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POLICY INSIGHT

When Is The Price Of A Drug Unjust? The Average Lifetime Earnings Standard

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ABSTRACT The majority of Americans believe that lowering drug prices should be the top health care priority for the federal government. Yet drug costs as a proportion of the country's medical expenditures have increased substantially in recent years. Because drugs are basic necessities, and because how much society should contribute toward providing basic necessities is a question of justice, policies regarding drug prices must fulfill principles of justice, not just economic efficiency. In this article I define a standard for when the price of a drug is unjust, using a cross-disciplinary ethical approach. Based on four principles, I propose the average lifetime earnings standard for affordability. According to this standard, a drug price is unfair if it exceeds 11 percent of the average American's disposable income. This suggests that current prices for many drugs are excessive and unjust.

Over 60 percent of Americans believe that lowering drug prices should be the top health care priority for the federal government.[1] Recent public controversies surrounding the drug companies Turing and Valient and the pricing of sofosbuvir, EpiPens, insulin, nusinersen, and ivacaftor attest to deep public concerns over the increasingly high prices of drugs (exhibit 1). Drug costs as a proportion of US medical expenditures have increased with the growth of specialty drugs and substantial price hikes for some existing brand-name and generic drugs.[2] For instance, since 2012 the proportion of Medicare spending going to drugs (Part D) has increased from 17 percent to 23 percent.[3] Prescription drug spending is expected to increase by an average of 6.3 percent per year through 2025.[4] Recently approved drugs have gargantuan prices, some of which exceed $500,000 per treatment. As more specialty drugs are approved and drug prices continue to increase, public concern over the costs of pharmaceuticals is likely to intensify.

The inescapable question underlying the controversies over drug pricing is this: When is the price of a drug unjust?

Why Care About Unjust Drug Prices?

Why should we even debate the fairness of drug prices? No one argues about unfair prices for restaurant meals or $1,000 smartphones. Someone might object that a $1,000 restaurant meal was not "worth it," but no one would say the price was unfair or unjust. Conversely, many people believe that a $300,000 drug is unjust.

Neither restaurant meals nor $1,000 smartphones are basic necessities.[5–7] Like food and housing, many health care goods and services are basic goods necessary to live a decent human life.[8] (Some drugs, such as those for wrinkles or alopecia, are not basic necessities but luxuries.) Broadly accepted theories of justice, as well as human rights statements such as Article 25 of the UN Universal Declaration of Human Rights, classify medical care as a basic necessity.[9]

Excessively high prices for basic necessities such as drugs are unjust because they represent price gouging and therefore constitute exploita-

EXHIBIT 1

Annual retail prices for specialty drugs and treatments

Generic name	Brand name	Dosing	Disease	Annual retail price
Nusinersen[a]	Spinraza	4 loading doses of 12 mg, followed by a dose every 4 months for life	Spinal muscular atrophy	$750,000 for year 1, $375,00 for subsequent years
Eculizumab[b]	Soliris	600 mg/week for 4 weeks	Paroxysmal nocturnal hemoglobinuria	$542,640
Voretigene neparvovec[c]	Luxturna	One-time treatment	Genetic blindness (RPE65 defect)	$500,000 per eye
Chimeric antigen receptor T cell therapy	Kymriah[d]	One-time treatment	B-cell acute lymphoblastic leukemia	$475,000
Axicabtagene ciloleucel	Yescarta[d]	One-time treatment	Lymphoma	$373,000
Ivacaftor[b]	Kalydeco	300 mg/day for duration of life	Cystic fibrosis	$368,688
Bevacizumab[b]	Avastin	10 mg/kg as long as side effects are manageable	Colorectal cancer	$149,893
Imatinib[b]	Gleevec	400 mg/day until remission	Chronic myelogenous leukemia	$145,764
Ipilimumab[b]	Yervoy	10 mg/kg every 3 weeks for 4 doses, then every 3 months for 3 years	Melanoma	$143,838
Saprotein dihydrochloride[b]	Kuvan	5–20 mg/kg daily for life	Phenylkentonuria	$113,232
Ledispasvir 90/Sofosbuvir 400	Harvoni[e]	One-time treatment	Hepatitis C	$94,500
Sofosbuvir	Sovaldi[e]	One-time treatment	Hepatitis C	$84,000
Deflazacort[f]	Emflaza	22.75 mg/ml as long as side effects are manageable	Duchenne muscular dystrophy	$35,000

