AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 802
(I-19)

Introduced by: Medical Student Section

Subject: Ensuring Fair Pricing of Drugs Developed with the United States Government

Referred to: Reference Committee J
(_____, Chair)

Whereas, The United States spends almost twice as much on healthcare as other comparable high income countries despite similar utilization rates, driven in part by higher spending on prescription drugs than other comparable nations[1,2,3,4,5,6,7]; and

Whereas, The United States spends between 30% and 190% more on pharmaceutical drugs per capita as compared to other comparable high income countries despite similar utilization rates[3,4,5,6]; and

Whereas, Many drugs cost significantly more in the United States than in other comparable industrialized countries, imposing an undue financial burden on American consumers of pharmaceutical compounds, particularly the uninsured, Medicare beneficiaries, and those whose insurance plans do not cover medicines they need[3,4,5,6,7,8]; and

Whereas, The United States government is the world's largest funder of the basic science research that supports the development of new pharmaceutical compounds[9,10,11]; and

Whereas, The United States government licenses drugs discovered in its laboratories to for-profit entities in order to facilitate commercialization[12,13,14]; and

Whereas, Numerous examples exist of drugs funded in whole or in part by the US government being sold in the United States for higher prices than in other comparable industrialized countries[3,15,16,17,18,19,20,21,22,23]; and

Whereas, Pharmaceutical companies and industry advocacy groups excuse high prices by explaining they are necessary for research and development of new drugs[25,26,27]; and

Whereas, A report by the US Government Accountability Office found that pharmaceutical sales increased by 45% globally over the period from 2006 to 2015 and two thirds of pharmaceutical companies saw their profit margins increase over that time period, while annual research and development investment in the United States increased by only 8% over the period from 2008 to 2014[28]; and

Whereas, Pharmaceutical companies have a higher average profit margin than all comparable industries, including software development which is often cited as a similar industry with high upfront R&D costs and low relative distribution costs[28,29]; and

Whereas, The United States pays an estimated 70% of all pharmaceutical profits obtained from OECD nations despite only accounting for 34% of the OECD's GDP[30]; and

Whereas, While the 1980 Bayh-Dole Act grants US government agencies the authority to unilaterally revoke licenses to companies or order that additional licenses be granted in order to ensure access (so-called “march in rights”), this extraordinary power has never been used to ensure fair pricing[31,32,33]; and

Whereas, The NIH has repeatedly decided that it does not have the statutory authority to use its march-in rights to force licensees to set fair prices for American consumers as this is under the purview of Congress[34,35,36]; and

Whereas, 29 European countries currently use a model called international reference pricing (IRP) to set drug prices whereby insurers and/or socialized healthcare programs agree to pay a maximum price for drugs set to an index of prices paid by comparable nations or use such an index as a benchmark for negotiations to set prices[37,38]; and

Whereas, Studies of the effectiveness of IRP have found that it lowers prices, increases utilization of drug classes to which the model is applied, and reduces expenditures with no negative effects on health outcomes[39,40,41,42,43]; and

Whereas, One of the most common concerns regarding IRP is that it may incentivize pharmaceutical companies to delay or eliminate product launches in countries with a lower willingness to pay[44,45,46,47]; and

Whereas, Analyses of IRP’s effects on pharmaceutical product launch delay have found the effect is weak and is limited to countries with a lower willingness to pay[48,49,50]; and

Whereas, The United States is one of the nations with the highest willingness to pay in aggregate, implying IRP’s tendency to delay pharmaceutical product launch in lower-income countries would likely not apply to the United States[8,9,47,48]; and

Whereas, The Institute for Medicare and Medicaid Innovation in the Department of Health and Human Services (HHS) has proposed a new model for Medicare Part B reimbursement for single-source pharmaceuticals and biologics to be phased into 50% of Medicare Part B plans between 2020 to 2025 that shifts the reimbursement structure to an IRP model, using 126% of the average price paid for a drug in 16 comparable OECD countries for which drug pricing information is widely and publicly available as a benchmark[2,49,50,51]; and

Whereas, Over the five years of its implementation, the proposed model is expected to save $17.2 billion overall including $3.4 billion in direct out-of-pocket savings without changing Medicare Part B’s benefit structure[50,51]; and

Whereas, The AMA has expressed concern that the involuntary nature of the trial program may pose risks to patient access to necessary medications should third party vendors be unable to negotiate prices for drugs that fall at or under Medicare’s target price for reimbursement[52]; and

