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Talk is Actually Cheap: Implementing an Administrative Agency to Set Pricing Caps and Negotiate for Improved Pharmaceutical Pricing in the United States

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Introduction

Healthcare in America has been a hot topic of the past few elections. Determining the system that will be the best course for bettering the health outcomes of the 334 million people that reside here is complex for many reasons, one being the intricate task optimizing pharmaceutical access.[1] Other comparable countries, including Germany and the UK, have established pricing caps on what pharmaceutical companies will be reimbursed for through the public healthcare system, lowering the total amount spent on medications. By contrast, the US has large healthcare costs, of which high medication pricing is partially to blame. The US system is not a comprehensive universal public system, unlike those of the UK and Germany that cover most of their populations. We do not have entities that exist to independently assess the fair value of pharmaceuticals, or to negotiate for maximum pricing reimbursements.

Current healthcare spending in the US is almost double that of the next highest spending country, Germany.[2] For reference, the average total spending among wealthy countries is $5,829, which is less than half of the US's $12,318 total spending on healthcare. [3] In 2018, while

[1] *Population Clock*, Census.gov, https://www.census.gov/popclock/ (last visited May 14, 2023).
[2] $12,318 versus $7,383. *How Does the U.S. Healthcare System Compare to Other Countries?*, PETER G. PETERSON FOUNDATION (July 19, 2022), https://www.pgpf.org/blog/2022/07/how-does-the-us-healthcare-system-compare-to-other-countries (last visited May 14, 2023).
[3] *Id.*

prescription drugs and medical goods accounted for thirteen percent of total US healthcare spending and sixteen percent on average in comparable countries, the total actual spending on prescription drugs and medical goods specifically in comparable countries, was about half that of the US.[4] The comparable countries included Germany and the UK, as well as all other countries also in the Organization for Economic Cooperation and Development (OECD).[5] Our patent system, although not unlike international patent systems, creates an environment for pharmaceutical pricing regulation issues with the support of strong lobbyist groups.[6]

This essay will advocate for the creation of an independent administrative agency that will be able to assess and establish maximum pricing for the reimbursement of medications. Compliance with pricing maximums will be required for government-run plans, but will be strongly suggested for all private plans. To help ensure this, a pact dedicating a private insurance company's plan to following the established maximum pricing rates can be publicly agreed to, with tax benefits for companies that comply. A badge or certification of compliance can and should be advertised with the plan, making it clear to insurees that they can expect pricing maximums to be followed. Additionally, it would be required that all employer-sponsored fully-insured plans participate in the pact.

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[4] *Distribution of Health, By Spending Category, 2018*, Peterson-KFF Health System Tracker; https://www.healthsystemtracker.org (comparing 13% of $10,637 total in the US [$1383] with 16% of $5527 [$884] for the average comparable countries).

[5] *Id.; The Organization for Economic Cooperation and Development (OECD)*, https://www.state.gov/the-organization-for-economic-co-operation-and-development-oecd/#:~:text=and%20Development%20(OECD)-,The%20Organization%20for%20Economic%20Cooperation%20and%20Development%20(OECD),to%20promote%20sustainable%20economic%20growth. (last visited May 14, 2023) ("The Organization for Economic Co-operation and Development (OECD) is a unique forum where the governments of 37 democracies with market-based economies collaborate to develop policy standards to promote sustainable economic growth.").

[6] Peter Loftus, *Drugmakers, Worried About Losing Pricing Power, Are Lobbying Hard Pharmaceutical industry attacks proposals in Washington that could cut deeply into companies' sales*, The Wall Street Journal, Sept. 24, 2019, https://www.wsj.com/articles/drugmakers-worried-about-losing-pricing-power-are-lobbying-hard-11569317406.

To establish said pricing, either the same or a different entity will facilitate negotiations with pharmaceutical companies, by comparing and contrasting the US healthcare system pricing with those of other comparable countries. Through this, methodologies will be implemented for keeping medication costs lower, and therefore less burdensome on our system. The focus will be not on ultimate out-of-pocket costs to consumers, but rather the overall cost of pharmaceuticals to our healthcare system.

By focusing on making medications more affordable and establishing a channel for negotiations between pharmaceutical companies and third-party administrative agencies, our population will have a greater likelihood of becoming healthier. The saved funds can hopefully be reallocated to bettering the quality of other healthcare services offered and improve overall healthcare access. If public and private health insurance companies can reap the benefits of reduced drug pricing, then some of the money that is saved can be applied elsewhere, like towards increased funding for public healthcare programs, subsidies for health insurance, investments into preventative care, or the expansion of healthcare infrastructure. Germany and the UK have ways that they have overcome such healthcare access barriers, while understanding the competing interests of preserving patents and the incentivization of research and development with establishing a more balanced system that is less at the mercy of the whims of the pharmaceutical companies.

The companies that predominantly sell in these countries still participate in active research and development, which is often cited as a fear of limiting funding to pharmaceutical companies.[7] Conversely, a legitimate fear in reducing pharmaceutical pricing in the US is that

[7] Susan Peschin & Duana Schulthess, *International pricing index 'accomplishes nothing it sets out to do'*, STAT (Oct. 21, 2019), https://www.statnews.com/2019/10/21/international-pricing-index-research-development/ (last visited May 14, 2023).

these companies make up for lower agreed-upon payments in other countries by charging more in the US.[8] If prices are capped here, then the global profit margins would be reduced, which is an important potential repercussion to highlight.[9] By understanding the process by which pharmaceuticals make their way to citizens, and the way that these items are priced, either by government intervention or otherwise, important lessons can be learned and applied to our system here.

The first two parts of this essay will dive into the healthcare systems of the UK and Germany and discuss how they regulate the pricing and costs of supplying pharmaceuticals to their citizens. Additionally, critiques of each approach will be included. The third part of this essay will explore the current healthcare system in the US and how pharmaceutical pricing regulation is handled here. Lastly, this essay will explore the application of elements that make these countries more successful in how they reduce costs, while addressing concerns about the adoption of such measures.

Part I. The UK's Healthcare System and its Relationship to Pharmaceuticals

A. The UK's Approach to Pharmaceutical Pricing

The National Health Service System (NHS) of the United Kingdom is a socialized system financed by general taxation.[10] Access to providers is free for consumers at the point of service,

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[8] Paul Ginsburg & Steven M. Lieberman, *Government regulated or negotiated drug prices: Key design considerations*, Brookings (Aug. 30, 2021), https://www.brookings.edu/essay/government-regulated-or-negotiated-drug-prices-key-design-considerations/#:~:text=If%20the%20U.S.%20government%20sets,other%20individual%20high-income%20countries. (last visited May 14, 2023).

