# Sjostrom/Verska Aff – Cypress Bay v2

## Contention 1 – A Crisis In Innovation

#### Elisabeth Hoen indicates in 2018 that:

Elisabeth Hoen, 4-9-18, “Practical Applications of the Flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights”, <https://medicineslawandpolicy.org/wp-content/uploads/2018/03/EllentHoen_dissertatie_Practical_Implications_2018.pdf>, Date Accessed 11-2-2018 // JM

A number of new initiatives have been launched to address the problem of insufficient research into the neglected diseases. These include more than two dozen public-private product development partnerships, such as the Drugs for Neglected Diseases initiative86 and a “priority review voucher” from the US Food and Drug Administration, awarded for the development of a new pharmaceutical for a neglected tropical disease (the voucher can be applied to any new drug application to speed up regulatory review time). 87 88 At the global level, two years of intergovernmental negotiations culminated in the 2008 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, adopted at the 2008 World Health Assembly. 89 The search is on for new ways to generate needs-driven medical innovation that will meet the needs of both the world’s rich and poor. Indeed, the crisis in innovation is not limited to developing countries or neglected diseases alone. While globally, the level of patent protection has increased over the past 20 years, the rate of pharmaceutical innovation has fallen, with an increasing number of “me-too drugs” of little or no therapeutic gain. Prescrire International found that 68% of the 3096 new products approved in France between 1981 and 2004 offered “nothing new” over previously available medicines. Furthermore, an analysis of more than 1000 new drugs approved by the US FDA between 1989 and 2000 found that more than three-fourths have no therapeutic benefit over existing products. 90

#### Richard Frank explains in 2017 that this view of innovation exists now because:

Richard G. Frank & Paul Ginsberg, 11-13-2017, "Pharmaceutical Industry Profits And Research And Development," No Publication, https://www.healthaffairs.org/do/10.1377/hblog20171113.880918/full/, Date Accessed 11-2-2018 // JM

The pharmaceutical industry is what economists call a high-fixed low-cost marginal cost industry. This means that the cost of bringing a new drug to market is very high and the process is risky, while the cost of producing an extra unit of a product that is on the market is frequently “pennies a pill”. There is energetic disagreement about the exact cost of bringing a new drug to market, but there is widespread recognition that the [costs run into at least many hundreds of millions of dollars](https://delauro.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf) per new drug product. In addition, for many drugs the costs of imitation are low. It is simple and low cost for a firm that did not develop the drug to produce a copy of a new drug. This means that if free competition were permitted, firms spending hundreds of millions of dollars to bring a new drug to market would be unlikely to recoup those investments, as competition would drive prices down to production costs ("pennies a pill"). It is these features of the economics of new drug development that make the establishment of intellectual property rights through the patent system and regulation of marketing exclusivity so important to promoting innovation in prescription drugs. Establishing temporary monopoly power for makers of new prescription drug products enables innovator companies to raise prices above the level of production costs and realize economic profits to compensate for the investment in pharmaceutical R&D. The fact that patents are granted and marketing exclusivity for new drugs is established does not mean there in no competition. Competition between patented drugs that treat the same medical conditions does occur, but it is based on the clinical features of the drugs and to a more limited extent on price. This is referred to as “differentiated” product competition. One feature of such competition is that manufacturers of the products can raise prices above production costs. In the case of differentiated competition, prescription drug manufacturers will tend to pursue R&D investments where the size of markets and the potential price-cost margins are greatest. Because pharmaceutical manufacturers are uncertain about the investments that their rivals are making and long lead times are generally required to bring a new product to market, there are incentives for rival companies to all chase big markets, for example dementia or prevalent cancers, in the hope of realizing large returns. The result of this type of [in a] “arms race” is “overinvestment” in certain clinical areas and lower rates of return on investment than hoped for. This state of affairs can continue indefinitely, eluding normal market self-correction mechanisms, due to prescription drug insurance that has become more common and more generous (see below) and to public-sector drug programs that are often passive purchasers.

#### There are two implications to this type of innovation in the status quo. First, me-too drugs neglect chronic diseases. Josh Gagne argues:

Joshua J. Gagne, & Niteesh K. Choudhry, 2-15-2011, “How Many “Me-Too” Drugs Is Too Many?,” <https://scholar.harvard.edu/files/nkc/files/2011_me_too_generic_commentary_jama.pdf>, Date Accessed 10-30-2018 // JM

In contrast, more options in a therapeutic class may make treatment decisions more difficult and may undermine clinical outcomes.3 Producing me-too drugs focuses research and development resources on drugs for conditions for which treatment options currently exist, while neglecting other conditions of more pressing public health importance.4 The proprietary nature of rebate information makes estimating the savings from within-class competition a matter of speculation, especially if generic drugs already exist in the class. Even at heavily discounted prices, brand-name drugs almost certainly cost more than generic medications. The associated spending differentials may have important implications for consumers and the health care system as a whole.5 Newly approved me-too drugs are much more likely to be heavily marketed than multisource generic drugs, which leads to greater prescribing of brand-name products despite the absence of data that their higher prices translate into appreciable differences in clinical outcomes.6 For patients, high drug costs [which] are a central reason for nonadherence to essential medications.7 In addition, at the time of approval little information about the benefits and safety of me-too drugs is available to patients, prescribers, and payers compared with the often extensive postmarketing history of products that were previously approved.

