Ensuring Equitable Access to Affordable Prescription Medications

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Abstract

Prescription drug prices in the United States are higher than in any other industrialized nation in the world, mainly owing to the increased use of new, more expensive drugs and the steady price rise of brand-name prescription drugs. High prices and inadequate insurance make medicines unattainable for many patients in this country. Patents and market exclusivities and collusion agreements with the pharmaceutical industry remain the main barriers to competition in the generic and biosimilar market. Universal access to effective, safe, and affordable medications requires a comprehensive national drug formulary system along with drug pricing and reimbursement systems. Evidence-based national drug formularies provide an opportunity to address inconsistent and inequitable decision making with regard to prescription drug coverage, prescribing practices, and reimbursement for cost-effective drugs of therapeutic value. In addition, formularies have the potential to reduce medication errors and are an effective tool to foster rational use of drugs. However, current prescription drug coverage in formularies is driven by undisclosed rebates and discounts. The U.S. reimbursement system often reimburses the use of expensive new pharmaceutical products regardless of their comparative safety and effectiveness. Access to prescription drugs should be driven by patients' health care needs, not their financial capabilities. To ensure equal access to affordable prescription medicines, this policy statement takes a public health perspective addressing four key dimensions of the pharmaceutical sector: increasing drug market competition, enhancing clinical research and drug development centered on patients and population health outcome improvements, streamlining public and private drug pricing and reimbursement systems, and expanding affordable drug insurance to all Americans.

Relationship to Existing APHA Policy Statements

- APHA Statement 20006: Making Medicines Affordable: the Price Factor
- APHA Statement 20031: Supporting Legislation for Independent Post-Marketing (Phase IV) Comparative Evaluation of Pharmaceuticals
- APHA Statement 20219: Adopting a Single-Payer Health System
- APHA Statement 201512: Ensuring That Trade Agreements Promote Public Health
- APHA Statement 9615: Supporting National Standards of Accountability for Access and Quality in Managed Health Care

- APHA Statement 202112: Lessons from the COVID 19 Pandemic: The Importance of Universal Health Care in Addressing Health Care Inequities
- APHA Statement 20153: Universal Access to Contraception
- APHA Statement 200613: Regulating Drugs for Effectiveness and Safety: A Public Health Perspective

Problem Statement

Access to health care is a basic human right and a well-established public health principle.[1] Critical to the right to health care is people's timely access to safe, effective, and affordable prescription drugs reflecting high medical standards of care. In the United States, access to prescription drugs is in the context of a for-profit pharmaceutical system that often leads to enormous financial burdens for health care systems, health care providers, and, ultimately, consumers. Thus, health care is inextricably linked to access to affordable prescription drugs, and drug affordability remains a major public health challenge in this country. The combination of high prices and inadequate insurance places drugs out of reach for many patients.

In the past four decades, drug prices have increased faster than inflation and economic growth. Drug prices in the United States are higher than in any other developed nation's economy. U.S. outpatient prescription drug spending increased from $12.0 billion in 1980 to $348.4 billion in 2020. Outpatient prescription drug spending increased faster than all other health care spending, as well as the Consumer Price Index for all items excluding health care and the gross domestic product.[2,3] Prescription drug expenditures per capita increased from $140 in 1980 to $1,073 in 2018[4] and $1,631 in 2020.[5] In 2018, outpatient prescription drug spending averaged $2,700 per Medicare Part D enrollee and $530 per Medicaid enrollee. Overall, prescription drug spending has increased by 20% in the United States, both as total expenditures and as a percentage of total health care expenditures, over the past 10 years.[6] This has been driven by the increase in the use of new, costlier pharmaceuticals approved by the Food and Drug Administration (FDA) and the steady increase in prices of brand-name prescription drugs.[4]

After adjustment for differences in purchasing power, outpatient prescription drug spending among Organisation for Economic Co-operation and Development countries averaged $564 per person in 2017, with spending highest in the United States ($1,220), Switzerland ($963), and Japan ($838).[7] While high prescription drug prices are an endemic problem in health care systems across the world,[8] prices are 2.5 times higher in the United States than in any other developed economy.[9] The average price, after discounts and rebates, of brand-name prescription drugs increased steadily between 2009 and 2018, from $149 to $353 in Medicare Part D and from $147 to $218 in Medicaid.[4] Conversely, the average price for generic drugs in

