From: bill small
Sent: Wednesday, March 15, 2017 10:40 AM
Subject: 005: (3rd email, be careful out there) AGAIN, I WOULD LIKE A COPY OF THIS LETTER IN REGULATIONS. GOV FOR PETITION # FDA-2012-P-0119 and FDA-2013-P-0735, AGAIN MS LESLIE KUX, THE ASSOCIATE COMMISSIONER OF POLICY, WILL NOT FOLLOW THE LAW.

Ma-rio Mor-ais

Re: Docket Number: FDA-2012-P-0119 and Docket Number: FDA-2013-P-0735 my request to place my comment in the FDA folder

----------Letter Date is: March 13, 2017

----------Todays Date is: March 15, 2017

MS. KAREN KENNARD / THE SUPERVISOR AT DOCKETS MANAGEMENT

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

DIVISION OF DOCKETS MANAGEMENT (HFA-305)

5630 FISHERS LANE, ROOM 1061

ROCKVILLE, MD. 20852

005: (3rd email, be careful out there) AGAIN, I WOULD LIKE A COPY OF THIS LETTER IN REGULATIONS. GOV FOR PETITION # FDA-2012-P-0119 and FDA-2013-P-0735, AGAIN MS LESLIE KUX, THE ASSOCIATE COMMISSIONER OF POLICY, WILL NOT FOLLOW THE LAW. HER DECISIONS AND THE PEOPLE THAT GIVE MS KUX ANY POWER, ALLOW PEOPLE TO COME TO THE CONCLUSION THAT THE FDA IS CORRUPT. WHY IS MS KUX ABLE TO AVOID FOLLOWING THE LAW WITHOUT ANY CONSEQUENCES! The FDA issued a NEWS RELEASE regarding the dangers of a simple procedure know as CCSVI-- The federal FDA law requires that i can request that my comment be included in the FDA folder AND AGAIN MS KUX WENT AGAINST THE LAW AND DENIED MY REQUEST!

DEAR MS. KAREN KENNARD AND MS. DYANNA BIGBY: first, i am sorry for typing in all small letters or all caps, but i have multiple sclerosis and my legs are both paralyzed, as i use a motorized wheelchair to be

mobile. also my right hand will not obey my brain and is in a constant fist position, so i type using my left only.

ALL I'VE EVER TRY ED TO DO IS INFORM THE FDA AND ALLOW THE FDA TO BETTER SERVE THE SICK PERSONS NEEDS. I AM SURE THERE IS A BLOOD FLOW ASPECT TO MULTIPLE SCLEROSIS (MS). THE PROCEDURE KNOW AS CCSVI WAS THE BEST PROCEDURE I EVER HAD FOR MY MS. A SIMPLE OUTPATIENT PROCEDURE HAS CHANGED MY LIFE FOR THE BETTER, YET THE FDA HAS CLOSED ''warned'' ALL CLINICS TO STOP THIS SIMPLE AND EFFECTIVE TREATMENT. THE FDA HAS TREATED STOPPING THIS SIMPLE OUTPATIENT PROCEDURE LIKE A WITCH HUNT----------

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AGAIN, MS KUX IS NOT PROTECTING SICK PEOPLES LIVES, INSTEAD MS KUX IS PROTECTING THE DRUG COMPANIES. ITS A CASE OF THE WOLF PROTECTING THE HEN HOUSE. I BELIEVE, MS KUX'S ACTIONS ALLOW ME AND OTHERS TO FEEL LIKE THE FDA IS CORRUPT!

FOLLOWING IS MY APPEAL FOR # FDA-2012-P-0119 and FDA-2013-P-0735.

My first petition # FDA-2012-P-0119 was not addressed at all in the first FDA response made by ms kux's (see CC2) so i will address my first petition in another letter. I will only discuss my second petition, # FDA-2013-P-0735, in this letter.

All requests in my second petition, # FDA-2013-P-0735, were LAWFUL and yet ms kux denied MY LEGAL REQUESTS! MY REQUESTS WERE:

l) "I would still like my comment to be included in the FDA folder for the procedure CCSVI"; this is a lawful request of the FDA. the FDA's own law states that if the FDA issues a news release, and the FDA did, i have the lawful right to have my comment input into the FDA folder!.....

YET, MS LESLIE KUX STATES:your comments concerning CCSVI have been forwarded to FDA's Executive Secretariat and are publicly available on the www.regulations.gov Internet website.

***THAT IS NOT MY REQUEST!! WHAT MS KUX IS DOING IS ILLEGAL! MY COMMENT REGARDING CCSVI STILL NEEDS TO BE IN THE FDA FOLDER!