SOURCE Author's analysis of information from the cited sources. **NOTE** Retail prices often differ from the prices that patients and insurance companies eventually pay due to negotiations, discounts, and rebates. [a]Picchi A. The cost of Biogen's new drug: $750,000 per patient. CBS News [serial on the Internet]. 2016 Dec 29 [cited 2019 Feb 26]. Available from: https://www.cbsnews.com/news/the-cost-of-biogens-new-drug-spinraza-750000-per-patient/. [b]America's Health Insurance Plans. High-priced drugs: estimates of annual per-patient expenditures for 150 specialty medications [Internet]. Washington (DC): AHIP: 2016 Apr [cited 2019 Feb 26]. Available from: https://www.ahip.org/wp-content/uploads/2016/04/HighPriceDrugsReport.pdf. [c]CBS News. FDA approves gene therapy for rare form of blindness. CBS News [serial on the Internet]. [Updated 2017 Dec 20; cited 2019 Feb 26]. Available from: https://www.cbsnews.com/news/gene-therapy-drug-rpe65-blindness-luxturna-spark-therapeutics/. [d]Silverman E. Those high-priced CAR-T therapies are actually cost effective. STAT [serial on the Internet]. 2017 Dec 21 [cited 2019 Feb 26]. Available from: https://www.statnews.com/pharmalot/2017/12/21/novartis-gilead-car-t-cost-effective/. [e]Toich L. Will hepatitis C virus medication costs drop in the years ahead? Pharmacy Times [serial on the Internet]. 2017 Feb 8 [cited 2019 Feb 26]. Available from: https://www.pharmacytimes.com/resource-centers/hepatitisc/will-hepatitis-c-virus-medicaton-costs-drop-in-the-years-ahead. [f]Court E. PTC Therapeutics' DMD drug Emflaza to cost $35,000 a year and launch within the coming weeks. MarketWatch [serial on the Internet]. [corrected 2017 May 8; cited 2019 Feb 26]. Available from: https://www.marketwatch.com/story/ptc-therapeutics-dmd-drug-emflaza-to-cost-35000-a-year-and-launch-within-the-coming-week-2017-05-08.

tion.[10–14] They take advantage of a person's compromised circumstances and deliver a valuable good, but at an excessively high price. When a rescuer demands that a drowning person sign over their house to be rescued, we condemn such an act as exploitative and unjust.[11–14] Excessive drug prices are analogous. A particularly high-price drug, especially one that offers to save a life or substantially improve the quality of life, exploits a person's ill health for a company's profit.

The unfairness is magnified by the fact that society, rather than individuals, largely pays for drugs. Few people can afford to pay $300,000 annually for drugs. Through health insurance or direct government funding, we collectively pay for each person's drugs. The US has laws such as the Emergency Medical Treatment and Labor Act of 1986 that require hospitals to examine, treat, and stabilize a patient regardless of insurance or income when that patient presents with an emergency condition. Similarly, it was widely deemed unjust—not unfortunate—when Arizona refused to pay for lifesaving transplants for Medicaid patients. These cases, as well as the Affordable Care Act, embody—albeit imperfectly—the view that health care services are basic goods that society should pay for with collective resources.[9]

Because society ultimately pays, excessive drug prices are exploitative in an additional sense. High prices exploit citizens' sense of obligation for one another—our unwillingness to let someone suffer or die from the lack of a high-price drug. The fairness of drug prices is something that we all have to care about, because we all foot the bill.

To resolve the controversy over excessive drug prices, we must develop a standard to determine when a drug is excessively priced. Normally, determining a fair price would be done by the market. However, because of patents, Food and Drug Administration (FDA) marketing exclusivity, and third-party payment, the market does not work for drug prices.