Medicare Part D and Medicaid fell over that period.[4] The average price of a generic prescription drug fell from $22 to $17 in Medicare Part D and from $27 to $23 in Medicaid from 2009 to 2018. Uninsured and underinsured patients are unable to pay the high out-of-pocket costs of prescription drugs. Increasing prescription drug prices are straining insurers and public health insurance program budgets and leading to increased patient copayments and reduced drug coverage.[10]

High prescription drug prices are not a new problem. A report from the Senate Judiciary Antitrust and Monopoly Subcommittee published in 1961 showed that prescription drug prices were unreasonable in relation to industry costs and prices in other countries.[11] Equally relevant to the current situation, the subcommittee's report revealed that high prescription drug prices were related to a lack of market competition, shortcomings of the patent system, prescription drug marketing, direct-to-consumer advertising, and drug pricing mechanisms.

Despite overwhelming evidence that high prices make prescription drugs unaffordable for a growing number of Americans, in the past four decades the U.S. Congress has increased patent and exclusivity regulations for pharmaceuticals[12] while postponing legislation aimed at containing prescription drug prices.

Evidence-Based Strategies to Address the Problem

Several proposals to address increasing prescription drug prices have been put forward.[13–17] This policy statement takes a public health perspective and aims to ensure equitable access to affordable prescription drugs by addressing four key dimensions of the pharmaceutical sector: drug market competition, clinical research and drug development centered on patients and population health outcome improvements, public and private drug pricing and reimbursement systems, and affordable drug insurance for all Americans.

Call to increase drug market competition: Adequate drug safety, efficacy, and price information is a necessary condition for a competitive prescription drug market. Generic and biosimilar competition (to the extent competition exists) significantly reduce prices of prescription drugs and biologics, making pharmaceutical products more affordable. However, patents and market exclusivities and pharmaceutical industry collusive agreements remain the main barriers to generic and biosimilar market competition.

During the past 40 years, the U.S. Congress has enacted regulations that have proven to favor a profitable pharmaceutical industry, including regulations extending the patent and market exclusivities of prescription drugs. Examples of such regulations are the Orphan Drug Act of 1983 (orphan exclusivity), the Drug Price Competition and Patent Term Restoration Act (Waxman-Hatch Act) of 1984 (market exclusivity and patent

extension), the Food and Drug Administration Modernization Act of 1997 (extending the Waxman-Hatch Act provision to antibiotics), the Affordable Care Act (ACA) of 2010 (market exclusivity for biologics), and the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (adding market exclusivity for anti-infective drugs).[18] International trade agreements, particularly the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, implemented in 1995, set global minimum pharmaceutical patents and exclusivities that generated substantial gains for the pharmaceutical industry in developed economies and reduced the affordability of and accessibility to pharmaceuticals in less developed economies.[19]

In addition, despite the fact that many pharmaceutical company patent infringement claims are deemed invalid in litigation processes, ongoing appeals effectively delay market competition.[20] Between September 24, 1984, and December 31, 2001, generic companies filed 1,340 paragraph IV certifications before the FDA, claiming that patents listed by brand pharmaceutical companies were invalid or had not been infringed.[21] According to the Federal Trade Commission, pharmaceutical companies effectively blocked generic competition by offering patent settlements to pay generic companies not to market lower-cost generic drug therapeutic alternatives (pay for delay).[22,23]

Safety, efficacy, and price information remain the cornerstone of a competitive pharmaceutical market, and it is essential to maximize the benefits and minimize the harms of prescription drugs. The FDA has been the primary source of reliable knowledge on prescription drug efficacy prior to approval, labeling, and postmarketing monitoring for safety. Federal regulations enacted since the early 1990s, including the Prescription Drug User Fee Act of 1992 (PDUFA), the Biologics Price Competition and Innovation Act (part of the Patient Protection and Affordable Care Act of 2010), and FDASIA, have effectively expedited the drug development process and reduced FDA regulatory review time, leading to a significant increase in the number of prescription drugs approved and the use of expedited approval pathways to bring more prescription drugs to the U.S. market faster.[24] Whether these new drugs represent any added value for patients or address unmet medical needs (defined by the FDA as conditions whose treatment or diagnosis is not addressed adequately by available therapy) is unknown.[18]

Unmet medical need is a relatively easily met criterion for many noncurative treatments, suggesting an ever-widening window for new drugs whose potential benefits over existing products may not be robustly established. For example, FDASIA amended the accelerated approval of new drugs for serious or life-threatening diseases and removed the requirement for evidence of added therapeutic benefit. Also, the Cures Act (2016) established the limited population antimicrobial drug regulatory pathway that reduced the

requirements for approval of new antimicrobials. More recently, the Cures 2.0 Act (H.R. 6000) included several economic incentives for the development of new antibiotics such as federal reimbursement for newly developed antibiotics irrespective of demonstration of improved patient outcomes relative to already-marketed alternatives.[25]

Moreover, PDUFA (1992) authorized the FDA to collect fees from drug sponsor companies to enable the agency to hire staff to reduce the regulatory review time for drug approval. PDUFA raises conflict of interest and other ethical concerns about the FDA receiving financial support from the companies it regulates.[26]

While the U.S. regulation requires pharmaceutical companies to provide evidence of new drug benefits outweighing risks at the time of approval, it does not require proof of comparative safety and efficacy. As a result, patients, clinicians, and health care payers lack the information on long-term effectiveness and safety of medicines necessary for comprehensive, evidence-based clinical and population-based decision making.

Call to enhance drug development by featuring patient-centered and population-based health outcomes: Clinical drug trials are seldom designed to assess added benefits for patients with unmet medical needs.[27] Therefore, clinical evidence of improved outcomes in patient populations lacking therapeutic alternatives is often not available during the FDA regulatory review for determination of approval. Postmarketing studies required by the FDA at approval are often delayed and provide limited evidence of added value. Clinical trials frequently evaluate surrogate outcomes rather than direct measures of patient quality of life, functioning, or survival,[28] increasing the uncertainty about whether new drugs address health outcomes. Pharmaceutical companies are not required to disclose proprietary data derived from clinical trials and postmarketing studies, further reducing the information available for clinical and population-based decision making. The unknown clinical value of new drugs is often accompanied by expensive drug promotion and advertising campaigns. Until 1985, the pharmaceutical industry abided by a voluntary agreement to restrict prescription drug promotion to medical professionals. Rescinding this agreement, a blitz of multimedia marketing activities followed and began to target clinicians and patients through direct-to-consumer advertising strategies.[29]

In a drug development world with public benefit at its core, research and development (R&D) would be geared toward maximizing population health. While many new drugs are approved by the FDA each year, only a minority represent advances in patient and population health outcomes.[30] By contrast, pharmaceutical R&D often focuses on marginal changes to differentiate similar drugs (“me too” products or formulation changes), anticipating higher potential return on investment rather than focusing on new

scientific paradigms aimed at reducing morbidity and mortality. Furthermore, R&D has limited public sector oversight and input from patients and health care professionals.

Call to streamline public and private drug pricing and reimbursement systems: Universal access to prescription drug coverage requires the establishment of a national formulary and a pricing and reimbursement system that ensure that drugs are affordable for patients and the society at large. Currently, each managed care organization, drug plan, and health care provider in the United States has its own drug formulary with different drugs covered and different copayment schemes. Large organizations have several formularies depending on the premium and out-of-pocket costs paid by their members. Drug selection for inclusion in drug formularies is driven by rebates and discounts that insurers, pharmaceutical benefit managers, and health plans negotiate with drug companies behind closed doors. By contrast, the Department of Veterans Affairs (VA) national drug formulary shifts prescribing practices toward preferred formulary drugs, achieving higher front-end discounts from drug manufacturers and reducing drug expenditures without compromising patient outcomes.[31] The VA national formulary approach applied to Medicare would result in substantial reductions in unnecessary drug spending for Medicare enrollees and taxpayers at large.[32]

