

-----A-OF-12-----

MARIO MORAIS  
4 GLEN ROAD APT 103  
HUDSON, MASS. 01749-1365  
HOME PHONE # 978-212-5156 / EMAIL [mariomorais8@gmail.com](mailto:mariomorais8@gmail.com)

2013 JUN 11 A 11:45

LETTER MADE IS ON JUNE 01, 2013

Division of Dockets Management,  
DOCKET MANAGEMENT BRANCH (HFA-305)  
FOOD AND DRUG ADMINISTRATION  
5630 FISHERS LANE, ROOM 1061  
ROCKVILLE, MD. 20852

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RE: RESENDING CITIZENS PETITION AS I WAS TOLD THAT THE ORIGINAL  
CITIZENS PETITION WITH TRACING # 7012221000043380988 WAS NOT  
RECEIVED.

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**TO THE FOLKS AT DOCKETS MANAGEMENT AT THE FDA:**

I SUBMITTED A CITIZEN'S PETITION WITH TRACKING #  
7012221000043380988, BUT I WAS TOLD BY DOCKETS MANAGEMENT  
THAT THE CITIZENS PETITIONS WAS NOT RECEIVED!

I DID SEND THE ORIGINAL CITIZENS PETITION AND I WILL TRY TO  
CONFIRM THAT IN THE FIRST 3 PAGES OF THIS LETTER. I HAVE MADE  
PAGES A-B-C OF 12! PAGE A IS A LETTER TO THE DOCKETS FOLKS,  
PAGE B IS A COPY OF MY RETURNED LETTER TELLING ME THAT THE  
FOOD AND DRUG ADMINISTRATION (FDA) RECEIVED MY CITIZENS  
PETITION, PAGE C IS THE PATH THAT THE CITIZENS PETITION TOOK TO  
GET TO THE FDA.

SINCE MY ORIGINAL CITIZENS PETITION WAS NOT RECEIVED, I WILL  
NEED TO CALL DOCKETS TO CONFIRM RECEIVING THIS PACKAGE, AS I  
DO NOT WANT TO RESEND IT AGAIN..

THE NEXT 12 PAGES OF THIS LETTER ARE THE ORIGINAL CITIZENS  
PETITION I HAVE ALSO INCLUDED AMENDMENT # 1 AND # 2. THANKING  
YOU IN ADVANCE FOR YOUR TIME.

SINCERELY YOURS

  
MARIO MORAIS

SENT AGAIN REGISTERED MAIL ALSO INCLUDES THE ORIGINAL  
CITIZENS PETITION AND AMENDMENT # 1 AND # 2 TO THE FOLKS AT  
DOCKETS MANAGEMENT AT THE FDA.

FDA-2013-P-0735

2013-4622  
CP

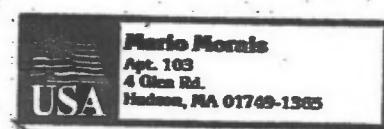
<b>SENDER: COMPLETE THIS SECTION</b>		<b>COMPLETE THIS SECTION ON DELIVERY</b>	
<ul style="list-style-type: none"> <li>■ Complete Items 1, 2, and 3. Also complete Item 4 if Restricted Delivery is desired.</li> <li>■ Print your name and address on the reverse so that we can return the card to you.</li> <li>■ Attach this card to the back of the mailpiece, or on the front if space permits.</li> </ul>		<p>A. Signature <b>X</b></p> <p><input type="checkbox"/> Agent      <input type="checkbox"/> Addressee</p> <p>B. Received by (Printed Name)</p> <p>C. Date of Delivery</p> <p>D. Is delivery address different from item 1? <input type="checkbox"/> Yes If YES, enter delivery address below: <input type="checkbox"/> No</p> <p><b>PSC Mail Facility Parklawn Bldg Rockville, MD 20857</b></p>	
<p>1. Article Addressed to:</p> <p><b>US Food + Drug Docket Management ADH 5630 Fishers Lane PMB 101 Rockville, MD 20852</b></p>		<p>3. Service Type</p> <p><input checked="" type="checkbox"/> Certified Mail      <input type="checkbox"/> Express Mail  <input type="checkbox"/> Registered Mail      <input type="checkbox"/> Merchandise  <input type="checkbox"/> Insured Mail      <input type="checkbox"/> C.O.D.</p> <p>4. Restricted Delivery? (Extra Fee) <input type="checkbox"/> Yes</p>	
<p>2. Article Number (Transfer from service label)</p> <p><b>7012 2210 0000 4338 0988</b></p>			
<p>PS Form 3811, February 2004</p>		<p>Domestic Return Receipt</p> <p>102595-02-M-1540</p>	