#### The impact of neglecting more pressing concerns means millions die each year. The National Health Council quantifies that:

National Health Council, 7-29-2014, “About Chronic Diseases,” <http://www.nationalhealthcouncil.org/sites/default/files/NHC_Files/Pdf_Files/AboutChronicDisease.pdf>, Date Accessed 10-30-2018 // JM

Generally incurable and ongoing, chronic diseases affect approximately 133 million Americans, representing more than 40% of the total population of this country.2 By 2020, that number is projected to grow to an estimated 157 million, with 81 million having multiple conditions.3 About half of all adults have a chronic condition, and approximately 8 percent of children ages 5 to 17 were reported by their parents to have limited activities due to at least one chronic disease or disability.4,5 More and more people are living with not just one chronic illness, such as diabetes, heart disease or depression, but with two or more conditions. Almost a third of the population is now living with multiple chronic conditions. 6 In 2009, 7 out of 10 deaths in the U.S. are due to chronic diseases. Heart disease, cancer and stroke account for more than half of all deaths each year.7 According to the New England Journal of Medicine, people with chronic conditions receive only 56% of recommended preventive health care services.

#### Second, me-too drugs lead to a prescription errors. Iti Chauhan explains in 2018 that since:

Iti Chauhan, Mohd Yasir, Madhu Kumari, Madhu Verma, July 2018, “The pursuit of rational drug use: Understanding factors and interventions”, <https://www.researchgate.net/publication/326682708_The_pursuit_of_rational_drug_use_Understanding_factors_and_interventions>, Date Accessed 11-3-2018 // JM

Market is flooded with large number of “Me too” drugs. Availability of too many not needed doubtful medicines in market [it] leads to lack of consistent supply of needed drugs and variation of individual prescribing preferences and inconsistent prescribing leading to numerous prescribing and dispensing errors.[3,7]

#### Brianna da Silva concludes that:

Brianna A. da Silva, and Mahesh Krishnamurthy, 9-7-2016, “The alarming reality of medication error: a patient case and review of Pennsylvania and National data”, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5016741/>, Date Accessed 11-3-2018 // JM

Errors occurred at multiple care levels, including prescribing, initial pharmacy dispensation, hospitalization, and subsequent outpatient follow-up. This exemplifies the Swiss Cheese Model of how errors can occur within a system. Adverse drug events (ADEs) account for more than 3.5 million physician office visits and 1 million emergency department visits each year. It is believed that preventable medication errors impact more than 7 million patients and cost almost $21 billion annually across all care settings. About 30% of hospitalized patients have at least one discrepancy on discharge medication reconciliation. Medication errors and ADEs are an underreported burden that adversely affects patients, providers, and the economy.

#### Luckily, the Trump administration recognizes that’s prices are too high now and adopting price controls is the answer to the system. Leela Barham indicates that:

Leela Barham, 11-7-2018, "International Reference Pricing, US Style," No Publication, http://www.pharmexec.com/international-reference-pricing-us-style, Date Accessed 11-9-2018 // JM

President Trump has had big pharma in his sights for some time. As his presidency continues, more has emerged about the administrations plans to tackle an industry that Trump has suggested has [gotten away with murder](https://www.politico.eu/article/donald-trump-america-first-agenda-on-drug-pricing-could-backfire-around-the-world/). The [latest [with his latest] proposals](http://www.pharmexec.com/pharma-blasts-trump-reference-pricing-proposal) — an International Pricing Index — amount[ing] to international reference pricing (IRP). IRP is something that countries in Europe have been doing for years, so what lessons are there? US international reference pricing proposals Trump announced in October 2018 that Medicare could pay for some prescription drugs based on prices paid in other industrialized countries. Trump is credited with pointing out that basing prices to be paid via a state funded purchaser would be "[revolutionary](https://www.nytimes.com/2018/10/25/us/politics/medicare-prescription-drug-costs-trump.html)". That’s not the case, with European countries using the prices paid by their peers for years, although the moniker used to describe it can vary, popular is using the moniker External Reference Pricing (ERP). For US IRP, a demonstration project will be run through the Center for Medicare and Medicaid Innovation, created under the Affordable Care Act. The Trump proposals are not going to take effect until late 2019, or early 2020. While the full details aren’t yet agreed – there is a window of time allowing people to comment on the proposals – there is already discussion of which countries could be in the basket for price comparisons. They could be the full set of countries that were looked at in [a comparison of US and international prices for top Medicare Part B drugs](https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf), a government funded report that illustrated just how different prices can be in other countries for a selection of drugs. That list included Austria, Belgium, Canada, Czech Republic, Finland, Grance, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden and the UK. DRG, a market access consultancy, speculate based on their experience, that the [reference countries](https://decisionresourcesgroup.com/drg-blog/international-reference-pricing-potentially-coming-u-s/) could be Germany, the UK, Canada, France and Japan. There are some circularities that could be introduced with some of these countries; for example, Japan already references US prices in it’s own IRP. There are also some issues with the price taken into account for IRP; secret discounts are common in the UK for example. Plus no small matter of the timing of the comparison; companies can set their price freely for the first year in Germany, but the price may change following a review and price negotiation after that first year; that’s if there is still a German price. Some companies have chosen to withdraw their product rather than take a far lower price implied by comparisons to generics. International reference pricing in Europe 29 countries in Europe have IRP [in place](https://books.seedmedicalpublishers.com/index.php/seed/catalog/download/Pharmaceutical_MA_developed/PDF/747.ch16?inline=1). That’s where the similarities ends though; the countries in the reference basket differ, and the price used to inform their own countries price may be the lowest in the basket or an average. It amounts to a pick-and-mix approach and it can change as and when policymakers and payers decide to tweak the system. There is a wealth of research that looks at what the impact has been of IRP in Europe, some has specifically looked at [what IRP could mean for the US](https://scholar.harvard.edu/nkc/files/2012_reference_pricing_systematic_review_ajmc.pdf) based on experience in other countries, concluding it could be a useful policy. There is also [research](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5645904/) that illustrates perversity in the policy: countries with lower GDP seem to pay more than those countries with higher GDP in a study that looked at IRP and orphan drugs, adjusting for a number of affordability factors. All the research inevitably has to look back to explore the impact of IRP. Things move on though. In today’s European market place for drugs, there is no small matter of the difficulty of using real prices in an IRP system. List prices are just that; on a list. Transaction prices aren’t on a public list. Transaction prices are influenced by a host of complexities in a specific market, not least of which is the option to strike deals – called patient access schemes, managed entry agreements plus other labels – where a confidential discount is agreed. So much so, that some had predicted the [demise of IRP in Europe](https://link.springer.com/article/10.1007/s40258-015-0182-5). Instead, value-based pricing (VBP) would take over. Getting the least-worst version of IRP Experience in Europe has led to the development of [principles](http://whocc.goeg.at/Literaturliste/Dokumente/BooksReports/Euripid_BestPracticeReport_final_May2017.pdf) in using IRP. They include applying to on-patent medicines, not those with generic alternatives as well as seen in the broader, international context to avoid logic inconsistencies as well as different abilities to pay. Predictably industry has been quick to criticize the proposals; engaging and applying lessons from Europe could achieve the least-worst of the IRP options open to the US.

