

6-3-2021

TO: Xavier Becerra >The Secretary of Health and Human Services - UNITED STATES OF AMERICA

> VIA POSTED AGENT: (Jerry.Menikoff@hhs.gov)

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

Dear US Health and Human Services Secretary Xavier Becerra,
(https://en.wikipedia.org/wiki/Xavier_Becerra)

Congratulations! on your confirmation to be the "Secretary" of US Health and Human Services - in the Biden/Harris Administration.

My name is: Susan Neuhart. I am a retired American SENIOR; - and, I recently learned [that] YOU have "authority" over the United States Food and Drug Administration (US-FDA).

That is, on the FDA web site - they state "... *FDA is an agency within the Department of Health and Human Services.*

[<https://www.fda.gov/about-fda/fda-organization>] ..."

As a retired American citizen, I presume this means [that] YOU - as "Secretary of HHS" - have some authority over their "final actions".

Sir, I have a complaint - of some urgency - related to a FDA regulated "Medical Device". [[Definition & Overview](#)]

I realize (after reading your [biography](#)) that your work experience and education – ARE primarily – in LAW Enforcement areas – so, I will explain (related medical details) – as needed. HOWEVER, your "LAW

enforcement” AND “legal” background -are perfectly ‘on point’ for my concerns.

In fact, 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 you) I was the first (of my mother’s seven children) – to attend College. I Graduated from the University of Wisconsin’s Green Bay campus – with a B.S. in Environmental Science & Communications (1982).

THE FOLLOWING SPECIFICS ARE RELATIVE TO MY COMPLAINT:

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](#) DEVICE 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.

6) I began (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) As a “legal professional” - you may know, - 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 am contacting YOU today – 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.

11) Indeed, I was 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.

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.

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 1.5 Tesla power.**

In SUMMARY, Sir - 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; AND, B) the team made numerous inquiries (also) – to go forward. C) My own doctors scheduled the procedures – on those 3-TESLA 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.

INDEED Sir (Secretary Becerra), 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, the 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, 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 – 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 & Medicare 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. 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]

Sir, in part - I accepted this responsibility (**to notify YOU!**) of the dangers (**literally approved by the FDA – you control**) - from a member of my SAFETY team ; because 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. 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 message represents my FIRST NOTIFICATION - to the US-HHS.

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 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>.

AND, other concerns urge me on (also): I am (in fact) overdue – for a routine “follow-up” using MRI/MRA diagnostic scans – and, experiencing symptoms of [Vertigo](#) – when performing certain Yoga poses. My neurologist wants me – to get these scans done SAFELY – and soon. **Thus, time is of the essence**

I am aware [that] your agents **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 LOOK FORWARD TO WORKING WITH YOUR HHS AGENTS - 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 - 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 your FDA agency] – can literally move and/or cause harmful reactions - 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 your HHS 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 office – 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