UNITED STATES POSTAL SERVICE

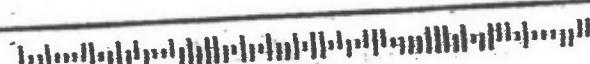


First-Class Mail  
Postage & Fees Paid  
USPS  
Permit No. G-10

• Sender: Please print your name, address, and ZIP+4 in this box •



M



-----C-OF-12

U.S. Postal Service Track & Confirm email Restoration - 7012221000 0043380988

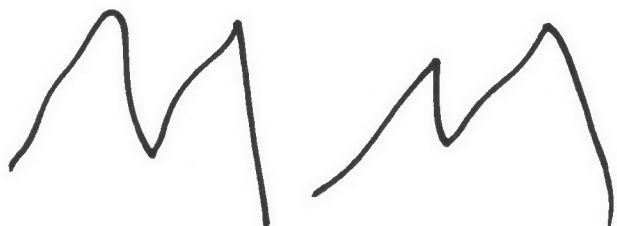
MARIO MORAIS has requested that you receive this restoration information for Track & Confirm as listed below.

Current Track & Confirm e-mail information provided by the U.S. Postal Service.  
Label Number: 70122210000043380988

Service Type: Certified Mail

Shipment Activity	Location	Date & Time
Delivered	ROCKVILLE MD 20850	April 18, 2013 10:32 am
Forwarded	ROCKVILLE MD	April 17, 2013 10:39 am
Arrival at Unit	ROCKVILLE MD 20852	April 17, 2013 10:37 am
Depart USPS Sort Facility	GAITHERSBURG MD 20898	April 17, 2013
Processed through USPS Sort Facility	GAITHERSBURG MD 20898	April 17, 2013 4:00 am
Depart USPS Sort Facility	GAITHERSBURG MD 20898	April 17, 2013
Processed through USPS Sort Facility	GAITHERSBURG MD 20898	April 16, 2013 11:18 pm
Depart USPS Sort Facility	GAITHERSBURG MD 20898	April 13, 2013
Processed through USPS Sort Facility	GAITHERSBURG MD 20898	April 13, 2013 3:48 am
Depart USPS Sort Facility	SHREWSBURY MA 01546	April 11, 2013
Processed at USPS Origin Sort Facility	SHREWSBURY MA 01546	April 10, 2013 10:11 pm
Dispatched to Sort Facility	HUDSON MA 01749	April 10, 2013 1:50 pm
Acceptance	HUDSON MA 01749	April 10, 2013 11:16 am

USPS has not verified the validity of any email addresses submitted via its online Track & Confirm tool.



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**CITIZENS PETITION TRYING TO INCORPORATE THE FDA REQUIREMENTS  
AS STATED ON THE FDA WEB PAGE:  
<http://www.fda.gov/RegulatoryInformation/Dockets/Comments/Default.htm>**

MARIO MORAIS

4 Glen Road, Apartment # 103  
Hudson, Mass., 01749-1365

Home Phone number is 978-212-5156, Email mariomorris8@gmail.com

LETTER MADE IS ON MARCH 21, 2013

SUBMITTED TO THE U.S. FOOD AND DRUG ADMINISTRATION (HFA-125)  
CITIZENS PETITION FOLKS  
U.S. FOOD AND DRUG ADMINISTRATION  
DOCKET MANAGEMENT BRANCH (HFA-125)  
FOOD AND DRUG ADMINISTRATION  
5630 FISHERS LANE, ROOM 1061  
ROCKVILLE, MD. 20852

TEL: 301-827-6860 / Fax 301-827-6870 / Email fdadockets@oc.fda.gov

SUBMITTED TO THE U.S. FOOD AND DRUG ADMINISTRATION (HFA-125)

**TO THE FOLKS AT DOCKETS MANAGEMENT AT THE FDA:**

I SUBMITTED WHAT I THOUGHT WAS A CITIZEN'S PETITION. THE  
TRACKING NUMBER OF MY PARCEL WAS 70112970000158942428.

THE ORIGINAL CITIZENS PETITION INCLUDED BOTH ATTACHMENT 1 AND  
ATTACHMENT 2, HOWEVER I WAS TOLD BY THE DOCKETS MANAGEMENT  
THAT THIS WAS NOT THE CORRECT FORMAT, SO I'M SUBMITTING  
ANOTHER CITIZEN'S PETITION TO COMPLY.

