DATE: 7-20-2021 a "TuesDAY"

T**O:** Agents of United States FDA, CDRH, CBER – HHS

SUBJECT: ATTEMPT 2 - ACTION NEEDED- RE:FDA Approved Medical Device

Dear Agent for the US Health and Human Services Administration (HHS) AND/OR FOOD AND DRUG AGENCY (FDA) - "Medical Devices" section, et all.

My name is Susan Neuhart. I am a retired American.

My records reflect this is my SECOND ATTEMPT - to get YOU to HELP ME! – and/or respond - related to the Titanium Aneurysm Clip - installed in my brain - in year 2012 - in Asheville, NC. FIRST ATTEMPT:
(https://hansandcassady.org/FDA-CDRH-CBER-HHS-version-6-7-2021-pdf-VERSION.pdf)

As you are aware - if YOU were able to read my FIRST request (shown) - I need to have my brain "imaged" - using magnetic resonance (MR) technology - related to the SAH/MCA stroke [that] I suffered - in 2012. I am a "survivor" - of that December 2012 stroke event .

However, I do experience VERTIGO - when performing YOGA poses – (that) I must perform daily - to prevent the effects of degenerative disc disease.

As you may know, "VERTIGO" … is known to be a precursor to stroke. Thus, my CURRENT Medical Doctors (a Neurologist

and a Family physician) need me to be "MR imaged" - in a safe manner - so that they can medically advise me.

The Sugita aneurysm clip's manufacturer - or, the manufacturer - of the MR imaging devices - in question – in my previous (6-7-2021) message - have not responded - yet.
[request to Mizuho Medical - Japan]

You may visit my web site - for easy access to my personal research efforts - and, copies of my previous attempts to obtain your - and other agencies assistance. http://hansandcassady.org/
[https://hansandcassady.org/FDA-CDRH-CBER-HHS-version-6-7-2021-pdf-VERSION.pdf]

IN SUMMARY, it appears the US Gov -FDA/HHS has approved medical device technology - for use in America – [that] has the potential to harm some Americans - while simultaneously - failing to **require the medical device manufacturers - to accept continuing responsibility for: the technology [that] they previously deployed - in America**; and, the "installed base" - of American Stroke Survivors - who carry their previous “medical devices” – in our bodies. Yet, continued support is “standard practice” – in America – for most technology products - in use – in mission critical systems.

In fact, **I** had no knowledge [that] the titanium alloy aneurysm clip - placed into my brain - in 2012 - has a "shelf-life" - at all – until my recent research efforts. Indeed, perhaps (the approved “clip”) did not have a “shelf-life” – in 2012 – as MR imaging technology – has evolved – since that year.

Dr. Victor Perry is a talented neurosurgeon - a graduate of Yale University. I am a retired Software Engineering Technical Writer. The "scientists" - who designed and built the titanium alloy aneurysm clip (placed inside me) **may have** known. **But, thus far - they are not responding - to my pleas - for information:**

(https://hansandcassady.org/V2-EMAIL-Mizuho-Medical-PDF-VERSION.pdf)

I REQUEST AGAIN, [THAT] YOU PLEASE "REQUEST" THE MANUFACTURERS - OF THESE "MEDICAL DEVICES" - the aneurysm clips and the MR machines – (shown here) TO DETAIL THEIR PRODUCT'S "LIFE CYCLE" – [that] THEY HAVE DETERMINED BY SCIENTIFIC MEANS - to the American public – that is utilizing – their technology.
[https://hansandcassady.org/SEND-TO-MRI-SAFETY.html]

IF THE DEVICE MANUFACTURERS DO THIS, STEPS CAN BE TAKEN - IN A TIMELY MANNER - TO REPAIR AND/OR REPLACE THE CLIP INSIDE MY (and other Americans) BRAINS (and bodies) - IF NEEDED.

The other issue I raised (first on 6-7-2021) - regarded US medical professionals - being properly informed - and/or reminded - regarding the potential - for NEW "Stronger" TESLA power MR imaging devices (recently approved by the FDA) - to move! [by magnetic flux] previously installed aneurysm clips.

In fact: The previous generation of clips (currently installed in thousands of Americans) were only - approved - for the lower TESLA ("weaker") - previous generation - of MR imaging devices. That is, 1.5 TESLA (and less). In fact, MR diagnostic devices operate AT up to 10 Tesla today. (Nature article). As detailed in my previous message – I was scheduled to be imaged on a 3.0 Tesla Magnetic Resonance Device – when my alert "Patient Safety Team" – prevented this from happening – due to lack of information.

I hope to successfully message (by email) - and alert - ALL of the aspects - of the related MEDICAL DEVICE industry (shown here) – which I uncovered – in my internet search :

https://hansandcassady.org/SEND-TO-MRI-SAFETY.html ;

IF useful - My personal research (NOTES) on the related MEDICAL DEVICE - approved by the FDA - is documented here: https://hansandcassady.org/Brain-Implant-information.html.

I am aware [that] [United States FDA, CDRH, CBER] **may** need to interview me. I am legally disabled (since the 2012 stroke event) and prefer Email contact: SusanCN@handSANDcassady.org - to establish a time and mode. Which, please ONLY suggest a means – that is "documentable" via HTML- which, I may "publish" – on my personal web site. **I will not submit to an unrecorded telephone call.** Please allow sufficient time. I am

VERY “detail oriented … I LOOK FORWARD TO WORKING WITH YOU- TO ADDRESS THE ISSUES PRESENTED.

Please act soon! - to prevent the "harm" - that I was able to avoid - because of the conscientious "Patient Safety Team" assigned to me - at Miami Valley Hospital North - Ohio.

My research indicates, [that] other Americans (**including children!)** have NOT been so lucky. In fact, any human - with metal installed - in their body is at risk; including - **soldiers** – with shrapnel and bullet fragments.

THAT IS, Americans with metals (as “constituents” of systems) – [WHICH] are safe and non-reactive - in a lower Tesla Unit era - may be "unsuspecting" - AS WAS I [that] **the more powerful magnetic systems [approved by the FDA] – can literally move – these metal constituents – inside their bodies.**

For example, my installed (2012) ANEURYSM clip may have been approved -by the FDA (in 1999) for 1.5 maximum Tesla Unit operating environments.
[https://www.accessdata.fda.gov/cdrh_docs/pdf/k990202.pdf]

But, since the records are not specific – I do not know. I only know that I was billed for an aneurysm clip – cited as “Sugita” on my bill.

At a minimum, the "ignorance" - surrounding this dangerous (to some) NEW MRI technology must be

eliminated. Which- I believe, this "ignorance" could be eliminated - with a HHS **National Press Release** - and EDUCATION EFFORT. I noted [that] there is an "education" complement - to the FDA organization:

[https://www.fda.gov/about-fda/cdrh-offices/division-industry-and-consumer-education]

Surely, Americans will clamor for information - about the "SAFETY" - of the metal installed in them - if alerted - and informed – by your offices – using media outlets – available to YOU – about the importance of knowing (exactly) what was installed – to them.

Again, I look forward to working with your agents. Please use my Email – to notify me of specific arrangements:
SusanCN@handSANDcassady.org

Sincerely, - Susan (a retired person – in Ohio)

ps: At this writing – circa 7/20/2021– one FDA person (Jana Delfino) – has responded to my June message. I thanked her. The company – in Japan – that produces (a Sugita Titanium clip) – cited on my hospital billing documents (12-18-2012) – has not responded – yet.

(https://hansandcassady.org/V2-EMAIL-Mizuho-Medical-PDF-VERSION.pdf)