U.S. FOOD & DRUG ADMINISTRATION

Jeffrey A. Mattes, M.D.
(b) (6)
[redacted]

October 11, 2023

Re: Docket No. FDA-2022-P-3067

Dear Dr. Mattes:

This letter responds to your citizen petition, which was received by the Food and Drug Administration (FDA) on December 6, 2022 (Petition). The Petition discusses an investigation involving Practice Fusion Inc. (Practice Fusion)[1] and cites an online news article that states Practice Fusion "admitted that it solicited and received kickbacks from a major opioid company in exchange for utilizing EHR [electronic health record] software to influence physician prescribing of opioid pain medications" through the use of "clinical decision support (CDS) alerts."[2] The Petition expresses concern that "drug companies, sometimes in collusion with EHR vendors and e-prescribing systems," may be "manipulating supposedly objective information to increase use" of specific drug products.[3] Consequently, the Petition requests that:

> FDA issue a guidance or a rule to require that any involvement of drug companies with e-prescribing systems, either by way of a [CDS] 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.[4]

The Petition also asks FDA to obtain information about certain arrangements alleged to have been made between Practice Fusion and other pharmaceutical companies that were subject to a civil settlement between the United States government and Practice Fusion.[5]

FDA has carefully considered the issues raised in your Petition. For the reasons stated below, your Petition is denied.

To the extent your Petition is asking FDA to require the submission of promotional communications disseminated through EHR or similar means, FDA already has regulations in place that require the submission of promotional communications for human prescription drugs to FDA made by, or on behalf of, manufacturers, packers, and distributors (collectively, firms). Under 21 CFR 314.81(b)(3)(i), "specimens of mailing pieces and any other labeling or advertising devised for the promotion of a drug product" (collectively, promotional

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[1] Petition at 1-2.
[2] Landi H, *Practice Fusion to pay $145M settlement for taking kickbacks aimed at increasing opioid prescriptions* (January 27, 2020) available at https://www.fiercehealthcare.com/tech/allscripts-practice-fusion-to-pay-145m-settlement-doj-opioid-case.
[3] Petition at 4. We interpret the Petition's use of the term "drugs" to describe human drugs.
[4] Id. at 1-2.
[5] Id. at 2.

communications) must be submitted to FDA using Form FDA 2253 "at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product."[6] Consequently, when promotional communications are disseminated through EHR software or similar means by, or on behalf of, firms, submission of these promotional communications to FDA is required at the time of initial dissemination under FDA's regulations. Thus, FDA believes the Petition's concerns about the disclosure to FDA of promotional communications made by, or on behalf of, firms through EHR or e-prescribing software are addressed by our existing regulations.

Further, to the extent your Petition is asking FDA to issue a guidance or a rule to require that any involvement of drug companies with e-prescribing systems by way of software, including CDS software, be reported to or reviewed by FDA,[7] FDA already regulates software, including CDS software, when it meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h)). Pursuant to section 520(o)(1)(E) of the FD&C Act (21 U.S.C. 360j(o)(1)(E)), certain CDS software is excluded from the definition of a device; FDA issued guidance on "Clinical Decision Support Software," which clarifies the types of CDS software functions that are excluded from the device definition.[8] Thus, FDA believes the Petition's concerns about FDA review of certain software functions that are devices are appropriately addressed by our existing statutory authority, regulations, and guidances.[9]

We also highlight FDA's Bad Ad Program, which is an outreach program that includes a continuing education course and other resources designed to help healthcare providers recognize potentially false or misleading prescription drug promotion.[10] The Bad Ad Program also provides avenues to report potentially false or misleading prescription drug promotion to FDA. Reporting through the Bad Ad Program is among the ways that FDA can become aware of promotional communications that were not properly submitted to FDA as required under the regulations discussed above.

In addition, we deny the Petition's request that FDA "obtain information about" the 13 additional arrangements between Practice Fusion and other pharmaceutical companies "to evaluate the ways in which drug companies to date have managed to influence e-prescribing and EHR systems."[11] To the extent that the Petition is encouraging FDA to

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[6] In limited cases, firms may be required to submit certain draft promotional communications before first use. See, e.g., 21 CFR 314.550 and sections 506(c)(2)(A)(ii) and 506(h)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)(2)(A)(ii); 356(h)(3)(B)) (describing submission requirements for promotional materials related to accelerated approval products and limited population antibacterial and antifungal drugs, respectively).

[7] Petition at 1-2.

[8] See FDA's guidance for industry and FDA staff *Clinical Decision Support Software* (September 28, 2022) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software. FDA's guidances are updated from time to time. For the most recent version of a guidance, check the FDA guidance web page at https://www fda.gov/regulatory-information/search-fda-guidance-documents.

[9] See FDA's Guidances with Digital Health Content available at https://www fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content.

[10] See FDA, *The Bad Ad Program*, available at https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program.

[11] See Petition at 2. The Petition describes "14 similar deals" to the arrangement between Practice Fusion and the opioid company. Id. However, there were 14 relevant arrangements in total between Practice Fusion and

examine these additional agreements to inform the requested guidance or rulemaking, we note that, as discussed above, FDA's existing statutory authority, regulations, and guidances already address the Petition's concerns about disclosure to or review by FDA of firms' promotional communications disseminated through e-prescribing and EHR software, and review by FDA of software that is a device. Finally, to the extent that the Petition is suggesting that FDA should initiate further enforcement action against Practice Fusion, such requests are not within the scope of FDA's citizen petition procedures.[12] Thus, we deny the Petition's request that FDA obtain information about the 13 additional arrangements between Practice Fusion and other pharmaceutical companies.

For the reasons described in this response, the Petition is denied.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2023.10.11 09:16:30 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

pharmaceutical companies related to admitted and alleged CDS alerts designed to increase product sales. See Department of Justice, *Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations* (Jan. 27, 2020) available at https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0.

[12] See 21 CFR 10.30(k).