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Division of Dockets Management
Dept. of Health and Human Services
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

VIA USPS

CITIZEN PETITION

This petition for administrative action is submitted on behalf of the undersigned Petitioner pursuant to 21 C.F.R. & 10.30 and related relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

The Practice Fusion Lawsuit (see "Statement of Grounds" below) makes it clear that drug companies at times have tried to influence e-prescribing systems and electronic health records. To date, to my knowledge, only the involvement related to opioids has been fully investigated, but it's clear from the evidence available that a somewhat similar approach was used with other medications. I think it's fair to assume that if drug companies are making arrangements to pay EHR vendors to influence e-prescribing systems, that they are doing this to promote their medications, so the FDA should be regulating this involvement.

The intent of e-prescribing and EHR systems and Clinical Decision Support guidances are to provide objective information regarding medication. All of the major Drug Compendium which are involved in e-prescribing systems emphasize that they are free of bias and are not influenced by drug company marketing. Any involvement by drug companies can be presumed to be less objective, since it will be intended to benefit drugs manufactured by that company.

I. ACTION REQUESTED

My request in this Citizen's Petition is that the FDA issue a guidance or a rule to require that any involvement of drug companies with e-prescribing systems, either by way of a "Clinical Decision Support" program or other involvement, in particular if the drug company is paying the EHR or e-prescribe vendor for a particular

action, should be reported to the FDA as promotional, and preferably reviewed by the FDA before implementation.

The FDA should also obtain information about the "14 similar deals" mentioned in the "Statement of Grounds" (below), to evaluate the ways in which drug companies to date have managed to influence e-prescribing and EHR systems.

II. STATEMENTS OF GROUNDS

Several years ago, in what was referred to as the "Practice Fusion Lawsuit" [information can be found on a website from the United States Department of Justice, at https://www.justice.gov/usao-vt/pr/electronic-health-records-vendor-pay-largest-criminal-fine-vermont-history-and-total-145 (a copy of this document is attached)] a drug company was sued and agreed to a large settlement because it somewhat surreptitiously manipulated an electronic prescribing system (part of an electronic health record system) to encourage use of the drug company's opioid pain medication (instead of other opioid pain medications). Practice Fusion was the company that managed the e-prescribing system.

The Practice Fusion Lawsuit was motivated partly by the large number of opioid overdose deaths, but the EHR vendor and the drug company involved did not predict the large number of overdose deaths; the drug company was simply trying to market its products. There's no reason to think that this was done only for opioids or that drug companies did not use similar approaches to market other medications. One of the news sources available online (Fierce Healthcare https://www.fiercehealthcare.com/tech/allscripts-practice-fusion-to-pay-145m-settlement-doj-opioid-case) states "in the civil settlement the DOJ alleges that Practice Fusion had similar deals with other drug companies. Between November 2013 and August 2017 the company struck 14 similar deals with pharmaceutical companies, the government claimed in its civil case. Practice Fusion admitted only to the opioid agreement" (a copy of this article is also attached).

The fact that the government was involved in this case allowed for "discovery", which enabled the prosecutor to get information from the EHR vendor and the drug company to support the allegations. The government apparently has not pursued the other 14 "similar deals" and has not sought "discovery" to look for other ways that drug companies might be influencing EHR's.

With most drug company manipulation of EHR's, one would not expect excessive deaths. The main outcome, and the goal of the drug companies involved, is simply to increase sales of their more expensive newer medications.

All of the major Drug Compendium which are involved in e-prescribing systems emphasize that they are free of bias and are not influenced by drug company marketing. If drug companies influence e-prescribing systems and/or EHR's to increase use of their patented medications, this (I think) should be considered promotion and should then be regulated by the FDA. I think that the FDA should investigate the "14 similar deals" noted above, since one would assume that these too were attempts to increase sales of particular products.

It may be that some drug company promotion involving EHR or e-prescribing systems, intended to increase the use of particular drugs, does not involve direct payments. Rather, it may be more surreptitious, perhaps trying to encourage e-prescribe or EHR systems to focus on side effects or interactions of competitor drugs. But this Citizen's Petition focuses on payments to EHR's or e-prescribing systems.

Some drug company activity may "look like" it's due to a valid clinical concern, e.g., regarding drug interactions or side effects, when it's really promotion. I think it would be helpful to encourage "whistleblowers" in drug companies to notify the FDA if activity which may not initially look like "promotion" is actually promotion, including attempts to reduce use of competitor drugs.

Drug companies appear to unduly influence the drug compendia which create these drug interaction databases [see McKinney R, Abernethy AP, Matchar DB, et al. White paper: Potential Conflict of Interest in the Production of Drug Compendia. (Prepared by the Duke Evidence Based Practice Center under Contract HHSA 290 2007 10066 l.) Rockville, MD: Agency for Healthcare Research and Quality. April 2009, available at: https://pubmed.ncbi.nlm.nih.gov/25392901]. Some of these same drug compendia also compile databases of drug indications used by insurance companies to decide whether to reimburse for drugs for non-FDA approved indications. The McKinney et al paper, commissioned by CMS (Center for Medicaid/ Medicare Solutions), was an attempt by Duke researchers to determine whether drug companies influenced the decision as to whether drugs were approved for additional indications (e.g., whether cancer drugs would be approved for additional types of cancer). They found evidence for considerable concern, caused apparently by a selective literature review, focusing on studies likely to increase drug company profits.

The Practice Fusion Lawsuit involved a comparison among opiates regarding efficacy and risks. There is an FDA guidance, ("Guidance for Industry", available at https://www.fda.gov/media/70844/download) indicating that the FDA can regulate comments that drug companies make regarding competitors. The guidance (third paragraph on page 64096) suggests that company supported activity which relates to "competing products" is more likely to be considered promotional rather than educational.

In summary, drug companies, sometimes in collusion with EHR vendors and e-prescribing systems, should not be manipulating supposedly objective information to increase use of their newer patented medications. The FDA should require that any interaction between drug companies and e-prescribing systems or EHR's be reported to them, and noted as being promotional; this will discourage drug companies from engaging in such behavior. Drug companies would not be inclined to violate an FDA requirement of this type, since there is always a risk that such activity (if not reported to the FDA) would be identified (perhaps by a whistleblower) with an appropriate punishment.

III. ENVIRONMENTAL IMPACT

Petitioner states that the approval requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.R.F. Section 25.30 and 25.31.

IV. ECONOMIC IMPACT

The cost of medication is a large percentage of total medical costs, paid by patients, Medicare, Medicaid, and private insurance companies. Reducing the effect of drug company promotion of expensive new medication, when older generic medications may be just as good, would result in substantial cost savings.

V. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,