I HAVE ALSO INCLUDED ATTACHMENT 3, SAYING THAT THE  
DEPARTMENT OF HOMELAND SECURITY ALLOWS ME TO SUBMIT A  
CITIZENS PETITION.

ATTACHMENT 1 AND ATTACHMENT 2 WAS A STRONG ATTEMPT BY  
MYSELF TO TRY TO GET THE CDRH OMBUDSMAN, MR. DAVID BUCKLES,  
TO CONTACT ME.

IF YOU READ BOTH ATTACHMENTS (1 AND 2), I HOPE YOU COME TO THE  
SAME CONCLUSION. I HAVE TYRED MY VERY BEST TO GET SOME  
CONCRETE CONTACT FROM THE CDRH OMBUDSMAN!



TO THE WRITING OF THIS LETTER THE CDRH OMBUDSMAN, MR. DAVID BUCKLES HAS WRITTEN ME TWO EMAILS. I HAVE HAD NO OTHER CONTACT WITH MR. BUCKLES. HE HAS NEVER RETURNED MY MESSAGES WHEN I FIRST CALLED, AND NOW HE HAS BLOCKED MY CALLS FROM HIS PHONE NUMBER!

LET ME OFFER A LITTLE HISTORY. I HAVE PROGRESSIVE MS AND I UNDERWENT THE PROCEDURE KNOW AS CCSVI, IT WAS A TWO-HOUR OUT PATIENT PROCEDURE. AFTER THIS PROCEDURE, MY QUALITY OF LIFE WAS SO MUCH BETTER. THIS PROCEDURE WAS THE BEST THING THAT I HAVE DONE SINCE BEING DIAGNOSED WITH MS!

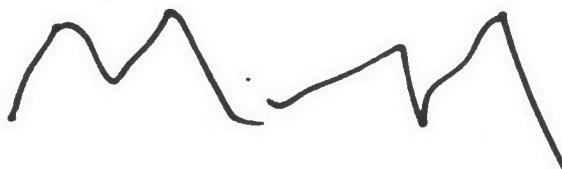
THEN THE FDA ISSUED A NEWS RELEASE WARNING CLINICS TO STOP PERFORMING THE PROCEDURE KNOW AS CCSVI. THE FDA EVEN ASKED THE CLINIC WHERE I HAD THIS PROCEDURE TO STOP PERFORMING THIS PROCEDURE! THIS CLINIC STOPPED ADVERTISING AND PERFORMING THIS SIMPLE PROCEDURE!

SO THIS IS WHAT I DID! FIRST I SENT MY POSITIVE COMMENT REGARDING THE PROCEDURE KNOWN AS CCSVI TO MS. LINDSEY LLOYD, SHE IS THE SECRETARY OF DR. MAISEL, I SENT THE COMMENT BY EMAIL AND SHE ACKNOWLEDGED RECEIVING MY COMMENT BY EMAIL, I WAS INITIALLY TOLD BY MS LLOYD THE COMMENT WAS GOING TO 'the exec secretariate' BUT I FOUND OUT MY COMMENT WAS NEVER SENT OR RECEIVED BY THE EXECUTIVE SECRETARIAT THEN MS. LLOYD WOULD NO LONGER RETURN MY PHONE MESSAGES AND FINALLY MS. LLOYD BLOCKED MY CALLS FROM HER PHONE NUMBER.

SO MS. LLOYD DID NOT WANT ANY MORE COMMUNICATION WITH ME. I THEN TYRED TO GET IN CONTACT WITH THE CDRH OMBUDSMAN, MR. DAVID BUCKLES, BUT MR. BUCKLES WOULD NOT CONTACT ME EITHER, INSTEAD HE CONTACTED THE DEPARTMENT OF HOMELAND SECURITY. I RECEIVED A LETTER FROM POLICE OFFICER MR. R. BUCHANAN.

ALL THAT BECAUSE THE OMBUDSMAN DID NOT WANT TO PERFORM HIS OMBUDSMAN DUTIES! SO, AMENDMENT 1 AND AMENDMENT 2 WAS MY ATTEMPT TO GET SOME RESPONSE FROM MR. BUCKLES TO TRY TO GET HIM TO PERFORM HIS REGULATOR DUTIES! BUT NETHER AMENDMENT WORKED.

THE TWO AMENDMENTS WERE RECEIVED BY DOCKETS MANAGEMENT ON DECEMBER 07, 2012. I WAITED TO GET A CITIZENS PETITION NUMBER BUT I DID NOT RECEIVE ANY. SO I CALLED DOCKETS MANAGEMENT. I WAS ASKED BY MR. RYAN CLEAVER IF I WOULD ALLOW MR BUCKLES 5



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DAYS TO CONTACT ME. I ALLOWED OVER A WEEK BUT MR. BUCKLES DID NOT CONTACT ME. I CALLED BACK AN MR CLEAVER TOLD ME TO CALL MR. BUCKLES DIRECTLY, SO I DID, I CALLED 301-796-5447. HOWEVER MR BUCKLES STILL HAS MY NUMBER BLOCKED FROM HIS PHONE NUMBER!

I CALLED BACK AGAIN AND MR. CLEAVER WAS GOING TO LOOK INTO THE MATTER. AGAIN I CALLED BACK BUT THIS TIME MR. CLEAVER SAID HE COULD NOT TALK TO ME BECAUSE OF THE DEPARTMENT OF HOMELAND SECURITY.

I SENT A LETTER TO DOCKETS MANAGEMENT, THE TRACKING NUMBER FOR THIS LETTER WAS: 70112970000158942343. THIS LETTER WAS TELLING DOCKETS MANAGEMENT THAT THEY COULD TALK TO ME BECAUSE THE DEPARTMENT OF HOMELAND SECURITY, HAS ALLOWED ME TO CREATE A CITIZENS PETITION! THIS LETTER WAS RECEIVED ON FEBRUARY 04, 2013 BY DOCKETS MANAGEMENT FOLKS.

I WAITED ONE MONTH THEN I AGAIN CALLED THE DOCKETS MANAGEMENT FOLKS, MR. RYAN CLEAVER ANSWERED THE PHONE AND HE TRANSFERRED ME TO HIS MANAGER, MS. KAREN KENNARD, MS. KENNARD TOLD ME THAT I NEEDED TO FOLLOW THE FDA REQUIREMENTS LISTED ON THE WEB SITE:

<http://www.fda.gov/RegulatoryInformation/Dockets/Comments/Default.htm>

NOW, THERE MAY BE SOME DUPLICATE INFORMATION BUT I WANTED TO EXPLAIN WHAT I HAVE DONE SO FAR.

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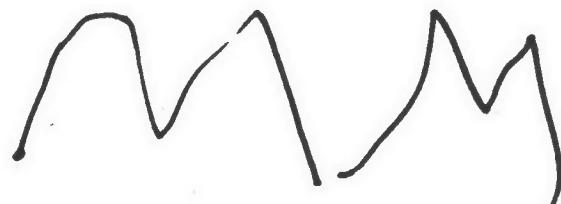
**THIS IS MY ATTEMPT TO PERFORM THE FDA REQUIREMENTS:**

**Petitions**

Another way to influence the way FDA does business is to petition the agency to issue, change or cancel a regulation, or to take other action. The agency receives about 200 petitions yearly.

**THIS CITIZEN'S PETITION IS TO TAKE OTHER ACTION!**

I HAVE MULTIPLE SCLEROSIS AND I HAD RECEIVED A POSITIVE RESULT FROM A SIMPLE PROCEDURE CALLED CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY (CCSVI). AFTER I HAD THIS PROCEDURE MY QUALITY OF LIFE WAS MUCH BETTER THAN BEFORE THIS PROCEDURE.

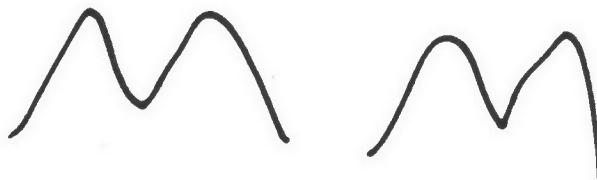


I HAVE BEEN TRYING VERY VERY HARD TO GET A POSITIVE COMMENT  
ACKNOWLEDGED BY THE FDA. I EVEN GOT A TRACKING NUMBER (0807-1412-2413) FOR MY POSITIVE COMMENT, BUT THE CDRH OMBUDSMAN  
WOULD NOT ANSWER OR ACKNOWLEDGE MY COMMENT.

I WAS TOLD BY KATHLEEN SEBELIUS'S CORRESPONDENCE  
DEPARTMENT THAT THE FDA SHOULD ANSWER MY COMMENT, I WAS  
EVEN GIVEN THE NUMBER OF MS. MARTINA VARNADO AT THE FDA, I  
BELIEVE MS. VARNADO IS THE DIRECTOR OF THE EXECUTIVE  
SECRETARIAT SHE'S AT 1-121-796-4568, BUT MS. WOULD NOT CALL ME  
BACK. I LEFT HER 3 MESSAGES AND I EMAILED HER AT  
[martina.varnado@fda.hhs.gov](mailto:martina.varnado@fda.hhs.gov) BUT SHE HAS NEVER RETURNED MY CALL.

THIS SIMPLE OUT-PATIENT PROCEDURE HELPED MY BLOOD FLOW AND  
MY QUALITY OF LIFE, SHOULDN'T THE FDA WANT GOOD COMMENTS  
FROM SICK FOLKS LIKE MYSELF?

I BELIEVE THAT IF I HAD THIS PROCEDURE 10 YEARS AGO, I WOULD  
HAVE NEVER NEEDED A MOTORIZED WHEELCHAIR TO BE MOBILE!



## Petitions submitted to FDA must contain:

-----#1-----

- Action requested--What rule, order, or other administrative action does the petitioner want FDA to issue, amend or revoke?

MY JUGULAR VEINS WERE INDEED CLOGGED AND THIS SIMPLE PROCEDURE (CCSVI) UNBLOCKED THESE VEINS!

THE SIMPLE PROCEDURE KNOWN AS CCSVI FOR ME, WAS A SIMPLE TWO HOUR OUT-PATIENT PROCEDURE AND HAS TRANSFORMED MY LIFE FOR THE BETTER. HERE IS THE THEORY ABOUT CCSVI

### The Complete Theory

Zamboni – whose own wife has MS – recognized that in many patients, the three veins responsible for draining blood from the brain (the two jugulars and the azygos) are tangled or constricted. He named this symptom “chronic cerebrospinal venous insufficiency,” or CCSVI. In a healthy adult, blood vessels in the brain are impermeable to many of the blood’s contents – the blood brain barrier protects the brain from potential harm (e.g. bacterial cells) and only gives passage to smaller molecules like oxygen, carbon dioxide, hormones, and so on. Zamboni hypothesizes that poor drainage caused by CCSVI might cause a reflux of blood into the brain that increases blood pressure. The results of this pressure are twofold. First, iron is deposited out of the blood and into the brain. Second, if blood vessels are stretched out, they can tear microscopically and leak immune cells into the brain. The immune system then attacks the iron deposits, and MS results.

MY MIND IS FINER AND I THINK BETTER MY COMEDY WIT HAS COME BACK, AND MY WIT IS MUCH FASTER, MY MEMORY OF HISTORY IS BETTER, I REMEMBER WORDS TO SONGS NOW! THE FEELING IN MY BODY IS MUCH BETTER, MY STRENGTH IS BETTER AND I AM MUCH STRONGER, MY CIRCULATION IS MUCH BETTER, MY FEET WERE ALWAYS VERY COLD ALL THE TIME, NOW MY FEET ARE MUCH WARMER NOW. MY BED SORES HAVE COMPLETELY HEALED. IN FACT SINCE THE PROCEDURE KNOWN AS CCSVI, I HAVE NOT RECEIVED ANOTHER BED SORE, THANK GOD!

I AM LESS EFFECTED BY HEAT NOW, I CAN TOLERATE MUCH MORE HEAT WITHOUT FEELING TIRED. I NOW FEEL THAT MY BODY CAN WITH STAND HEAT WITHOUT DRAINING ALL MY ENERGY.

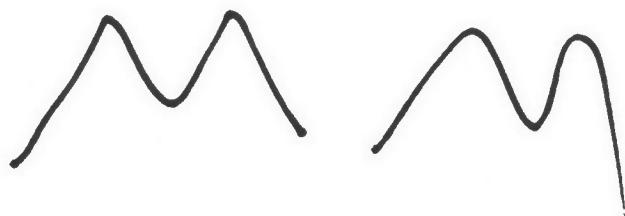


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**THIS PROCEDURE KNOWN AS CCSVI WAS THE BEST PROCEDURE I'VE EVER HAD SINCE I WAS DIAGNOSED WITH MS OVER 20 YEARS AGO.**

THE FOLLOWING ARE THE THREE (3) REGULATORY REQUESTS REQUIRED BY THIS CITIZENS PETITION.

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**REGULATORY REQUEST # 1**

I WOULD LIKE THE Ombudsman for the Center for Devices and Radiological Health (CDRH), MR. DAVID BUCKLES, OR SOMEONE ELSE, TO SEND MY COMMENT TO THE 'The Executive Secretariat'.

