The Role of the US Government in Prescription Drug Pricing and Policies

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***Abstract*— This paper provides a historical overview of the role of the United States government in prescription drug pricing and policies. Specifically, it provides a reflective view of governmental drug policies as early as 1906 to 2023. International governmental drug pricing models – including Canada and Germany are explored. Thereafter, this paper includes governmental policies to manage drug costs and pricing through the years from the lens of drug types, governmental drug payments (price-based competition / value-based healthcare) and regulatory legislation. The roles of the Food and Drug Administration, the Centers for Medicare and Medicaid Services are included. Finally, governmental efforts such as price transparency, generic substitutes, Medicare Part D negotiation, medication price caps and other specific bill proposals are highlighted.**

Keywords—prescription drug prices, drug costs, governmental drug policies

I. INTRODUCTION / HISTORY OF US GOVERNMENTAL POLICIES TO ADDRESS HIGH PRESCRIPTION DRUG COSTS AND PRICING

The United States needs to play an active role in addressing the high costs of prescription drugs for its citizens – through pricing and policies. Over the years, the United States government has taken a limited role in drug policies and regulation – often aimed at controlling drug industry costs and prices through legislation. This research reviews United States drug pricing policies over the years to the current time – with suggestions for improvement. Specifically, the purpose of this research is to review and assess the role of the United States government in prescription drug pricing and policies; make international governmental model comparisons related to prescription drug prices and polices; review United States government policies on prescription drug pricing and costs through the years from 2000 and beyond through a review of actions on various drug types; and finally to examine how planned government policies and legislative acts on prescription drug pricing and costs will shape the future in effort to contain drug costs.

In the United States, the primary federal agency whose role has evolved in the regulation of safe and effective drugs and medical devices is the Food and Drug Administration (FDA) of the Department of Health and Human Services.[1] As early as 1906, the FDA was authorized to take action only after drugs that were sold to consumers caused harm.[1] Other regulations followed related to the efficacy and safety of drugs and devices: 1938 Federal Food, Drug and Cosmetic Act; and 1962 Drug Amendments for prior approval for drug marketing.[1]

Continual increases in the cost of prescription drugs have affected virtually every segment of the U.S. healthcare system.[2] Over the last two decades drug expenditures across the United States healthcare system have grown from 106.1 billion in 1998 to $421.3 billion in 2015.[3] Lockwood, 2019, reported that annual expenditures for pharmaceuticals account for $500 billion or 16.7% of the total U.S. spending and cost for branded drugs are increasing at an unsustainable 15% per year. [4]

Cost incentives for drug production began to play a significant role in 1983 with the passage of the Orphan Drug Act and its amendments. [1] Specifically, the 1980s brought pressure for the FDA to allow rapid access to new drugs for the treatment of human immunodeficiency virus (HIV) infection.[1] The Orphan Drug Act of 1983 provided incentives and grant funding for pharmaceutical firms to develop new drugs for more rate diseases and conditions. [1]

However, Lockwood, 2019, described the Orphan Act of 1983 as an adverse governmental regulation in relation to its influence on drug pricing.[4] It has also been reported that the cost of prescription drugs in the United States continues to be a concern for patients, policy makers and government officials.[5]

Further, Hennessy, 2023, discussed how prescription drug patent exclusivity was extended during the Hatch-Waxman Act of 1985.[6] The act allowed negotiations to increase generic drug access and overall drug affordability. The act also aimed to preserve incentives for innovation through procedures for patent litigation.[6] Following the Hatch-Waxman Act of 1985, the generic products share of total prescriptions in the United States increased from 36% in 1994 to 90% in 2019. [7] In 1988, the Medicare Catastrophic Coverage Act added limits to Medicare's total out-of-pocket expenses for Part A and Part B, along with a limited prescription drug benefit.[8]

