NHSDLC Fall 2020: Main Research Packet

Resolved: Countries should not impose price controls on the pharmaceutical industry.

Academic Committee of the NHSDLC *

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1 Letter from the Directors

1.1 Introduction

It is highly recommended that debaters begin by reading the Topic Introduction post on the NHSDLC website. Once debaters are more familiar with the general idea of the topic, then they can proceed with reading the rest of the research packet.

This research packet is a tool for preparing students to debate the topic, **Resolved: Countries should not impose price controls on the pharmaceutical industry.** This will be the topic for the NHSDLC Fall 2020 season.

The first section contains background information about the topic, including some background articles to discuss the terms of this topic. The second section will contain a brief topic introduction written by the NHSDLC Academic Committee. The final two sections will contain evidence that supports either the Pro or Con side.

It is up to each debater to read the articles and incorporate their arguments and evidence into their cases accordingly, considering bias, context, and how these articles present their evidence. Additionally, an article under "Pro" may still have sections or statements that support or sound more like the Con side. These categories are not meant to be "only Pro" evidence; they are only designed to help debaters find some basic starting evidence and ideas for each side of the topic. Some of the resources here have been shortened with an ellipsis [. . .]. However, most of the articles have been posted in their full original length since reading the whole article allows greater understanding of the context and primary idea.

Each article is introduced with a note from the NHSDLC which provides a brief summary of the article and some context of the article (e.g. the value of the article, ways debaters might use this article, etc.). The introduction of each article will also contain questions about the article that debaters can use to check their comprehension of the article. We recommend that debaters read these questions before reading the article and then try to answer the questions after they've finished reading the article. We have also included all the questions at the end of the packet for easy reference.

There is an additional advanced supplemental packet for more advanced students. The supplemental packet is not required to understand the topic. It will contain cards (formatted debate evidence) over many of the core controversies on this topic. It is highly recommended that debaters read through this research packet first before reading the supplemental packet as the supplemental packet does not contain the introductory material in this research packet. After reading through our provided research packets and cards, it is also highly recommended to find articles, evidence, and ideas from your own research, as the most successful debaters tend to find unique evidence and arguments that are truly their own.

1.2 Making the Most of the Research Packet

We'd like to provide some advice on utilizing our research packet and sample cases. This advice is helpful for coaches, parents, and debaters alike. The length of this packet can seem intimidating, so here is some advice for using the research packet.

1. We recommend reading the topic analysis after reading this letter and before reading the other sections. This is because the topic analysis will provide an overarching framework for understanding the topic. It is usually more effective to get a broad understanding of the topic as a whole and then fill in the specific missing knowledge later.
2. We recommend strategies of active reading. Simply reading and re-reading the material isn't an effective way to understand and learn as students will likely forget the material. Here's some suggestions for active reading, taken from the Open University:
    - Underline or highlight key words and phrases as you read. When you return to it later on, you can easily see which points you identified as important. Be selective - too much highlighting won't help.
    - Make annotations in the margin to summarise points, raise questions, challenge what you've read, jot down examples and so on. This takes more thought than highlighting, so you'll probably remember the content better. (Use sticky notes if you don't want to mark the text.)
    - Read critically by asking questions of the text. Who wrote it? When? Who is the intended audience? Does it link with other material you've studied in the module? Why do you think it was written? Is it an excerpt from a longer piece of text?
    - Test yourself by reading for half an hour, putting the text away and jotting down the key points from memory. Go back to the text to fill in gaps.
    - Look for 'signposts' that help you understand the text - phrases like 'most importantly', 'in contrast', 'on the other hand'.
    - Explain what you've read to someone else.
    - Record yourself reading the module material or your notes, and listen to the recording while you're travelling or doing household chores.[1]
    - Another way to think about active reading is through the SQ3R method. It is good for revision as well as reading something for the first time.

[1]Critical reading techniques: Active reading", 2 March 2018, The Open University, https://help.open.ac.uk/active-reading.

'SQ3R' stands for the five steps involved. SKIM through the text quickly to get an overall impression. QUESTION. If you are reading it for a particular purpose (for example, to answer an assignment), ask yourself how it helps. Also ask questions of the text: Who? What? Where? When? How? READ. Read the text in a focused, and fairly speedy way. REMEMBER. Test your memory - but don't worry if you can't remember much. REVIEW. Read the text in more detail, taking notes. Use your own words.

3. For teachers or coaches, we recommend creating lesson plans that incorporate active reading into the assignments. For example, you could assign students to read an article and submit a short paper that contains annotations, notes, questions, and a summary of the article that they just read. You could also assign students to give mini-presentations on an article they were assigned to read where they have to summarize the article as well as identify arguments (claims, warrants, and impacts) in the article. You can also use the questions we've introduced at the beginning of each article as an assignment.

2 Topic Introduction

Lawrence Zhou was formerly a Debate League Director at the NHSDLC. He is currently a Graduate Assistant at the University of Wyoming. In high school, he was the 2014 National Speech and Debate Association National Champion in Lincoln-Douglas Debate.

2.1 Background

What are price controls? They are exactly what they sound like: "government-mandated legal minimum or maximum prices set for specified goods."[2] They are usually designed to make certain goods more affordable. Price controls can either be mandated minimum prices, called price floors, or mandated maximum prices, called price ceilings.

In the context of drugs (medicine), price controls are almost always designed to cap, or limit, the price of drugs. The details of how different price controls work will be explored in the background evidence section.

What is the pharmaceutical industry? Sometimes shortened to "pharma," the industry is the "part of the healthcare sector that deals with medications. The industry comprises different subfields pertaining to the development, production, and marketing of medications. These more or less interdependent subfields consist of drug manufacturers, drug marketers, and biotechnology companies. The main goal of the pharmaceutical industry is to provide drugs that prevent infections, maintain health, and cure diseases."[3]

The only other phrase that might be troubling is "countries." One could interpret this as being "two or more countries." That's clearly not that what this topic means. It's about whether or not, generally, countries should or should not impose price controls.

One thing that makes this topic a little strange is that many countries have some price controls for drugs. It's really just the United States that that (in)famously doesn't have any price controls. It's also no surprise that the United States also has some of the highest healthcare costs in the world. In particular, it has some of the highest drug costs in the world.[4] In fact, the same drugs that might cost just a few hundred in a European or Asian nation might cost two or three times as much in the United States.

[2]Will Kenton, "Price Controls," Investopedia, 10 February 2020, https://www.investopedia.com/terms/p/price-controls.asp

[3]Sybil Prowse, "An Easier Way to Understand the Pharma Industry," Market Realist, 6 December 2019, https://marketrealist.com/2019/12/easier-way-understand-pharma-industry/

[4]Hannah Kuchler, "Why prescription drugs cost so much more in America," Financial Times, 18 September 2019, https://www.ft.com/content/e92dbf94-d9a2-11e9-8f9b-77216ebe1f17

So this topic would be asking the United States not to impose price controls (which it currently doesn't have) and for most European and Asian nations to eliminate their price control systems.

2.2 Main Clashes

This topic is fairly straightforward. While there are many unique arguments for each side, 95% of the arguments on this topic can be boiled down to the clash of **innovation** versus **access**.

For the Con, they will want to argue that price controls are key to making drugs more affordable. Prescription drugs are a huge cost in the United States while they are relatively affordable for most citizens of European countries. Price controls are the most blunt instrument the government can use for making drugs more affordable. If the government just simply prevents drug costs from ever exceeding a set amount, it would guarantee that drugs, especially life saving drugs, would never be too expensive. The high cost of drugs not only decreases access to drugs which has huge consequences for the health of a society, but it also causes immense financial strain on families that struggle to pay for medicine. The Con will want to argue that making drugs more affordable is the primary goal of government.

For the Pro, they want to argue that the high cost of drugs is precisely what ensures there are life saving drugs in the first place. In particular, the United States has become the global leader in medicinal research and innovation particularly because there are huge financial incentives to develop drugs. If those high drug costs were taken away, there would be less interest in companies developing drugs because drugs are so expensive to research and produce. Without innovation, access to life saving drugs is severely reduced.

This is a topic where both teams will need to spend a decent chunk of time delving into the details of their arguments as well as spend a lot of time thinking about how to weigh (compare) these competing arguments.

Good luck to all!

3 Background Evidence

3.1 Cost Control

"Cost control: drug pricing policies around the world," Pharmaceutical Technology, 12 February 2018, https://www.pharmaceutical-technology.com/features/cost-policies-around-world/.

Note from the NHSDLC: This article covers some of the different drug pricing polices around the world.

Questions:

1. How much are you willing to pay for your medicine? Why might there be a right to affordable medicine?
2. What is the balance that must be considered here?
3. What are some of the differences between the US and other countries?

What value do we ascribe to innovative medicines, and how much are we willing to pay for them? The answers to these two questions are often quite different. There is little argument that advances in medical science are of inestimable value to society, and that high-quality medicines and healthcare interventions are a key component in improving lives around the world.

This value is recognised in the United Nations' (UN) Sustainable Development Goals, which include, under the third goal to ensure healthy lives and promote well-being for all, a target to provide "access to safe, effective, quality and affordable essential medicines and vaccines for all".

Providing universal access to modern medical innovations has been no easy feat, anywhere in the world. Even in the wealthiest countries, striking a balance between rewarding innovative drug developers and catering to the needs of budget-strained health systems is an ongoing discussion, whether strict government-level price control is in place, like in the UK, or a more free-market system is being followed, as in the US.

And for developing countries, where medicines can represent up to 60% of healthcare spending and the vast majority of people pay out-of-pocket for prescription drugs, the stakes are even higher. A lack of widespread access to innovative treatments has a major impact on public health. A vital method of boosting access is forming coherent national pricing policies that best serve the health of a country's population while maintaining a viable, as acknowledged by the World Health Organization.

"Strategies for measuring, monitoring and managing prices are essential for promoting access to medicines," the UN health agency noted on its website. "There

is not one single approach that suits all systems. But all systems need to promote equity in access to new products, by ensuring that medical advances are affordable and working with a viable pharmaceutical industry that responds to public health needs."

Below are five case studies showcasing how countries around the world manage the price of pharmaceutical products, and the latest discussions on developing a pricing system that works for everyone.

US: the high price of innovation

The US system of pharma reimbursement is multi-faceted and somewhat opaque, and often results in different prices for different buyers. The US doesn't directly regulate drug prices, meaning that drug companies can set whatever sticker price they deem fit, as Gilead did in 2013 when it set a price of $84,000 for a 12-week course of its breakthrough hepatitis treatment Sovaldi, kicking off a sustained backlash on drug pricing that rages on today.

Medicaid, the federal programme to cover the medical costs of low-income individuals, receives a mandated discount, but Medicare – which provides insurance for Americans over 65 and is the pharma industry's biggest single customer, spending $137bn on prescription drugs in 2015 – is not allowed to negotiate at the federal level.

Insurance companies that have been contracted to administer Medicare are able to negotiate, but with limitations such as having to cover all treatments across six broad drug categories. The private insurance system, which covers many Americans who are not on Medicare or Medicaid, is fragmented into hundreds of different employers and insurance providers, limiting their ability to negotiate steep discounts.

While pharma companies have attempted to deflect public and political criticism on drug pricing with self-regulation – many companies have pledged to limit price rises to no more than 10% per year – there appears to be little chance of fundamental reform to US drug pricing policy in the short term, despite President Donald Trump's tough words on the subject, who described pharma companies as "getting away with murder". Nevertheless, US legislators are reportedly considering a new measure to stop drugmakers unfairly delaying the launch of generic competition to their products.

UK: strict cost-effectiveness analysis

A voluntary system called the Pharmaceutical Price Regulation Scheme (PPRS) is the primary touchstone for setting drug prices in the UK. The PPRS is a non-contractual agreement between the UK Department of Health and the members of the Association of the British Pharmaceutical Industry (ABPI), and is usually reviewed every five years. The current iteration, launched in 2014 and set to expire

on 31 December 2018, uses a value-based pricing mechanism and limits the profits that pharma companies can make from drug sales to the NHS, rather than the prices themselves.

The main body tasked with determining the value of new branded drugs in the UK is the National Institute of Health and Care Excellence (NICE). This non-departmental body of the Department of Health evaluates the cost-effectiveness of drugs based on quality-adjusted life years (QALY), which measure the ability of a treatment to both extend and improve a patient's life. Generally, NICE will not approve any drug for sale to the NHS that costs more than £30,000 per QALY, although exceptions have been made.

In April last year, the UK Government implemented a budget impact test, which stipulates that any treatment that would cost the NHS more than £20m in any of its first three years of use would trigger additional negotiations with the health service to mitigate the financial burden on the public health system. This was criticised by some health charities and many companies in the industry as a step too far, and the ABPI applied for a judicial review of the test, arguing that many drugs that have been deemed cost-effective by NICE would be affected by the new measure.

This legal tussle is emblematic of the downside of the UK's strict value-based approach to drug pricing, which some argue does not support innovation and leaves patients waiting longer for innovative new treatments. Last year, NICE negotiated lower prices for two life-extending branded drugs for the treatment of metastatic breast cancer – palbociclib and ribociclib, developed by Pfizer and Novartis/Astex respectively – allowing them to be used by the NHS, but by that time the drugs had already been available to patients in the US for nearly two years.

China: drug pricing reform

For the last few years, Chinese authorities have been working to pursue the twin goals of creating a less centralised, more market-driven drug pricing system, as well as combating monopolies and ensuring that new, branded drugs are made available at affordable prices.

Currently, the National Development and Reform Committee has traditionally set medicine pricing policy and has final approval on the national product price list, while provincial committees compile a list of reimbursable products for different regions. Hospitals, meanwhile, purchase drugs direct from wholesalers, and use expert councils to evaluate the safety, efficacy and cost-effectiveness of drugs before buying them through tender processes.

The Drug Price Policy implemented by the government in June 2015 is intended to gradually transition from a centralised, double government-controlled system to a more indirect, incentive-driven market. New mechanisms introduced included reimbursement standards for drugs included in the Health Insurance Formulary and

a move towards greater reliance on tendering processes with local buyers.

The new policy has been criticised by some as rather confused. "Some elements of the reform seem not to be well aligned or even contradictory, like introduction of the reimbursement standard and maintaining the tendering system," wrote the authors of a 2016 Pfizer-sponsored study into the reforms. "This indicates that, given complexity of the market, foreign pricing policies cannot be transferred to China without being properly adjusted for local healthcare specificities."

While the country is in the process of moving away from centralised drug price regulation, the government has shown its willingness to negotiate aggressively with companies, leveraging the size of state health insurance schemes (and its broader pharmaceutical market) to bring prices down. In early 2018, China reduced the prices of 36 drugs, predominantly branded medications developed by multinational pharma companies, by an average of 44% as a condition of being made reimbursable under government health insurance.

India: price controls and generic competition

Just as the US is well-known for its hands-off, free-market approach to drug price policy, India is famed for its hard-line stance on regulating drug prices and encouraging generic competition. Strict price controls and a permissive attitude to the development of generic versions of branded drugs for the domestic market – sometimes within a product's patent period – has alienated big pharma and international trade partners to some extent, as well as transforming India's generics industry into one of the world's leading providers of low-cost medicines.

