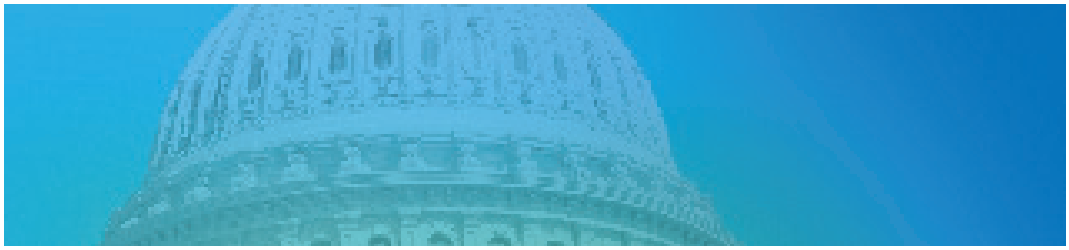

Prescription drug pricing, costs and transparency

Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on our patients, on physician practices, and on the broader health care system. Patients delay, forgo, or ration their medication when treatments are cost prohibitive, putting their health at risk. At a time of significantly increasing drug prices, the American Medical Association believes that increased competition and fair and transparent markets are more important than ever. The AMA looks forward to working with Congress and the administration to develop and implement well-crafted and effective public policy solutions to address the rising cost of prescription drugs that will improve access, lower costs, and reduce the administrative burdens without stifling innovation.

The AMA urges Congress to consider advancing the policies outlined below.

Increase pharmaceutical market competition and combat anticompetitive practices

The AMA continues to vigorously support expanded authority and funding for the Federal Trade Commission (FTC) in a number of areas to address anticompetitive practices as well as to advance consumer protections. The AMA strongly supports increased resources and direction to:

- Stop patent pay-for-delay settlements, whereby a brand-name pharmaceutical manufacturer pays a potential generic competitor to abandon its patent challenge and delay offering a generic drug product for a number of years for anti-competitive purposes.
- Limit efforts by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections.
- More rigorously and expansively evaluate the impact of mergers and consolidations among pharmaceutical companies on competition as well as consumer access by, among other things, expanding clinical expertise within the FTC and consulting with the relevant national medical specialty societies.
- Recommend enforcement action against manufacturers that engage in anticompetitive actions to the U.S. Department of Justice.

The AMA also continues to support measures to address the misuse of Food, Drug, and Cosmetic Act (FDCA) provisions for anti-competitive purposes while at the same time advocating for modifications to FDCA to increase access to some of the most-costly prescription medications: biologicals. The AMA strongly urges action to:

- End the ability of generic manufacturers to indefinitely "park" the 180-day exclusivity period authorized by the FDCA by delaying final approval of their application by the U.S. Food and Drug Administration (FDA) as part of a settlement agreement with a brand manufacturer.
- Further expand the ability of the FDA to address anticompetitive abuse of risk evaluation and mitigation strategies by brand manufacturers—particularly voluntary elements to assure safe use that involve proprietary measures that pose barriers to use by generic competitors.
- Make necessary refinements to law to prevent the inappropriate extension of the exclusivity and patent life of pharmaceuticals.

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Finally, the AMA urges Congress to shorten the exclusivity period for biological products. The AMA was an early and strong supporter of establishing a pathway for follow-on biologicals. The reduction in the exclusivity period is warranted to spur competition while not decreasing the impetus to innovate.

Require pharmaceutical supply chain transparency

The second component of AMA advocacy has been to encourage transparency throughout the pharmaceutical supply chain. The ability of patients and physicians to have the information they need to make key decisions regarding medication, and of policymakers to craft viable solutions to high and escalating pharmaceutical costs, has been hampered by the often byzantine and confidential arrangements that are driving increased medication prices without a clear and justifiable reason. The practices and policies of pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and health insurers warrant steps by Congress to interject much needed transparency. To that end the AMA strongly supports:

- Requiring pharmaceutical manufacturers to provide public notice before increasing the price of any drug by 10 percent or more each year or per course of treatment and provide justification for the price increase.
- Requiring pharmaceutical manufacturers to publicly disclose a variety of information, which could include research and development costs, expenditures on clinical trials, total costs incurred in production, and marketing and advertising costs.
- Requiring PBMs to apply manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale to ensure that patients benefit from discounts as well as eliminate some incentives for higher drug list prices.
- Requiring insurers to provide increased transparency in formularies, prescription drug cost-sharing, and utilization management requirements for patients and physicians at the point-of-prescribing as well as when beneficiaries make annual enrollment elections.
- Prohibiting removal of drugs from a formulary or moving to a higher cost tier during the duration of the patient's plan year unless a change is made for safety reasons.

Urge your senators and your representative to support legislation to combat anticompetitive pharmaceutical company practices and improve drug price transparency throughout the distribution chain.

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