#### This idea isn’t new as Austin Frakt argues that:

Austin Frakt, 10-19-2015, "To Reduce the Cost of Drugs, Look to Europe," No Publication, https://www.nytimes.com/2015/10/20/upshot/to-reduce-the-cost-of-drugs-look-to-europe.html, Date Accessed 10-23-2018 // WS

When anyone proposes reducing prescription drug prices — as [Hillary Rodham Clinton](https://www.hillaryclinton.com/p/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs/) and [Bernie Sanders](https://berniesanders.com/press-release/sanders-plan-would-stop-runaway-prescription-drug-prices/) recently have — the most commonly heard criticism is that it would [squelch innovation](http://phrma.org/media-releases/phrma-clinton-proposal-would-turn-back-the-clock-on-medical-innovation). But not all pharmaceutical innovation is valuable. Though some drugs are breakthroughs, some offer only marginal benefits at exorbitant cost. There is a way to keep prices low while encouraging drug companies to innovate: Look to Europe and elsewhere, where drug prices are a fraction of those in the United States. Germany, Spain, Italy and a half dozen other countries have pushed drug prices lower with a system called reference pricing. It has led to drug price decreases and significant savings in the Canadian province of [British Columbia](http://www.ncbi.nlm.nih.gov/pubmed/16174135) as well as in [Germany](http://www.ncbi.nlm.nih.gov/pubmed/19639351), [Italy](http://www.ncbi.nlm.nih.gov/pubmed/15760698), [Norway](http://www.sciencedirect.com/science/article/pii/S001429210800024X), [Spain](http://www.ncbi.nlm.nih.gov/pubmed/17235443) and [Sweden](http://www.ncbi.nlm.nih.gov/pubmed/16473436). A study published in the [American Journal of Managed Care](http://www.ajmc.com/journals/issue/2012/2012-11-vol18-n11/A-Systematic-Review-of-Reference-Pricing-Implications-for-US-Prescription-Drug-Spending/) found that price reductions ranged from 7 percent to 24 percent. Here’s how it works: [In reference pricing systems] Drugs are grouped into classes in which all drugs have identical or similar therapeutic effects. For example, all brands of ibuprofen would be in the same class because they contain the same active agent. The class could include other nonsteroidal anti-inflammatory agents like aspirin and naproxen because they are therapeutically similar. The insurer pays only one amount, called the reference price, for any drug in a class. A drug company can set the price of its drug higher, and if a consumer wants that one, he or she pays the difference. Setting the reference price low enough puts considerable pressure on drug manufacturers to reduce prices for drugs for which there are good substitutes. If they don’t, consumers will [switch to lower-cost products](http://www.ncbi.nlm.nih.gov/pubmed/11944760). In British Columbia and in Italy, [the reference price](http://www.ncbi.nlm.nih.gov/pubmed/21142276) is set at the lowest-price drug in the class; Germany uses an average price across drugs; Spain also uses an average, but only of the lowest-priced products that account for at least 20 percent of the class’s market.

