AFF BLOCKS

Weighing Overview

Prefer impacts to access to innovation for two reasons

1. Access is a prerequisite to innovation; If the drugs are to expensive afford, that's functionally the same as not having them on the market.

2. People benefit much less from modest innovations than from the ability to afford those drugs at all. Light 12 at the University of New Jersey finds that, up to 90% of new drugs provide few or no advantages for patients. This is because of the law of diminishing returns, where every new drug provides fewer benefits but costs more.

Light 12 Donald W Light [Department of Psychiatry, University of Medicine and Dentistry of New Jersey], 8-7-2012, "Pharmaceutical research and development: what do we get for all that money?," BMJ, doi: 10.1136/bmj.e4348 //DF

More relevant than the absolute number of new drugs brought to the market isthe 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.12 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.13 **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**.14-19 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 2010.20 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.21 Post-market evaluations during the same period are much less generous in assigning significant therapeutic advances to medications.18 21 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.22

That's because each new drug offers a diminishing return over the previous one (Stott, a biotech analysit and journalist, 18)

Kelvin Stott [biotech analyst and writer with decades of prize-winning experience in journalism. A co-founder of Endpoints News, he has covered biopharma for the past 15 years], 11-1-2018, "Pharma's broken business model: An industry on the brink of terminal decline," Endpoints News [independent news organization, reporting and analyzing the top global biotech and pharmaceutical R&D news of the day],

https://endpts.com/pharmas-broken-business-model-an-industry-on-the-brink-of-terminal-decline/ //DF

Now the scariest thing about this analysis, is just how robust, consistent and rapid is the downward trend in return on investment over a period of over 20 years. But moreover, these results confirm that return on investment in pharma R&D is already below the cost of capital, and projected to hit zero within just 2 or 3 years. And this despite all efforts by the industry to fix R&D and reverse the trend. I mentioned earlier that this analysis is based on one assumption, the average investment period which is quite stable and well-defined, but here below we see that the results are not sensitive to this single assumption in any case. The downward trend is just as clear, as is the projected IRR of 0% by 2020:So what is driving this trend, and why haven't we been able to do anything about it? Law of Diminishing Returns Many different causes and drivers have been suggested to explain the steady decline in pharma R&D productivity, including rising clinical trial costs and timelines, decreasing success rates in development, a tougher regulatory environment, as well as increasing pressure from payers, providers, and increasing generic competition, however there is one fundamental issue at play that drives all these factors together: The Law of Diminishing Returns**. As each new drug improves the current standard of care, this only raises the bar for the next drug, making it more expensive, difficult and unlikely to achieve any incremental improvement**, while also reducing the potential scope for improvement. Thus, **the more we improve the standard of care, the more difficult and costly it becomes to improve further, so we spend more and more to get diminishing incremental benefits and added value for patients** which results in diminishing return on investment, as illustrated here: But why does the analysis above suggest a linear decline that will hit 0% IRR by 2020? Shouldn't the decline slow down and curve away so that it never reaches 0% IRR? No. 0% IRR corresponds to breaking even and getting exactly your original investment back, but as anyone who has worked in pharma will know all too well, you can easily lose all your original R&D investment as most drugs fail without making any return at all, so the minimum theoretical IRR is in fact negative 100%. There is no reason why the IRR should stop declining before it reaches 0%, or even -100%, besides the limited patience of investors.

Extras

G. Caleb Alexander [chair of the FDA's Peripheral and Cen- tral Nervous System Advisory Committee, serves as a paid consultant to QuintilesIMS, serves on the Advisory Board of MesaRx Innovations, and serves as a paid member of OptumRx's National P&T Committee. This arrangement was reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies], 2017 "Reducing Branded Prescription Drug Prices: A Review of Policy Options," Journal of Pharmacotherapy, doi: 10.1002/phar.2013 //DF

Although budgetary impacts of high-cost spe- cialty drugs are noteworthy, an even greater con- cern is that these prices are restricting access to care. For example, **in the case of hepatitis C, despite the availability of remarkably efficacious and safe treatments, fewer than one in five patients with the disease are receiving treatment**.7 A Senate Finance Committee report found that the manufacturer's pricing models never assumed that most people with hepatitis C would get access to the drug.8 A study by the Centers for Disease Control and Prevention (CDC) found that **despite the availability of a cure that is nearly 100% effective, deaths from hepatitis C continue to rise while deaths from other infectious diseases** reported to the CDC **have continued to fall**.9 Public programs, ranging from state Medicaid programs to the Veterans Administration and Bureau of Prisons,10 are faced with difficult choices about who should receive certain drugs given their budget constraints.11 Fourteen state Medicaid programs spent more on one hepatitis C drug (Sovaldi [sofosbuvir], Gilead Sciences, Inc, Foster City, CA) than on any other drug, yet only 2.4% of ~700,000 Medicaid enrollees infected with hepatitis C were treated in 2014.12 In the private insurance market, health plans have cre- ated high cost-sharing tiers for specialty products with coinsurance levels as high as 25–33%.13 Even though Medicare has an out-of-pocket maxi- mum for pharmaceuticals, beneficiaries still must pay 5% of the cost once their out-of-pocket maxi- mum is reached.14 This means that a Medicare beneficiary with prescription drug coverage could still pay as much as 40% of total annual income from Social Security for a drug to treat hepatitis C. The ongoing policy challenge is to ensure patients have access to needed medications even if they have prescription drug insurance.

Even if pharma makes worthwhile drugs, prices determine if anyone can afford them (Kliff 18 at Vox)

Sarah Kliff (Senior policy correspondent at Vox.com, awarded fellowships from the Association of Health Care Journalists and the Annenberg School of Journalism at the University of Southern California.) , 5-10-2018, "The true story of America's sky-high prescription drug prices," Vox, https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained //EH

Countries like Australia, Canada, and Britain don't regulate the price of other things that consumers buy, like computers or clothing. But they and dozens of other countries have made the decision to regulate the price of drugs to ensure that medical treatment remains affordable for all citizens, regardless of their income. Medication is treated differently because it is a good that some consumers, quite literally, can't live without. This decision comes with policy trade-offs, no doubt. Countries like Australia will often refuse to cover drugs that they don't think are worth the price. In order for regulatory agencies to have leverage in negotiating with drugmakers, they have to be able to say no to the drugs they don't think are up to snuff. This means certain drugs that sell in the United States aren't available in other countries — and there are often public outcries when these agencies refuse to approve a given drug. At the same time, just because there are more drugs on the American market, that doesn't mean all patients can access them. "To think that patients have full access to a wide range of products isn't right," says Aaron Kesselheim, an associate professor of medicine at Harvard Medical School. **"If the drugs are so expensive that you can't afford them, that's functionally the same thing as not even having them on the market."** It also doesn't mean we're necessarily getting better treatment. Other countries' regulatory agencies usually reject drugs when they don't think they provide enough benefit to justify the price that drugmakers want to charge. In the United States, those drugs come onto market — which means we get expensive drugs that offer little additional benefit but might be especially good at marketing. This happened in 2012 with a drug called Zaltrap, which treats colorectal cancer. The drug cost about $11,000 per month — twice as much as its competitors — while, in the eyes of doctors, offering no additional benefit. "In most industries something that offers no advantage of its competitors and yet sells for twice the price would never even get on the market," Peter Bach, an oncologist at Sloan-Kettering Memorial Hospital, wrote in a New York Times op-ed. "But that is not how things work for drugs. The Food and Drug Administration approves drugs if they are shown to be 'safe and effective.' It does not consider what the relative costs might be."

2. More affordable drugs will have a greater impact on people's lives than slightly improved drugs

Max Nisen, 11-30-2017, "Pharma's Status Quo May Be Doomed," Bloomberg, https://www.bloomberg.com/news/articles/2017-11-30/pharma-s-status-quo-may-be-doomed //DF

The fundamentals of Stott's argument are pretty simple and hard to dispute. At its core, pharma involves plowing money into R&D and collecting profits from successful drugs. But those research efforts are subject to the law of diminishing returns -- they're getting more expensive and less profitable over time. There are many reasons for that, including rising clinical trial cost and complexity, higher failure rates, and pressure from payers. But all of those are symptoms of a more basic issue: A lot of the low-hanging drug-development fruit has already been picked. *Pharma has* understandably *prioritized the biggest, easiest, and cheapest opportunities. As a result, there are a lot of good medicines already out there, and many are available as cheap generics or soon will be*. Drugmakers now must spend more and work harder to make even incremental improvements on the current standard of care. More and more companies are avoiding big and heavily researched disease areas and moving to smaller, more difficult, and inherently less valuable niches such as rare diseases. Or they're just duplicating each other's efforts. More money is being spent for lesser results, or on less-productive activities such as advertising in crowded drug classes. Regeneron Pharmaceuticals Inc. Chief Scientific Officer George Yancopoulos griped about that Thursday at a Forbes Health Care conference, noting there were only three first-in-class drugs approved by the FDA last year in big disease areas out of 23 total new drug approvals.

NU: innovation decreasing now

Jewell 18 Michael Jewell [healthcare partner at sell-side mergers and acquisitions (M&A) advisory firm Cavendish Corporate Finance, writes an Expert View piece on the potentially busy year ahead for dealmaking in the pharma sector], 1-3-2018, "Signs that 2018 will be a record year for pharma M&A," PharmaLetter, https://www.thepharmaletter.com/article/signs-that-2018-will-be-a-record-year-for-pharma-m-a //DF
The loss of patents means there will be stiffer competition from generic drugs and biologic alternatives and as more generic drugs are approved, prices of big pharma's previously patented drugs will fall. Losers will include major firms including Pfizer (NYSE: PFE), Johnson&Johnson (NYSE: JNJ) and GlaxoSmithKline (LSE: GSK), all of which are on strategic acquisition drives to mitigate any potential threat to their revenues, including looking at potential acquisitions of smaller pharma players, which have promising drug development programmes. The performance of big pharma's R&D departments is also a factor. The world's 12 biggest drug companies are making a return of just 3.2% on their research and development spending this year — down from 10.1% in 2010. Investing in R&D is a high-risk, high-reward endeavor for big pharma companies and they face many challenges to recoup investments, including increased competition, expiring patents, declining profitability and mounting regulatory scrutiny so acquiring new drugs via buying other more innovative pharma businesses is an increasingly attractive option. Furthermore, many of the big pharma companies are facing pressures due to aging and, increasingly, weak new pipelines. An MIT study found that only 14% of drugs in clinical trials are eventually approved by the US Food and Drug Administration. Thus, it is often more cost-effective for big pharmas to strengthen their pipelines through acquisitions of smaller firms that have specialist drugs.

Light 12 Donald W Light [Department of Psychiatry, University of Medicine and Dentistry of New Jersey], 8-7-2012, "Pharmaceutical research and development: what do we get for all that money?," BMJ, doi: 10.1136/bmj.e4348 //DF
How have we reached a situation where so much appears to be spent on research and development, yet only about 1 in 10 newly approved medicines substantially benefits patients? The low bars of being better than placebo, using surrogate endpoints instead of hard clinical outcomes, or being non-inferior to a comparator, allow approval of medicines that may even be less effective or less safe than existing ones. Notable examples include rofecoxib (Vioxx), rosiglitazone (Avandia), gatifloxacin (Tequin), and drotrecogin alfa (Xigris). Although the industry's vast network of public relations departments and trade associations generate a large volume of stories about the so called innovation crisis, the key role of blockbuster drugs, and the crisis created by "the patent cliff,"28 the hidden business model of pharmaceuticals centres on turning out scores of minor variations, some of which become market blockbusters. In a series of articles Kalman Applbaum describes how companies use "clinical trial administration, research publication, regulatory lobbying, physician and patient education, drug pricing, advertising, and point-of-use promotion" to create distinct marketing profiles and brand loyalty for their therapeutically similar products.29 Sales from these drugs generate steady profits throughout the ups and downs of blockbusters coming off patents. For example, although Pfizer lost market exclusivity for atorvastatin, venlafaxine, and other majorsellersin 2011, revenues remained steady compared with 2010, and net income rose 21%.30 Applbaum contends that marketing has become "the enemy of [real] innovation."31 This perspective explains why companies think it is worthwhile paying not only for testing new drugs but also for thousands of trials of existing drugs in order to gain approval for new indications and expand the market.32 This corporate strategy works because marketing departments and large networks of sponsored clinical leaders succeed in persuading doctors to prescribe the new products.33 An analysis of Canada's pharmaceutical expenditures found that 80% of the increase in its drug budget is spent on new medicines that offer few new benefits.16 Major contributors included newer hypertension, gastrointestinal, and cholesterol drugs, including atorvastatin, the fifth statin on the Canadian market. Complementing the stream of articles about the innovation crisis are those about the costs of research and development being "unsustainable" for the small number of new drugs approved. Both claims serve to justify greater government support and protections from generic competition, such as longer data exclusivity and more taxpayer subsidies. However, although reported research and development costs rose substantially between 1995 and 2010, by $34.2bn, revenues increased six times faster, by $200.4bn.25 Companies exaggerate costs of development by focusing on theirself reported increase in costs and by not mentioning this extraordinary revenue return. Net profits after taxes consistently remain substantially higher than profits for all other Fortune 500 companies.34 This hidden business model for pharmaceutical research, sales, and profits haslong depended less on the breakthrough research that executives emphasise than on rational actors exploiting ever broader and longer patents and other government protections against normal free market competition. Companies are delighted when research breakthroughs occur, but they do not

depend on them, declarations to the contrary notwithstanding. The 1.3% of revenues devoted to discovering new molecules 23 compares with the 25% that an independent analysis estimates is spent on promotion,35 and gives a ratio of basic research to marketing of 1:19.

R/T Drug Delays

The comparison is a 4 week delay versus 20 years because people can't afford the drug

G. Caleb Alexander [chair of the FDA's Peripheral and Cen- tral Nervous System Advisory Committee, serves as a paid consultant to QuintilesIMS, serves on the Advisory Board of MesaRx Innovations, and serves as a paid member of OptumRx's National P&T Committee. This arrangement was reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies], 2017 "Reducing Branded Prescription Drug Prices: A Review of Policy Options," Journal of Pharmacotherapy, doi: 10.1002/phar.2013 //DF

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R/T Hill Evidence

The original study says nothing about price controls - is just talking about amenable deaths (EuroStat)

EuroStat, 2018, "Amenable and preventable deaths statistics", https://ec.europa.eu/eurostat/statistics-explained/index.php/Amenable_and_preventable_deaths_statistics#deaths_from_potentially_avoidable_causes (NK)

In 2015, **over 570 000 deaths in the EU could have potentially been avoided with health care systems offering timely and effective medical treatments (amenable deaths)** and more than 1 million deaths could have been prevented through better public health interventions (preventable deaths). The total number of potentially avoidable deaths - which accounts for the fact that certain diseases are both preventable and amenable – is more than 1.2 million in 2015.[2] The leading cause of avoidable mortality was ischaemic heart diseases. 571 000 deaths from potentially avoidable causes In 2015, deaths from potentially avoidable causes in the EU amounted to 571 000 In the European Union (EU), 1.7 million persons aged less than 75 years died in 2015. Among them, around 571 000 deaths (or 127 deaths per 100 000 inhabitants) could have been avoided in the light of better healthcare systems (amenable deaths). The change compared to 2014 is negligible, showing that these figures are rather stable in the short run. Across EU Member States a substantial number of deaths can be considered as potentially avoidable and variations depend on Member States' population size.

Ramkisoon 13 Faye E. Ramkissoon [Norwich University Medical School, University of Toronto], 2013, "Commentary on "In Amenable Mortality – Deaths Avoidable Through Health Care – Progress in the US

Lags That of Three European Countries," Annals of medicine and surgery, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4326114/ //DF

Health care systems are often compared to evaluate and improve the delivery of healthcare to patients. The concept of 'amenable mortality' has been introduced as an indicator of quality of care.1 Amenable mortality is defined as deaths from a collection of diseases, such as diabetes and appendicitis, that are potentially preventable given effective and timely health care.1 This serves as a marker that highlights the performance of a health care system, although it has its limitations. A study by Nolte et al. found that the United States was slower to progress in improving amenable mortality when compared to United Kingdom, Germany, and France.1 Table 1 showed that amenable mortality declined in all countries, although there was significant variation.1 Further, the authors compared those under 65 to those over 65 years old between the countries. Those in the US under 65 had larger amenable mortality compared to other countries. Whilst Those over 65 in all the countries declined in amenable mortality, the US had a slower improvement rate.1 **In 2007 the US spent** $7,290 US per capita on health care, **more than twice the amount of France, Germany, and United Kingdom** ($3,601; $3,588; $2,992 respectively) and **yet the improvement in amenable mortality is half as good** in certain populations **compared to other Western countries**.2 The commonality amongst the three European countries is that they provided universal health care, while the US did not have this option. This appears to be further evidence for the need for health care reform in the US.1

However, despite spending 2x more on healthcare than European companies, our improvements in amenable mortality is half as good as it has been in these countries (Science direct - 2013)
https://www.sciencedirect.com/science/article/pii/S2049080113700189

R/T Innovation

Link Defense

Price controls wouldn't reduce r&d spending for two reasons

1. Pharma companies make so much money that they could lose substantial profits and still spend the same on r&d (Emanuel 15 at NYT)

Ezekiel J. Emanuel, 9-9-2015, "The Solution To Drug Prices" NYT, [provost at the University of Pennsylvania.] https://www.nytimes.com/2015/09/09/opinion/the-solution-to-drug-prices.html (NK)

If the United States were to consider such an approach, drug companies would immediately raise two objections: the high risks associated with drug development and, related, the high cost of research and development. But both of these arguments are fatuous. It is true that a vast majority of drugs fail. On average, only one in every 5,000 compounds that drug companies discover and put through preclinical testing becomes an approved drug. Of the drugs started in clinical trials on humans, only 10 percent secure F.D.A. approval. Regardless of the risks, many drug companies are making huge profits. Gilead, maker of Sovaldi, has profits of around 50 percent. Biogen, Amgen and other biotech firms have profits of around 30 percent. **[Companies like] Merck and Pfizer are seeing profits of 18 percent or more. Even if profits were cut by** a third or **a half, there would be sufficient incentive to assume the risks of drug development.** What should be done? The United States government has created myriad special pricing arrangements that pervert incentives. For instance, Medicaid generally gets the lowest prices in the market. This discourages drug companies from experimenting with other payers on lower price arrangements, knowing that they will most likely have to give the same deal to Medicaid. Similarly, through the Orphan Drug Act of 1983 the United States created many incentives for developing drugs for orphan diseases — those with fewer than 200,000 patients nationwide.

They don't show you that price controls will reduce profits so severely that they will hamper r&d

2. Marketing would be cut instead for two reasons

a. There is much more fat from marketing to cut. While companies spend significantly on advertisements, according to (Light 05)

Light 05 Donald W Light [Department of Psychiatry, University of Medicine and Dentistry of New Jersey], 10-22-2005, "Foreign free riders and the high price of US medicines," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1261198/ //DF

Contrary to claims of American dominance, pharmaceutical research and development in the US has not produced more than its proportionate share of new molecular entities. The US accounts for just under 48% of world sales and spent 49% of the global total on research and development to discover 45% of the new molecular entities that were launched on the world market in 2003, less than its proportionate share. European countries account for 28% of world sales, 36% of total research and development spending, and 32% of new molecular entities, more than its proportionate share.13 Limited investment in breakthrough research Pharmaceutical research and development is traditionally divided into three categories: Basic—work to discover new mechanisms and molecules for treating a disorder Applied—work that develops a discovery into a specific practical application, including research on manufacturing processes and preclinical or clinical studies Other—work that includes drug regulation submissions, bioavailability studies, and post-marketing trials. Although all types of research are valuable, it is basic research that leads to important therapeutic breakthroughs. Only a fraction of overall industry expenditure is on basic research, and it does not require the high prices currently seen in the US to support it. The Pharmaceutical Research and Manufacturers of America reports that companies invest on average about 18-19% of domestic sales into research.9 This figure is considerably higher than that produced by the US National Science Foundation.16 Its 1999 data show that drug companies invest 12.4% of gross domestic sales on research and development (10.5% in-house and 1.9% contracted out), but only 18% of the amount spent in-house went on basic research. Assuming that 18% of contracted out research is also spent on basic research (the actual figure is not reported) then only 2.2% (18%×12.4%) of revenue goes to basic research. The after tax cost of $1 of research and development expenditures in the US seems to be $0.53 to $0.61, owing to tax incentives to do research.17 Thus **US pharmaceutical companies devote a net of only about 1.3 cents** (2.4%×(0.53+0.61)/2) **of every dollar from sales to innovation**.Only 10-15% of newly approved drugs provide important benefits over existing drugs.18,19 From a drug company's point of view, investing principally in research to produce new variations of existing drugs makes sense. Government protections from normal price competition do not distinguish between the lower risk, less costly derivative kind of research and high risk basic research needed to discover new molecules.

B. Price controls would create an incentive for companies to spend the money they make on ads into r&d. That's because right now, companies make profits by selling drugs to consumers and doctors. With price controls, companies make more profits by selling drugs that are clinically beneficial (Keckley Deloitte 14)

Keckley, 2014, "Value-based pricing for pharmaceuticals: Implications of the shift from volume to value" Deloitte, https://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf

Health care reform and industry trends are driving pharmaceutical (pharma) companies to rethink strategy in their U.S. pursuits. The move to bundled payments, accountable care, comparative effectiveness research (CER), evidence-based medicine (EBM),1 and payments linked to performance are the direct result of regulatory and market pressures to reduce health costs without compromising safety and quality. For pharma companies, these trends represent a paradigm shift in the structure of the U.S. market and call for innovative approaches to commercialization and pricing. **In a new value-driven health care system, pharma companies will need to provide pharmaceuticals that demonstrate real, measurable value to stakeholders**. As a result, value-based pricing – the alignment of incentives between purchasers and manufacturers – is getting increased attention. In this Issue Brief, we summarize what is known to date about valuebased pricing and identify opportunities for additional exploration.

The proof is in the pudding. Prefer our reasons why r&d won't go down to their because of three examples

1. If high prices enabled more r&d spending, we should be seeing an increase in r&d, but the opposite is true (Open Markets Institute 15)

"High Drug Prices & Monopoly," 2015, Open Markets Institute, https://openmarketsinstitute.org/explainer/high-drug-prices-and-monopoly/ (NK)

Americans must pay the highest drug prices in the world because of the high cost of innovation, or so say lobbyists for big pharmaceutical companies. If the United States adopted policies to bring its drug prices in line with those in other advanced nations, they warn, drug companies would be forced to cut their spending on research and development, resulting in fewer cancer drugs, treatments for Alzheimer's, and the like.

Yet there is a problem with this argument. **In recent years, the prices Americans pay for drugs have only soared higher, even as innovation in the pharmaceutical industry slackens. The average number of new drugs approved each year has declined since the 1960s**. The drop-off has been particularly steep since 1996, when 54 new drugs came on line, compared to only 30 in recent years. Moreover, today's new pills typically have only modest, if any, proven therapeutic value over existing treatments. As a study in the Journal of the American Medical Association found, nearly half of the drugs approved by the Food and Drug Administration between 2005 and 2011 lacked any tangible health benefits, such as prolonging life or relieving symptoms.

That's because companies have figured out that they can make the most money by price gouging, not innovating (Pearl Stanford 17)

Robert Pearl, *(Former CEO of The Permanente Medical Group, the largest medical group in the nation, and clinical professor of surgery at Stanford University, M.D.)*, 1-19-2017, "Why Patent Protection In The Drug Industry Is Out Of Control," Forbes, https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/#14ee64fe78ca //AM

The intent of the patent process and the balance between the dual objectives have been warped over the past decade. **Increasingly, drug companies are not investing in R&D proportional to the profits they earn from the drugs they bring to market**, despite their protests to the contrary. Instead, **many have figured out that it's simpler and safer from a financial perspective to** either buy the rights to drugs developed by others and raise the prices many times over, as with Sovaldi, or **to obtain a medication already in existence and, using monopolistic control, raise the price** as much as 500% or more, as in the case of the EpiPen. As a consequence, the patent protection process now primarily serves the drug companies, most often not on behalf of the American people, but, rather, at their expense.