[9] *Id.*

[10] *England*, Commonwealth Fund, https://www.commonwealthfund.org/international-health-policy-center/countries/england (last visited May 14, 2023).

including regular provider and hospital visits.[11] Most providers and hospitals are controlled by the state.[12] As such, the state directly pays for care and services provided through tax revenue.[13] The government pays capitated rates, meaning that the hospital or provider will be reimbursed per patient served, not by service provided.[14] As the care is financed through the government, a strict budget that cannot be exceeded exists, imposing a cost containment predicament for the UK government.[15]

i. The UK's National Institute for Health and Care Excellence (NICE)

In determining how to regulate pharmaceutical spending, the UK's National Institute for Health and Care Excellence (NICE) utilizes the Quality Adjusted Life Year (QALY) or Incremental Cost Effectiveness Ratio (ICER).[16] NICE does not negotiate pricing, but appraises medications and treatments based on the value they bring to an individual in relation to their cost. [17] NICE is also responsible for recommending whether NHS should pay for new medications at the prices set forth by the manufacturer.[18]

When a new drug becomes available, the manufacturer typically sets a price for that drug.[19] NICE then conducts a health technology assessment (HTA) to determine whether the drug provides sufficient clinical benefit and represents value for money within the NHS budget.[20]

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[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *7 Assessing Cost Effectiveness*, NICE | The National Institute for Health and Care Excellence, https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness (last visited May 14, 2023).
[17] *Drug Pricing*, Houses of Parliament: Parliamentary Office of Sci. & Tech. POSTNOTE 364 (Oct. 2010), https://www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf.
[18] *7 Assessing Cost Effectiveness*, NICE | The National Institute for Health and Care Excellence, https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness (last visited May 14, 2023).
[19] *Technology Appraisal Guidance*, NICE, https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance (last visited May 14, 2023).
[20] Victoria Charlton, *NICE and Fair? Health Technology Assessment Policy Under the UK's National Institute for Health and Care Excellence, 1999–2018*, 28 Health Care Analysis 193, (2019), https://doi.org/10.1007/s10728-019-00381-x (last visited May 14, 2023).

During the assessment, NICE considers factors such as the drug's effectiveness, safety, and cost-effectiveness in relation to existing treatment options.[21]

Based on the assessment, NICE issues recommendations on whether the NHS should provide funding for the drug.[22] These recommendations are made in the form of technology appraisal guidance.[23] If NICE determines that the drug provides sufficient clinical benefit and represents value for money, it recommends that the NHS should pay for the drug at the price set by the manufacturer.[24]

However, if NICE determines that the drug does not provide sufficient value for money, it may issue a recommendation stating that the NHS should not fund the drug or that it should only be funded under specific circumstances or conditions.[25] In some cases, NICE may recommend that further price negotiations take place between the manufacturer and the NHS to make the drug cost-effective.[26]

A QALY is determined to be one additional year of perfect health.[27] The QALY score ranges from zero to one, with negative amounts possible as some health states are seen as worse than death (zero), and is calculated by multiplying a "quality of life" value by the length of life applicable.[28] In determining if a new treatment should be paid for, the difference between the QALY's of an existing treatment and a new, proposed treatment are evaluated for significant

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[21] *NICE Health Technology Evaluations: The Manual*, NICE, (Jan. 31, 2022) https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741.
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Sanofi Short Guide: The QALY Explained*, Sanofi (July 2019), https://www.sanofi.co.uk/dam/jcr:7ea802d6-13f3-4fe7-af2d-111d4d2ea5f0/The%20QALY%20Explained.pdf.
[28] *Id.*

gain.[29] In essence, NICE considers the QALY value of a new treatment in relation to what already exists as the standard of care. Treatments are compared taking into account both the total cost per year of the treatment (the total cost is the cost minus any savings), as well as the outcomes associated with that treatment (the QALY gain).[30] This provides a value of cost per QALY.[31] Calculating the cost per QALY allows treatments to be compared based on their total cost per additional QALY achieved, as opposed to the price of the treatment. [32] In England, NICE sets thresholds to determine whether a treatment is cost-effective and should therefore be made available on the NHS.[33] NICE has a £20,000 cost per QALY threshold, with treatments with a cost per QALY over this amount less likely to be made available on the NHS. [34]

NICE is prepared to pay more per QALY under certain conditions. [35] If an individual is at the end of their life, a larger monetary threshold QALY will be supported.[36] This stems from the belief that humans have respect for the aging process. As a person is closer to death, extra time may be seen as more valuable. End-of-life medications aim to extend one's life for short periods of time, and despite how expensive they are, NICE allows for greater expenditures.[37]

Similarly, individuals with severe or rare diseases are a designated class that also allots larger thresholds.[38] Because some people may not be lucky with the genetics they end up with,

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[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Sanofi Short Guide: The QALY Explained*, Sanofi (July 2019), https://www.sanofi.co.uk/dam/jcr:7ea802d6-13f3-4fe7-af2d-111d4d2ea5f0/The%20QALY%20Explained.pdf.
[34] *NICE Methods and Process Evolution*, The Association of the British Pharmaceutical Industry, https://www.abpi.org.uk/value-and-access/nice-methods-and-process-evolution/ (last visited May 14, 2023).
[35] *Id.*
[36] *End of Life Care for Adults: Quality Standards*, NICE, https://www.nice.org.uk/guidance/qs13 (last visited May 14, 2023).
[37] *Id.*
[38] *NICE Methods and Process Evolution*, The Association of the British Pharmaceutical Industry, https://www.abpi.org.uk/value-and-access/nice-methods-and-process-evolution/ (last visited May 14, 2023).