There has been extensive economic analysis of

drug prices, which often focuses on whether the market is efficient. But efficiency does not capture normative considerations in drug pricing. Some of the economic analysis of drug prices relies on cost-effectiveness analysis, which relates fair prices to the relative costs and outcomes of the specific drugs. Without extensive argument, discussions of value-based pricing and cost-effectiveness of drugs assume ethical principles, such as maximizing outcomes. Nevertheless, they disregard other principles such as distributional impacts and benefiting the worst off. While cost-effectiveness analysis is necessary for determining an excessive drug price, it is not sufficient.

To ask when the price of a drug is unjust is to ask a cross-disciplinary question, one that is fundamentally ethical but must be informed by economics. Recently, researchers have begun attempting to integrate economics and ethics when considering drug prices.[15] This article moves beyond economic analysis of efficiency and cost-effectiveness analysis and attempts to advance the integration of economics and ethics to determine when a drug price is excessive.

Four Principles To Establish A Fair Price

Because most drugs are basic necessities, and because the amount society should contribute toward providing basic necessities is a question of justice, drug pricing policy must fulfill principles of justice. Every determination of an unjust price will be controversial, because *justice* and *fairness* are normative concepts, derived from disputed underlying ethical theories.[6,9,11] Nevertheless, four principles that elicit widespread support can establish bounds on fair drug prices (exhibit 2).

First, the complete life principle specifies that benefits and costs should be considered over a whole life, not just a narrow time frame. The unit of analysis in justice is the course of a whole life. As Thomas Nagel wrote, "Individual human lives, rather than individual experiences, [are] the units over which any distributive [justice] principle should operate."[16] Thus, we need to consider the cumulative, lifetime costs of a drug, not the per dose or annual costs.

Second is the limited resources principle. As economists and ethicists emphasize, resources are inherently scarce. Without scarcity there would be no need for principles of justice to allocate resources.[6,7] We value many things in life and want to ensure that we can live complete lives, to pursue whatever our interests and ends might be; thus, we must allocate resources to diverse interests and ends.[6,7,9] Fair drug prices must ensure that there are sufficient resources for people to pursue other valuable activities and life goals.

Third, the value principle suggests that there should be a relationship between price and benefits: Greater benefits should be proportional to higher prices.[17] A drug of high value—one that generates a reasonable improvement in longevity or quality of life—is a basic necessity and should command a higher price.

Fourth is the comprehensiveness principle. When determining whether a drug has an unfair price, we should consider the positive and negative impacts of the treatment on the average person's education, employment, social interactions, and other valuable life activities. A drug that allows the average person to obtain a normal education or continue to work should be priced higher than one that merely keeps someone alive but not well enough to be employed, or one that extends life but produces debilitating side effects. The former drug is also more desirable and can afford to be priced higher, because it saves costs in other nonmedical domains.

These principles motivate two standards for determining unfair drug prices.

The Value-Based Price Standard

The familiar value-based price standard holds that higher clinical and social benefits should

EXHIBIT 2

Four principles informing the standard of whether a drug price is unjust

Principle	Explanation
Complete life	The unit of analysis should not be a year or other limited time frame, but rather the impact over a whole lifetime
Limited resources	The just price of a drug should reserve enough resources for people to pursue valuable life activities
Value	There should exist a close relationship between the actual benefits of an intervention and its price
Comprehensiveness	Life activities other than health matter; in considering the benefits of a treatment, we should also consider how it affects education, employment, and other valuable life activities

SOURCE Author's analysis.

The ALE standard does not overly restrict drug company profits, and lifesaving innovation will still occur.

translate into higher drug prices.[18] Typically, cost-effectiveness analysis is used to determine a value-based price, using quality-adjusted life-years (QALYs) gained or disability-adjusted life-years (DALYs) reduced as the measure of clinical benefits.[19,20] The value-based price standard has been adopted by the National Institute for Health and Care Excellence (NICE) in Britain, by Australia, and in the Global Burden of Disease assessment.[21,22]

The value-based price standard engenders some controversies, such as whether the various methods for determining value accurately capture both clinical and nonmedical benefits[23,24] and whether it discriminates against the old, the disabled, and people with rare conditions by discounting the value of life-years for these groups.[25]

