NEG BLOCKS

Weighing Overview

1. Scope: whole world vs America

2. Timeframe: prices will go down, but lost treatments will never come

3. Link-in:

a. Increases overall health care access

Rosenblatt 17 Michael Rosenblatt [Chief Medical Officer at Merck & Co. from 2009 to 2016, 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], 11-20-2017, "Reframing the Conversation on Drug Pricing," NEJM Catalyst, https://catalyst.nejm.org/reframing-conversation-drug-pricing///DF

Focusing on drug price alone ignores savings that effective drugs generate in other parts of the health system. In many cases, the cost to society of not having a treatment (that is, <u>the</u> direct and indirect <u>costs of the</u> <u>disease</u>) **is much greater than the initial cost of a drug**, even if that cost is five or six figures. The Congressional Budget Office calculates that a 1% increase in spending on prescriptions by Medicare beneficiaries yields a 0.2% decrease in expense across all of Medicare's medical spending, translating to roughly <u>a twofold return for every dollar spent on drugs</u>. Statins are a good example: they <u>have enabled a dramatic improvement in public health by preventing heart attacks</u>, strokes, and cardiovascular deaths. They were a relative bargain even when first introduced, and are an extraordinary one

<u>now that generics cost only pennies a day</u>. However, our health care system doesn't pay for drugs in a way that highlights and captures that value. Drug expense is often front-loaded, whether to the insurer or the patient, but the benefits may accrue over years or even decades. Introduction of bisphosphonate drugs was associated with a 40% decline in osteoporotic fractures, decreasing suffering and saving thousands of lives while creating large savings for the health system. People tend to forget those lessons when looking at the steep price tag for a new breakthrough drug.

Drugs prevent costly hospital treatments for chronic conditions

Watanabe 15 Jonathan Hirohiko Watanabe [University of California San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences], 2015, "Association of increased emergency rooms costs for patients without access to necessary medications," Research in Social & Administrative Pharmacy, <u>https://escholarship.org/content/qt8zp228f0/qt8zp228f0.pdf</u> //DF

Prescription medications prevent the acute sequelae of chronic diseases that result in emergency and inpatient care. 1,2 Suboptimal consumption of necessary medications translates into poor management of chronic illnesses3 and is associated with higher utilization of health care. 4–8 Osterberg and Blaschke estimated that 33–69% of hospital admissions were related to poor medication adherence at an associated cost of

<u>\$100 billion a year</u>.9 Research by Law et al discerned four unmet needs in the medication use process: 1) Patients see the physician at the right time. 2) Patients use medications as directed. 3) Patients receive adequate counseling. 4) Patients are monitored appropriately. This work revealed that patients understood the importance of taking their medications as directed and that they shared some responsibility in accomplishing in doing so.10 Van Servellen et al found that factors associated with access to care in terms of cost and ability to see medical specialists were correlated with adherence in patients with HIV.11 However, the scientific literature is confounded by a variation in the

explanatory factors of appropriate consumption and a wide range in the measured extent of their impact.12,13 Publications from controlled clinical trials with robust internal validity are likely needed to ascertain predictive characteristics. Individuals who are not able to receive needed

medications are at risk for diminished management of their syndrome.14,15 Separate recent studies found appropriate medication

<u>consumption was associated with a 18–19% reduction in coronary artery disease events</u>.16,17 This loss of therapeutic control translates to increases in catastrophic health service use and the concomitant medical costs.18,19 However, the subsequent health care resource use is largely unknown for patients who specifically realize they are in need of prescription medications, but are unable to obtain them. Thus, additional research is needed in quantifying the association between access to medications and downstream health system costs. Our goal was to quantify the association between individual emergency room costs and inability to receive necessary medications using a pooled 10- year publically available, health services dataset of people living in the U.S.

b. Increases wages and ability to pay for healthcare

Chen 18 Alice J. Chen [PhD, Leonard D. Schaeffer Center for Health Policy and Economics and Sol Price School of Public Policy, University of Southern California], 2018 "Productivity Benefits of Medical Care: Evidence from US-Based Randomized Clinical Trials," Value in Health, https://doi.org/10.1016/j.jval.2018.01.009 //DF

Background: One of the key recommendations of the Second Panel on Cost-Effectiveness in Health and Medicine is to take a societal perspective when evaluating new technologies—including measuring the productivity benefits of new treatments. Yet relatively little is known about the impact that new treatments have on labor produc- tivity. Objectives: To examine the relationship between new drug treat- ments and gains in labor productivity across conditions in the United States and to evaluate which randomized clinical trials (RCTs) collected labor productivity data. Methods: We collected data on US-based RCTs with work-ability surveys from searches of Google Scholar, PubMed, Scopus, the Cochrane Central Registry of Clinical Trials, and Clinical- Trails.gov. Combining RCT data with survey data from the Medical Expenditure

Panel Survey, we assessed productivity changes from new drug treatments. Results: During the last decade, SOME disease condi-tions

have seen treatments that improve ability to work by as much as 60%. The annual increase in productivity gains attributable to new drug treatments was modest 1.1% (P 1/4 0.53). Of the 5092 RCTs reviewed, ability- to-work measures were collected in 2% of trials. Work productivity surveys were more likely among prevalent medical conditions that affected individuals who worked, earned higher wages, and experienced larger reductions in hours worked as a consequence of disease diagnosis. Conclusions: From our data, we estimated

that drug innovation increased productivity by 5.5 million work days per year and \$233 billion in wages

per year. These labor-sector benefits should be taken into account when assessing the socially optimal cost for new drug innovation. One of the key recommendations of the Second Panel on Cost- Effectiveness in Health and Medicine is to take a societal perspective when evaluating new technologies [1]. When considering the resource costs associated with the use of health care interventions, one should account for societal benefits from increased productivity, a dimension that is not traditionally captured by preference-based or health-based measures. This societal perspective is important given that medical innovation is a global public good, and efficiently managing resource both across and within countries relies on a complete understanding of the health and nonhealth welfare impacts. In the United States, non-health considerations are particularly salient because most Americans obtain their health insurance through their employers. In 2015, employers covered, on average, 72% to 83% of average annual premiums, which totaled \$6,251 for single coverage and \$17,545 for family coverage [2]. Despite the significant subsidies that employers provide, little is known about the impact that medical treatments have on labor productivity. This issue is particularly relevant for employees, who often take prescription drugs for primary or secondary prevention, with the goal of maintaining good function. US-based estimates of the productivity losses as a result of poor health are large. In 2003, 885 million days were lost because of own or family-related illnesses that prevented employees from concentrating at work or coming into work [3]. An additional 18 million adults aged 19 to 64 years remained unemployed because of health reasons. Both workers and firms bear the burden of these health costs: Individuals experience the impaired or lost ability to work, and firms face the costs of rehiring and retraining replaced workers, which can include higher wages, lost revenues, and idle assets [4,5]. Estimates of health-related productivity losses sum to around \$226 to \$260 billion every year [3,6,7].

R/T Affordability

UQ – R/T Prices High Now

Long-term prices are significantly lower than what is known because of generic price reductions and healthcare savings

Lakdawalla 17 Darius Lakdawalla, [PhD, University of Southern California] 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 Branded drug prices might overstate the true long-run cost of brand name drugs by 40% to 75%, accounting for generic price reductions and medical cost offsets. Ultimately, the LAC net lies about halfway between the branded price at patent expiration and the long-run generic price. This point may acquire particular salience for policy makers and HTA bodies measuring the costs and benefits of making new drugs available. HTA reports inevitably rely on a number of modeled outcomes, including utilization, effectiveness, and other key parameters. These reports might also consider building in models of long-run costs that align with the LAC. A simple approach would be for payers interested in a societal perspective to incorporate at least an 11% discount to the brand price at launch to account for the lower long-run prices of drugs to patients. Focusing only on current brand prices may overestimate the true costs to patients and thus underestimate the long-run cost-effectiveness of new troatmonts.

treatments. To ensure that all drugs providing long-run value enter the marketplace, market access and other policy decisions should consider these long-term costs.

