Exhibit 1

To: FDA FOIA Officer
Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

From: Katherine Eban, Vanity Fair Magazine
623 11th Street, Brooklyn, NY 11215
EbanVF40@gmail.com
917-821-9634

From: Pearl Steinzor, freelance journalist
527 Old Bridge Tpke #3236
East Brunswick, NJ 08816

From: Breona Couloote, freelance journalist
11 Radstock Ave
Valley Stream, NY 11580

Date: 11/22/2021

Dear FDA FOIA Officer,

We are journalists, working jointly on an article that is proceeding towards publication. It will be significant for public understanding and involve urgent matters of public health. I, Katherine Eban, am a Contributing Editor at Vanity Fair magazine with 25 years of journalism experience. Ms. Steinzor and Ms. Couloote are published, freelance journalists working at my direction.

Under the Freedom of Information Act, 5 U.S.C. § 552, we are each requesting the follow documents:

RECORDS SOUGHT

THE LIVING BRAIN PROJECT

I am requesting all FDA records within any and all divisions, including the Center for Devices and Radiological Health, mentioning “The Living Brain Project” (LBP), also known as “A

Multiscale Investigation of the Living Human Brain," conducted by the Brain and Data Sciences Lab, also known as the "Charney Lab," at the Icahn School of Medicine at Mount Sinai, 1 Gustave L. Levy Place, New York, NY 10029-5674, which includes, but is not limited to:

Clinical Research

1. Any and all study reports by clinical researches pertaining to the review process of "The Living Brain Project, which includes, but is not limited to:
    a. The clinical research design of "The Living Brain Project."
    b. Reports and memos of Clinical Research Phase Studies of "The Living Brain Project."
    c. IND applications to the FDA on "The Living Brain Project."
    d. Reports, emails, letters between the IND FDA Review Team for "The Living Brain Project," including but not limited to: project managers, medical officers, staticians, and pharmacologists.
    e. Approval or delay/hold reports by the FDA review team on "The Living Brain Project."

2. Any and all emails or letters from the clinical research developers to the review team that mentions any new protocols, serious adverse events of side effects such as injury or death during the research and review of "The Living Brain Project."
3. Any and all internal documentation such as emails, letters, reports, analyses, and reviews between the FDA and The Mount Sinai IRB that mentions "The Living Brain Project."
4. Any and all emails, letters, or reports of conflicting interest between medical device companies, Medtronic Inc, and Blackrock Neurotech involving:
    a. Brain H. Kopell, MD, IRB principal investigator
    b. Alexander Charney, MD, PhD, (title)

Medical Devices

1. Any and all emails, letters, applications, requests for review, and reports between medical device companies to the FDA concerning the use of the devices listed in "The Living Brain Project":
    a. Medtronic Inc - Medtronic Activa Tremor Control System P96009
    b. Blackrock Neurotech - Blackrock Neuroport Array System K042384

2. Inspection reports by the FDA of the following devices:
    a. Medtronic Inc - Medtronic Activa tremor Control System P96009
    b. Blackrock Neurotech - Blackrock Neuroport Array System K042384

Inspections

MAUDE DATA

1. Any and all emails, letters, and other forms of communication between 01/01/2013 - date of search that mentions the risk of brain segment removal
2. Inspection reports and findings by the Living Brain Project
3. Review and approval records of medical devices including, but not limited to:
    a. Medtronic Activa Tremor Control System P96009
    b. Blackrock Neurotech Neuroport Array System K042384

Name: Alexander Charney, MD, PhD
City and State: New York, NY

1. Records for inspection between 01/01/2013 - date of search. This includes appendices or other documents, if any, associated with an inspection report mentioning "The Living Brain Project."
2. Any responses from Dr. Charney or his institution pertaining to these inspection reports mentioning "The Living Brain Project," and any documents showing further FDA notifications to Dr. Charney or his institution.
3. Letters or other documents subsequent to these inspections that state what if any later actions FDA took, or the final disposition of this case.
4. Financial reports stating Dr. Charney's monetary entitlement or stakes in Medtronic Inc, "The Living Brain Project," or The Brain and Data Sciences Lab/ the "Charney Lab."

Name: Brian H. Kopell, MD
City and State: New York, NY

1. Records for inspection between 01/01/2013 - date of search. This includes appendices or other documents, if any, associated with an inspection report mentioning "The Living Brain Project."
2. Any responses from Kopell or his institution pertaining to these inspection reports mentioning "The Living Brain Project," and any documents showing further FDA notifications to Kopell or his institution.
3. Letters or other documents subsequent to these inspections that state what if any later actions FDA took, or the final disposition of this case.
4. Financial reports stating Kopell's monetary entitlement or stakes in Blackrock Neurotech, "The Living Brain Project," or The Brain and Data Sciences Lab/ the "Charney Lab."

MOUNT SINAI HOSPITAL (clinical research)

1. Any and all emails, letters, and other forms of communication between principal investigator, Brian H. Kopell, and the IRB at the Icahn School of Medicine at Mount Sinai that mentions "The Living Brain Project," or deep brian stimulation (DBS.)

2. Any and all emails, letters, and other forms of communication between the IRB at the Icahn School of Medicine at Mount Sinai with outside reviewers/experts that mentions "The Living Brain Project," or deep brain stimulation (DBS.)

DEVICES

I am requesting all reports between 03/01/1997 - date of search submitted to MAUDE - Manufacturer and User Facility Device Experience database on medical devices categorized with an Event Type of "Malfunction", "Injury", or "Death" that fits any of the following requirements—

1. The name of the Manufacturer contains "Medtronic" or "MPRI"
2. The Brand Name contains "ACTIVA", "UNKNOWN IMPLANTABLE NEUROSTIMULATOR", "UNKNOWN NEUROSTIMULATOR"

I request that searches of all electronic and paper/manual indices, filing systems, and locations for any and all records relating or referring to the subject of my request be conducted.

REQUEST FOR EXPEDITED PROCESSING

According to 5 U.S.C. § 552(a)(4)(A)(ii), which codified the ruling of Nat'l Security Archive v. Dep't of Defense, 880 F.2d 1381 (D.C. Cir. 1989), the term "a representative of the news media" means any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work and distributes that work to an audience. This is consistent with the definition provided in DoD 5400.7-R C6.1.5.7.1. This means, I, Katherine Eban, should be considered a representative of the news media.

If the fees can not be waived, please inform me of the total charges I owe before completing my request.

If for any reason my request or any portion of my request is denied, please inform me of the reasons for the denial in writing.

Thank you in advance for your time. I look forward to receiving your response to this request within 5 business days as the statute requires.

Sincerely,

Katherine Eban, Pearl Steinzor & Breona Couloote

FDA

LBP:

Clinical Research

1. Review processes research study (any and all divisions including CDRH)
2. Adverse events (injury/death)
3. Internal FDA documentation (specify) related to LBP Mount Sinai IRB

Medical Devices

1. Reviewing medical devices related to the LBP

Inspecting the clinical research

-(possibly) (different division) “records related to the inspection of…”

MAUDE Data:

-DBS malfunctioning

-specific activa device

-include different name of the LBP

-communications (from and to)

-date of search (better language)

-disclosure of conflict of interest (clinical research study)

-any and all communications from the device makers to the fda related to the use of the devices for the LBP