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NEGOTIATING PRESCRIPTION DRUG PRICES TO CONTROL HEALTHCARE COSTS

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ABSTRACT

Healthcare's market failures need to be addressed while seeking solutions for rising healthcare costs, a significant portion of which is due to prescription drugs. A recent Department of Health and Human Services report, estimates prescription drug spending will continue rising faster than overall health spending, with specialty drugs rising above all other types. Current policy, under the Patient Protection and Affordable Care Act made notable changes to coverage, costs, and care, but left out making changes to the pharmaceutical industry (largely unregulated), only requiring that it pay for some of the law's increased drug coverage. The lack of regulations has led to the sick using more services, at the expense of the healthy. Possible solutions to this problem include: 1) efficiently using treatments already available, leaving resources for investments and preventative care; 2) embracing techniques used by other OECD countries such as health technology assessments, restrictions on patients' eligibility for new drugs, and requiring strict evidence of the value of new drugs; 3) implementing proposed legislation such as The Affordable and Safe Prescription Drug Importation Act, allowing drug importation specifically by wholesalers, licensed U.S. pharmacies, and individuals from FDA-inspected sites from Canadian licensed sellers; and 4) compulsory licensing, giving third parties permission to make, use, or sell a patented invention without the patentee's consent.

INTRODUCTION

Health care has a myriad of market failures that arise from moral hazard, adverse selection, information asymmetry and negative externalities. On top of market failures, the U.S. faces rising healthcare costs, and spends more than twice as much per capita on health care as the average developed country (PGP Foundation, 2015). The spending per capita measure exceeds all OECD countries except Norway and the Netherlands (PGP Foundation, 2015). A significant part of the rising healthcare spending is due to prescriptions drugs (OASPE, 2016). While recent legislation has made strides in controlling costs, lawmakers still have a long way to go.

According to a recent report by the Department of Health and Human Services, prescription drug prices, particularly specialty drugs, are expected to continue rising faster than overall health spending (OASPE, 2016). The report

found that of the total $457 billion spent on prescription drugs last year, $328 billion (71.9 percent) went to retail drugs and $128 billion (28.1 percent) was spent on non-retail drugs (OASPE, 2016). Between the years of 2010 to 2014, prescription drug spending increases were due to population growth (10 percent), an increase in prescriptions per person (30 percent), overall economy-wide inflation (30 percent), and changes in the composition of medication prescribed toward higher priced products or price increases for drugs that together drove average price increases over general inflation (30 percent) (OASPE, 2016).

CURRENT POLICY

Current healthcare policy is mandated under the Patient Protection and Affordable Care Act (PPACA) or commonly referred to as the ACA or Obamacare. The ACA has made notable changes to coverage, costs, and care (HHS, 2017). The coverage changes ended the exclusion of children (under the age of 19) with pre-existing conditions, keeps young adults on their parent's health plan until age 26, ends arbitrary cancellation of coverage, and guarantees the right to appeal a denial of payment. In terms of costs, there are no longer lifetime limits on coverage (for most benefits). The Affordable Care Act requires insurance companies to explain unreasonable rate hikes and ensures premium dollars are spent primarily on health care (not on administrative costs). The final category of changes impacts care, with the ACA covering free eligible preventative care, allowing patients to choose their primary doctors, and allowing patients to seek emergency care at hospitals outside their health plan's network.

Unfortunately, the ACA left out making major changes to the pharmaceutical industry (largely unregulated) but did require it to pay for some of the law's increased drug coverage (Owens, 2016). Per Rep. Henry Waxman (D-CA), the decision to avoid imposing regulations on pharmaceuticals was largely political, to acquire the necessary support for legislation in exchange for favorable provisions (Owens, 2016). The law passed by a very small margin and was made more difficult after the necessary 60 votes were no longer available due to the passing of the late Senator Edward Kennedy (Owens, 2016). Those involved in the negotiation process claim to have done as much as they could to get the bill passed, but failed to address the restriction on the federal government from negotiating with the pharmaceutical industry, because of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2005 (Frank et. Al., 2008). Public officials should have taken the time to address voters' top health care concerns, one of them being the unaffordability of medications with one-third of Americans experiencing dramatic increases in drug prices (Consumer Reports, 2015). As we saw on the campaign trail, several presidential candidates put forth plans to tackle the affordability of Medicare prescription drugs by negotiating prices (Leonard, 2016).

