REPORT OF THE BOARD OF TRUSTEES

B of T Report 14-JUN-21

Subject: Pharmaceutical Advertising in Electronic Health Record Systems

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Referred to: Reference Committee B

INTRODUCTION

At the 2019 Interim Meeting Policy D-478.961, "Pharmaceutical Advertising in Electronic Health Record Systems," was adopted by the House of Delegates (HOD). The policy directs our American Medical Association (AMA) to study the prevalence and ethics of direct-to-physician advertising at the point of care, including advertising in electronic health record (EHR) systems.

This report provides information about the prevalence and ethical implications of direct-to-physician pharmaceutical advertising, with specific attention to advertisements and alerts in the EHR.

BACKGROUND

Pharmaceutical companies have a long history of marketing to physicians in the clinical setting. In recent years access to physicians has become more challenging for pharmaceutical companies—nearly half of physicians restrict visits from pharmaceutical sales representatives.[1] Perhaps making up for the decline in direct access, the amount of money spent on marketing and advertising to physicians continues to increase. Pharmaceutical companies spent $20.3 billion on marketing to physicians in 2016 through advertisements, samples, direct payments, personal visits and gifts from pharmaceutical representatives, up from $15.6 billion 20 years earlier.[2] Spending on advertising in digital channels such as search engines and social media platforms also continues to increase.[3] The EHR system has risen as a unique opportunity to directly provide information about prescription drugs to prescribers, given that physicians spend more than 15 minutes per patient in the EHR.[4] However, there are ethical concerns with pharmaceutical advertising in the EHR, and whether this is a common practice or a sustainable business model for EHRs has yet to be explored.

AMA POLICY

The AMA supports the American pharmaceutical manufacturing industry in its efforts to develop and market pharmaceutical products meeting proper standards of safety and efficacy for the benefit of the American people (Policy H-100.995, "Support of American Drug Industry"). In addition, the AMA supports a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices (H-105.988, "Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices").

AMA *Code of Medical Ethics* Opinion 9.6.7, "Direct-to-Consumer Advertisements of Prescription Drugs," states physicians should remain objective about advertised tests, drugs, treatments, and devices, avoiding bias for or against advertised products. The Opinion also states physicians should

resist commercially-induced pressure to prescribe tests, drugs, or devices that may not be indicated. Although this Opinion does not specifically address physician-directed pharmaceutical advertisements, the substance and meaning are applicable. Similarly, *Code of Medical Ethics* Opinion 9.6.2, "Gifts to Physicians from Industry," asserts that gifts from industry, including pharmaceutical organizations, can create conditions in which professional judgment can be put at risk of bias. This Opinion suggests that to preserve the trust that is necessary in patient care, physicians should decline gifts from entities that have a direct interest in physicians' treatment recommendations. AMA policy also states that no gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices (H-140.973, "Gifts to Physicians from Industry").

In Policy H-175.992, "Deceptive Health Care Advertising," the AMA encourages physicians and medical societies to monitor and report to the appropriate state and federal agencies any health care advertising that is false and/or deceptive in a material fact and encourages medical societies to keep the Association advised as to their actions relating to medical advertising.

To mitigate adverse effects of pharmaceutical advertisements on women's health, the AMA also urges the FDA to assure that advertising of pharmaceuticals to health care professionals includes specifics outlining whether testing of drugs prescribed to both sexes has included sufficient numbers of women to assure safe use in this population and whether such testing has identified needs to modify dosages based on sex (Policy D-105.996, "Impact of Pharmaceutical Advertising on Women's Health).

DISCUSSION

Pharmaceutical industry influence on physicians

Pharmaceutical companies spend billions of dollars every year trying to influence physicians through a variety of tactics. For decades, physicians have been a prime target for pharmaceutical advertisers, made evident by the frequent placement of ads in medical journals. Pharmaceutical companies historically have had a presence in physician offices through visits by sales representatives, gifts, drug samples, sponsorship of continuing medical education, token items such as notepads and pens, and more valuable incentives such as travel or dinners. This access to physicians gave these companies key opportunities to influence physicians' prescribing behaviors.

