

EXECUTIVE ORDER

REDUCING THE COST OF MEDICAL PRODUCTS AND ENHANCING AMERICAN BIOMEDICAL INNOVATION

By the authority vested in me as President by the Constitution and the laws of the United States of America, in order to increase the access to affordable, safe and effective medical products, and continue to promote American biomedical innovation it is hereby ordered as follows:

Section 1. Policy

It shall be the policy of the Executive Branch, to the extent consistent with Federal law, to:

- a) Efficiently advance to market safe and effective medical products for American patients, including new and innovative medical products, competitor medical products, such as generic drugs, complex generic drugs, and biosimilars, and novel therapies that employ cutting-edge scientific advances tailored to patients' individual medical needs, such as gene and regenerative therapies.
- b) Reduce burdens caused by regulatory and administrative actions that inflate or distort prices for beneficiaries of Federal health programs or that provide more favorable pricing for intermediate actors in the medical product supply chain than the prices available to beneficiaries.
- c) Facilitate, where appropriate, the ability of Federal health programs to enter into reimbursement arrangements for medical products that are based on the value of such products to patients rather than the volume of such products purchased.
- d) Ensure that the laws intended to help lower-income or vulnerable Americans and strengthen the safety net healthcare providers that serve them are carried out in such a way, that the benefits of such programs accrue primarily to the intended populations, including by the rescinding or revising of regulatory or administrative actions.
- e) Ensure that American citizens do not disproportionately subsidize medical product innovation for the rest of the world, or allow foreign governments to unfairly devalue American innovation.
- f) Rescind, revise or simplify regulations and other administrative actions that inappropriately or unfairly contribute to higher prices or cost-sharing for medical products for American patients.
- g) Engage with patients, families, and caregivers to hear their suggestions about relief from rising drug costs and the impact of our proposed reforms
- h) Support the work of healthcare providers to educate patients about how to access safe, effective, and affordable medical products that improve quality and lower the total cost of care, including patient education, informed e-prescribing, counter-detailing, and medication therapy management.

2. Food and Drug Administration

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall take steps to advance innovation and encourage lower-cost alternatives in order to enhance access to safe and effective medical product options for patients. Such actions shall leverage biomedical discovery, advance the timely development of medical products, increase drug competition, enable generic entry for complex drugs, and address unintended consequences of existing rules that may reduce competition.

3. Centers for Medicare & Medicaid Services

The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall take steps to explore and develop, with stakeholder input, new models and demonstrations that lower drug and medical product costs for beneficiaries of the Medicare and Medicaid programs without decreasing quality. Additionally, enable innovative approaches to benefit design to modernize the Medicare and Medicaid benefits to improve quality, reduce out of pocket spending, and lower the total cost of care.

4. Health Resources and Services Administration

The Secretary of Health and Human Services shall ensure that resources provided by the program established by Section 340B of the Public Health Service Act are directed in such a way they primarily benefit the lower income or otherwise vulnerable Americans for which the program was intended, including by rescinding or revising regulatory or other administrative actions that have allowed benefits of the program to accrue to other populations or entities other than the safety net healthcare providers that the program was intended to strengthen.

6. Internal Revenue Service.

The Commissioner of the Internal Revenue Service shall update the preventive care safe harbor under Section 223(c)(2)(C) of the Internal Revenue Code to include services or benefits, including medications, intended to prevent chronic disease progression or complications, for the purpose of helping patients adhere to clinical regimens and thereby reducing costs of healthcare.

7. United States Trade Representative.

The United States Trade Representative (USTR), in consultation with the Secretary of State, the Secretary of Health and Human Services, and the Secretary of Commerce, and the Secretary of Commerce, shall conduct a comprehensive review of the international drug purchasing and supply system including price differentials between foreign governments and the United States, multilateral and bilateral agreements that need to be revised to promote greater intellectual property protection and competition in the global market, and potential violations of trade agreements and what enforcement mechanisms may be available to the United States under such agreements.

8. General regulatory relief. Conduct a review to identify harmful regulations, policies and laws.

- (a) The Secretary of Health and Human Services, the Secretary of Commerce, the Executive Director of the Federal Trade Commission, the United States Trade Representative (USTR), the Secretary of State, and the Director of the Office of Management and Budget, shall conduct a comprehensive review, consistent with the policy established pursuant to Executive Order [2-for-1 EO number], within their purview, of:
 - i. The bio-pharmaceutical research, development, supply and purchasing chain to identify inefficiencies, poorly constructed statutes, burdensome regulations and negative policies;
 - ii. Those regulations or policies that unnecessarily increase expenses for patients;
 - iii. Those regulations or policies that unnecessarily increase expenses for bio-pharmaceutical researchers and manufactures;
 - iv. Regulations and policies that unnecessarily restrict competition and artificially increase prices;
 - v. Policies, regulations and statutes that create unnecessary complexity, reduce transparency and result in inefficient and irrational allocation of resources throughout the pharmaceutical supply chain and ultimately high prices for drug purchasers including both government and private purchasers;
 - vi. Statutes that need to be updated to ensure that America remains the world's leader in bio-pharmaceutical innovation;
 - vii. Costs and benefits associated with agencies' proposed administrative actions, regulatory reform, and legislative proposals; and
 - viii. Lawful and appropriate actions to remedy or correct deficiencies identified pursuant to subsections (a)(i) through (a)(vii) of this section.
- (b) Balancing the need to reward innovation and nurture a thriving American bio-pharmaceutical ecosystem with the need for achieving lower drug prices for Americans, the relevant agencies will engage with external stakeholders as appropriate to identify regulatory and legislative barriers and solutions.
- (c) The Secretary of Health and Human Services, The Secretary of Commerce, The U.S. Trade Representative, and the heads of all other relevant executive departments and agencies, after due consultation with the Executive Office of the President, shall pursue administrative actions that the agencies can immediately execute, and identify longer term administrative actions, using all authority and discretion available to remedy or correct deficiencies identified pursuant to subsections (a)(i) through (a)(viii).
- (d) Contained within their submissions to the Director of the Office of Management and Budget for the President's FY 2019 Budget, the Secretary and the heads of all other relevant executive departments and agencies shall submit their findings and additional recommendations, including legislative proposals.

9. General Provisions

- (a) Nothing in this order shall be construed to impair or otherwise affect:
 - i. The authority granted by law to an executive department or agency, or the head thereof; or
 - ii. The functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

THE WHITE HOUSE,
June XX, 2017.