

We Affirm Resolved: The United States federal government should impose price controls on the pharmaceutical industry

Many countries have adopted a system of reference pricing to control drug costs. Stalter explains the concept in 2015, writing that **“Under reference pricing, interchangeable medicines<sup>6</sup> are divided into groups.<sup>7</sup> The prices of these drugs are then compared to the prices for the same drugs in select international markets and set accordingly.<sup>1</sup>**

The US should follow these countries’ lead and implement this form of Price control.

C1: Decreasing prices

Drug prices are dangerously high in the status quo. Mohammed 2015 finds **“American drug prices are among the highest in the world. Prices in advanced countries are often 50% cheaper than what Americans pay for drugs”<sup>2</sup>**

Crucially, implementing a reference pricing system decreases drug costs in 2 key ways

## 1 Generics

By creating limits on prices for brand name drugs, reference pricing incentivises the use of lower-cost generic medicines. Brekke 2015 confirms **“On the one hand, for given prices, RP increases the demand for generic drugs due to a higher brand-name copayment”<sup>3</sup>**, which provides the generic drug producers with an incentive to set higher prices and in turn makes generic entry more profitable. For this reason, after looking at an implementation of reference pricing in Norway, he concludes that **“The number of generics in a given market is significantly higher after the introduction of RP”<sup>4</sup>** Increased use of generics is key to decreasing costs, as Brennan 2017 **“Generic drugs are a boon in health care. Typically lower in cost and as effective as their branded counterparts, they help control pharmacy spending and increase access to important therapies for patients who could be deterred by the high cost of some branded drugs”<sup>5</sup>**

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<sup>1</sup>Stalter 2015 (Marie Stalter, J.D., 2015, Northwestern University School of Law; B.A., 2010, Washington University in St. Louis, “Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?”, *Northwestern Journal of International Law & Business*, Summer 2015, <https://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1785&context=njilb>. DOA: October 19th 2018) TG

<sup>2</sup>Mohammed 2015 (Rafi Mohammed is the founder of Culture of Profit, a consultancy that helps companies develop and improve their pricing strategies, “It’s Time to Rein in Exorbitant Pharmaceutical Prices”, *Harvard Business Review*, September 22<sup>nd</sup> 2015, <https://hbr.org/2015/09/its-time-to-rein-in-exorbitant-pharmaceutical-prices>. DOA: October 18th 2018) TG

<sup>3</sup>Brekke et. al 2015 (Kurt R. Brekke, Department of Economics, Norwegian School of Economics, Chiara Canta, Department of Economics, Norwegian School of Economics, Odd Rune Straume, Department of Economics/NIPE, University of Minho, “Does Reference Pricing Drive Out Generic Competition in Pharmaceutical Markets? Evidence from a Policy Reform”, *NHH*, June 2015, <https://brage.bibsys.no/xmlui/bitstream/handle/11250/284853/DP%2011.pdf?sequence=1>. DOA: October 30<sup>th</sup> 2018) TG

<sup>4</sup>Brekke et. al 2015 (Kurt R. Brekke, Department of Economics, Norwegian School of Economics, Chiara Canta, Department of Economics, Norwegian School of Economics, Odd Rune Straume, Department of Economics/NIPE, University of Minho, “Does Reference Pricing Drive Out Generic Competition in Pharmaceutical Markets? Evidence from a Policy Reform”, *NHH*, June 2015, <https://brage.bibsys.no/xmlui/bitstream/handle/11250/284853/DP%2011.pdf?sequence=1>. DOA: October 30<sup>th</sup> 2018) TG

<sup>5</sup>Brennan 2017 (Troyen A. Brennan, M.D., M.P.H., is Executive Vice President and Chief Medical Officer of CVS Health, “Why Are Physicians Still Prescribing High Cost Brand Name Drugs? Ask Pharma.”, *CVS Health*, June 5<sup>th</sup> 2017, <https://cvshealth.com/thought-leadership/why-are-physicians-still-prescribing-high-cost-brand-name-drugs-ask-pharma>. DOA: October 24<sup>th</sup> 2018) TG

## 2 Control of non-generic drugs

By implementing a system of price controls, the prices for branded drugs will be equal to prices for generics, as Farkas 2006 finds that **"In effect, reference pricing allows payers to impose generic prices on drugs still under patent protection."**<sup>6</sup> In fact, in an empirical review of literature on all countries adopting reference pricing, Galizzi 2010 concludes that **"Concerning the evidence on prices, virtually any country that implemented generic RP experienced a significant price reduction for drugs under RP"**<sup>7</sup>

### The impact Prescription drugs

In the status quo, prescription drugs aren't affordable, as quantified by Brenza in 2017, who finds that, "By Consumer Reports' estimates, that means **3.8 million Americans might be going without their necessary medications.**"<sup>8</sup> With decreased prices, medicines become more accessible. The impact is terminalized by Brody in 2017, who finds that. **This lack of adherence,** the Annals authors wrote, **is estimated to cause approximately 125,000 deaths** and at least 10 percent of hospitalizations, and to cost the American health care system between \$100 billion and \$289 billion **a year.**<sup>9</sup>

### C2: : Smarter innovation

Historically, companies have simply made small improvements to existing drugs to make money. These marginal improvements are known as "me-too" drugs. Light and Lexchin 2012 terminalize that **"Out of 218 drugs approved by the FDA from 1978 to 1989, only 34 (15.6%) were judged as important therapeutic gains"**<sup>10</sup> Because companies can simply rely on what is functionally fake innovation to make money, Israel 2018 concludes that **This incentive structure functions as a deterrent for breakthrough therapies.**<sup>11</sup>

Reference pricing leads to smarter innovation in two ways.