Another example is the Department of Defense (DoD) uniform drug formulary (TRICARE formulary) implemented in 2005. Implementation of the DoD drug formulary was associated with an estimated $986 million in cost avoidance in fiscal year 2007, representing approximately a 13% reduction in drug expenditures.[33] TRICARE has an annual $7.3 billion pharmacy spend.[34] Harmonizing drug formularies across health systems would reduce the amounts and types of medications on hand and increase drug discounts and buying power through bulk purchasing.[35,36] In 2008, the DoD began collecting discounts for drugs dispensed through TRICARE retail network pharmacies. These pricing discounts represent significant savings to the DoD. The Military Health System estimated an $825 million savings in retail pharmacy refunds on most brand-name retail drugs in fiscal year 2020.[34] As of December 2020, DoD savings derived from drug pricing discounts totaled approximately $14.3 billion. Further savings can be achieved through national drug formularies by decreasing the cost associated with medication inventory and waste.[37]

The Elijah E. Cummings Lower Drug Costs Now Act (2019) requires the Department of Health and Human Services to negotiate maximum prices for certain drugs including insulin products, single-source brand-name drugs that do not have generic competition and that account for the greatest national or Medicare prescription drug benefit and Medicare Advantage spending. It also requires negotiating prices for other single-source

brand-name drugs and newly approved single-source brand-name drugs that meet or exceed a specified price threshold. The negotiated prices must be offered under Medicare and Medicare Advantage and may also be offered under private health insurance unless the insurer opts out.[38]

Legislative and regulatory initiatives for reforming drug pricing and regulation have been effectively counteracted by large campaign donors and lobbyists in the pharmaceutical industry. A recent study showed that, among all industries, the pharmaceutical and health care industry ranked first in terms of federal-level lobbying expenditures.[39]

The U.S. reimbursement system often reimburses for the use of costly new pharmaceutical products irrespective of their comparative safety and effectiveness. Drug manufacturers' marketing and advertising strategies focus on differentiating drugs that are clinically equivalent to low-cost generic alternatives. Unnecessary use of pharmaceutical products does not improve patient outcomes and diverts scarce resources from other health care needs. By contrast, most developed economies, including Australia, Canada, France, Germany, and the United Kingdom, use health technology assessments (HTAs) more comprehensively than the United States to inform their public health care system formulary additions, pricing, and reimbursement of new drug decisions.[40,41] HTAs involve the comparative effectiveness and economic evaluations of new drugs. The United States does not have a centralized process for HTAs. Even the several federal public insurance programs have different processes for formulary decision making and drug reimbursement. Drug manufacturer sponsors set different prices for the same drug for different public and private payers, and final drug prices, discounts, and rebates paid by different programs are confidential.

Call to expand affordable drug insurance to all Americans: Access to prescription drugs should be determined by patients' medical needs as opposed to their financial means. In the United States, 27.4 million people were uninsured in 2020.[42] About 13% of U.S. residents do not have any form of health insurance to pay for prescription medications, and even those who have coverage are often unable to afford drug copayments and other cost-sharing mechanisms. One in four adults in the United States reports difficulty affording drug out-of-pocket costs. The impact of an inequitable prescription drug delivery system is most poignant when reviewing cost-related nonadherence to medications. Cost-related medication nonadherence in the United States is two to four times higher than in other developed countries.[43] Thirty percent of adults report not taking their medicines as prescribed in the past year because of drug costs, including 16% who report not filling a prescription and 13% who cut their pills in half or skip a dose of a prescribed medicine.[44]

The adverse impact of lacking comprehensive insurance has also been documented in the literature. While the poor and the elderly may have access to prescription medications through public programs (Medicaid and Medicare, respectively), adults in the 19–45-year-old group, even if they are partially insured, are often most at risk due to moderate incomes, copayments, and deductible requirements.[45] Adults 19–64 years of age are three times less likely to fill a prescription if they are underinsured.[45] Patients with chronic conditions are disproportionally affected. Chronic illness without regular access to medications is one key dimension in need of repair to ensure equitable medication access in the United States. According to one study, a cost sharing of $10.40 per prescription drug led to a 22.2% drop in medication use and a 32.7% increase in monthly mortality.[46] Thus, the income and insurance status of individuals in this country greatly affects their sense of security in terms of accessing regular health care and prescription medications.