NICE's use of increased thresholds is rooted in the belief that society should not hold having diseases against an individual as it is something that is not within his or her control. Rare diseases, although granted more funding relatively, generate a higher cost per QALY than for other more common diseases.[39]

Severe diseases are evaluated under the proportional shortfall and the absolute shortfall. [40] The proportional shortfall refers to the difference in health outcomes achieved by the new treatment compared to existing treatments in relation to the additional cost.[41] NICE evaluates whether the treatment provides a sufficient increase in health benefits that justifies the additional expense compared to current alternatives.[42] If the health benefits gained from the treatment are substantial relative to the cost, it may be considered cost-effective and recommended for use within the NHS.[43] The absolute shortfall refers to the difference in health outcomes between the new treatment and existing alternatives in absolute terms, regardless of cost.[44] NICE considers whether the treatment provides significant clinical benefits compared to current options, regardless of the additional expenses involved.[45] If the treatment offers substantial improvements in health outcomes, it may be recommended by NICE.[46] By considering both the proportional and absolute shortfalls, NICE aims to ensure that treatments for severe diseases offer value for money and provide significant clinical benefits compared to existing alternatives.[47] This

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[39] *NICE's Severity Modifier: A Step in the Right Direction, but Still a Long Way to Go - OHE*, OHE(Mar. 23, 2022), https://www.ohe.org/insight/nices-severity-modifier-step-right-direction-still-long-way-go/ (last visited May 14, 2023).
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *NICE's Severity Modifier: A Step in the Right Direction, but Still a Long Way to Go - OHE*, OHE(Mar. 23, 2022), https://www.ohe.org/insight/nices-severity-modifier-step-right-direction-still-long-way-go/ (last visited May 14, 2023).
[46] *Id.*
[47] *Id.*

evaluation process helps guide the decision-making on whether the NHS should fund the treatment and make it accessible to patients.

Medication pricing with QALY places value in how well a medicine treats patients, the value that health systems may place on a medicine in a disease area, and how many patients might benefit from it when deciding on pricing between potentially competing products. [48] As mentioned, the concept of cost-effectiveness in evaluating cost per QALY plays a significant role in determining what will be available through the NHS. Since 1999, NHS has only paid what NICE deems is cost-effective. [49] Using NICE's appraisals of the effectiveness of medications, the NHS negotiates with the pharmaceutical companies to agree upon prices. As of 2017, if a medicine is believed to have a significant budget impact, NHS will negotiate for discounts or only allow those most in need have access to the medication for its first two years. [50]

It's important to note that NICE's recommendations are influential in shaping drug access and funding decisions within the NHS. While NICE's role does not involve direct price negotiations, their assessments and recommendations have a significant impact on the decision-making process regarding the affordability and value of new drugs within the UK healthcare system.

ii. NHS's Price Regulation Scheme

NHS's voluntary price regulation scheme functions to keep pharmaceutical pricing in the UK low. Since 2014, "statutes and a voluntary scheme have required branded manufacturers to pay the government rebates to recoup the difference between the global pharmaceutical budget

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[48] *NICE Methods and Process Evolution*, The Association of the British Pharmaceutical Industry, https://www.abpi.org.uk/value-and-access/nice-methods-and-process-evolution/ (last visited May 14, 2023).
[49] Marc A. Rodwin, *How the United Kingdom Controls Pharmaceutical Prices and Spending: Learning From Its Experience*, 51 International Journal of Health Services 229, (2021), https://doi.org/10.1177/0020731421997094 (last visited May 14, 2023).
[50] *Id.*

and actual spending." [51] This applies to hospitals in how generic and patented medications are competitively matched, as well as to pharmacies that aim to "beat average generic market prices."[52]

The Pharmaceutical Price Regulation Scheme (PPRS) exists between the UK Department of Health and The Association of the British Pharmaceutical Industry (ABPI) to achieve a balance in reasonable pharmaceutical costs for the NHS.[53] The PPRS is a voluntary agreement negotiated between the Department of Health and Social Care (DHSC) and the ABPI, which represents the pharmaceutical industry in the UK.[54] The PPRS focuses on value-based pricing that links the price of a drug to its cost-effectiveness.[55] After a drug is determined to be supported by NICE and therefore available on the NHS, patient access schemes exist to regulate pricing.[56]

The key aspect of the PPRS is the negotiation of pricing for branded medicines.[57] The DHSC and ABPI engage in negotiations to determine the allowable level of sales growth for the pharmaceutical industry and to agree on the pricing of medications.[58] These negotiations consider factors such as the cost of research and development, production costs, and the expected therapeutic benefits of the drugs.[59] The PPRS includes provisions for the profit control caps, and price cuts after a period of time for older drugs. [60] The agreement also sets limits on the profit

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[51] *Id.*
[52] *Id.*
[53] *The Pharmaceutical Price Regulation Scheme: Eleventh Report to Parliament*, Department of Health, (Feb. 2012), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215156/dh_132793.pdf.
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] *Drug Pricing*, Houses of Parliament: Parliamentary Office of Sci. & Tech. POSTNOTE 364 (Oct. 2010), https://www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf.

margins that companies can achieve through sales of their pharmaceuticals.[61] This helps ensure that prices are reasonable and that companies do not excessively profit from NHS sales. The PPRS includes mechanisms for pharmaceutical companies to make payments to the NHS based on the sales of branded medicines.[62] These payments are intended to reflect the value provided by the medicines and contribute to the overall cost of healthcare in the UK.

These schemes can be either financially-based or outcome-based. [63] Financially-based schemes are implemented when a company does not alter the list price of a medication, but offers discounts or rebates linked to numbers or types of patients treated, the response of patients that have been treated or the number of doses required, or an alteration of list pricing. [64] Outcome-based schemes include when a company agrees to a later increase in price, or a rebate, based on specified outcomes of evidence. [65] If the medication demonstrates the desired outcomes or value, pricing adjustments may occur. [66] This can involve a negotiated increase in price for the medication or providing rebates to the payer or healthcare system. [67] These adjustments aim to ensure that the pricing of the medication aligns with its proven value.

For those companies that do not agree to the scheme, prices are determined through other mechanisms. One approach is to use external reference pricing. This involves comparing the price of a drug in question to its prices in other countries where it is marketed. By benchmarking against prices in other countries, the UK government can negotiate prices with non-PPRS

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[61] *The Pharmaceutical Price Regulation Scheme: Eleventh Report to Parliament*, Department of Health, (Feb. 2012), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215156/dh_132793.pdf.
[62] *Id.*
[63] *Drug Pricing*, Houses of Parliament: Parliamentary Office of Sci. & Tech. POSTNOTE 364 (Oct. 2010), https://www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf.
[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] *Id.*

companies based on these comparisons. The goal is to ensure that prices are reasonable and aligned with international standards. Non-PPRS companies may also undergo health technology assessments (HTA) conducted by NICE that evaluate the clinical and cost-effectiveness of drugs. The outcomes of the HTA process can influence the pricing negotiations for non-PPRS drugs. Pricing negotiations can take place on an individual basis between the non-PPRS company and the UK government or NHS. These negotiations consider factors such as the therapeutic value, clinical need, and budget impact of the pharmaceutical. The aim is to establish a price that is fair and provides value for money for the NHS while ensuring the company receives reasonable compensation for its products. Lastly, in some cases, non-PPRS companies may enter into commercial agreements with the NHS or other healthcare organizations. These agreements can involve price discounts, volume-based purchasing arrangements, or other contractual arrangements to ensure access to the drugs at an affordable price.