When Medicare was created in 1965, it was created to cover most needs for the elderly, but at the time prescriptions weren't developed enough to seem

necessary (Gruber, 2013). It wasn't until the 1990s that major advancements were made for common illnesses such as hypertension, depression, peptic ulcers, diabetes, among others (Gruber, 2013). By 2003, Medicare recipients were spending about $2,500 each on drugs, more than twice what the average American spent on all healthcare in 1965 (Gruber, 2013). Covering these prescription costs for the elderly became a major part of the 1998 and 2002 congressional campaigns, and the 2000 presidential campaign, with Democrats wanting to negotiate the lowest prices and Republicans calling for subsidies to private insurers (Gruber, 2013). The result was Medicare Part D, through the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2005, which created the system Republicans wanted while compromising with Democrats, allowing for government reinsurance or ceding some of the financial risk, to deal with adverse selection problems of very sick, costly patients (Gruber, 2013).

Medicare Part D has been widely criticized over the years for creating a "donut hole" in moderate coverage ranging from $2,500 to $5,100 (Gruber, 2013). The "donut hole" is a coverage gap that requires patients to pay for their prescription drugs out-of-pocket after the patient and their drug plan have met their limit (Gruber, 2013). In 2016, the" donut hole" or out-of-pocket expenses for prescription drugs began if a patient's plan limit was $3,310 and ended once they had spent $4,850 total in prescription drugs (Q1Group LLC). The ACA did address this problem by requiring drug companies to offer seniors a discount and by taxing drug manufacturers and importers (Owens, 2016). The "donut hole" will gradually be closed over the next decade, with 75 percent of coverage up to the catastrophic limit (or the plan's deductible) being met by 2019, followed by 95 percent after that (Gruber, 2013).

MARKET FAILURE/SUCCESS

In the absence of government, there wouldn't be as much of an incentive to improve medications and treatments given how expensive the research is and the fact that most new ideas for prescription treatments fail. There also would not be regulations in place to test the safety of new drugs; patients would be in the dark about what they are consuming and whether it is worth taking. Thus, the government largely subsidizes research and development, particularly at universities and government agencies. Patent protections incentivize drug creation but lead to a monopoly. This allows developers to temporarily charge high prices, until the patents expire and generic drugs can be created (McClellan and Rivlin, 2014). The use of generics may result in decreased spending; a 2008 study found that drug spending decreased 22 percent over four years (2003-2007) (McClellan and Rivlin, 2014).

The process of creating a new prescription drug is designed to reduce many levels of information asymmetry in the patent, development, testing, and approval process. There is still very little transparency between how much drugs cost to be produced and the profits that are being generated by sale prices. There is also the

use of direct-to-consumer advertising which targets potential consumers to purchase medications that they may not need or fully understand the side effects for. This causes consumers to go to their doctors and inquire about a specific medication. Doctors have every incentive to prescribe a medication their patient wants because of our current fee-for-service system, resulting in unnecessary medications being prescribed, driving up the demand for health care and higher profits for companies. Patients with more generous insurance coverage are more likely to use new technology, driving up costs and spending, because they lack the incentive to guard against morally hazardous risks. (McClellan and Rivlin, 2014).

Aside from our fee-for-service system, our health care system has other weaknesses, such as the failure to deliver care efficiently across providers and care settings, along with a lack of innovative care at lower-cost treatment sites and wireless services that are not compensated by traditional payment systems (McClellan and Rivlin, 2014). To improve, the government should look at efficiently using the treatments that are already available to leave resources for investments and preventive health care (McClellan and Rivlin, 2014). McClellan and Rivlin (2014) suggest these improvements to send a message of what is considered worthy of additional payments.