2) "CDRH would not give me a tracing number for my comment to CCSVI so i called HHS the HHS folks could do nothing for me but were able to give my comment a tracking number, # 0807-1412-913.

again, having a tracking number for my comment from HHS, my request that CDRH answer the news release over the phone is a lawful request of the FDA. the FDA's own law states that if the comment gets a tracking number, then the FDA needs to respond! THAT IS WHY I GOT A TRACKING NUMBER!

YET, MS LESLIE KUX STATES:

''further discussion of this matter is not warranted. The Agency, therefore, respectfully declines your requests for further telephone calls with CDRH and a designated contact in the Commissioner's office.

ALSO MS KUX SAYS::

''your comments concerning CCSVI have been forwarded to FDA's Executive Secretariat''

The reason to send a comment to Executive Secretariat, IS TO GET A TRACKING NUMBER AND HAVE THE NEWS RELEASE ANSWERED OVER THE PHONE.

YET MS KUX GIVES ME NO TRACKING NUMBER AND NO ANSWER TO MY COMMENT OVER THE PHONE!

***AGAIN MY REQUEST WAS DENIED AND AGAIN WHAT MS KUX IS DOING IS ILLEGAL! MS KUX DOES NOT FOLLOW THE FDA LAW!

MY EXAMPLE OF WHAT THE FDA IS DOING:

i get pulled over by the cop for SPEEDING on the highway and i say:

''sorry officer but I respectfully decline to go 60 MPH''

YEA RIGHT I KINOW THE COP WILL EXCEPT THAT ANSWER! THE LAW IS THE LAW IS THE LAW AND ''I respectfully decline'' IS STILL AGAINST THE LAW!

THANK YOU FOR YOUR TIME

If you have any questions or concerns please feel free to call me

SINCERELY YOURS,

Mar-io Mor-ais

ATT1. THE RESPONSE BY MS. LESLIE KUX TO MY CP # FDA-2013-P-0735.

CC1 : Copy of response written by ms leslie kux and AGAIN telling me that the FDA WILL NOT FOLLOW THE LAW! The FDA issued a NEWS RELEASE regarding the dangers of a simple procedure know as CCSVI-- The federal FDA law requires that i can request that my comment be included in the FDA folder-- but ms kux is being illegal by again denying my request!

CC2 : Complete copy of the answer to my original citizens petition from ms. leslie kux dated JUN 19, 2014, showing ms. kux was wrong and no issues from petition # FDA-2012-P-0119 were ever addressed..

----------CC1----------

CC1 : Copy of response written by ms leslie kux and AGAIN telling me that the FDA WILL NOT FOLLOW THE LAW! The FDA issued a NEWS RELEASE regarding the dangers of a simple procedure know as CCSVI-- The federal FDA law requires that i can request that my comment be included in the FDA folder-- but ms kux is being illegal by again denying my request!

III. CONCLUSION

You made four requests in your petition and stated: (I) "I would still like my comment to be included in the FDA folder for the procedure CCSVI"; (2) " I would like my first citizen petition # FDA-2012-P-0119 addressed and answered"; (3) "I would like the CDRH to formally answer my positive comment by telephone"; and, (4) "I would like the Commissioner's office to issue me a contact that will contact me and answer my phone calls and my messages." 10

FDA has responded to each of these requests. As described in the Agency's June 19, 2014, decision, your comments concerning CCSVI have been forwarded to FDA's Executive Secretariat and are publicly available on the www.regulations.gov Internet website. In addition, FDA has reconsidered its June 19, 2014, decision and has provided a complete answer to Petition FDA-2012-P-0119 as described above. Given that FDA substantively responded to your various concerns, further discussion of this matter is not warranted. The Agency, therefore, respectfully

declines your requests for further telephone calls with CDRH and a designated contact in the Commissioner's office. Further, FDA considers these matters closed and does not intend to respond to future correspondence regarding these issues.

Sincerely,

Leslie Kux

Associate Commissioner for Policy

----------CC2----------

CC2 : Complete copy of the answer to my original citizens petition from ms. leslie kux dated JUN 19, 2014, showing ms. kux was wrong and no issues from petition # FDA-2012-P-0119 were ever addressed..