India's stance is understandable, given that the majority of prescription drug costs in the country are paid out-of-pocket, leaving many trapped in poverty by the weight of medical costs. Still, the Modi government is treading a tightrope as it pursues its goal of access to affordable drugs while promoting its 'ease of doing business' policy.

In August last year, the Indian Department of Pharmaceuticals issued a new draft pharmaceutical policy, which could shake up the country's regulation of drug prices. Under the proposal, the National Pharmaceutical Pricing Authority (NPPA) would lose some of its discretionary control as the government looks to bring pricing regulation further under its control. In November, the NPPA announced it had capped the prices of 51 essential formulations, reducing their cost by up to 53

The new policy would restrict the NPPA's pricing oversight to the government's National List of Essential Medicines, losing its power to implement price controls on drugs and medical products that fall outside of the list under special circumstances, as it has done before. The draft policy also recommended banning the sale of generic drugs under brand names, which are often used to jack up prices. Branded generics represented around 80% of the Indian pharma industry's $30bn in revenues

for 2017. Generic drugs would instead have to be marketed using their standard generic names.

However, in January this year the government appeared to back off from its reform plans, primarily due to pressure from the domestic pharmaceutical industry, which cited quality issues and damage to the industry. According to Bloomberg, a new draft of the policy is not expected before the end of the government's current term in 2019.

"It appears to be a hurriedly prepared document with several flaws," said Indian Pharmaceutical Alliance secretary general DG Shah. "It is more a product of perceptions than evidence."

South Africa: has the Single Exit Price worked?

Just as in India, South Africa is working to improve access to effective medical treatments, with out-of-pocket costs high and medical schemes unaffordable for many citizens. The country has introduced price control measures such as capped annual price increases and mandatory generic substitution for branded drugs that have gone beyond patent protection.

In 2004, South Africa introduced transparent drug pricing mechanisms, including a Single Exit Price (SEP). The SEP sets a price at which a prescription drug maker must sell to all pharmacies. The policy was designed to discourage the unnecessary prescribing of expensive drugs where alternatives are available, as pharmacies and doctors are able to add a small logistics fee, avoiding the informal arrangement of bonuses, incentives and rebates that can drive prices up for patients.

Studies have shown that the SEP had an immediate effect on the price of medicines in South Africa, with a 22% reduction on prescription medicine prices in the first year after its introduction. But there remains a dearth of data on the long-term effectiveness of transparent pricing in the country.

"Despite efforts to increase transparency in the supply chain, prices reflected in South African medicine price registries may not be a true reflection of prices negotiated between manufacturers and distributors/wholesalers," wrote V Bangalee and Fatima Suleman of the University of KwaZulu-Natal in a 2016 study published in the South African Health Review. "Initiatives to conduct larger, in-depth pharmaco-economics evaluations are required for a deeper understanding of market trends."

3.2 Examining Two Approaches to U.S. Drug Pricing

Bipartsan Policy Center, "Examining Two Approaches to U.S. Drug Pricing: International Prices and Therapeutic Equivalency," October 2019, https://bipartisanpolicy.org/wp-content/uploads/2019/10/.

Note from the NHSDLC: This article briefly looks like at different price control strategies.

Questions:

1. What are some key drivers of drug prices in the United States?
2. What is reference pricing?
3. What is internal reference pricing?

Introduction

A vibrant, innovative pharmaceutical market is vital to optimizing the health of all Americans. Scientific advances in the pharmaceutical sector have led to new treatments for a multitude of acute and chronic illnesses. While policymakers value the need to support continued innovation, they also seek ways to increase the affordability and accessibility of pharmaceuticals. The United States is the world's largest market for pharmaceuticals, with high prices and high utilization of new pharmaceuticals.1 The United States spends more per capita on pharmaceutical drugs than any other high-income country.2 (Hereafter, the term "drugs" refers to pharmaceutical drugs).

Many new types of drugs, such as biologics, gene therapies, and immunotherapies, require sophisticated, resource-intensive technologies for safe and reliable production. Often, these drugs are the first in their therapeutic class and have limited to no market competition. Patients' accessibility to these novel drug treatments is becoming more of a concern as rising drug prices affect patients' out-of-pocket costs as well as the budgets of private and public payers in the United States.3

For example, health professionals now treat many cancers, autoimmune diseases, and genetic disorders that previously resulted in death and/or a sharply curtailed life span as chronic conditions because of innovative drug treatments. However, the sustainability of paying thousands of dollars per month for such treatments on an ongoing basis is becoming a public concern.

Higher prices for existing drugs (whether generic drugs or brand-name drugs) are also an area of concern with respect to rising drug prices. There has recently been an unprecedented rise in the prices of generic drugs, thought to be largely secondary to manufacturer consolidation.4 In addition, the trend of year-to-year increases in

the price of brand-name drugs continues despite its length of time on the market and despite the presence of other drugs with therapeutic equivalency.5

As a result, an increasing number of Americans and their families must choose between paying for drugs or spending money on necessities such as food, housing, and transportation. About one-quarter of people taking a prescription drug in the United States report that it is either somewhat or very difficult to afford.6 Evidence shows that high drug prices are forcing patients to either delay therapies or preventing them from accessing them at all.7

Policymakers are responding to the challenges in various ways with possible solutions generally falling into three categories: (1) increasing competition; (2) increasing transparency; and (3) increasing value-based payments based on outcomes achieved. This report examines two additional tools—external reference pricing and internal reference pricing—both of which are used more commonly abroad to curb the high prices of drugs.

These tools are generally consistent with the categories outlined above. External reference pricing uses the prices of drugs in other countries in order to potentially set or negotiate the price of drugs. It focuses largely on single-source brand-name drugs or biologics without therapeutic or generic competition. Internal reference pricing, which can ensure that therapeutically equivalent drugs are priced similarly, encourages the use of the least costly alternative therapy.

[...]

Background

DRUG PRICING AND REIMBURSEMENT IN THE UNITED STATES

People often describe prescription drug pricing and reimbursement as opaque due to confusion surrounding the drug pricing determinants. Although a drug's initial price is determined by manufacturers, a drug may eventually have several different prices for various payers and consumers. Prescribers and patients may not have access to these varying prices or to information on how the process for prices is determined. Therefore, making informed decisions about a therapeutically appropriate drug at the most economical price is challenging.

Key Actors Influencing Drug Pricing

Drug manufacturers use gross (from here on referred to as "list") prices to initiate the drug pricing process. List prices are known as an Average Wholesale Price or Wholesale Acquisition Cost and can be likened to sticker prices for cars, as the rationales for prices are not completely transparent.8 Equally opaque to consumers are net drug prices, which are the true drug prices paid by third-party payers (that is, health insurers) and patients after the total value of manufacturers' discounts, rebates, and other price concessions are taken into account.

In addition to the pricing opacity, drug manufacturers can create a monopoly on specialty drugs, such as many single source brand-name drugs and biologics, through patent protection and FDA marketing exclusivity of their products.9 These monopolies can lead to excessive drug prices in a market where other actors and consumers have little leverage.

Another key influencer of drug prices are intermediaries known as pharmacy benefit managers (PBMs) who support health care payers in managing pharmacy costs. PBMs use their ability to set drug formularies for private health insurance plans, including the private health plan formularies in Medicare Part D, as a tool for negotiating discounts from drug manufacturers.10 Private payers, including those participating in Medicare Part D, pay a net (discounted) price to drug manufacturers plus some payment to PBMs.11 This nontransparent price discount between manufacturers and PBMs creates confusion for those who aren't involved in the negotiating process when attempting to understand pharmaceutical pricing dynamics, as discounts may or may not change with changes in list prices.12

In recent years, PBMs have come under closer scrutiny from policymakers due to a perception that PBMs drive up drug prices in their negotiations with drug manufacturers and thereby interfere with patients' access to prescription medications. PBMs charge fees to pharmacies, for example, retail business pharmacies or community oncology practices, and in some cases, these fees have increased dramatically in recent years.13 On the other hand, a recent Government Accountability Office study found that in the case of Medicare Part D drugs, PBMs retained less than 1 percent of the rebates they negotiated with Medicare Part D manufacturers.14

Each of these actors affect drug prices in different ways, some more clear-cut than others. One clear and prevailing theme is that drug spending is growing rapidly and is an ongoing issue area that policymakers are interested in addressing. Prescription Drug Spending in the United States

The Centers for Medicare and Medicaid Services (CMS) defines prescription drug spending as "retail" sales of human-use dosage-form drugs, biological drugs, and diagnostic products that are available only by a prescription from a provider. A complete picture of spending on pharmaceuticals also includes the non-retail segment. The non-retail drug segment includes drugs that are purchased by providers such as hospitals, physician offices, nursing homes, and home health agencies and billed to patients as part of the provider bill.15 U.S. retail prescription drug spending was $333 billion in 2017.16 Non-retail drug spending was estimated at $148 billion (adjusted for rebates), for total U.S. prescription drug spending of $481 billion in 2017.17 After accounting for rebates, the majority (82 percent) of U.S. retail prescription drug spending was incurred by the three major sources of health care payment in the U.S. health system: private health insurance, Medicare, and Medicaid. Among these three payers, private health insurance accounted for the largest

share of drug spending, at 42 percent, followed by Medicare at 30 percent, and Medicaid at 10 percent. Patient out-of-pocket costs represented 14 percent of total retail drug spending.18

According to CMS's 2018-2027 projections of national health expenditures, the U.S. retail prescription drug spending will have grown 3.3 percent in 2018, due to faster than anticipated utilization growth partially driven by an increase in new drug introductions. CMS also projects that retail prescription drug spending growth will further accelerate to 4.6 percent in 2019, followed by a 6.1 percent per year on average growth for the years thereafter. Higher use of costly new drugs and efforts by employers and insurers to encourage patients with chronic conditions to consistently treat their diseases are driving factors contributing to projected retail prescription drug spending.19

U.S. Federal Drug Spending

Medicare is the largest driver of federal drug spending. Medicare pays for drugs through the mechanisms of Medicare Parts B and D, which are described in the following paragraphs. Medicare Part B covers drugs and biologics that are bought and administered by infusion or injection in physician offices and hospital outpatient departments, and certain other drugs provided by pharmacies and suppliers.20 Of total spending for Part B in 2017, about $32.1 billion was spent on drug benefits,21 and spending on Part D benefits totaled $95 billion in 2017 (a sum of Medicare Parts B and D drug benefits totaling $127.1 billion).22 Medicare Part B concentrates drug spending in a small number of expensive products called biologics.

Health care providers use many biologics to treat cancer or its side effects, while others use them to treat macular degeneration, rheumatoid arthritis, and other inflammatory conditions.23 Subsequently, the Medicare program compensates these providers for their acquisition costs. This is the so-called "buy and bill" system for financing physician-administered drugs. Medicare pays for most drugs covered under Part B using an average sales price (ASP) methodology. ASP is based on the weighted-average prices of drugs sold by manufacturers, which reflect discounts and rebates off list prices. The ASP calculation excludes certain types of sales, including sales to Medicare Part D plans and to entities covered by the Section 340B drug purchase program.24

The Medicare Modernization Act of 2003 established the Medicare statutory payment rate at 106 percent of ASP for most Part B drugs. The 6 percent add-on helps cover extra costs associated with these treatments, some of which involve special storage and handling protocols.25 Physicians get a separate fee for administering drugs that must be injected or infused. Despite the statute setting Part B drug reimbursement at 106 percent of ASP, budget "sequestration" has reduced payment to 104.3 percent of ASP since 2013.26 Intended to cover any added acquisition-related expenses, the percentage add-on can also have the unintended consequence of pay-

ing physicians more for prescribing drugs with higher costs than for prescribing less expensive therapeutic alternatives.27

Medicare Part D is a voluntary outpatient prescription drug benefit for people with Medicare, provided through private plans approved by the federal government. Medicare Part D accounts for 3.4 times greater Medicare spending compared with Medicare Part B.28 Beneficiaries can choose to enroll in either a stand-alone prescription drug plan to supplement traditional Medicare or a Medicare Advantage prescription drug plan, mainly HMOs and PPOs, that cover all Medicare benefits including drugs.29 In 2018, more than 43 million of the 60 million people with Medicare were enrolled in Part D plans.30

Other federal drug plans require price discounts from manufacturers who wish to have their drugs covered.31 Medicaid, the Veterans Health Administration, the U.S. Department of Defense, and the 340B drug program require price discounts from manufacturers with various tools (specific to each of these federal drug plans).32 Price controls, usually in the form of required discounts from the average price paid by other purchasers and negotiated pricing, in which the government uses its market power to bargain for favorable rates from pharmaceutical suppliers, are some of the tools used to achieve price discounts.33

High Prices Are Concerning to Policymakers

Despite the existing drug cost-management tools available to payers and PBMs, high drug prices continue to be of great concern to patients, taxpayers, employers, and the federal government. A defense of the status quo often invokes the concern that reducing drug prices may stifle innovation by discouraging research and development. However, others point to data suggesting that many of the largest pharmaceutical companies spend far more on sales and marketing than on research and development.34

The current dialogue taking place across the country, perhaps most notably the dialogue initiated by the Trump administration, reflects the growing burden of pharmaceutical costs on consumers.35 Efforts at the federal and state levels and the vested interests of other stakeholders suggest that the opportunity may be ripe for collaboration on paths forward to address the challenge of high prices.

[...]

International and U.S. Experience With Reference Pricing

EXTERNAL REFERENCE PRICING ABROAD

Most European countries use international reference pricing as a tool to determine payment strategies for pharmaceutical drugs. The World Health Organization (WHO) Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies defines external price referencing as "the practice of using the price(s) of

a medicine in one or several countries in order to derive a benchmark or reference price for the purpose of setting or negotiating the price of the product in a given country."49

A recent analysis found that 36 of 41 countries surveyed by WHO in the Europe region apply external price referencing for some medicines. Of those 36, 26 apply the tool as the sole or main pricing policy, although this could be limited to specific sectors, such as the outpatient sector. The number of reference countries ranged between one (Luxembourg) and 31 (Poland), with the selection criteria consisting largely of similarities in economic conditions and geographic proximity. The majority of countries (25) used the manufacturer (list) price when conducting external reference pricing. The most common formula used to calculate the reference price was to average the prices or to use the average of the three lowest prices of reference countries. Most countries surveyed monitor and revise prices on a regular basis; however, the duration of the intervals ranged from three months to five years. Countries dealt with challenges related to the non-availability of price information in various ways, including requiring data availability in at least a minimum number of reference countries. Beyond Europe, external reference pricing has also been applied, reportedly, in 23 countries worldwide; however, there is considerably less published information on its use.50

It should be stated that while there are several common practices among countries using external price referencing, overall, there is a significant amount of heterogeneity in its application. This variation makes it difficult to assess the overall impact of external reference pricing on outcomes such as the affordability and accessibility of medicines. Even within a country, impact analyses are limited because external reference pricing is often not the only approach used in pricing.51 Other approaches include value based pricing and internal reference pricing, to name a few.