Another controversy centers on the threshold value used in economic analysis to determine when a drug price is excessive and unjust. NICE uses a sliding cost-effectiveness analysis threshold of £20,000–£30,000 (or $25,000–$38,000) per QALY—roughly, the per capita gross domestic product (GDP) in Britain.[20,26,27] Norway uses a similar threshold, albeit informally, of $31,500 (or 275,000 kroner) per QALY for its technology assessments of drugs.[28,29] Without any principled justification, the World Health Organization recommended a threshold of three times a nation's per capita GDP, or approximately $170,000 per QALY for the United States in 2016.[30] Empirical assessments of actual health service trade-offs—that is, what a society's spending indicates it is willing to pay per QALY in practice—suggest a threshold of about half the per capita GDP, or $29,000 per QALY for the US.[27] In the US, the generally accepted threshold ranges from $50,000 to $150,000 per QALY, amounts used by the Institute for Clinical and Economic Review and endorsed by professional organizations such as the American College of Cardiology and by many academics doing cost-effectiveness analysis.[26,31–33]

Moreover, thresholds over $50,000 assume that few people will need high-price drugs. As we saw with Sovaldi, a few hundred thousand people taking treatments that are deemed cost-effective at $50,000 per QALY can raise the total cost of health care substantially. If two or three million people take a drug deemed cost-effective, that could raise costs by hundreds of billions of dollars. Ironically, as high-price drugs are more widely used, the lower the threshold must be.

The value-based price standard is relative, capturing only part of the concern about unfair drug prices: the cost of a drug compared to its effectiveness, and the relative prices of different drugs. There is a further concern about the total amount that society spends on drugs. The difference between these two concerns is illustrated by the price of sofosbuvir, used to treat hepatitis C. It is cost-effective using a threshold of $50,000 per QALY. Yet politicians, journalists, and the public deemed its price excessive.[34] Indeed, treating the estimated 3.5 million Americans with hepatitis C at a price of $50,000 would have cost over $170 billion—one-third of annual US drug spending in 2018.[35] Similarly, the FDA is likely to approve gene therapies for hemophilia.[36] Proposed prices for the treatment range from $1.5 million to $2 million per patient. This price might be cost-effective, but with 20,000 hemophilia patients it could cost $40 billion. Very high drug prices might satisfy the value-based price standard and still be unfair because they violate the complete life and limited resources principles—that is, they consume an excessive amount of resources, preventing people from pursuing other worthy life activities.[9]

The Average Lifetime Earnings Standard For Affordability

A second standard is necessary, one focused on total social cost or affordability. Australia has an affordability standard: When the cumulative cost of a drug—its price times its estimated utilization—exceeds $20 million, the drug and its price require cabinet approval. Similarly, the Institute for Clinical and Economic Review has an affordability standard set at a point when the overall health care cost from a drug would exceed growth in GDP plus 1 percent.[31]

I propose a novel approach for setting drug price affordability based on average lifetime earnings (ALE). Drugs cannot consume all—or even the majority—of a person's lifetime resources. How much of available resources should drugs consume?

One version of the ALE standard might be that cumulative lifetime drug costs cannot exceed

lifetime disposable income—that is, lifetime income minus the costs of basic necessities (food, housing, and transportation) raising children to age seventeen, and paying for a college education.

Exhibit 3 shows how the ALE can be calculated. Average lifetime earnings for a male with a bachelor of arts degree born in 1966 are estimated at $2.27 million (2009 dollars).[37] Data from the Department of Agriculture show that the cost of raising one child through age seventeen is $233,610 (2015 dollars).[38,39] Subtract from the average lifetime earnings an estimated cost of $1,631,203 for raising one child, basic necessities, and paying for college, and what remains is the maximum of an average person's lifetime disposable income of approximately $638,797. (The online appendix contains more details on the methods used to estimate the costs of basic necessities—food, housing, and transportation—as well as health care and other expenditures.)[40]

All disposable income cannot be spent only on medical care. Disposable income must also be available for other goods that contribute to a complete life. In the twenty-first century there are other necessities, such as cell phones, internet access, and retirement savings. In addition, a reasonable life incorporates activities beyond necessities, such as entertainment, books, vacations, and avocational interests. The cost of medical services other than drugs, such as hospitalizations and diagnostic tests, also has to be considered. Thus, drugs cannot be priced to consume all of a person's disposable income. How much of disposable income should go toward health care and, in particular, drugs?