Viewing society through the lens of economic disparities raises the importance of the interaction of race with economic status.[47] A for-profit health care delivery system has a deep impact on marginalized low-income groups such as people of color, incarcerated individuals, and undocumented immigrants. Institutional racism in health care has been identified as inaction in the face of need.[48] Nowhere is that need more apparent than in the health service research literature identifying unmet health needs among people of color, leading to great disparities in health outcomes.[49]

Incarcerated individuals, particularly adult men of color, generally face both economic and social challenges. Adults account for 99% of jail inmates, 86% of them are males, and more than half are people of color.[50] Incarcerated people are not eligible to purchase private health insurance. In addition, adults in the criminal justice system largely have low incomes and are uninsured, which leads to the need for Medicaid coverage. However, Medicaid has traditionally played a very limited role in providing health insurance coverage, and few inmates are covered by Medicaid. With the Medicaid coverage expansions, there may be opportunities to provide health coverage for people in the criminal justice system, particularly those faced with financial difficulties.

Public health concern for the undocumented population is notable in the state of California, where the undocumented population is sizable (10.6 million).[51] The uninsured rate is 46% among undocumented Californians, as compared with 10% among U.S.-born Californians. Laudable efforts have been made to cover children, youth, and pregnant women. However, adults are restricted to emergency room access or to coverage for limited chronic conditions. Ongoing efforts to cover the undocumented population have been fueled by the emergence of COVID-19 and its variants.

In general, cost sharing for brand-name drugs and specialty drugs is set at a percentage of the retail drug price.[52] Those who lack health insurance, those whose plan does not include coverage for prescription drugs, and those who have not met their insurance plan's annual deductible have to pay the full drug price. The scant insurance coverage and the increasing cost sharing, along with reduced treatment adherence, result in a worsening of health outcomes. This dilemma is particularly troublesome for people with limited incomes, those with employer-based insurance and job insecurity, and the incarcerated and undocumented population.

Opposing Arguments/Evidence

Patent extensions and market exclusivities are necessary to incentivize pharmaceutical innovation and to reward private enterprise: Pharmaceutical companies argue that they should be rewarded with more patent extensions and market exclusivities to incentivize drug innovation and to recover drug research and development investments because developing a new drug is a costly and uncertain process and less than 12% of drugs entering clinical trials are approved by the FDA.[53] According to PhRMA, the estimated average R&D cost per new drug, including products that never entered the market, reached $2.6 billion in the early 2010s.[54]

Several laws and regulations include provisions that increased the patent and market exclusivity periods for pharmaceutical products. The Orphan Drug Act provided 7-year market exclusivity to drugs with orphan designation. The Waxman-Hatch Act authorized 5 years of market exclusivity for new drugs and 3 years of market exclusivity for drugs containing active ingredients already approved for marketing in the United States. The Food and Drug Administration Modernization Act established a 6-month exclusivity period as a reward for drug manufacturers that conduct FDA-approved pediatric research. The ACA granted brand-name biologics 12 years of market exclusivity. Also, FDASIA added 5 years of market exclusivity for certain anti-infective drugs. During the 1-year provisional patent term, the 20-year patent statutory term, patent extensions, and market exclusivity periods, pharmaceuticals do not face generic competition. Hence, pharmaceutical companies set prices of new drugs to maximize profits.[55,56]

Patent and market exclusivities for finite periods reward pharmaceutical companies. Companies often strategically leverage the patent and drug approval systems to prolong their monopolies irrespective of the clinical significance of new approved drugs.[57] Further extending patents and market exclusivities has been associated with higher drug prices, prolonged monopolies,[58] and a flourish of "me too" drugs of little or no therapeutic value brought to the market to lengthen monopoly prices.[57] Budget constraints are necessary to

better align pharmaceutical company incentives with patients' ability to pay for pharmaceuticals in the context of public health–oriented drug development.