In 1992, the Prescription Drug User Fee Act was passed to allow the FDA authorization to collect application fees from drug companies to provide additional resources to shorten the application process – for approval to be issued.[1] The accelerated review process may have caused an increase in safety rights and recalls.[1]

In 1997, Congress passed the Food and Drug Administration Modernization Act to increase patient access to experimental drugs and medical devices – especially when the benefit of the new drug outweighed the current therapies.[1] Shortly after the addition of Medicare's Part C (Medicare Advantage) in late 2003, the Medicare Prescription Drug Improvement and Modernization Act of 2003 added an optional prescription drug benefit known as Medicare Part D.[1] Medicare was initially created to cover only the elderly but was expanded in 1973 to cover nonelderly disabled Social Security recipients and individuals with end stage renal disease.[1]

Shi and Singh, 2023, further reported that the Medicare Prescription Drug Program of the Modernization Act of 2003, was fully implemented in 2006 – with participation eligibility for individuals in Medicare Part A and B and Medicare Advantage.[1] In 2017, Thompson reported that there were more than a dozen distinct bills addressing drug pricing in the 115th Congress, with ideas on drug importation and negotiations for Medicare Part D covered drugs.[8] None of the bills were expected to leave their committee as a self-standing bill. Perhaps, a drug pricing bill may later become a part of a large bill, such as the next iteration of the Prescription Drug User Fee Act – which originated in 1992.[8]

According to Daniel and Bornstein, 2019, the continued influx of baby boomers into Medicare from private health insurance plans was expected to affect trends in spending growth in the program for the next decade.[5] In 2015, the Part D Prescription Plan spent $137.4 billion on drugs. As of 2018, more than 43 million beneficiaries were enrolled in Part D of the Medicare Prescription Plan.[5] Daniel and Bornstein, 2019, also reported that the United States spends more than other countries on prescription drugs and as the number of persons covered by Medicare increases for the high-cost brand name drugs, action will be needed to ensure affordability for patients and government purchases.[5]

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II. INTERNATIONAL GOVERNMENTAL MODELS AS A GUIDE ON PRESCRIPTION DRUG PRICING AND POLICIES

According to Daniel and Bornstein, 2019, several reasons for high-cost prescription drug spending by the United States, when compared to other international countries, include pricing of medical goods and services and the lack of direct price controls.[5] Lockwood, 2019, reported that internationally among eleven highest income nations, the United States had the highest pharmaceutical spending per capita at $1443 compared to $749 for all other countries.[4] In Canada, drug pricing is controlled by the Patent Medicines Price Review Board which compares the price of a given drug in other European nations and the United States in order to determine the price in Canada.[9] Drug prices in the United States are approximately one-third higher than in Canada.[9]

Among developed countries, healthcare is seen as a public product. Pharmaceutical coverage is included in the basic health plans of almost all developed countries except Canada – where coverage varies across territories.[10] Some countries with National Health Insurance that provide pharmaceutical coverage include Israel, Australia, Belgium, Denmark, France, Germany, Hungary, Italy, Japan, South Korea, the Netherlands, Norway, Poland, Portugal and Spain.[11] In Canada, coverage for inpatient and most outpatient drugs are covered under private health insurance. [11]

In many countries, excluding Canada, basic plans include pharmaceutical coverage for selected medicines – except in Germany and the United Kingdom, where all medicines are usually included in a reimbursement basket.[11] Germany and the United Kingdom automatically cover all marketed medicines unless they are specifically excluded from public financing. Most countries have a structured process for evaluating new drugs or indications for existing products submitted for inclusion in public plans prior to marketing.[12] Suggestions to control prescription drug prices include reimporting medications from Canada or for the government to place price caps on expensive pharmaceuticals.[9]