Prices aren't high for three reasons

1. Generics

Rosenblatt 17 Michael Rosenblatt [Chief Medical Officer at Merck & Co. from 2009 to 2016, 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], 11-20-2017, "Reframing the Conversation on Drug Pricing," NEJM Catalyst, https://catalyst.nejm.org/reframing-conversation-drug-pricing///DF

Atorvastatin (Lipitor), a leading statin for treating elevated cholesterol, was introduced in 1996 at over \$5 per tablet. When it became generic in 2012, the price fell by 95% to \$0.3 per tablet. Alendronate (Fosamax) for osteoporosis was \$2.60 daily, but is now \$0.28. These low prices will likely persist in perpetuity, and **90% of prescriptions written in the U.S. are for generics that have had** similar **precipitous price drops**. So what is the true cost of these medicines to society — the price on day one or the average price over decades? Today's generic was yesterday's innovative medicine. No other health care expense drops so dramatically, so routinely. (Most only increase.) Society's purchases of a drug in its early years, when it is under patent protection and the price is highest, are a kind of annuity for the health system, underwriting a steady pipeline of new drugs that will continue to provide benefits long after they go off patent. **Even before patent expiration, the prices of many drugs drop substantially along the way as competition enters the market. Even breakthrough drugs can rapidly be made obsolete by competition. The breakthrough hepatitis C therapy, telaprevir** (Incevik), **introduced 6 years ago, was withdrawn from** the market by Vertex **only 3 years after approval because a better new drug, sofosbuvir** (Sovaldi), **became available**. The same happened to Merck's boceprevir (Victrelis). The initial price for Sovaldi, **the first real cure for hepatitis C**, sparked outrage: \$1,000 per tablet or **\$80,000 for a course of treatment. But within 18 months, competition entered the field and the list price of sofosbuvir fell by 40–60%.** Initially, there also was anger that the drug was considerably more expensive in the U.S. than in

the U.K. and other parts of Europe. Now, 2 to 3 years after market entry and well before the patent will expire, <u>sofosbuvir is less</u> expensive in the U.S. than in the U.K., because competitive drugs have already lowered the U.S. price while they are still making their way through the U.K.'s regulatory and reimbursement review processes. These <u>price drops due to competition are</u> a major reason <u>Why</u> the Congressional Budget Office projects that <u>Medicare Part</u> <u>D spending will be lower than originally expected over the next decade</u>. It found that spending in 2013 was nearly 50% less than expected (\$50 billion compared to the projected \$99 billion). Health systems and insurers can't usually predict when a breakthrough therapy will come along to strain their budgets, even as it promises unprecedented benefits for patients. There is no perfect solution: the economic reality is that not every drug can be equally available to every patient on day one. (The same is true for breakthrough surgical procedures or medical devices.) Nor should each breakthrough be made available to all on day one. Rather, it may be possible to create tiered or staged access. Take the example of the drugs for hepatitis C. Many patients with subclinical or mild disease can safely wait for a period until receiving the new drug. In fact, many physicians "warehoused" such patients in anticipation of the availability of a new, better medication. Staging access over time, when medically appropriate, can enable the health care system to absorb the cost of a breakthrough therapy.

2. Healthcare tradeoffs

Rosenblatt 17 Michael Rosenblatt [Chief Medical Officer at Merck & Co. from 2009 to 2016, 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], 11-20-2017, "Reframing the Conversation on Drug Pricing," NEJM Catalyst, https://catalyst.nejm.org/reframing-conversation-drug-pricing///DF

Focusing on drug price alone ignores savings that effective drugs generate in other parts of the health system. In many cases, the cost to society of not having a treatment (that is, <u>the</u> direct and indirect <u>Costs of the</u> <u>disease</u>) **is much greater than the initial cost of a drug**, even if that cost is five or six figures. The Congressional Budget Office calculates that a 1% increase in spending on prescriptions by Medicare beneficiaries yields a 0.2% decrease in expense across all of Medicare's medical spending, translating to roughly <u>a twofold return for every dollar spent on drugs</u>. <u>Statins</u> are a good example: they <u>have enabled a dramatic improvement in public health by preventing heart attacks</u>, strokes, and cardiovascular deaths. <u>They were a relative bargain even when first introduced</u>, and are an extraordinary one <u>now that generics cost only pennies a day</u>. However, our health care system doesn't pay for drugs in a way that highlights and captures that value. Drug expense is often front-loaded, whether to the insurer or the patient, but the benefits may accrue over years or even decades. Introduction of bisphosphonate drugs was associated with a 40% decline in osteoporotic fractures, decreasing suffering and saving thousands of lives while creating large savings for the health system. People tend to forget those lessons when looking at the steep price tag for a new breakthrough drug.

Drugs prevent costly hospital treatments for chronic conditions

Watanabe 15 Jonathan Hirohiko Watanabe [University of California San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences], 2015, "Association of increased emergency rooms costs for patients without access to necessary medications," Research in Social & Administrative Pharmacy, https://escholarship.org/content/qt8zp228f0/qt8zp228f0.pdf //DF

Prescription medications prevent the acute sequelae of chronic diseases that result in emergency and inpatient care.1,2 Suboptimal consumption of necessary medications translates into poor management of chronic illnesses3 and is associated with higher utilization of health care.4–8 Osterberg and Blaschke estimated that 33–69% of hospital admissions were related to poor medication adherence at an associated cost of

<u>\$100 billion a year</u>.9 Research by Law et al discerned four unmet needs in the medication use process: 1) Patients see the physician at the right time. 2) Patients use medications as directed. 3) Patients receive adequate counseling. 4) Patients are monitored appropriately. This work revealed that patients understood the importance of taking their medications as directed and that they shared some responsibility in

accomplishing in doing so.10 Van Servellen et al found that factors associated with access to care in terms of cost and ability to see medical specialists were correlated with adherence in patients with HIV.11 However, the scientific literature is confounded by a variation in the explanatory factors of appropriate consumption and a wide range in the measured extent of their impact.12,13 Publications from controlled clinical trials with robust internal validity are likely needed to ascertain predictive characteristics. Individuals who are not able to receive needed

medications are at risk for diminished management of their syndrome.14,15 Separate recent studies found appropriate medication

<u>consumption was associated with a 18–19% reduction in coronary artery disease events</u>.16,17 This loss of therapeutic control translates to increases in catastrophic health service use and the concomitant medical costs.18,19 However, the subsequent health care resource use is largely unknown for patients who specifically realize they are in need of prescription medications, but are unable to obtain them. Thus, additional research is needed in quantifying the association between access to medications and downstream health system costs. Our goal was to quantify the association between individual emergency room costs and inability to receive necessary medications using a pooled 10- year publically available, health services dataset of people living in the U.S.