DEPARTMENT 0F HEALTH & HUMAN SERVICES Public Health service

. Food and Drug Administration

JUN 1 9 2014 New Hampshire Avenue

Silver Spring, MD 20993

Mr. Ma-rio Mora-is

Re: Dockets Number: FDA-2012-P-0119 and

Dockets Number: FDA-2013-P-0735

Dear Mr. Mora-is:

This responds to citizen petition dated December 5, 2011, filed on February 29, 2012, and assigned docket number FDA~2012-P-0119 and your citizen petition dated June 1, 2013, filed on June 11, 2013, and assigned docket number FDA-2013-P-0'735. In your petitions, you request that the Food and Drug Administration (FDA) acknowledge receipt of your positive comments on the chronic cerebrospinal venous insufficiency (CCSVI) procedure and request FDA take certain actions in response to your comments. We have carefully reviewed the arguments in your citizen petitions and for the reasons stated below We are partially granting and partially denying your requests.

l) Request that your comment be submitted to the Executive Secretariat

In your June 1, 2013, petition, you request that your comment be submitted to the Executive Secretariat. It appears that your "comment" refers to your citizen petitions dated December 5 , 2012, and June 1, 2013. Copies of the two citizen petitions have been forwarded to the FDA Executive Secretariat. Therefore, We grant your request.

2) Include your comment in the U.S. Food and Drug Administration's .. …….(FDA'S) folder for the agency's news release warning about the CCSVI …….procedure

In your June 1, 2013, petition, you request your comment be submitted "inside the FDA folder for the news release warning about this procedure know[n] as CCSVI." It appears that your reference to the "news release Warning" refers to the Agency's FDA Safety Communication: Chronic Cerebrospinal Venous Insufficiency Treatment in Multiple Sclerosis Patients, issued on May 10, 2012.l

Further, we assume that, by comment, you are referring to your citizen petitions

dated December 5, 2011, and June 1, 2013. Please be advised that FDA does not post citizen petitions as part of its safety communications to the public. However, your citizen petitions, and the supplements, have been posted on Regulations.gov and are currently available to the public. Therefore, We are denying this request.

3) Respond by telephone to your comment submitted to F DA and …….assigned tracking number 0807-1412-913

We are unable to find a document submitted to the Agency with tracking number 0807-1412-913. However, we believe you are referring to an email you sent on

June 11, 2012, which is attached to this response. We are granting your request by commenting below.

While FDA appreciates your interest in alternative treatments for multiple sclerosis (MS), FDA is not aware of Valid scientific evidence demonstrating that the CCSVI procedure is effective in treating MS. As outlined in FDA'S May 10, 2012 Safety Communication: Chronic Cerebrospinal Venous Insufficiency Treatment in Multiple Sclerosis Patients (http ://www.FDA. govfMedicalDevices/ Safety/A1ertsandNotices/ucm3 033 1 8.htm), data to support CCSVI as a clinical entity on its own or its relationship with MS are at times contradictory and therefore inconclusive. In addition, CDRH has received adverse event reports, including a fatal event, related to CCSVI procedures.2 With respect to the information you have conveyed to us regarding your personal experience with CCSVÍ intervention, though We empathize With and share your desire for effective, FDA cleared or approved products for MS, personal anecdotes and testimonials do not constitute valid scientific evidence. See 21 CFR 860.7(c)(1) ("the agency relies upon only valid Scientific evidence to determine Whether there is reasonable assurance that the device is safe and effective") and 21 CFR 860.7(c)(2)(defining "valid scientific evidence").

Please also note that the requests you made in your December 11, 2011, citizen petition were previously addressed in the email From the CDRH Ombudsman David Buckles to you dated September 15, 2012. We are attaching copy of that email and incorporating it by reference into this response.

FDA has determined that the requests in your citizen petitions are either the same or substantially similar to numerous previous communications from you. The Agency has previously responded to your requests and has exercised due diligence in providing information responsive to the issues you have cited. The September 15, 2012, email From the CDRH Ombudsman is one example.

Further, you have been informed repeatedly that all contacts with the Agency be directed in writing to David Buckles, CDRH Ombudsman, at the address indicated in Dr. Buckles' September 15, 2012, email. Despite our attempts to direct your communications to Dr. Buckles, recently you have repeatedly contacted multiple individuals Within CDRH and other components of FDA concerning the CCSVI procedures. In the past several months, you have called and emailed numerous individuals Within FDA, leaving lengthy messages and sent many faxes.

For the reasons outlined above, we grant your requests to forward your comments to the FDA Executive Secretariat and to comment on your email dated June 11, 2012. We deny the remaining requests made in your citizen petition.

Sincerely,

Leslie Kux

Assistant Commissioner for Policy

Enclosures

l. June 11, 2012, email from you to FDA

2- September 15, 2012, email from CDRH Ombudsman David Buckles to you

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----------END OF EMAIL----------