Higher prices and reimbursement rates are necessary to incentivize the development of new medicines to address patient needs: Pharmaceutical companies argue that higher prices and reimbursement are necessary to reward innovation and that drug pricing regulations would affect the profits of existing drugs and expected returns on investment for future drugs, leading to fewer new drugs in the U.S. market.[59]

The profitability of the U.S. drug industry is the subject of ongoing debate and complex quantitative analyses resulting in confusion and biased interpretation depending on methodology, data sources, underlying assumptions, and funding sources. Ledley et al. reported on a comparison of 2000–2018 proprietary data between drug companies and S&P 500 companies showing net income margins of 13.8% and 7.7%, respectively.[60] DeAngelis, former editor of JAMA, raised a challenging question: what is a fair and legitimate profit for a drug?[61] Reflecting on average 18% profit margins, with more than 20% among the top five large companies, DeAngelis noted several conditions contributing to these exorbitant profits. For example, in contrast to all other developed countries other than New Zealand, the drug industry in the United States can sets its own drug prices independent of government authority. Not surprisingly, drugs such as Solvadi, the hepatitis C drug, cost $1,000 per pill.[62]

Many in the public sector see the greater return on revenue of the U.S. drug industry as reflecting excessive profits. However, industry proponents justify such profits, claiming costly R&D. The cost of bringing a new drug to market has yielded estimates as high as $2.6 billion. Such exorbitant estimates have fueled outcries in the press.[63] An independent assessment of the cost of bringing a prescription drug to market revealed that the median capitalized R&D was $985.3 million per new drug entity, still a substantial figure[64] and subject to debate in terms of the contribution of ancillary costs (e.g., marketing, lobbying, payments to prescribers). As a result, marketing and administration can contribute more than twice the cost of R&D to the total cost of bringing a drug to market.[65]

In 2018, large pharmaceutical companies accounted for most pharmaceutical revenues, whereas small drug companies accounted for more than 70% of the total pharmaceutical R&D pipeline.[66] Furthermore, major innovative drugs have been discovered in public universities (e.g., enzalutamide) funded through grants from the National Institutes of Health (NIH), and patent rights have been purchased after drug discovery by private companies, generating enormous revenues for drug companies. The NIH allocates more than $40 billion each year to fund biomedical research.[67] Hence, U.S. taxpayers end up paying twice for

pharmaceutical products.[67] Initially, taxpayers pay for pharmaceuticals discovered and developed with NIH funding and orphan drug designations through grants and tax credits. Taxpayers pay again for pharmaceuticals included in public health care programs such as Medicare and Medicaid.

Medicines discovered with taxpayers' money should be affordable to all Americans.[57] Some pharmaceutical products, including COVID-19 vaccines, were funded by the government and, once discovered, were purchased by public health programs at high prices. For example, the oral antiviral drug that reduces the severity of COVID-19 (molnupiravir) is sold at many times the manufacturing cost, resulting in calls for congressional action.

Action Steps

To this end, APHA urges the U.S. Congress to:

1. Enact policies to reduce barriers to market entry to increase market competition, bringing the patent and market exclusivity regulation of pharmaceuticals in line with U.S. intellectual property regulations, and end "pay-for-delay" settlements and other agreements that block generic competition in the pharmaceutical industry.
2. Enhance standards of pharmaceutical R&D centered on improving patient-level and population-based health outcomes and making data on drug safety, efficacy, and prices available to clinicians and researchers. Specifically, direct measures of morbidity and mortality outcomes should be used in clinical trials; the clinical and statistical significance and comparative effectiveness of new pharmaceutical products should be assessed; standards for postapproval effectiveness and safety monitoring should be implemented, particularly in Phase 4 of the drug development process, and independent publicly funded postmarketing surveillance studies should be conducted; comparative safety, efficacy, and pricing data should be disclosed in marketing and advertising activities; and federal and state public R&D support should be directed toward the development of new drugs with evidence of improving safety and efficacy and addressing unmet medical needs.
3. Mirror the VA system in designing and implementing a national drug formulary and utilization criteria for all federal and state public programs, including Medicare, Medicaid, the Department of Defense, and the Indian Health Service. The national drug formulary should also apply to all federal and state employee insurance programs.
4. Support universal drug coverage and affordable copayments and other cost sharing as part of the single-payer health system reform endorsed by APHA in 2021.[68]

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