AND SINCE I HAVE A BAD HISTORY WITH CDRH. I WOULD LIKE TO CALL THE EXECUTIVE SECRETARIAT FOLKS TO CONFIRM THAT THEY RECEIVED MY COMMENT.

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**REGULATORY REQUEST # 2**

ALSO I WOULD LIKE THE Ombudsman for the Center for Devices and Radiological Health (CDRH) TO INCLUDE MY COMMENT INSIDE THE FDA FOLDER FOR THE NEWS RELEASE WARNING ABOUT THIS PROCEDURE KNOW AS CCSVI.

AND AGAIN SINCE I HAVE A BAD HISTORY WITH CDRH. I WOULD LIKE TO CALL THE FOLDER FOLKS TO CONFIRM THAT MY COMMENT WAS INCLUDED IN THE FDA FOLDER.

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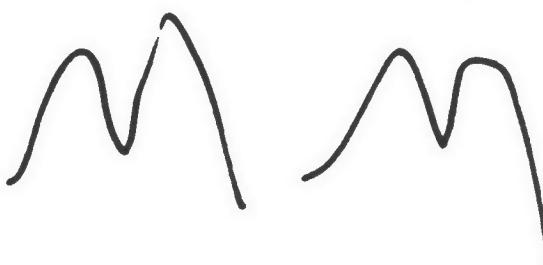
**REGULATORY REQUEST # 3**

ALSO I WOULD LIKE THE Ombudsman for the Center for Devices and Radiological Health (CDRH) OR FROM ANOTHER ORGANIZATION WITHIN FDA TO ANSWER MY POSITIVE COMMENT WITH TRACKING NUMBER 0807-1412-913.

AS I AM IN A MOTORIZED WHEELCHAIR, I WOULD LIKE MY POSITIVE COMMENT ANSWERED BY PHONE!

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THAT'S IT THAT'S ALL. MR. RYAN CLEAVER HAS SAID THAT CDRH MIGHT NOT HAVE ENOUGH TIME TO DO THESE 3 THINGS BUT I BELIEVE THE CDRH GROUP AND MR. BUCKLES HAVE SPENT MUCH MORE TIME AVOIDING MY COMMENT.



-----#2-----

- Statement of grounds--The factual and legal grounds for the petition, including all supporting material, as well as information known to the petitioner that may be unfavorable to the petitioner's position.

CDRH HAS REGULATORY LAWS THAT ARE APPLICABLE TO ALL CITIZENS!  
HERE IS THE EXPLANATION OF THE CDRH OMBUDSMAN. THIS  
INFORMATION COMES FROM THE FDA WEB SITE.

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## CDRH Ombudsman

The CDRH Ombudsman investigates complaints from outside FDA and facilitates the resolution of disputes between CDRH and the industry it regulates. The CDRH Ombudsman is a good starting point if you have a complaint, question, or dispute of a scientific, regulatory, or procedural nature. He can answer questions, follow up on a complaint, discuss appeal and dispute resolution options, or mediate a dispute. While providing this assistance, he maintains his impartiality and neutrality. The Ombudsman advises the Center Director, to whom he reports, on ways to assure that our procedures, policies and decisions are of the highest quality and are fair and equitable.

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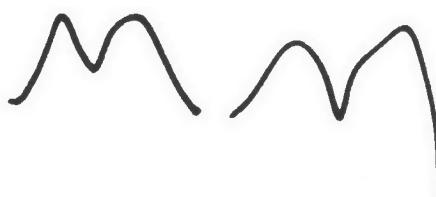
## SO THE CDRH GROUP HAS A RESPONSIBILITY TO

**SICK FOLKS** 'The Ombudsman advises the Center Director, to whom he reports, on ways to assure that our procedures, policies and decisions are of the highest quality and are fair and equitable. WELL POSITIVE COMMENTS LIKE MINE WILL LEAD TO 'policies and decisions are of the highest quality'

-----#3-----

- Environmental impact--This information is generally required if the petition requests approval of food or color additives, drugs, biological products, animal drugs, or certain medical devices, or for a food to be categorized as GRAS (generally recognized as safe). Procedures for preparing environmental impact statements can be found in Title 21, Part 25 of the Code of Federal Regulations<sup>9</sup>. If an environmental impact statement is not required, petitions should include a statement to that effect.

I DO NOT FEEL THAT THERE WILL BE ANY IMPACT TO THE ENVIRONMENT FROM MY POSITIVE COMMENT.



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-----#4-----

- The following official certification statement --"The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition."