2. Most innovation actually happens in government labs with much smaller budgets than pharma companies (Kesselheim 16)

Aaron S. Kesselheim, *M.D., J.D., M.P.H., Associate Professor of Medicine at Harvard Medical School and faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital,* 8-30-2016, "The High Cost of Prescription Drugs in the United States," American Medical Association, https://jamanetwork.com/journals/jama/article-abstract/2545691 //AM

The pharmaceutical industry has maintained that high drug prices reflect the research and development costs a company incurred to develop the drug, are necessary to pay for future research costs to develop new drugs, or both. It is true that industry often makes expensive investments in drug development and commercialization, particularly through late-stage clinical trials, which can be costly.84 These assertions have been used to justify high prices on the grounds that if drug prices are constrained, the pipeline of new medications will be adversely affected. Some economic analyses favored by the pharmaceutical industry contend that it costs $2.6 billion to develop a new drug that makes it to market.85 However, the rigor of this widely cited number has been disputed.86,87 A number of factors weigh against these rationales for high drug prices. First, important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health. A recent analysis **of the most transformative drugs of the last 25 years** found that **more than half** of the

26 products or product classes identified **had their origins in publicly funded research** in such nonprofit centers.88 Other analyses have highlighted the importance of small companies, many funded by venture capital. These biotech startups frequently take early-stage drug development research that may have its origins in academic laboratories and continue it until the product and the company can be acquired by a large manufacturer, as occurred with sofosbuvir. Arguments in defense of maintaining high drug prices to protect the strength of the drug industry misstate its vulnerability. The biotechnology and pharmaceutical sectors have for years been among the very best-performing sectors in the US economy. The proportion of revenue of large pharmaceutical companies that is invested in research and development is just 10% to 20% (Table 4); if only innovative product development is considered, that proportion is considerably lower.91 The contention that high prescription drug spending in the United States is required to spur domestic innovation has not been borne out in several analyses.92 A more relevant policy opportunity would be to address the stringency of **[even though] congressional funding for the National Institutes of Health**, such that its budget **has barely kept up with inflation for most of the last decade**. Given theevidence of the central role played by publicly funded research in generating discoveries that lead to new therapeutic approaches, this is one obvious area of potential intervention to address concerns about threats to innovation in drug discovery. Thus, there is little evidence of an association between research and development costs and drug prices93; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear. This explanation also helps to account for several high-profile case studies, including high-priced new branded products and exorbitantly priced generic drugs described above.95 In preparation for recent hearings on this topic, the US House Committee on Oversight and Government Reform subpoenaed internal correspondence from Turing and Valeant Pharmaceuticals, which had sharply increased the prices of older drugs the companies had acquired.

3. Companies based in countries with price controls spend more, not less, on r&d (Keyhani National Institutes of Health 10)

Keyhani, 2010, "US Pharmaceutical Innovation in an International Context," National Institute of Health, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866602/ (NK)

We explored whether the United States, which does not regulate pharmaceutical prices, is responsible for the devolopment of a disproportionate share of the new molecular entities (NMEs; a drug that does not contain an active moiety previously approved by the Food and Drug Administration) produced worldwide. Methods. We collected data on NMEs approved between 1992 and 2004 and assigned each NME to an inventor country. We examined the relation between the proportion of total NMEs developed in each country and the proportion of total prescription drug spending and gross domestic product (GDP) of each country represented. Results. The United States accounted for 42% of prescription drug spending and 40% of the total GDP among innovator countries and was responsible for the development of 43.7% of the NMEs. **The United Kingdom, Switzerland, and a few other countries innovated proportionally more than their contribution to GDP or prescription drug spending**, whereas Japan, South Korea, and a few other countries innovated less. Conclusions. Higher prescription drug spending in the United States does not disproportionately privilege domestic innovation, and many countries with drug price regulation were significant contributors to pharmaceutical innovation.

Link Turns

Price controls will improve innovation in two ways

1. Putting a higher premium on r&d

Low competition now in the pharma industry discincentivizes r&d (Morton 17 at Brookings)

Morton 17 Fiona Scott Morton [Theodore Nierenberg Professor of Economics at the Yale University School of Management where she has been on the faculty since 1999] and Lysle Boller [Statistician at Yale's School of Management, where he works on research related to healthcare policy and competition in pharmaceutical markets], 5-2-2017, "Enabling competition in pharmaceutical markets," Brookings, https://www.brookings.edu/research/enabling-competition-in-pharmaceutical-markets/ //DF

The United States, unlike many other industrialized nations, does not regulate the price of pharmaceutical products directly. There are advantages to this approach. The U.S. generic market is one of the most dynamic and cost-effective in the world due to competition between manufacturers. The inventor of a socially valuable patented drug may charge high prices in the U.S. market, and the ensuing profit incentivizes innovation that benefits consumers. Subsequent competition between substitute therapies, even those on patent, can push down these prices over time. Generic entry after patent expiration pushes down prices even further. This form of price discipline, generated by market forces, rewards the attributes and efficacies that consumers want. For example, if a particular drug is differentiated from its competitors in a useful way, it will be able to command a higher price. Prices that reflect value create exactly the incentives society desires for innovation. If the forces of competition are always strong, then the way for a pharmaceutical company to earn high profits is to invent a valuable treatment. **If competitive forces weaken,** then **high prices for drugs may not reflect value but instead a lack of market discipline**, sometimes exacerbated by regulations that enable or maintain high prices. **When manufacturers can earn high profits by lobbying for regulations that weaken competition**, or by developing mechanisms to sidestep competition, **the system no longer incentivizes the invention of valuable drugs. Rather, it incentivizes firms to locate regulatory niches where they are safe from competition on the merits with rivals.** The U.S. system performs well when competitive forces are strong, as this yields low prices for consumers as well as innovation that they value. Weak competitive forces are more damaging to consumers in the pharmaceutical sector than some others. Patients in the U.S. are typically both insured and uninformed about therapeutic substitutes for the medications they take; thus, without effective rules and frameworks provided by the government, they face difficulty in creating market forces on their own. Without market pressures, drug makers may sell at arbitrarily high prices to insured consumers. Therefore, the policy environment in which those consumers shop is critical to maintaining effective price competition.

That's why we're seeing higher profits but *less* r&d investment

Price controls fix these incentives by pegging the price of drugs to he value they bring to society (Keckley 14 at Deloitte)

Keckley, 2014, "Value-based pricing for pharmaceuticals: Implications of the shift from volume to value" Deloitte, https://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf (NK)

Recent examples demonstrate that pharma companies are incorporating stakeholder values into their pricing agreements (Figure 6) and forming stakeholder partnerships to understand value definitions and obtain value-based data (Figure 7). **Many of the countries in which the government plays a role in pricing** and price negotiations **of pharmaceuticals** (unlike in the U.S.) **have focused on reducing costs through value-based pricing agreements** as a response to budgetary pressures.27 In Denmark, for example, Bayer entered into a "no cure, no pay" initiative on Levitra (vardenafil) for erectile dysfunction in 2005; patients not satisfied with the treatment were eligible for a refund.28 In 2007, **[for example] after the United Kingdom**'s (U.K.) National Institute for Health and Clinical Excellence (NICE) initially **concluded that [the medicine] Velcade** (bortezomib) **was too expensive relative to its estimated benefit to the population, Johnson & Johnson offered (in response) to forgo charges for patients who did not have an adequate medication response**.29 In Sweden, Willis, et al, (2010) conducted a case study of Duodopa (levodopa/ carbidopa) in advanced Parkinson's disease to gain insights into value-based pricing agreements in combination with conditional coverage.30,31 The study concluded that: (1) stakeholders benefited from analysis of real-world (postmarket) data (in addition to pre-launch, trial-based data); and (2) conditional coverage allowed for effective risk-sharing (between a payer and pharma company) and sufficient access to pharmaceuticals by consumers. These examples provide insight about the types of pharmaceuticals that might be candidates for future agreements. "Products with simple methods for measuring the treatment effects (e.g., decreased blood pressure or cholesterol level), as well those products with clearly defined outcomes (e.g., did the tumor respond to treatment or not) are likely candidates

This will make drugs better for everyone (Keckley continues)

Keckley, 2014, "Value-based pricing for pharmaceuticals: Implications of the shift from volume to value" Deloitte, https://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf (NK)

Health care reform and industry trends are driving pharmaceutical (pharma) companies to rethink strategy in their U.S. pursuits. The move to bundled payments, accountable care, comparative effectiveness research (CER), evidence-based medicine (EBM),1 and payments linked to performance are the direct result of regulatory and market pressures to reduce health costs without compromising safety and quality. For pharma companies, these trends represent a paradigm shift in the structure of the U.S. market and call for innovative approaches to commercialization and pricing. **In a new value-driven health care system, pharma companies will need to provide pharmaceuticals that demonstrate real, measurable value to stakeholders**. As a result, value-based pricing – the alignment of incentives between purchasers and manufacturers – is getting increased attention. In this Issue Brief, we summarize what is known to date about valuebased pricing and identify opportunities for additional exploration.

That's why, according to [ ], almost all of the significant innovations are made in Europe, and they have better overall healthcare outcomes.

US healthcare outcomes aren't better despite higher spending

Madhavan 17 Guru Madhavan [biomedical engineer and senior policy adviser. He conductsresearch at the National Academy of Sciencesand has been named a distinguishedyoung scientist by the World EconomicForum] 11-2017, "Making Medicines Affordable: A National Imperative," The National Academies of Science, Engineering, Medicine, https://www.nap.edu/resource/24946/11302017AffordableDrugsHighlights.pdf //DF

The trend of increasing spending on health care, including on biopharmaceuticals, is projected to con- tinue for the foreseeable future as the Baby Boomer generation ages. No other nation in the world approaches the level of U.S. health care expenditure, yet various studies indicate that many nations have healthier populations. The United States now ranks 25th in the world in life expectancy at birth, yet among the 10 nations with the largest gross domestic product (GDP), the United States spends about twice as much on health care as a fraction of GDP as the average of the other nine. Annual expenditures on biopharma- ceuticals in the United States now exceed a half trillion dollars, and prescription drugs are among the fastest- growing segments of health care spending. Research and development of new drugs, the lifeblood of the pharmaceutical industry and its contribution to health care, is also extremely costly. The canonical statement about the cost of a new drug—"The first pill can cost over a billion dollars while the second costs only a dime"—captures an important truth: New drugs are exceptionally expensive to develop, and failures are commonplace.

Price controls will also make drug development safer. Right now, their relentless quest for profits is leading them to overlook health risks of drugs (Whoriskey 12 at the Washington Post)

Peter Whoriskey, 11-24-2012, "As drug industry's influence over research grows, so does the potential for bias," Washington Post, https://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9_story.html (NK)

"We now have clear evidence from a large international study that the initial use of [Avandia] is more effective than standard therapies," a senior vice president of GlaxoSmithKline, Lawson Macartney, said in a news release. What only careful readers of the article would have gleaned is the extent of the financial connections between the drugmaker and the research. The trial had been funded by GlaxoSmithKline, and each of the 11 authors had received money from the company. Four were employees and held company stock. The other seven were academic experts who had received grants or consultant fees from the firm. Whether these ties altered the report on Avandia may be impossible for readers to know. But while sorting through the data from more than 4,000 patients, the investigators missed hints of a danger that, when fully realized four years later, would lead to Avandia's virtual disappearance from the United States: The drug raised the risk of heart attacks. "If you looked closely at the data that was out there, you could see warning signs," said Steven E.