NON-MARKET (GOVERNMENT) FAILURE/SUCCESS

In response to healthcare research being a public good, the government provides subsidies, targeted at universities and government research agencies. Government subsidies result in many prescription drug developments that would never happen otherwise, given the price, risk and failures of innovation. A suboptimal level of medications would threaten the health and safety of our country, as is the case with developing countries where demand is low and investments are minimal. The investments made by the government result in greater demand causing price discrimination, a segmented market and creating opportunity for political differences.

With new prescription drugs comes information asymmetry, primarily concerning safety. The information asymmetry is two-tailed, with a null hypotheses (Ho) of zero effect and an alternative hypothesis (Ha) of not safe. Both decisions result in errors with varying political costs. If the alternative hypothesis is rejected, causing a Type I error, the drug is denied market entry, and many potential beneficiaries are denied treatment. On the flip side, there is always the potential that the null hypothesis is rejected, and a drug is approved that ends up being harmful, causing a Type II error, allowing for an unsafe drug to enter the market. The Food and Drug Administration (FDA) avoids Type II errors, unintentionally causing Type I errors in the process, through their use of extra precautions, which can be avoided by using a larger random sample during the testing process. The approval process can be complicated given the non-homogeneity of drugs, many of which appear initially positive, but have side effects that are not immediately observable.

The ACA made improvements to the healthcare system, but failed short of regulating pharmaceuticals, which set their own prices, have no restrictions on profit margins and little transparency on the pricing process, creating information asymmetry between them and their consumers (Owens, 2016).

The result has been the sick using more services, increasing market growth, specifically for specialty drugs with more of the costs falling on patients and the healthy. This is particularly true for patients with health plans through the exchanges, 46 percent of which combine medical and pharmaceutical deductibles, compared to 12 percent of employer plans, per a Milliman analysis sponsored by the Pharmaceutical Research & Manufacturers Association (Owens, 2016). Independent studies have found that insurers shift more drug costs to patients than to hospitals or medical care, which coincidentally is also what the pharmaceutical industry argue insurers do (Owens, 2016).

THEORETICALLY PREFERRED POLICY RESPONSE

As healthcare prices continue to rise with the changing demographics, the U.S. has every incentive to control costs. Soon the country won't be able to afford being the highest per capita drug spender, which is largely due to the fast uptake of new and more expensive drugs compared to other countries, falling victim to the "innovation effect" (Anderson et. al., 2013). The government should be considering using treatments that are already available more efficiently to leave resources for investments and preventive health care (McClellan and Rivlin, 2014).

Given the current system, the government could learn from some examples that have led to cost savings. The Employer Benefit Research Institute (EBRI) found that high-deductible health insurance plans (over $2,000) decreased health spending by 25 percent compared to the control group in the first year, and by 8 percent in the second year (McClellan and Rivlin, 2014). Insurance plans with higher co-pays also decrease health spending by deterring higher office visits for prescription drugs among retirees in the California Public Employee Retirement System (CalPERS), per a study in the American Economic Review journal from 2000-2003 (McClellan and Rivlin, 2014). While these methods decrease health spending, there is a concern they deter necessary visits, preventative care should have no copays.

A Pareto improving solution for our out of control prescription costs would be to adopt techniques used by other OECD countries, such as health technology assessments and restrictions on patients' eligibility for new drugs, in addition to requiring strict evidence of the value new drugs add (Anderson, 2013). The evidence on the value the drug would make could then be used to assess the value it will bring to the market, and prices would be negotiated accordingly (Chien, 2003). While a new drug may be beneficial, it may not necessarily make a much greater impact on patients' health that warrants a more expensive drug on the market. This would also prevent abuses by drug companies such as Turing Pharmaceuticals, whose CEO Martin Shkreli increased the price of Daraprim, used to treat toxoplasmosis, a rare,

parasitic disease (Russell, 2015). Another notable example is the price increase of EpiPen, an emergency allergy treatment, whose price rose from $100 to $600 from 2007 to 2016, as profits for the drug grew over the same period, along with increases in CEO Heather Bresch's salary from $2.5 million to over $18 million (Clarke, 2016).