#### 1. Eliminating "me too" drugs

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<sup>6</sup>Farkas and Henske 2006 (Chuck Farkas is a Bain & Company partner based in Boston and head of Bain's North American health care practice. Preston Henske is a Bain partner based in New York, "Reference Pricing For Drugs", *Forbes*, April 14<sup>th</sup> 2006, [https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx\\_cf\\_0414pharma.html#6468933951e4](https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx_cf_0414pharma.html#6468933951e4). DOA: October 19th 2018) TG

<sup>7</sup>Galizzi et. al 2010 (Matteo M Galizzi is Research Fellow at the Centre for the Study of Incentives in Health, LSE Health, London School of Economics, London, UK. Simone Ghislandi is Assistant Professor of Public Economics, Econpubblica, Department of Institutional Analysis, Bocconi University, Milan, Italy. Marisa Miraldo is Assistant Professor of Health Economics, Health Management Group, Imperial College London, Business School, London, UK, "What do we really know about reference pricing for pharmaceuticals?", *health Policy Developments*, 2010, <http://apps.who.int/medicinedocs/documents/s20964en/s20964en.pdf>. DOA: October 19th 2018) TG

<sup>8</sup>Brenza 2017 (Amber Brenza, reporter for Vox, "1 in 7 People Don't Fill Their Prescriptions Because They Cost Too Much", *Vox Tonic*, June 12<sup>th</sup> 2017, [https://tonic.vice.com/en\\_us/article/payqbv/high-drug-prices-14-percent-of-americans-dont-fill-their-prescriptions](https://tonic.vice.com/en_us/article/payqbv/high-drug-prices-14-percent-of-americans-dont-fill-their-prescriptions). DOA: October 21st 2018) TG

<sup>9</sup>Brody 17 (Jane E. Brody, personal health columnist for the New York Times. "The cost of not taking your Medicine", Apr 17 2017, <https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html> DOA 10/13/18) KJR

<sup>10</sup>Light and Lexchin 2012 (Donald W Light professor, Department of Psychiatry, University of Medicine and Dentistry of New Jersey, Joel R Lexchin professor, York University School of Health Policy and Management, Toronto, Ontario, Canada, "PHARMACEUTICAL R&D What do we get for all that money?", *British Medical Journal*, August 11th 2012, <https://www.bmj.com/bmj/section-pdf/187604?path=/bmj/345/7869/Analysis.full.pdf>. DOA: October 21st 2018) TG

<sup>11</sup>Israel 2018 (Shoshanna Israel, Junior at UPenn, worked as PA for the Attorney General and in the office of Rep. Conor Lamb, fellow at Rough Draft Ventures. September 10, 2018. *UPenn Wharton Public Policy Initiative*. REFERENCE PRICING: IMPLEMENTING VALUE BASED PAYMENT IN PRESCRIPTION DRUGS, <https://publicpolicy.wharton.upenn.edu/live/news/2606-reference-pricing-implementing-value-based-payment>. DOA: October 29, 2018.) ALP

Israel 2018 explains **Reference pricing functions by requiring drug companies to submit clinical evaluations of drug effectiveness compared to existing therapies,** proving not that drugs are safe and effective, but that they are more effective than therapies already on the market.<sup>12</sup> This pushes me-too drugs out of the market, which is why Israel concludes **We can extend these lessons to US pharmaceuticals through a system of reference pricing which would reward pharmaceutical companies for value rather than allow companies to set prices at almost random.**<sup>13</sup>

## 2. Shifting innovation funding

Since Reference pricing prices similar drugs in the same manner, Farkas 2006 explains that **“One likely consequence will be a shift in research toward diseases not currently treated by multiple drug therapies. The reason is simple: These drugs would be literally incomparable”**<sup>14</sup> In other words, reference pricing shifts investment towards underdeveloped diseases and new types of cures to from new categories with higher price caps. For this reason, Gallizi et al 2010 concludes that **RP** can discourage Research and Development (R&D) efforts by lowering the profitability of the drugs included in the clusters. At the same time, it **can** **encourage a reallocation of R&D towards more innovative and breakthrough drugs to increase expected profits.** Hence, the overall effect on R&D is ambiguous.<sup>15</sup>

The impacts are twofold:

### 1 Superbugs

In order to combat drug resistant diseases, we need more research capabilities, as Easton 2018 finds that **Yet there remain huge unmet needs for new and better treatments for** most cancers; all neurological problems, especially **Alzheimer’s disease;** most autoimmune diseases; most major gastrointestinal disorders; macular degeneration; and diabetes — not to mention **the global scourge of drug-resistant bacterial and viral infections.**<sup>16</sup> However, in the status quo, Companies are slowing investment in superbug innovation. Hu 2018 finds that “Just two years after **Novartis** announced it would embrace the challenge of searching for cures for life-threatening infections known as superbugs,

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<sup>12</sup>Israel 2018 (Shoshanna Israel, Junior at UPenn, worked as PA for the Attorney General and in the office of Rep. Conor Lamb, fellow at Rough Draft Ventures. September 10, 2018. *UPenn Wharton Public Policy Initiative*. REFERENCE PRICING: IMPLEMENTING VALUE BASED PAYMENT IN PRESCRIPTION DRUGS, <https://publicpolicy.wharton.upenn.edu/live/news/2606-reference-pricing-implementing-value-based-payment>. DOA: October 29, 2018.) ALP

<sup>13</sup>Israel 2018 (Shoshanna Israel, Junior at UPenn, worked as PA for the Attorney General and in the office of Rep. Conor Lamb, fellow at Rough Draft Ventures. September 10, 2018. *UPenn Wharton Public Policy Initiative*. REFERENCE PRICING: IMPLEMENTING VALUE BASED PAYMENT IN PRESCRIPTION DRUGS, <https://publicpolicy.wharton.upenn.edu/live/news/2606-reference-pricing-implementing-value-based-payment>. DOA: October 29, 2018.) ALP

<sup>14</sup>Farkas and Henske 2006 (Chuck Farkas is a Bain & Company partner based in Boston and head of Bain's North American health care practice. Preston Henske is a Bain partner based in New York, “Reference Pricing For Drugs”, *Forbes*, April 14<sup>th</sup> 2006, [https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx\\_cf\\_0414pharma.html#6468933951e4](https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx_cf_0414pharma.html#6468933951e4). DOA: October 19th 2018) TG

<sup>15</sup> (Matteo M Galizzi is Research Fellow at the Centre for the Study of Incentives in Health, LSE Health, London School of Economics, London, UK. Simone Ghislandi is Assistant Professor of Public Economics, Econpubblica, Department of Institutional Analysis, Bocconi University, Milan, Italy. Marisa Miraldo is Assistant Professor of Health Economics, Health Management Group, Imperial College London, Business School, London, UK, “What do we really know about reference pricing for pharmaceuticals?”, *health Policy Developments*, 2010, <http://apps.who.int/medicinedocs/documents/s20964en/s20964en.pdf>. DOA: October 19th 2018) TG

<sup>16</sup>Easton 2018 (Robert J. Easton, co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors, 1/22/2018, Stat News, “Price controls would stifle innovation in the pharmaceutical industry,” <https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/>, 10/2/18. TRH

the drugmaker **said last week it would exit antibacterial and antiviral research. Novartis' retreat follows a growing trend of big pharmaceutical companies** — including AstraZeneca, Sanofi, and Allergan — that are exiting from this type of research because of a lack of profit<sup>17</sup>. Fortunately, by changing the profit incentives in the industry towards finding new cures, this trend can be reversed

The result is disease. Without new innovations millions of lives, as Biba 2017 finds that **“If left unchecked, antibiotic resistance could lead to 10 million deaths by 2050 worldwide**, costing some £66 trillion.”<sup>18</sup>

## 2 Cancer

These new smart innovations can target some unexplored and deadly diseases, as Farkas 2006 finds that **“Some of the big underserved markets are obvious, such as Alzheimer's disease, multiple sclerosis, diabetes and oncology”**<sup>19</sup>. Continuing to explore and cure oncological diseases like cancer could save millions, as the National Cancer Institute quantifies in 2018 that **“In 2012, there were 14.1 million new cases and 8.2 million cancer-related deaths worldwide”**<sup>20</sup>

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<sup>17</sup>Hu 2018 (Charlotte Hu, writer for Business Insider, “Pharmaceutical companies are backing away from a growing threat that could kill 10 million people a year by 2050.”, *Business Insider*, July 21<sup>st</sup> 2018, <https://www.businessinsider.com/major-pharmaceutical-companies-dropping-antibiotic-projects-superbugs-2018-7>. DOA: October 30<sup>th</sup> 2018) TG

<sup>18</sup>Dickinson 94 (Susan Dickinson, correspondent for The Scientist, 4 April 1994, “Fear Of ‘De Facto’ Price Controls Forcing Cuts In Biotech Innovation, Officials Say”<https://www.the-scientist.com/news/fear-of-de-facto-price-controls-forcing-cuts-in-biotech-innovation-officials-say-59351> DOA 10/18/18) MDS

