Making medicines affordable: New report calls for government negotiation of drug prices

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Consumer access to effective and affordable medicines is an imperative for public health, social equity, and economic development, but this need is not being served adequately by the biopharmaceutical sector, says a new report from the National Academies of Sciences, Engineering, and Medicine. The report offers eight recommendations with 27 actions for their implementation (a sample of actions in each area appears below) to improve the affordability of prescription drugs without discouraging the development of new and more effective drugs for the future.

"Over the past several decades, the biopharmaceutical sector in the United States has been successful in developing and delivering effective drugs for improving health and fighting disease, and many medical conditions that were long deemed untreatable can now be cured or managed effectively," said Norman Augustine, former chairman and CEO of Lockheed Martin Corp., former chairman of the National Academy of Engineering, and chair of the committee that conducted the study and wrote the report. "However, high and increasing costs of prescription drugs coupled with the broader trends in overall medical expenditures, which now equals 18 percent of the nation's gross domestic product, are unsustainable to society as a whole. Our report seeks to address the market failures that currently permeate the biopharmaceutical sector, such as lack of competition due to distortions in the application of the patent protection process, the imbalance

between the negotiating power of suppliers and purchasers, and the convoluted structure of the supply chain. Although changes within the current system will be demanding, they are likely to better serve the nation."

As defined in the report, the "biopharmaceutical sector" encompasses a wide range of participants including researchers, physicians and other care providers who can prescribe medications, public and private payers, intermediaries such as pharmacy benefit managers, health care organizations, and patient advocacy organizations.

Drug pricing and formulary design

Consolidate and apply governmental purchasing power, strengthen formulary design, and improve drug valuation methods.

Congress should modify existing legislation to allow the U.S. Department of Health and Human Services (HHS) to directly negotiate prices with producers and suppliers of medicines, including acting on behalf of any relevant state agency that elects to participate in the process. Because prices tend to be lower when the purchaser has bargaining power that is at least comparable to that of the seller, the U.S. could achieve lower prices for prescription drugs by consolidating its bargaining power and providing greater flexibility in formulary design. A formulary describes which drugs a health care payer will cover for which disease indications, and at what cost. Formulary control in the U.S. relies heavily on tiering, which has mixed consequences because placement of a drug in a higher tier can reduce adherence to a treatment plan, with potential harm to patient health, but the tiered price mechanism can also be used by insurers to negotiate lower prices for branded drugs. Congress should authorize HHS, related federal agencies, and associated private payers to expand flexibility in formulary design, including very selective exclusion of drugs, such as when less costly

drugs provide similar clinical benefit.

Generics and biosimilars

Accelerate the market entry and use of safe and effective generics as well as biosimilars and foster competition to ensure the continued affordability and availability of these products.

The U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) should vigorously deter manufacturers from paying other producers for the delayed entry into the market—known as "pay-for-delay agreements"—of generics and biosimilars (products that are demonstrated to be interchangeable with branded, FDA-approved products). DOJ and FTC also should expand the enforcement of policies that preclude mergers and acquisitions of firms among companies possessing significant competing generics and biosimilars and possessing a significant share of the market, as these strategies reduce access to reasonably priced drugs. State legislatures should develop policies to restrict the use of the "dispense as written" practice by prescribers that may unnecessarily impede the use of generics and biosimilars, the report says. In addition, Congress should authorize the U.S. Food and Drug Administration (FDA) to seek reciprocal drug approval arrangements for generics and biosimilars between the regulatory agencies of the U.S. and countries such as the U.K., Germany, Canada, Australia, and Japan because in the absence of evidence of harm, importation of these drugs could provide cost savings.

Financial transparency in the biopharmaceutical supply chain

Assure greater transparency of financial flows and profit margins in the biopharmaceutical supply chain.