Nissen, a Cleveland Clinic cardiologist who issued one of the earliest warnings about the drug. "But they were overlooked." A Food and Drug Administration scientist later estimated that **[2.] just one dangerously produced drug]** the drug **had been associated with 83,000 heart attacks and deaths.** Arguably the most prestigious medical journal in the world, the New England Journal of Medicine regularly features articles over which pharmaceutical companies and their employees can exert significant influence. Over a year-long period ending in August, NEJM published 73 articles on original studies of new drugs, encompassing drugs approved by the FDA since 2000 and experimental drugs, according to a review by The Washington Post. Of those articles, 60 were funded by a pharmaceutical company, 50 were co-written by drug company employees and 37 had a lead author, typically an academic, who had previously accepted outside compensation from the sponsoring drug company in the form of consultant pay, grants or speaker fees. The New England Journal of Medicine is not alone in featuring research sponsored in large part by drug companies — it has become a common practice that reflects the growing role of industry money in research. Years ago, the government funded a larger share of such experiments. But since about the mid-1980s, research funding by pharmaceutical firms has exceeded what the National Institutes of Health spends. Last year, the industry spent $39 billion on research in the United States while NIH spent $31 billion. The billions that the **[1.] drug companies** invest in such experiments help fund the world's quest for cures. But their **aim is not just public health. That money is also part of a high-risk quest for profits, and over the past decade corporate interference has repeatedly muddled the nation's drug science, sometimes with potentially lethal consequences.** Over a decade, controversies over blockbuster drugs such as Vioxx, Avandia and Celebrex erupted amid charges that the companies had shaped their research to obscure the dangerous side effects. When the company is footing the bill, the opportunities for bias are manifold: Company executives seeking to promote their drugs can design research that makes their products look better. They can select like-minded academics to perform the work. And they can run the statistics in ways that make their own drugs look better than they are. If troubling signs about a drug arise, they can steer clear of further exploration. Maybe the most widely reported research controversy arose over the arthritis drug Vioxx, which had been featured positively in a NEJM article. The article reported the results of a trial that was funded by Merck and was co-written by two company researchers.

Lower profit means less incentive to conduct this risky research and switch to value (Baker 13 at the CEPR)

Baker, CEPR, 2013, "Reducing Waste with an Efficient Medicare Prescription Drug Benefit"
http://cepr.net/documents/publications/medicare-drug-2012-12.pdf (NK)

It is worth briefly discussing an objection that the pharmaceutical industry often makes to allowing Medicare to negotiate lower drug prices. It claims that the high prices in the United States provide much of the revenue and incentive to finance research into new drugs. While it is true that the profits from patent monopolies do provide an incentive to conduct research, they also provide an incentive to market drugs for uses that may be inappropriate and to misrepresent evidence on the quality and safety of drugs. This is the reason that there have been so many scandals in recent years such as the one involving Vioxx, where it is alleged that Merck concealed evidence that the drug increased the risks of heart attacks and strokes. 6 The perverse incentives created by patent monopolies also have led to the corruption of scientific research, which is a widely recognized problem among medical researchers.7 **Lower profit margins will reduce the incentive for this sort of corruption, which** presumably **means that** we can anticipate that the **drug companies will be more honest in marketing their drugs and revealing their research findings**. There are alternative mechanisms for supporting biomedical research that are less susceptible to the same sort of corruption. The government already funds $30 billion a year in biomedical research through the National Institutes of Health. While most of this research is focused on more basic science, there is no reason in principle that additional funding could not be directed toward developing drugs and bringing them through the Food and Drug Administration's approval process.8

2. Decreasing big pharma mergers.

Mergers are increasing now because companies are awash with cash (Fisher 15)

Fisher 15 Nicole Fisher, 4-22-2015, "Are M&A Replacing R&D In Pharma?," Forbes, https://www.forbes.com/sites/nicolefisher/2015/04/22/are-ma-replacing-rd-in-pharma/ //DF

A $15.8 billion dollar bidding war for Salix Pharmaceuticals just came to a dramatic end as Valeant Pharmaceuticals beat Endo International with an all-cash offer for the company. While some sectors would view this as game changing, **the pharmaceutical industry is beginning to see [mergers]** this **as status quo**. In 2015, **pharma deals have**, "**reached $59.3 billion, a 94% increase over that same period a year ago**, and the highest value for this stage in any year since 2009," according to Thompson Reuters. Given the flurry of merger and acquisition activity in the life science space over the past few years, this is not surprising to many pharmaceutical regulatory and compliance attorneys. After having lived through three acquisitions in 18 months, a California lawyer recently joked that the same company has laid her off twice without her ever having worked for it. The spike in mergers and acquisitions in pharma is beginning to make the industry look more like a pyramid where more companies develop drug molecules at the bottom than commercialize drug products at the top. This shift has many in the space wondering what exactly is happening and how it will affect health care in the short and long-term. Biotechnology Changing Pharma Research Landscape With many best-selling products recently losing market exclusivity and advances in biotechnology undercutting the entire concept of a drug, pharma is being pushed to fill product pipelines faster than individual R&D departments can develop new compounds or transform them for commercialization. For example, A drug used to be conceived as a small-molecule, chemically-manufactured product. These pharmaceuticals were made more effective during late 20th century, and now the current market for their development is concentrated in finding novel doses, administrations or uses for existing drugs. Today, large-molecule biologics are the real center of drug innovation, and medical devices are even competing with traditional drug therapies.

Mergers are costly and will decrease with less profit

Stiebale 16 Justus Haucapjoel Stiebale, 8-3-2016, "Research: Innovation Suffers When Drug Companies Merge," Harvard Business Review, https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge //DF

These new insights from our research and the forthcoming work of other scholars are likely to affect the decision-making of antitrust authorities. We believe that potential effects on innovation activities will very soon become a much more important factor in the approval or rejection of M&As in the future. For now, drug company executives should take notice. **Mergers and acquisitions are extremely costly, even when they're not approved**. Senior leaders should take into greater consideration how a potential merger will affect innovation at the combined company and at its rivals. Regulators may no longer be so quick to approve mergers between companies with overlapping drug pipelines. By the same token, if the merging parties can show that R&D synergies may increase their capabilities to be innovative, or induce their rivals to innovate, antitrust authorities might be more willing to say yes to the acquisition.

Mergers decrease r&d because they are expensive and lower competition

LaMattina 11 John L. LaMattina [former President of Pfizer Global Research and Development, and is currently Senior Partner at Puretech Ventures, Boston], 2011 "The impact of mergers on pharmaceutical R&D," Nature Reviews //dF

From a business perspective, mergers and acquisitions are often considered to be attractive as they remove duplication, reduce costs and produce synergies. Furthermore, in the early days of mergers in the pharmaceutical industry, organizations often described them as being part of a growth story. In these situations — for example, the merger of Bristol Myers with Squibb in 1989 — the R&D divisions were fused. Programme overlap was minimized and new projects were added, and major R&D cuts did not occur. This has changed radically in the past decade. **In major mergers today, not only are R&D cuts made, but entire research sites are eliminated**. Nowhere is this more evident than with Pfizer. Before 1999, Pfizer had never made a major acquisition. Over the next decade, it acquired three large companies — Warner-Lambert (in 2000), Pharmacia (in 2003) and Wyeth (in 2009) — and

multiple smaller companies, such as Vicuron, Rinat and Esperion (Supplementary information S1 (figure)). Over this time frame, to meet its business objectives (a euphemism for raising its stock price) Pfizer closed numerous research sites in the United States, includ- ing those at Kalamazoo, Michigan (formerly a site for Upjohn), Ann Arbor, Michigan (formerly a site for Warner-Lambert) and Skokie, Illinois (formerly a site for Searle). It has also recently announced the closure of the Sandwich site in the UK. These sites housed thou- sands of scientists, and many major drugs — such as atorvastatin (Lipitor), amlodipine (Norvasc) and silde- nafil (Viagra) — were discovered there. The same pat- tern has been observed after most of the mergers and acquisitions by other major pharmaceutical companies during the past decade. There is another key aspect to such cuts. Historically, the pharmaceutical industry has prided itself on invest- ing more in R&D (as a percentage of revenues) than any other industry. At times, companies have invested as much as 20% of top-line revenues into their pipeline. However, Pfizer now projects that in 2012 this figure will only be 11% (between US$6.5 and $7 billion). The extent of this decrease is further emphasized by com- parison with the pre-merger R&D expenses of Pfizer and Wyeth in 2008: $7.95 billion and $3.37 billion, respec- tively, and $11.3 billion in total. Other large pharma- ceutical companies have announced similar cuts in recent years.

Stiebale 16 Justus Haucapjoel Stiebale, 8-3-2016, "Research: Innovation Suffers When Drug Companies Merge," Harvard Business Review, https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge //DF

To be more precise, we analyzed 65 pharma mergers that were all scrutinized, but eventually approved, by the European Commission and also other jurisdictions. We wanted to know measurements of innovation (such as R&D spending and resulting patents) change after a merger for both the merging parties and for their rivals. What makes our study unique is that we compared firms' innovation activities not only before and after acquisitions, but we also compared those merging companies to firms in similar pharmaceutical markets without merger activities. Our results very clearly show that **R&D and patenting within the merged entity decline substantially after a merger**, compared to the same activity in both companies beforehand. Then we applied a market analysis, the same one used by the European Union in its models, to analyze how the rivals of the merging firms change their innovation activities afterward. On average, **[and] patenting and R&D expenditures of non-merging competitors** also **fell — by more than 20% — within four years after a merger**. Therefore, pharmaceutical mergers seem to substantially reduce innovation activities in the relevant market as a whole. What's the reason for this? At least for the mergers we looked at, acquirers often target firms that have a relatively similar patent portfolio. That means there's less competition for discovering and developing new therapies. If a non-merging rival is also researching similar therapies, that outside firm also now has one less competitior. It experiences a similar reduction in competition as the acquiring firm. So if these mergers have been reducing competition and the prospects for new life-improving and life-saving drugs, why are U.S. and European regulators approving them? It's not that authorities are unaware that mergers may reduce innovation incentives of competitors. As long ago as in 2000, an EU report on the merger between Glaxo Wellcome and SmithKline Beecham recognized that "competitors have also indicated that the operation as notified would discourage any tentative research and development attempts by third parties to develop anti-viral drugs." Still, innovation activities rarely play a decisive role in merger decisions.

We know this because they peak innovations happened when there were many companies

LaMattina 11 John L. LaMattina [former President of Pfizer Global Research and Development, and is currently Senior Partner at Puretech Ventures, Boston], 2011 "The impact of mergers on pharmaceutical R&D," Nature Reviews //dF

When people bemoan the poor productivity of the phar- maceutical industry at present, they often refer back to the heyday of new drug approvals by the US Food and Drug Administration (FDA): the 1990s. Indeed, in terms of the number of new drugs that were approved, this decade was more productive, with an average of 31 drugs per year between 1990 and 1999 (compared with 24 per year between 2000 and 2009), with a peak of 54 drugs in 1996. One possible contributory factor is that multiple entries in a single drug class (such as statins) were more economically viable at the time. However, another underlying factor contributing to the productivity observed in the 1990s was the large number of

pharmaceutical companies at that time. Many of the drugs that were approved in 1996 origi- nated from companies that no longer exist; indeed, out of the 42 members of the Pharmaceutical Research and Manufacturers of America (PhRMA) in 1988, only 11 (~25%) remain today (see Supplementary information S1 (figure)). The R&D portfolios of these companies, although differing in size, tended to be broader in scope than

More m&a and less r&d

Kaick 17 Alex Kacik, 12-28-2017, "The amount spent on meds has nearly doubled in the past 30 years as pharma profits soar.," Modern Healthcare, https://www.modernhealthcare.com/article/20171228/NEWS/171229930 //DF

Mergers and acquisitions in the pharmaceutical space have also been linked to rising drug prices. For both brand-name and generic manufacturers, expanding the size of their drug portfolio may improve their bargaining position with pharmacy benefit managers, which negotiate rebates with pharmaceutical companies on behalf of payers, process claims and negotiate tiered networks where the beneficiaries can fill prescriptions. But how that translates to cost to the consumer is hazy, given that there is no transparency into these negotiations. "The rebates never make their way to the provider or consumer," Knoer said. **While the number of mergers and acquisitions involving one of the largest 25 pharmaceutical companies more than doubled** from 2006 to 2015, **research and development spending has slowed**, which pharmaceutical companies often cite as a primary reason for higher prices. Worldwide company reported R&D spending, most of which went to drug development rather than research, increased slightly from $82 billion to $89 billion from 2008 to 2014, according to the report. "Companies are clearly making more profits—there is a lot of talk about innovation and that's why prices are so high, yet R&D spending hasn't increased very much," said Erin Fox, who directs the Drug Information Center at the University of Utah.

