

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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March 22, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

I am writing to request information about the Food and Drug Administration's (FDA) regulation of the HeartWare Ventricular Assist Device (HVAD) System—a heart pump device associated with more than 20,000 patient injuries and 3,000 deaths before it was recalled in June 2021. This long overdue recall arrived too late for too many, including the 2,000 U.S. patients who still have the heart device implanted.¹ I am concerned by FDA's slow action, over multiple administrations, to protect patients from this product despite early warning signs.

The HVAD System, which received FDA approval in November 2012, helped patients with heart failure pump blood to the rest of the body.² The device was either a temporary aid for a patient awaiting a heart transplant, or a permanent solution for a patient ineligible for a transplant.³

In June 2014, FDA issued a Warning Letter after its factory inspection revealed that the device was “adulterated,” meaning it was non-compliant with federal manufacturing standards. Shockingly, FDA knew in 2014 that problems with the device's external controller had been linked to 27 complaints, four injuries, and two deaths, yet FDA simply asked HeartWare to

¹ *Thousands of Patients Were Implanted with Heart Pumps That the FDA Knew Could Be Dangerous*, ProPublica (Aug. 5, 2021) (online at www.propublica.org/article/heartware-patients-implanted-fda).

² Food and Drug Administration, *Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers* (June 3, 2021) (online at www.fda.gov/medical-devices/letters-health-care-providers/stop-new-implants-medtronic-hvad-system-letter-health-care-providers); Food and Drug Administration, *Medtronic Stops Distribution and Sale of HeartWare HVAD System Due to Risk of Neurological Adverse Events, Mortality, and Potential Failure to Restart* (Aug. 12, 2021) (online at www.fda.gov/medical-devices/medical-device-recalls/medtronic-stops-distribution-and-sale-heartware-hvad-system-due-risk-neurological-adverse-events).

³ Food and Drug Administration, *Medtronic Stops Distribution and Sale of HeartWare HVAD System Due to Risk of Neurological Adverse Events, Mortality, and Potential Failure to Restart* (Aug. 12, 2021) (online at www.fda.gov/medical-devices/medical-device-recalls/medtronic-stops-distribution-and-sale-heartware-hvad-system-due-risk-neurological-adverse-events).

verify that HeartWare’s “corrective actions”—editing the patient manual and sending a letter to doctors—were sufficient to address this serious issue.⁴

FDA failed to seize devices, stop HeartWare from selling them, or assess monetary penalties against HeartWare after the 2014 violations and despite continuing violations. A 2018 inspection showed seven separate violations. Three of them had appeared in FDA’s 2014 Warning Letter, but were still unresolved years later.⁵ Even then, the agency did not penalize the manufacturer.⁶

FDA also knew the device was dangerous because it was subject to more Class I recalls than any other high-risk device in FDA’s database. Between 2014 and 2021, the device underwent 15 company-initiated Class I recalls, first for assorted parts, including the external controller and battery cell, and finally for the entire defective system.⁷ A Class I recall takes place when there is a reasonable probability that using the device “will cause serious adverse health consequences or death.”⁸ Ultimately, Medtronic—which acquired HeartWare in 2016—removed the entire HVAD System from the market because it was more likely to cause death and neurological adverse events than other devices on the market, and had caused at least 14 deaths to date.⁹

Despite this troubling history, FDA never directly notified other stakeholder federal agencies of the life-threatening problems with the HVAD System before the device was recalled. Instead, the agency simply added the Warning Letter to an online database containing thousands of other letters, as required. As a result, between the 2014 FDA Warning Letter and the final device recall in 2021, the Centers for Medicare & Medicaid Services and the Department of

⁴ Food and Drug Administration, *Warning Letter FLA-14-14* (June 2, 2014) (online at www.documentcloud.org/documents/21034746-2014-_heartware-inc-6_2_14).

⁵ Food and Drug Administration, *Form FDA-483 Inspectional Observations* (Aug. 7, 2018) (online at www.documentcloud.org/documents/21034745-fla-do-heartware-483-71218_redacted).

⁶ *Thousands of Patients Were Implanted with Heart Pumps That the FDA Knew Could Be Dangerous*, ProPublica (Aug. 5, 2021) (online at www.propublica.org/article/heartware-patients-implanted-fda).

⁷ See, e.g., Food and Drug Administration, *Class I Device Recall HeartWare Ventricular Assist System* (Apr. 27, 2017) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=153628); Food and Drug Administration, *Class I Device Recall Ventricular Assist Device* (July 8, 2016) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=144646); Food and Drug Administration, *Class I Device Recall HeartWare HVAD Pump Implant Kit* (Aug. 6, 2021) (online at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=188071>); *Thousands of Patients Were Implanted with Heart Pumps That the FDA Knew Could Be Dangerous*, ProPublica (Aug. 5, 2021) (online at www.propublica.org/article/heartware-patients-implanted-fda).

⁸ Food and Drug Administration, *Recalls Background and Definitions* (July 31, 2014) (online at www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions).

⁹ MedTech Dive, *Medtronic’s HeartWare HVAD Ending Brings Questions About \$1B Acquisition* (June 8, 2021) (online at www.medtechdive.com/news/medtronics-heartware-hvad-ending-brings-questions-about-1b-acquisition/601452/); Medtronic, *Urgent Medical Device Communication Letter Medtronic HVAD™ System* (June 3, 2021) (online at www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/hvad-urgent-medical-device-notice-june-2021.pdf).

Veterans Affairs spent millions of taxpayer dollars to implant heart patients with a device that FDA officials knew may not be safe.¹⁰

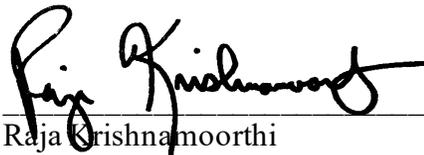
FDA is charged with ensuring patient access to safe, effective, and high-quality medical devices, but over multiple administrations the agency failed to protect consumers from the dangerous HVAD System. The agency likewise failed to adequately share knowledge of the device's defects with other agencies. FDA must take a more proactive role in its regulation of devices that have been the subject of Warning Letters and Class I recalls, and in its communication of product defects to other agencies responsible for patient health.

To assist the Subcommittee in its review of this matter, we request that you provide the following information by April 5, 2022:

1. What regulatory actions, if any, did FDA contemplate in the years after the 2014 Warning Letter, and why did the agency not believe further action was warranted?
2. What steps, if any, is FDA taking to revise its protocols to ensure that other agencies responsible for patient care are directly notified of agency Warning Letters and other critical device defects?
3. What steps, if any, is FDA taking to revise its protocols to ensure that doctors and patients are directly notified of agency Warning Letters and other critical device defects?

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi
Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

¹⁰ *A High-Risk Medical Device Didn't Meet Federal Standards. The Government Paid Millions for More.* ProPublica (Jan. 7, 2022) (online at www.propublica.org/article/a-high-risk-medical-device-didnt-meet-federal-standards-the-government-paid-millions-for-more).