A proposed piece of legislation that gained traction to reduce costs to consumers was The Safe and Affordable Drugs from Canada Act, sponsored by Sens. John McCain (R-AZ) and Amy Klobuchar (Lachman, 2014). The law would have made it legal for U.S. citizens to import prescription drugs from Canada, a practice that some citizens already take part in illegally, due to the price differences. Per a 2012 report, by the International Federation of Health Plans, a month's supply of Cymbalta, used for depression and chronic pain, costs about $149 in the U.S. compared to $113 in Canada (Lachman, 2014). The price difference is even greater for a month's supply of Nasonex, an allergy drug valued at $105 in the U.S. and $29 in Canada (Lachman, 2014). The problem with drug importation from Canada is that pharmaceuticals would charge Canadians more, or not sell to them at all.

There have been recent efforts to pass drug importation measures through Congress but all have failed. On January 11, 2017, an amendment proposed by Sens. Bernie Sanders (I-Vt) and Amy Klobuchar (D-Minn.) allowing drug importation from Canada by pharmacists, wholesalers, and individuals with a prescription was struck down (Karlin-Smith, 2017). Another proposed amendment that would have allowed drug importation, one by Sen. Lamar Alexander (R-Tenn.) was also unsuccessful (Karlin-Smith, 2017).

In late February, a new drug importation bill was introduced, this time with bicameral support from Sens. Bernie Sanders, Cory Booker, Bob Casey, Martin Heinrich, Angus King and Reps. Elijah Cummings and Lloyd Doggett (Ramsey, 2017). The Affordable and Safe Prescription Drug Importation Act would allow drug importation specifically by wholesalers, licensed U.S. pharmacies, and individuals from FDA-inspected sites from Canadian licensed sellers (Ramsey, 2017). The bill would also allow drug importation from OECD countries after two years, from FDA-certified sellers that would have to pay a fee to fund the program's administrative and enforcement functions (Ramsey, 2017). Whether the Affordable and Safe Prescription Drug Importation Act will pass in a highly-divided Congress with the pending repeal of the ACA remains to be seen.

To address the problem of rare diseases in developing countries, the use of compulsory licensing should be considered. Compulsory licensing is the price of authorizing third parties to make, use, or sell a patented invention without the patentee's consent (Chien, 2003). The concept was discussed in 1790 in the U.S. Senate, in 1851 by the British House of Lords, and in 1853 in Germany by policy makers seeking to "preserve the benefits of patent while minimizing their evil" (Chien, 2003). The 1873 Patent Congress in Vienna, resulted in the creation of the patent, to incentivize innovation, reward inventors, provide property rights

and prevent the public good problem that results from the creation of knowledge (Chien, 2003). Too much protection leads to abuse of monopoly power, blocking the activities of third parties, which can be particularly troublesome during a public health emergency.

Compulsory licensing would allow high priced, patented drugs to be accessible for consumers in developing countries, who typically pay for medications out of pocket, due to the lack of healthcare infrastructure (Chein, 2003). While many argue that patents are necessary to protect innovation, compulsory licenses would still generate revenue through a "reasonable royalty" floor for infringement compensation (Chien, 2003). It would also broaden the distribution and increase the access of patented technologies, allowing for pharmaceutical patent opportunities domestically and abroad (Chien, 2003). With regards to the AIDS crisis, it has allowed for lower drug prices and increased access to patented medications in developing countries (Chien, 2003). Different licenses could be used in the United States and other developing countries to incentivize innovation in those areas.

While we need to protect developers, and incentivize them to continue creating prescription drugs that will battle our current and future diseases, we also need to consider the value they will add to our world. Research is a public good, but for society to reap its benefits, the medications created must address the diseases they are meant to treat and be accessible to those who need it most. Politicians on both sides of the aisle have recognized the need for sensible and affordable healthcare; it's time for official's to also recognize the need for affordable drugs so individuals receive the care they need and the assistance they deserve.

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