3. Sick days. Innovation saves a lot of money through restoring productivity

Chen 18 Alice J. Chen [PhD, Leonard D. Schaeffer Center for Health Policy and Economics and Sol Price School of Public Policy, University of Southern California], 2018 "Productivity Benefits of Medical Care: Evidence from US-Based Randomized Clinical Trials," Value in Health, https://doi.org/10.1016/i.jval.2018.01.009 //DF

Background: One of the key recommendations of the Second Panel on Cost-Effectiveness in Health and Medicine is to take a societal perspective when evaluating new technologies—including measuring the productivity benefits of new treatments. Yet relatively little is known about the impact that new treatments have on labor produc- tivity. Objectives: To examine the relationship between new drug treat- ments and gains in labor productivity across conditions in the United States and to evaluate which randomized clinical trials (RCTs) collected labor productivity data. Methods: We collected data on US-based RCTs with work-ability surveys from searches of Google Scholar, PubMed, Scopus, the Cochrane Central Registry of Clinical Trials, and Clinical- Trails.gov. Combining RCT data with survey data from the Medical Expenditure

Panel Survey, we assessed productivity changes from new drug treatments. Results: During the last decade, some disease condi-tions

have seen treatments that improve ability to work by as much as 60%. The annual increase in productivity gains attributable to new drug treatments was modest 1.1% (P 1/4 0.53). Of the 5092 RCTs reviewed, ability- to-work measures were collected in 2% of trials. Work productivity surveys were more likely among prevalent medical conditions that affected individuals who worked, earned higher wages, and experienced larger reductions in hours worked as a consequence of disease diagnosis. Conclusions: From our data, we estimated

that drug innovation increased productivity by 5.5 million work days per year and \$233 billion in wages

per year. These labor-sector benefits should be taken into account when assessing the socially optimal cost for new drug innovation. One of the key recommendations of the Second Panel on Cost- Effectiveness in Health and Medicine is to take a societal perspective when evaluating new technologies [1]. When considering the resource costs associated with the use of health care interventions, one should account for societal benefits from increased productivity, a dimension that is not traditionally captured by preference-based or health-based measures. This societal perspective is important given that medical innovation is a global public good, and efficiently managing resource both across and within countries relies on a complete understanding of the health and nonhealth welfare impacts. In the United States, non-health considerations are particularly salient because most Americans obtain their health insurance through their employers. In 2015, employers covered, on average, 72% to 83% of average annual premiums, which totaled \$6,251 for single coverage and \$17,545 for family coverage [2]. Despite the significant subsidies that employers provide, little is known about the impact that medical treatments have on labor productivity. This issue is particularly relevant for employees, who often take prescription drugs for primary or secondary prevention, with the goal of maintaining good function. US-based estimates of the productivity losses as a result of poor health are large. In 2003, 885 million days were lost because of own or family-related illnesses that prevented employees from concentrating at work or coming into work [3]. An additional 18 million adults aged 19 to 64 years remained unemployed because of health reasons. Both workers and firms bear the burden of these health costs: Individuals experience the impaired or lost ability to work, and firms face the costs of rehiring and retraining replaced workers, which can include higher wages, lost revenues, and idle assets [4,5]. Estimates of health-related productivity losses sum to around \$226 to \$260 billion every year [3,6,7].

<u>Link Turns</u>

Price controls will increase prices for two reasons

1. Creating a grey market

Price controls make drug manufacturers shut down production

Kathryn Nix, 10-21-2011, "How Medicare Price Controls Have Contributed to Drug Shortages," Heritage Foundation, <u>https://www.heritage.org/health-care-reform/report/how-medicare-price-controls-have-contributed-drug-shortages</u> //RDM According to the Food and Drug Administration (FDA), there were 178 drug shortages reported in 2010, 132 of which were sterile injectable drugs, which are administered by health care providers.[1] Shortages increased in 2011 and will continue to grow. Oncology has the largest share of shortages, affecting more than half a million cancer patients.[2] <u>Reasons behind the drug shortages are</u> complex and vary from drug to drug, but one of the biggest problems is <u>that Medicare drug reimbursement under Part B keeps prices low</u>. At the same time, <u>drug</u> <u>manufacturers face increasing production costs but cannot easily adjust prices, leading many to halt production</u>. Medicare's Disastrous Drug Pricing Medicare price fixing for outpatient drugs covered under Part B is one of the major reasons for shortages. The program pays based on the average sales price (ASP) posted for more than six months. This scheme was enacted in response to the consequences of price controls that preceded it. Before passage of the Medicare Modernization Act of 2003, Medicare payments were based on drugs' average wholesale price (AWP), a suggested retail price set by manufacturers completely independent of what providers actually paid to acquire the drugs.

Phil Goldberg, 7-6-2015, "Eliminating Pharmaceutical Gray Markets," RealClearPolitics,

https://www.realclearpolicy.com/blog/2015/07/07/eliminating pharmaceutical gray markets 1356.html //AM

Yet when a shortage involves a life-sustaining or significantly life-enhancing drug and there is no substitute, statistics do not convey the full impact of this situation. So <u>when these drugs are not available through traditional channels, gray markets emerge. Gray markets involve the trading of drugs that have been stockpiled by wholesale distributors. While legal, this activity is unofficial, unauthorized, and unintended by the original manufacturer. <u>It's also profitable, because shortages facilitate price-gouging.</u> And as these drugs are processed by wholesaler distributors and pharmacies, which can involve the drugs changing hands four or five times, they may be repackaged, relabeled, stored under improper conditions, or replaced by counterfeits.</u>

Drug shortage leads to a gray market of counterfeits

Kathryn Nix, 10-21-2011, "How Medicare Price Controls Have Contributed to Drug Shortages," Heritage Foundation, https://www.heritage.org/health-care-reform/report/how-medicare-price-controls-have-contributed-drug-shortages//RDM Drug shortages have an obvious, negative impact on patient care._Critical treatments are delayed as patients are put on waiting lists, and physicians must pursue alternative treatment options with which they are less familiar, increasing the risk of mistakes._ Health care spending increases when doctors have to substitute more expensive drugs or patients' illnesses worsen due to delayed care. <u>Another consequence of drug shortages is the emergence of a gray market , defined as "a supply channel that is unofficial, unauthorized, or unintended by the original manufacturer."[7] When providers cannot purchase a scarce drug from standard suppliers, they look elsewhere. According to the Department of Health and Human Services (HHS), the problem occurs when secondary distributors purchase drugs from end users and then re-sell them to other end users.[8] <u>Drugs supplied on the gray market may be stolen or counterfeit, and their cost is exorbitantly higher.</u> The Premier Healthcare Alliance, which includes more than 2,500 hospitals, <u>reported an average markup of 650 percent</u>, but the most significant markups were as high as 4,533 percent. The disruption to the normal distribution process has increased concerns that patients will receive drugs that have been improperly stored and handled. This can cause treatments to lose their efficacy, threatening patient safety in addition to raising costs.</u>

