6-7-2021 - a “MONDAY”

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

As already sent to: Xavier Becerra >The Secretary of Health and Human Services - UNITED STATES OF AMERICA [shown here]

SUBJECT: ACTION NEEDED- RE:FDA regulated "Medical Device".

Dear US Agents of (the) United States **FDA**, **CDRH**, **CBER**

My name is: Susan Neuhart. I am a retired American SENIOR. What follows is a version of a message – that I have already sent to: US Health and Human Services Secretary - Xavier Becerra;
VIA his POSTED AGENT: (Jerry.Menikoff@hhs.gov) when I learned [that] Secretary Becerra has authority over your activities – and “final authorization” decisions.

I use this *understanding* “advisedly”. My personal experience is in American private business. IE – I was never a “civil servant” -although I did want to work for the EPA.

I am “retired” – from a long professional career – as a “Software Engineering Technical Writer”. I did NOT document “Medical Device” USE; However, my work experience – is relevant – as I will explain.

Similar (to HHS Secretary **Becerra**) I was the first (of my mother’s seven children) – to attend College. My father died –

related to “Mesothelioma” – when I was ten years old (1964). He had an established business – carpentry AND placing “wall-paper’ coverings in Columbus, Ohio homes. He performed the work himself. He (also) bid and won a contract to remove “asbestos” – from Columbus Public Elementary Schools. I was his “helper” – in the private homes – of Columbus. When he passed, my mother received Social Security “survivors’ benefits” AND some small monthly amount - related to his death - from work with The Columbus Public School System. Despite the money (which fed us) - my mother sank into a very deep depression – at 48 years of age. [PHOTO: Mary & Milo Gerald CassAdy] She task me – when I showed interest – with explaining (to her) – what had happened to my father. I Graduated from the University of Wisconsin’s Green Bay campus – with a B.S. in Environmental Science & Communications (1982). In the course of my education – I learned – and informed my mother – what had harmed my dad.

THE FOLLOWING SPECIFICS ARE RELATIVE TO MY COMPLAINT (THAT - I have already shared with the Secretary & posted to MEDwatch. – confirmation image):

1) I ARRIVED - AS INSTRUCTED - on 5-18-2021 - FOR *"BACK-2-BACK"* MRI & MRA RADIOLOGICAL diagnostic PROCEDURES – as SCHEDULED BY MY MEDICAL DOCTORS [SADIKOV & GOLDSTICK] – AT A LOCAL HOSPITAL (Miami Valley North Ohio)

2) This hospital offers many Magnetic Resonance scanning devices; However, the medical procedures were scheduled (by my doctor's offices) - to take place - UTILIZING the 3 TESLA Magnetic Resonance (MRI) Imaging DEVICES offered.

3) In fact, the scheduled medical procedures did not take place (that day). Because**, A)** I did not possess a "card" - which was requested – by my "MRI Patient Safety Team"; and, **B)** my attempt - to supply [the limited information – [that] I did have] - was NOT accepted. [image cite]

4) After endeavoring for, almost one-hour, to "**find** information" - related to the specific aneurysm clip – [image cite] - installed in my brain (in 2012) - a member of my "Patient Safety Team" - informed me – "with regret"- [that] they could not "go forward" - and, perform the ordered tests - because of a "Tesla concern" [they had]. It was – at this point [that] I was informed the MR scanning device (scheduled to be used on me) was a "3 TESLA" MAGNETIC RESONANCE power unit.

5) Surprised - that I even knew what "Tesla units" were - I re-assured the agent - that - I was capable - of finding the "required information" – to "re-schedule" - and, we parted. **I am in search of this information now – as an assigned "mission".** [PDF] **As you can see (here), I have contacted the "clip's" manufacturer – located in Japan [with sales offices – also in California, USA.]** [https://hansandcassady.org/Brain-Implant-information.html#Mizuho%20Medical%20co%C2%A0Japan%C2%A0%20&%20America] –

THEY HAVE NOT RESPONDED - YET. But **– because my tone – is "polite"; my request is "sincere" – and, I am informed** – I REMAIN HOPEFUL [THAT] THEY WILL RESPOND.