Link – R/T $2.6 Billion

This study was produced by the pharma industry and over inflates the costs of drug production

Light 12 Donald W Light [Department of Psychiatry, University of Medicine and Dentistry of New Jersey], 8-7-2012, "Pharmaceutical research and development: what do we get for all that money?," BMJ, doi: 10.1136/bmj.e4348 //DF

Although the pharmaceutical industry emphasises how much money it devotes to discovering new drugs, little of that money actually goes into basic research. Data from companies, the United States National Science Foundation, and government reports indicate that companies have been spending only 1.3% of revenues on basic research to discover new molecules, net of taxpayer subsidies.23 More than four fifths of all funds for basic research to discover new drugs and vaccines come from public sources.24 Moreover, despite the industry's frequent claims that the cost of new drug discovery is now $1.3bn (£834m; €1bn),25 this figure, which comes from the industry supported Tufts Center,26 has been heavily criticised. **Half that total comes from estimating how much profit would have been made if the money had been invested in an index fund of pharmaceutical companies** that increased in value 11% a year, compounded over 15 years.26 While used by finance committees to estimate whether a new venture is worth investing in, **these presumed profits** (far greater than the rise in the value of pharmaceutical stocks) **should not be counted as research and development costs on which profits are to be made. Half of the remaining** $0.65bn **is paid by taxpayers through company deductions and credits**, bringing the estimate down to one quarter of $1.3bn or $0.33bn.27 **The** Tufts **study authors report that their estimate was done on the most costly fifth of new drugs** (those developed in-house), **which** the authorsreported **were 3.44 times more costly than the average**, reducing the estimate to $90m. **The median costs were** a third less than the average, **or $60m. Deconstructing other inflators would lower the estimate of costs even further.**

Link – R/T Biotech Startups

Price controls wouldn't stifle innovation from startups because they don't spend a lot to develop drugs (Goozner 18 at Modern Healthcare)

Goozner 18 Merill Goozner [Editor of Modern Healthcare from December 2012 to April 2017. As Editor Emeritus, he continues to write a weekly column, participate in Modern Healthcare education, events and awards programs and provide guidance on coverage related to healthcare transformation issues], 11-1-2018, "Drug price controls? A good idea, but don't bet on it," Modern Healthcare, https://www.modernhealthcare.com/article/20181101/NEWS/181109993 //DF

Don't look for the next Congress to enact this either. Most Democrats, like their Republican colleagues, take tons of pharmaceutical industry cash. Once the heat of the campaign dissipates, a majority in both parties will remain susceptible to their main argument that high prices are necessary to promote innovation. That's the big lie, of course. The drug industry spends just one-fifth of its revenue on research and development and a significant portion of that is devoted to coming up with drugs that are no improvement to drugs already on the market. It spends twice as much on marketing and overhead and takes home more in profits than it spends on R&D. The reality is that innovation doesn't come from pouring more money into the coffers of the pharmaceutical industry. If that were true, we would have had a cure for cancer two generations ago. Rather, **innovation comes from** the advance of medical science, which is slow, arduous and totally dependent on **government- and philanthropy-funded basic research. Most medical breakthroughs occur in NIH-funded labs. Those technologies are then transferred free of charge to biotech startups, which in turn sell them late in the development process to Big Pharma companies**. In some cases, the inventors make the leap to biotech early enough in the process that the NIH-funded institution doesn't even get royalties. And what does it cost to develop the new therapies? A recent study in JAMA Internal Medicine estimated that **biotech startups spend a quarter of what the pharmaceutical industry claims it costs to bring a new therapy to market**. Big Pharma won't be the only industry deploying platoons of lobbyists to emasculate the administration's proposal. Physicians and hospitals will also challenge the plan since it scraps tying their reimbursement to the price of drugs (the average sales price plus 6% formula). That's long overdue since the current formula creates an unhealthy incentive to use pricier drugs when cheaper alternatives are available. After all, 6% of a $10,000-a-month drug is 10 times more lucrative than 6% of a $1,000-a-month drug.

IL – R/T Orphan Drugs

They get a 50% tax deduction (Angell - 45)

The government makes it easier for companies to develop these drugs, so they wouldn't be the first cut

Investopedia 18 Investopedia, 10-28-2018, "How does government regulation impact the drugs sector?,"
https://www.investopedia.com/ask/answers/032315/how-does-government-regulation-impact-drugs-sector.asp //DF

This process is a significant barrier to entry in the pharmaceutical industry. As a result, mergers and acquisitions (M&As) are common. New companies and larger companies both benefit from mergers. Big companies take advantage of opportunities to acquire profitable new products and small companies benefit from the financial boost and expertise of a large partner. Because of the regulatory expense, companies have a strong incentive to offer support to only the most promising drugs. M&As usually happen only after new drugs begin to show promise in trials. Orphan Drugs Some drugs benefit from additional government incentives. **Orphan drugs receive special consideration from the FDA in order to encourage pharmaceutical companies to develop treatments for rare diseases**. Incentives for the development of orphan drugs **include quicker approval time and potential financial assistance for development**. Companies are often permitted to charge substantial prices for orphan drugs, making them more profitable than they would be without government intervention. **As a result, the development of orphan drugs continues to grow at a faster rate than the development of traditional pharmaceuticals**. Overall, government regulation of the drug sector has resulted in a longer, more-expensive product development process that favors treatments for rare illnesses. All approved drugs have been rigorously tested by the FDA to protect consumers from harmful or ineffective treatments. This process is designed to occur over a long period of time to ensure that only the safest and most effective drugs arrive on the market.

Extras

Gagnon, York University, 7 January 2008, "Big Pharma Spends More On Advertising Than Research And Development, Study Finds.". www.sciencedaily.com/releases/2008/01/080105140107.htm (NK)

A new study estimates the U.S. pharmaceutical industry spends almost twice as much on promotion as it does on research and development, contrary to the industry's claim. **The U.S. pharmaceutical industry spent 24.4% of the sales dollar in 2004 on**

promotion, versus 13.4% for research and development, as a percentage of US domestic sales of US$235.4 billion. The study's findings supports the position that the U.S. pharmaceutical industry is marketing-driven and challenges the perception of a research-driven, life-saving, pharmaceutical industry.

3. Investment into other healthcare tech that makes drugs more effective

New healthcare technologies are reducing the cost of drug development

Fisher 15 Nicole Fisher, 4-22-2015, "Are M&A Replacing R&D In Pharma?," Forbes, https://www.forbes.com/sites/nicolefisher/2015/04/22/are-ma-replacing-rd-in-pharma/ //DF

According to recent literature, it may now costs an average of $2.5 billion to get a novel drug to market. Further, very few products ever hit blockbuster status - $1 billion in annual sales – making the investment for R&D increasingly costly for companies. Despite the claims that it takes billions to bring a drug to market, new technologies such as Molecular modeling and computer assisted drug design and DNA sequencing are allowing research to occur at lower costs, especially in the early stages. A small team of the right scientists, for example, can advance an investigational product into Phase II clinical trials far less expensively today than ever before. This means that Big Pharma companies don't necessarily have an advantage over lean start-ups during the early stages of the product lifecycle. However, even in the case that a small company has an approved drug, it isn't any easier to commercialize products in the United States. Commercialization Trumped By M&A Growth through M&A is not a new concept. It is a model that formerly small – to mid-sized pharma companies like Gilead, Valeant, and Activis have pursued aggressively over the past decade. While certain changes may have made successful research more feasible at smaller firms, they have not made commercialization any less challenging.

Only doing these deals with European countries (Pollack - New York Times)

Andrew Pollack, 7-14-2007, "Pricing Pills by the Results," New York Times, https://www.nytimes.com/2007/07/14/business/14drugprice.html (NK)

Drug companies like to say that their most expensive products are fully worth their breathtaking prices. Now **one company is putting its money where its mouth is — by offering a money-back guarantee. Johnson & Johnson has proposed that Britain's national health service pay for the cancer drug Velcade, but only for people who benefit from the medicine, which can cost $48,000 a patient**. The company would refund any money spent on patients whose tumors do not shrink sufficiently after a trial treatment. The groundbreaking proposal, along with less radical pricing experiments in this country and overseas, may signal the pharmaceutical industry's willingness to edge toward a new pay-for-performance paradigm — in which a drug's price would be based on how well it worked, and might be adjusted up or down as new evidence came in. "I think payers will say, 'If the product works and it creates value, we will reward you for it,' " said Anthony Farino, a pharmaceutical industry consultant at PricewaterhouseCoopers. " 'If not, we won't reward you.' " It is far too soon to tell whether such a pricing paradigm can actually work, in particular because it can be difficult in many cases to measure how well a drug is working. And the approach would probably be most feasible in countries, like Britain, where the government is the primary payer. Continue reading the main story But even here in the United States, Medicare and private insurers are already experimenting with new ways to create cost-justified payment systems for medical treatments. The potential benefits might go beyond simply saving money. Pay-for-performance pricing could make it easier for patients and their doctors to try expensive treatments without busting the bank or forcing insurers to make all-or-nothing decisions about reimbursement. That was the rationale behind another experiment that is already under way in Britain. **Four makers of multiple sclerosis drugs have agreed eventually to lower the prices of their drugs — which can currently cost as much as $18,000 a year — if the medicines do not fully meet expectations. GlaxoSmithKline also says it has made similar agreements with two European governments**, although it declined to identify either the countries or the drugs involved. Such "risk sharing" deals, as they are being called, would be harder to arrange in this country. "There's no way we could ask for it and have any leverage," said Dr. Lee N. Newcomer, senior vice president for oncology at the large American insurance company UnitedHealthcare. He said that state regulations and marketplace pressures make it virtually impossible for an insurer to refuse to pay for a drug that has been approved by the Food and Drug Administration, regardless of its price. Yet UnitedHealthcare is trying a risk-sharing experiment with Genomic Health, a company that sells a $3,460 genetic test meant to help determine whether a woman with early-stage breast cancer would benefit from chemotherapy.

Keyhani, 2010, "US Pharmaceutical Innovation in an International Context," National Institute of Health, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866602/ (NK)

Canada uses a mixture of measures to control drug prices in different provinces.24 Denmark, Germany, the Netherlands, Italy, Norway, Spain have all implemented a form of reference drug pricing.1 Belgium, Switzerland, Sweden, Italy, Austria, and Finland set the manufacturer price, the reimbursement price, or both.1 Although many researchers20,21,25 have speculated that reference drug pricing in the United States would have dire consequences for innovation, our data suggest that the pharmaceutical innovation of countries with reference drug pricing is more or less what one would expect given their prescription drug spending or even the general size of their economies. Many countries with significant price regulation were important innovators of pharmaceuticals; therefore, our data suggest that country-specific pricing policies probably do not affect country-specific innovation. For example, although prices in the United Kingdom are much less than are prices in the United States, the industry continues to be very profitable and innovative.11 In Canada, income from domestic sales of brand name companies is, on average, about 10 times greater than is research and development costs, even in the face of prices that are approximately 40% lower than in the United States.11 In addition, **companies in the United Kingdom invest proportionately more revenue from domestic sales into research and development activity than do their US counterparts**.11 Despite the above average profitability of US-based companies,26the higher prices paid by US consumers are not rewarded by more than expected domestic innovation. US consumers pay disproportionately higher prices for brand name drugs,6 but the United States is not disproportionately innovative. Our study had several limitations that deserve comment. Fifty-eight drugs were excluded from the analyses involving patents because they could not be assigned to any particular country. For these drugs, we determined the FDA applicant and investigated whether we could substitute the country where the FDA applicant resided as the innovator country. We searched the Securities and Exchange Committee filings and found that the FDA applicant for most of these NMEs was a company with international subsidiaries and was not exclusive to 1 country.