Koons 18 Cynthia Koons, 4-11-2018, "Why We May Lose Generic Drugs," Bloomberg, <u>https://www.bloomberg.com/news/articles/2018-04-11/are-drug-prices-too-low</u> //DF The industry's w can be summed up in two words: plummeting prices. Far removed from the pharmacy pick-up counter is an arcane world of supply chains ruled by <u>a tightknit band of players forcing prices for most generic drugs lower and lower</u>, both with their increasing purchasing clout and because they're able to select from an ever-growing universe of generic drug suppliers. <u>The top</u> **three manufacturers**—Teva, Mylan, and the Sandoz generic drug division of Novartis AG—**control only about a third of the** market by sales. That leaves lots of smaller players vying for business. Industry executives say new entrants have been popping up—sometimes small outfits led by former managers of other generics companies who hire contract manufacturers around the globe to make their drugs. They elbow into the market by offering lower prices. That flies in the face of the public perception that all medical costs are spiraling upward. While many health-care products, including branded drugs-those still under patent-routinely command big price hikes, that's not the case with most generics. A deflation tracker developed by researchers at Evercore ISI Research shows generic drug prices are falling about 11 percent a year, while brand-name drugs are rising about 8 percent a year. About five years ago middlemen in the drug-delivery supply chain started to form buying consortia to gain more leverage over drugmakers. The consolidation has since become so extreme that just four groups now control 90 percent of drug buying in the U.S. And two of those four are joining forces to purchase generics, which likely will lower prices further. The squeeze is leading some manufacturers to stop making some critical low-margin drugs. "We have supported the consortiums to the point where we're discontinuing products and shutting facilities," says Paul Campanelli, chief executive officer of Endo International Plc, the fourth-largest generics maker in the U.S. "We are not in the position to provide more price reductions." Endo has slashed its workforce in half, to about 3,000, over the last 18 months, closing manufacturing facilities in Huntsville, Ala., and Charlotte. The drugmaker's generic division, known as Par, has stopped making 85 products. Endo was one of the biggest makers of the popular blood pressure medication lisinopril, for example, but decided to stop manufacturing it because the drug was no longer making enough money.

2. price controls may, at best, decrease drug prices for American consumers, but will increase drug prices in the developing world.

Schweitzer 11 Stuart O. Schweitzer [professor in the School of Public Health at the University of California, Los Angeles], 8-2011, "Prices Of Pharmaceuticals In Poor Countries Are Much Lower Than In Wealthy Countries," Health Affairs, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923 //DF

Three studies report ratios of marginal cost, determined in this manner, to the price of products that are still patented. David Reiffen and

Michael Ward "find that the implied ratio of marginal cost to pre-expiry branded prices when there are 11 or more firms is approximately 50 percent." 22(p44) Richard Frank and David Salkever report that "with each additional [generic] entrant there is a fall in the average price of a generic product of between 5.6 percent and 7.2 percent." 23(p88) Accordingly, increasing the number of generic producers from one to eleven would lead to a price reduction of more than 50 percent from the price of the original drug. And Richard Caves and colleagues find that with ten generic drug producers in a particular market, generic prices average fully 70 percent below the original price. 24 PRICES IN THE UNITED

STATES AND ELSEWHERE These benchmark figures can be compared with the price data in our study. Exhibit 3 shows that the **average**

prices for patented drugs in developing countries are less than 20 percent of those in the United

States, while prices in middle-income countries average 32 percent of US prices. These prices are thus below the benchmark estimates of US marginal costs. Although it is possible that marginal costs of pharmaceutical production are lower in developing or middle-income countries than in the United States, the effect of such reduced costs could not be large because most patented drugs are manufactured in industrialized countries. For these drugs, therefore, current prices outside the United States are generally lower than marginal costs. It is more difficult to draw firm conclusions about the fairness of pricing for drugs that are no longer patented (Exhibit 3). Although for some of these products, prices in developing countries approach marginal costs, that is not always the case. For essential drugs, however, it is clear that prices are not higher than marginal costs. There is little indication, therefore, that average drug prices in developing and middle-income countries exceed the standard set by marginal costs.

Glassman 18 James K. Glassman [former under secretary of state, is an adviser to several health care companies], 5-9-2018, "How to End Unfair Foreign Drug-Price Disparities," RealClearPolitics,

https://www.realclearpolitics.com/articles/2018/05/09/how to end unfair foreign drug-price disparities 136997.html //DF The result is that U.S. consumers fund new pharmaceutical discoveries, and the rest of the world benefits. As the authors of the JAMA study say, "Although the United States' high prices of pharmaceuticals are controversial, these prices have been viewed as critical to innovation." Firms based in the U.S. invent the majority of new medicines; no other country is close. "The United States both conducts and finances much of the biopharmaceutical innovation that the world depends on, allowing foreign governments to enjoy bargain prices for such innovations," said a February study by the President's Council of Economic

governments to enjoy bargain prices for such innovations," said a February study by the President's Council of Economic Advisors. "This indicates that our current policies are neither wise nor just. Simply put, other nations are free-riding, or taking unfair advantage of the United States' progress in this area." The CEA estimates that <u>70 percent of patented pharmaceutical profits come</u> from sales to U.S. patients. Those profits are plowed back into R&D, whose results benefit people in countries that produce little or no profits. But **if U.S. revenues and profits are reduced, there will be a sharp decline in new treatments – and in overall health – for** Americans as well as **foreigners**. A study by Thomas Abbott and John Vernon, published as a working paper by the National Bureau of Economic Research, found that "cutting prices by 40 to 50 percent in the United States will lead to between 30 and 60 percent fewer R and D projects being undertaken in the early stage of developing a new drug." Conversely, what would happen if other OECD (Organisation for Economic Cooperation and Development) countries lifted or significantly relaxed price controls? A USC study concludes that if European prices were just "20 percent higher, the resulting increased innovation would generate \$10 trillion in welfare gains for Americans, and \$7.5 trillion for Europeans over the next 50 years." Economists know the answer to the problem. In 2004, more than 200 of them, including the late Nobel Prize winner Milton Friedman and current CEA Chairman Kevin Hassett, signed a public letter on how to tackle the price-disparity problem. They said, "The ideal solution would be for other wealthy nations to remove their price controls over pharmaceuticals. America is the last major market without these controls. <u>Imposing price</u> **controls here would have a major impact on drug development worldwide, harming not only Americans** but people all over the world. On the other hand, removing foreign price controls would bolster research incentives."

Duggan 06 Mark Duggan [University of Maryland and National Bureau of Economic Research Yale University School of Management], 2-2006, "The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing," The Quarterly Journal of Economics, <u>https://academic.oup.com/gje/article-abstract/121/1/1849004</u> //DF

In 2003 the federal-state Medicaid program provided prescription drug coverage to more than 50 million people. To determine the price that it will pay for each drug, Medicaid uses the average private sector price. When Medicaid is a large part of the demand for a drug, this creates an incentive for its maker to increase prices for other health care consumers. Using drug utilization and expenditure data for the top 200 drugs in 1997 and in 2002, we investigate the relationship between the Medicaid market share (MMS) and the average price of a prescription. Our estimates imply that a 10-percentage-point increase in the MMS is associated with a 7 to 10 percent increase in the average price of a prescription. In addition, the Medicaid rules increase a firm's incentive to introduce new versions of a drug in order to raise price. We find empirical evidence that firms producing newer drugs with larger sales to Medicaid are more likely to introduce new versions. Taken together, our findings suggest that government procurement rules can alter equilibrium price and product proliferation in the private sector.

Low prices are needed to ensure people in poor countries can afford the medicines

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).

WHO 13 2013, "WHO Guideline on Country Pharmaceutical Pricing Policies," World Health Organization https://www.ncbi.nlm.nih.gov/books/NBK258628///DF

Medicines account for 20–60% of health spending in low- and middle-income countries, compared with 18% in countries of the Organisation for Economic Co-operation and Development. Up to 90% of the population in developing countries purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food. As a result, medicines, particularly those with higher costs, may be unaffordable for large sections of the global population and are a major burden on government budgets. The Millennium Development Goals include the target: "[I]n cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries." Initiatives to stimulate availability and access through manufacturing innovations, procurement mechanisms, or supply chain improvements require management of pricing to have sustainable impact. The past ten years have seen the introduction of several initiatives at both global and regional levels to support countries in managing pharmaceutical prices. Despite some clear successes, many countries are still failing to implement the policy and programme changes needed to improve access to affordable medicines.