<sup>19</sup>Farkas and Henske 2006 (Chuck Farkas is a Bain & Company partner based in Boston and head of Bain's North American health care practice. Preston Henske is a Bain partner based in New York, “Reference Pricing For Drugs”, *Forbes*, April 14<sup>th</sup> 2006, [https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx\\_cf\\_0414pharma.html#6468933951e4](https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx_cf_0414pharma.html#6468933951e4). DOA: October 19th 2018) TG

<sup>20</sup>National Cancer Institute 2018 (The National Cancer Institute, a section of the National Institute of Health, part of the Department of Health and Human Services. April 27, 2018. National Cancer Institute. “Cancer Statistics”, <https://www.cancer.gov/about-cancer/understanding/statistics>. DOA: September 21, 2018.) ALP

Reference pricing is popular across the world and divides medicines into categories

**Stalter 2015** (Marie Stalter, J.D., 2015, Northwestern University School of Law; B.A., 2010, Washington University in St. Louis, “Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?”, *Northwestern Journal of International Law & Business*, Summer 2015, <https://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1785&context=njilb>. DOA: October 19th 2018) TG

*Many countries use reference pricing as a method for pricing pharmaceuticals for government reimbursement.<sup>4</sup> Reference pricing is usually enacted through a healthcare reform law, and then put into action through specially created government committees or already existing public health committees.<sup>5</sup> Under reference pricing, interchangeable medicines<sup>6</sup> are divided into groups.<sup>7</sup> The prices of these drugs are then compared to the prices for the same drugs in select international markets and set accordingly.<sup>8</sup> Which countries are used for comparison is either specified in the originating law or determined by a government agency.*

US drug prices are sky high

**Mohammed 2015** (Rafi Mohammed is the founder of Culture of Profit, a consultancy that helps companies develop and improve their pricing strategies, “It’s Time to Rein in Exorbitant Pharmaceutical Prices”, *Harvard Business Review*, September 22<sup>nd</sup> 2015,

<https://hbr.org/2015/09/its-time-to-rein-in-exorbitant-pharmaceutical-prices>. DOA: October 18th 2018) TG

*As the ire over high prescription drug prices in the United States escalates, it's easy to blame pharmaceutical companies. But pharmaceutical companies aren't to blame. They've executed well on the rules set by the U.S. government as well as the "make the most money" dictum set by their stockholders. Over the last five years, returns for the S&P Pharmaceuticals Select Industry Index have been virtually double that of the S&P 500 (roughly 24% vs. 12% annually). But blaming them for their high prices is short-sighted finger pointing. Americans need to take some responsibility for deciding how drug prices are set, and they need to ask the larger question for the future: how should future pharmaceutical advancements be funded?*

*American drug prices are among the highest in the world. Prices in advanced countries are often 50% cheaper than what Americans pay for drugs. The AARP estimates prices for commonly used brand name prescription drugs in the U.S. rose by 8 times the general inflation rate in 2013. The annual expense for a recently developed cancer drug cocktail is \$295,000. (No wonder health insurance expenses are one of the biggest costs facing many employers.)*

## RP increases generic demand

Brekke et. al 2015 (Kurt R. Brekke, Department of Economics, Norwegian School of Economics, Chiara Canta, Department of Economics, Norwegian School of Economics, Odd Rune Straume, Department of Economics/NIPE, University of Minho, “Does Reference Pricing Drive Out Generic Competition in Pharmaceutical Markets? Evidence from a Policy Reform”, *NHH*, June 2015, <https://brage.bibsys.no/xmlui/bitstream/handle/11250/284853/DP%2011.pdf?sequence=1>. DOA: October 30<sup>th</sup> 2018) TG

In this paper we conduct an empirical analysis of the impact of RP on generic entry and the corresponding effects on drug prices, sales, and expenditures. To motivate our empirical analysis, we develop a general theoretical model that allows us to identify the key effects of RP on generic entry. The theoretical analysis shows that *the impact of RP on generic entry depends on the relative strength of two counteracting effects. On the one hand, for given prices, RP increases the demand for generic drugs due to a higher brand-name copayment, which provides the generic drug producers with an incentive to set higher prices and in turn makes generic entry more profitable. . On the other hand, RP pushes the brand-name producer to reduce its price to counteract the (expected) reduction in demand.* If the brand-name producer's price response to RP is sufficiently aggressive, so that the generic drug producers also reduce their prices, the net effect on generic entry may be negative. Thus, the impact of RP on generic entry is theoretically ambiguous and consequently an empirical question.

## RP leads to more generics

Brekke et. al 2015 (Kurt R. Brekke, Department of Economics, Norwegian School of Economics, Chiara Canta, Department of Economics, Norwegian School of Economics, Odd Rune Straume, Department of Economics/NIPE, University of Minho, “Does Reference Pricing Drive Out Generic Competition in Pharmaceutical Markets? Evidence from a Policy Reform”, *NHH*, June 2015, <https://brage.bibsys.no/xmlui/bitstream/handle/11250/284853/DP%2011.pdf?sequence=1>. DOA: October 30<sup>th</sup> 2018) TG

The main results on generic entry are reported in the first column of Table 4. ***The number of generics in a given market is significantly higher after the introduction of RP***. The effect (1.4) is quite high if compared with the average number of entrants in the pre-reform period (1.6). As our descriptive statistics and Figure 2 in the Appendix illustrate, this positive and strongly significant effect is mostly due to a decline in the number of generics for molecules in the control group, which was much less pronounced for drugs in the treatment group.



