**
>38,000 Venture deals
>106,000 Partnerships
>21,000 M&A
>300,000 **Patents**
>200 **Countries**

Business intelligence to support multiple functions

Market research

Monitor market-moving events like patent expiries, incidence/prevalence rates, historical/forecasted sales across the industry

Competitive intelligence

Track competitors' pipelines, financials, deals and patents

Clinical research

Global status on product development at the company and drug level, trends in new MOA's and disease targets

Licensing oportunities

In- and out-licensing and other commercialization trends such as royalty and milestone payments by phase

Investment research

Financial deals and venture capital data by region and therapy area for target prospecting and evaluating investment trends

Business development

Contact screening for relationship management

How We Do It

Rigorous editorial process

CAPTURE

Event Based Updates

- Daily scanning of companies, news channels
- SEC filings, earnings presentations, transcripts and annual reports
- Trial and regulatory agencies
- Investor and partnering conferences

CREATE/UPDATE

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- Analysts review newly identified content
- Update or create record with new information
- Review and resolve any data discrepancies

REVIEW

Routine record review

- Each record undergoes a scheduled comprehensive review
- Existing url's reviewed for new information

Questions

- Drug pricing is obviously a big political issue; why do you think this has become a zero-sum game from the standpoint of the US vs. Europe? How can we better explain the differences of the systems and the outcomes between them to the public and politicians?

Questions

- Given that science is leading us down a path to targeted medicines, effective therapies will be, by definition, for smaller and smaller populations. What changes to the regulatory system should be made to reflect this reality?

Questions

- Commissioner Gottlieb was promoting methodologies that would foster more flexible market entry as well as flexible reimbursement. Do we think Stephen Hahn will be as willing to experiment? Why do you think adaptive and flexible models have been taken out of the discussion since they were initially floated in January of 2017?

Questions

- Given 85%+ of the increases in US medical expenses are driven by hospital costs, why is the focus on pharmaceuticals?

Questions

- One of the stated goals of Medicare Part D reform in 2002 was to promote innovative and needed new medicines; has it been a success?

Questions

- The raw populism sounds logical, make Europe pay their ‘fair share’ of medicine costs. Aside from the hospital exemption, why is this not likely?