Nevertheless, several researchers have attempted to isolate the impact of external reference pricing within and across sectors. In general, these studies demonstrate that external reference pricing leads to lower medicine prices immediately, but this effect may diminish over time.52 In addition, methodological specifications have a significant impact on reductions in pricing. For example, one study demonstrated that more frequent monitoring and systematic price revisions led to greater price reductions. Further modeling suggests that the size of the market basket of countries, the exclusion of either lowest-income countries or highest income countries, and the calculation formula also impact the average external reference price.53

Research has also investigated potential unintended consequences of external reference pricing schemes. For example, one study demonstrated that external reference pricing policies may encourage higher pricing in low-income countries, directly undermining affordability of medicines in these countries.54 Other studies suggest that external reference pricing may discourage incremental innovation and invest-

ment in research and development, particularly in the short-term.55,56 Additional studies have pointed to external reference pricing leading to spillover effects, such as manufacturer launch delays, particularly in countries with lower prices and strict regulations.57 Some researchers have proposed that governments consider compensating manufacturers for the overall small negative impact on manufacturer revenue.58

To support European countries implementing external pricing schemes, the European Integrated Price Information Database (EURIPID) collaboration maintains a database with information on national prices and pricing regulations of medicinal products in a standardized format.59 In 2018, EURIPID, with funding support from the European Union Health Programme, jointly developed 12 "Guiding Principles," which are meant to serve as best practices for countries in establishing external reference pricing schemes.

Of these principles, the one with the greatest debate involves the selection of price type (principle 5). The EURIPID collaboration argues that external reference pricing must be applied at the first possible price type, such as the "ex-factory," or list price. Doing so negates the need to take into account the various price differentials along the pharmaceutical distribution chain (for example, tariffs, duties, taxes). It has also argued that the application of external reference pricing at the retail price level is challenging due to the frequent lack of transparency in supply chain negotiations.61

However, a previous study on enhanced cross-coordination in the area of pharmaceutical product pricing using a basic simulation model found that external reference pricing could garner larger savings if real prices paid by payers (discounted prices) were used. Many have questioned the political feasibility of such an approach given not only the likely opposition from the pharmaceutical industry, but perhaps from countries themselves, who may fear being granted fewer discounts.62

INTERNAL REFERENCE PRICING ABROAD

Internal reference pricing is defined by the WHO as the "practice of using the price(s) of identical medicines or similar products or even with therapeutic equivalent treatment (not necessarily a treatment) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country."63 While many countries apply this strategy to set generic prices in relationship to originator medicines (versus fostering generic competition in the United States), more relevant for American policymakers is the practice of reimbursing therapeutically equivalent drugs similarly by setting a reference price. The reference price is typically the maximum level of reimbursement for a group of drugs. Given that patients are often asked to pay the difference between the reference price and the price of more expensive drugs, they are encouraged to opt for the lower-priced therapeutic equivalent. As of 2017, 22 out of 28 EU member

states used this form of internal reference pricing.64

A Cochrane systematic review of 17 studies a focused on the impact of internal reference pricing on health outcomes, health care utilization, drug expenditures, and drug use. While the overall quality of evidence was low, the review found that internal reference pricing may reduce third-party drug expenditures immediately and up to two years. The review suggested that reference pricing may increase the use of reference drugs while reducing the use of more expensive drugs requiring patient cost-sharing. Effects on drug prices, patients' out-of-pocket payments, health outcomes, or health care utilization were uncertain due to lack of evidence. There is no documentation identified that the use of internal reference pricing could lead to disincentives to pharmaceutical innovation.65

A previous review of internal reference pricing policies in OECD countries found that internal reference policies led to price decreases, particularly for drugs that were already facing generic competition prior to reference pricing. The review found that brand-name drugs originally priced above the reference price decreased their prices to a greater extent. There was no association between clustering therapeutically equivalent drugs and health losses for patients.66 Finally, a Harvard Medical School metaanalysis of 16 studies evaluated various internal reference pricing policies and found that this tool reduced drug prices and promoted switching from expensive products to alternatives at or below the reference price. These outcomes were associated with reductions in both patient out-of-pocket and total payer expenditures.67

[...]

4 Pro Evidence

4.1 Price Controls Would Slow a COVID Vaccine

Kenneth E. Thorpe (a professor of health policy at Emory University, Atlanta, and chairman of the Partnership to Fight Chronic Disease), "Your View: Why price controls would slow work on a coronavirus vaccine," mcall, 19 May 2020, https://www.mcall.com/opinion/mc-opi-coronavirus-vaccines-price-controls-thrope-20200519-w4j4muuprzbn3ph5lnpgvh7mm4-story.html.

Note from the NHSDLC: This article argues that price controls, specifically in the United States, would hurt the innovation necessary to develop a COVID-19 vaccine.

Questions:

1. Why does the United States lead the world in medical innovation?
2. Why is innovation so expensive?
3. Why might price controls hurt innovation?

American scientists are working furiously to develop treatments for the novel coronavirus, COVID-19. Right here in Southeast Pennsylvania, Inovio Pharmaceuticals is in the midst of Phase I human testing for its coronavirus vaccine candidate and hopes to launch Phase II and III trials this summer.

No group of patients needs a vaccine more than those with chronic conditions. Patients with just one chronic disease who contract COVID-19 are 80% more likely to experience a "poor outcome" — such as hospitalization or death — than those without any chronic conditions, according to recent studies.

Fortunately for Americans living with chronic disease, the United States leads the world in medical innovation. As long as policymakers protect this innovation ecosystem, they'll surely produce vaccines and treatments relatively quickly — and keep our nation healthy through this crisis and for years to come.

Americans are rightly worried about COVID-19. World Health Organization officials say the virus is far deadlier than the seasonal flu. More than 90,000 Americans have died from COVID-19, while more than 1.5 million have tested positive for the disease. Health officials expect those numbers to rise exponentially in the coming weeks.

Patients with chronic diseases are particularly vulnerable. Forty percent of hospitalized COVID-19 patients have some type of cardiovascular or cerebrovascular disease. Other chronic conditions — such as arthritis, diabetes, and cancer — could make it harder for the body to fight the virus.

But our scientists will rise to this challenge and invent new therapies, just as they have countless times in the past. Heart disease death rates have declined 36% between 2000 and 2014, largely thanks to new and better medicines. Similarly, cancer death rates have declined 27% since the 1990s.

Overall life expectancy for all Americans has increased by 10% since the 1950s.

Health gains like this come at a hefty price. It takes up to 15 years and $2.6 billion to develop just one new medicine. And only 12% of drugs that begin clinical trials ever make it to pharmacy shelves. Drug companies and their investors will only roll the dice on novel research projects if they have a chance of recouping their development losses and earning a return.

Because the United States fairly values medicines, scientists have a strong incentive to launch research projects here. In 2018 alone, drug companies poured nearly $100 billion into U.S. research projects. All told, American firms develop half of the world's new medicines.

Meanwhile, researchers tend to flee countries whose governments arbitrarily cap prices of new medicines. Consider how price controls decimated pharmaceutical research in Europe. In the 1970s, Europe produced more than half of the world's new medicines. But throughout the 1980s, many European countries imposed increasingly strict price controls on drugs. As a result, today Europe produces only 33% of all new drugs.

Unfortunately, some lawmakers want to implement similar price controls in the United States. A few members of Congress attempted to slip a price control into the COVID-19 spending package. The provision would have allowed the government to dictate the price of any COVID-19 vaccine that resulted from the emergency funding.

Congress wisely stripped out that provision, which would have discouraged investments into COVID-19 cures, vaccines and therapies. Congress' decision is great news for every American hoping for a COVID-19 vaccine, especially those living with chronic disease.

COVID-19 poses an enormous threat to American society — but our smartest scientists are already on the case. Let's hope our policymakers don't put any stumbling blocks along their path to a cure — whether for coronavirus or any other dangerous disease.

4.2 Get Europe to Drop Its Price Controls

Pietro Paganini (an adjunct professor at John Cabot University in Rome and at Temple University Fox School of Business, and president of Competere, an Italian think tank committed to advancing innovation and sustainable growth), "The real prescription for lower drug prices: Get Europe to drop its price controls," Washington Examiner, 29 June 2018, https://www.washingtonexaminer.com/opinion/op-eds/the-real-prescription-for-drug-prices-get-europe-to-drop-its-price-controls.

Note from the NHSDLC: This article argues that price controls in Europe have not been as effective as advocates claim and cites evidence to show that price controls have hurt Europe's ability to innovate.

Questions:

1. What evidence does the article provide to show that Europe once led the world in drug innovation?
2. What does the article is the best way to lower drug prices in the long term?
3. Why should Europe lift its drug price controls?

It's no secret that transatlantic relations have been a bit stormy recently, due in part to President Trump disparaging European countries as "freeloaders" who invest comparatively less in research and development for new medicines while suppressing drug prices through government controls.

Nor is it surprising that Europeans have taken exception to his belligerent tone. But pundits on both sides of the Atlantic should note that an altogether calmer American politician, the respected Sen. Orrin Hatch, R-Utah, is making the same point, albeit with less inflammatory language. Innovation reduces the cost of medicines by fostering competition, but price controls hinder this process.

The U.S. is the world's primary source of research and development for new drugs. According to the European Commission, America spent 61B on pharmaceutical RD in 2016 — about 46 percent of the global total — even though the U.S. represents just over 4 percent of the world's population and just under a quarter of global GDP in nominal terms. The overwhelming majority of this innovation is privately funded, and research has revealed a strong correlation between drug companies' profitability and RD spending: The more money they take in, the more they invest in innovation.

But in Europe, innovators are subject to arbitrary price controls, instituted by national governments more interested in rationing and keeping drug prices artificially depressed than in finding new cures. Thanks to measures like price caps and

compulsory rebates, on average the 31 members of the Organisation for Economic Co-operation and Development spent 474 per capita on prescription drugs in 2015, compared to 750 in the U.S. Once again, because of the strong link between income and innovation, that means less money for new cures: While the U.S. drug industry spent 199 per capita on RD in 2014, for the European members of the OECD the figure was just 47 per capita.

Ironically, these market-distorting interventions actually help prop up drug prices in the long term, by stifling the only reliable means of lowering them through real economic forces: innovation and competition.

A number of studies have shown that pharmaceutical RD results in lower drug prices by spurring competition. Since patents cover specific molecules but not the natural biological processes they interact with, following the discovery of a new drug rival companies have every incentive to develop drugs which exploit the same process — often offering additional benefits, such as greater efficacy or tolerability — thereby forcing down the price of the first drug, even while it remains under patent protection.

One study of twenty new "follow-on" drugs found that 80 percent launched at a discount relative to the first drug, with an average discount of 26 percent. Another study identified discounts of 21 percent to 61 percent for seven major "follow-on" drugs launched in recent years. Regulators from the European Medicines Agency confirmed that in some cases "availability of these products can drive down prices almost as much as the availability of generics," citing the example of follow-on drugs for hepatitis C, with eight new competitors forcing price reductions of 40 to 65 percent in just a few years.

This process happens very quickly. The time needed for competitors to develop a "follow-on" drug plunged from 10.2 years in the 1970s to 1.2 years in the 1990s, while the period of "marketing exclusivity" fell from 8.2 years to 1.8, yielding price reductions with remarkable speed, and without the need for price controls or tampering with patents protections.

Crucially these price reductions were not the result of government fiat, but rather the product of market dynamics that allowed innovation to flourish. As such they will extend to every healthcare system in the world, provided free market principles are allowed to operate. Transparent pricing policies, strong protections for intellectual property, incentives to innovate — these are the lodestars that should guide American trade representatives seeking fairer trade terms in bilateral negotiations with the United Kingdom, the EU, and other trade partners.

According to a new study supported by the World Economic Forum and the MacArthur Foundation, eliminating price controls in OECD nations would increase global pharmaceutical R D spending by 9 percent to 12 percent, producing 8 to 13 new drugs

per year and extending the average lifespan of a 15-year-old living in these countries today by around a year.

Lifting drug price controls would also help restore Europe to its rightful place as a leader in scientific innovation — a role it forfeited in the 1990s, not coincidentally at the same time price-controls became widespread. This is not just a matter of pride, but economic good sense: European champions, currently constrained by price controls at home, would be unshackled, boosting R D investment and creating tens of thousands of new jobs through direct and indirect employment networks. Setting aside the enormous potential gains in health and wellbeing, it seems perverse that the EU, with a population over 50 percent larger than the U.S., should employ 14 percent fewer people in its pharmaceutical industry, with less than half the value added per employee.

While American politicians are understandably focused on lowering drug prices at home, this issue is important for Europeans too. Arbitrary government interventions have distorted our markets for too long, sacrificing medical advances, depressing economic growth, and ceding scientific leadership. Europeans have paid a steep price, trading long-term progress for short-term savings, and now we are headed in exactly the wrong direction, threatening to further reduce incentives for innovation and competition in the pharmaceutical sector. It is time we faced reality and let the markets do their work — even if that means admitting Trump was right.

4.3 A Prescription for Disaster

Citizens Against Government Waste, "Pharmaceutical Price Controls: A Prescription for Disaster," 2016,
https://www.cagw.org/reporting/pharmaceutical-price-controls.

Note from the NHSDLC: This article gives a comprehensive list of reasons why price controls in the United States would be particularly harmful.

Questions:

1. What are some historical examples of price controls in the United States that have failed?
2. What are some historical examples of price controls specific to drugs in the United States that have failed?
3. What are some of the recommendations the paper gives for how to improve access to drugs?

Introduction

Throughout history, governments around the world have tried to control the prices of goods and services. These efforts have disrupted the marketplace and created shortages or excesses. But just like zombies, price controls keep rising from the dead because politicians seem to think they can create a better methodology. They never learn that price controls do not work and end up hurting the economy, consumers, and taxpayers.

The latest effort to control prices is focused is on prescription drugs. Politicians in Washington, D.C., and around the country are calling for a variety of policies to control drug prices, such as restricting how much drug companies spend on research and development; capping out-of-pocket expenses; penalizing an "unjustified" price; allowing the importation of drugs from other countries; utilizing Medicaid-style rebates; and, allowing the secretary of the Department of Health and Human Services (HHS) to "negotiate" prices for Medicare Part D.

There have been efforts within Congress and state legislatures to enact "transparency" legislation to force pharmaceutical companies to release reams of proprietary information, such as the details of clinical trials and regulatory costs; manufacturing and administrative outlays; and acquisition, patent, and licensing costs in a supposed attempt to understand how drugs are priced.

It is understandable that patients, insurers, and politicians react passionately to high costs, but more competition, not price controls, will resolve this matter. The added benefit of competition is more research and innovation, which otherwise would be hampered with price controls.

In 2000, Citizens Against Government Waste released, Price Controls on Drugs: Hazardous to Your Health. At that time, President Bill Clinton was considering the creation of a prescription drug benefit for Medicare beneficiaries. Although his plan did not specifically call for price controls, the proposed pricing mechanisms would have yielded such a result.