The PPRS allows for adjustments to accommodate changes in the pharmaceutical market and ensure the continued affordability and availability of medicines. Periodic reviews and updates of the PPRS agreement take place to address emerging challenges and changing circumstances. As of 2009, the PPRS permits for flexible pricing in that the pharmaceutical companies are allowed to change their listed prices for certain medications after they have been marketed if new evidence of effectiveness comes to light.[68] Usually, the pricing would otherwise remain stable. [69]

[68] *Drug Pricing*, Houses of Parliament: Parliamentary Office of Sci. & Tech. POSTNOTE 364 (Oct. 2010), https://www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf.
[69] *Id.*

Compliance with the PPRS is monitored by the DHSC and ABPI.[70] Both parties work together to ensure that pharmaceutical companies adhere to the agreed pricing and payment terms outlined in the scheme.[71] Non-compliance can result in penalties or legal actions.[72] The PPRS is designed to balance the interests of the pharmaceutical industry, ensuring fair compensation for innovation and investment, while also safeguarding the affordability and accessibility of medicines for the NHS. It is a collaborative approach that seeks to achieve a sustainable and cost-effective pharmaceutical market in the UK.

B. Critique of the UK's Pharmaceutical Approach

Even though this system helps dictate fiscal responsibility, it enforces an outcome that is rooted in numerically rating the value of an individual's life. This makes what is an extremely subjective evaluation, an objective one, and is bound to be inherently flawed. It is impossible to judge what the improvement or extension of one's life at any given time can mean to that person or to the people around that person. If a medication is found to be too expensive, and a modifier is not applicable, an individual may not get approved for his or her treatment. In theory, a person may then be forced to live without a medication that would manage symptoms to improve his or her quality of life because the system deems it too expensive to be worth it. That person's only option is to try to pay for it entirely out of pocket which would be extremely difficult for the average person to do.

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[70] *The 2019 Voluntary Scheme for Branded Medicines Pricing and Access - Chapters and Glossary*, Dept. of Health & Social Care, ABPI (Dec. 2018), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf.
[71] *Id.*
[72] *Id.*

Although it is understood that, with its current system, NHS cannot pay for all new drugs regardless of their cost, a drug should be evaluated more on the benefits produced. In order to push pharmaceutical sciences forward, if a medication is found to be more beneficial than an existing medication on the market, then it should be covered even without being in an approved QALY range. As the procedure currently stands with medications, because a balancing of factors occurs, cost-effectiveness is prioritized over effectiveness. This reduces the implementation of more effective medications even though health outcomes would be better. Even if it is decided that NHS won't cover a medication, subsidies should be available for those who pay out of pocket for medications that are found to beneficial.

A major issue to flag in adopting such a system would be in the approach to medications that only benefit a small population of individuals, like those who must resort to experimental or alternative treatments. Although QALY does have greater allowance for such situations, like as they apply to those with rare diseases, the expense may still be outweighed significantly enough that an experimental procedure is deemed beyond the QALY threshold. These may ultimately be denied altogether and a person may lose a vital opportunity. These people are then left to either live with their symptoms insufficiently treated or pay large amounts of money to fund the experimental treatments themselves. The US has often been sought after for offering treatment, even in studies that are ongoing for such rare diseases. Here, we also do not fund experimental or alternative treatments, so adopting another similarly flawed system would not be beneficial. At least here, due to private pharmaceutical and university grant money, there are many opportunities for individuals to participate in research for treatments, as these organizations are motivated to see a large return on their investment in the US. This may create other pathways of getting treatment. If a company in the UK feels they will never see a monetary advantage or

potential reimbursement, they may be less likely to engage in such type of research, unless of course anticipating recouping their investment in the US. The US, although fueled more by capitalism, may have more opportunities and ultimately less financial strain on those who need to resort to experimental or alternative treatments.

The UK's use of the PPRS is a positive to its system, however. Even though it still utilizes NICE's QALY-based recommendations, the way the DHSC and ABPI determine pricing is valuable. Pricing is evaluated and negotiated from the perspective of cost of production, not from an arbitrary or subjective value. They want pharmaceutical companies to still make money, but they want that profit margin to be reasonable and not exploitative. The ability to modify pricing if increased efficacy is discovered also helps to ensure the level of fairness that is intended by this scheme.

The United States is particularly unique in that it often inspires hope where none can be elsewhere found. The QALY standard does not seem in line with that principle, as it can rather harshly dictate what medications and procedures will be covered for an individual based on a formula, discouraging approval of certain treatments if the QALY threshold is not met. Without approval, that notion of hope can no longer flourish.

Part II. Germany's Healthcare System and its Relationship to Pharmaceuticals

A. Germany's Approach to Pharmaceutical Pricing

Germany's healthcare utilizes the Bismarck type system.[73] This is distinguished as being a state-mandated insurance model that is funded by an employment-based system.[74] Here, compulsory wage contributions finance sickness funds, with a percentage of gross wages being applied up to a certain cap.[75] An individual's employer pays half of this amount while the employee pays the other half.[76] There is autonomy in choosing which fund the money will go to.[77] If an individual is unemployed, the government will pay for what the individual cannot.[78] Seventy-four percent of the funds are publicly funded; meanwhile, funds can charge up to an additional one percent of an individual's income for the inclusion of additional benefits if an individual so chooses.[79]

In terms of regulating pharmaceutical spending in Germany, the "Arzneimittelmarktneuordnungsgesetz," (AMNOG) framework exists, which translates to the "Pharmaceuticals Market Reorganization Act."[80] A non-governmental, non-profit organization is tasked with reviewing new medications and assessing their clinical benefits to patients.[81] Recommended pricing is then determined based on provided evidence and clinical study

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[73] *Germany*, Commonwealth Fund, https://www.commonwealthfund.org/international-health-policy-center/countries/germany (last visited May 14, 2023).
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] *AMNOG Procedure Is the Name of the German HTA Procedure*, Optimizing Market Access, https://www.healthecon.com/amnog/index_eng.html#:~:text=This%20system%20divides%20drugs%20into,for%20these%20reference%20price%20groups. (last visited May 14, 2023); *German AMNOG Process: Federal Social Court Decides Pharma Companies Can Now Take Direct Legal Action Against Negative Benefit Assessments*, Sidley Austin LLP (Oct. 29, 2020), https://www.sidley.com/en/insights/newsupdates/2020/10/german-amnog-process-federal-social-court-decides-pharma-companies-can-now-take-direct-legal-action (last visited May 14, 2023).
[81] *German Model for Drug Price Regulation May Be Good for U.S.*, Harvard T.H. Chan, https://www.hsph.harvard.edu/news/hsph-in-the-news/german-model-for-drug-price-regulation-may-be-good-for-u-s/#:~:text=A%20five-year-old%20drug,Chan%20School%20of%20Public%20Health. (last visited May 14, 2023).