6) I began – trying to "SAFELY re-schedule" – for an MRI (5-18-2021), by doing internet research & documenting my findings. I am capable of creating web sites & HTML pages [albeit slowly] – thus, I did so – to organize and document my efforts – and aid communications – SUCH AS THIS:.
[https://hansandcassady.org/Brain-Implant-information.html]

7) In fact, **prior to my "retirement"** - I was often employed to create END-USER Manuals - for American companies – related to software and/or technology products - they had developed. Such "documentation" was typically deployed – using HTML and web sites.

8) Our current US Secretary of Health and Human Services – has an extensive legal background. **As a "legal professional"** – I felt he **may** know [that] - in addition to providing "INSTRUCTIONS" - for the USE of a product (by the designated "END-USER") - the TECHNICAL WRITER'S responsibilities - often have LEGAL IMPLICATIONS. Specifically – an American PRODUCT'S "END-USER Manual" often contains "warnings" - and statements of *"Failure To Follow"* – which are designed to ANTICIPATE, defend,

ABSOLVE and protect - the issuing company – in a US Court-of-LAW – if necessary.

9) Thus, it is with this experience AND perspective [that] - I did contact Secretary **Becerra** – And, (also) a sense of ALARM! – as I will explain.

10) Specifically, I am legally "dis-abled" -- but almost re-habilitated – from a SAH@MCA stroke event- that occurred [on Dec 18, 2012]. This kind of stroke is statistically rare (in Caucasian women – which, I think I am) – and, few people survive (them – at all) – without some permanent mental and physical disability.

NOTE: My maternal Grandmother is (the) "Zora Elizabeth Sprouse (nee Miller – Roby 1883-1953). She was married to George Sprouse. They had 13 children – before George's death – circa 1928. At which time, my mother – and her siblings – were placed into the Franklin County OHIO Children's Home.

I give this detail – because my survival & rehabilitation (from SAH@MCA stroke) – are "unusual" – I have been told. Moreover, I was born with "Pectus carinatum" – which, I out-grew – at my puberty – as is typical – for persons born with this birth defect. In fact, I became an elementary school tetherball champion – because – one of the last things – my father did – [before his death] was build me a regulation tether ball court – in the "back yard" – of our rented house. This was long before "Venus and Serena Williams". My father did not want a "crippled kid" – and, he believed – what the doctors had said:

"Milo, … brace her … and straighten her – and, some day – she'll be just like any other kid." They did… And, at puberty (when my body started making the correct molecules) I mostly was – "like the other kids" .

11) Indeed, I was (again) very fortunate [that] Victor Perry MD [a neurosurgeon] – was on "emergency duty" – when my Life-Flight helicopter delivered me to the top – of Asheville, NC's Mission Hospital.

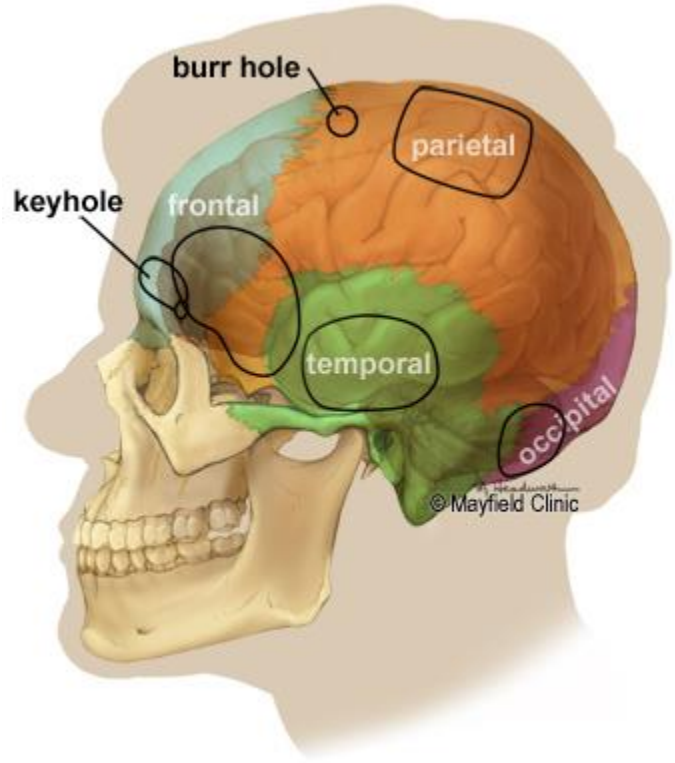
12) Dr. Perry met the helicopter, gave swift instructions, performed the required craniotomy surgery – and installed a FDA approved "aneurysm clip" – to my brain's main cerebral artery – at the site of the burst aneurysm. [SAH@MCA]