Although they still accept payments, gifts, samples, and other incentives from pharma, most physicians do not believe they are affected by pharmaceutical industry interactions and believe they are immune to the influence of their marketing strategies.[5] Multiple studies, however, have found associations between exposure to information provided by pharmaceutical companies and higher prescribing frequency, higher costs, or lower prescribing quality.[6] For example, exposure to physician-directed advertising has been shown to be associated with less effective, lower-quality prescribing decisions.[7] This evidence suggests that some physicians, particularly those faced with interactions with pharmaceutical advertising, are susceptible to influence by various types of interactions with pharmaceutical companies, whether it be from gifts, payments, sponsorships, drug samples, travel, or research funding. These interactions can influence physicians' clinical decision making, potentially leading to greater prescriptions of certain types of drugs.[5]

Pharmaceutical influence on physician decision-making was tested in a case study by Merck, which partnered with Practice Fusion in a public health initiative to test the incorporation of EHR messages alerting each provider during a patient visit when the patient might be due for a vaccine.[8] The message alerts, while not considered formal advertisements, suggested specific treatment to

prescribers in an intervention group at the point of care, demonstrating that the alerts functioned primarily to influence prescriber behavior. The test program, which included more than 20,000 health care providers divided into intervention and control groups, led to a 73 percent increase in recorded vaccinations and the administration of more than 25,000 additional vaccines. Whether the increase in vaccinations is a positive outcome is not the question to be debated in this report; however, the appropriateness of the pharmaceutical company's influence in the decisions about patient care should be questioned.

Prevalence of advertising in the EHR

One health care marketing agency that focuses in part on pharmaceutical clients described the EHR as an opportunity to influence the prescribing decision with advertisements. In its report, they describe banner advertisements within the administrative or consultation workflow as reminders that can be targeted by physician specialty, geography, past prescribing behavior, patient demographic, current therapy, or diagnosis. Their report continues, "When a [health care provider] is reached in a clinical prescribing environment, the opportunity to impact behavior is greater." The agency recommends prioritizing the moment within either the health records or e-prescribing interface that is most meaningful based on brand objective.[9] It is clear from these descriptions that the patient-physician visit, particularly a vulnerable moment such as the discussion of medications, is viewed by pharmaceutical marketers as an opportunity for financial gain.

It is estimated there are currently more than 300 EHR system vendors in the U.S.[10] The vast number of EHR products makes it challenging to determine the exact number of ad-supported EHRs. It is known to pharma marketers that the largest EHRs do not have a business model that supports advertising.[9] Physician advisers to the AMA were consulted about the presence of advertisements in the top five EHR systems, which comprise 85 percent of the market share.[11] None were aware of advertisements featured in these commonly used platforms. There may be a small portion of the remaining 15 percent of EHR platforms that generate revenue through ads, but currently only a handful offer partnerships with pharmaceutical companies.[10]

Considering the volume of information required in pharmaceutical advertisements to health care professionals, as regulated by the FDA[12], pharmaceutical manufacturers and advertisers may look for other means by which to promote their products at the point of care. In addition to traditional banner ads, there are points of interaction between a prescriber and the EHR throughout the clinical encounter that present opportunities for promotion of specific pharmaceuticals, such as clinical decision support (CDS) alerts in the patient information screens. Information about specific drugs may also appear during the prescribing workflow in an e-prescribing system.

Practice Fusion, a San Francisco-based company that was purchased by Allscripts in 2018, was a free EHR software that provided space for pharmaceutical text and banner ads within certain screens of the EHR.[13] Practice Fusion was found to be the market share leader for solo and small practices in 2015.[14] In a broad search of articles about free or low-cost EHRs featuring an ad-supported revenue model, Practice Fusion is repeatedly referenced as the prime example and is the only EHR consistently mentioned throughout the literature.

Although many articles referenced Practice Fusion in positive light and touted it as an innovative solution to the decrease in access to physicians, they all pre-dated recent legal developments involving Practice Fusion. In early 2020, after months of federal investigation, Practice Fusion admitted to soliciting and receiving kickbacks from a major opioid manufacturer, later discovered to be Purdue Pharma, in exchange for CDS alerts that promote unnecessary opioids at the point of prescribing in their EHR system.[15] The Pain CDS in Practice Fusion's EHR displayed alerts more

than 230,000,000 times between 2016 and 2019. Health care providers who received the Pain CDS alerts prescribed extended release opioids at a higher rate than those that did not,[16] suggesting that the alerts succeeded in influencing prescribing behavior.