outcomes.[82] Medications that are deemed to be more innovative and more impactful than others being proposed or that currently exist thus reward their pharmaceutical manufacturer with higher negotiating strength. [83] Because of AMNOG, the annual growth rate of pharmaceuticals between 2009 and 2013 in Germany was -0.7%, versus +2.7% in the US. [84] "US. net prices for the most expensive drugs are up to four times higher than their German equivalents." [85]

The Federal Joint Committee (G-BA) assesses the added benefit of new drugs and medical treatments compared to existing standard therapies.[86] The assessment is based on clinical effectiveness, patient-relevant outcomes, and cost-effectiveness considerations.[87] The G-BA evaluates the clinical benefits of a treatment by analyzing clinical studies, real-world evidence, and other relevant data.[88] They consider parameters such as improved survival rates, reduced symptoms, increased quality of life, and other patient-centered outcomes.[89] The assessment also considers the potential risks, side effects, and overall safety profile of the treatment.[90]

Germany allows for a drug manufacturer, when launching a new drug, to set the initial price for a maximum of 12 months, with no restrictions.[91] However, "the manufacturer must submit a dossier to the Federal Joint Committee (G-BA) that proves the additional benefit of the

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[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] *Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts*, Commonwealth Fund, https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/drug-price-moderation-germany-lessons-us-reform-efforts (last visited May 14, 2023).
[86] *How Drug Prices Are Negotiated in Germany*, Commonwealth Fund, https://www.commonwealthfund.org/blog/2019/how-drug-prices-are-negotiated-germany (last visited May 14, 2023).
[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] *Id.*
[91] *AMNOG Procedure Is the Name of the German HTA Procedure*, Optimizing Market Access, https://www.healthecon.com/amnog/index_eng.html#:~:text=This%20system%20divides%20drugs%20into,for%20these%20reference%20price%20groups. (last visited May 14, 2023).

drug."[92] This is based on the results of clinical trials and studies.[93] After three months, the G-BA releases its decision regarding its assessment of the therapeutic value of medication.[94] If it is found to provide an addition benefit, "the GKV-Spitzenverband (GKV-SV, the umbrella organization of the German statutory health insurance sickness funds) and the manufacturer negotiate the price at which the drug will be reimbursed by the statutory health insurance funds" within six months, with room for arbitration and adjustment.[95] If no value is found, the medication will be included in the "reference group price system," which includes maximum set amounts for reimbursements of similar pharmaceuticals.[96] The pharmaceutical manufacturer can then choose to withdraw the medication from the market, as it will not be able to raise its price after the initial negotiations.[97]

The G-BA is presumed to be fair because it consists of representatives from various stakeholder groups, including physicians, hospitals, health insurers, and patient organizations. This composition ensures that multiple perspectives and interests are considered in the decision-making process, promoting a balanced and inclusive approach. The panel also bases its assessments and decisions on scientific evidence and health technology assessments (HTAs) that help ensure that decisions are grounded in rigorous evaluation and analysis, reducing the potential for bias and arbitrary judgments. The G-BA operates with a high level of transparency, making its processes and decisions publicly available. It allows for public consultations, enabling input from patients, healthcare professionals, industry stakeholders, and the general public. The G-BA includes independent experts in its decision-making bodies, such as the Medical Methods

[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*

Committee and the Drug Committee. These experts bring specialized knowledge and experience to the assessments and contribute to the credibility and objectivity of the G-BA's reviews.

The GKV-SV is responsible for drug price negotiations, not each insurer. [98] Negotiations are intended to keep prices as low as possible. Because the negotiated price covers all sickness funds and insurers, regardless of the volume that may be used by each, a large discount can be reached. [99] This discounted price applies to all payers, and is "not a rebate that varies across insurers based on their scale and volume of drug purchases." [100] The new price is transparent to any entity willing to subscribe to the publicly maintained Lauer- Taxe database (originally developed so that pharmacies know which price to pay to drug distributors). [101] "Germany is the only nation for which negotiated net prices, and not merely manufacturer-established list prices, are transparent."[102] As in the UK, manufacturers are prohibited from raising prices after initial negotiations have been reached, unless new evidence of safety or efficacy is presented.[103]

B. Critique of Germany's Pharmaceutical Approach

Germany's major issue in its approach involves its reference pricing. Germany bases its pricing limits, in part, on the values set by other countries, which on its face seems reasonable. However, the problem resides in that reliance. By relying on other countries, what is determined to be reasonable for pricing is a groupthink-like composite with potentially skewed bases.

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[98] *Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts*, Commonwealth Fund, https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/drug-price-moderation-germany-lessons-us-reform-efforts (last visited May 14, 2023).
[99] *Id.*
[100] *Id.*
[101] *Id.*
[102] *Id.*
[103] *Id.*

Unfortunately, even though it may not apply a QALY-like standard itself, some of the countries that it relies on in its referencing do apply such a standard. This results in an indirect application and reinforcement of a QALY evaluation. This is tricky because although it seems fair to keep one's prices in line with those of similar countries, if the basis for pricing could be improved, then the approach to the whole reference pricing system is flawed. However, the transparency in pricing is commendable and should be implemented in the US as well.

What would be needed is an independent and new way of evaluating a fair market price for medications. Until a reference pricing evaluation is developed that removes reliance on other QALY-like standards, the same above issue in the UK critique would continually be faced. Numeric value would be arbitrarily created in a realm that should be better guided by placing value in the individual, not on him or her. This issue would need to be resolved for a better approach to reference pricing. Germany did not use a QALY-like standard in favor of keeping an open mind towards pharmaceutical innovation and availability, if proven to be effective. The effectiveness is not on cost, but on impact to the individual.

A possible resolution would be to utilize reference pricing as only the first step of many in determining price setting. With the G-BA, and the independent practitioners, the approach can be more like that of government contracts in the US. This is referencing how the government, with its enormous buying power, essentially asks companies who are producing goods for them what their cost of manufacturing the good is.[104] The government then negotiates and agrees upon a satisfactory markup price based on that value.[105] A similar reasoning could perhaps be applied to reference pricing. Considering sufficient clinical trial costs, manufacturing costs,

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[104] *Government Contracts Cost and Pricing – A Brief Overview of the Regulatory Landscape | JD Supra*, JD Supra (Mar. 30, 2023), https://www.jdsupra.com/legalnews/government-contracts-cost-and-pricing-a-7494364/ (last visited May 14, 2023).
[105] *Id.*

administrative costs, and others, with generous room still for profit, the pricing can be established based more off of what it actually costs to produce, rather than what a company arbitrarily says it is worth.