III. UNITED STATES GOVERNMENTAL POLICIES TO ADDRESS PRESCRIPTION DRUG PRICING AND COSTS THROUGH THE YEARS

Cohn, 2016, discussed the drug controversy related to pricing for special drugs. [13] Namely, Cohn, 2016, reported on an anti-viral drug called Sovaldi – a miracle cure for hepatitis C. According to Cohn, the drug costed $85,000 per regimen and put a strain on public and private insurance companies. [13] Among the ten drugs that accounted for 21% of Part D spending was Harvoni (ledipasvirsofosbuvir) also for hepatitis C.[5] High priced antiviral drugs have also been associated with recent increases for Medicaid pharmaceutical spending. Medicaid spending on outpatient drugs increased from 25% (from $22.4 billion to $28 billion) between 2013 and 2014 and another 13% (to $31.7 billion) between 2014 and 2015.[14] In a study by Gallup and West, a rising percentage of adults reported not having enough money in the past twelve months to pay for needed medicine or drugs that a doctor prescribed to them.[15]

Wilensky, 2016, presented the historical growth of the spending of prescription drugs from 2000 to 2015 – including price hikes for new branded products called biologics and specialty drugs. The pricing evolution of specific drugs for diseases such as hepatitis C, malarial infections, allergic reactions and cancer drugs was highlighted. [16] Wilensky,

reported in 2015, Turing Pharmaceutical increased the price of Daraprim, an old drug used to treat protozoal and malarial infections to $75 a pill.[16] In 2016, Mylan raised the price of the EpiPen, a delivery device for epinephrine for severe allergic responses from about $100 to $600.[16]

Augustine, et al., 2018, also reported that the specialty drug, Daraprim, to treat toxoplasmosis in AIDS patients was reported as increasing from $13.50 to $750 per table. [17] Again, it was reported that the EpiPen two pack went from $160 to $600 – with $300 going to the Pharmacy Benefit Manager. [18] Other drugs such as the tuberculosis drug cycloserine went from $500 to $10,800 for 30 capsules.[18] Cohn, 2016, reported how Nexium, a popular treatment for acid reflux (marketed by AstraZeneca) generated a great expense for Medicare Part D in 2014 ($2.66 billion).[13]

McQueen, 2022, presented the most expensive drugs in the United States by manufacturers and annual costs: Zolgensma to treat spinal muscular atrophy (Novartis Gene Therapies, $2,125,000); Zokinvy an orphan drug to treat Hutchinson-Gilford progeria syndrome (Eiger Biopharmaceuticals, $1,073,760); Danyelza to treat neuroblastoma in the bone or bone marrow (Y-mAbs Theraptupics, $1,011,882); Kimmtrak to treat surgically untreatable uveal melanoma (Immocore, $975,520); Myalept to treat lipodystrophy (Amryt Pharmaceuticals, $929,951); Luxturna to treat retinal dystrophy (Spark Therapeutics, $850,000); Folotyn to treat peripheral T-cell lymphoma (Acrotech Biopharma, $842,585); Brineura to treat Batten Disease (BioMarin Pharmaceuticals, $755,898); Blincyto to treat rare form of acute lymphoblastic leukemia (Amgen, $754,720); and Ravicti to treat urea cycle disorders (Horizon Therapeutics, $695,970). [19]

According to Corso, 2022, other commonly prescribed prescription drugs generally range from $12.41 - $97.57 on average for out-of-pocket retail costs. Some of the drugs include: Atorvastatin (Liptor) to lower cholesterol – $64.02; Lisinopril to lower blood pressure – $12.41; Albuterol for wheezing and shortness of breath - $55.0;, Levothyroxine for hypothyroidism - $16.49; Amlodipine to treat high blood pressure - $27.79; Gabapentin to prevent seizures - $78.20; Omeprazole (Prilosec) for stomach and esophagus problems - $62.69; Metformin for Type II Diabetes - $15.01; Losartan to treat high blood pressure - $33.30 and Hydrocodone for severe pain - $97.57.[20] The cost of the prescription drug will largely depend on whether a generic or brand name drug is purchased. Generic drugs cost 85% percent less on average when compared to brand name drugs. [20]