This activity by Practice Fusion demonstrates how the EHR can present opportunities for stakeholders to abuse the system, inappropriately influence physicians' decisions, and put patients at risk. The practice of generating revenue by placing advertisements in the EHR was a key feature of the system developed by Practice Fusion. Like the CDS alerts, the ads were tailored to display information about specific drugs, using patient and physician data and targeting the prescriber at the point of care. This ad-supported business model was abandoned by Practice Fusion in 2018 after its purchase by Allscripts.[17]

The literature search conducted in writing this report showed no evidence that ad-supported EHRs have a significant presence in the EHR market or are on the rise. There was little to no mention of specific ad-supported EHRs other than articles written about Practice Fusion, suggesting this single company, which is now virtually defunct, had the bulk of this market captured. The conduct of Practice Fusion and its extreme consequences may, for other EHR providers, put into question prospective partnerships with pharmaceutical companies and slow potential growth in adoption of ad-supported models.

Advertising in other physician-facing channels

Sometimes during patient encounters physicians require just-in-time education or review of drug indications, dosage, interactions, contraindications, and pharmacology at the point of care. Prescribers may consult with peers and medical experts, search for and read about drug information in an authoritative medical journal, or simply search online for relevant information. In addition, point-of-care medical reference applications, such as Epocrates or Medscape Mobile, provide easy access to drug prescribing and safety information that physicians can use quickly during a patient visit. These applications often feature advertisements for pharmaceutical products. Seventy percent of Epocrates' revenue is from selling point of care pharmaceutical advertising, in the form of "DocAlerts."[18] Anecdotal feedback from physician users of Epocrates suggests that while they appreciate using the app at no cost, they do question the appropriateness of the advertisements.[18,19]

Ethical implications

Advertising at the point of care, through EHRs or other mechanisms, carries the risk of influencing physician judgment inappropriately and undermining professionalism, which may ultimately compromise quality of care and patient trust. While there are few data yet available about the specific influence of advertisements in EHRs, studies do suggest that distributing sample medications to physicians' offices, an indirect form of such advertising, does affect physicians' treatment recommendations in ways that can be problematic. For example, data suggest that physicians who have access to samples prefer prescribing brand name drugs over alternatives, even when the branded sample is not their drug of choice or is not consistent with clinical guidelines. Moreover, as one article has noted, physicians may be "less aware of when they are encountering digital marketing than they are with traditional marketing."[20]

Advertising at the point of care can undermine physicians' ethical responsibility "to provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment."[21] Whether a physician prescribes a medication or device should rest "solely on medical considerations, patient need, and reasonable expectations of effectiveness for the particular patient."[22] By influencing decision making, such advertising can

also undermine physicians' responsibility to be prudent stewards of health care resources and to "choose the course of action that requires fewer resources when alternative courses of action offer similar likelihood and degree of anticipated benefit compared to anticipated harm for the individual patient but require different levels of resources."[23]

There are emerging regulations at the state and federal levels that will require prescription cost information to be visible in the EHR at the point of prescription. While the AMA is largely in support of drug price transparency, and has clear policy encouraging EHR vendors to include features that facilitate price transparency (D-155.987, "Price Transparency"), the availability of this information at the point of care has the potential to influence a prescriber's decision. This potential influence and its effects on prescriber patterns should be considered in future study.

While physicians have a clear ethical responsibility to ensure safe, evidence-based care, developers of EHRs also have ethical responsibilities to patients. The stated goal of electronic records is to facilitate seamless patient care to improve health outcomes and contribute to data collection that supports necessary analysis[24]—not to serve as a vehicle for promoting the interests of third parties. Practices and health care institutions that deploy EHRs have a corresponding responsibility to ensure that their record systems are directed in the first instance to serving the needs of patients.