The German approach also has many positive elements. It implements a third-party that is presumed fair in its review because of its independence and other above-mentioned elements, while still advocating for reimbursement for worthy innovations. The panel is made up of a variety of individuals with applicable backgrounds who have no personal incentive to promote a medication. It allows for flexibility in pricing if advancements have been shown to be worthy of price increases, but otherwise encourages competition among cheaper products that more or less perform similar functions. This type of healthy competition and price evaluation allows independent researchers to evaluate the actual benefit society is receiving from having another pharmaceutical available.

Germany's approach to “benefit” is better than that of the UK for a few different reasons. Germany's benefit assessment takes into account a wide range of clinical and patient-centered outcomes, allowing for a comprehensive evaluation of a treatment's overall value, but is not reduced down to a QALY value. This approach considers not only clinical effectiveness but also patient-relevant factors, potentially capturing a broader perspective of the benefits of a treatment. Germany's G-BA includes representatives from various stakeholder groups, including physicians, hospitals, health insurers, and patient organizations. This multi-stakeholder approach ensures that different perspectives are considered during benefit assessments, potentially leading to a more inclusive decision-making process.

The German process encourages more purposeful innovation and research and development because there is greater financial incentive to bring a product to market that has a

greater impact on the residents of the country. While the UK's National Institute for Health and Care Excellence (NICE) also considers cost-effectiveness, Germany's G-BA places a significant emphasis on the cost-effectiveness of treatments. The G-BA evaluates the cost-effectiveness of a treatment based on its added benefit compared to existing therapies, which can help ensure that healthcare resources are used efficiently. There is still room for increased innovation and the increased likelihood of being fairly reimbursed for one's research as well.

Part III. The United States Healthcare System and its Relationship to Pharmaceuticals

A. The United States' Current Approach to Pharmaceutical Pricing

The United States currently utilizes an open market approach to healthcare. [106] Most services provided are fee-for-service, meaning that the costs of services are reimbursed based on the services actually performed, as opposed to a bundled upfront cost reimbursement (although plans like this do exist, like Medicare's use of DRGs for hospital care).[107] Managed Care Organizations (MCOs), a type of health insurance company, can set maximum rates for reimbursement, but these vary significantly between plans and MCOs.[108] Government programs exist in the forms of Medicare and Medicaid to supply healthcare to those who qualify either for age, physical status, or financial status.[109] Rate setting does exist in some circumstances for Medicare and Medicaid as well.

The government programs of Medicare and Medicaid have been the only entities that have been required to engage in discussions of pharmaceutical pricing. Otherwise, the free

[106] Clark, Brown,Gatter, et al., Health Law Cases, Materials and Problems, 9th ed. (2022).
[107] *Id.*
[108] *Id.*
[109] *Id.*

market pricing approach has discouraged regulating pricing.[110] The total cost of prescription drugs is increasing, with expected growth from 2017 to 2027 of sixty percent.[111] This includes public spending on programs like Medicare and private spending on out-of-pocket costs and payments made by private insurance companies.[112] The rising cost can be attributed to the price of pharmaceuticals, increasing at a rate of approximately six percent, which is higher than that of inflation.[113] Prescription drugs account for ten percent of total health expenditures.[114] Government programs like Medicare and Medicaid paid for forty-three percent of pharmaceutical expenses and is expected to contribute forty-nine percent by 2027.[115]

The US generally does not regulate pharmaceutical pricing. There are limited requirements in place for government programs to undergo negotiations with pharmaceutical manufacturers, and none exist for private insurance companies. The US patent system disincentivizes competition, leaving brand-name prescriptions to flourish, with only ten percent of the market equaling almost eighty percent of total prescription drug costs.[116] Additionally, many of these companies are likely to buy out smaller competing companies through mergers and acquisitions, limiting competition even more.[117] Although this is not necessarily different than the patent systems that exist in other countries, the US has strong lobbying groups that,

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[110] *How Much Does the United States Spend on Prescription Drugs Compared to Other Countries?*, Peter G. Peterson Foundation (Nov. 7, 2022), https://www.pgpf.org/blog/2022/11/how-much-does-the-united-states-spend-on-prescription-drugs-compared-to-other-countries (last visited May 14, 2023).
[111] *Why Are Prescription Drug Prices Rising and How Do They Affect the U.S. Fiscal Outlook?*, Peter G. Peterson Foundation (Nov. 14, 2019), https://www.pgpf.org/blog/2023/03/why-are-prescription-drug-prices-rising-and-how-do-they-affect-the-us-fiscal-outlook (last visited May 14, 2023).
[112] *Id.*
[113] *Id.*
[114] *Id.*
[115] *Id.*
[116] *Id.*
[117] *Id.*

without any required price regulation, enjoy the freedom to continually increase pricing at their whims.

There have been pushes for some government-based programs to encourage negotiations and keep costs more consistent with those of comparable countries. The Inflation Reduction Act of 2022 covers many areas of proposed governmental reform, including tax & climate change, but also focused on the pharmaceutical pricing within the Medicare program.[118] One of its goals is to control pricing for some of the top-selling pharmaceuticals covered under Medicare, to ultimately reduce the government's cost burden.[119] This is the first time since 2010, with the Affordable Care Act, that the government has proposed an intervention in regard to Medicare benefits.[120] Due to strong pharmaceutical lobbyists, as previously mentioned, this realm was previously untouchable.[121] In an effort to save over two hundred billion dollars, the government is finally required to negotiate prices.[122] One of the main focuses for negotiations Because would be on biologics, or large molecule drugs, which are harder to make generics of, as a patient would generally need an injection of it.[123] This is in contrast to small molecule medications which usually include oral medications that are easier to make in generic form.[124] Because of the

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[118] *Summary: The Inflation Reduction Act Of 2022*, Senate Democrats, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_one_page_summary.pdf.
[119] *HHS Releases Initial Guidance for Medicare Prescription Drug Inflation Rebate Program*, U.S. Department of Health and Human Services (Feb. 9, 2023), https://www.hhs.gov/about/news/2023/02/09/hhs-releases-initial-guidance-for-medicare-prescription-drug-inflation-rebate-program.html#:~:text=As%20part%20of%20President%20Biden's,dispensed%20to%20people%20with%20Medicare. (last visited May 14, 2023).
[120] Richard Payerchin, *Inflation Reduction Act Significant for Drug Costs, Medicare, Those With ACA Insurance*, MedicalEconomics (Aug. 11, 2022), https://www.medicaleconomics.com/view/inflation-reduction-act-significant-for-drug-costs-medicare-those-with-aca-insurance (last visited May 14, 2023).
[121] *Id.*
[122] Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/:~:text=The%20Inflation%20Reduction%20Act%20requires,inflation%20(CPI-U). (last visited May 14, 2023).
[123] *Id.*
[124] *Id*.

difficulty associated with making generics of biologics, price gauging is more likely by those who own the patents on said medications. This Act aims to tackle this problem through required negotiations.