Marketing pushes prescribers away from low cost generics

Brennan 2017 (Troyen A. Brennan, M.D., M.P.H., is Executive Vice President and Chief Medical Officer of CVS Health, “Why Are Physicians Still Prescribing High Cost Brand Name Drugs? Ask Pharma.”, *CVS Health*, June 5<sup>th</sup> 2017, <https://cvshealth.com/thought-leadership/why-are-physicians-still-prescribing-high-cost-brand-name-drugs-ask-pharma>. DOA: October 24<sup>th</sup> 2018) TG

**Generic drugs** are a boon in health care. Typically lower in cost and as effective as their branded counterparts, they help control pharmacy spending and increase access to important therapies for patients who could be deterred by the high cost of some branded drugs.

*In fact, research shows that the use of generic drugs produces annual savings in excess of \$200 billion. Why, then, are some physicians still prescribing the higher cost, branded versions of these drugs? The devil may be in the “detailing.” Pharmaceutical detailing – a common marketing practice whereby physicians receive sales visits from pharmaceutical reps – is pervasive and can keep certain drugs top-of-mind for physicians, influencing their prescribing behavior.*

Reference pricing decreases prices and shifts the industry

**Farkas and Henske 2006** (Chuck Farkas is a Bain & Company partner based in Boston and head of Bain's North American health care practice. Preston Henske is a Bain partner based in New York, "Reference Pricing For Drugs", *Forbes*, April 14<sup>th</sup> 2006,

[https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx\\_cf\\_0414pharma.html#6468933951e4](https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx_cf_0414pharma.html#6468933951e4). DOA: October 19th 2018) TG

*Reference pricing is also likely to shape life for U.S. consumers and profits for pharmaceutical companies as Massachusetts' new deal in health care emerges. A bill signed by the state's governor this week mandates universal health care coverage by requiring all of its residents to have medical insurance. Although the Massachusetts plan has yet to define what an "affordable" health care plan is, the principles of reference pricing all point to what the future may look like. Reference pricing is supposed to save money for governments and patients. Those who want the more expensive brands can pay the difference between the cost of those drugs and the lower reimbursement, but that might amount to tens or even hundreds of dollars per week. The cost could be huge for the pharmaceutical industry as well, reaching \$30 billion to \$35 billion in lost profits over the next three to four years, according to analysis by Bain & Company. In effect, reference pricing allows payers to impose generic prices on drugs still under patent protection. That power will change the pharmaceutical landscape.*

## RP lowers prices

Galizzi et. al 2010 (Matteo M Galizzi is Research Fellow at the Centre for the Study of Incentives in Health, LSE Health, London School of Economics, London, UK. Simone Ghislandi is Assistant Professor of Public Economics, Econpubblica, Department of Institutional Analysis, Bocconi University, Milan, Italy. Marisa Miraldo is Assistant Professor of Health Economics, Health Management Group, Imperial College London, Business School, London, UK, “What do we really know about reference pricing for pharmaceuticals?”, *health Policy Developments*, 2010, <http://apps.who.int/medicinedocs/documents/s20964en/s20964en.pdf>.

DOA: October 19th 2018) TG

Concerning the evidence on prices, *virtually any country that implemented generic RP experienced a significant price reduction for drugs under RP. Price reductions are larger for prices originally higher than the Reference Price (as predicted by theory) and for markets where generic competition is stronger. Prices of substitute products not under RP can also be affected.* However, the empirical results here are ambiguous and no robust conclusion can be drawn. Finally, the empirical literature does not provide sound evidence on the pricing behaviour of the firms producing generic drugs. It is not clear, for example, how prices of generics react once the Reference Price is introduced and how the RP changes as a consequence of generics competition. Further empirical research on this topic is needed.

3.8 million people can't afford their prescriptions and simply go without them

**Brenza 2017** (Amber Brenza, reporter for Vox, "1 in 7 People Don't Fill Their Prescriptions Because They Cost Too Much", *Vox Tonic*, June 12<sup>th</sup> 2017, [https://tonic.vice.com/en\\_us/article/payqbv/high-drug-prices-14-percent-of-americans-dont-fill-their-prescriptions](https://tonic.vice.com/en_us/article/payqbv/high-drug-prices-14-percent-of-americans-dont-fill-their-prescriptions). DOA: October 21st 2018) TG

