



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

May 30, 2019

Mr. Joe Kiani
Patient Safety Movement Foundation
15776 Laguna Canyon Rd.
Irvine, CA 92618

Dear Mr. Kiani:

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) writes this letter in support of the principle of openly sharing data reflected by efforts like yours. Openly sharing data with patients, healthcare providers and public health researchers may do the following:

- help empower patients to actively participate in the development and evaluation of medical devices that meet their needs;
- facilitate medical device surveillance and potentially help identify and prevent adverse events; and
- enrich our understanding of the benefits and risks of the technologies, thereby maximizing patient safety.

We write to express our support of sharing data—especially in the interest of protecting patients and promoting public health.

We encourage policymakers, healthcare entities including hospitals, digital health technology companies, medical device manufacturers, and others to share data to support patient safety.

Sincerely,

Jeffrey Shuren, M.D., J.D.

Director

Center for Devices and Radiological Health

cc: Michelle Tarver, M.D., Ph.D., CDRH/OST
Ms. Anindita Saha, CDRH/OST/PAIRS
Bakul Patel, CDRH