Evidence of this is China, who is the world's second biggest pharmaceutical market, and is also the fastest growing pharmaceutical market, despite price regulations (Tan - CNBC)

Huileng Tan, 4-1-2018, "China's pharmaceutical industry is poised for major growth," CNBC, https://www.cnbc.com/2018/04/19/chinas-pharmaceutical-industry-is-poised-for-major-growth.html (NK)

China, the world's manufacturing powerhouse, is moving toward a more value-add economy and there's one major industry where the country could dominate both as a maker and consumer: health care. That's because China rocketed into its position as the world's second-largest economy in a matter of decades under a strict one-child policy, contributing to a rapidly aging society with rising medical needs. According to health-care information company IQVIA, **China was the world's second-largest national pharmaceutical market in 2017** — worth $122.6 billion. **It was also the biggest emerging market for pharmaceuticals with growth tipped to reach $145 billion to $175 billion by 2022**. "The development of China's healthcare industry is still in its infancy, evidenced by its low healthcare expenditure as a percentage of GDP ... and a smaller proportion of its population aged 60 and over," DBS analysts Mark Kong and Chris Gao said in a recent note. "That implies plenty of room to grow because as the population ages, the demand for medicines will increase." There's still scope for growth, experts said, even though the Chinese pharmaceutical market's compound annual growth rate from 2013 to 2017 was 9.4 percent.

1. Many drug companies are making huge profits.

US Companies get far more profit off of the drugs they sell than is necessary to fund R&D (Yu - Health Affairs)

Nancy Lu, 3-7-2017, "R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices," Health Affairs, https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/ (NK)

We found that the premiums **pharmaceutical companies earn from charging substantially higher prices for their medications in the US compared to other Western countries generates substantially more than the companies spend globally on their research and development.** This finding counters the claim that the higher prices paid by US patients and taxpayers are necessary to fund research and development. Rather, t**here are billions of dollars left over even after worldwide research budgets are covered.** To put the excess revenue in perspective**, lowering the magnitude of the US premium to a level where it matches global R&D expenditures across the 15 companies we assessed would have saved US patients, businesses, and taxpayers approximately $40 billion in 2015**, a year for which the Centers for Medicare and Medicaid Services (CMS) reported that total US spending on pharmaceuticals was $325 billion. Although we can conclude that premium pricing exceeds what is needed to fund global R&D, our analysis does not address whether prices in European countries or in the US are appropriate. We do know that all of the European countries included in

our analysis use pharmacoeconomic analyses in their price negotiations, while this cannot be said of the US. Importantly, our analysis cannot inform the question whether or not it is appropriate for US patients, taxpayers, and businesses to bear the burden of funding pharmaceutical research for the world.

We know that high drug prices don't lead to more innovation in two areas.

Kantarjin 16 Hagop Kantarjian [chairman of the Leukemia Department at the University of Texas MD Anderson Cancer Center and a Baker Institute scholar for health policies at Rice University], 12-12-2016, "The Harm of High Drug Prices," US News & World Report, https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-high-drug-prices-to-americans-a-continuing-saga //DF

Under criticism, the drug industry repeats the same arguments: 1) high cost of research and development; 2) benefit justifies price; 3) market forces; and 4) regulating prices stifles innovation. But all four arguments lack validity. The cost of research and development is only 10 percent of the $1-2.6 billion figure that is claimed in industry-supported studies. More than 50 percent of important discoveries are made in independent academic centers, funded by taxpayers, and 85 percent of basic research is conducted in academic centers. The drug industry spends 1.3 percent of its budget on basic research, but 20-40 percent on advertisements and related activities. Some studies show no relationship between drug benefits and price. Drug companies enjoy monopoly-like conditions that discourage competition based on price. Finally, innovation is driven by independent investigators who will continue to conduct research even if drug prices fall.

Price controls definitely wouldn't reduce profitability of these companies

Engelberg 15 Alfred B. Engelberg [retired intellectual property lawyer and philanthropist. During his legal career, he was a patent examiner at the US Patent Office, a patent trial attorney at the US Department of Justice, and a member of the New York City law firm of Amster, Rothstein and Engelberg. As counsel to the generic drug industry, he played a major role in drafting the Hatch-Waxman Act of 1984, which created the modern generic drug industry], 10-29-2015, "How Government Policy Promotes High Drug Prices," HealthAffairs, https://www.healthaffairs.org/do/10.1377/hblog20151029.051488/full/ //DF

Why does Congress, in the face of outrageous drug prices, continue to advance laws like the 21st Century Cures Act which bestow even more monopolies on the pharmaceutical industry? Quite simply, the pharmaceutical lobby has used its money and influence to sell the false notion that high drug prices and monopolies are necessary to support the high cost of research. Yet public financial data shows that high drug prices simply produce high profits! For decades, the pharmaceutical industry has been one of the most profitable industries in America enjoying a median return on assets which is two to three times higher than the median return for all Fortune 500 companies. In 1984, when the Hatch-Waxman Act enabled an expedited FDA approval process for generic drugs, the market capitalizations of Merck & Pfizer were each less than $7 billion-$16 billion in 2015 inflation-adjusted dollars. Their market capitalizations are now more than 10 times that amount. Where Does Industry Invest? **Annual industry expenditures on research have averaged less than 15 percent of sales and have less impact than that on profit because of the tax benefits associated with research spending**. The industry's enormous profits are what remains after all of its research and marketing expenses which is why the industry is awash in cash. Pfizer now holds $74 billion in unrepatriated profits overseas and Merck holds $60 billion – enough to fund their respective annual research budgets for 10 years. Meanwhile, taxpayers are spending $30 billion a year on basic biomedical research the benefit from which flows to the pharmaceutical industry free of charge. Under current law, ownership of the patents on drugs discovered with taxpayer money is given away to the academic institutions that discover them. They license those patents to the pharmaceutical industry in exchange for the payment of a royalty which the public actually pays since the royalty increases the price charged for a drug. Federal law essentially socializes the cost of drug discovery while privatizing the profits since it does nothing to limit the prices that can be charged or the profits that can be earned from drugs discovered at public expense. In 1984, I represented the Generic Pharmaceutical Industry Association in the negotiations with Congress and PhRMA which sought to strike a balance between the pharmaceutical industry's demand for greater incentives to invest in innovation and

the public's need for low-cost medicines. The deal which was struck then has not withstood the test of time. The monopolies created by Hatch-Waxman and subsequent legislation providing 12 years of exclusivity for biologic drugs clearly went too far in compensating the pharmaceutical industry at the public's expense.

This is proved by a JAMA study which found that half of the drugs approved by the FDA had no tangible health benefits (Open Markets)

Open Markets, "High Drug Prices and Monopolies", 2015, https://openmarketsinstitute.org/explainer/high-drug-prices-and-monopoly/ (NK)
Yet there is a problem with this argument. In recent years, the prices Americans pay for drugs have only soared higher, even as innovation in the pharmaceutical industry slackens. The average number of new drugs approved each year has declined since the 1960s. The drop-off has been particularly steep since 1996, when 54 new drugs came on line, compared to only 30 in recent years. Moreover, today's new pills typically have only modest, if any, proven therapeutic value over existing treatments. **As a study in the Journal of the American Medical Association found, nearly half of the drugs approved by the Food and Drug Administration between 2005 and 2011 lacked any tangible health benefits, such as prolonging life or relieving symptoms**. How is America managing to get the worst of all worlds when it comes to drugs? Many explanations trace to public policy changes that have led to the monopolization of the drug industry over the last generation. From the end of the WWII through the 1960s, Americans benefitted from an unprecedented parade of wonder drugs, from broad-spectrum antibiotics, steroids and antihistamines, to the first chemotherapies, and the oral contraceptive known as "the pill." Though there were complaints about affordability, most of these wonder drugs were reasonably priced by today's standards.

90 million of this drug is sold per year which has no health benefits (Epstein

David Epstein and Propublica, February 2017, "An Epidemic of Unnecessary Treatment," Atlantic, https://www.theatlantic.com/health/archive/2017/02/when-evidence-says-no-but-doctors-say-yes/517368/ (NK)
According to Vinay Prasad, an oncologist and one of the authors of the Mayo Clinic Proceedings paper, medicine is quick to adopt practices based on shaky evidence but slow to drop them once they've been blown up by solid proof. As a young doctor, Prasad had an experience that left him determined to banish ineffective procedures. He was the medical resident on a team caring for a middle-aged woman with stable chest pain. She underwent a stent procedure and suffered a stroke, resulting in brain damage. Prasad, now at the Oregon Health and Sciences University, still winces slightly when he talks about it. University of Chicago professor and physician Adam Cifu had a similar experience. **Cifu had spent several years convincing newly postmenopausal patients to go on hormone therapy for heart health—a treatment that at the millennium accounted for 90 million annual prescriptions—only to then see a well-designed trial show no heart benefit and perhaps even a risk of harm.** "I had to basically run back all those decisions with women," he says. "And, boy, that really sticks with you, when you have patients saying, 'But I thought you said this was the right thing.'" So he and Prasad coauthored a 2015 book, Ending Medical Reversal, a call to raise the evidence bar for adopting new medical standards. "We have a culture where we reward discovery; we don't reward replication," Prasad says, referring to the process of retesting initial scientific findings to make sure they're valid.

R/T Developing World

Link Defense

The price discounts haven't been large enough to give people access

Bosely 12 Sarah Boseley, 11-28-2012, "Big Pharma ups its game in providing drugs to people in poor countries," Guardian, https://www.theguardian.com/global-development/2012/nov/28/big-pharma-drugs-poor-countries //DF
Although there has been improvement and a greater willingness among companies to change their business practices, it is not yet enough. More companies are using tiered pricing – **offering a discount for poorer countries** – for a broader range of products, "**but it is unclear whether the price reductions are enough to meaningfully increase affordability**", says the report. Only five companies varied their pricing in 2010 but 12 did it this year. Yet

they do not always disclose the full extent of the reduction nor take account of mark-ups by sales agents within a country. The best performer on tiered pricing is Gilead Sciences, which makes some of the leading Aids drugs. GSK has fallen to second place for a number of reasons, including reducing prices in fewer countries than Gilead. More companies are researching and developing medicines for diseases of poor countries. Some now have as much as 20% of their pipeline – drugs they are in the process of researching which one day will get to market – devoted to them. But there are concerns that Big Pharma is not demonstrating real influence over the private contractors it now increasingly uses to carry out drug trials in the developing world. No company is publicly transparent about all the Contract Research Organisations (CROs) it employs, says the report. The foundation says companies must ensure they hold these CROs to account for ensuring the wellbeing of volunteers in trials and conducting the trial scrupulously. Only four companies – Merck and Co, Sanofi, GSK and Eisai – provided evidence to show that they could and would use disciplinary measures to ensure CROs carried out trials in a safe and ethical manner. "Access to medicine is a multi-faceted challenge and therefore responsibility for improving it lies with a number of different actors, but the pharmaceutical industry has a critical role to play. While the index shows it has made strides in many areas, companies that have sector-leading practices also show us there is more the industry can contribute," Leereveld said.

They can't pay for expensive medications

Wagner 04 Judith L. Wagner [Institute of Medicine], 2004, "INTERNATIONAL DIFFERENCES IN DRUG PRICES," Annual Review of Public Health, https://www.annualreviews.org/doi/pdf/10.1146/annurev.publhealth.25.101802.123042 //DF

The weight of the evidence suggests that residents of the United States may pay more of the manufacturer's share of the cost of single-source drugs than do residents of certain other high-income countries, but the differences are not as large as commonly claimed by critics of differential pricing and may be concentrated in buyers who have no insurance. Health plans in the United States have used mechanisms similar to those applied by national governments to obtain price concessions from manufacturers. U.S. health plans may be hindered by the Medicaid "best price" law, however, which effectively limits their ability to bargain with drug makers for rebates on drugs with close therapeutic competitors. **Low-income countries** are in a special position. **The vast majority** of their residents **are unwilling to pay for effective drugs that are widely available in high-income countries simply because they are unable to pay for them**. For those countries, active price discrimination by manufacturers, buttressed by political acceptance of such pricing strategies by rich countries and rigid enforcement of separate markets, is a potential solution to the problem of access to the most effective single-source drugs in low-income countries.