13) After the surgery, I was placed into an induced "cold" coma – to enable healing to take place and reduce anticipated swelling.

14) After one month of "intensive care" – I was "phase released" (from the hospital) – to my husband's care. He did a wonderful job! A strong man – until I was able to walk – he carried me. (image Hans)

15) In the next weeks and months – my brain literally rewired itself – related to neural "pathways "– that were disrupted by the required surgical entry [through the Sylvian fissure] – to the areas of interest. If metal screws were used to secure my "craniotomy bone flap"– or remain installed, I do not know.

[https://mayfieldclinic.com/pe-craniotomy.htm]



16) After one year of rest and rehabilitation (in my husband's care) – I began to perform "Yoga poses" – at the suggestion of my Columbus, Ohio neurologist – Xiaosong Zhao, MD- AND, the US Veterans YOGA project.

17) I bought books - related to practicing "YOGA as medicine" – and, continued to physically heal. I purchased a URL and

began to build a web site – [https://hansandcassady.org/] – to engage my mind – in subjects [that] interest me. This includes politics!

18) I very early supported Kamala Harris. Joe is lucky [that] she said "Yes"; and, this encouraged my support for "their team".

19) I made videos in support of their candidacy. I hope [that] they helped. VIDEO My videos are popular – with Seniors – at the YMCA – and, THEY VOTE!…

20) FINALLY, after my recent INTERNET investigation (related to my Aneurysm Clip- installed in 2012) – AND – the 3+ Tesla Magnetic Resonance (MR) imaging device – that, I was scheduled to be "scanned" in [cite], **I AM ALSO - NOW**

AWARE - OF HOW PRECARIOUSLY CLOSE - I CAME - TO BEING EVEN MORE DISABLED - OR KILLED - HAD THE SCHEDULED [MRI/MRA] PROCEDURES GONE FORWARD.

21) REITERATING! …After an ***earnest effort*** - by the members of my "MRI Patient Safety Team" - I was "*regrettably*" informed [that] they were not able to locate information - specific to my installed aneurysm clip - identified

in my 2012 Hospital Discharge Documentation. [cite] – which they had. Indeed, we were all – so "earnest" – "nice" and" polite" (that day). I am certain they had no intentions of harming (or killing) me. **But – had we gone forward – this would have been the result! That is, the aneurysm clip (identified in my hospital discharge/billing document) is approved – by the FDA 1999 – for "UP TO" 1.5 Tesla power. NOTE: *Celia Witten* (** ASSISTANT DIRECTOR - Center for Biologics Evaluation and Research -- ALSO REFERRED TO AS: CBER) is the signatory on the 1999 "FDA" approval document. Thus, I am copying her organization – also.

In SUMMARY, my personal research - SUBSEQUENT TO THE PREVIOUS EVENTS [stated 1 through 21 above] - indicates – [that] an Agency - of US Health and Human Services (the US-FDA) has approved the USE of technology that represents **"A CLEAR AND PRESENT DANGER" to many "unsuspecting" Americans" – when sited in the "profit center" or "diagnostic areas" of a hospital ..**

The record is clear – [cite] Americans have been harmed – by this short-sighted US-FDA decision – to permit the sale AND siting of NEW and MORE POWERFUL MAGNETIC RESONANCE IMAGING DEVICES – IN HOSPITALS – AND DIAGNOSTIC SERVICE CENTERS. I was obviously fortunate – to encounter an ALERT and responsible "Patient Safety Team" – at my local hospital; **however, it should be**

noted: A) I tried to supply information – to encourage them to proceed; B) the team made numerous inquiries (also) – to go forward. AND C) My own doctors scheduled the procedures – on those "3-TESLA" power machines - [that] -had THE SCHEDULED PROCEDURES gone forward – could have moved (by MAGNETIC FLUX) and/or reacted with - the earlier approved aneurysm clip installed in my brain – near my middle cerebral artery.