For example, the Clinton plan would have allowed the Health Care Financing Administration (HCFA) [now the Centers for Medicare and Medicaid Services] to utilize only one pharmaceutical benefit manager (PBM), after a bidding process, for each of 15 defined geographic areas. HCFA could even have decided to utilize one PBM to oversee several regions, creating a monopsony, a situation in which one purchaser is so large it controls the price. Such a proposal, had it been implemented, would have stifled competition and limited access to some pharmaceuticals while giving more control to government bureaucrats.[1] Fortunately, the Clinton proposal was not passed into law.

With the 2016 presidential election on the immediate horizon, drug prices remain a hot-button issue. Both former Secretary of State Hillary Clinton (D) and Donald Trump (R) have offered drug-pricing proposals. For example, former Secretary Clinton has called for controls on pharmaceutical research and development and Medicaid rebates for low-income Medicare beneficiaries. Both candidates have called for the government to "negotiate" drug prices in Medicare Part D and allow importation of drugs from abroad.[2]

Despite the implication that no price negotiations occur in Medicare Part D, it is not true. PBMs administer prescription drug plans and negotiate every day with pharmaceutical companies and pharmacies to find the best deal for the clients they serve: Medicare beneficiaries, the Federal Employee Health Benefits Program (FEHBP), insurers, unions, and companies that provide health plans for their employees. They use a variety of tools, such as mail order delivery; creating networks of more affordable pharmacies; encouraging the use of generic drugs; negotiating rebates from manufacturers; reducing waste; and counseling patients to take their medications in order to stay healthy and lower healthcare costs.[3]

Medicare Part D was signed into law on December 8, 2003, and the Congressional Budget Office (CBO) predicted in 2005 that the benefit would cost the government $127 billion in 2012; however, its cost in that year was $55 billion.[4] Compare that result to Medicare Parts A and B, which use government price controls to pay providers. In 1967, the House Ways and Means Committee predicted the entire Medicare program would cost taxpayers $12 billion in 1990; its cost that year was $98 billion.[5]

Because of Medicare Part D's "non-interference" clause, which prevents the HHS secretary from interfering in price negotiations among stakeholders, private-sector competition has kept premium costs low and beneficiary satisfaction high. Medicare

Part D has often been cited as a model to restructure the entire Medicare program for future beneficiaries, as suggested in the House Republicans' June 22, 2016 policy document, "A Better Way – Healthcare."[6]

Regarding importation, there are significant and serious pitfalls to purchasing drugs from other countries. While the Food and Drug Administration (FDA) does allow some importation of drugs for personal use in very special circumstances, the agency has long expressed anxiety about drug importation in general. Many drugs sold overseas have different formulations or, worse, the drugs could be adulterated and dangerous. The FDA website notes, "many drugs obtained from foreign sources that claim or appear to be the same as U.S.-approved drugs are, in fact, of unknown quality and may even be counterfeit. There is also a possibility that drugs coming to U.S. consumers through Canada, or that claim to be from Canada, may not actually be Canadian drugs. FDA cannot assure the authenticity, safety, or effectiveness of drugs from foreign countries."[7]

Some politicians argue drug importation is a trade or "free market" issue, but it is not. Importing another country's drugs because the prices are lower is simply importing that country's price controls. Furthermore, it is unlikely a research-based pharmaceutical company will ship more drugs to a foreign country, such as Canada, than its population needs. It is also unlikely that Canadian pharmacies will ship their supplies of drugs to U.S. markets without increasing prices. Even worse, allowing importation would encourage unscrupulous actors to utilize counterfeit drugs made in third-world countries, camouflage them as Canadian prescription drugs, and ship them to unsuspecting Americans.[8]

Price Controls: Always a Misguided Policy

In their 1978 book, Forty Centuries of Wage and Price Controls, authors Robert Scheuttinger and Eamonn Butler ably demonstrated that price controls are damaging, whether utilized in 2150 B.C. or 2016 A.D. From the Babylonian Code of Hammurabi, to President Nixon's Economic Stabilization Act, to rent control in San Francisco and New York, the authors laid out how price controls interfered with the marketplace, caused shortages, and hurt the very population they were intended to help.[9]

Economist Gary North wrote in a May 1, 1974, article, "The Puritan Experiment with Price Controls," that although colonial leaders were trained in law and theology, most were farmers, craftsmen, and artisans. The study of economics was a fledging discipline in England and, therefore, when shortages occurred – perhaps because of a bad growing season or little competition or a lack of craftsmen for a particular product or service – citizens complained of price gouging and exploiters. The response to these circumstances was to employ "'tried and true' medieval economic concepts."[10]

For example, in 1630, the colonial leaders of the Massachusetts Bay Company passed a law that:

established wage ceilings for carpenters, joiners, bricklayers, sawyers, and thatchers. Common laborers were limited to twelve shillings a day, or six if meat and drink were provided by the employer. Any artisan violating this statute was to be assessed a ten shilling fine. The effect of these wage ceilings must have presented itself almost immediately: an excess of demand for the services of artisans over the available supply. Under such conditions, it is always difficult to recruit labor. Within six months, these wage ceilings were repealed, leaving wages 'free and at liberty as men shall reasonably agree.'[11]

North pointed out that, even after this first failed attempt at price controls, similar restrictions were adopted in subsequent years. In 1633, magistrates imposed a general profit margin of 33 percent on any imported good, but added a clause that warned citizens against violating the "intent" of the law forbidding "excessive wages" and "unreasonable prices for such necessary merchandise or other commodities as shall pass from man to man." Those who violated the intent of the law would be punished with fines or incarceration. The law gave enforcement agents broad discretion to determine the meaning of "intent" and "excessive," which led to "a considerable degree of uncertainty in economic exchanges." The law was repealed two years later.[12]

Finally, after even more attempts by colonial leaders to control prices, in 1650 there was a relaxation of economic regulations. As trade grew, so did market transactions, and the colonists benefitted from more competition, more specialized production, greater economic productivity, and lower prices.[13]

Wage and Price Controls in the 1970s

During the 1970s, inflation had taken its toll on the American economy due to prolific spending in the 1960s on massive new social programs and the Vietnam War. This led to high inflation and a weakening of the dollar, because the dollar was fixed to a specific amount of gold and other countries' exchange rates were tied to it. The pressure on the dollar became unbearable in mid-1971, and President Nixon abandoned the gold exchange standard.[14] As inflation rose, President Nixon made a fateful decision. Under the authority of the Economic Stabilization Act of 1970, he issued Executive Order 11615 on August 15, 1971, to "stabilize prices, rents, wages, and salaries in order to improve our competitive position in world trade and to protect the purchasing power of the dollar."[15]

Although the executive order was only supposed to last for 90 days, several iterations were implemented: Phases Two, Three, and Four. After Phase Four was executed on August 12, 1973, Secretary of the Treasury George Schultz announced that the goal of the administration was to reduce inflation to 3 percent per year or less. Phase

Four lasted nine months and, during that time, the Wholesale Price Index (WPI) went up by 18.3 percent and the Consumer Price Index (CPI) went up at an annual rate of 11.4 percent.[16]

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 the most striking impact of Nixon's decision was the evasive action that followed in numerous industries. For example, with price controls in place on conventional cuts of beef, grocers invented new cuts of beef, such as the "watermelon roast," which did not fall under price controls. Lumber producers took advantage of a loophole for imported lumber, which was exempt 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]

Another adverse impact of price controls was a greater reliance on imported oil. In October 1973, when the OPEC nations announced an oil embargo to countries that had given assistance to Israel during the Yom Kippur War, gas shortages, price gouging, and long lines at the pumps became even more pervasive.[21] Drivers looked for green flags outside service stations, which signaled gas was available; license plate numbers determined what day consumers could buy gas.

Most price controls ended by April 1974, but the control of oil prices was transferred to the Federal Energy Office. Instead of getting rid of price controls, Congress de-

cided to "punish" oil companies in 1976 for continued high prices and extended price controls indefinitely. The price controls further discouraged domestic production of oil and encouraged even greater reliance on foreign oil that often came from unstable parts of the world.[22]

With energy costs still high and an increased reliance on foreign oil, President Carter asked Congress to turn the Federal Energy Office into the U.S. Department of Energy. His administration then increased the fuel efficiency mandates created under the Nixon administration, pumped billions of tax dollars into alternative energy, and required energy savings standards on home appliances. Millions of dollars were wasted on projects that were not economically sound, such as coal gasification. The end result was that oil consumption rose from less than 15 million barrels a day in 1970 to more than 18 million barrels a day in 1979.[23]

The 1979 Iranian oil crisis, caused by the Iranian Revolution, suppressed output and pushed gas prices higher. Panic ensued and lines began to form at gasoline pumps. In an effort to make more fuel available, Carter began to dismantle the price controls on oil and gasoline. Prices quickly rose and businesses passed along their costs, which helped to create sky-high inflation; and unions demanded large cost-of-living increases. The Federal Reserve, reacting to the crisis, increased interest rates, which plunged the nation into a recession.[24]

When President Reagan entered the White House, one of the first actions he took was to remove the oil price controls and abolish approximately 200 energy regulations. Over time, consumption and oil prices fell in real terms as domestic oil production increased for the first time in 10 years. The free market did more to control the price and improve access than any government program.[25]

The price controls of the Nixon era had a broad array of odd, distorted, and unintended effects, which the president realized far too late. Nixon said:

What did America reap from its brief fling with economic controls? The August 15, 1971, decision to impose them was politically necessary and immensely popular in the short run. But in the long run I believe that it was wrong. The piper must always be paid, and there was an unquestionably high price for tampering with the orthodox economic mechanisms.[26]

Price Controls for Insurers Has Not Worked

President Obama promised lower costs and greater accessibility if the Patient Protection and Affordable Care Act (ACA), or Obamacare, became law. The opposite has happened. While the federal government has engineered insurance premiums and insurers' profits, promising less strain on everyone's wallets, in reality Americans are experiencing higher premiums, sky-rocketing deductibles, and large out-of-pocket costs. On October 24, 2016, HHS announced that the average premium increase for the benchmark Obamacare plan would be 25 percent.[27]

Under free-market conditions, younger people would pay less for health insurance because they tend to be healthier and utilize fewer services compared to those in their late sixties. Prior to Obamacare, some form of community rating was mandated in 18 states to spread risk across the community and people paid the same rates no matter their health status or factors such as age or gender. In the states that used community rating, insurance premium costs were higher.[28] Under ACA's adjusted community rating, insurers can adjust insurance premiums based on only four factors: individual or family enrollment; geographic area; age; and, tobacco use. With respect to age, the law will not allow insurers to charge an older adult more than three times the rate charged a younger person.

This policy has driven up health insurance premiums for younger, healthy people, particularly those between the ages of 18 and 30, to the point they would rather pay a fine than purchase insurance. According to March 2016 data from the Centers for Disease Control and Prevention's National Center for Health Statistics, approximately 16 percent of Americans aged 25 to 34 do not have health insurance and 14 percent of those between the ages of 35 to 44 are also without coverage.[29] Yet, these are the very participants Obamacare needs in order to stabilize the marketplaces. Younger purchasers know a bad deal when they see it and are rejecting the high premiums and deductibles.

In addition, the four compulsory cost-sharing metallic plans, Platinum, Gold, Silver, and Bronze, dictate actuarial value costs. Under a Platinum Plan, the insurer is required to cover about 90 percent of healthcare costs; under Gold about 80 percent; under Silver about 70 percent; and, under Bronze about 60 percent. In each case, consumers pick up the rest of the costs, which can vary depending on whether they qualify for government subsidies.

Obamacare controls the amount an insurer spends from premium dollars on claims, administration, and profits, known as the medical loss ratio (MLR). The law requires health insurers that cover individuals and small businesses to spend 80 percent of premium funds on covering healthcare claims and 20 percent on administration. For insurers covering large group plans, the MLR is 85 percent. If insurers fail to meet their MLR benchmark, they must pay a rebate to their customers. For 2015, the average rebate amount was approximately $129 per family, or less than 11$ per month.[30]

An insurer's revenue will vary from year to year, depending on the number of patients and cost of claims. America's Health Insurance Plans (AHIP), the national association representing the health insurance industry, cautioned in 2012 that administrative costs are not driving healthcare costs and capping them would make it more difficult to improve care. Items such as deterring fraud, credentialing in-network providers to make sure they provide quality care, and providing patients with online and mobile access to claims histories are considered administrative costs

and, therefore, fall into the 20 percent side of the ledger. The industry argues that capping these types of improvements would hurt healthcare delivery.[31]

Price Controls for Drugs Will Not Work Either

In spite of all the evidence that price controls do not work at any time or for any purpose, politicians and advocacy groups are still clamoring to place them on pharmaceuticals.

Proponents have been spreading false narratives that there is no regulation in drug pricing and somehow pharmaceutical companies have free rein to do whatever they want, or that Obamacare left the pharmaceutical industry unscathed.[32] To the contrary, U.S. pharmaceutical companies have been dealing for years with a variety of price control measures, such as Medicaid rebates and the 340B discount program, which were intensified under Obamacare. These price control measures, among others, have distorted the market, shifted costs, and stifled innovation.

Medicaid Rebates

In 1990, congressional hearings were held on prescription drug pricing for Medicaid. Focus was placed on the lower-than-average prices the Department of Veterans Affairs (VA) had obtained since World War II from some drug companies. Members of Congress, led by Sen. David Pryor (D-Ark.), chairman of the Special Committee on Aging and a member of the Senate Finance Committee, queried witnesses as to why similar prices were not provided to state Medicaid drug programs. At that time, coverage of prescription drugs was an optional Medicaid service provided by all states and the District of Columbia with a federal upper payment limit[33] and there was no requirement that manufacturers sell drugs through the Federal Supply Schedule (FSS) or VA depots at discounted prices.[34]

New Medicaid pricing bills were introduced which proffered several policy options, such as restrictive formularies and a requirement that drug manufacturers provide rebates to the state Medicaid programs based on best price and average manufacturer price (AMP). During these hearings, there were warnings that implementing price controls would be counterproductive.

For example, during a September 14, 1990, House Energy and Commerce Committee hearing, a discussion ensued about how and why some pharmaceutical companies had given the VA discounts of between 41 and 67 percent off the average wholesale price for single-source drugs and 39 to 93 percent for multi-source drugs. The witness replied that, although some pharmaceutical companies' prices to the VA were close to their commercial prices, others companies had given sizable discounts because the VA represented only 1 to 2 percent of the total U.S market. The witness characterized the lower prices as an "historical anomaly that has evolved from World War II efforts to bolster the government's access to needed medicines." However, he cautioned, if these lower prices were utilized to determine the best price available

to calculate Medicaid discounts, the hefty discount would affect a larger percentage of total sales, as much as 15 percent. Offering such a discount would no longer be "commercially reasonable for a broader sector of the market."[35] Discounts at this scale could not be absorbed by many companies, thus forcing cuts to research and development, layoffs, and/or price increases.