Another important change requires companies to pay a medication rebate to Medicare if the price of its medication rises faster than the inflation rate or price on the market.[125] However, pharmaceutical companies would not be prevented from setting their original prices very high to get around this. Ultimately though, it would become a ceiling for out-of-pocket expenses.

Another proposal to help control pharmaceutical pricing is the Elijah Cummings Lower Drug Costs Now Act of 2019 ("H.R. 3").[126] This Bill requires that the HSS negotiates pricing on certain pharmaceuticals to reduce costs.[127] This would apply to 125 drugs in total over time (first to twenty-five drugs in 2023, and then to fifty more in 2024).[128] This approach would be similar to reference pricing in that it may not exceed one-hundred twenty percent of the average price for a pharmaceutical in Australia, Canada, France, Germany, Japan, and the United Kingdom or eighty-five percent if not included.[129]

There are many concerns that economists have when it comes to imposing restrictions on pharmaceutical pricing. First, as a study conducted by Vital Transformation noted, imposing pharmaceutical pricing restrictions would reduce earnings by sixty-two percent for impacted

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[125] *HHS Releases Initial Guidance for Medicare Prescription Drug Inflation Rebate Program*, U.S. Department of Health and Human Services (Feb. 9, 2023), https://www.hhs.gov/about/news/2023/02/09/hhs-releases-initial-guidance-for-medicare-prescription-drug-inflation-rebate-program.html#:~:text=As%20part%20of%20President%20Biden's,dispensed%20to%20people%20with%20Medicare. (last visited May 14, 2023).
[126] H.R.3 - Elijah E. Cummings Lower Drug Costs Now Act, 117th Congress (2021-2022).
[127] *The Elijah E. Cummings Lower Drug Costs Now Act: How It Would Work, How It Would Affect Prices, and What the Challenges Are*, Commonwealth Fund, https://www.commonwealthfund.org/publications/issue-briefs/2020/apr/lower-drug-costs-now-act-hr3-how-it-would-work (last visited May 14, 2023).
[128] *Id.*
[129] *Id.*

companies, with one-third having reductions of more than ninety-five percent of earnings. [130] Because of the earnings being reduced, it is believed that these pharmaceutical companies' investments into smaller pharmaceutical company R&D would subsequently diminish. [131] Additionally, it is believed that it would reduce the number of pharmaceuticals developed by such small companies by ninety percent. [132] Altogether, the study showed that there would be a disproportionate reduction in new treatments for rare diseases, oncology, etc. [133]

In response to these concerns, these numbers, if anything only highlight how severely inflated the pharmaceutical industry has been allowed to become. It makes it clear that certain companies hold a monopoly of sorts over future innovation. These companies believe it is their duty and their entitlement to buy out the smaller companies. Because of their exhaustive resources, they believe they should not fail to a capitalist approach, justified by indirectly producing worthwhile pharmaceutical advancements through bought-out companies. By eliminating the severe discrepancy, smaller companies may have a better chance to grow on their own accord, instead of being absorbed by the already inflated large players. The study does not indicate that new treatments altogether would be eliminated, but rather that new treatments by these key players would start to diminish.

The International Pricing Index Model, introduced by the Trump administration in 2018, is another proposal focused on stabilizing pharmaceutical pricing.[134] "The IPI Model would test whether increasing competition for private-sector vendors to negotiate drug prices, and aligning Medicare payments for drugs with prices that are paid in foreign countries, improves beneficiary

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[130] *H.R. 3 and Reference Pricing. Total Market Impact - Vital Transformation*, Vital Transformation, https://vitaltransformation.com/2021/03/5984/ (last visited May 14, 2023).
[131] *Id.*
[132] *Id.*
[133] *Id.*
[134] *International Pricing Index (IPI) Model*, CMS Innovation Center, https://innovation.cms.gov/innovation-models/ipi-model (last visited May 14, 2023).

access and quality of care while reducing expenditures." [135] Support for this was lacking because of the fear that this would negatively impact companies that fund research and development into new treatments and products.[136] It was ultimately withdrawn.[137] As articulated previously, the lobbying power of these large pharmaceutical companies is strong, but the notions encouraged are not much different than what other countries regularly follow.

B. The United States Should Adopt an Approach Similar to That of Germany

Germany's approach is the most reflective of a system that would be well-received here. The US should implement a third-party administrative agency or entity to assess the value of medications to taxpayers and negotiate pricing, like in Germany. The US has a quasi-public entity called the Patient-Centered Outcomes Research Institute (PCORI).[138] This body conducts and commissions comparative clinical assessments, but these cannot be used in setting pharmaceutical pricing or in determining insurance coverage.[139] The private, nonprofit Institute for Clinical and Economic Review (ICER) conducts clinical and cost-effectiveness studies and recommends price benchmarks, "which are currently used on a voluntary basis by payers such as the U.S. Department of Veterans Affairs, Express Scripts, and CVS Caremark."[140]

Despite PCORI's assessments and ICER's studies, they lack the authority to force agreement. What is needed is an organization that can suggest pricing, but also enforce it.

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[135] *Id.*
[136] Susan Peschin & Duana Schulthess, *International Pricing Index 'Accomplishes Nothing It Sets Out To Do'*, STAT (Oct. 21, 2019), https://www.statnews.com/2019/10/21/international-pricing-index-research-development/(last visited May 14, 2023).
[137] *International Pricing Index (IPI) Model*, CMS Innovation Center, https://innovation.cms.gov/innovation-models/ipi-model (last visited May 14, 2023).
[138] *Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts*, Commonwealth Fund, https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/drug-price-moderation-germany-lessons-us-reform-efforts (last visited May 14, 2023).
[139] *Id.*
[140] *Id.*

Administrative agencies would have the binding effect necessary for compliance, while having the deference to hold noncompliant entities accountable. Additionally, utilizing an administrative agency would create enough separation between itself and the traditional "big government" that would allow for independent reviews to be processed without doubt from the general public.