Any precise number will seem arbitrary and contestable. It will be influenced by life goals, preferences, and location. Reliance on current spending is also arbitrary—an empirical fact, not a justified ethical standard. To secure agreement, I set the threshold for excessive drug price at a generous level that no reasonable person would deem too low, though many might deem it excessively high. Using this approach, an excessive drug price should be widely perceived as excessive.

Currently, average lifetime costs for health care are estimated at 31 percent of disposable income.[41] Drugs account for 17 percent of health care expenses. A threshold for medical care as a share of disposable income that is set 10 percentage points higher than the current average amount spent on medical care (at 41 percent, or $261,907) is generous, as is a threshold for drug costs as a share of medical costs set 10 percentage points higher (at 27 percent, or $70,715) than the current share (exhibit 3).

EXHIBIT 3

Quantifying the average lifetime earnings (ALE) standard

Cost category	Dollar amount for average male with bachelor of arts degree born in 1966, life expectancy of 79 years
Lifetime earnings[a,b]	$2.27 million
Average cost of raising one child[c]	$233,610
Average lifetime cost of basic necessities[b]	
Food	$243,430
Housing	$769,718
Transportation	$304,085
Average lifetime cost of nonmedical discretionary expenditures[d]	
Public college	$80,360
Private college	$181,480
Maximal lifetime disposable income (lifetime earnings minus costs of raising one child, basic necessities, and public college)	$638,797
Maximal lifetime resources for medical expenses (41% of disposable income)	$261,907
Maximal lifetime resources for drugs (27% of all medical expenses, or 11% of disposable income)	$70,715

SOURCE Author's analysis of information from the cited sources. **NOTE** Details on calculations and sources are in the appendix (see note 40 in text). [a]Carnevale AP, et al. The college payoff (see note 37 in text); Julian T, Kominski R. Education and synthetic work-life earnings estimates [Internet]. Washington (DC): Census Bureau; 2011 Sep [cited 2019 Feb 26]. (American Community Survey Reports). Available from: https://www.census.gov/prod/2011pubs/acs-14.pdf. [b]Bureau of Labor Statistics. Consumer Expenditure Survey (see note 41 in text). [c]Lino M. The cost of raising a child (see note 39 in text). [d]College Board. Trends in higher education: average published undergraduate charges by sector and by Carnegie classification, 2018–19 [Internet]. New York (NY): College Board; c 2019 [cited 2019 Feb 26]. Available from: https://trends.collegeboard.org/college-pricing/figures-tables/average-published-undergraduate-charges-sector-2016-17.

Using these standards, the costs for all of the drugs a person takes in a lifetime should not consume more than 27 percent of medical costs, or $70,715. This constitutes 11 percent of lifetime disposable income.

If the price of a drug over a lifetime exceeds this ALE standard, then the price would consume an excessively high level of resources and be unjust. This would either force people to live impoverished lives (because there would be insufficient resources to pursue other valuable activities) or require other people to contribute the resources to pay for the drugs (which would limit their life activities). We should not make Paul live an impoverished life to pay high drug prices for Peter's illness, nor should Peter live an impoverished life because he happened to fall ill.

Quantifying When A Drug Price Is Unjust

Just as there are persistent disagreements about how precisely to calculate the poverty level, there will be disagreement about how to calculate the ALE standard. Regardless, $70,715 is a generously high threshold for drug companies. At this level, medical costs exceed lifetime spending on food and on raising a child through age seventeen, and drug costs would greatly exceed all spending on physician services.

