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February 26, 2018

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

Comments on Center for Devices and Radiological Health; Medical Devices and Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers
Docket No. FDA-2017-N-6730

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, submits these comments with regard to the December 26, 2017, *Federal Register* notice "Center for Devices and Radiological Health; Medical Devices and Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers" (Docket No. FDA-2017-N-6730).[1] The notice sought comment on a proposed program for manufacturer reporting of certain device malfunction medical device reports in summary form — the Voluntary Malfunction Summary Reporting Program.

Of particular concern, the *Federal Register* notice announcing the proposed program stated the following:

> In the MDUFA IV Commitment Letter (Ref. 4), [the Food and Drug Administration (FDA)] and industry agreed to certain goals for streamlining malfunction reporting that would help achieve these benefits. These goals include permitting manufacturers of devices in certain product codes to report malfunctions on a quarterly basis and in a summary format. FDA also agreed to publish a list of device product codes for which manufacturers would be eligible to submit malfunction reports on a quarterly basis and in a summary MDR format As explained in the MDUFA IV Commitment Letter, this list is to include product codes for class II implantable devices and class III devices, as appropriate, and reflect FDA's consideration of a list proposed by industry representatives."

Public Citizen strongly opposes the FDA's proposal to allow voluntary, quarterly malfunction summary reporting for class III devices and those class II devices that are permanently implantable, life-supporting, or life-sustaining. Allowing such summary reports for these moderate- and high-risk devices could allow device manufacturers to obscure — either

[1] 82 FR 60922.

intentionally or unintentionally — important information about individual device malfunction events, which could undermine the ability of the FDA and the public to fully understand the root causes and safety implications of these events.

Before proceeding with the proposed program, Public Citizen urges the FDA to issue another *Federal Register* notice requesting comments that provides a complete list of the Product Classification Codes for those categories of medical devices that will be eligible for voluntary, quarterly malfunction summary reporting. Without this list, it is impossible for members of the public to fully understand the safety implications of the proposed program. Action on the proposed program should be deferred until this additional notice has been published and the FDA has received and considered comments responding to it.

Thank you for the opportunity to comment on this important public health matter.

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