R/T Boosley Evidence

This is old evidence from 2006

Sarah Boseley, 11-14-2006, "Rich countries 'blocking cheap drugs for developing world'," Guardian, <u>https://www.theguardian.com/society/2006/nov/14/internationalaidanddevelopment.medicineandheal</u> <u>th</u> //DF

In the case study, accompanying the article below, we said that <u>1.42 billion people in India could not afford the drugs they</u> <u>needed to save their lives</u>. That is the figure Oxfam gives for developing countries such as India, rather than India alone. <u>Poor</u> <u>people are needlessly dying because drug companies and the governments of rich countries are blocking</u>

the developing world from obtaining affordable medicines, a report says today. Five years to the day after the Doha declaration - a groundbreaking deal to give poor countries access to cheap drugs - was signed at the World Trade Organisation, Oxfam says things are worse. The charity accuses the US, which champions the interests of its giant pharmaceutical companies, of bullying developing countries into not using the measures in the Doha declaration and the EU of standing by and doing nothing. Doha technically allows poor countries to buy cheap copies of desperately needed drugs but the US is accused of trying to prevent countries such as Thailand and India, which have manufacturing capacity, making and selling cheap generic versions so as to preserve the monopolies of the drug giants. "Rich countries have broken the spirit of the Doha declaration," said Celine Charveriat, head of Oxfam's Make Trade Fair campaign. "The declaration said the right things but needed political action to work and that hasn't happened. In fact, we've actually gone backwards. Many people are dying or suffering needlessly."

Much more recently, companies are increasing access to drugs in the developing world by making generics easier to access

Kollewe 16 Julia Kollewe, 3-31-2016, "GlaxoSmithKline to lower drug prices in poorer countries," Guardian,

https://www.theguardian.com/business/2016/mar/31/glaxosmithkline-to-lower-drug-prices-to-help-po orer-countries //DF

<u>GlaxoSmithKline is taking action to make medicines more affordable in developing countries,</u> <u>including waiving patent protection for new drugs in the world's poorest nations.</u> Britain's biggest <u>drugmaker said it would not file patents for new medicines in the poorest countries, such as Afghanistan</u>,

Rwanda and Cambodia, allowing cheaper generic versions to come on the market without the threat of legal

action. GSK's chief executive, Sir Andrew Witty, said the company was already doing this in some countries, but wanted to streamline its approach to "recognise the realities of the world". He said the move would have little effect on the group's profits. In lower middle income countries such as Kosovo, Pakistan, Morocco and Ukraine, the drugmaker will offer licences to generic drugmakers for 10 years, in return for a

small royalty on sales. The measures will affect 85 countries, helping more than 2 billion people, and benefit

Africa most, according to GSK. Any GSK medicines on the World Health Organisation's list of essential medicines will be automatically included. Rohit Malpani, director of policy and advocacy at Médecins Sans Frontières, gave a muted response. He noted that the world's poorest countries were already exempt from patent protection rules until 2033 under a World Trade Organisation agreement, and added that it did not make commercial sense for the pharmaceutical industry to seek patents in many other developing countries. He said GSK's move

excluded generic drug producing countries such as India, Brazil and China, as well as many other middle income countries that are struggling to pay for medicines. He argued that it was not clear how it would work in practice, and that it should be up to governments, not companies, to make such decisions. Speaking from New York before a UN panel meeting on access to medicines, Witty said GSK would adopt a "customised approach" as standards of living rise in developing countries.

Extras

Prices aren't high when you look at them as a share of overall health care costs

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-control s/#406cbfc6639b //DF

For starters, the justification for price controls on prescription drugs is based in myth. <u>The claim that U.S. drug spending is</u> growing out of control is simply not true. <u>Spending on prescription drugs as a share of all health care</u> <u>spending in the U.S. is the same as it was 60 years ago.</u> As the Manhattan Institute pointed out in a 2015 report, <u>spending in the U.S. on drugs accounts for about 10% of total health care spending</u>. In fact, drugs account for a lower percentage of total health care spending in the U.S. than in Europe, where drug price controls have been on the books for decades. Upon further investigation, it becomes clear pharmaceutical price controls – like those now being debated in eight state capitals – are misguided solutions in search of a problem, and are a red herring when it comes to the effort to bend the overall health care cost curve. The problem for drug price control proponents like Gov. Cuomo and Bernie Sanders is that, despite their claims, pharmaceutical manufacturers do not reap excessive profits. In fact, profits for the pharmaceutical manufacturing industry, among the most research-intensive sectors, are middle of the road. Additionally, drug makers reinvest tens of billions in profits every year on research and development.

Drug companies themselves are actually working to lower drug prices

Johnson 18 Carolyn Y. Johnson [She previously covered the business of health, the pharmaceutical industry and the affordability of health care to consumers], 1-2-2018 "Pharma, under attack for drug prices, started an industry war," Washington Post,

https://www.washingtonpost.com/business/economy/pharma-under-attack-for-drug-prices-started-anindustry-war/2017/12/29/800a3de8-e5bc-11e7-a65d-1ac0fd7f097e_story.html?noredirect=on&utm_te rm=.89e0b902fe2c //DF

Meanwhile, two of the country's largest PBMs and employers, public-sector employees and unions came together at the beginning of 2017 in the Coalition for Affordable Prescription Drugs. Without a clear direction coming from government, the players are working toward their own solutions for the high cost of drugs. A number of drug companies reacted to public scrutiny of prices by vowing to limit their price increases on existing drugs, and many informally followed suit last year. Pharmaceutical companies have started to link the price of some drugs to how well

they work, for example, offering rebates to insurance companies if a cholesterol-lowering drug fails to prevent a heart attack. CVS Health recently announced it would provide real-time information to physicians writing prescriptions about the specific cost of that drug to patients. The goal is to avoid sticker shock and to prod doctors to make the most cost-effective choices for their patients. Other changes may start to come from employers. Pacific Business Group on Health, which includes some of the West Coast's largest employers, is studying the possible pros and cons of drafting its own formulary, the list of covered prescription drugs. That could transform employers' relationships with PBMs and how they are paid — although the work is still in exploratory stages. "The escalating cost of drugs hit the radar for employers, which means employers started asking a lot of questions — to pharma, to PBMs," said Lauren Vela, senior director of member value for the Pacific Business Group on Health. "Of course, they're all pointing fingers at each other. What has happened is they got caught — the entire industry got caught — making a lot of money, in ways that people didn't fully understand."

The increase in drug prices has been because of drugs for high-cost treatments

Langreth 18 Robert Langreth [Bloomberg], 5-11-2018, "High U.S. Drug Prices Fuel Outrage, Innovation Debate: QuickTake," Washington Post,

https://www.washingtonpost.com/business/high-us-drug-prices-fuel-outrage-innovation-debate-quickt ake/2018/05/11/ce712a0e-5539-11e8-a6d4-ca1d035642ce_story.html?utm_term=.93212a0adb5d //DF Drug companies increasingly have become the subject of outrage and scrutiny in the U.S. Lawmakers have probed how they set prices, and the Justice Department is investigating possible price collusion by more than a dozen companies that make generic drugs. Some politicians have accused drugmakers of price gouging. Trump has said that with their "astronomical" prices, they're "getting away with murder." Martin Shkreli became a symbol of greed in 2015 when the company he then headed, Turing Pharmaceuticals, bought rights to an old anti-parasitic drug and raised its price more than 50-fold to \$750 a pill. Turing later offered hospitals discounts on the drug of up to 50 percent. <u>Prescription drug</u> <u>spending in the U.S. began to surge in 2014</u> after six years of increases held down by the spread of generic drug use. It rose 8.5 percent in 2015 and 4.8 percent in 2016 before flattening out in 2017. <u>Specialty drugs (high-cost treatments, mostly for</u> <u>complex conditions) account for much of the spending growth</u>. The current backlash first erupted in 2013 when Gilead Sciences released the groundbreaking hepatitis cure Sovaldi at \$84,000 for a 12-week course. The steep price and stampede of patients to get the drug led many insurers to restrict coverage to the sickest patients.