It would be helpful for the US to utilize or create its own system of reference pricing to be determined by the above administrative agency, like in Germany.[141] This would increase this agency's ability to negotiate with the pharmaceutical companies on behalf of the ultimate consumers and insurance companies. Government-run plans will be mandated to comply with pricing maximums, while all private plans will be strongly encouraged to do so. To ensure compliance, private insurance companies can publicly commit to adhering to the established maximum pricing rates, with potential tax benefits as incentives. Plans should prominently display a badge or certification indicating compliance, reassuring policyholders that pricing maximums will be respected. Moreover, employer-sponsored fully-insured plans would be obligated to participate in the commitment.

The German approach promotes more targeted innovation and research and development by offering increased financial motivation to introduce products to the market that can have a significant effect on the well-being of the country's population. The US would benefit from this greatly, especially with the clogging of extended patent families that prevent the further development and innovation on existing pharmaceuticals. By incentivizing purposeful innovation and research and development, the US could foster a more dynamic pharmaceutical landscape, leading to enhanced access to improved treatments and the potential for breakthrough advancements.

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[141] *Id*.

While not in support of the UK's system generally, the utilization of the PPRS in the UK healthcare system is a beneficial aspect. While it incorporates NICE's QALY-based recommendations, the approach taken by the DHSC and ABPI in determining pricing is valuable. Instead of relying on arbitrary or subjective assessments, pricing is evaluated and negotiated based on production costs, aiming for reasonable profit margins that are not exploitative. Additionally, the ability to adjust pricing in response to increased efficacy contributes to fairness, not unlike what should be aimed for here.

Additionally, it would be helpful to broaden the Inflation Reduction Act, so that it applies to all medications, but not just for Medicare. The other systems mentioned have allowed for and encourage negotiation in their pricing systems between the health system and the pharmaceutical manufacturers. Traditionally, the US has approached pricing with a laissez-faire attitude, but now with a rising deficit that is becoming an increasing burden, this has changed.[142] The Inflation Reduction Act of 2022 encourages the negotiations between Medicare and pharmaceutical manufacturers to keep the prices of some medications low.[143] If an administrative agency would be too difficult to create, we must go beyond Medicare, and mandate private insurance companies that offer employer fully-funded plans to negotiate as well. If the standards set for Medicare are met, while keeping increases to the inflation rate and establishing a starting price of medication at a reasonable limit, based on the reference pricing determined by a third-party entity, then perhaps offering a tax incentive for the pharmaceutical companies could be

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[142] *How Much Does the United States Spend on Prescription Drugs Compared to Other Countries?*, Peter G. Peterson Foundation (Nov. 7, 2022), https://www.pgpf.org/blog/2022/11/how-much-does-the-united-states-spend-on-prescription-drugs-compared-to-other-countries (last visited May 14, 2023).

[143] H.R.5376 - Inflation Reduction Act of 2022, 117th Congress (2021-2022); Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/:~:text=The%20Inflation%20Reduction%20Act%20requires,inflation%20(CPI-U) (last visited May 14, 2023).

provided. If an agency that can legally bind pharmaceutical companies to pricing schedules is too difficult to achieve politically, then in the alternative, these companies must be incentivized to keep their prices more affordable. This can be done through tax credits.

Reproposing the Elijah Cummings Lower Drug Costs Now Act of 2019 ("H.R. 3")[144] or the International Pricing Index would allow for fairer pricing more in line with that of other comparable countries. Concerns regarding market health can be addressed, but only as much as encouraging innovation amongst smaller companies. If it is seen that smaller companies are having a harder time affording staying in business, due to a lack of funding from mergers with larger pharmaceutical companies, then the government may want to step in with some type of temporary financial stimulus or repayable or reimbursable grant to allow for them to stay in business. The expectation is for the company to pay the government back in time. Otherwise, keeping in line with the pricing of comparable countries seems commonsense.

Lowering pharmaceutical prices can ultimately expand healthcare access. Governments could allocate a portion of the savings generated from lower drug prices to increase funding for public healthcare programs. This could involve expanding existing programs or creating new initiatives aimed at improving access to healthcare services, such as increasing the number of healthcare facilities, hiring more healthcare professionals, or reducing wait times for certain procedures.

Governments could also use the savings to provide subsidies to individuals or families who struggle with the cost of health insurance or prescription medications. This could help make healthcare coverage more affordable and accessible, particularly for low-income individuals who might otherwise face financial barriers to accessing necessary healthcare services.

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[144] H.R.3 - Elijah E. Cummings Lower Drug Costs Now Act, 117th Congress (2021-2022).

Another approach would be to allocate savings towards investments in preventive care and public health initiatives. By focusing on preventive measures, such as health screenings, vaccinations, and education campaigns, healthcare systems can reduce the burden of preventable diseases and improve overall population health. This, in turn, can lead to cost savings and improved access to care in the long run.

Lastly, savings from lower drug prices could be used to expand healthcare infrastructure, such as building new clinics or hospitals in underserved areas. This would help ensure that individuals in remote or underserved communities have improved access to healthcare services, reducing geographic barriers to care.

Conclusion

The UK and Germany have both encouraged some type of third-party or government entity to step in and impose restrictions on the free market of pharmaceutical pricing within their countries. With a similar backing of a US government administrative agency, pharmaceutical companies in the US would be more limited in what they could realistically charge, if they would not have a chance of being fully reimbursed. Establishing both mandatory and suggested caps on reimbursement pricing would upset lobbying efforts, but would ultimately reduce the burden of pharmaceutical costs to the system. Adopting an approach most similar to Germany's non-government organization would be most helpful. To encourage compliance, an administrative agency would be most effective here. As an insurance company, participating in a compliant negotiations would be something to advertise to attract insurees, as this would allow an individual to anticipate a certain standard of medication costs.

By setting limits based on a newly organized reference pricing evaluation, the US can pave the way for a fair approach to pharmaceutical pricing. Taking a page from the UK's PPRS methodologies would help to establish fairness in reference pricing by considering profit margins as something worth capping, especially if exploitative. Challenges would still exist in determining reference pricing. Being that other countries that are being referenced rely on QALY-type models, avoiding directly using the QALY system would not eliminate its utilization. Although through implementations like the Inflation Reduction Act, there have been pushes to control the drug prices for government programs like Medicare, this is not enough. If an administrative agency cannot be implemented, then wider negotiation encouragement via tax incentives amongst insurance companies should be promoted. Having such large coverage pools, the number of individuals that are covered are high, giving a lot of weight to the negotiating power that they may possess, resulting in less financial burden on the healthcare system.