INDEED - I DO - based on my research - *SIMULTANEOUSLY APPRECIATE* THE DESIRE TO UTILIZE *"IMPROVED TECHNOLOGY"* - AS IS THE CASE - IN THIS INSTANCE. The "results" are more definitive – etc.

HOWEVER, TO IMPLEMENT - *"IMPROVED TECHNOLOGY"* - WHICH MAY SAVE LIVES - WHILE SIMULTANEOUSLY TAKING AND DAMAGING OTHER AMERICAN LIVES – AND, AT A MINIMUM, PLACING SOME AMERICANS IN GREAT JEOPARDY - IS WRONG!

As a retired "Technical Writer" I ask:
"Why was this NEW & POWERFUL MAGNETIC RESONANCE (MR) "technology" so blithely approved (with a "wink and a nod") - without complementary SAFEGUARDS "built-in" (as a REQUIREMENT! TO USING IT)? (I do not know…).

However, (THIS MEDICAL TECHNOLOGY'S) continued and

UN-abated USE & PRACTICE **(without proper safeguards!)** - is "reckless" - and it should be addressed IMMEDIATELY!

Because of my work "experience" (described above) - I am keenly aware of THE Magnetic Resonance Imaging (MRI) Device manufacturers - **desire** to "shift the legal responsibility" - for "SAFETY" - to END USERS .

However - this product's instantiation [AS AN "FDA APPROVED MEDICAL DEVICE"] with ***complementary monetary interests*** ALSO exist. That is, these "diagnostic medical devices" – become "profit centers" – in hospitals – where "speed" & "throughput" is emphasized. **AND - the resulting harms - may PREVENT or disable the injured from pursuing "justice" – in a US court of LAW - AND/OR even – cause the victim's - death.**

TO BE CLEAR - I AM **NOT** (AT THIS TIME) "INJURED" - OR **WAS NOT** "INJURED" - ON 5-18-2021 **– BUT (THIS WAS), *ONLY* BECAUSE** THE "PATIENT SAFETY TEAM" ASSIGNED (TO ME) - ACTED RESPONSIBLY - - while simultaneously expressing 'regret" AND "searching for information" – to proceed – as my Medical Doctors had requested.

In fact, even I - and my husband – were urging them – to consider my previous MRI experiences. And, my husband (Hans) and I – did previously - literally joke [that] I have a "titanium" clip installed in my head (like the bionic woman –

from television) – ***Unaware*** [in fact] of the dangers – inherent-in such an installation – WE WERE …

I am ALSO (today) aware – from my research – [that] my "safety team's actions - probably did cause their employer [a local hospital] - to lose income - in a typical "profit center" - of the overall hospital operation. **That is, hospital's and related businesses – can bill Medicaid & Medi-CARE several thousand dollars – for "completed" Magnetic Resonance related diagnostic procedures. The most expensive – that (I saw) – was $6,000.**

Thus, ALL those in my case - should be commended - for their good actions; AND, my case (also) illustrates (the need) for firm "RULES – that should be brought into existence – by HHS (and FDA). That is, "Rules" - which can prevent and STOP further harm - IN SIMILAR CIRCUMSTANCES. AND THOSE, WHO BREAK OR IGNORE THESE "RULES"-SHOULD BE PROSECUTED - BY A JURY - OF THE VICTIM'S "PEERS" – to the fullest extent of the law… [US & International]

Finally, in part - I accepted this responsibility **(to notify YOU!)** of the dangers (literally approved by the FDA) - from a member of my SAFETY team ; <u>because</u> of my unique qualifications.