Big pharma doesn't make drugs affordable for two reasons

1. Not enough people can pay for it to make it economically viable (Wagner 04 at the Institute of Medicine)

Wagner 04 Judith L. Wagner [Institute of Medicine], 2004, "INTERNATIONAL DIFFERENCES IN DRUG PRICES," Annual Review of Public Health, https://www.annualreviews.org/doi/pdf/10.1146/annurev.publhealth.25.101802.123042 //DF

As the impact of HIV/AIDS, malaria, tuberculosis, and other diseases on the lowest-income countries has become impossible to ignore, governments, international agencies, nongovernmental organizations, and industry have begun to address how to make highly effective drugs available at an acceptable cost.13 There are other hurdles in getting such drugs to those who need them most, such as the lack of social infrastructure, including adequate health delivery systems. These hurdles are becoming increasingly important because for certain highly visible diseases the cost of the drug itself is unlikely to remain the principal impediment to treatment for much longer, as drug companies negotiate with international organizations to provide their drugs at low cost while protecting their pricing structures in high-income countries. Some diseases endemic to low-income countries are rare in high-income nations. **The potential market for future therapies is therefore small, and private R&D is simply not pursued for many such diseases** (31). Offering low prices to low-income countries cannot solve the problem because there are no products available on the market. Rather, the problem is one of inadequate incentives for the private sector to engage in R&D for such drugs. A recently announced initiative of Medicins Sans Frontier, the World Health Organization, foundations, and drug companies, called Drugs for Neglected Diseases, will fund investments in R&D for such drugs (19).14 The success of such an effort will depend on the ability to find sources of R&D subsidy in the governments and institutions of high-income countries.

2. Companies are worried that super low-price drugs will be resold cheaply in the U.S. (Wagner furthers)

Wagner 04 Judith L. Wagner [Institute of Medicine], 2004, "INTERNATIONAL DIFFERENCES IN DRUG PRICES," Annual Review of Public Health, https://www.annualreviews.org/doi/pdf/10.1146/annurev.publhealth.25.101802.123042 //DF

As discussed above, manufacturers of single-source drugs should be willing to charge lower prices in low-income countries. Although some single-source drugs have been made available for free or at nominal charge to developing countries with high endemic rates of diseases such as HIV/AIDS and tuberculosis (15), manufacturers of single-source drugs are reluctant to offer vastly lower prices across the wider spectrum of drugs. For countries with extreme rates of poverty, anything but very low prices would render single-source drugs unavailable to all but the few wealthy residents. **The principal impediments to low prices are the fears of the drug companies that a resale market would develop across national borders from low-income countries to high-income countries** or that political pressures would develop in high-income countries to demand the lower prices given to the low-income countries (20). These fears may be justified given the history in the United States of consumer groups and policy makers questioning the need for high markups on production costs (27) and calling for relaxation of rules governing cross-border trade in pharmaceuticals (24, 28).

Link – R/T Reduce Sales

If they are selling the drugs now then they are profitable, so they wouldn't stop because of an unrelated decision in the U.S.

Impact – R/T Less Innovation

Companies aren't developing drugs for diseases in the developing world

Tomasz Pierscionek [doctor specialising in psychiatry. He was previously on the board of the charity Medact, is editor of the London Progressive Journal], 11-2-2018, "Big pharma limiting access to drugs in developing world," RT International, https://www.rt.com/op-ed/378403-big-pharma-world-medicine-drugs/ //DF

An issue affecting both poor and wealthy nations alike is insufficient R&D funding to develop medicines that provide low financial returns, but are still necessary to treat diseases. Antibiotics are one example. Treatments for serious infectious diseases are another. A 2016 UN report entitled Promoting Innovation and Access to Health Technologies states: "Experts warn that drug-resistant viruses, bacteria, parasites and fungi could cause 10 million deaths a year worldwide by 2050… Meanwhile, neglected **tropical diseases** (NTDs) **continue to receive inadequate funding for R&D** and access to health technologies… The situation is driven by the relatively low purchasing power of people disproportionately affected by such conditions." The report advocates striking a "new deal to close the health innovation and access gap," while taking note of the contention between the "right to health on the one hand, and intellectual property and trade on the other." Malebona Precious Matsoso, director general of the South African National Department of Health, states that "**with no market incentives, there is an innovation gap in diseases that predominantly affect neglected populations,** rare diseases and a crisis particularly with antimicrobial resistance, which poses a threat to humanity." Christian Wagner-Ahlfs of the Federal Coordination of Internationalism (also known as BUKO), comprising 130 German campaign groups intent on scrutinizing the practices of the German pharmaceutical industry in developing nations, acknowledges that"so-called neglected diseases are typical for poor countries... diseases that practically do not exist in Germany anymore and are thus of no interest to the commercially-oriented pharmaceutical industry... **There has been practically no research in this field for the past decades**." It seems pharmaceutical giants are becoming more cognizant of the negative publicity surrounding their practices and are seeking to improve their image. The Access to Medicines Index ranks the top 20 drug companies according to how much they are doing to improve access to medicines in the developing world. It includes markers such as their willingness to offer pharmaceuticals at reduced prices or whether they are conducting research into diseases prevalent in these nations. However, it remains uncertain if "the price reductions are enough to meaningfully increase affordability."

Bosely 12 Sarah Boseley, 11-28-2012, "Big Pharma ups its game in providing drugs to people in poor countries," Guardian, https://www.theguardian.com/global-development/2012/nov/28/big-pharma-drugs-poor-countries //DF

Although there has been improvement and a greater willingness among companies to change their business practices, it is not yet enough. More companies are using tiered pricing – offering a discount for poorer countries – for a broader range of products, "but it is unclear whether the price reductions are enough to meaningfully increase affordability", says the report. Only five companies varied their pricing in 2010 but 12 did it this year. Yet they do not always disclose the full extent of the reduction nor take account of mark-ups by sales agents within a country. The best performer on tiered pricing is Gilead Sciences, which makes some of the leading Aids drugs. GSK has fallen to second place for a number of reasons, including reducing prices in fewer countries than Gilead. **More companies are researching and developing medicines for diseases of poor countries.** Some now have as much as 20% of their pipeline – drugs they are in the process of researching which one day will get to market – devoted to them. **But** there are concerns that **Big Pharma is not demonstrating real influence over the private contractors it** now increasingly **uses to carry out drug trials in the developing world.** No company is publicly transparent about all the Contract Research Organisations (CROs) it employs, says the report. The foundation says companies must ensure they hold these CROs to account for ensuring the wellbeing of volunteers in trials and conducting the trial scrupulously. **Only four companies** – Merck and Co, Sanofi, GSK and Eisai – **provided evidence to show that they could and would use disciplinary measures to ensure CROs carried out trials in a safe and ethical manner.** "Access to medicine is a multi-faceted challenge and therefore responsibility for improving it lies with a number of different actors, but the pharmaceutical industry has a critical role to play. While the index shows it has made strides in many areas, companies that have sector-leading practices also show us there is more the industry can contribute," Leereveld said.

R/T Generics

Not affordable damn

Michael Alkire, 3-21-2016, "Unpacking Drug Price Spikes: Generics,"Health Affairs, https://www.healthaffairs.org/do/10.1377/hblog20160321.054028/full/ (NK)

It should be noted that one of the first things some generics manufacturers do when they find themselves in a monopoly or duopoly position is steer clear of the competitive friction inherent in the group purchasing organization (GPO) contracting process, which leverages the combined purchasing power of hospitals and health systems to advocate for lower pricing on high-quality products. Instead, these manufacturers thrive on cornering the market and then holding it hostage. Case in point: According to a Premier analysis, **price increases for the top 20 non-GPO contracted generic drugs (in terms of money spent annually) increased on average by 413 percent over the three-year period 2013 through 2015, with some price spikes into the thousands of percent**. Moreover, only one or two manufacturers existed in all but one instance. In contrast, the price of the top 20 Premier GPO-contracted generics with the highest member spend *decreased* on average by 8 percent during this period.

R/T Politics DA

Link Turn

Price controls will slash pharma company profits and destroy their lobbying strategies

Stan Finkelstein [M.D. Senior Research Scientist at MIT], 2008, “Reasonable Rx: Solving the Drug Price Crisis,” Pearson Education, (39-40) //DF

The pharmaceutical industry and the U.S. government are closely entwined, and the industry–particularly since the 1960s–works diligently to develop and influence government rules on safety, efficacy, and marketing to its advantage. Lobbyists for the major drug companie are no strangers to the halls of power in Washington, and political contributions from the industry fuel elections from coast to coast. And why not? **The fortunes of the pharmaceutical industry are tied closely to what**

government does, and the high earnings of drug companies make these investments in political influence possible. As described earlier, the U.S. government's involvement with medications goes back to the 1906 *Pure Food and Drugs Act*. But it was during the Great Depression that federal regulation of the drug industry began to make a significant mark. The New Deal philosophy that industries need regulation to operate properly had a direct impact on drug companies. In 1993, Congress saw a first draft of what eventually became the 1938 *Federal Food, Drug* and *Cosmetic Act*, one of many so-called "Second New Deal" measures designed to lift the United States out of its economic woes. Although the bill repeatedly came up for a vote, it always failed to muster enough support. It took yet another drug disaster to propel it to passage.

R/T Lobbying

1. Pharma influence is decreasing. Overwhelming opposition to high prices is meaning that pharma's money isn't doing them much good

JOHN JONES, 3-5-2018, "Big Pharma's lobbyists are losing despite their 'pass the buck' campaigns," TheHill https://thehill.com/opinion/healthcare/376699-big-pharmas-lobbyist-are-losing-despite-their-pass-the-buck-campaigns //DF

However, their polling numbers remain as low as before their advertising blitz began as Americans have overwhelmingly negative views of drugmakers and the pricing schemes of "Pharma Bro" Martin Shkreli and others who increased drug prices simply because they found that thoey could. The response from the drugmaker lobby has been to rollout slick public relations slogans like "Share the Savings" and "Let's Talk About Cost" that use fancy infographics in an attempt to move the conversation away from those setting the price of the drug (drug companies) to everyone else who uses or pays for their products, like employers, hospitals, pharmacy benefit managers, insurers, and others. This isn't surprising and certainly not unpredictable, but ignores the basic challenge facing drug companies: **no amount of money can change the fact that Republicans and Democrats know the problem is high drug prices and that drugmakers alone set those prices**. So **despite all this overwhelming lobbying and financial firepower, the question remains: Why are drugmakers losing**? In the recent budget bill, drugmakers were singled out by both parties to pay billions more in discounts to help seniors in the Medicare prescription drug benefit "donut hole." This comes as **states across the country are taking a harder look at drugmaker pricing schemes and passing legislation** in California and Nevada **that faced significant pushback from drug companies** (and their surrogates). Like the emperor who wore no clothes, drugmakers have confused politician's fear of speaking out against them with support for their pricing practices. It appears that most politicians will tolerate, but not believe in the drug lobby's messages or goals. Drug manufacturers have a number of options to alter public perception of their pricing strategies. They can assert that their products are a great value at any price but there is definitely a level where that argument fails. They can also compete on price and refrain from automatic pricing increases that obviously impact healthcare affordability. Instead, they peddle distracting narratives and government mandates that undermine federal programs and result in huge industry profit windfalls. One recent example would be to prevent brand discounts and rebates from being used to lower premiums for seniors. According to the White House's budget proposal, this mandate alone would cost the government about more than $42 billion and lead to higher premiums for Medicare beneficiaries. This is yet another distraction from the real problem of excessive drug pricing. If the drugmakers were truly concerned about affordability, the drug companies would simply reduce their prices. That would have a direct impact on the cost of health care to every American consumer. Simply put, drugmakers have failed to give policymakers the one thing they need: real solutions that reduce costs. They've offered no solutions that score savings — in fact, they all raise costs. Their relentless, ongoing PR blitz is simply an effort to pass the buck and direct attention away from their pricing strategies. **The drug lobby has underestimated the one politician, with whom their money and power doesn't carry much weight: President Trump**. It was only last year that he said drugmakers were "getting away with murder." If the record is any indicator, he still thinks Big Pharma is one of the creatures lurking in the swamp he intends to drain.