Various participants in the biopharmaceutical supply chain point to other participants as the main contributors to high and rising drug costs, the report says, so to help understand the root causes of price increases and when they are appropriate, Congress should require disclosure of information from insurance plans about the average net prices paid for prescription drugs, including patients' cost-sharing among plans, and from biopharmaceutical companies about average net volume of and prices paid for drugs across each active sales channel. HHS should curate, analyze, and publicly report the data, collected at the level of National Drug Codes, on a quarterly basis to the public and congressional committees, and the FTC should examine the data to identify and act upon any anti-competitive practices.

Marketing

Promote the adoption of industry codes of conduct, and discourage direct-to-consumer advertising of prescription drugs as well as direct financial incentives for patients.

Large biopharmaceutical companies spend substantially more on marketing and administration than on research and development that could lead to new drugs, the report says, and direct-to-consumer advertising of prescription drugs can adversely influence consumer choices. Therefore, Congress should disallow direct-to-consumer advertising of prescription drugs as a tax-deductible business expense. In addition, manufacturers and suppliers should adopt industry codes of conduct that reduce or eliminate direct-to-consumer advertising of prescription drugs and should increasingly support efforts to enhance public awareness of disease prevention and management. Clinicians, medical practices, and hospitals also should substantially tighten restrictions on pharmaceutical companies' direct visits to clinicians, the acceptance and use of free drug samples, special payments, and other inducements paid by biopharmaceutical companies.

Insurance benefits

Modify insurance benefit designs to mitigate prescription drug cost burdens for patients.

Current insurance benefit designs for prescription drugs often expose consumers to considerable financial risk and can unfavorably affect patients' medication adherence, the report says. Congress should establish limits on the total annual out-of-pocket costs paid by enrollees in Medicare Part D plans that cover prescription drugs by removing the cost-sharing requirement for patients who reach the catastrophic coverage limit. Congress also should direct the Centers for Medicare & Medicaid Services to modify the designs of plans offered through Medicare Part D and government health insurance exchanges to limit patients' out-of-pocket payments for drugs when there is clear evidence that treatment adherence for a particular indication can reduce the total cost of care, as determined by HHS.

Federal discount programs

Eliminate misapplication of funds and inefficiencies in federal discount programs that are intended to aid vulnerable populations.

Congress should expand the authority of the HHS to provide increased oversight and regulation of the 340B program to ensure that participation by covered entities, contract pharmacies, and drug manufacturers is consistent with the original intent of the program—to improve the access of low-income populations to medicines at discounted rates.

Rare diseases

Ensure that financial incentives to develop drugs for the prevention and

treatment of rare diseases are not extended to widely sold drugs.

Congress should revise the Orphan Drug Act—designed to foster the development of innovative drugs for rare conditions—to ensure that financial incentives for the prevention and treatment of rare diseases are not diverted to widely sold drugs, by promoting agreements between biopharmaceutical companies and HHS that enable HHS to obtain favorable concessions on launch prices, annual price increases, and other practices important to public health. In addition, FDA should be directed to limit the market exclusivity awarded to orphan drugs to one seven-year extension.

Reimbursement

Increase available information and implement reimbursement incentives to more closely align clinicians' prescribing practices with treatment value.

Current insurer reimbursement policies for clinician-administered drugs in the outpatient setting minimize incentives for medical providers to select treatments and settings for patient care that are the most cost-effective. These policies may serve to inflate the prices of these drugs charged by manufacturers and other members of the supply chain who profit from the current system, and put patients at clinical and financial risk. Therefore, payers should establish payment policies for drugs administered by clinicians in medical practices and hospitals that do not differentiate for the site of care, the report says. Hospitals, vendors of electronic health records, insurers, and professional societies should ensure that clinicians have readily accessible and routinely updated information regarding drug cost and efficacy, including relative clinical benefits of alternative treatment regimens and the relative financial costs of treatment settings to both patients and payers, to support sound prescribing decisions at the point of care.

The report also contains a dissenting viewpoint, which says the report's set of recommendations as a whole would reduce prices too much and diminish future investments in innovation, and a minority perspective, which says that even stronger actions are needed to make prescription drugs more affordable.

More information: www.nap.edu/catalog/24946/maki … -national-imperative

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