In a September 17, 1990, Senate Finance Subcommittee on Health for Families and the Uninsured hearing on Medicaid prescription drug pricing, then-HCFA Administrator Dr. Gail Wilensky said, "My concern about the explicit way of ensuring that you keep the best price over time is that it sounds an awful lot like a price control to me."[36]

Sen. Orrin Hatch (R-Utah) testified against the Medicaid rebate legislation, saying that the states were already "doing a terrific job" of negotiating prices and should be allowed to continue to do so because, in some cases, they received lower prices than those created in the bills. Hatch stated, "I believe this type of legislation is either going to cause prices to go even higher in the final result or most importantly it is going to stifle innovation."[37]

In the same hearing, Sen. John Chafee (R-R.I.) remarked that he understood how a drug company could have had a long and almost philanthropic relationship with the VA, or perhaps a charitable healthcare institution that served the indigent, since they only made up a small percentage of their total sales. He went on to say that if all "future sales to the Medicaid program, for example, would have to be tied to that lowest price, one of the actions I suppose might be you wouldn't sell it at the lowest price to that entity anymore. So we might be shooting ourselves in the foot."[38]

Congress ignored the warnings and passed the Medicaid rebate legislation as part of the Omnibus Budget Reconciliation Act, which was signed into law by President George H. W. Bush on November 5, 1990. The law required a manufacturer entering into a Medicaid outpatient drug rebate agreement to provide a rebate for a covered single-source or innovator multiple source drug in an amount equal to the lower of 12.5 percent of the average manufacture price (AMP) until December 31, 1992, and 15 percent of the AMP thereafter, or the difference between the AMP and the "best price" for the drug. The best price was "defined as the lowest price charged to any wholesaler, retailer, nonprofit entity, or governmental entity in the United States, excluding depot prices or single award contract prices to a government agency, to a maximum discount of 50 percent of the AMP."[39]

Sen. Chafee's warning was prescient. The substantial discounts to the VA and other healthcare entities ended. Many companies that had given steep price reductions to the VA could not absorb the costs of the rebates based on an expanded "best price" without harming their businesses.

Another way to think of this result is as follows: suppose a grocer decided to give returning veterans and their families a 40 percent discount on certain groceries. Since veterans' families represented only 1 percent of the grocer's total business, the cost could be absorbed. Suddenly, the grocer's state legislature declares that, if this price were offered to veterans, the same price must be offered to other deserving customers. Now the population receiving the lower price makes up 10 to 15 percent of the grocer's total sales. The only ways the grocer could prevent such a hit to the business's bottom line is to stop providing discounts to veterans or to raise costs and cut workers.

It wasn't long before the results of this faulty legislation became evident. Drug prices to the VA increased but, rather than blame the law they had passed and their misunderstanding of economics, members of Congress were at it again within a year, trying to "fix" the problem they had created in the marketplace. Several bills, debated in both the House and Senate, were merged into a compromise bill, the Veterans Health Care Act of 1992 (P.L. 102-585), which was signed into law on November 4, 1992. The law created two new price-controlled systems, the VA Federal Ceiling Price (FCP) Program and the 340B drug discount program. The law also excluded these drug prices from the Medicaid rebate calculus.[40]

The VA FCP Program

Although many will claim the VA "negotiates" drug prices, it does not; the prices charged to the VA are based on statutorily mandated prices and discounts. The Veterans Health Care Act requires pharmaceutical manufacturers to list covered drugs on the FSS and that their prices be no greater than 76 percent of the non-Federal Average Manufacturer Price (non-FAMP), minus any additional discounts as determined each year. This cap on pricing applies to purchases made by the VA, the Department of Defense, the Public Health Service (including the Indian Health Service), and the Coast Guard, which are often called the "Big Four." If a manufacturer does not comply with P.L. 102-585, it cannot sell drugs to any of the Big Four and Medicaid.[41]

The VA also uses other price-controlled formulas. For example, under the FSS, the prices are the lowest prices that manufacturers charge their most-favored customers. Sometimes these prices are lower than the FCP. Greater discounts can be obtained under blanket purchasing or performance-based incentive agreements for an additional discount of between 5 to 15 percent of the FSS price. The VA chooses the mechanism that provides the lowest price on a case-by-case basis.[42]

However, the VA's price-controlled drugs and strict formulary result in fewer choices for veterans compared to those received by Medicare Part D beneficiaries and federal government employees through the FEHBP. The VA is a closed system run by government employees; however, the federal government acts as an administrator in Medicare Part D and FEHBP, in both of which private healthcare plans compete

with one another and provide the benefits.

An October 2013 Lewin Group study compared the VA national formulary with the two highest- enrollment plans in the Medicare Part D and FEHBP drug plans. The study found that Medicare Part D and FEHBP drug plans provided "greater breadth of drug coverage than the VA formulary." For example, only 78 percent of the 274 most-prescribed drugs in the U.S. are in the VA formulary. However, the two most popular Medicare Part D plans covered 97 and 95 percent of the drugs, respectively. FEHBP covered 91 percent of the 274 drugs. In addition, the two highest enrollment Part D plans and FEHBP did not impose prior authorization, step therapy (starting with the less expensive therapy and proceeding to a newer, riskier, or costlier drug if the first did not work as hoped), or quantity limit requirements on the majority of the 274 drugs.[43]

The 340B Drug Discount Program

The VA was not the only organization that received special discounts from pharmaceutical companies prior to the 1990 Medicaid rebate legislation. Some federally-funded clinics and hospitals that served large numbers of low-income and uninsured patients also received large discounts and donations from pharmaceutical companies. Since the Medicaid rebate law required these discounted prices to be included in the overall rebate calculus, the recipients saw their generous discounts or free medications disappear as well.

The 1992 VA legislation attempted to correct the problem by establishing a new provision in the Public Health Service Act (PHS), Sec. 340B, which required drug companies to give certain "covered entities" the same discounts as those given to Medicaid. These entities included such federally-funded facilities as community health centers, black lung clinics, tuberculosis clinics, and hemophilia treatment centers. Also included were certain disproportionate share hospitals (DSH),[44] which are hospitals that receive extra government funding depending on the number of low-income Medicare and Medicaid patients they treat, as well as uninsured indigent patients.

Congress intended that the savings from the discounted drugs would allow the covered "entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[45] However, because the law did not require covered entities to pass along drug savings to their patients and the definition of a 340B patient has been broadly interpreted, the program has been used by hospitals and pharmacies primarily as a profit-making scheme.[46]

The 340B program has been particularly detrimental in the field of cancer care. Due to the lack of a clear definition of 340B-eligible patients, such as whether they have insurance or the ability to pay, 340B hospitals have utilized the program as a way to generate revenue. By purchasing oncology physician offices, the 340B

hospitals can administer their heavily discounted cancer drugs to newly-acquired insured outpatients, accept their co-pays, and charge insurers the full reimbursable price, pocketing the difference. As a result, the locations where patients receive chemotherapy infusion has dramatically shifted from lower-cost physician offices to higher-cost hospital outpatient settings.[47]

Furthermore, a June 2015 Government Accountability Office (GAO) report found "per-beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at DSH 340B hospitals than at non-340B hospitals." According to the GAO, these findings indicate that, on average, "beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs, than beneficiaries at the other hospitals." The differences appeared not to be due to a hospital's characteristics or patients' health status. Instead, the GAO believes the drug discount program provides "a financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries."[48]

The ACA has made the market distortions caused by these programs worse by increasing the Medicaid rebate amount from 15.1 percent to as much as 23.1 percent for brand-name drugs and from 11 percent to 13 percent of the AMP for generic drugs. The ACA also expanded the types of covered entities that can participate in the 340B discount program. In addition, in 2010, the Health Resources and Services Administration (HRSA), the agency that oversees the 340B program, allowed covered entities to use a limitless number of contract pharmacies to fill patients' prescriptions, even though the statute does not permit the agency to do so.[49]

Price control measures such as Medicaid rebates, the 340B program, and the VA pricing structures have distorted the pharmaceutical market and caused price shifting. In a November 4, 2010, letter to then-House Budget Committee Ranking Member Paul Ryan (R-Wisc.), the CBO confirmed that Obamacare's increased Medicaid discounts and mandated new Medicare Part D discounts in the cover gap (more commonly referred to as the "donut hole" between the end of initial coverage and the start of catastrophic coverage), would likely cause manufacturers to raise prices to offset the costs of new discounts.[50]

Markets respond to pricing pressure as if it were an inflated balloon: push down on one side and the other expands. It should come as no surprise that some drug costs are being shifted to the private sector because of government price controls.

Speed Up the Drug Approval Process

The best way to lower consumer prices for pharmaceuticals is to encourage a vibrant, competitive marketplace, not overlay more government intervention in drug pricing. Using modern scientific methods and improving performance at the FDA would enable research-based and generic pharmaceuticals to enter the marketplace

faster.

It takes between 10 and 12 years to collect the clinical data necessary to submit a New Drug Application (NDA) before receiving FDA approval, at an average cost of $2.6 billion per approved compound.[51] Generic drug manufacturers also face expensive roadblocks. In June 2015, there was a backlog of more than 4,000 Abbreviated New Drug Approvals (ANDAs), the process generic drug manufacturers undertake to get their products to the marketplace.[52]

Research-based and generic companies pay user fees to get their drugs approved in a timely manner. Congress passed the Prescription Drug User Fee Act (PDUFA 1) in 1992 after hearing from constituents that the FDA approval process took too long and was far slower than in many European countries, particularly with AIDS/HIV drugs. The law allowed the FDA to collect user fees from drug manufacturers to fund the approval process for a new drug. In exchange for the funding, the FDA must meet certain performance targets.

A similar user fee law for the generic drug industry, the Generic Drug User Fee Amendments (GDUFA), was signed into law in 2012. Both user fee laws need to be reauthorized every five years.

In 2017, the cost for a research-based drug company to submit an NDA with clinical data will be $2,038,100 and a generic firm will pay $70,480 for an ANDA. Companies also pay many other charges, such as establishment and supplement fees, to get their drugs approved.[53]

PDUFA stakeholders are generally pleased with the user fee law, under which the FDA review process has become faster and more efficient. On March 29, 2016, the California Life Sciences Association and the Boston Consulting Group released an analysis which demonstrates that FDA review times have dropped from an average of 21 months in 2009 to 10 months in 2015. The fastest reviews have occurred with oncology, infectious diseases, and rare disease drugs.[54]

On July 15, 2016, the Pharmaceutical Research and Manufacturers of America (PhRMA) announced its agreement with the FDA on the sixth iteration of PDUFA. Congress will take up PDUFA for reauthorization in 2017. PhRMA stated, "For nearly 25 years, PDUFA has helped bring innovative medicines to patients by providing greater consistency, certainty and predictability in the U.S. drug review process. The PDUFA VI agreement is an important step forward in ensuring patient safety, maintaining the FDA's high standards of regulatory review and promoting timely access to safe and effective medicines for patients."[55]

On the other hand, generic firms have been more critical of GDUFA's implementation. The law's three main goals were to ensure safety, access, and transparency. By December 2014, the FDA had hired almost 1,000 new employees, a year ahead of schedule according to Center for Drug Evaluation and Research Director Janet

Woodcock. She stated that the new hires would help approve most ANDAs within 10 months.[56]

In a January 28, 2016, press release, Generic Pharmaceutical Association (GPhA) Senior Vice President for Regulatory and Scientific Affairs David Gaugh noted:

In 2011 when GDUFA [negotiations] began, median review time to approval was at 30 months. Since then, median review times increased to 31 months in FY2012, 36 months in FY2013 and an estimated 42 months in FY2014. At the industry's best estimate, current fiscal year median approval times will be 48 months – the slowest it has ever been.

Too many generic drug applications including potential first generics have been sitting with the Agency for many years before being picked up by a reviewer. These delays contribute significantly to rising health care costs and impact access to pharmaceuticals for millions of patients.[57]

Mr. Gaugh went on to say that, while the FDA had expressed concerns about the quality of the applications, the agency "has not defined or provided data on what constitutes 'quality' or completeness of generic applications." In addition, because so many ANDAs have languished at the agency with no action, Gaugh noted that the agency "continues to deem applications submitted three to four years ago to be of 'poor quality' because they don't meet new, more recent standards updated while these applications sit in the backlog."[58]

GDUFA required the FDA to review and take regulatory action on 90 percent of the ANDA backlog by September 2017. The agency recently claimed it had met that goal a year ahead of time. But that does not mean consumers can expect a flood of generic drugs to enter the marketplace. According to the Regulatory Affairs Professionals Society, the FDA continues to seek more information from companies or require them to fix easily correctable deficiencies for the vast majority of ANDAs. In fact, by July 2016, the FDA rejected far more ANDAs than it approved.[59] In other words, most of the action taken by the FDA was to return the majority of ANDAs to the manufacturers for more information or corrections. According to the GPhA, the current backlog at the FDA stands at more than 3,100.[60]

In an August 31, 2016, press release, GPhA noted that the FDA and the industry had reached agreement on a package of program enhancements and resource commitments to reauthorize GDUFA in 2017. Key provisions include addressing the ANDA backlog; providing priority, as opposed to standard review, for generic drugs where there is no competition; FDA performance reporting; and, enhanced communications between the agency and manufacturers.[61]

Only time will tell if the FDA lives up to expectations and approves generics in a timely way. It will be up to Congress to hold the FDA's feet to the fire to make sure these goals are met.

New Actions to Speed Up Approvals and Enhance Competition

While user fees have sped up the drug approval process, at least in regard to the NDAs, they are certainly not a panacea. A 2014 Manhattan Institute study entitled, "An FDA Report Card: Wide Variance in Performance Found Among Agency's Drug Review Revisions" found that some divisions within FDA's Center for Drug Evaluation and Research (CDER) have a better performance record than others.[62]

For example, the Oncology and Antivirals divisions approve drugs roughly two times faster than the CDER average and three times as fast as the least efficient drug-review divisions. The authors of the study "estimate that a modest narrowing of the CDER divisional productivity gap would reduce drug costs by nearly $900 million annually." More importantly, the value of the benefit to patients "would be far greater if the agency could accelerate access to an additional generation of (about 25) drugs every year. Greater agency efficiency would be worth about $4 trillion annually in value to patients, from enhanced U.S. life expectancy."[63]

The report called for the FDA to determine what is working in its high-performing drug divisions and promote the adoption of these best practices throughout the rest of the agency to improve efficiency and expedite drug approvals, and to brief Congress on a regular basis on their quality improvement efforts. The report also called for more FDA transparency, such as continual self-examination of approval delays and denials in order to address what caused these actions, or even an inaction. When the agency does not have in-house expertise to review complex new technologies, it should augment FDA staff by utilizing personnel from other trusted organizations, such as the National Institutes of Health, the Critical Path Institute, or the Reagan-Udall Foundation.[64]

The report noted that the FDA must be prepared for innovations in medical science and the development of new therapies, such as personalized medicine, in which a drug will be developed based on an individual's genome. New thinking and new methods will be required to approve these drugs because for many years pharmaceutical research and development was one-size-fits-all. Thousands of people were tested in clinical trials to obtain evidence that the drug benefited more people than it did not. With the new technologies that utilize the human genome, researchers will be able to quickly discover which drugs will work best on particular individuals.[65]

For example, Vioxx was a very popular drug to treat arthritis and provide pain relief, but it was withdrawn from the market in 2004 when a study showed it had caused heart attacks and sudden cardiac deaths for thousands of people. Vioxx's earliest critic had argued that "genetic testing could identify and exclude from the patient population the minority of people at risk from serious side effects, and thus that Vioxx would be a useful drug to have on the market."[66]

Biotechnology and the mapping of the human genome allows researchers and doctors to fight diseases at the molecular level. Government policy must not lag behind these pioneering treatments. Certain research tools and methods, such as biomarkers and surrogate endpoints, will help to speed up clinical trials and the drug approval process, thus improving patient access to life-saving pharmaceuticals. In addition, patient experience data and allowing more patients in clinical trials should become part of the regulatory approval process. These ideas and others are addressed in H.R. 6, the "21st Century Cures Act," a bill that passed the House of Representatives in July 2015, but is still under consideration in the Senate.

