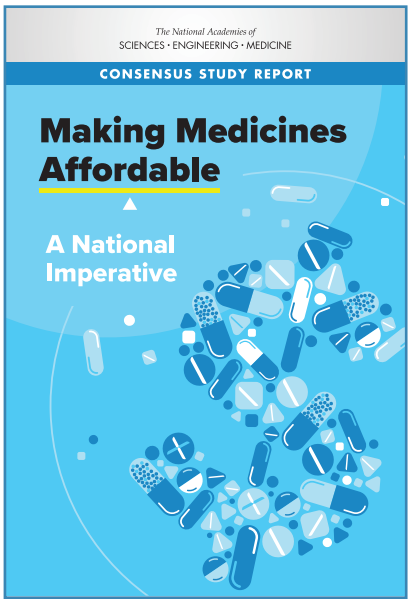
Consensus Study Report
HIGHLIGHTS
November 2017

Making Medicines Affordable

A National Imperative



Over the past several decades, the U.S. biopharmaceutical sector[1] has been very successful in developing and delivering effective drugs for improving health and fighting disease. Many medical conditions that were long deemed untreatable can now be cured or managed effectively. Yet this success has come at a cost: Spending on prescription drugs has been rising dramatically, to the point that many people have difficulty paying for the drugs that they or their family members need. Drug costs are a significant part of the nation's total spending on health care.

With support from a host of sponsors, the National Academies of Sciences, Engineering, and Medicine conducted a study to recommend policy actions that address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address significant needs in health care. The resulting report, *Making Medicines Affordable: A National Imperative,* provides several strategies to tackle the rising costs of prescription drugs without discouraging the development of new and more effective drugs for the future.

The challenge is formidable. There may be trade-offs between current drug affordability and new drug availability. Controlling drug costs too rigidly, for example, could potentially reduce the expected profits of drug companies, which could alter their decisions regarding major investments to develop new drugs. Furthermore, the complexity of the medical system—which includes patients, clinicians, hospitals, insurance companies, drug companies, pharmacists, pharmacy benefit managers, various government agencies, advocacy organizations, and many others—makes it very difficult to predict the precise effects of any specific policy change. This challenge is magnified by the lack of transparency concerning the financial transactions between the various participants in the biopharmaceutical supply chain.

Nonetheless, there are a number of measures that can and should be taken to improve the affordability of prescription drugs for patients in the United States.

[1]The term "biopharmaceutical sector" used in the report encompasses a wide range of participants from researchers and physicians to industrial producers, from public and private payers to intermediaries such as pharmacy benefit managers, and from health care organizations and care providers who can prescribe medications to patient advocacy organizations.

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THE FUNDAMENTAL TENSION

The trend of increasing spending on health care, including on biopharmaceuticals, is projected to continue for the foreseeable future as the Baby Boomer generation ages. No other nation in the world approaches the level of U.S. health care expenditure, yet various studies indicate that many nations have healthier populations. The United States now ranks 25th in the world in life expectancy at birth, yet among the 10 nations with the largest gross domestic product (GDP), the United States spends about twice as much on health care as a fraction of GDP as the average of the other nine. Annual expenditures on biopharmaceuticals in the United States now exceed a half trillion dollars, and prescription drugs are among the fastest-growing segments of health care spending.

Research and development of new drugs, the lifeblood of the pharmaceutical industry and its contribution to health care, is also extremely costly. The canonical statement about the cost of a new drug—"The first pill can cost over a billion dollars while the second costs only a dime"—captures an important truth: New drugs are exceptionally expensive to develop, and failures are commonplace.

An implicit tradeoff exists when setting drug prices: Investments in research and development can increase the cost of current drugs, but failure to make investments in research and development will ultimately limit the number of new, improved drugs with which to treat future patients.

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THE REPORT'S RECOMMENDATIONS

Consumer access to effective and affordable medicines is an imperative for public health, social equity, and economic development; however, this imperative is not being adequately served by the biopharmaceutical sector today.

To approach the proper balance between affordability and future availability of medicines in the interest of public health, this report offers a set of eight specific recommendations, with interlinked implementation actions in the biopharmaceutical sector. To read the supporting findings and the report's recommendations directed at the U.S. Congress, federal agencies, and other participants in the biopharmaceutical sector, please visit nationalacademies.org/NASEMAffordableDrugs.

The federal government should consolidate and apply its purchasing power to directly negotiate prices with the producers and suppliers of medicines, and strengthen formulary design and management. The government should also improve methods for assessing the "value" that drugs provide and also ensure that incentives to develop drugs for rare diseases are not extended to widely sold drugs. In addition, increased disclosure about the financial flows and profitability among the participants in the biopharmaceutical sector should be required.

Actions to continually foster greater access to off-patent generic drugs, which are usually much less expensive than branded products, should be taken. One way this could be accomplished would be to prevent the common industry practices that delay entry of generics into the market and extend market exclusivity of branded products. Another critical step is to speed up the review processes that are required of manufacturers to produce generic drugs, to ensure healthy competition and lower costs.

Various actions should be taken to eliminate incentives in the system that encourage clinicians and patients to prescribe or use more expensive drugs rather than less

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expensive alternatives that provide comparable results. One such action would be to discourage direct-to-consumer advertisements for prescription drugs and to provide more useful information to patients about the potential benefits and costs of treatments, thereby reducing inappropriate demand for higher-priced drugs.

Current insurance benefit designs for prescription drugs often expose consumers to considerable financial risk and can unfavorably affect patients' adherence to treatment regimens. Insurance plans should be modified to reduce the financial burden that patients and their families currently experience when they need costly prescription drugs, and individual cost-sharing arrangements that are based on drug prices should be calculated as a fraction of net purchase prices rather than the list prices from manufacturers. Limits should also be placed on the total annual out-of-pocket costs paid by enrollees in Medicare plans that cover prescription drugs by removing the cost-sharing requirement for patients who reach the catastrophic coverage limit. The government should also tighten qualifications for discount programs that have drifted from their original intent to help vulnerable populations.

Financial incentives for the prevention and treatment of rare diseases should not be extended to widely sold drugs. Congress should revise the Orphan Drug Act to achieve its original intent, by ensuring that drugs with orphan designation receive benefits only for the target rare disease (and not other indications), and getting rid of unnecessary sub-categories that can create artificial eligibility for orphan drug status.

Finally, actions can be taken to increase available information and implement reimbursement incentives to more closely align prescribing practices of clinicians with treatment value. Specifically, payment policies should not differentiate among differing sites of care. Payment practices based on the list prices of drugs should be replaced with fixed fees that support clinical care and the costs of storing and administering drugs in outpatient clinics.

A NATIONAL IMPERATIVE

The biopharmaceutical sector is critically important to public health, social equity, economic development, and, in some circumstances, the national security of the United States. Yet the impact of the unaffordability of prescription drugs on people in the United States is very clear: It ultimately harms people's health, sometimes even resulting in death. The report's recommendations are intended to achieve a significantly improved system that makes drug therapies affordable to patients while still enabling the continuing development of new drugs—always keeping in mind that the foremost responsibility of the biopharmaceutical sector is to serve the patient.

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