Link – R/T Levi Evidence

Levi advocates for "modest price controls," but says that all OECD countries use aggressive price controls

Levy 14 Moshe Levy, 2014, "The Pricing of Breakthrough Drugs: Theory and Policy Implications," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4244177/ //DF The analysis is conducted in the standard expected utility framework, where well-being, or "utility", is a function of both health and wealth [8]–[10]. We employ recent empirical findings in [11] about the shape of the utility function of health and wealth to formulate a model of the optimal monopolistic pricing of breakthrough drugs. This optimal monopolistic price then serves as the basis for price regulation, i.e. the regulated price is determined in terms of the monopolistic price. Thus, the model provides a theoretical foundation and benchmark for setting price caps. The model allows us to quantify the costs and benefits of drug price regulation. We find that mild price regulation can substantially increase consumer surplus and the number of patients using the drug, while having only a second-order effect of the revenues of the pharmaceutical companies. For example, setting the price cap at 20% lower than the optimal monopolistic price increases the consumer surplus by about 10%, and increases the number of patients using the drug by about 23%. This increase in the number of users almost completely offsets the adverse effect of the price regulation from the perspective of the pharmaceutical company – its revenues decrease by only about 1%. However, more aggressive price regulation leads to a substantial revenue reduction, and may stifle innovation. The price caps in OECD countries, which are up to 67% lower than the U.S. unregulated prices, lead to a lower ratio between the consumer surplus and the loss of revenue for the pharmaceutical company, and thus certainly seem excessive. There seems to be a "golden path" of mild regulation that on the one hand greatly improves patient welfare, and on the other hand does not stifle the pharmaceutical industry and the important economic incentive for drug innovation.

Link – R/T Mergers & Aquisitions

Mergers and aquisitions increase funding for innovative drugs

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-s ector.asp //DF

Research and Development Throughout this period of research and development, pharmaceutical companies must have dependable sources of financing. Typically, this financing is in the form of either investments and loans or revenue from sales of other products. Government regulation gives a distinct competitive advantage to companies large enough to maintain secure funding. Major drug manufacturers with profitable products already in the market usually do not require the ongoing fundraising and venture capital that startups do. This process is a significant barrier to entry in the pharmaceutical industry. As a result, mergers and acquisitions (M&As) are common. <u>New Companies and larger companies both benefit from mergers</u>. 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

<u>trials</u>. 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.

This actually increases the number of startups because they want to be purchased.

Jennifer Alsever May 13, 2016, 5-13-2016, "Big Pharma Innovation in Small Places," Fortune, <u>http://fortune.com/2016/05/13/big-pharma-biotech-startups/</u>//DF

A crucial part of the allure: Pint-size ventures are driving pharma innovation. The majority of drugs approved in recent years originated at smaller outfits—64% of them last year, according to HBM Partners, a health care investing firm. Giants like Pfizer (PFE, +0.72%) have tried to become more entrepreneurial, and some behemoths have beefed up R&D. Yet rarely do they conduct early scientific research anymore. Increasingly, the big players leave that to startups, then later cut deals to acquire or license the drugs. "Biotech is becoming more important than ever to Big Pharma and becoming the fuel source for their drug pipelines," says Nicholson, who once scouted for such acquisitions at Merck. Small companies received \$5.6 billion in upfront licensing payments in 2014, double the prior year, according to the trade group BIO. Small companies offer the classic high-risk, high-reward dichotomy: a lot of the former, and handsome payouts in the case of the latter. Tony Coles, who spent 22 years at Bristol-Myers Squibb (BMY, +1.61%) and Merck, walked away with \$62 million after serving as CEO of Onyx Pharmaceuticals, which was acquired by Amgen (AMGN, +0.95%) in 2013 for \$9.7 billion. (Coles has since launched another startup.) Former Amgen executive Terry Rosen started Flexus Biosciences and sold it 17 months later for \$1.3 billion. (His share was undisclosed.) It helps that investor money has flooded in, aided by FDA efforts to accelerate approvals for breakthrough drugs. Last year venture capitalists sank a record \$7.4 billion into biotechs, the largest sum in the 20-year history of the PwC MoneyTree report.

Link – R/T Monopolies

Monopolies increase innovation

Ringel 17 Michael S. Ringel [Michael S. Ringel is a Boston-based senior partner of The Boston Consulting Group and global leader of its research and product development topic], 7-24-2017, "A new wave of pharma mergers could put innovative drugs in the pipeline," STAT, https://www.statnews.com/2017/07/24/mergers-pharma-drug-development/ //DF To determine whether mega-mergers benefit patients, we looked at what happened to research and development productivity in all of the major mergers going back to 2001, including the last big wave in 2009 that brought together Merck & Co. and Schering-Plough, Pfizer and Wyeth, and Roche and Genentech. As expected, the results varied from year to year and company to company. But our report in Drug Discovery Today showed that mergers generally appeared to drive productivity up — and did so significantly. Why might this be so? While mergers undoubtedly bring disruption to research and development, they also can be catalysts for addressing the fatal flaw of most research and development enterprises: the high cost of failure. More than 90 percent of pharmaceutical industry spending on research and development goes into projects that never reach the market. Any intervention that helps reduce this waste can be a real boon to productivity. There are really only two ways to fix the industry's cost-of-failure problem: 1) start with better science, so you have fewer failures; and 2) employ better decision-making about when to stop projects so you can reallocate that capital to more-promising opportunities. Mergers can help with both of these dimensions. They bring the best combined science of the merged organizations to bear on the difficult questions of which pathways, modalities, and molecules to pursue. Mergers also trigger reviews that drive the leadership of the new company to take a fresh look at research and development. These reviews can offer the leadership an opportunity to soberly and objectively reassess its scientific hypotheses in each disease area and reevaluate the combined research and development portfolio, eliminating those projects least likely to produce advances in treatment. This spring cleaning can have a cathartic effect. The combination of the two factors — fresh science and a fresh look at the portfolio — can create a renewed research and development enterprise better able to bring new medicines to patients.