2. Loopholes wouldn’t apply to pharma

"FDA Basics > Is it legal for me to personally import drugs?," Food and Drug Administration, https://www.fda.gov/aboutfda/transparency/basics/ucm194904.htm //DF

In most circumstances, it is illegal for individuals to import drugs into the United States for personal use. This is because drugs from other countries that are available for purchase by individuals often have not been approved by FDA for use and sale in the United States. For example, if a drug is approved by Health Canada (FDA’s counterpart in Canada) but has not been approved by FDA, it is an unapproved drug in the United States and, therefore, illegal to import. FDA cannot ensure the safety and effectiveness of drugs that it has not approved. FDA, however, has a policy explaining that it typically does not object to personal imports of drugs that FDA has not approved under certain circumstances, including the following situation:

a. The US doesn't import drugs, we export them

3. Democrats won the house and they have na incentive to expand health care

R/T Public Opposition

Price controls actually play well with the general public and are used by politicians in populist appeals

Gleason 17 Patrick Gleason [vice president of state affairs at Americans for Tax Reform, and a senior fellow at the Beacon Center of Tennessee], 2-15-2017, "States Consider Imposing Drug Price Controls," Forbes, https://www.forbes.com/sites/patrickgleason/2017/02/21/states-consider-imposing-drug-price-controls/#406cbfc6639b //DF

This state legislative activity represents the continuation of a debate that featured prominently in the 2016 election cycle on two fronts. In addition to Bernie Sanders and Hillary Clinton touting their proposals for drug price controls throughout the primary and general election campaigns, there was an initiative on the California ballot, one of the most expensive ballot measure fights of 2016, which would’ve imposed drug price controls in the most populous state in the country. While both Clinton & Sanders were unsuccessful, and the California ballot measure was rejected by voters, **the debate over drug price controls carries on in at least eight 2017 state legislative fights. Politicians, predominantly Democrats, have found that touting drug price controls is an effective way to stoke populist passions on the campaign trail.** However, the facts and numbers demonstrate two things: 1) Prescription drugs are the wrong target for those who want to tamp down health care costs, and 2) Price controls, whether applied to drugs or other goods, do not work and have unintended negative consequences. Anyone who disagrees should look at what is going on in Venezuela right now.

R/T Cutting Medicare

Republicans cannot cut medicare without Democratic support; they have failed when they tried in the past

Kessler 18 Glenn Kessler [has reported on domestic and foreign policy for more than three decades], 10-23-2018 "Are Republicans seeking to 'get rid of Medicare, Medicaid and Social Security'?," Washington Post, https://www.washingtonpost.com/politics/2018/10/23/are-republicans-seeking-get-rid-medicare-medicaid-social-security/?utm_term=.271f63578869 //DF

In an Oct. 19 interview on the Terry Meiners radio program, McConnell again emphasized that the three programs were not coming under the knife unless both parties agreed to make changes: "Everybody knows those are the most secure programs in the federal government; nobody has to worry about any of those programs being in danger. ... And they won't be adjusted without some kind of bipartisan agreement. There's nothing on our agenda to do that unless we have an agreement with the Democrats that we can all sign on to." Meaghan McCabe, a spokeswoman for the Whitehouse campaign, defended the ad. "Congressional Republicans have been unequivocal about their goal to dismantle Medicare, Medicaid and Social Security. The enormous deficits being created under President Trump pose a serious threat to the future of these vital programs," she said. As examples, she pointed to plans advanced over the years to "turn Medicare into a voucher program," "to block-grant Medicaid," and "for privatizing Social Security, which would change the program beyond recognition." One could quibble whether these concepts would have eliminated these programs as opposed to changing their nature. Certainly, these are ideas that some Republicans have pushed from time to time, but all of them have failed. The idea of allowing the option of private investments in Social Security, in addition to regular Social Security accounts, was a major goal of President George W. Bush in 2005, but it did not even get a vote from a Republican-led Congress. The idea has been all but dead and gone for more than a decade, though Democrats still love to bring it up during campaign season. In fact, the failure of these Republican ideas would seem to reemphasize McConnell's point — that only a bipartisan solution would effectively reduce costs. Republican-only ideas have not gained much traction. "In the context of the full ad, Senator Whitehouse's message is that Republicans charged enormous tax cuts for the wealthy to the national credit card, and are now using that deficit as an excuse to dismantle critical programs that seniors rely on," McCabe argued. When we asked McCabe about McConnell's comments that any changes to entitlement programs would need to be bipartisan, she replied: "Senator McConnell's comments are an acknowledgment that Democrats currently hold enough seats in the Senate to prevent such cuts from going forward. That's why it's so important this November to protect every Democratic Senate seat and elect more members of Congress who will protect the vital benefits Americans have paid for over a lifetime of hard work."

Indicts

Mikel Berdud

The guy works at a pharma company

Lakdawalla 17 Darius Lakdawalla, [PhD, Chief Scientific Officer of Precision Health Economics (PHE) and an investor in its parent company, Precision Medicine Group. PHE provides consulting and research services to a variety of firms in the pharmaceutical, biotechnology, and health insurance industries] 2017 "What Do Pharmaceuticals Really Cost in the Long Run?" The American Journal of Measured Care, http://ajmc.s3.amazonaws.com/_media/_pdf/AJMC_08_2017_Lakdawalla%20(final).pdf //DF
Author Affiliations: University of Southern California (DL), Los Angeles, CA; Precision Health Economics (JPM), Los Angeles, CA; National Pharmaceutical Council (RD, KW), Washington, DC; Office of Health Economics (MB, AT), London, UK. Source of Funding: This study was funded by the National Pharmaceutical Council, a biopharmaceutical industry-funded health policy research organization that is not involved in lobbying or advocacy. Author Disclosures: Darius Lakdawalla is the Chief Scientific Officer of Precision Health Economics (PHE) and an investor in its parent company, Precision Medicine Group. PHE provides consulting and research services to a variety of firms in the pharmaceutical, biotechnology, and health insurance industries. Dr MacEwan is an employee of Precision Health Economics, a research consulting firm owned by Precision Medicine Group and compensated by the National Pharmaceutical Council to conduct the study. Dr Dubois and Ms Westrich are employees of the National Pharmaceutical Council. **Dr Berdud is an employee of the Association of British Pharmaceutical Industry (ABPI) and his company, the Office of Health Economics, received a research grant from ABPI**. Mr Towse is an employee of the Office of Health Economics, which receives research and consulting income from pharmaceutical companies.

Robert Dubois

The guy works at the National Pharmaceutical Council

Lakdawalla 17 Darius Lakdawalla, [PhD, Chief Scientific Officer of Precision Health Economics (PHE) and an investor in its parent company, Precision Medicine Group. PHE provides consulting and research services to a variety of firms in the pharmaceutical, biotechnology, and health insurance industries] 2017 "What Do Pharmaceuticals Really Cost in the Long Run?" The American Journal of Measured Care, http://ajmc.s3.amazonaws.com/_media/_pdf/AJMC_08_2017_Lakdawalla%20(final).pdf //DF
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Darius Lakdawalla

The guy is an employee and investor in a firm that provides consulting to pharma companies

Lakdawalla 17 Darius Lakdawalla, [PhD, Chief Scientific Officer of Precision Health Economics (PHE) and an investor in its parent company, Precision Medicine Group. PHE provides consulting and research services to a variety of firms in the pharmaceutical, biotechnology, and health insurance industries] 2017 "What Do Pharmaceuticals Really Cost in the Long Run?" The American Journal of Measured Care, http://ajmc.s3.amazonaws.com/_media/_pdf/AJMC_08_2017_Lakdawalla%20(final).pdf //DF
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John Lamattina

The guy was literally a pharma CEO

John Lamattina, 1-23-2018, "About Those Soaring Pharma Profits," Forbes, https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaring-pharma-profits/#7a06c0e43f9d //DF

The drug pricing debate that has been underway is certainly warranted. One can even argue that it has led to some positives, particularly with respect to greater transparency around the rationale for how new drugs are priced. In addition, companies are moderating annual price increases and pledging to raise prices only once a year. Furthermore, it is important to recognize that while a company may raise the price of a drug by 9.9%, that is the LIST price of the drug. The actual increase negotiated by insurance companies and other payers is a lot less. By all means, we should continue to find ways to make new prescription drugs more affordable. But let's not attack the industry with accusations of obscene profits. It is not true. *Thanks to Ms. Holly Campbell of PhRMA for these data. **I was the president of Pfizer Global Research and Development in 2007** where I managed more than 13,000 scientists and professionals in the United States, Europe, and Asia.

Joanna P. MacEwan

They works at a pharma company and is paid to write studies by the National Pharma Council

Lakdawalla 17 Darius Lakdawalla, [PhD, Chief Scientific Officer of Precision Health Economics (PHE) and an investor in its parent company, Precision Medicine Group. PHE provides consulting and research services to a variety of firms in the pharmaceutical, biotechnology, and health insurance industries] 2017 "What Do Pharmaceuticals Really Cost in the Long Run?" The American Journal of Measured Care, http://ajmc.s3.amazonaws.com/_media/_pdf/AJMC_08_2017_Lakdawalla%20(final).pdf //DF
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Michael Rosenblatt

Rosenblatt worked for a pharma company

Rosenblatt 17 Michael Rosenblatt,, 11-20-2017, "Reframing the Conversation on Drug Pricing," NEJM Catalyst, https://catalyst.nejm.org/reframing-conversation-drug-pricing/ //DF
Our nation must find a way to contain its health care costs, but it must not be at the expense of solutions that spur pharmaceutical innovation. As we have seen so often before — with hepatitis, heart disease, osteoporosis, and vaccines against infectious disease — those innovations themselves can help contain health care costs. And they do it by making all of us healthier — which, after all, should be our ultimate goal. **Dr. Rosenblatt served as Chief Medical Officer at Merck & Co. from 2009 to 2016**, and Mr. Termeer built the pioneering biotechnology company Genzyme from a tiny start-up in the early 1980s to a company worth more than $20 billion when it was acquired by Sanofi in 2011. Dr. Rosenblatt's views also have been informed by a long career in academic medicine, holding leadership positions at Tufts University School of Medicine, Harvard Medical School, and Beth Israel Deaconess Medical Center.

Merck is big and bad pharma

Hiltzik 18 Michael Hiltzik, 7-20-2018, "Merck joins the parade of Big Pharma companies offering Trump bogus cuts in drug prices," latimes, http://www.latimes.com/business/hiltzik/la-fi-hiltzik-merck-prices-20180720-story.html //DF

The big drug company Merck, scurrying to get on President Trump's good side on drug prices, announced Thursday a raft of initiatives aimed at showing its "commitment to responsible pricing." The company said it would lower the price of its hepatitis C treatment Zepatier by 60% and cut prices on six other drugs by 10%. Merck also pledged to not increase the average net price of its overall product portfolio by more than the inflation rate annually. Hold your applause. Not a single one of these initiatives will do anything significant to lower prices or even stem the rise in key products. The pledge on average net prices amounts to a huge loophole allowing Merck to hike the price at will of the drugs it really cares about. In other words, this is a bogus commitment, just like Pfizer's pledge a few days ago to roll back some of its recent price increases ... temporarily. The drug industry's desire to meet Trump's demand for lower prices is understandable. What company wants to be in the crosshairs of the tweeter-in-chief? But offering price cuts with imaginary impacts isn't going to cut it in the long run. "What Merck did was not of much benefit at all," says Walid Gellad, an expert at pharmaceutical policy and pricing at the University of Pittsburgh. "In fact, it's counterproductive if the industry is saying it wants to help but really is just pretending." Let's open up Merck's announcement to find the pretense. First, Zepatier. This product has been an also-ran in the shrinking market for hepatitis C cures, badly trailing Gilead Sciences' Harvoni and Sovaldi even though its list price of about $54,000 is almost half their list price. But the Gilead products have been heavily discounted, in part to meet the competition from Merck and AbbVie, the maker of another hepatitis C drug, and in part because these formulations are so effective as cures that the available patient pool is falling fast.

Henry Termeer

Terneer was literally an entrepreneur for a pharma company

Rosenblatt 17 Michael Rosenblatt,, 11-20-2017, "Reframing the Conversation on Drug Pricing," NEJM Catalyst, https://catalyst.nejm.org/reframing-conversation-drug-pricing/ //DF

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Adrian Towse

Pharma employee

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Kimberly Westrich

They work at the National Pharmaceutical Council

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