In the methods adopted, each determination was biased to produce a high threshold for drug prices. Median income was based on that of American males with a bachelor of arts degree. Yet just 33 percent of American adults have this or a higher degree, and women earn 80 percent of what men do.[42] The methods assume full-time, year-round work, yet fewer than 40 percent of American workers are employed in such positions.[43]

The allocation for basic necessities excludes many basic items such as clothing and internet access. The methodology excludes large families, assuming that each person supports only one child. The standard assumes a future inflation rate of 2 percent for basic necessities, which is a historically low rate[37] (see the appendix for more details on the methods).[40] Finally, the ALE standard assumes that medical costs account for 41 percent of disposable income—10 percentage points higher than the current 31 percent ($198,433). Similarly, drugs account for 27 percent of medical spending—significantly higher than the 17 percent currently spent.[44,45]

Disagreements about calculations—for example, why use the income of Americans with a bachelor of arts degree, or why should 27 percent of medical expenditures go toward drugs—will only lower the threshold for excessive drug prices. Indeed, if we used the current spending on health care as the threshold for excessive drug prices, then cumulative lifetime spending on drugs should not exceed $33,665.

The ALE standard provides a maximum fair price for all drugs over a lifetime. If one drug's price exceeds the lifetime amount allotted for all drugs, then the price is unfair. Thus, $70,715 defines the absolute upper limit to any single drug's price.

Implications And Advantages Of The Two Standards

There are many implications and advantages of the value-based price and average lifetime earnings standards. First, the two standards work together. The ALE standard sets a maximal threshold for excessive drug prices, while the value-based price establishes a mechanism to determine an appropriate relative price below the ALE limit. If either standard is not met, the price of a drug is unfair.

Second, the two standards consider the affordability of drugs from the average person's perspective, not from that of drug companies, insurers, or physicians.

Third, the ALE standard implies that the prices for many drugs today are unjust, as shown in exhibit 1. These prices greatly exceed the ALE threshold for lifetime drug costs.

Fourth, stretching drug payments out over time, as advocated by some policy makers for one-time curative drugs, is consistent with the complete life principle. But it does not make prices that exceed the ALE standard fair.[46]

Fifth, the ALE standard implies that the threshold for unfair drug prices is socially relative—relative to the average person's lifetime earnings in a particular society. Justice suggests that drug prices should be globally tiered, higher in developed countries whose citizens have higher average lifetime earnings.

Sixth, there is no reason to limit the application of these four principles and the ALE standard to drugs. They could help define excessive prices for medical interventions more generally. However, that task is beyond the scope of this article.

Seventh, using the average person's earnings calibrates the price of drugs to what society can pay for all of its members, regardless of their actual earning potential or disabilities. People who unfortunately suffer from disabilities or live in poverty are still entitled to the same medical benefits at the same value as every other citizen.

Eighth, the traditional economic recommendation for monopolies is to regulate the prices they can charge. The ALE standard provides

a mechanism to determine a fair regulated price for drugs consistent with widely shared principles.

Finally, the ALE standard does not overly restrict drug company profits, and lifesaving innovation will still occur. The standard may reduce revenue, but that does not require reduction in research and development. Instead, the reduction could be taken from marketing or administration costs or profits—or, more likely, from some combination of them—which would still ensure sufficient resources for research and development.[32] As the automobile and petroleum industries show, companies with profit margins significantly lower than those in the pharmaceutical industry still invest substantially in innovative products.[47,48] Moreover, the value-based price and ALE standards might better direct pharmaceutical innovation. Companies are unable to pursue every possible innovative path. Today, choices about what potential drugs to pursue are based on distorted drug prices. Consequently, research and development is tilted toward high-price cancer drugs rather than valuable antibiotics.[49] Pricing drugs using the value-based price and ALE standards would incentivize the development of higher-value drugs such as antibiotics.

