



## Congress Starts Investigation into FDA Regulation of a High-Risk Heart Pump that Has Caused Thousands of Deaths and Injuries

### Description

The Food and Drug Administration (FDA) has a long history of approving unsafe products. The examples are countless and include an [unsafe surgically implanted heart pump](#) that has caused thousands of deaths and injuries. In 2021, these pumps were taken off the market; however, they are too dangerous to remove in patients who have them. Additionally, these patients are reportedly [not getting the assistance they were promised](#) by the FDA or the manufacturer. Now Congress has started an investigation into all of this.

From [ProPublica](#):

---

## Congress Opens Investigation Into FDA's Handling of a Problematic Heart Device

**The investigation follows ProPublica's reporting on safety problems surrounding the FDA and the HeartWare Ventricular Assist Device.**

by [Neil Bedi](#)

A congressional oversight subcommittee [is investigating](#) the Food and Drug Administration's regulation of a high-risk heart pump, citing safety issues [detailed by ProPublica](#).

The HeartWare Ventricular Assist Device, created to treat patients with severe heart failure, stopped meeting key federal standards as early as 2014. But the FDA took no decisive action even as those problems persisted, and thousands of Americans continued to be implanted with the pump.

By the end of 2020, the FDA had received more than 3,000 reports of deaths related to the HeartWare device, according to a ProPublica data analysis. A father of four died as his children tried to resuscitate him when his device suddenly stopped. A teenager died after vomiting blood in the middle of the night, while his mother struggled to restart a faulty pump.

"I am concerned by FDA's slow action, over multiple administrations, to protect patients from this product despite early warning signs," said [Rep. Raja Krishnamoorthi, D-Ill.](#), [in a scathing letter](#) sent Tuesday to the agency's commissioner, Dr. Robert Califf.

Krishnamoorthi, the chairman of the U.S. House Committee on Oversight and Reform's Subcommittee on Economic and Consumer Policy, requested information on how the FDA made regulatory decisions related to the HeartWare device and why it didn't take further action.

The FDA did not provide comment to ProPublica on the subcommittee's investigation and said it would respond directly to Krishnamoorthi. It also reiterated its response to ProPublica's findings and said the agency had been closely overseeing the HeartWare device since 2012, with patient safety as its "highest priority."

Medtronic, the company that acquired HeartWare in 2016, took the device off the market in June 2021. The company said that new data showed a competing heart pump had better outcomes. In response to the ProPublica investigation two months later, the company said it took the FDA's inspections seriously and had worked closely with the agency to address issues with the device.

Medtronic declined to comment on the subcommittee's investigation.

Krishnamoorthi asked in the letter if any steps were being taken to address how patients, doctors and [other federal agencies](#) are notified of problems that the FDA finds with medical devices.

### [\*\*A High-Risk Medical Device Didn't Meet Federal Standards. The Government Paid Millions for More.\*\*](#)

Many patients told ProPublica they were never informed of issues with the HeartWare pump before or after their implants. Some people who still have the device said they [weren't told](#) when it was taken off the market. Medtronic said in December it had confirmed 90% of U.S. patients had received notification of the HeartWare discontinuation, but that it was still working to reach the other 10%.

[About 2,000 patients](#) still had HeartWare pumps as of last year. The FDA and Medtronic recommended against removing those devices barring medical necessity because the surgery to do so carries a high risk.

In his letter, Krishnamoorthi gave the FDA a deadline of April 5 to respond.

---

By B.N. Frank

### **Category**

1. Freedom-Free speech-Resistance & H-rights
2. Health-Wellness-Healing-Nutrition & Fitness
3. Main
4. Politics-Geopolitics-Gov.-Events

### **Date Created**

03/27/2022

---