In 2014, it was reported that the 21st Century Cures Act was passed to allow for faster approval of drugs and devices for life threatening conditions. [1] In 2018, the Right to Try Act was passed to make investigational treatments available to people with life threatening illnesses, after the exhaustion of standard treatments.[1] Sharfstein, 2019, suggested that creative ways be sought to solve problems associated with the high cost of drugs to treat diseases like hepatitis C and the challenges of the opioid crisis. [21] Studin, 2021, suggested that value propositions for the pharmaceutical industry require a balancing act between price and clinical benefit. Consideration will need to be given to treatments for orphan diseases and rare cancers.[14]

Governmental efforts to moderate high drug costs have stemmed from the role of the Centers for Medicare and Medicaid Services. In 1977, the Health Care Financing Administration (now called the Centers for Medicare and Medicare Services - CMS) was created to manage Medicare and Medicaid separately for the Social Security Administration.[1] Another specific role of the CMS is to calculate rebates. The Medicaid Drug Rebate Program (MDRP) requires drug manufacturers to enter into an agreement with the Department of Health and Human Services in exchange for coverage of the manufacturers' drugs by state Medicaid Programs. In the MDRP, manufacturers are required to pay states a rebate for each unit of a drug covered by the state Medicaid Program. The rate is calculated by CMS.[5]

Likewise, at least two million Medicare Part D beneficiaries were enrolled in the low-income subsidy cost-sharing program. However, CMS estimated that Medicare could have saved nearly $9 billion if equivalent generics had been used instead of brand name drugs.[5] Wilensky, 2016, reported that the Centers for Medicare and Medicaid Services (CMS) nor the Department of Health and Human Services (HHS) negotiates prices in Medicare (Part D).[16]

Lyford and Lash (2019-2020) reported the Centers for Medicare and Medicaid Services was taking steps towards value-based care models to redirect financing incentives towards reduced cost, better health outcomes and more patient-centered care.[22] Likewise, prescription drugs have been priced too high – and need to rebalance incentives to increase price competition. Even so, Medicare is prohibited again from negotiating drug prices to force prescription drug manufacturers to lower their prices. [22]

Thompson (2017) reviewed Congressional action on rising drug prices. Some of the proposed bills presented were the Prescription Drug User Fee Act, which funds FDA's drug approval activities; Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017; Fair Access For Safe and Timely Generics Act of 2017 and Fair Accountability and Innovative Research Drug Pricing Act of 2017. [8] The access bills were designed to address the abuse related to preventing generic drugs from moving forward. Other acts included the Fair Accountability and Innovative Research Drug Pricing Act of 2017 and the Compounding Quality Act of the Drug Quality and Security Act of 2013. These bills provide a timeline of the efforts to control pharmaceutical costs through the years using various legislative acts – most of which were not enacted. The efforts of an organization to advance pharmacy practice was also highlighted.[8]

Perez, 2019, stated that the Prescription Drug Pricing and Reduction Act addressed challenges in Medicare Part B (ambulatory care / prescription drugs) and Part D (prescription drugs).[23] The act would cap out of pocket costs for Medicare Part D participants and require pharmaceutical companies to justify drug price increases to the Department of Health and Human Services.[23]

IV. PLANNED AND FUTURE GOVERNMENTAL POLICIES TO ADDRESS PRESCRIPTION DRUG PRICING AND COSTS

Through many years and efforts to address prescription drug prices, novel solutions are still needed to combat runaway costs. Socal and Anderson, 2020, presented a study on older Americans' preference between lower drug prices and prescription drug plan choice. They reported that 82% of the 1440 older adults studied supported Medicare negotiating drug pricing directly with the manufacturers.[24] The Medicaid beneficiaries indicated that they would also support a unified formulary that limits plan choice – as long as drug prices actually decrease. [24]