THAT IS, In addition to my "profession" & "work experience"-previously disclosed - above – I was employed by General

Electric - related to "GE military systems" - being deployed – in the mid-eighties. However, as you may know, “GE Health CARE” also manufactures several Magnetic Resonance (MR) device models. [cite, IMAGE]

My hope is, (that) - in a uniform USA market place - GE will act responsibly – for the “greater good”. They are certainly “situated” - to design and implement - a **“Medical Device User SAFETY Interface [MDUSI]”** - that will not permit their powerful RADIATION devices to operate (AT ALL!) - unless specific "SAFETY" criteria are met. THAT IS, in conjunction with a **"automated Medical Device - Operation Approval System"** - the ***occasional serious harms*** (now occurring) could be prevented - entirely. In fact, I was ‘ask for’ a “card” (which I had no knowledge of). Perhaps a “medical alert” tag – could be clipped onto American’s ears – who have metal installed. Such systems already exist for our pets.

In fact, I was also a "software system designer" - for - the University of Wisconsin (1981) and Battelle Research (1986+). I designed and implemented - the school's “Automated Weather Station” – for the US National Science Foundation; AND - the US Army's Medical Research & Evaluation Facility's(MREF) “Automated Scheduling System” - managed by Battelle Research - for the US Army’s Chemical Weapons Defense Efforts] .

This is among my FIRST NOTIFICATIONS - to the US-Government. I have previously notified the aneurysm clip

manufacturer – AND, the hospital – to compliment and THANK THEM! I printed and mailed – the document [that] I sent to our Secretary of HHS – to US Medical Doctors: Sadikov, Goldstick, Perry (today). THEY ARE ALL GOOD DOCTORS!

However, 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 rearch :

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.

AND, other concerns urge me on (also): I am now over-due – for a routine "follow-up" using MRI/MRA diagnostic scans – **and,** experiencing symptoms of Vertigo – when performing certain Yoga poses. My neurologist (Goldstick)wants me – to get these scans done SAFELY – and soon. **Thus, time is of the essence!**

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. Please allow sufficient time. I am VERY “detail oriented”, ASK LOTS OF QUESTIONS – and, get “mixed-up”.

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 brave and 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 American - 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”) - 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 and/or cause harmful reactions – INCLUDING BURNS- in the metal residing in them.** For example, my installed (2012) ANEURYSM clip was approved -by the FDA (in 1999) for 1.5 maximum Tesla Unit operating environments.
[https://www.accessdata.fda.gov/cdrh_docs/pdf/k990202.pdf]

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 them. FOR EXAMPLE, I believe, [that] AMERICANS WILL RESPOND TO A MESSAGE CITING:

"NEW POWERFUL MAGNETS" APPROVED BY THE US GOVERNMENT - THAT ARE CAUSING METALS - PREVIOUSLY INSTALLED (TO AMERICANS) - TO REACT AND/OR MOVE -pose a DANGER!"

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

Sincerely, - Susan

ENTIRE LIST

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

SENT TO TODAY “Monday” 6-7-2021 – after 5PM, Ohio time. :

[**US-FDA**]

jana.delfino@fda.hhs.gov
ting.song@fda.hhs.gov
sunder.rajan@fda.hhs.gov
shingchunbenny.lam@fda.hhs.gov
wolfgang.kainz@fda.hhs.gov
Daniel.Krainak@fda.hhs.gov
combination@fda.gov
FDAImportsInquiry@fda.hhs.gov
DICE@fda.hhs.gov
reglist@cdrh.fda.gov
device.reg@fda.hhs.gov

[C**DRH Management - HHS/fda**]

jeff.shuren@fda.hhs.gov
Douglas.KellyMD@fda.hhs.gov
Ellen.Flannery@fda.hhs.gov
Elizabeth.Hillebrenner@fda.hhs.gov
Melissa.Torres@fda.hhs.gov
Nicole.Ellis@fda.hhs.gov
Nancy.Braier@fda.hhs.gov
Olga.Claudio@fda.hhs.gov
Cathy.Oliveri@fda.hhs.gov
Jerry.Menikoff@hhs.gov >>>>> **done**
Julia.Gorey@hhs.gov
douglas.diekema@seattlechildrens.org
ocrmail@hhs.gov
OCRMedia@hhs.gov

[**Center for Biologics Evaluation and Research -- ALSO REFERRED TO AS: CBER**]

Peter.Marks@fda.hhs.gov
email@asn-online.org
khi@asn-online.org
cberombudsman@fda.hhs.gov