A biomarker is described by the FDA as a "defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions." A surrogate endpoint is a type of biomarker used in clinical trials as a "substitute for a direct measure of how a patient feels, functions or survives."[67]

A biomarker may be as commonplace as monitoring blood pressure when evaluating a patient's response to an antihypertensive drug; or more complex and genetically-based, such as a gene mutation that determines a patient's risk for breast cancer, or one that causes a particular kind of leukemia that can be targeted and eliminated by a powerful drug, sparing healthy cells in the process. A surrogate endpoint, such as the reduction in size of a tumor, can be used by the FDA to quickly approve a new cancer drug rather than waiting several years to determine a survival rate.

A January 2015, House Energy and Commerce Committee whitepaper entitled the "21st Century Cures Discussion" noted that the FDA already has broad authority to use biomarkers and surrogate endpoints and has done so to expedite drug approvals for life-threatening diseases. By codifying their use and requiring the FDA to issue guidance to assist with the development and identification of more biomarkers and surrogate endpoints, as well as providing for collaboration outside the agency, biomarkers and surrogate endpoints could be used to enhance drug development and speed up even more approvals.[68]

H.R. 6 also brings patients into the drug approval process because "no one understands a particular condition or disease better than patients living with it."[69] The bill would establish a framework to collect meaningful patient experience data, such as an assessment of desired benefits and tolerable risks, and incorporate them into the regulatory approval process. It would also allow a more open process so that additional patients could learn about and possibly participate in investigation of drugs going through clinical trials.

Many provisions in H.R. 6 are contained in PDUFA 6, which is scheduled for reauthorization in 2017.

Additional bills such as H.R. 3012, "The Right to Try Act," introduced in July 2015,

and S. 2912, "The Trickett Windler Right to Try Act," introduced in May 2016, could provide greater access to life-saving drugs for patients with terminal diseases. The bills would prevent the government from restricting access to an investigational new drug that has completed Phase 1 clinical trials for safety, but has not yet been approved by the FDA.

State governments across the country are not waiting for Congress and have implemented right-to-try laws to allow terminally ill patients access to investigational drugs. According to the Goldwater Institute, which is leading the charge on right-to-try laws, the FDA grants compassionate use exceptions for approximately 1,000 patients a year. The right-to-try laws are attempting to expand that number. So far, 32 states have right-to-try laws in place.[70]

There are also calls for reciprocity of regulatory approvals between the U.S. and a select group of countries. Sens. Ted Cruz (R-Texas) and Mike Lee (R-Utah) have introduced S. 2388, the Reciprocity Ensures Streamlined Use of Lifesaving Treatments (RESULT) Act, which would amend the Food, Drug, and Cosmetic Act. The legislation would require the FDA to approve a drug application from a sponsor within 30 days if the drug were already approved and sold in certain developed and trustworthy countries, including Australia, Canada, the European Union (EU), Israel, and Japan.

If a promising application for a life-saving drug is declined by the FDA, Congress can override the FDA decision by a majority vote on a joint resolution. According to Sens. Cruz and Lee, the legislation would allow Americans suffering from chronic and life-threatening conditions to access drugs which are already saving lives in developed countries but are not yet approved in the U.S.[71]

S. 2388 has both critics and fans. In a December 11, 2015, Regulatory Affairs Professionals Society article, Larry Stevens, a former FDA official and consultant with the Massachusetts-based FDA Group, was quoted as saying while the bill "sounds good," reciprocity will not work because "no developed country has the expertise to review a product like the FDA does" and that, if Congress should override an FDA decision, it would be responsible for the drug's safety.[72]

Likewise, Washington University Associate Professor Rachel Sachs noted in a December 12, 2015, Harvard University Bill of Health blog that a majority of new drugs are approved in the U.S. first and the "FDA consistently has the speediest review times of the major drug regulatory agencies."[73]

But Hoover Institution Senior Fellow Henry Miller, M.D., a former FDA drug reviewer and founding director of the FDA Office of Biotechnology, believes reciprocity is an antidote for escalating drug prices. He cites the drug pirfenidone, which is used to treat a pulmonary disorder called idiopathic pulmonary fibrosis, a disease which kills thousands of Americans annually, as an example of FDA's lassitude and hyper-

cautiousness. The drug was approved in Japan in 2008, in Europe in 2011, and in Canada in 2012. An FDA advisory committee recommended approval in 2010, but the FDA requested another major clinical study. The FDA approved the drug in October 2014. More than 150,000 patients died between 2010 and 2014.[74]

In a February 14, 2014, Health Affairs blog, "If a Drug is Good Enough for Europeans, It's Good Enough for Us," Manhattan Institute Center for Medical Process Director Paul Howard expressed his support for reciprocity. He cited a deadly bacterial meningitis outbreak (serogroup B) at Princeton University in 2013. Meningitis is an acute inflammation of the protective membranes of the brain and spinal cord, which is caused by a virus, bacteria, or other microorganisms. The mortality rate for bacterial meningitis in the U.S. is 10 percent. Although a vaccine named Bexsero was approved in the EU for this particular strain of meningitis, it was not available in the U.S. because it was still in clinical trials. Nonetheless, Princeton received permission from the FDA to obtain Bexsero and vaccinated students and faculty within nine months of the outbreak.[75] The FDA approved the drug in January 2015.

Howard argued that, because the EU and the U.S. share many commonly used drugs, there is a "net loss for society by requiring manufacturers to essentially jump through the same hoops over and over, expending more RD dollars and human resources running multiple trials of the same medicine for different regulatory jurisdictions." Howard wrote that while the FDA and the European Medicines Agency (EMA) "engage in high level discussion and collaboration, true reciprocity of approvals has never really been on the table. Why? Regulators may fear losing clout, and application review fees – about $672 million in 2012 – that come with submitting new drug approvals to the FDA. After all, if access to the large and lucrative U.S. market could be obtained by going to the EMA rather than the FDA, there might be a mass exodus of drug applications to the E.U." Howard believes, instead of a "race to the bottom," that "international regulatory competition would mainly benefit consumers who would gain faster access to new medicines, and (potentially) lower prices if development costs and times fell as well. Most importantly, it would save lives."[76]

The Cruz-Lee bill, or provisions within the bill, certainly could gain more support if the reauthorized user fees do not produce the expected results, the approval process at the FDA slows down, and the reforms found in the 21st Century Cures Act do not come to fruition.

Conclusion

Competition and market forces, not price controls, will drive down drug costs and will do so better than any heavy-handed legislation or regulation. In early 2014, reactions to drug prices reached a fever pitch after Gilead announced its $84,000 list price tag for a 12-week course of the hepatitis C drug Sovaldi and reached a crescendo

when Turing Pharmaceuticals, led by former hedge fund manager Martin Shkreli, raised the price of its drug Daraprim from $13.50 a tablet to $750 in September 2015.

Prices for Gilead's hepatitis C drug began to drop when AbbVie began to market its hepatitis C drug Viekira Pak in early 2015.[77] In January 2016, the FDA approved Merck's hepatitis C drug Zepatier; it was priced approximately 35 percent below Gilead's price.[78] In addition, drug companies, PBMs, and other healthcare providers negotiate lower pricing agreements based on volume and other factors, such as formulary placement.

Unfortunately, there is little discussion about the other side of the ledger: how much the hepatitis C drugs save in future medical costs by curing people of a chronic disease and keeping them out of the hospital, making liver transplants unnecessary, and allowing patients to become productive citizens. A September 26, 2016, Inside Health Policy article noted usage of hepatitis drugs dropped by 40 percent among Medicaid patients in 2015. While the introduction of AbbVie's drug in early 2015 brought down costs, usage apparently fell due to the Gilead drug's 90 percent cure rate. Patients who took Gilead's drug in 2014 were cured and did not need to continue to take the drug in 2015.[79] Since AbbVie's hepatitis cure rate is between 97 and 100 percent,[80] it is likely this trend will continue.

Although retail drug spending was 9.8 percent of total national health expenditures in 2014, politicians are still agitating to implement government price controls.[81] Yet it has been proven through the centuries that price controls do not work. They distort the marketplace, cause shortages, and hurt the very people they were intended to help. Former Democratic National Committee Chairman Howard Dean, M.D., a 2014 Democratic presidential candidate, agrees that price controls are harmful. In a September 18, 2015, New York Times Letter to the Editor he wrote, "The American drug industry is by far the most successful and innovative in the world in addition to being the most expensive because we are the only country that pays the true research and development costs, not only for Americans, but for the rest of the world as well."[82]

Dean rejected the notion that negotiations do not occur in Medicare Part D because PBMs, HMOs, and insurance companies "already negotiate with drug companies far more effectively than the government, and they should continue to do so." He closed by saying, "schemes to launch a federal attack on one of the last growing, innovative industries in America are in the long run counterproductive for both job creation and, more important, for the health of human beings around the world. By all means let us try to reduce the cost of drugs. But over the years, advances in drug efficacy and scope have saved us far more in hospital costs than we have spent on drugs."[83]

Pharmaceutical companies, both researched-based and generic, are not monolithic

entities. Price controls adversely affect them in different ways. They are, however, fierce competitors providing valuable products that keep citizens healthy and able to live productive lives. Policy makers should reject destructive price controls in favor of policies that speed up drug approvals and improve patient access. In that way, they can provide an environment that allows drug makers to continue to compete and drive down prices.

4.4 Price Controls Are Not The Answer To Expensive Drugs

Wayne Winegarden (a Senior Fellow in Business and Economics at the Pacific Research Institute and the Director of PRI's Center for Medical Economics and Innovation), "Price Controls Are Not The Answer To Expensive Drugs," Forbes, 18 October 2019, https://www.forbes.com/sites/waynewinegarden/2019/10/18/price-controls-are-not-the-answer-to-expensive-drugs/#56035ab6715e.

Note from the NHSDLC: This article covers some reasons why price controls wouldn't solve the problem of expensive drugs.

Questions:

1. What are some potential consequences of implementing price controls?
2. How might price controls slow down RND?
3. Why would a competitive market lower the cost of drugs?

Despite their abysmal track record, government solutions are back in vogue. Ostensibly, government's scale, leverage, and freedom from profit will unlock potential health care savings that are beyond the reach of the private sector.

At their most extreme, reforms such as "Medicare for all" call for a complete government takeover of the health care system. Proponents of single payer reforms claim that only a complete government takeover of the health care sector can eliminate the health care sector's inefficiencies and ensure 100 percent patient coverage.

Of course, if government's scale and freedom from having to earn a profit was so effective, then why does FedEx and UPS consistently outperform the U.S. Postal Service? Or, why is Amtrak always teetering on the brink of insolvency? In the health care space, if scale and the freedom from having to pay a profit is so important, why is the health care provided by the Veteran's Administration and the Indian Health Service so abysmal?

Heightening these concerns, 80 percent of primary care doctors will accept new patients that are covered by private insurance, but only 72 percent will accept new Medicare patients and 45 percent new Medicaid patients. This lower acceptance rate is linked to Medicare's and Medicaid's uneconomical reimbursement levels. And, herein lies the rub.

Whether it is state Medicaid programs, the federal Veteran Affairs health system, or nationalized health systems in other countries, government-run health care creates savings by restricting access and reducing the quality of care. It is folly to believe that government will be able to provide high quality health care services at a reasonable cost.

Others preach that, instead of a complete government takeover of the health care system, the best way to lower the cost of health care is through increased government regulations. These piecemeal proposals will identify a specific problem that plagues the health care system, and then offer targeted government programs to address each one.

Take the cost of medicine. In response to the high cost of branded and originator biologic medicines, there has been a bipartisan push to impose price controls on drugs. Here too, history argues that the big-government approach will disappoint its proponents.

In post-revolution France, for instance, the government imposed grain price controls to ease the pain from the grain shortages that were plaguing the country. The price controls not only failed to alleviate the problem, they worsened the shortages and helped create an even greater economic crisis.

Rent control policies also exemplify the adverse consequences from government mandated pricing. The purpose of rent control is to expand the availability of affordable housing. The actual consequences, as exemplified by cities like New York and San Francisco, are housing shortages and sharp declines in housing quality.

No matter where they have been tried, price controls have always made bad situations worse because it is impossible for policymakers to have the necessary knowledge to dynamically set the efficient price level. Just as all of these past price control experiments ended up making a bad situation worse, applying price controls to the U.S. health care sector will further reduce the quality of care and create inequitable outcomes.

The advocates of price controls now are targeting the pharmaceutical industry with these ill-considered policies. Take H.R. 3, the Lower Drug Costs Now Act. As the name implies, the bill's proponents hope to lower the cost of drugs by empowering the Centers for Medicare & Medicaid Services (CMS) to negotiate prices on certain drugs. Manufacturers who refused to negotiate with the government would face a 95% tax on sales revenue (not profits). Such a lopsided structure is not a negotiation, it is the government mandating a price regardless of its economic viability.

The consequences from implementing price controls on the pharmaceutical industry will be no different than the consequences that occurred in the grain or housing markets. But, one does not even have to look toward these markets to see the consequences. Just look to the European Union's drug industry, where pharmaceutical price controls were implemented two decades ago.

Before its price controls, EU firms were the global leaders in biopharmaceutical innovation. Since the implementation of price controls, research spending in the EU has stagnated, much of it diverting to the U.S. where price controls do not exist. Over time, these diverging trends have enabled the U.S. to become the global

innovation leader.

As a result, the EU has endured many adverse consequences. Access to existing medicines have faltered. While the U.S. has access to nearly 90% of newly launched medicines, patients in Germany only have access to 71%. In France, the access rate is even lower at 48%.

By some estimates, the R&D slowdown has led to 46 fewer medicines being introduced into the marketplace. The actual costs to patients (worldwide) from not having access to new (possibly better) treatments is unknowable. The lost savings potential these medicines could have created, by avoiding the need for other more expensive health care treatments (e.g. surgeries), is also unknowable. The EU has also faced economic consequences as the lost R&D activity has cost the EU nearly 1,700 high paying research jobs.

History clearly illustrates that government mandated prices create more harm than good. Should drug price controls, such as H.R. 3, be implemented, the U.S. will not be exempt from the adverse consequences. Instead, access will be reduced, innovation will suffer, and the economy will be less vibrant.