Lockwood, 2019 highlighted interventions / failed interventions that may have impacted high drug pricing such as the actions of pharmacy benefit managers, exclusive manufacturing rights, suppression of generic competition and generic market distortions, lack of drug importation and the inability of Medicare to negotiate drug prices.[4]

According to Wilensky, 2016, during the 2016 presidential campaign, both Hiliary Clinton and Bernie Sanders supported the right for Medicare to negotiate drug prices.[16] The role of patents and pharmacy benefit managers in the pricing of pharmaceutical drugs was so presented. The common solution that has been proposed for many years was the Medicare drug price negotiations.[16]

Planned or suggested prescription drug cost containment measures have included generic substitutes, public hearings on proposed remedies, modernizing research and development in the pharmaceutical industry and price transparency. Ben- Aharon et al., 2017 proposed the regulation of drug prices and health technology reimbursement as drug cost containment tools.[11] Other cost containment tools included "delisting services, reviewing administrative price costs, erosion of pharmacy's profits, reduction in Value Added Tax (VAT) for drugs, promoting generic substitutes and increasing co-payment. Due to the complexity of generic substitutes, policy changes are likely to be made slowly.[11]

Traynor, 2019, provided highlights of testimony at a hearing of the House Committee on Oversight Reform that underscored the magnitude and impact of high prescription drug costs. [25] According to Traynor, 2019, the hearing was entitled "Examining the Actions of Drug Companies in Raising Prescription Drug Prices." During the hearing, the life story of a 22-year-old Type I diabetic was presented.[25] The negative plight of drug prices on seniors, hospitals, retirees and professional organizations was depicted. Some of the remedies proposed included shortening drug marketing exclusivity periods, including patent reforms and allowing the government to negotiate prices for medications covered under the Medicare Part D prescription benefit.[25]

Weschler, 2022, reported that the November midterm election of 2022 blocked agreement on many important legislative and regulatory initiatives for the FDA (U.S. Food and Drug Administration).[26] Some of the initiatives included a "delay in Congress renewing user fees for drugs, biologics, generic drugs, medical devices, and biosimilars".[25] Also, there were barriers to the federal 340B program designed to provide discounts on certain drugs for hospitals and clinics. Some suggestions for modernizing research and development in the pharmaceutical industry were initiating "less cost clinical trials with the incorporation of remote and online systems to enroll study participants and oversee treatment and patient status, adoption of advanced manufacturing systems and support of regulatory programs designed to ensure production of high-quality treatments. [26]

In 2019, Quallich provided an overview of the Affordable Care Act and its role in continuing to encourage reduced spending for patients as a result of expanding coverage and mandates for coordination of care while shifting to value based payment.[27] Based on government initiatives through the Center for Medicare and Medicaid Services, price transparency and listing of services has been sought for hospitals. In October 2018, the Centers for Medicare and Medicaid Services proposed that prescription drug manufacturers post the price of medications in any direct-to-consumer television advertisement.[27] Price transparency requires more accountability from manufacturers. Drug price reduction is the aim using various measures requiring both governmental and industrial compliance.

Shahriar et al., 2021 reviewed databases from 2015 to 2020 to locate drug pricing legislation.[28] Thirty-two transparency bills were identified in twenty states. Eighteen affordability review bills were identified in thirteen states. Sixteen anti-price gouging bills were identified in nine states.[28] According to Shahriar et al. (2021) modifications to legislative language relating to timing, reporting and drug types could increase the impact of state transparency and drug affordability legislation.[28]

Cohrs, 2019, reported that former President Trump's FDA pick Dr. Stephen Hahn voiced support for facilitating generic and biosimilar drug approvals.[29] According to Cohrs, 2019, Dr. Hahn also stated that he would address gaming by biologic markers to prevent biosimilar competitors from coming to market.[29]