Implications for patient safety

Studies of advertising in EHRs were not identified at the time of writing this report, so it is premature to describe or quantify associated patient safety risks. However, physician-directed pharmaceutical advertising has been commonplace in medical journals for decades, and there is an abundance of research about the implications for patient safety and ethics of such ads. Pharmaceutical advertisements, including those in medical journals, are regulated by the Food and Drug Administration (FDA). A 2011 cross-sectional analysis of medical journals evaluated the adherence of these advertisements to FDA regulations. The analysis showed few physician-directed journal advertisements adhered to *all* FDA guidelines and over half of them failed to quantify serious risks of the advertised drug.[25] Given the high risk associated with many advertised drugs, and the observation that many ads do not adhere to FDA regulations or disclose known risks, any propensity of pharmaceutical ads to influence prescribing—regardless of the channel—may pose threats to patient safety. Thus, it is up to the physician or prescriber to base their prescribing decisions on clinical evidence and sound judgment, rather than marketing tactics.

The Practice Fusion scheme is a prime example of an EHR vendor allowing commercial interests to take precedence over patient safety. Although CDS tools are not advertisements in the traditional sense, if the drug information in the CDS popup is presented in a way that the prescriber has little choice but to view the product displayed, it is in effect an advertisement. The U.S. Department of Justice highlighted the risk to patient safety in its January 2020 press release. "During the height of the opioid crisis, the company took a million-dollar kickback to allow an opioid company to inject itself in the sacred doctor-patient relationship so that it could peddle even more of its highly addictive and dangerous opioids. The companies illegally conspired to allow the drug company to have its thumb on the scale at precisely the moment a doctor was making incredibly intimate, personal, and important decisions about a patient's medical care, including the need for pain medication and prescription amounts."[26]

Implications for physician and patient data privacy

There are important implications for the privacy of physician prescribing data and patient data when it is used by advertisers to provide timely patient-specific advertisements. If an EHR vendor

is collecting and sharing prescribing patterns of an individual physician, or even specific patient information, with the pharmaceutical company, this invites the risk of physician and/or patient data misuse. Currently, there is little known about what data is being collected for this purpose, to whom it is being provided, and how it is being used.

The AMA published privacy principles that define what it considers appropriate guardrails for the use of patient health information outside the traditional health care setting. The principles shift the responsibility for privacy from individuals to data holders, meaning that third parties who access an individual's data should act as responsible stewards of that information, just as physicians promise to maintain patient confidentiality.[27] It is AMA's position that these principles apply to any entity that collects, retains, and uses patient and/or physician prescribing data for marketing and other purposes.

CONCLUSION

Although some EHRs and e-prescribing programs may present opportunities for advertisers to inappropriately influence patient care, they appear to have a small presence in today's EHR market. And while pharmaceutical companies continue to advertise to physicians through other digital channels, such as journals or medical reference applications, prescribers should continue to provide care and prescribe treatments using evidence-based information and their best judgment, and practices should be intentional in deploying systems that function primarily to serve patient care. There is little evidence that ad-supported EHR systems are highly prevalent or gaining popularity. However, where pharmaceutical advertisements *are* present at the point of care, they can present significant threats to patient safety and the integrity of patient care. In addition, it is evident that despite prescribers' best intentions there are instances in which decision-making can be influenced by external factors such as CDS alerts or advertisements. Considering the information presented in this report, it is recommended that AMA establish policy opposing the practice of pharmaceutical advertising in electronic systems used at the point of care and continue to monitor the practice in the future.

RECOMMENDATIONS

The Board of Trustees recommends that Policy D-478.961 be amended as follows and the remainder of the report be filed:

Our AMA: (1) opposes direct-to-prescriber pharmaceutical and promotional content in electronic health records (EHR); and (2) opposes direct-to-prescriber pharmaceutical and promotional content in medical reference and e-prescribing software, unless such content complies with all provisions in Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices (H-105.988); and (3) encourages the ~~federal government to~~ study of the effects of direct-to-~~physician~~prescriber advertising at the point of care, including advertising in ~~Electronic Health Record Systems~~ (EHRs~~)~~, on physician prescribing, patient safety, data privacy, health care costs, and EHR access for ~~small~~physician practices.~~; and (2) will study the prevalence and ethics of direct-to-physician advertising at the point of care, including advertising in EHRs.~~

Fiscal note: Less than $500

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