In contrast to this government approach, as I have discussed here, there is a better way. Too many market barriers currently exist that are inhibiting a more competitive market for medicines (particularly the high-cost biologic medicines) to develop. The best way to achieve the dual goals of incenting innovation and promoting affordability is to remove these barriers and empower a competitive market to directly lower the costs of medicines.

5 Con Evidence

5.1 The True Story of America's Sky-High Prescription Drug Prices

Sarah Kliff (senior policy correspondent at Vox), "The true story of America's sky-high prescription drug prices," Vox, 18 May 2018, https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained.

Note from the NHSDLC: This article walks through the reasons why the United States has such high prescription drug prices.

Questions:

1. What is the central trade off of the price controls debate?
2. What does it mean that "other countries regulate the price of drugs because they see them as a public utility"?
3. Do you think you'd be comfortable paying higher prices for drugs to get more innovation?

Let's say you're at the doctor. And the doctor hands you a prescription.

The prescription is for Humira, an injectable medication used to treat a lot of common conditions like arthritis and psoriasis. Humira is an especially popular medication right now. In 2015, patients all around the world spent $14 billion on Humira prescriptions — that's roughly the size of Jamaica's entire economy.

Let's say your doctor appointment is happening in the United Kingdom. There, your Humira prescription will cost, on average, $1,362. If you're seeing a doctor in Switzerland, the drug runs around $822.

But if you're seeing a doctor in the United States, your Humira prescription will, on average, run you $2,669.

How does this happen? Why does Humira cost so much more here than it does in other countries?

Humira is the exact same drug whether it's sold in the United States, in Switzerland, or anywhere else. What's different about Humira in the United States is the regulatory system we've set up around our pharmaceutical industry.

The United States is exceptional in that it does not regulate or negotiate the prices of new prescription drugs when they come onto market. Other countries will task a government agency to meet with pharmaceutical companies and haggle over an

appropriate price. These agencies will typically make decisions about whether these new drugs represent any improvement over the old drugs — whether they're even worth bringing onto the market in the first place. They'll pore over reams of evidence about drugs' risks and benefits.

The United States allows drugmakers to set their own prices for a given product — and allows every drug that's proven to be safe come onto market. And the problems that causes are easy to see, from the high copays at the drugstore to the people who can't afford lifesaving medications.

What's harder to see is that if we did lower drug prices, we would be making a trade-off. Lowering drug profits would make pharmaceuticals a less desirable industry for investors. And less investment in drugs would mean less research toward new and innovative cures.

There's this analogy that Craig Garthwaite, a professor at Kellogg School of Management who studies drug prices, gave me that helped make this clear. Think about a venture capitalist who is deciding whether to invest $10 million in a social media app or a cure for pancreatic cancer.

"As you decrease the potential profits I'm going to make from pancreatic cures, I'm going to shift more of my investment over to apps or just keep the money in the bank and earn the money I make there," Garthwaite says.

Right now America's high drug prices mean that investing in pharmaceuticals can generate a whole bunch of profits — and that drugs can be too expensive for Americans to afford.

Let's say you're a pharmaceutical executive and you've discovered a new drug. And you want to sell it in Australia. Or Canada. Or Britain.

You're going to want to start setting up some meetings with agencies that make decisions about drug coverage and prices.

These regulatory bodies generally evaluate two things: whether the country wants to buy your drug and, if so, how much they'll pay for it. These decisions are often related, as regulators evaluate whether your new drug is enough of an improvement on whatever is already on the market to warrant a higher price.

So let's say you want to sell your drug in Australia. You'll have to submit an application to the Pharmaceutical Benefits Advisory Committee, where you'll attempt to prove that your drug is more effective than whatever else is on the market right now.

The committee will then make a recommendation to the country's national health care system of whether to buy the drug — and, if the recommendation is to buy it, the committee will suggest what price the health plan ought to pay.

Australia's Pharmaceutical Benefits Advisory Committee is not easy to impress: It has rejected about half of the anti-cancer drug applications it received in the past decade because their benefits didn't seem worth the price.

But if you do succeed — and Australia deems your drug worthy to cover — then you'll have to decide whether the committee has offered a high enough price. If so, congrats! You've entered the Australian drug market.

Other countries regulate the price of drugs because they see them as a public utility

Countries like Australia, Canada, and Britain don't regulate the price of other things that consumers buy, like computers or clothing. But they and dozens of other countries have made the decision to regulate the price of drugs to ensure that medical treatment remains affordable for all citizens, regardless of their income. Medication is treated differently because it is a good that some consumers, quite literally, can't live without.

This decision comes with policy trade-offs, no doubt. Countries like Australia will often refuse to cover drugs that they don't think are worth the price. In order for regulatory agencies to have leverage in negotiating with drugmakers, they have to be able to say no to the drugs they don't think are up to snuff. This means certain drugs that sell in the United States aren't available in other countries — and there are often public outcries when these agencies refuse to approve a given drug.

At the same time, just because there are more drugs on the American market, that doesn't mean all patients can access them. "To think that patients have full access to a wide range of products isn't right," says Aaron Kesselheim, an associate professor of medicine at Harvard Medical School. "If the drugs are so expensive that you can't afford them, that's functionally the same thing as not even having them on the market."

It also doesn't mean we're necessarily getting better treatment. Other countries' regulatory agencies usually reject drugs when they don't think they provide enough benefit to justify the price that drugmakers want to charge. In the United States, those drugs come onto market — which means we get expensive drugs that offer little additional benefit but might be especially good at marketing.

This happened in 2012 with a drug called Zaltrap, which treats colorectal cancer. The drug cost about $11,000 per month — twice as much as its competitors — while, in the eyes of doctors, offering no additional benefit.

"In most industries something that offers no advantage of its competitors and yet sells for twice the price would never even get on the market," Peter Bach, an oncologist at Sloan-Kettering Memorial Hospital, wrote in a New York Times op-ed. "But that is not how things work for drugs. The Food and Drug Administration

approves drugs if they are shown to be 'safe and effective.' It does not consider what the relative costs might be."

What happens when you don't price-regulate drugs? Just look at the United States.

The United States has no government panel that negotiates drug prices. There are thousands of health insurance plans all across the country. Each has to negotiate its own prices with drugmakers separately. Because Americans are fragmented across all these different health insurers, plans have much less bargaining power to demand lower prices.

In other words: Australia is buying drugs in bulk, like you would at Costco, while we're picking up tiny bottles at the local pharmacy. You can guess who is paying more.

"You could say that American health care providers and pharmaceuticals are essentially taking advantage of the American public because they have such a fragmented system," Tom Sackville, president of the International Federation of Health Plans, says. "The system is so divided, it's easy to conquer."

There is one especially large health insurance plan in the United States: Medicare, which covers about 55 million Americans over the age of 65. But federal law expressly prohibits Medicare from negotiating drug prices or making decisions about which drugs it covers. Instead, Medicare is required to cover nearly all drugs that the Food and Drug Administration approves. This means that Medicare must cover drugs that aren't an improvement over what currently exists, so long as the FDA finds they're safe for human consumption.

Drugmakers know that as long as their products are safe, Medicare will buy them. "For Medicare, the sky really is the limit," on drug prices, says Jamie Love, who has studied drug pricing and directs the DC nonprofit Knowledge Ecology International.

Americans end up spending way more on prescription drugs than anyone else

The result of this system is that Americans spend $858 per person on prescription drugs. That's about twice as much as Australians and three times as much as the Dutch.

Americans aren't buying lots more drugs. We're just spending more on the ones we do buy. There isn't much evidence that Americans use an inordinately high amount of prescription drugs. It's just that when we buy prescription medications, we pay more for the exact same product.

These are the prices for the cancer drug Avastin in different countries.

And these are the prices for Harvoni, a drug that cures hepatitis C.

Pick any brand-name drug, and you'll almost certainly find that the price in the United States is significantly higher than in other countries.

What would happen if the United States started price-regulating drugs?

For one thing, we'd spend less on prescription drugs. If the United States set up an agency that negotiated drug prices on behalf of the country's 319 million residents, it would likely be able to demand discounts similar to those of European countries.

This would mean that health insurance premiums wouldn't go up nearly as quickly — they might even go down.

There would be trade-offs. We'd likely have to give up some of the choice of drugs that our insurance plans cover. If a national board made decisions about what prices were appropriate for drugs, it would need to have the ability to reject the drugs that didn't make the cut.

Consider the Veterans Health Administration, which does negotiate drug prices. It gets drugs that are usually 40 percent cheaper than what Medicare pays. But it also covers fewer products.

Margot Sanger-Katz recently reported for the New York Times that "many older patients who get their health insurance from the V.A. also sign up for Medicare drug plans to cover medicines that the V.A. won't." At the same time, VA doctors do say their patients are generally able to obtain the medications they prescribe.

Economic research suggests that price regulation might mean less innovative drugs, too Investors respond to economic incentives. When they see a market that will pay lots of money for their products, they'll put more money toward developing the type of drugs that market wants.

Consider the hypothetical venture capitalist from earlier, who is thinking about whether to fund a biotech firm or a social media startup.

Part of that decision will revolve around the type of business that interests her — and part around what profits she thinks can be made.

We've seen this happen in real life, too: When the government mandates the coverage of a new type of drug, there are more clinical trials to develop that particular treatment.

Consider the work of MIT economist Amy Finkelstein. She looked at what happened after Medicare began covering the flu vaccine for its millions of enrollees. And she found that with the usage of the flu vaccine guaranteed to increase, there was a 2.5-fold increase in clinical trials for new flu vaccines.

Separate research shows a significant increase in research dollars for drugs that the elderly typically take after Medicare began covering prescription drugs in 2005.

Right now, the United States' exceptionally high drug prices help subsidize the rest of the world's drug research. We benefit from that work with new and better prescriptions — and so does the rest of the world.

In other words: Right now, the United States is subsidizing the rest of the world's drug research by paying out really high prices. If we stopped doing that, it would likely mean fewer dollars spent on pharmaceutical research — and less progress developing new drugs for Americans and everybody else.

This is a central dilemma in drug pricing policy: Should we trade off some innovation for some access? Every policy decision comes with trade-offs, and that's true of regulating drug prices. If the United States began to price regulate drugs, medications would become cheaper. That would mean Americans have more access to drugs but could also expect a decline in research and development of new drugs.

We might have fewer biotech firms starting up, or companies deciding it's worth bringing a new drug to market.

That might be okay: We might decide as a society that we are willing to trade some level of innovative to lower drug prices and make medication more financially accessible to those who need them right now.

It's a hard question to think about: Do we want to lower the price of the hepatitis C cure that hit the market for $84,000 — knowing that price controls might lead to less investment in pursuing other cures in the future?

"If you have hepatitis C today, you probably want to have the drug for a cheaper price," Garthwaite says. "If you have pancreatic cancer today, you probably want to do everything you can to get more money put into the research and development pipeline to cure that disease."

He adds, "This isn't an easy question to think about, how much innovation we're comfortable paying for — or the idea that we might be spending too much on innovation."

But it's a conversation that America's exceptionally high drug prices are forcing us to consider, as drug prices skyrocket — and one in four Americans report trouble paying for their prescription drugs.

Are we, as a country, comfortable paying higher prices for drugs to get more innovation? Or would we trade some of that innovation to make our drugs more accessible to those of all income levels?

5.2 Other Countries Control Drug Prices

Allan Coukell (The Pew Charitable Trusts' senior director for health programs), "Other countries control drug prices the US could, too," The Hill, 7 December 2017, https://thehill.com/opinion/healthcare/363583-other-countries-control-drug-prices.

Note from the NHSDLC: This article covers some different strategies that the United States could use to contain rising drug prices.

Questions:

1. Why are Americans so worried about rising drug prices?
2. What are some of the different strategies other countries use to control drug prices?
3. Which one do you find the most plausible?

Public opinion surveys show that most Americans are deeply concerned about rising drug prices. That's not surprising: Overall, we spend twice as much on drugs as our counterparts in other developed countries. For example, in 2015, the most recent year for which data are available, an American patient and insurer could expect to pay about $2,670 for a month's supply of adalimumab, a drug commonly used to treat rheumatoid arthritis. A patient and insurer in the United Kingdom would pay about $1,360 for the same supply of the same drug; in Switzerland, about $820.

That's because while drug prices in the United States have continued to rise, with insurance companies and public programs such as Medicare and Medicaid struggling to rein in the cost, their counterparts in Europe and elsewhere have used a variety of payment and coverage policies to more effectively manage their drug spending.

Of course, not every solution that works well in another country could be easily applied here. But strategies used abroad could help inform U.S. efforts to control rising health care costs and make lifesaving drugs more affordable and accessible. A recent report by The Pew Charitable Trusts, "Payment Policies to Manage Pharmaceutical Costs," examined six policies that have been used successfully by other countries to control pharmaceutical spending.

External benchmarking In 29 of 31 European countries, the health care systems consider a drug's price in other countries when determining what they are willing to pay for it. Use of such a model could lead to short-term cost savings for Medicare in the United States. Over time, however, the effect could diminish since drugmakers could increase list prices around the world and then enter into agreements with payers to provide confidential discounts and rebates.

Internal benchmarking Australia is among the many countries that set payment rates for drugs based on the cost of clinically comparable products, when such

comparables exist. This strategy has been shown to sharply reduce drug prices in many health systems. A similar approach was used for some drugs in Medicare from 1995-2010 and could help the program significantly reduce costs for drugs when comparable therapeutic alternatives exist.

Value-based benchmarking Australia, England, Italy, the Netherlands, New Zealand, the U.K., and most Canadian provinces use some kind of value-based benchmarking, which draws on various analytic methods to help determine coverage or the appropriate price for a drug based on its health benefits. In the U.S., stakeholders disagree over how to determine value, but individual payers and hospitals may decline to cover or use a drug if they determine that a lower-cost alternative is equally effective. Evidence suggests, however, that certain value-based benchmarks may help U.S. payers determine the correct price, particularly for specialty drugs, which are typically priced much higher than their traditional counterparts.

Restricting off-label uses Australia, Canada, Germany, and Japan limit coverage for medicines that are prescribed for purposes other than those approved by regulatory authorities, which is known as off-label use. This practice could produce savings in the U.S. by prioritizing use of lower-cost, Food and Drug Administration-approved on-label drugs. Off-label use of medications is widespread and may be appropriate in some cases; however, there is often insufficient data on the safety and effectiveness of these uses. Therefore, it's unclear what effect restricting off-label use could have on health outcomes.

Payer-seller agreements These agreements between payers and pharmaceutical companies take many forms and can reduce drug costs through discounts, rebates, protection from higher than expected utilization, or linking payment to patient outcomes. Health systems in European countries including Germany, Italy, and the U.K. have used payer-seller agreements to negotiate price discounts of up to 50 percent off the list price.

While these types of agreements are used in the U.S., the large number of private insurance providers limits each insurer's individual negotiating power, since each represents only a share of the national market. And Medicare, which does have significant negotiating power, is legally prohibited from using these agreements.