#### Frakt continues that this system:

Austin Frakt, 10-19-2015, "To Reduce the Cost of Drugs, Look to Europe," No Publication, https://www.nytimes.com/2015/10/20/upshot/to-reduce-the-cost-of-drugs-look-to-europe.html, Date Accessed 10-23-2018 // WS

In pushing prices down, reference pricing doesn’t suppress innovation; it encourages a different form of it. The market still rewards the invention of a cutting-edge drug with novel therapeutic effects. Such a drug might be placed in a new class and therefore could be priced high. But, within classes, the market also rewards innovations that lead to lower-priced drugs, because consumers switch to them to avoid out-of-pocket costs. In these ways, reference pricing promotes cost-effectiveness. Consider, for example, the price of new anti-cholesterol drugs known as PCSK9 inhibitors: about $14,000 a year. A recent report from the [Institute for Clinical and Economic Review](http://www.icer-review.org/) (ICER) received [considerable attention](http://www.nytimes.com/2015/09/09/business/new-cholesterol-drugs-are-vastly-overpriced-analysis-says.html?module=inline) when it argued that the drugs were priced too high for the value they offered patients. Reducing the prices to close to $2,000 would make them both cost effective and would help keep American health spending below a widely accepted growth target, according to ICER’s analysis. As it stands, other countries are far ahead of the United States in pricing drugs to promote cost-effective pharmaceutical innovation. But interest is growing here in new approaches. Peter B. Bach, a physician at Memorial Sloan Kettering Cancer Center, recently proposed a variation on reference pricing that considers how the cost-effectiveness of a cancer drug varies by what disease it is used to treat. He noted that the drug Tarceva costs the same whether it is used to treat patients with a kind of lung cancer or patients with pancreatic cancer. But the results are wildly different. On average, Tarceva extends a lung cancer patient’s life by just over three months; it extends a typical pancreatic cancer patient’s life by a mere week and a half. Critics of Dr. Bach’s idea, ours and the approach of ICER claim they would restrain innovation that could benefit patients. However, they are devised specifically to [and] reward smarter innovation, which is precisely what we need.

#### **And, prices are the crucial part of this debate -- Standish Fleming wrote on Tuesday that:**

Standish Fleming, 11-6-2018, "Why Pharma Risk Is Inherently Unpredictable And Why It Matters," Forbes, https://www.forbes.com/sites/stanfleming/2018/11/06/inherently-unpredictable-why-pharma-has-an-innovation-crisis-and-how-to-fix-it/, Date Accessed 11-10-2018 // JM

High costs and increasing uncertainty prevent drug makers from increasing the size of their portfolios. Since they can’t scale-up operations, researchers have focused on improving the efficiency of the process, relying on knowledge and technology to find more blockbusters. It hasn’t worked, because they are implicitly assuming that drug development is a “normal,” high-risk process. In fact, outcomes are inherently unknowable, regardless of how skilled or well-equipped the drug developer. [Managers have structured the industry for high-quality, high-cost production in the expectation of "increasing the proportion of blockbusters in the product mix in …[a] predictable way," a strategy at odds with the nature of pharmaceutical risk.](https://twitter.com/intent/tweet?url=http%3A%2F%2Fwww.forbes.com%2Fsites%2Fstanfleming%2F2018%2F11%2F06%2Finherently-unpredictable-why-pharma-has-an-innovation-crisis-and-how-to-fix-it%2F&text=Managers%20favor%20high-quality%2C%20high-cost%20production--a%20strategy%20at%20odds%20with%20the%20nature%20of%20pharmaceutical%20risk.) The only way to find more blockbusters is to test more drugs, and the only way to do that is to reduce costs until they align with expected gains (modest) in sales and increased uncertainty. That requires [changing](https://www.forbes.com/sites/stanfleming/2018/02/25/pharma-must-use-tax-reform-windfall-to-make-more-drugs-or-face-backlash-part-ii/#4041c91c5aff) the high-cost, limited-production business model to one that places [equal importance](https://www.forbes.com/sites/stanfleming/2018/09/11/how-to-fix-pharmas-innovation-crisis-part-2/#4d8b51791784) on quality and quantity. Inherently uncertain means inherently expensive. Whether pharma can reduce costs sufficiently to solve its innovation crisis remains to be seen. Society might simply decide that it cannot afford new drugs and impose price controls, accelerating the decline of already failing profitability. In the meantime, pharma must try new “quantity” models. Any improvement in costs and scale will increase the likelihood of survival for both the industry and patients.

#### This is why we’ve seen changes in European drug development. The EMA quantifies that in 2017 – 38% of the drugs developed in the European Union were novel drugs, whereas the United States only produced around 5% of novel drugs as 95% of the drugs approved by the FDA were generics or me-too drugs.

European Medicines Agency, 1-23-2018, "Human medicines: highlights of 2017," No Publication, https://www.ema.europa.eu/en/news/human-medicines-highlights-2017, Date Accessed 11-3-2018 // JM

The European Medicines Agency (EMA) has published an [overview of its key recommendations of 2017](https://www.ema.europa.eu/documents/report/human-medicines-highlights-2017_en.pdf)regarding the authorisation of new medicines and the safety monitoring of medicines. Advances in medicines authorisations are essential for public health as they have the potential to improve the treatment of diseases. In 2017, EMA recommended 92 medicines for [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation). Of these, 35 had a new [active substance](https://www.ema.europa.eu/en/glossary/active-substance), which has never been authorised in the European Union (EU) before. Many of these medicines represent a significant improvement in their therapeutic areas; they include medicines for children, for rare diseases and advanced therapies. An overview can be found in the document published today. Once a medicine is placed on the market, EMA and the EU Member States continuously monitor the quality and the benefit/risk balance of the medicine under its authorised conditions of use. In 2017, EMA gave new safety advice to manage risks observed with a number of medicines on the market in the EU. Regulatory measures ranged from a change to the [product information](https://www.ema.europa.eu/en/glossary/product-information) to the suspension or withdrawal of a medicine or the recall of a limited number of batches. An overview of some of the most notable recommendations is also included in the document.