I ACKNOWLEDGE THAT THIS CITIZENS PETITION AND THE OTHER THREE AMENDMENTS (1 AND 2 AND 3 INCLUDED IN THIS LETTER), THE OTHER 3 ATTACHMENTS WERE ALSO SENT TO DOCKETS MANAGEMENT BY REGISTERED LETTER #70112970000158942428A AND REGISTERED LETTER #70112970000158942343,

SO THIS CITIZENS PETITION AND THE THREE ATTACHMENTS INCLUDED WITH THIS PETITION ARE MY COMPLETE INFORMATION THAT I HAVE SUBMITTED TO THE DOCKETS MANAGEMENT FOLKS FOR THIS PETITION.



MARIO MORAIS

6-1-2013

DATE

-----10-OF-12

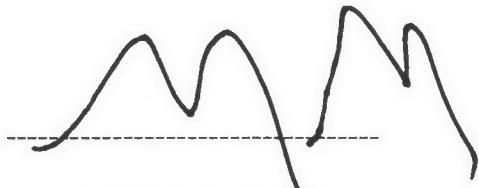
-----#5-----

- Identifying information-- The petition must be signed and include the petitioner's address and phone number.

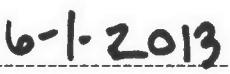
MARIO MORAIS

4 Glen Road, Apartment # 103  
Hudson, Mass., 01749-1365

Home Phone number is 978-212-5156, Email mariomorris8@gmail.com



MARIO MORAIS



6-1-2013

DATE

**In addition, some petitions may require information on:**

- Economic impact--This information is required only if FDA requests it after review of the petition.

I HAVE NOT BEEN ASKED TO ANSWER 'economic impact' BUT I WILL DO MY BEST.

THIS SIMPLE PROCEDURE (IF ALLOWED TO CONTINUE) COULD SAVE PATIENTS MILLIONS OF DOLLARS AND INCREASE THEIR QUALITY OF LIFE. IN A PREVIOUS PARAGRAPH I MENTION SOME OF THE BENEFITS TO MY LIFE..

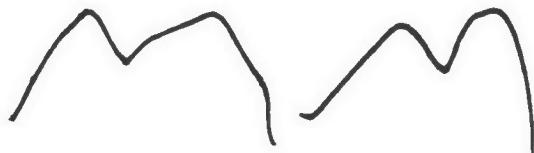
THIS SIMPLE PROCEDURE INCREASED THE QUALITY OF MY LIFE MORE THAN ALL THE YEARS THAT I WAS TAKEN THE DAILY INJECTION CALLED COPAXON.

THE DAILY INJECTION CALLED COPAXON COSTS OVER \$1,700.00 EACH AND EVERY MONTH! THAT'S OVER \$20,400.00 EACH AND EVERY YEAR! AND THAT'S ONLY FOR MYSELF....THINK OF ALL THE FOLKS THAT HAVE MULTIPLE SCLEROSIS AND HOW MUCH THEY ALL SPEND ON MONTHLY DRUGS!

NOW THINK HOW MUCH WILL BE LOST IN DRUG REVENUE IF THIS SIMPLE PROCEDURE HELPED PATIENTS HAVE A BETTER QUALITY OF LIFE.

PLUS WE MAY NEED TO LOOK AT THIS DISEASE (MS) AS IN PART DUE BECAUSE OF RESTRICTED BLOOD FLOW FROM THE BRAIN AND A FIX KNOWN AS CCSVI COULD HELP THE PATIENTS GREATLY! I AM ABSOLUTLY SURE THAT RESTRICTED BLOOD FLOW EFFECTED MY MS ENORMOUSLY.

HOWEVER AND UNFORTUNATELY, PATIENTS AND QUALITY OF LIFE DOES NOT GENERATE LOTS OF MONEY, AND OUR CURRENT SYSTEM SEEMS TO BE DRIVEN BY MONEY. THE FOLKS THAT HAVE LOTS OF MONEY SELL DRUGS AND MAKE LOTS OF MONEY FROM SICK PATIENTS.



-----12-OF-12

ALSO, EVERYONE I HAVE EVER TALKED TO, IS VERY HAPPY THEY WERE ABLE TO HAVE THIS PROCEDURE KNOW AS CCSVI. I TALKED TO ALLOT OF FOLKS BECAUSE I WANTED TO DO SOME RESEARCH ON THIS PROCEDURE BEFORE I HAD IT DONE ON MYSELF! ALSO I ASKED THE DOCTOR THAT PERFORMED THIS PROCEDURE, HE TOLD ME HE FOLLOWS UP ON HIS PATIENTS AND HE TOLD ME THAT WITHOUT EXCEPTION EVERY PATIENT HAS HAD A VERY POSITIVE RESULT FROM THE PROCEDURE KNOW AS CCSVI.