Denying coverage for medicines deemed unaffordable This approach, used in Australia, Canada, and New Zealand, can reduce costs but would face significant social, cultural, and legal barriers in the United States. Although U.S. payers can consider a drug's cost in reimbursement decisions when therapeutic alternatives exist, there are few mechanisms for an insurer to deny payment for an effective medicine based on price alone.

Pharmaceutical spending in the U.S. reached an estimated $477 billion in 2016, according to HHS. These costs are expected to rise as new, high-priced, brand-name

and specialty medications hit the market. To address this challenge, momentum is building in Congress, federal and state governments, and private payers to address the issue of high drug costs. As these decision-makers look for solutions, the strategies other countries use could offer lessons here at home.

5.3 To Reduce the Cost of Drugs Look to Europe

Austin Frakt (a health economist with several governmental and academic affiliations. He blogs at The Incidental Economist), "To Reduce the Cost of Drugs, Look to Europe," New York Times, 19 October 2015, https://www.nytimes.com/2015/10/20/upshot/to-reduce-the-cost-of-drugs.

Note from the NHSDLC: This article argues that Europe provides a good model of how to contain rising drug prices.

Questions:

1. What is reference pricing? How does it work?
2. Why might reference pricing not decrease incentives to innovate?
3. How would reference pricing keep drug prices low?

When anyone proposes reducing prescription drug prices — as Hillary Rodham Clinton and Bernie Sanders recently have — the most commonly heard criticism is that it would squelch innovation. But not all pharmaceutical innovation is valuable. Though some drugs are breakthroughs, some offer only marginal benefits at exorbitant cost.

There is a way to keep prices low while encouraging drug companies to innovate: Look to Europe and elsewhere, where drug prices are a fraction of those in the United States. Germany, Spain, Italy and a half dozen other countries have pushed drug prices lower with a system called reference pricing. It has led to drug price decreases and significant savings in the Canadian province of British Columbia as well as in Germany, Italy, Norway, Spain and Sweden. A study published in the American Journal of Managed Care found that price reductions ranged from 7 percent to 24 percent.

Here's how it works: Drugs are grouped into classes in which all drugs have identical or similar therapeutic effects. For example, all brands of ibuprofen would be in the same class because they contain the same active agent. The class could include other nonsteroidal anti-inflammatory agents like aspirin and naproxen because they are therapeutically similar. The insurer pays only one amount, called the reference price, for any drug in a class. A drug company can set the price of its drug higher, and if a consumer wants that one, he or she pays the difference.

Setting the reference price low enough puts considerable pressure on drug manufacturers to reduce prices for drugs for which there are good substitutes. If they don't, consumers will switch to lower-cost products. In British Columbia and in Italy, the reference price is set at the lowest-price drug in the class; Germany uses an average

price across drugs; Spain also uses an average, but only of the lowest-priced products that account for at least 20 percent of the class's market.

In pushing prices down, reference pricing doesn't suppress innovation; it encourages a different form of it. The market still rewards the invention of a cutting-edge drug with novel therapeutic effects. Such a drug might be placed in a new class and therefore could be priced high. But, within classes, the market also rewards innovations that lead to lower-priced drugs, because consumers switch to them to avoid out-of-pocket costs. In these ways, reference pricing promotes cost-effectiveness.

Consider, for example, the price of new anti-cholesterol drugs known as PCSK9 inhibitors: about $14,000 a year. A recent report from the Institute for Clinical and Economic Review (ICER) received considerable attention when it argued that the drugs were priced too high for the value they offered patients. Reducing the prices to close to $2,000 would make them both cost effective and would help keep American health spending below a widely accepted growth target, according to ICER's analysis.

Reference pricing could help drive down the prices of the PCSK9 inhibitors if they were put in the same therapeutic class as other, cheaper generic cholesterol drugs, like statins. If this happened, PCSK9 manufacturers — Amgen and Regeneron Pharmaceuticals — would face powerful incentives to reduce their prices.

However, some people might reasonably argue that PCSK9 inhibitors are superior to statins and therefore should not be grouped with them. Because ICER's price is based on cost-effectiveness, it incorporates such performance differences by recommending a higher price for more effective drugs, though in the case of PCSK9s, a lower price than the manufacturers may want.

The promise of reference pricing goes beyond prescription drugs. In a paper presented at Brookings this month, the Harvard economist Amitabh Chandra, the University of Michigan law professor Nicholas Bagley and I proposed extending the approach to a wider range of medical technologies.

We suggested that Medicare should pay more for a new therapy for a given condition only if that new therapy is better than existing therapies. (In 2010, David Leonhardt wrote about a similar idea.) In no case, we proposed, should Medicare pay more for a therapy than a generally accepted cost-effectiveness standard. If patients wanted cost-ineffective therapies, they could pay the difference out of pocket, a departure from current Medicare policy.

As it stands, other countries are far ahead of the United States in pricing drugs to promote cost-effective pharmaceutical innovation. But interest is growing here in new approaches. Peter B. Bach, a physician at Memorial Sloan Kettering Cancer Center, recently proposed a variation on reference pricing that considers how the cost-effectiveness of a cancer drug varies by what disease it is used to treat. He

noted that the drug Tarceva costs the same whether it is used to treat patients with a kind of lung cancer or patients with pancreatic cancer. But the results are wildly different. On average, Tarceva extends a lung cancer patient's life by just over three months; it extends a typical pancreatic cancer patient's life by a mere week and a half.

Dr. Bach's insight is that we should be paying for what we care about — life gained — not the drug itself. He therefore proposed that the price of Tarceva be sharply reduced for pancreatic cancer patients to bring the cost per duration of life gained in line with that of lung cancer patients.

Critics of Dr. Bach's idea, ours and the approach of ICER claim they would restrain innovation that could benefit patients. However, they are devised specifically to reward smarter innovation, which is precisely what we need.

5.4 Why The US Has Higher Drug Prices Than Other Countries

Simon F. Haeder (Assistant Professor of Political Science, West Virginia University), "Why the US has higher drug prices than other countries," Conversation, 7 February 2019, https://theconversation.com/why-the-us-has-higher-drug-prices-than-other-countries-111256.

Note from the NHSDLC: This article shows that the United States can take steps to tackle rising drug prices, including looking at some lessons from Europe.

Questions:

1. Why do Americans pay so much more for drugs?
2. Why might a negotiation approach to tackling drug prices not succeed?
3. How would cost-benefit analyses help reduce costs?

Spending on pharmaceuticals is on the rise worldwide. And it well should be. Today, we are able to cure some diseases like hepatitis C that were virtual death sentences just a few years ago. This progress required significant investments by governments and private companies alike. Unquestionably, the world is better off for it.

Unfortunately, as President Trump pointed out in the State of the Union address, the United States has borne a significant amount of the negative effects associated with this development. For one, its regulatory apparatus has focused largely on drug safety, yet regulators have failed to emphasize cost-effectiveness when it comes to both new and existing drugs.

At the same time, the United States also pays significantly higher prices than the rest of the developed world when it comes to prescription drugs, due primarily to limited competition among drug companies.

These two problems are well-known to policymakers, consumers and scholars alike. The Trump administration's recent proposal seeks to lower costs by restructuring drug discounts that occur between pharmaceutical companies, health insurers and entities called pharmacy benefit managers.

But in my view as a health policy scholar, the plan does little to address the underlying problems of prescription drugs in the U.S. I believe the U.S. can refocus its regulatory approach to pharmaceuticals, adapted from the one used in Europe, to better connect the value prescription drugs provide and their price.

The US and other countries

Until the mid-1990s, the U.S. was really not an outlier when it came to drug spend-

ing. Countries like Germany and France exceeded the U.S. in per capita drug spending. However, since then, spending growth in the U.S. has dramatically outpaced other advanced nations. While per capita spending in the U.S. today exceeds US$1,000 a year, the Germans and French pay about half that.

And it is not like Americans are overly reliant on prescriptions drugs as compared to their European counterparts. Americans use fewer prescription drugs, and when they use them, they are more likely to use cheaper generic versions. Instead the discrepancy can be traced back to the issue plaguing the entirety of the U.S. health care system: prices.

The reasons for the divergence starting in the 1990s are relatively straightforward. For one, dozens of so-called blockbuster drugs like Lipitor and Advair entered the market. The number of drugs grossing more than $1 billion in sales increased from six in 1997 to 52 in 2006. The recent introduction of extremely pricey drugs treating hepatitis C are only the latest of these.

Lacking even rudimentary price controls, U.S. consumers bore the full brunt of the expensive development work that goes into new drugs. These costs were further augmented by marketing expenditures and profit seeking by all entities within the pharmaceutical supply chain. Consumers in Europe, where there are government-controlled checks on prices, were not as exposed to those high costs.

The Food and Drug Administration has also consistently moved to relax direct-to-consumer advertising regulations, a practice that is either banned or severely limited in most other advanced nations. While there are limited information benefits to consumers, this practice has certainly increased consumption of high-priced drugs.

Additionally, the overall complexity of the U.S. health care system and the lack of transparency in the drug supply chain system create conditions favorable to limited competition and price maximization.

All entities in the pharmaceutical supply chain, including manufacturers and wholesale distributors, have become extremely skilled at finding regulatory loopholes that allow them to maximize profits. This includes, for example, creatively expanding the life of patents, or having them recategorized as “orphan drugs” for rare disease to preserve monopolies. So-called pharmacy benefit managers, the middlemen that administer prescription drug programs, add further complexity and often may be driven by profit maximization.

Finally, the U.S. has undergone a series of coverage expansions, including the prominent creation of the Children’s Health Insurance Program, Medicare Part D, and the Affordable Care Act. For many of the newly covered, this meant access to prescription drugs for the first time and pent-up demand was released. However, it also encouraged pharmaceutical companies to take advantage of the newfound payers for

their drugs.

Trump's proposed fixes

The consequences of pricey pharmaceuticals are significant in terms of costs and diminished health. Close to 20 percent of adults report skipping medications because they are concerned about costs. Nonetheless, the U.S. may be spending close to $500 billion annually.

The plan proposed by the Trump administration basically replaces an opaque discount arrangement between drug makers, insurers and middlemen called pharmacy benefit managers with a discount program directly aimed at consumers. Particularly benefiting from the change would be those individuals requiring costly non-generic drugs. Unquestionably, their lives would improve due to increased access and lower costs.

At the same time, costs would be shifted to healthier consumers who do not rely on expensive drugs, as well as those relying on generic versions. Both will be faced with higher overall insurance premiums while not seeing any reductions in the prescription drug bills. That's because insurers would no longer be able to use drug discounts to hold down premiums.

The Trump administration's discounting approach, however, is not uncommon. The Veterans Health Administration's has done so quite successfully, obtaining discounts in the range of 40 percent. Likewise, Medicaid programs are also using their purchasing power to obtain discounts. And calls for Medicare to negotiate discounts with pharmaceutical companies are common.

The way I see it, there are three major issues inherent in negotiating discounts for drugs.

For one, true negotiations would only take place if Medicare or any other entity was willing to walk away from certain drugs if no discounts could be obtained. In a country that heavily values choice, and where such activities would become a political football, this is highly unlikely.

Moreover, it would only work for drugs where viable alternatives are available. After all, most Americans would likely be hesitant to exclude a drug, even at high costs, when no alternative cure exists.

Yet even if some version of a discount program were to be implemented more widely, such a program does not change the underlying pricing or market dynamics. Crucially, relying on discounts does nothing to reduce list prices set by manufacturers. Pharmaceutical companies and all other entities in the supply chain remain free to set prices, bring products to the market, and take advantage of loopholes to maximize corporate profits.

Ultimately, pharmaceutical companies and all other entities involved in the pharmaceutical supply chain are unlikely to be willing to simply give up profits. Quite likely, steeper discounts for Medicaid and Medicare may lead to higher costs for employer-sponsored plans.

Focusing on effectiveness and consumer information

The question then emerges: What could be done to truly improve the twin issues of high costs and limited cost-effectiveness when comes to pharmaceuticals in the U.S. health care system?

While Americans are often hesitant to learn from other countries, looking to Europe when it comes to pharmaceuticals holds much promise. Countries like Britain and Germany have taken extensive steps to introduce assessments of cost-effectiveness into their health care systems, refusing to pay higher prices for new drugs that do not improve effectiveness of treatment over existing options.

Since reforming its system in the early 2010s, Germany has allowed manufacturers to freely set prices for a limited period when bringing new drugs to the market. It then uses the data available from that period for a nongovernmental and nonprofit research body to evaluate the benefit provided by the new drug, as compared to existing alternatives. This added benefit, or lack thereof, then serves as the foundation for price negotiations between drug manufacturers and health plans.

While the legal restrictions and the fragmented nature of the U.S. health care system severely limit the ability of the U.S. to fully translate such a model, in my opinion, the underlying approach bears great value.

Lacking the corporatist nature of the Germany economy, the U.S. should resort to a bottom-up approach focused on investing in assessing and subsequent publicizing of cost-effectiveness data as well as cost-benefit analyses for all drugs. In order to minimize politicization, these analyses would be best handled by one or multiple independent research institutes.

Ultimately, knowing what drugs provide what value would equally benefit consumers, providers, and payers, and serve as a meaningful first step towards connecting the prices we pay for prescriptions to the value we derive from them.

6 Review Questions

Cost Control

1. How much are you willing to pay for your medicine? Why might there be a right to affordable medicine?
2. What is the balance that must be considered here?
3. What are some of the differences between the US and other countries?

Examining Two Approaches to U.S. Drug Pricing

1. What are some key drivers of drug prices in the United States?
2. What is reference pricing?
3. What is internal reference pricing?

Price Controls Would Slow a COVID Vaccine

1. Why does the United States lead the world in medical innovation?
2. Why is innovation so expensive?
3. Why might price controls hurt innovation?

Get Europe to Drop Its Price Controls

1. What evidence does the article provide to show that Europe once led the world in drug innovation?
2. What does the article is the best way to lower drug prices in the long term?
3. Why should Europe lift its drug price controls?

A Prescription for Disaster

1. What are some historical examples of price controls in the United States that have failed?
2. What are some historical examples of price controls specific to drugs in the United States that have failed?
3. What are some of the recommendations the paper gives for how to improve access to drugs?

Price Controls Are Not The Answer To Expensive Drugs

1. What are some potential consequences of implementing price controls?
2. How might price controls slow down RND?
3. Why would a competitive market lower the cost of drugs?

The True Story of America's Sky-High Prescription Drug Prices

1. What is the central trade off of the price controls debate?
2. What does it mean that "other countries regulate the price of drugs because they see them as a public utility"?
3. Do you think you'd be comfortable paying higher prices for drugs to get more innovation?

Other Countries Control Drug Prices

1. Why are Americans so worried about rising drug prices?
2. What are some of the different strategies other countries use to control drug prices?
3. Which one do you find the most plausible?

To Reduce the Cost of Drugs Look to Europe

1. What is reference pricing? How does it work?
2. Why might reference pricing not decrease incentives to innovate?
3. How would reference pricing keep drug prices low?

Why The US Has Higher Drug Prices Than Other Countries

1. Why do Americans pay so much more for drugs?
2. Why might a negotiation approach to tackling drug prices not succeed?
3. How would cost-benefit analyses help reduce costs?