Richman, Duke, "Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition", 2017

https://scholarship.law.duke.edu/cgi/viewcontent.cgi?referer=https://www.statnews.com/&httpsredir=1&article=6441&context=faculty_schol arship (NK)

The global pharmaceutical industry is exhibiting meaningful structural changes, evidenced most clearly by ongoing growth in industry-wide M&A deals. This exploratory review finds evidence that the predominant concerns over megamergers among pharmaceutical giants might be misplaced. Changes in the scientific landscape of competitive innovation generated a vibrant marketplace for discovery, which megamergers do not necessarily threaten and instead might actually invigorate. Although megamergers may create some monopsony power for the purchase of discoveries, an active VC and biotech financing market, along with speculating contract research organizations and virtual companies, would counteract that. And the development of alternative information mechanisms to spread pharmaceutical information and effectiveness data, which would inform physicians and bulk purchasers of drugs, reduces the importance of pharmacy sales

information and effectiveness data, which would inform physicians and bulk purchasers of drugs, reduces the importance of pharr representatives, thus mitigating any competition concerns with downstream drug marketing and distribution

R/T Generics are expensive

Generics are NOT expensive, just making new drugs is

Richard Frank [Margaret T. Morris Professor of Health Economics in the Department of Health Care Policy - Harvard Medical School] and Paul Ginsburg [Director - Center for Health Policy, USC-Brookings Schaeffer Initiative for Health Policy Leonard D. Schaeffer Chair in Health Policy Studies Senior Fellow -Economic Studies], 11-17-2017, "Pharmaceutical industry profits and research and development," Brookings,

<u>https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2017/11/17/pharmaceutical</u> <u>-industry-profits-and-research-and-development/</u>//DF

Pharmaceutical innovation has produced an enormous amount of social value. The evidence on this point is strong and comes from multiple sources. Studies of disease-specific spending on prescription drugs, macro-comparisons in the United States, and international comparisons have all pointed to high social returns with respect to longevity and functional health outcomes.[1] Those benefits from pharmaceutical innovation stem in great measure from patent policy and the granting of marketing exclusivity to new drug products. The pharmaceutical industry is what economists call a high-fixed low-cost marginal cost industry. This means that the cost of bringing a new drug to market is very high and the process is risky, while the cost of producing an extra unit of a product that is on the market is frequently "pennies a pill". There is energetic disagreement about the exact cost of bringing a new drug to market, but there is widespread recognition that the costs run into at least many hundreds of millions of dollars per new drug product. In addition, for many drugs the costs of imitation are low. It is simple and low cost for a firm that did not develop the drug to produce a copy of a new drug. This means that if free competition were permitted, firms spending hundreds of millions of dollars to bring a new drug to grices down to production costs ("pennies a pill").

R/T Value-Based System

Big pharma has lots of lobbying power and would probably just rig the value-based part so that they don't have to demonstrate a lot of value

Goozner 18 Merrill 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

It would defy political logic for the Trump administration to give the CMS the authority to negotiate drug prices, which is a Democratic proposal. Instead, HHS Secretary Alex Azar embraced letting foreign healthcare bureaucrats do the negotiating, even as he and the president deride them as free riders. I am skeptical that anything even remotely resembling HHS' latest plan to lower spending on Part B drugs will get enacted. As

Azar noted at a Brookings Institution forum, the proposal was contained in an advanced notice of proposed rulemaking. That's inside-the-beltway speak for giving Big Pharma lobbyists much of the next year to

defang if not totally derail this pre-election embrace of price controls. 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.

Drug companies wield massive amounts of influence

Rosenberg 18 Tina Rosenberg, 9-18-2018, "H.I.V. Drugs Cost \$75 in Africa, \$39,000 in the U.S. Does It Matter?," No Publication, https://www.nytimes.com/2018/09/18/opinion/pricing-hiv-drugs-america.html //DF

This isn't an accident. H.I.V. drug pricing is a mess because <u>drug companies have so much sway over government policy</u>. For example: <u>Medicare is not allowed to negotiate with drug companies on price — although 92 percent of</u> <u>Americans think it should.</u> If Medicare could get the same prices that, say, the Department of Veterans Affairs gets, it would save nearly \$3 billion a year on just the 20 most-prescribed drugs, according to a study by Senate Democrats. <u>Pharmaceutical companies</u> <u>have built a system in which no one in a position to limit costs wants to do so</u>. The federal panel on antiretroviral guidelines now does include references to drug costs, said Dr. Rochelle Walensky, chief of infectious diseases at Massachusetts General Hospital and a guidelines panel member. "But the first-line regimens recommended still favor the absolute best — and often most expensive — drugs available. It's 'if this were my dad, what would I want him to have?''' she said. Insurers should care about price. But it's hard for them to refuse to cover a recommended drug, and they can pass their costs along in the form of higher premiums. Taxpayers should care about price; after all, health care represents 18 percent of the national economy. But the industry has proved too powerful. Drugmakers have designed a system in which parties that would otherwise campaign for cheaper drugs actually have an interest in high prices. For example, clinics that serve H.I.V. patients also, perversely, benefit from high prices. Their pharmacies can buy drugs at Medicaid prices. But if a patient has commercial insurance, they can bill the insurer at commercial prices.

Companies have been shown to take advantage of loopholes with past price controls

CAGW 17 Citizens Against Government Waste, 2-2-2017, "Pharmaceutical Price Controls: A Prescription for Disaster," https://www.cagw.org/reporting/pharmaceutical-price-controls/ //DF

From August 15, 1971 to April 30, 1974, the entire length of the Nixon price controls, the WPI and CPI increased at annual rates of 12.0 and 7.2 percent, respectively. In the 12 months before price controls were implemented, the WPI and CPI had annual rate increases of 3.3 and 4.3 percent, respectively.[17] Perhaps <u>the most striking impact of Nixon's decision was the evasive action that</u> <u>followed in numerous industries</u>. For example, <u>with price controls in place on conventional cuts of beef,</u> <u>grocers invented new cuts of beef, such as the "watermelon roast," which did not fall under price</u> <u>controls. Lumber producers took advantage of a loophole for imported lumber, which was exempt</u>

from price controls. They simply exported lumber to Canada and then imported it back into the United States. Another loophole was created for "customized" work. Enterprising contractors drilled holes in plywood, then filled the holes back up again to create a customized product.[18] While some evasive maneuvers were clever and successful, others were almost tragic. Cattle were withheld from the market, driving up the cost of beef; baby chickens were drowned; and, food shelves were sparsely stocked.[19] Other, perhaps more memorable examples of price controls, were the gas shortages of the 1970s. Because price controls lead to distortions in the marketplace, the government's regulatory systems often promulgate layers of complex rules to address the irrational behavior resulting from them. Although domestic oil prices were under a price control regime, the cost of foreign oil had been left free to rise and fall based upon market conditions. Because refiners had access to domestic and foreign oil in different proportions, the Nixon administration sought to equalize their costs. Thus, its Cost of Living Council created a two-tier pricing system to equalize the price of all petroleum products from refiners. Prices for foreign oil and domestic oil from "new" wells were allowed to rise while oil from "old" domestic wells were controlled. This intervention in the conservation and allocation of oil supplies caused Americans in various regions of the country to line up for hours to get access to gasoline.[20]

In India, pharma industry corruption of regulatory agencies led to it selling drugs that escaped regulations

Banerje 18 Anubrata Banerje, 4-26-2018, "The side effects of drug price controls," Forbes India,

http://www.forbesindia.com/article/isbinsight/the-side-effects-of-drug-price-controls/50021/1 //DF