One in four Americans say they now pay more out of pocket for at least one of their prescription medications than they did a year ago—and it's a trend that researchers don't see stopping any time soon. The findings come from a recent Consumer Reports survey which polled 1,000 people nationwide who regularly take prescription drugs; 25 percent of whom reported an increase how much they pay at the pharmacy now than they did 12 months ago. Some of the increases were drastic: people paid as much as \$100 more for a single prescription. *"Those are big, burdensome increases for nearly 28 million consumers with very little indication that rising costs will be solved anytime soon," said Lisa Gill, deputy editor of Consumer Reports' prescription drug program, Best Buy Drugs, in a statement. That 28 million figure comes from the nationally representative 1,000-person survey, extrapolated to the estimated 110 million regular prescription drug users across the US. Some people who saw a price increase just ate the extra cost (37 percent), asked their pharmacist or doctor for a less expensive drug (35 percent), or asked their insurance company if they'd cover more of the cost (20 percent), but about 14 percent chose not to fill their prescription at all. By Consumer Reports' estimates, that means 3.8 million Americans might be going without their necessary medications.* Nearly 75 percent of those who had to pay more didn't even receive a notification in advance of the price increases and, worst of all, about 24 percent of regular prescription medication users said they're "not at all confident" that they'll have access to affordable medicine in the future. \

## Not taking medications has huge costs to the consumers and medical system

**Brody 17** (Jane E. Brody, personal health columnist for the New York Times. "The cost of not taking your Medicine", Apr 17 2017, <https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html> DOA 10/13/18)KJR

*There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It's called nonadherence to prescribed medications, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts. The numbers are staggering. "Studies have consistently shown that 20 percent to 30 percent of medication prescriptions are never filled, and that approximately 50 percent of medications for chronic disease are not taken as prescribed," according to a review in Annals of Internal Medicine. People who do take prescription medications — whether it's for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. This lack of adherence, the Annals authors wrote, is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations, and to cost the American health care system between \$100 billion and \$289 billion a year.*

Companies just make slightly different products to make money, most “innovations” aren’t really advancements

Light and Lexchin 2012 (Donald W Light professor , Department of Psychiatry, University of Medicine and Dentistry of New Jersey, Joel R Lexchin professor, York University School of Health Policy and Management, Toronto, Ontario, Canada, “PHARMACEUTICAL R&D What do we get for all that money?”, *British Medical Journal*, August 11th 2012,

<https://www.bmj.com/bmj/section-pdf/187604?path=/bmj/345/7869/Analysis.full.pdf>. DOA: October 21st 2018) TG

*More relevant than the absolute number of new drugs brought to the market is the number that represent a therapeutic advance. Although the pharmaceutical industry and its analysts measure innovation in terms of new molecular entities as a stand-in for therapeutically superior new medicines, most have provided only minor clinical advantages over existing treatments.* The preponderance of drugs without significant therapeutic gains dates all the way back to the “golden age” of innovation. *Out of 218 drugs approved by the FDA from 1978 to 1989, only 34 (15.6%) were judged as important therapeutic gains*.<sup>12</sup> Covering a roughly similar time period (1974-94), the industry’s Barral report on all internationally marketed new drugs concluded that only 11% were therapeutically and pharmacologically innovative.<sup>13</sup> Since the mid-1990s, independent reviews have also concluded that about 85-90% of all new drugs provide few or no clinical advantages for patients.<sup>14</sup><sup>19</sup> This small, steady increase in clinically superior drugs contrasts with the FDA granting “priority” review status to 44% of all new drugs from 2000 to 2010.<sup>20</sup> The percentage of drugs with a priority designation began to increase in 1992 when companies started funding the FDA’s approval process. *Other regulatory agencies have classified far fewer of the same medicines as needing accelerated reviews.*<sup>21</sup> Post-market evaluations during the same period are much less generous in assigning significant therapeutic advances to medications.<sup>18</sup> <sup>21</sup> *This is the real innovation crisis: pharmaceutical research and development turns out mostly minor variations on existing drugs, and most new drugs are not superior on clinical measures. Although a steady stream of significantly superior new drugs enlarges the medicine chest from which millions benefit, medicines have also produced an epidemic of serious adverse reactions that have added to national healthcare costs.*<sup>22</sup>

## Me too drugs discourage breakthrough therapies

Israel 2018 (Shoshanna Israel, Junior at UPenn, worked as PA for the Attorney General and in the office of Rep. Conor Lamb, fellow at Rough Draft Ventures. September 10, 2018. *UPenn Wharton Public Policy Initiative*. REFERENCE PRICING: IMPLEMENTING VALUE BASED PAYMENT IN PRESCRIPTION DRUGS,

<https://publicpolicy.wharton.upenn.edu/live/news/2606-reference-pricing-implementing-value-based-payment>. DOA: October 29, 2018.) ALP