Implementation

There are a number of ways to implement a drug pricing scheme informed by value-based price and average lifetime earnings standards. The approach described here requires the establishment of a national commission with the authority to negotiate drug prices with pharmaceutical manufacturers. The process might proceed as follows. When a pharmaceutical manufacturer submitted its application to the Food and Drug Administration for a new drug approval, it would simultaneously submit a dossier to the national drug pricing commission providing information on the drug's risks, clinical benefits, proposed price, and cost-effectiveness. The commission would then contract for its own cost-effectiveness analysis to inform value-based price principles, using widely accepted thresholds of $50,000–$150,000 per QALY.[26,31–33] Simultaneously, the commission would authorize projections of cumulative lifetime costs of the drug based on estimates of its use and price and accounting for any savings from forgoing medical services. These projections would inform adherence with the ALE standard. The commission would be empowered to negotiate maximal drug prices with pharmaceutical manufacturers, informed by both the value-based price and ALE standards.

The model would produce results based on the pharmaceutical manufacturer's proposal and value-based price thresholds of $50,000–$150,000 per QALY. These cumulative drug prices would be compared to standard economic projections of lifetime earnings; costs of housing, transportation, and other basic necessities; disposable income; and any other considerations deemed necessary for applying the ALE standard.

Using the model results, the commission could determine in any given year whether the cumulative costs of new drugs exceeded the ALE standard. If so, in its negotiations the commission could propose lower maximal prices. A drug's prices would be lowered to reflect its relative value so that all drugs collectively stayed within the ALE standard of affordability. There would be penalties for pharmaceutical manufacturers that failed to negotiate and adhere to the value-based price and ALE standards—such as the loss of patent exclusivity, as proposed in the recently introduced Medicare Negotiation and Competitive Licensing Act of 2018.

This commission need not be a governmental body. As in Germany, a nongovernmental body could be empowered to negotiate with drug companies and enforce the results of its negotiations.

As noted, the idea of using value-based price and affordability thresholds is not original. The novel proposal here is that the affordability threshold be linked to the lifetime earnings of an average citizen rather than an arbitrary dollar threshold, as in Australia, or a percentage of GDP.

Conclusion

The public believes that drug prices are excessive and unjust. A novel method for determining a fair price for a drug is the combination of the value-based price and average lifetime earnings standards. According to the latter, a drug price is unfair if it exceeds 11 percent of the average American's lifetime disposable income—defined as the average person's lifetime earnings minus the average costs of basic necessities and of raising a child and sending that child to college. Underlying the ALE standard is the belief that after paying for a lifetime's use of a drug, there must be enough resources left over from an average person's lifetime earnings for other medical services and to permit the pursuit of meaningful life activities. This ALE standard suggests that current prices for many drugs are excessive and unjust. ■

In addition to his University of Pennsylvania affiliations, Ezekiel Emanuel is employed by CNN and Oak HC/FT, a venture capital firm. He also is a speaker for the Leigh Bureau. He sits on the advisory board of the Peterson Healthcare Foundation in New York, for which he receives a stipend. He holds stock in Allergan, Amgen, Baxter, Gilead, Medtronics, and UnitedHealth Group. Within the past two years he gave a paid speech at Genentech.

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Appendix: Sources and Calculations for Exhibit 3

1) Table of Different Approaches to the Average Lifetime Earnings Standard

There are different ways to determine average lifetime earnings for average Americans and then for high income Americans in the top 1-2% as represented by physicians.

Average Lifetime Cost of Non-Medical Discretionary Expenditures

Category	B.A. (Male American Median)	Average American (Average Post-Tax)	High Income American—Physician
Lifetime Earnings	$2.27 million	$2.18 million	$6.17 million
Average Cost of Raising One Child*	$233,610	$233,610	$372,210
Average Lifetime Cost of Basic Necessities[$]	$243,430	$243,430	$448,518
Food	$769,718	$769,718	$1,506,486
Housing	$304,085	$304,085	$648,025
Transportation			
Average Lifetime Cost of Non-Medical Discretionary Expenditures			
Public College[+]	$80,360	$80,360	$80,360
Private College	$181,480	$181,480	$181,480
Harvard College	$274,484	$274,484	$274,484
Lifetime Disposable Income—"Everything Else"	$638,797	$552,512	$2,920,277
Lifetime Maximum for Medical Expenses (41% of "everything else")	$261,907	$226,530	$1,197,314
Lifetime Maximum for Drugs (27% of all medical expenses or one quarter of "everything else")	$70,715	$61,163	$323,275

*The cost of raising a child born in 2015 until age 17 without costs for private primary or secondary school or for college are derived from the US Department of Agriculture.[1] The $233,610 represents a middle class family and the $372,210 represents a higher income family.[2]

[$]The average lifetime costs for basic necessities is derived from the expenditures for food, housing, and transportation in the Average annual expenditures and characteristics,

Consumer Expenditure Survey, 2015-2016.[3] The highest category of income is used for physician expenditures on basic necessities.