Based on their research, Indian School of Business Professor Chatterjee and his co-authors take up this challenge and document how in the market for the anti-diabetic drug Metformin, firms coordinated to manipulate price controls. Their results demonstrate for the first time the issue of regulatory capture in price regulation in Indian pharmaceuticals. Many commentators have expressed concern about this issue for

public policy more broadly in India. <u>Regulatory capture is a phenomenon when a regulatory body gets influenced</u> by the economic interests of special interest groups that dominate the industry, rather than those of the

general public. Regulatory capture is a form of government failure, where government agencies fail to perform their duties. Although the evidence provided by the authors is limited by their single molecule context, and is based on a single-country setting in India, the findings in this paper offer new evidence that in practice, price controls may actually result in adverse welfare consequences. These can include, for example, exit by companies from selling products, inappropriate prescription of pills, problematic health outcomes because of inappropriate prescription etc. For this reason, price controls should be used sparingly by the policy maker with due evidence-based diligence. To provide some institutional context, note that Metformin was made an essential drug by the World Health Organization (WHO) in 1998 for its 500mg dosage. Following WHO, India also controlled the prices of Metformin 500 mg as part of the 2013 Drug Price Control Order (DPCO). The DPCO applied a price-capping formula on Metformin and 652 formulations of 348 other drugs. This formula was arrived at by collecting data of medicine prices from the market. The authors use this setting to create an experimental design, where the formulation on which an intervention (price control in this case) happened was 500 mg and their comparison formulation on which no intervention happened for Metformin, are the other dosage strengths and combinations of Metformin being sold in the market. The findings of the study show that given the control of prices in Metformin 500 mg, 16 out of the 112 firms selling Metformin in the market with at least 1% market share (and whose price data was taken by DPCO to come up with its 2013 price ceiling) coordinated more strongly relative to other firms in the market. These findings provide evidence of regulatory capture. In a nutshell, limiting the scope of regulation to the 500 mg dosage of Metformin (which accounts for 63% of the overall sales of Metformin) creates incentives for some firms more than others to more aggressively market unregulated formulations of the drug. Also as a result of price controls, the top three fixed dose combinations of Metformin with Glimperide, Pioglitazone and Glicazide outsold Metformin. Together, they accounted for 59.5% of sales. These results align with anecdotal evidence from other low- and middle-income economies where pharmaceutical firms divert their efforts into substitute markets to respond to partial price cap regulation. In other words, managers of profit maximizing firms may potentially receive a priori information on regulation and likely shift their efforts to designing new products that escape the brunt of regulation. For example, under Hugo Chávez, price controls imposed on essential food items in Venezuela led firms to switch from price-controlled white rice to non-controlled flavoured rice and from price-controlled milk to non-controlled cheese. These diversions led to shortages, according to a report titled "Feeding Frenzy" that appeared in The Economist in March 2009.

The pharma industry is prone to regulatory capture and corruption

Bennett 97 Sara Bennett, 1997, "Public-Private Roles in the Pharmaceutical Sector," Health Economics and Drugs, DAP Series No. 5, Action Programme on Essential Drugs, World Health Organization, http://apps.who.int/medicinedocs/en/d/Jwhozip27e/12.1.html //DF Where rapid growth in the private pharmaceutical sector takes place, government is often unable to invest in regulatory authorities at the same pace and the capacity of the regulatory authority is outstripped. This was certainly the case in India [46]. Lack of finance for regulation may mean that regulatory authorities have difficulty in attracting the scarce skills required in order to regulate effectively. This is particularly so since the skills required will also be sought after in the private sector, and there is commonly a considerable salary differential between the two sectors. In this context, experience with self-financing registration authorities (see Box 13) is particularly interesting. <u>A key problem in</u> regulation is regulatory capture whereby the regulatory authority serves the interests of the agencies it is trying to regulate more than those of the consumer. This is particularly a problem in specialized industries such as pharmaceuticals where staff of the regulatory authority and industry are likely to have <u>similar professional training and perhaps similar values</u>. Box. 13 Self-financed drug registration [127] The self-financing of drug registration is now being introduced in some developing countries. Formerly, it existed only in industrialized countries such as France, Sweden, the United Kingdom and the USA.

R/T Counterfeits

Xanax, which is usually sold in generic form (meaning its cheap), is still sold en masse on the black market. This means that even if prices are low, people will still go to the illegal market anyways (Reddy - WSJ)

Sumathi Reddy, 10-8-2018, "The Uphill Fight Against Fake Prescription Drugs," WSJ,

https://www.wsj.com/articles/the-uphill-fight-against-fake-prescription-drugs-1539009351 (NK)

The National Association of Boards of Pharmacy reviewed nearly 12,000 internet drug outlets selling prescription medications to U.S. patients. Of these, about 95% were found noncompliant with state and federal laws and NABP standards, according to a report published in September, which highlighted the role social media sites play. Pfizer manufactures **Xanax**, an antianxiety medication also known as alprazolam, but its **patent has expired. That means the vast majority of the medication is made and sold by other companies and available in a generic form**. Pfizer's global security team provides counterfeit-awareness training to law enforcement and customs agencies around the world, in addition to helping with investigations. Recently they spoke with a group of psychiatrists and separately, state attorneys general. **Over the past three years Pfizer has reported more than 10,000 Facebook accounts or profiles selling counterfeit Pfizer medications to the social media company**, says Neil Campbell, director of strategic intelligence at Pfizer. They've referred more than 1,000 Instagram accounts selling counterfeit Pfizer products over the past six months to Facebook, Instagram's parent company.

R/T Lobbying Decrease

It does not make sense for PHARMA companies to cut lobbying spending - they make a return of \$220 for each \$1 spent on lobbying (IHSP)

IHSP, October 2016, "A Profitable Stranglehold - The Pharmaceutical Industry's Investment in Lobbying and Politics",

https://nurses.3cdn.net/6bed845ab6dc3934e6 vlm6b8ji5.pdf (NK)

Studies suggest that ROI for lobbying expenditures can be incredibly lucrative. A study of the effect of lobbying on corporate taxation found that **lobbying returned in excess of \$220 for every \$1 spent on lobbying, or 22,000%.16 Over the past two decades, the Pharmaceutical industry has achieved one of its primary goals, protecting its massive profit margins by preventing Medicare from being permitted to negotiate drug prices.** Twenty-eight percent of all prescription drugs purchased in the U.S. are purchased by Medicare.17 If Medicare were permitted to negotiate over drug prices the federal government could save billions every year, with estimates ranging from \$21.9 billion to as high as \$54 billion annually.18 If one assumes that all of the Pharmaceutical industry's \$3.4 billion lobbying ranges from a \$123 return per every dollar spent (12,300% return) to a \$303 return per every dollar spent (30,300% return). If one were to assume that one half of the Pharmaceutical industry's lobbying expenditures are devoted to preventing Medicare from negotiating drug prices, these returns would double.

R/T America First

1. Doesn't make sense: why can't the US take a policy action that works for the greater global good? Ex. more liberal trade policies that may be somewhat disadvantageous for a US industry, like steel, but good for global free trade.

2. Problematic restriction: the idea that we should preclude discussion of the effect of policy on other peoples presupposes American superiority and justifies mistreating others in the name of nationalism. Ex. deporting undocumented immigrants that are violating our laws but fleeing violence and poverty

3. Thompson 17 explains that we have an obligation to help others because birth is a lottery, by which some infants are randomly gifted the guarantees and opportunities of a rich country while other infants are randomly subjugated to poverty and suffering – nationalist justifications are illusory

because we're randomly born into this nation

Thompson 17 Derek Thompson, 2-15-2017, "Is the H-1B Program a Cynical Attempt to Undercut American Workers?," Atlantic, https://www.theatlantic.com/business/archive/2017/02/the-dark-side-of-the-h-1b-program/516813/ //DF Finally, in the broader context of immigration policy, it is dispiriting that both conservative and liberal Americans remain so uninterested in improving the lives of people who didn't happen to be born on American soil. Yes, the H-1B program may be a fixed lottery system to benefit a handful of individuals at the expense of others. But so is American citizenship. Birth is a lottery, by which some infants are randomly gifted the guarantees and opportunities of a rich country while other infants are randomly subjugated to poverty and suffering. Fully eliminating this inequity would require the dissolution of the nation-state, which is going too far. But what about economic policies that dramatically improve the lives of foreigners and only hurt Americans a little bit? The political case against such a law is obvious. The moral case is harder to make.