Introduced by: Medical Student Section

Subject: Reevaluating the Food and Drug Administration’s Citizen Petition Process

Referred to: Reference Committee K

Whereas, Pharmaceutical drug prices in the United States are increasing at an alarming rate and are more expensive than the rest of the industrialized world\(^1\)-\(^3\); and

Whereas, Although brand name drugs account for about 15% of prescriptions dispensed by Medicaid and Medicare Part D, they account for about 75-80% spending on prescription drugs\(^1\),\(^4\); and

Whereas, In many situations, generic and brand name medications have the same clinical efficacy, risks and benefits because they have the same active ingredients and mechanism of action\(^5\); and

Whereas, Competition between generic drug companies and brand name manufacturers typically results in an 85% price reduction, and generic drugs saved the U.S. healthcare system $1.67 trillion from 2007 to 2016\(^5\),\(^6\); and

Whereas, The Food and Drug Administration’s (FDA) citizen petition process is intended as a method for average individuals, industry or consumer groups to formally request the FDA commissioner to invoke, amend, or revoke directives or pharmaceutical monographs as a democratic and transparent mode of regulation\(^7\),\(^8\); and

Whereas, Manufacturers of brand name drugs employ strategies including filing petitions to the FDA that delay and prevent the entry of generic drugs into the market and prevent this loss of profit\(^9\)-\(^11\); and

Whereas, An estimated 92% of citizen petitions filed against generic brands are filed by brand-name manufacturers\(^12\); and

Whereas, One of every five citizen petitions filed by brand-name manufacturers (including but not limited to pharmaceutical drugs) has had the potential to delay generic entry into the market\(^13\),\(^14\); and

Whereas, An analysis of four frivolous citizen petitions filed by brand-name manufacturers in a 2-year span found a total market delay time of 521 days (against generic drugs) which cost approximately $782 million to government-provided insurance programs and $1.9 billion total\(^15\); and

Whereas, The Federal Trade Commission (FTC) has filed a formal complaint that these “repetitive, serial, and meritless filings lacked any supporting clinical data” that have “succeeded in delaying generic entry at a cost of hundreds of millions of dollars to patients and other purchasers”\(^16\); and
Whereas, Despite the overwhelming empirical data on the abuse of the FDA citizen petition process, there is minimal official data on the true cost to society\textsuperscript{15}; and

Whereas, The FDA is not obligated to nor does it actively report to Congress which petitions have been filed fraudulently or the nature of generic entry market delay\textsuperscript{17}; and

Whereas, Increasing the transparency of the citizen petition process would facilitate more thorough research and analysis of petitions and lower unnecessary resource expenditure by the FDA\textsuperscript{17}; therefore be it

RESOLVED, That our American Medical Association support the research of anti-competitive practices on the Food and Drug Administration's (FDA) citizen petitions process (New HOD Policy); and be it further

RESOLVED, That our AMA advocate for further public transparency by the FDA in the content of each petition, the relationship between citizen petitions and decisions to delay generic approval, and the time and resources expended on petition reviews. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/05/22

REFERENCES:
RELEVANT AMA POLICY

Pharmaceutical Costs H-110.987
1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation.