agencies, clinicians, medical professional organizations, and patient advocacy groups should readily endorse and demand.

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In Reply—Electronic Health Records and Drugs Prescribed for Off-label Indications

We thank Dr Porter for his letter to the editor that highlights an emerging yet underrecognized form of off-label promotion that could undermine clinical care and population health outcomes. Dr Porter describes the presence of off-label prescribing information embedded in the commercial electronic health record (EHR) systems at his institution, a phenomenon that is likely pervasive across medical facilities throughout the country and a practice that may be influencing the prescribing habits of tens of thousands of physicians every day.

Dr Porter describes several real-life instances of questionable off-label indications (those not approved by the US Food and Drug Administration [FDA]) embedded in the indications module content of an EHR system at a major academic medical center. He also details 3 key risk factors for patient safety: (1) inclusion of off-label uses that are not approved by the FDA and that lack sufficient evidence, (2) possible exclusion of some FDA-approved indications, and (3) lack of differentiation between listed indications that are FDA approved vs those that are off-label. This raises a critical question: Who decides what is included in an EHR drug information module, and how are those decisions made?

It turns out that inclusion of off-label prescribing information in EHRs—health information technology systems that are now becoming the new norm in clinical decision making and directly enabling electronic prescribing—is an area that lacks sufficient transparency, regulation, and oversight. Critical decisions about off-label prescribing—ie, decisions that could adversely impact clinical care, result in a higher number of adverse events, and lead to waste and poor utilization of drugs—appear to be in the exclusive purview of drug data vendors themselves. These vendors, in turn, make decisions on inclusion using internal staff and editorial review boards and use these proprietary modules to compete for business. They also appear to unfairly rely on astute clinicians, like Dr Porter, to correct and remove unsubstantiated indications, a process that is inefficient and begs for greater quality processes and rigor on the part of drug knowledge base vendors and contractors that populate EHRs with drug prescribing information.

Importantly, the problem identified by Dr Porter is emblematic of a larger battle in our medical legal and regulatory environment. As detailed in our June commentary in this journal on the court decision *Amarin v FDA*[1] and as discussed in subsequent commentaries in journals such as the *New England Journal of Medicine*[2] and *JAMA Internal Medicine*,[3] recent court decisions have consistently eroded the FDA's regulatory authority over off-label promotion activities. This is happening despite hundreds of millions of dollars in off-label fraud and abuse settlements successfully prosecuted by the US Department of Justice, many of which involved egregious off-label marketing that has directly endangered patients (such as promoting a drug for an indication or patient population with a "black box" warning).[4]

At the heart of this debate is a simple question: Should the FDA evaluate and oversee the truthfulness and veracity of drug product claims or should this be left to decisions by the courts and/or self-regulation by manufacturers? This question now extends to EHRs, with court decisions like *Amarin* stripping away the FDA's ability to vigorously regulate how commercial entities like EHR data vendors market and disseminate off-label information. It also raises a more fundamental issue: should commercial free speech be constitutionally protected, even when it potentially endangers public health?

Collectively, we argue that leaving important scientific and clinical decisions about off-label promotion in the hands of commercially driven entities endangers the checks and balances of the FDA's drug approval processes that emphasize safety and efficacy. It also compromises the important role of clinicians as the learned intermediary because the easing of off-label regulation, the retreat of FDA oversight, and more selective US Department of Justice enforcement will likely lead to the proliferation of poor-quality off-label information that clinicians will have to navigate and interpret.[1]

In the case of EHRs and off-label prescribing data, hospital systems that license and pay for technology solutions of questionable quality and usefulness should be the first to take

action in light of current limitations of the regulatory environment. This action includes conducting internal reviews of EHR-based drug indication modules to evaluate how they present off-label indications, particularly to populations at higher risk for off-label prescribing behavior (eg, patients with cancer, those with rare diseases, and pediatric populations).[5] They should also only contract with data providers that have clear and transparent policies regarding off-label information inclusion criteria, that agree to external oversight and audit of their review committees/editorial boards, and that commit to working directly with their stakeholders (including hospital administrators, clinicians, and other prescribers) to ensure that off-label prescribing information is evidence based. At a minimum, hospital systems should demand that EHR service providers ensure—in a way that is clearly marketed and recognizable in EHR user interfaces—the clear disaggregation of FDA-approved indications vs those that promote off-label uses.

The FDA should also play an active role in addressing this new and emerging challenge in off-label promotion despite recent court decisions, given its potential impact on population health and patient safety. Facilitating regulatory certification of EHR drug prescribing modules while also developing open access data sources for drug indication information (such as publicly available data streams or application program interfaces that provide access and interaction with such data) could be crucial first steps. This process would shift the FDA from a reactive regulatory agency and allow it to become an unbiased and open source for evidence-based prescribing data that could be integrated directly into EHRs. Such actions would improve system interoperability and liberalize what is now fee-based licensed data.

Importantly, the presence of off-label information in EHRs represents the convergence of growing use of health information technology and a changing regulatory environment. Although EHRs and off-label prescribing have a critical role in the practice of medicine, it is important that these systems and policies promote patient safety and positive clinical outcomes, not simply generate profits for data providers and manufacturers.

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Managing Physicians' Medical Brand

To the Editor: We read with interest the recent article in *The Washington Post* entitled "Doctors fire back at bad Yelp reviews - and reveal patients' information online."[1] The overarching theme of the story focused on how physicians have responded to negative online reviews by posting their patients' protected health information in their responses, conveying a theme of physicians vs patients that is a result of perceived negative patient experiences. Clearly, physicians sharing protected information in a public platform is an inappropriate response, and the unethical violation of the Health Insurance Portability and Accountability Act regulations should never be condoned. However, in the current digital environment, how can physicians appropriately and professionally respond to unwelcomed and potentially unfair online evaluations?

In a prior era, negative encounters may have been simply ignored as irrational patient commentary. However, the current social media environment allows individuals the opportunity to relate an experience in a public, transparent manner that can directly promote or punish physicians' medical practices. Mobile and digital platforms allow amplification of the patient voice. The sooner we within the medical profession recognize this evolution, the better we will be prepared to position our practices for success.

Medical professionals can and should be active participants in digital media. A digital presence through social media and online platforms has the ability to influence physicians' referral patterns and grow practices.[2] It is also through an active presence in social media that medical professionals begin to take control of their online reputation or "brand." In large medical organizations, this may mean defining key characteristics that resonate across the organization. In smaller organizations, it may simply mean defining the key attributes of single physicians. In either case, a positive social media presence quickly dilutes negative online comments and reviews.

Professional social media sites like Doximity and LinkedIn allow medical professionals to connect with each other and to define areas of clinical focus, expertise, and training. Twitter (100 million daily logins, 1.3 billion registered users) and Facebook (1.7 billion monthly active users) offer a