[+]For college education, public school is used for average[4] while Harvard costs are for higher income Americans and represent full tuition, room, board, and fees for 2017-18 multiplied by 4 years and inflated at 3% per year (lower than the 4.1% increase between 2016-17 and 2017-18) available at: https://www.harvard.edu/about-harvard/harvard-glance.

2) Average Lifetime Earnings

We use two ways of calculating lifetime earnings. The first approach for the average earnings of American males with B.A.s and physicians we adopt the methods and numbers used by the Georgetown University Center on Education and the Workforce.[5] They use methods pioneered by the Census Bureau relying on data from the American Community Survey.[6] Their approach is to use:

> "Synthetic estimates of work-life earnings are created by using the working population's 1-year annual earnings and summing their age-specific average earnings for people ages 25 to 64 years. The resulting totals represent what individuals with the same educational level could expect to earn, on average, in today's dollars, during a hypothetical 40-year working life. Specifically, the Census approach looks at 5-year age groups — 25-29, 30-34, etc. — to get an average for each age group and then sums each of these 5-year averages of a particular demographic and/or educational group to estimate the average 40-year degree for that group."

Basically they take average earnings for men in 5 year age cohorts and sum them up over 40 years of a working life. Georgetown researchers do this for different occupations based on educational attainment and occupation. Which is what we report.

This approach produces a high estimate of median lifetime earnings because it is based on full time work for a full year, and less than 70% of Americans work full time each year. They also use earnings for males and for B.A.s in which most Americans do not have B.A.s.

The second approach uses the Consumer Expenditure Survey of the Bureau of Labor Statistics.[3] The CEX provides actual average earnings by age cohort from 1986 to 2016. In what we call the average American approach to determine the lifetime earnings of a representative individual born in 1966 who turns 21 in 1986, and then begins earning. We then sum actual average earnings using the income before taxes data from one-person consumer households in the appropriate age cohort. Actual earnings are summed from 1986 to 2016. In 2017 the average annual earnings are calculated based on average annual earnings from the previous year for the representative individual's appropriate age cohort and increased each year by 3%. Thus when the representative individual would be 60, we calculate the earnings in 2016 for a 60 year old, inflate by 3% annually, to determine the

average earnings. The earnings after 65 presumably are based on what earnings individuals in that age cohort have and this will include social security payments, pensions and other retirement earnings. This calculation includes earnings until age 79, the average life expectancy of Americans. This calculation produces an average lifetime earnings for an average American.

Each approach has advantages and disadvantages. Importantly, they rely on different data sources, use actual earnings, and inflate earnings a generous amount. The Georgetown results for male B.A.s using the Census Bureau's method and ACS data and the average American method using the CEX data differ by 7.7%.

3) Average Basic Necessities

The three highest cost basic necessities are food, horsing, and transportation. The lifetime costs for these basic necessities are determined from the Consumer Expenditure Survey of the Bureau of Labor Statistics. The CEX provides data on average expenditures by a single person household for food, housing, and transportation by income cohort.[3] Actual expenditures were summed from 1986 to 2016 and then subsequent expenditures until 79 years of age—2044—were made inflating the expenditure by 2% per year. In addition CEX provides data on the average expenditure for these basic necessities based on income. The amounts spent by high-income earners were determined by the same methods but based on CEX expenditure data for the highest income category.

4) Discretionary Spending

These determinations of lifetime earnings bias the results toward more earnings available for discretionary spending. Actual earnings and expenditure data are used for 30 years where available. Earnings estimates after 2016 are increased at 3% per year while expenditures on basic necessities of food, housing, and transportation are increased at 2% per year.

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