AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Michael C. Burgess, MD
Chairman
Subcommittee on Health
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515-6115

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Burgess and Ranking Member Green:

Thank you for the opportunity to testify before the Committee on Energy and Commerce Subcommittee on Health during the hearing entitled, "Examining the Drug Supply Chain." The American Medical Association (AMA) applauds your leadership and efforts to identify and address the factors, policies, and practices that impact access and affordability of medically necessary medication treatment for patients. The hearing was extraordinarily helpful to advancing informed public policy discussions. The AMA looks forward to working closely with you to identify and implement workable solutions.

Below are the AMA's responses to the follow-up questions posed by the Honorable Congressmen Earl L. "Buddy" Carter and Frank Pallone, Jr.:

The Honorable Earl L. "Buddy" Carter
Does your organization support increased transparency into the following aspects of the drug supply chain? Yes or No will suffice.

As outlined in my written testimony, the AMA strongly supports increased transparency. And, based on the hearing testimony, we support increased transparency in light of the complex policies and practices among insurers, distributors, pharmaceutical benefits managers (PBMs), and pharmacies.

1. Rebate pass throughs. *Yes, the AMA strongly supports increased transparency.*
2. PBM "Spread" Profits. *Yes, the AMA strongly supports increased transparency.*
3. Generic Drug Reimbursement Methodologies. *Yes, the AMA strongly supports increased transparency.*
4. True price for prescription drug at point of sale. *Yes, the AMA strongly supports increased transparency.*
5. Pharmacy Direct and Indirect Remuneration ("DIR") fees. *Yes, the AMA strongly supports increased transparency.*

The Honorable Frank Pallone, Jr.
I understand that the AMA has been supportive of a ban on direct-to-consumer advertising. Can you explain why your organization and your members support a ban, and how you think a ban could help to address rising drug costs?

The following is the actual language of policies adopted by our House of Delegates (HOD) addressing this issue. The HOD is comprised of every national medical specialty society and state medical association, and has adopted extensive policies on the topic of direct-to-consumer marketing that are the most responsive to the questions posed. In brief, during the numerous HOD discussions of policy related to direct-to-consumer marketing, physician delegates regularly cited concerns that such advertising may have some benefits, but noted that such advertising often diverts the very limited time patients and physicians have together to discussions that are not relevant to a patient's diagnosis or to medically necessary and reasonable treatment options. In addition, during the AMA policy development process, physicians have also observed that the drugs promoted through such methods often do not have the same documented risk profiles of more established and often less expensive treatment options. Physician representatives have also noted during these discussions that such marketing may create unrealistic expectations when less expensive albeit equally effective treatments are available. Throughout the policy discussion about the impact on patient health outcomes and the physician-patient relationship, there is a generalized concern that the advertising promotes more expensive, costly treatment alternatives when less expensive alternatives with established risk profiles and evidence of relative efficacy among a larger and more diverse patient population are available.

The specific policies:

Direct-to-Consumer Advertisement of Prescription Drugs*
Direct-to-consumer advertising may raise awareness about diseases and treatment and may help inform patients about the availability of new diagnostic tests, drugs, treatments, and devices. However, direct-to-consumer advertising also carries the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patients' health and safety, and compromising patient physician relationships. In the context of direct-to-consumer advertising of prescription drugs, physicians individually should:
(a) Remain objective about advertised tests, drugs, treatments, and devices, avoiding bias for or against advertised products.
(b) Engage in dialogue with patients who request tests, drugs, treatments, or devices they have seen advertised to:

> *(i) assess and enhance the patient's understanding of the test, drug or device;*
> *(ii) educate patients about why an advertised test, drug, or device may not be suitable for them, including providing cost-effectiveness information about different options.*

(c) Resist commercially induced pressure to prescribe tests, drugs, or devices that may not be indicated.
(d) Obtain informed consent before prescribing an advertised test, drug, or device, in keeping with professional standards.
(e) Deny requests for an inappropriate test, drug, or device.
(f) Consider reporting to the sponsoring manufacturer or appropriate authorities direct-to-consumer advertising that:

> *(i) promotes false expectations;*
> *(ii) does not enhance consumer education;*
> *(iii) conveys unclear, inaccurate, or misleading health education messages;*
> *(iv) fails to refer patients to their physicians for additional information;*
> *(v) does not identify the target population at risk;*
> *(vi) encourages consumer self-diagnosis and treatment.*

Collectively, physicians should:

(g) Encourage and engage in studies that examine the impact of direct-to-consumer advertising on patient health and medical care.
(h) Whenever possible, assist authorities to enforce existing law by reporting advertisements that do not:

> *(i) provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition;*
> *(ii) clearly explain warnings, precautions, and potential adverse reactions associated with the drug product;*
> *(iii) present summary information in language that can be understood by the consumer*
> *(iv) comply with applicable regulations;*
> *(v) provide collateral materials to educate both physicians and consumers.*

**AMA Principles of Medical Ethics. (The Opinions are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.)*

Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices
1. To support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices.
2. That until such a ban is in place, our AMA opposes product-claim DTCA that does not satisfy the following guidelines:

> *(a) The advertisement should be indication-specific and enhance consumer education about the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used.*
> *(b) In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the advertisement should convey a clear, accurate and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug's or device's approval for marketing.*
> *(c) The advertisement should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products.*
> *(d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as "Your physician may recommend other appropriate treatments," is recommended.*
> *(e) The advertisement should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well as its cognitive accessibility, should be comparable.*
> *(f) The advertisement should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without distraction of content, and will help facilitate communication between physician and patient.*
> *(g) The advertisement should not make comparative claims for the product versus other prescription drug or implantable medical device products; however, the advertisement should include information about the availability of alternative non-drug or non-operative management options such as diet and lifestyle changes, where appropriate, for the disease, disorder, or condition.*

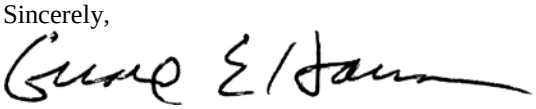
(h) In general, product-claim DTCA should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care professionals in DTCA, a disclaimer should be prominently displayed.
(i) The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.
(j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved.
(k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines.

3. That the FDA review and pre-approve all DTCA for prescription drugs or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product.
4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTCA.
5. That DTCA for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device product's sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.
6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTCA.
7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.
8. That our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.
9. That our AMA encourages physicians to be familiar with the above AMA guidelines for product-claim DTCA and with the Council on Ethical and Judicial Affairs Ethical Opinion E-9.6.7 and to adhere to the ethical guidance provided in that Opinion.
10. That the Congress should request the Agency for Healthcare Research and Quality or other appropriate entity to perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is detrimental to the public health, the Congress should consider enacting legislation to increase DTCA regulation or, if necessary, to prohibit DTCA in some or all media. In such legislation, every effort should be made to not violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.
11. That our AMA supports eliminating the costs for DTCA of prescription drugs as a deductible business expense for tax purposes.

12. That our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical and medical device industries to make policy changes regarding DTCA, as necessary.
13. That our AMA supports "help-seeking" or "disease awareness" advertisements (i.e., advertisements that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA).
14. Our AMA will advocate to the applicable Federal agencies (including the Food and Drug Administration, the Federal Trade Commission, and the Federal Communications Commission) which regulate or influence direct-to-consumer advertising of prescription drugs that such advertising should be required to state the manufacturer's suggested retail price of those drugs.

Thank you for considering the AMA's testimony and responses to the questions posed.

Sincerely,



Gerald E. Harmon, MD

cc: James L. Madara, MD