Katherine Ellen, 10-13-2017, "The US is approving more generic drugs than ever," Quartz, https://qz.com/1101897/more-generic-drugs-were-approved-by-the-us-fda-in-fy-2017-than-ever-before/, Date Accessed 11-3-2018 // JM

By the end of the 2017 fiscal year in September, the US Food and Drug Administration had approved 763 new generic versions of drugs—112 more than it had in 2016, almost twice as many as in 2014. This [record push](http://www.lachmanconsultants.com/2017/10/final-fy-2017-anda-numbers-are-in-holy-cow/) is part of an effort to lower prescription drug costs. Generic drugs, which work the same way as previously patented pharmaceuticals, are less expensive than name-brand drugs. And although the FDA has no control of how much pharmaceutical companies can charge for their drugs, more generic drugs on the market theoretically drives market prices down by adding in more competition.

Reuters, 1-2-2018, "2017 Saw the Most New Drugs Approved in Over 20 Years," Fortune, http://fortune.com/2018/01/02/new-drug-approvals/, Date Accessed 11-3-2018 // JM

U.S. drug approvals hit a 21-year high in 2017, with 46 novel medicines winning a green light—more than double the previous year—while the figure also rose in the European Union. The EU recommended 92 new drugs including generics, up from 81, and China laid out plans to speed up approvals in what is now the world’s second biggest market behind the United States. Yet the world’s biggest drugmakers saw average returns on their research and development spending fall, reflecting more competitive pressures and the growing share of new products now coming from younger biotech companies.

### Contention 2 – Employer Costs

#### Ali Diab argues in 2018 that:

Ali Diab, 2-28-2018, "American employers are in the healthcare business. – Collective Health Perspectives," Collective Health Perspectives, https://blog.collectivehealth.com/employer-driven-healthcare-270bfb7ee8c7?gi=e9aa453a98a, Date Accessed 10-31-2018 // JM

Employers play an outsized role in the purchase and provision of healthcare in the United States. To put the importance of employers in the U.S. healthcare economy in perspective: nearly 1 in 2 Americans — that’s 151 million of us — receive our healthcare coverage through an employer-sponsored health benefit plan. Of those, 3 out of 4, or about 108 million of us, receive health coverage through a self-insured employer plan, meaning our employer bears the financial risk of paying for the healthcare of its employees and their dependents. That dwarfs the 68 million Americans covered by Medicaid or the 58 million covered by Medicare. As a result, American employers spend nearly $1.2 trillion annually on healthcare for their employees and their families, equaling the $1.2 trillion spent annually by the federal government on Medicare and Medicaid combined. Measured in country terms, annual U.S. employer healthcare spend is larger than all but the world’s top 13 countries’ annual Gross Domestic Product (GDP). That means American employers spend more on healthcare each year than the entire economies of Indonesia (a country of 260 million) or Mexico (a country of 125 million). From 2006 to 2018, the total cost of healthcare per employee has risen 75%, while the median annual salary has only gone up 25% Moreover, the outsized inflation in healthcare costs over the past two decades has eaten into workers’ real wages, as well as the cash flow available to employers to re-invest in their businesses. From 2006 to 2018, the total cost of healthcare per employee (reflecting both employer and employee costs) has risen 75% from $8,079 to $14,156 a year, while the median annual salary of a full-time American worker grew by only 25%, from $35,464 to $44,564. The result? Not only are employers spending more on healthcare today than ever before, employees are seeing more and more of their compensation go toward healthcare costs each year. For a typical U.S. employer, healthcare often represents the second largest operating expense after employee wages. And for the vast majority of employers, it represents the fastest-growing operating expense — one that they feel they [employers] have little or no control in managing. As a result, the percentage of employers who have chosen to self-insure their employee healthcare plans has accelerated over the past two decades, as employers seek to gain more control over their healthcare spending and more mechanisms become available to incentivize and encourage workers to take better care of their health. In 1999, only 60% of U.S. employers with 200 employees or more self-insured their health benefits. By 2017, that number had risen to 79%. And it shows no sign of slowing down — today, 91% of covered workers at firms with 5,000 or more employees are on self-funded plans. Stated slightly differently, the biggest health insurance company in our country isn’t a health insurance company at all. It’s the tens of thousands of self-insured employers — along with our self-insured government — that underwrite the vast majority of Americans’ healthcare costs. So if you’re running a company in America, regardless of what industry you’re in, you’re in the healthcare business. And that means you need the right tools to be able to manage that critical line item in your corporate budget and drive a measurable return on your investment (ROI) in the experience and health outcomes of your employees.

#### Unforunately, Sarah O’Brien indicates in 2017 that:

Sarah O'Brien, 8-1-2017, "Employers to spend about $10,000 on healthcare for each worker," CNBC, https://www.cnbc.com/2017/08/09/employers-to-spend-about-10000-on-health-care-for-each-worker.html, Date Accessed 11-8-2018 // JM

