Collaboration for Research Integrity and Transparency
A PROGRAM OF YALE LAW SCHOOL, YALE SCHOOL OF MEDICINE AND THE YALE SCHOOL OF PUBLIC HEALTH

February 5, 2018

Via Electronic Submission

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Docket FDA-2015-N-2002
Yale Collaboration for Research Integrity and Transparency
Comments on FDA's Amendments to Regulations Regarding "Intended Uses"; Proposed Partial Delay of Effective Date

The Yale Collaboration for Research Integrity and Transparency submits these comments in support of the Food and Drug Administration's *Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"* (Final Rule), published on January 9, 2017.[1] We request that the agency consider implementation of the "intended uses" portions of the Final Rule, rather than delaying implementation of this portion of the Final Rule until further notice, as recently announced.[2]

The new language in the "intended uses" definitions in the Final Rule is appropriate, and adequately describes the FDA's approach to regulating medical products. The "totality of the evidence" language does not lower the evidentiary

[1] 82 Fed. Reg. 2193-2217 (Jan. 9, 2017)
[2] 83 Fed. Reg. 2092 (Jan. 16, 2018)

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standards for enforcement actions against manufacturers, but rather accurately characterizes the manner in which the FDA assesses whether labeling is adequate.

Although the changes to the last sentence of the "intended uses" definitions contained in 21 C.F.R § 201.128 and 21 C.F.R § 801.4 were not included in the Proposed Rule of September 25, 2015, there has now been adequate notice and opportunity to be heard regarding the Final Rule. The new language contained in the final rule accurately conveys the responsibilities of manufacturers with regard to marketing and labeling of medical products.

If the FDA engages in further deliberative process regarding the issue of intended uses and off label marketing, we urge the agency to build on the reasoned approach that it has used in addressing these issues in the past several years, to consider the testimony and written submissions at the two days of public hearing in November 2016, and to adopt the draft guidance documents released in January 2017.[3]

Some commentators have suggested that the FDA should revert to the original September 25, 2015, Proposed Rule that would have eliminated the final sentence of the

[3] U.S. Food and Drug Administration. FDA Memorandum--Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses Of Approved Or Cleared Medical Products. 2017; https://www.regulations.gov/document?D=FDA-2016-N-1149-0040; U.S. Food and Drug Administration. Drug And Device Manufacturer Communications With Payors, Formulary Committees, And Similar Entities –Questions And Answers Guidance For Industry And Review Staff, Draft Guidance. 2017;https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf; U.S. Food and Drug Administration. Medical Product Communications That Are Consistent with the FDA-Required Labeling — Questions and Answers Guidance for Industry, Draft Guidance. 2017; https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537130.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

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"intended uses" definitions contained in 21 C.F.R § 201.128 and 21 C.F.R § 801.4, so that the "knowledge" sentence is removed. We are opposed to the wholesale removal of the "knowledge" sentence, which has been in the regulations for decades. The comments received in response to the FDA proposal to eliminate this part of the definition highlight the need for additional language, rather than less language in the intended uses defintions.

We appreciate the opportunity to comment.

Sincerely,

Margaret McCarthy
Executive Director

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