*Companies pour billions into developing “Me Too” medicines because they are more likely to be approved by the FDA, with one study saying that submitting a “Me Too” drug for FDA approval, rather than a unique drug, doubled that drug’s likelihood of acceptance.*<sup>[13]</sup> *This incentive structure functions as a deterrent for breakthrough therapies.* *If we accept the premise that high drug prices translate into research dollars (an imprecise claim), then it follows that policymakers should pay more for breakthrough therapies at the expense of “Me Too” drugs. Then, hoping to snag a sliver of the market shares, companies waste even more patient dollars marketing these drugs to patients and providers; one ProPublica analysis found that top marketed drugs in five months of 2013 were not breakthroughs or top sellers, but were largely “Me Too” drugs where older and cheaper therapies were already available.*

**Reference pricing means that these drugs with marginal effectiveness are forced to lower prices.**

Israel 2018 (Shoshanna Israel, Junior at UPenn, worked as PA for the Attorney General and in the office of Rep. Conor Lamb, fellow at Rough Draft Ventures. September 10, 2018. *UPenn Wharton Public Policy Initiative*. REFERENCE PRICING: IMPLEMENTING VALUE BASED PAYMENT IN PRESCRIPTION DRUGS,

<https://publicpolicy.wharton.upenn.edu/live/news/2606-reference-pricing-implementing-value-based-payment>. DOA: October 29, 2018.) ALP

*Reference pricing functions by requiring drug companies to submit clinical evaluations of drug effectiveness compared to existing therapies, proving not that drugs are safe and effective, but that they are more effective than therapies already on the market. If the drugs are not,* in many countries such as Germany and Sweden, *the payer* (the government, a nonprofit insurance fund or similar) *will only reimburse the cost of the new drug up to an average price* (or other benchmark, such as lowest price of a drug with sufficient market share) *of similar drugs*. Drug companies can continue to charge whatever prices they choose to, but are forced to grapple with consumer demand if they choose to charge more than existing therapies that accomplish similar goals. In many countries, if a drug is uniquely effective, it negotiates with payers to reach an agreeable price. In Germany, in the few years after the policy launched, 63% of drugs reviewed were found to have some clinical benefit, leading to a reduction of new, expensive drugs on the market when existing therapies were just as effective.<sup>[15]</sup>



Reference pricing increases breakthrough drugs while decreasing prices.

Israel 2018 (Shoshanna Israel, Junior at UPenn, worked as PA for the Attorney General and in the office of Rep. Conor Lamb, fellow at Rough Draft Ventures. September 10, 2018. *UPenn Wharton Public Policy Initiative*. REFERENCE PRICING: IMPLEMENTING VALUE BASED PAYMENT IN PRESCRIPTION DRUGS, <https://publicpolicy.wharton.upenn.edu/live/news/2606-reference-pricing-implementing-value-based-payment>. DOA: October 29, 2018.) ALP

Meanwhile, in other health care sectors, the revolution of value-based payments and accountable care organizations has made tying payments to outcomes a real possibility.<sup>[4]</sup><sup>[5]</sup> *We can extend these lessons to US pharmaceuticals through a system of reference pricing which would reward pharmaceutical companies for value rather than allow companies to set prices at almost random. The result would speed the development of breakthrough therapies and decrease costs, while preserving the United States' continued subsidization of research and development in the pharmaceutical industry.*<sup>[6]</sup>

Reference pricing would shift research to more innovative sectors

**Farkas and Henske 2006** (Chuck Farkas is a Bain & Company partner based in Boston and head of Bain's North American health care practice. Preston Henske is a Bain partner based in New York, "Reference Pricing For Drugs", *Forbes*, April 14<sup>th</sup> 2006,

[https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx\\_cf\\_0414pharma.html#6468933951e4](https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx_cf_0414pharma.html#6468933951e4). DOA: October 19th 2018) TG

*One likely consequence will be a shift in research toward diseases not currently treated by multiple drug therapies. The reason is simple: These drugs would be literally incomparable. And in the testing phase, reference pricing forces companies to make their own therapeutic comparisons during clinical trials to cite significant improvements in outcomes compared with competing drugs, not placebos. Since worldwide standards don't exist, that is a gray area.* It is clear, though, that pharmaceutical companies will need new strategies to cope with the shift toward reference pricing. So far, pharma companies are looking at three ways to preserve profits in a world with diminished patent price protections.

## RP shifts spending

(Matteo M Galizzi is Research Fellow at the Centre for the Study of Incentives in Health, LSE Health, London School of Economics, London, UK. Simone Ghislandi is Assistant Professor of Public Economics, Econpubblica, Department of Institutional Analysis, Bocconi University, Milan, Italy. Marisa Miraldo is Assistant Professor of Health Economics, Health Management Group, Imperial College London, Business School, London, UK, “What do we really know about reference pricing for pharmaceuticals?”, *health Policy Developments*, 2010, <http://apps.who.int/medicinedocs/documents/s20964en/s20964en.pdf>. DOA: October 19th 2018) TG

The theoretical studies focus on different aspects of RP regulation, and it is thus difficult to sum up their results in few lines. In particular, the evaluation of the RP crucially depends on the policy used as a comparison, on the assumed characteristics of the market, and on the details of the policy design used in the theoretical model. However, some results seem robust to all specifications: 1. RP works well in reducing prices above the reimbursement level. 2. There are no strong incentives for generic firms to reduce prices once the Reference Price has been set. Hence, RP might not be effective in the long run. 3. RP can trigger price increases on therapeutic substitutes not covered by the policy. Again, this phenomenon might jeopardise the long-run effectiveness of the RP, especially if RP is applied to narrow clusters of products no longer covered by patents. 4. Firms can react to RP by setting prices strategically. In this sense, despite using market forces to regulate reimbursement prices, RP might not completely achieve the envisaged goal of perfectly competitive prices.

This partial failure is due to the strategic interactions that RP itself is likely to trigger. *RP* can discourage Research and Development (R&D) efforts by lowering the profitability of the drugs included in the clusters. At the same time, it *can encourage a reallocation of R&D towards more innovative and breakthrough drugs to increase expected profits*. Hence, the overall effect on R&D is ambiguous.

**Still lots of medicinal problems, pharma industry needs money to be able to solve these problems**

Easton 2018 (Robert J. Easton, co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors, 1/22/2018, Stat News, "Price controls would stifle innovation in the pharmaceutical industry,"

<https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/>, 10/2/18. TRH

Yet *there remain huge unmet needs for new and better treatments for* most cancers; all neurological problems, especially [\*Alzheimer's disease\*](#); most autoimmune diseases; most major gastrointestinal disorders; macular degeneration; and diabetes — not to mention *the global scourge of drug-resistant bacterial and viral infections.*

Companies are slowing investment in superbug innovation

**Hu 2018** (Charlotte Hu, writer for Business Insider, “Pharmaceutical companies are backing away from a growing threat that could kill 10 million people a year by 2050.”, *Business Insider*, July 21<sup>st</sup> 2018, <https://www.businessinsider.com/major-pharmaceutical-companies-dropping-anti-biotic-projects-superbugs-2018-7>. DOA: October 30<sup>th</sup> 2018) TG

*Just two years after Novartis announced it would embrace the challenge of searching for cures for life-threatening infections known as superbugs, the drugmaker said last week it would exit antibacterial and antiviral research. Novartis' retreat follows a growing trend of big pharmaceutical companies — including AstraZeneca, Sanofi, and Allergan — that are exiting from this type of research because of a lack of profit.*

That leaves Merck, Roche, GlaxoSmithKline, and Pfizer as the remaining pharmaceutical companies with active antibiotic programs, according to Nature Biotechnology. Only 12 antibiotics have been approved since 2000. Ever since the invention of penicillin, antibiotic development has been a treadmill. Patients who took too little or too much antibiotics would evolutionarily select for stronger strains by killing off only the sensitive bacteria. Antibiotics were once a lucrative business before inventing new drugs to catch up with the evolution of resistant strains became exhausting.

The issue of antibiotic resistance could result in millions of deaths

Erin Biba 2017 (Erin Biba, writer for BBC. June 8, 2017. "How can we stop antibiotic resistance" *BBC*. <http://www.bbc.com/future/story/20170607-how-we-can-stop-antibiotic-resistance>. October 5, 2018.)AO

*"And according to Public Health England, the "UK government considers the threat of antibiotic resistance as seriously as a flu pandemic and major flooding." If left unchecked, antibiotic resistance could lead to 10 million deaths by 2050 worldwide, costing some £66 trillion."*

## Reference pricing pushes companies to innovate in untouched sectors like for Alzheimer's and MS

**Farkas and Henske 2006** (Chuck Farkas is a Bain & Company partner based in Boston and head of Bain's North American health care practice. Preston Henske is a Bain partner based in New York, "Reference Pricing For Drugs", *Forbes*, April 14<sup>th</sup> 2006,

[https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx\\_cf\\_0414pharma.html#6468933951e4](https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx_cf_0414pharma.html#6468933951e4). DOA: October 19th 2018) TG

First, *pharma firms have started to screen their research pipelines differently. A once tried-and-true path for drug industry research was to focus on incremental improvements. A drug that was third or fourth to market was given the green light if it had a different active compound to fight a disease and companies could reasonably expect to earn some kind of return on their investment. Today, though, companies must re-examine the value of such "me too" innovation. Drugs that are not first or second to market will have to demonstrate clear superior efficacy for a targeted set of patients—or get cut. Hence, they are shifting even more attention to the markets where medical needs remain unmet. Some of the big underserved markets are obvious, such as Alzheimer's disease, multiple sclerosis, diabetes and oncology.* But others aren't as well known, which has prompted a scramble to understand these unmet needs.

**Cancer kills 8 million people per year.**

**National Cancer Institute 2018** (The National Cancer Institute, a section of the National Institute of Health, part of the Department of Health and Human Services. April 27, 2018. National Cancer Institute. "Cancer Statistics", <https://www.cancer.gov/about-cancer/understanding/statistics>. DOA: September 21, 2018.) ALP

**Cancer is among the leading causes of death worldwide. In 2012, there were 14.1 million new cases and 8.2 million cancer-related deaths worldwide.**