Employees at big companies should be prepared to pay 5 percent more for their [health care](https://www.cnbc.com/2017/07/29/young-adults-struggle-to-plan-amid-health-care-uncertainty.html) next year. New results from an industry organization's annual study shows that large employers expect the total average per-employee cost for health insurance benefits — which includes premiums and out-of-pocket costs for employees and dependents — to rise in 2018 to $14,156 from $13,482 this year. With employers covering about 70 percent of that cost, the average worker will pay 30 percent of the tab, or about $4,200. "I think you'll see [the 5 percent rise] in premium increases," said Brian Marcotte, president and CEO of the Washington, D.C.-based National Business Group on Health, which released the study this week. "Most people will probably see minimal changes to deductibles and co-pays unless they move to a [higher-deductible] plan." This marks the fifth consecutive year that health care costs are expected to rise by 5 percent, according to the study. That outpaces the rate of inflation, which was 2.54 percent in 2016 and 2 percent for the first half of 2017. Workers' salaries also aren't rising as quickly as health care costs. The most recent data from the Federal Reserve shows that wages are growing by 3.2 percent annually. The National Business Group of Health's annual study surveyed 148 companies, 79 percent of which have 10,000 or more employees. It shows that employers rank the cost of "specialty pharmaceuticals" as the top driver of cost increases, which is unchanged from last year's survey results. Basically, new treatments for specific conditions ranging from diabetes and asthma to hemophilia and immune disorders can come with hefty price tags. "There's a rich pipeline of specialty medicines," Marcotte said. "They can be thousands or tens of thousands of dollars per treatment."

#### However, price controls decrease this price – Michael Fischer argues that:

Joy Li-Yueh Lee, MS; Michael A. Fischer, MD, MS; William H. Shrank, MD, MSHS; Jennifer M. Polinski, ScD, MPH; and Niteesh K. Choudhry, MD, PhD, “A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending”, Harvard University, <https://scholar.harvard.edu/nkc/files/2012_reference_pricing_systematic_review_ajmc.pdf>, Date Accessed 10-30-2018 // JM

Reference price policies significantly decreased both patient and payer expenditures (Table 3). Three studies that evaluated changes in patient expenditures found out-ofpocket savings ranging from 12% to 18% per month. The 4 studies that reported the impact of reference pricing on payer expenditures found reductions of 14% to [by] 52% on targeted drug classes. These correspond to per capita savings of $81 to $650.26. Although the policies reduced payer spending, the 3 studies that evaluated the effects of reference pricing on hospitalizations and physician visits found no significant changes in these outcomes. While Schneeweiss et al found a temporary 11% (95% confidence interval [CI] 1.07-1.15) increase in physician visits shortly after British Columbia’s ACE inhibitor policy went into effect, perhaps as a result of patients visiting their physicians to switch to reference products, 3 to 10 months after the policy, there were no significant changes in physician visits compared with baseline, –3% (95% CI 0.86-0.91).22 The analysis by Schneeweiss et al of a reference pricing program for calcium channel blockers also revealed non-significant changes in physician visits and hospitalizations shortly after the implementation of the policy (95% CI 1.00-1.03 and 0.89-1.06), followed by significant decreases (4% and 15% respectively, 95% CI 0.95-0.98 and 0.79-0.93) at 3 to 10 months after implementation. The evaluation by Hazlet and Blough of British Columbia’s H2 antagonist policy found very similar results.18,24,25 Only 1 study directly evaluated the impact of reference pricing on clinical end points, and found non-significant differences in cardiovascular death rates between users exposed to reference pricing for ACE inhibitors, calcium channel blockers, and nitrates and those who were not (P = .11).16

#### O’Brien furthers that without a decrease in prices:

Sarah O'Brien, 8-1-2017, "Employers to spend about $10,000 on healthcare for each worker," CNBC, https://www.cnbc.com/2017/08/09/employers-to-spend-about-10000-on-health-care-for-each-worker.html, Date Accessed 11-8-2018 // JM

Marcotte said that the cost can vary depending on where the treatment is administered (i.e., a hospital or doctor's office or even in the home). The survey shows that 44 percent of companies plan to combat pharma costs in part by better managing where patients receive those high-price medicines. Employers also increasingly have been [by] offer[ing] high-deductible plans as a way to control costs. The study shows that by next year, 90 percent of large companies will offer this option. Under these plans — sometimes called consumer-driven health plans in industry lingo — employees can put away tax-deductible savings in a [health savings account](https://www.cnbc.com/2017/08/07/making-retirement-lemonade-from-health-insurance-lemons.html), or HSA. For 2017, contribution limits are $3,400 for individual coverage and $6,750 for family plans. An extra $1,000 is allowed for people age 55 or older. HSA balances can carry over from year to year, and withdrawals are tax-free as long as they go toward qualified medical expenses. The survey also says that without such various cost-cutting measures being implemented by employers, overall costs would increase by 6.6 percent next year instead of the anticipated 5 percent.

#### The problem is that these plans disproportionality affect lower income families. Alison Galbraith

Alison Galbraith, Ross-Degnan D, Soumerai Sb, Abrams Am, Kleinman K, Rosenthal Mb, Wharam Jf, Adams As, Miroshnik I, Lieu Ta., 2010, "High-Deductible Health Plans: Are Vulnerable Families Enrolled?," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/, Date Accessed 11-8-2018 // JM

Understanding the characteristics of HDHP enrollees who do not have a choice of plans is important. A national survey showed that approximately half of HDHP enrollees did not have a choice of plans,[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R2) and 89% of families with children in [high-deductible plans] HDHPs in the Harvard Pilgrim population that we studied did not have a choice of plans. Other studies suggest that families are less well represented among HDHP enrollees with a choice of plans.[23](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R23),[24](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R24) Employees without a choice of plans may be a higher risk population, because they are more likely to have lower incomes than those with choices.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R13) Our finding of an association between HDHP enrollment and residence in a low-income neighborhood for families with large employers is consistent with data that lower wage workers tend to be offered less generous plans.[25](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R25) Although offering an HDHP as the only plan may not be common among large employers,[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R1),[26](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R26) this smaller population seems to be a more vulnerable group. Our finding among families with small employers that those who were switched to HDHPs were healthier than those who were kept in traditional plans suggests that employer-level selection may exist in HDHP enrollment even when employees are offered no direct choice of coverage. Our data from key informant interviews supports the idea that small business owners may recognize when they have healthy employees and select HDHPs for their businesses as a way to lower premium costs. This raises concern that small employers with sicker families are more likely to choose to remain in traditional plans, which may contribute to increasing per-member costs in such plans.[27](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R27),[28](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R28) Given that employees in small firms nationally are less likely to have a choice of plans[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R1)and more likely to be enrolled in HDHPs[29](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R29) compared with those in large firms, this population merits monitoring. Future studies of HDHPs will need to account for this potential employer-level selection bias, which may make health care use and costs seem lower in HDHPs with many members from small employers. Despite the seemingly favorable selection of healthier families into HDHPs, however, approximately one third of families in HDHPs from both large and small employers had children with chronic conditions. Pediatric providers and health plans will need to be aware of the insurance coverage of children with chronic conditions to monitor whether the need to pay OOP to meet deductible costs adversely affects use of recommended services. From a clinician’s perspective, it may not be simple to infer which pediatric patients are enrolled in HDHPs. Clinicians who have populations in which many families have small employers or have large employers in manufacturing may be more likely to see children with HDHPs; however, routine information collected in pediatric visits about parental employment may not be enough for providers to determine which families are exposed to high deductibles, and it is still uncommon for patients and physicians to discuss OOP costs during clinical visits.[30](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R30) As high deductibles and other cost-sharing mechanisms become more prevalent, providers may need to inquire about patients’ type of insurance coverage and cost-sharing arrangements when recommending health services, especially those with potentially high costs. Enrollment in HDHPs may be influenced by factors that our study’s claims and enrollment data did not capture, such as family income, education, race/ethnicity, and employee premium; however, we were able to measure neighborhood income and education, which can serve as reasonable proxies for individual-level socioeconomic measures.[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R14),[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R15),[31](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R31) Children who live in low-income neighborhoods might not have families with low incomes, and low-income children are more likely to be enrolled in public insurance programs; however, ~40% of Massachusetts children with family incomes at 100% to 199% of the federal poverty level have private insurance.[32](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R32) Because our study used data from a single health insurer, our conclusions may not generalize to HDHPs that are offered by insurers in other areas or HDHPs that include health savings accounts; however, most HDHP enrollees nationally do not have such accounts to pay for OOP costs.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R2),[33](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683628/#R33) We are also unable to determine whether employers of families in HDHPs in our study provided payment for deductible costs outside of formal accounts. Because some families in our study did not have drug coverage, our analyses of baseline expenditures did not include pharmacy expenditures. Although expenditures are likely to be higher when pharmacy expenditures are included, we expect that the relative relationship between baseline expenditures and HDHP enrollment should be similar regardless of whether pharmacy expenditures are included. To test this, we examined mean baseline OOP expenditures for the subset of families with drug coverage and found similar relationships between OOP expenditures and HDHP enrollment regardless of whether pharmacy expenditures were included (data not shown).

#### The impact is rising inequality. Emily Gersema argues in 2018 that:

Emily Gersema, 4-5-2018, "High-deductible health plans raise risk of financial ruin for Americans," USC News, https://news.usc.edu/140182/high-deductible-health-plans-raise-risk-of-financial-ruin-for-vulnerable-americans-study-finds/, Date Accessed 11-8-2018 // JM

The study showed that enrollment in a high-deductible health plan also raised the probability of high out-of-pocket spending on health care. The percentage of those likely to spend more than $2,000 on care, for example, increased by nearly 10 percentage points among the full sample and the lower-income [families] subgroup. The percentage of chronically ill patients paying that much on care grew by 15 percentage points. “If you are low income or have a chronic condition, or both, and your employer switches to high-deductible insurance, then you are significantly increasing your chance of facing an excessive financial burden or even financial disaster,” said Sood, a professor at the USC Price School of Public Policy. The study, published today in The American Journal of Managed Care, was based on a 25 percent random sample of claims data from OptumInsight Clinformatics Data Mart, a subsidiary of UnitedHealth Group. The study covered claims filed in a full three-year period from 2011 through 2013 for commercially insured subscribers and their dependents. For comparison, the study focused on a control group that included 653,155 consumers on traditional plans and 36,387 consumers on high-deductible plans. Their ages ranged from 18 to 64.

#### Dan Mangan quantifies that:

Dan Mangan, 7-6-2016, "Big switch: Wealthy now spending more on health care than poor and middle class," CNBC, https://www.cnbc.com/2016/07/06/wealthy-spending-more-on-health-care-than-poor-and-middle-class-reversing-trend.html, Date Accessed 11-8-2018 // JM