Whereas, Existing AMA Policy (H-110.997, H-110.988, H-110.987, D-110.993, H-110.991, D-110.988, H-110.998, D-330.954) highlights the AMA’s continuing commitment to lowering prescription drug costs, so long as physician freedom of choice is preserved and appropriate incentives for pharmaceutical research and development are maintained; therefore be it

RESOLVED, That our AMA amend Policy H-110.987 by addition to read as follows:

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 will support trial programs using international reference pricing for pharmaceuticals as an alternative drug reimbursement model for Medicare, Medicaid, and/or any other federally-funded health insurance programs, either as in individual solution or in conjunction with other approaches. (Modify Current HOD Policy)

Fiscal Note:

Received: 08/28/19

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RELEVANT AMA POLICY

Cost of Prescription Drugs H-110.997
Our AMA:(1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs; (2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in

making these choices; (3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products; (4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies; (5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies; (6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and (7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.
Citation: BOT Rep. O, A-90 Sub. Res. 126 and Sub. Res. 503, A-95 Reaffirmed: Res. 502, A-98 Reaffirmed: Res. 520, A-99 Reaffirmed: CMS Rep. 9, I-99 Reaffirmed: CMS Rep.3, I-00 Reaffirmed: Res. 707, I-02 Reaffirmation A-04 Reaffirmed: CMS Rep. 3, I-04 Reaffirmation A-06 Reaffirmed in lieu of Res. 814, I-09 Reaffirmed in lieu of Res. 201, I-11 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: BOT Rep. 14, A-18

Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988
1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs.
2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients.
3. Our AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs.
4. Our AMA supports measures that increase price transparency for generic prescription drugs.
Citation: Sub. Res. 106, A-15 Reaffirmed: CMS 2, I-15 Reaffirmed in lieu of: Res. 817, I-16 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: BOT Rep. 14, A-18

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.
Citation: CMS Rep. 2, I-15 Reaffirmed in lieu of: Res. 817, I-16 Appended: Res. 201, A-17 Reaffirmed in lieu of: Res. 207, A-17 Modified: Speakers Rep. 01, A-17 Appended: Alt. Res. 806, I-17 Reaffirmed: BOT Rep. 14, A-18 Appended: CMS Rep. 07, A-18 Appended: BOT Rep. 14, A-19 Reaffirmed: Res. 105, A-19

Reducing Prescription Drug Prices D-110.993
Our AMA will (1) continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs; and (2) encourage state medical associations and others that are interested in pharmaceutical bulk purchasing alliances, pharmaceutical assistance and drug discount programs, and other related pharmaceutical pricing legislation, to contact the National Conference of State Legislatures, which maintains a comprehensive database on all such programs and legislation.
Citation: CMS Rep. 3, I-04 Modified: CMS Rep. 1, A-14 Reaffirmation A-14 Reaffirmed in lieu of Res. 229, I-14

Price of Medicine H-110.991
Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard.
Citation: CMS Rep. 6, A-03 Appended: Res. 107, A-07 Reaffirmed in lieu of: Res. 207, A-17 Appended: Alt. Res. 806, I-17 Reaffirmed: BOT Rep. 14, A-18 Appended: CMS Rep. 07, A-18 Reaffirmation: A-19 Appended: Res. 126, A-19

Prescription Drug Price and Cost Transparency D-110.988
1. Our AMA will continue implementation of its TruthinRx grassroots campaign to expand drug pricing transparency among pharmaceutical manufacturers, pharmacy benefit managers and health plans, and to communicate the impact of each of these segments on drug prices and access to affordable treatment.
2. Our AMA will report back to the House of Delegates at the 2018 Interim Meeting on the progress and impact of the TruthinRx grassroots campaign.
Citation: Alt. Res. 806, I-17

Cost of New Prescription Drugs H-110.998
Our AMA urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs.
Citation: Res. 112, I-89 Reaffirmed: Res. 520, A-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmed in lieu of Res. 229, I-14

Prescription Drug Prices and Medicare D-330.954
1. Our AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs.
2. Our AMA will work toward eliminating Medicare prohibition on drug price negotiation.
3. Our AMA will prioritize its support for the Centers for Medicare & Medicaid Services to negotiate pharmaceutical pricing for all applicable medications covered by CMS.
Citation: Res. 211, A-04 Reaffirmation I-04 Reaffirmed in lieu of Res. 201, I-11 Appended: Res. 206, I-14 Reaffirmed: CMS Rep. 2, I-15 Appended: Res. 203, A-17