In conclusion, in an effort to reduce prescription drug pricing, many presidential and Congressional initiatives have been proposed. In July 2020, former President Trump announced four

executive orders aimed at reducing prescription drug 340B discounts to lower patient's out of pocket cost for EpiPens and insulin through discounts to community health centers.[30] The other executive orders related to international reference pricing using fourteen countries for Medicare Part B payments; rebate ruling with plans to pass drug makers' discounts directly to the patients – although it would likely raise premiums for Medicare beneficiaries; and modification of importation guidelines to allow states and drug makers to import some prescription drugs from Canada. Also, the FDA issued a proposed rule in December 2022 that would allow states to pursue pilot programs.[30]

Gavulic and Dusetzima, 2021, presented an overview of prescription drug prices under the Biden Administration.[31] Prescription spending was estimated from 2019 to 2028.[31] Governmental actions to lower prescription drug prices were presented – including discussion on the negotiation of drug prices through Medicare. Accordingly, efforts to limit price increases through the reintroduction of the Prescription Drug Pricing Reduction Act of 2019 were included.[31] Efforts to improve prescription drug coverage and lower out of pocket spending were noted. As options to lower drug costs ensue,

> "President Biden may have more opportunities to pursue his proposed course of action if he can convince stakeholders that his approach would be less costly to the industry than using the lowest available price to set (Medicare) Part B prices." Bipartisanship is needed to advance legislation on drug prices – as it is currently a highly partisan issue.[31]

Hennessy, 2023, reported that a prescription drug crisis had arisen based on the fact that "10% of prescriptions have an average cost of $20 per day and account for 80% of all prescription drug spending, despite the fact that 90% of prescriptions are generic that cost an average $1 a day."[6] According to Hennessey, 2023, to address the issue President Joe Biden has signed the Inflation Reduction Act.[6] Recently, other legislation has been passed to cap the price of insulin. Federal agencies such as the FDA and the Centers for Medicare and Medicaid Services are preparing to "negotiate drug prices for the first time." Reflections from the Hatch-Waxman Act to increase generic drug access was discussed.[6]

The role of the government in prescription drug pricing and policies has continued to evolve over the years to the current time. The weight of prescription drug costs and drug availability affect United States citizens of all ages – especially evident among Baby Boomers. In recent years, numerous policies and legislative bills have been introduced to contain the cost and availability of prescription drugs. The magnitude of this highly politicized issue warrants ongoing recommendations for improvement from politicians, citizens, hospitals, and consumer groups.[25]

Governmental intervention in drug pricing and policies has been seen in large outlays for research and development as well as the administration of medical insurance for certain groups in the form of Medicare and Medicaid. Thus, the government may heighten its efforts to lower the price of prescription drug through regulatory actions and policies such as allowing more generic and biosimilar approvals, negotiating prices with Medicare Part D, allowing drug imports, instituting price caps and maximum price regulation, reviewing compensation to and drug pricing by pharmacy benefit managers, revision of funding and modernization techniques for research and development of drugs, stricter decisions regarding orphan and specialty drugs, reviewing exclusive drug manufacturing rights, reducing Value Added Tax, shortening drug marketing exclusivity periods, advancing drug manufacturing systems, patent reform, value based healthcare reimbursement, reviewing regulations to yield high quality drugs for treatment, using international reference pricing, and instituting rebates to pass discounts directly to patients.

In addition to cost savings, lower drug pricing appears to have a positive effect on medication adherence as revealed in a study comparing out-of-pocket costs of Medicare beneficiaries with generic drug discount programs.[32] Which drug pricing policies will be survive the legislative process and be implemented, remains to be seen – as pharmacy unions strive to align worker and corporate interests and as novel pharmaceutical delivery modes (e.g., Mark Cuban Pharmacy) enter the market. Areas for future research will likely include reflections on previous beneficial national policies such as the Hatch-Waxman Act, the formulation of new policies, and the incorporation of international perspectives and models of pharmaceutical pricing and delivery. Consensus holds that cost containment in the pharmacy industry will require multidisciplinary perspectives, corporate, Congressional and consumer voice.

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