Health-care inequality is the new income inequality. The rich in the United States — despite being healthier on average than the poor — have become the biggest buyers of health care, a dramatic shift in spending patterns across income groups, [according to a new Harvard study](http://content.healthaffairs.org/content/35/7/1189.abstract). The study also reveals that the poor — who as a group have more health needs and live shorter lives than higher income groups — in recent years have become the group with the lowest-spending per capita, after decades of being the biggest spenders. In other words: People who need health care the most are now getting less of it than the people who need it the least. The phenomenon came as a result of a reduction in per capita health spending by or on behalf of the poor, at the same time as spending by the rich ramped up significantly, according to [the study published in the journal Health Affairs.](http://content.healthaffairs.org/content/35/7/1189.abstract) "We fear it may presage deepening disparities in health outcomes," the authors of the study wrote. One of those authors, Dr. Steffie Woolhandler, said, "A major change happened." "Nothing like this has been seen since the full implementation of Medicare and Medicaid," said Woolhandler, professor in the CUNY School of Public Health at Hunter College, adjunct clinical professor at Albert Einstein College of Medicine and lecturer in medicine at Harvard Medical School. The study suggests that the downturn in overall health spending by the poorest quintile, or one-fifth of the population, may be at least partly blamed on stagnant wage growth for most workers, coupled with a big increase in the number of health insurance plans with high deductibles. A deductible is the money that health-care consumers must personally pay out of pocket before their insurance covers the cost of medical services or medications. Research has shown that high-deductible plans can discourage health-care usage, particularly among people with lower incomes. The study examined health spending for low-, middle- and high-income Americans from 1963 to 2012. Before 1965, "the lowest income quintile had the lowest [health] expenditures, despite their worse health compared to other income groups," the report said. But in 1965, legislation was passed creating the federal Medicare program, which provides health coverage primarily to senior citizens, and Medicaid, the joint federal-state program that provides such coverage to the poor. The two programs, which cover tens of millions of Americans, led to sharply higher spending on health care for lower-income people. "By 1977, the unadjusted expenditures for the lowest quintile exceeded those for all other income groups" by 23 percent, the report said. "This pattern persisted until 2004." Woolhandler said this pattern was one "like we ought to have," because health spending in different income groups was aligned with the relative health of those income groups. But after 2004, per capita spending for the poorest quintile fell at a rate of $19.27 annually, or 3.7 percent over an eight-year period until 2012, the study found. At the same time, per capita health spending for members of the richest quintile sharply spiked, rising at a rate of $106.04 annually, or 19.7 percent over eight years. Health spending by the middle three quintiles also grew, in contrast to what happened to the poor, but at a less dramatic rate — 12.5 percent during the same time period. By the end of the eight-year period, in 2011, per capita health spending for the poorest quintile, adjusted for age and health status, was $4,074, Woolhandler said. Spending for the middle quintile was $4,647 per capita, she said. But health spending in the richest quintile was $5,817 per capita. The divergence between income groups was due to changes in health spending among people under the age of 65, according to the study. Its authors noted that "the elderly of all incomes experienced similar, flat expenditure growth," with the poorest continuing to have the highest spending. Woolhandler said the data doesn't reveal whether the poor, as a group, are getting too little in the way of health care, or whether the rich are getting too much as a group. Both scenarios are possible, but "we cannot tell," she said. However, the shift revealed by the study "cannot possibly be an efficient use of resources" by the health-care system. "To be efficient, that has to track with need," Woolhandler said. While people with worse health status had higher health-related spending, "shifts in health status did not explain the recent divergence in health expenditures among income groups." Woolhandler noted that "poor men are living 15 years shorter lives [as a group] than rich men." "And for the poorest women, they're living 10 years shorter than the wealthiest women," she said. Woolhandler said that although she and her co-authors cannot prove that slow wage growth and the rise of high-deductible plans played a big role in slowing health spending by the poor, the theory is "highly plausible" given the fact that both occurred at the same time as the divergence in spending occurred. High deductibles, and cost-sharing features including co-payments and co-insurance, have become increasingly common in insurance plans as employers and insurers try to bend the cost curve of health spending — which has risen faster than overall inflation for decades — by discouraging overuse of medical services. "People say that co-payments and deductibles have bent the cost curve," Woolhandler said. "But it's come at the expense of poor people and middle-income people." The passage of the Affordable Care Act, known as Obamacare, has helped the health situation of the poor by allowing states to expand their Medicaid programs to cover more adults. Medicaid, as a rule, does not require premium payments from enrollees, and typically has no or fairly low cost-sharing requirements on enrollees. But Woolhandler also said the ACA has been "a partial solution" at best, because many of the individual health plans sold on government-run Obamacare exchanges "come with such huge deductibles." Those deductibles for "silver" plans, the most popular tier of Obamacare coverage, can run around $3,000 per year, while "bronze" plans, which have the lowest premiums, can have deductibles of $6,000. "The federal government has more or less endorsed the idea that these huge deductibles are acceptable, and that has been part of the problem," Woolhandler said.

# Extra Cards

#### Additionally, this smarter innovation happens quicker in a world of price controls as novel drugs are given priority status – Ali Shajarizadeh found in 2016 that:

Ali Shajarizadeh, September 2016, “Essays on Pharmaceutical Economics”, <https://prism.ucalgary.ca/bitstream/handle/11023/3396/ucalgary_2016_shajarizadeh_ali.pdf;jsessionid=9F2144FED887027447811ADA98D3F127?sequence=1>, Date Accessed 11-3-2018 // JM

Drugs with substantial therapeutic improvement, ceteris paribus, are submitted to Canada with less delay (approximately one year less, as shown in column 1) and to all jurisdictions with less delay (approximately 7 months less, as shown in column 3) than follow-on drugs. This result is robust to including the interaction terms and is not dependent on company size. Since drugs with priority status are more likely to be internationally price-referenced, this suggests firms may not see international referencing as an impediment to entering the Canadian market.