**SO WHY IS THE CDRH GROUP AVOIDING A POSITIVE COMMENT FROM A SICK PATIENT!**

THANK YOU

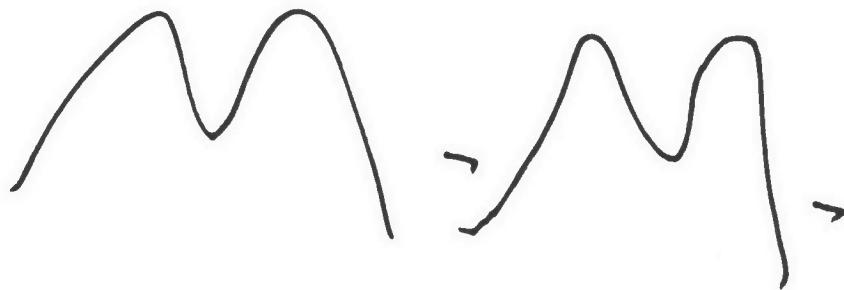
SINCERELY YOURS,

A handwritten signature in black ink, appearing to read "MARIO MORAIS". The signature is somewhat stylized and includes a small flourish at the end.

SENT REGISTERED MAIL TO THE FOLKS AT DOCKETS MANAGEMENT AT THE U.S. DEPARTMENT OF FOOD AND DRUG ADMINISTRATION (FDA).

## **AMENDMENT ONE**

**I WAS TRYING TO GET MR. BUCKLES TO  
PERFORM HIS REGULATORY DUTIES**



MARIO MORAIS  
4 GLEN ROAD, APARTMENT # 103  
HUDSON, MASS., 01749-1365  
PHONE: 978-252-4156 / Email: mariomorais8@gmail.com

-----DATE SEPTEMBER 12, 2012

## The Department of Food and Drug Administration – Office of CDRH

TO; MR. DAVID S. BUCKLES, CDRH OMBUDSMAN AND MR. LAWRENCE ROMANELLI, CDRH DEPUTY OMBUDSMAN, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)  
10903 NEW HAMPSHIRE AVENUE, WO66-G414  
SILVER SPRINGS, MD 20993  
OFF # 301-796-5447 / FAX 301-847-8516 / EMAIL ADDRESS  
CDRHombudsman@fda.hhs.gov, david.buckles@fda.hhs.gov,  
lawrence.romanell@fda.hhs.gov,  
#####

RE; THIS IS MY OFFICIAL COMMUNICATION TO MR. DAVID BUCKLES!  
THIS LETTER IS MAILED REGISTERED RETURN RECITE TO MR. DAVID BUCKLES ALSO TO MR. R. BUCKANAN, POLICE OFFICER, ALSO TO MR. JOSHUA HENRY, SPECIAL AGENT, AND A COPY OF THIS LETTER WILL BE FAXED TO MR. BUCKLES AT FAX NUMBER 301-847-8516. ALSO SENT TO OTHER FOLKS SEE DATA BELOW SIGNATURE.

THIS LETTER REQUESTS 5 ACTIONS FROM MR. BUCKLES IN HIS 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)', 4 REGULATOR ACTIONS AND 1 ACTION FOR AN APPROXIMATE COMPLETION DATE. I ALSO WANT MR. BUCKLES OR HIS AGENT TO CONFIRM RECITE OF THIS FAX!

I AM FOLLOWING THE RESTRICTIONS SET ON MYSELF IN THE LETTER FROM THE US DEPARTMENT OF HOMELAND SECURITY, IN RETURN I EXPECT MR. BUCKLES TO HONOR HIS POSITION AS THE CDRH OMBUDSMAN, NOW, MR. BUCKLES HAS NOT!

#####  
I ADMIT THAT IN THE PAST WEEK, I HAVE SENT MR. BUCKLES ALLOT OF EMAILS BUT THAT IS BECAUSE I WANTED TO GET HIS ATTENTION! FOR OVER TWO MONTHS MR. BUCKLES HAS WANTED NO CONTACT WITH ME. BUT INSTEAD OF MR. BUCKLES CALLING ME AND I WOULD HAVE GLADLY STOPPED. HE INSTEAD CALLS MR. R. BUCKANAN, POLICE OFFICER, US DEPARTMENT OF HOMELAND AND MAKES A COMPLAINT AGAINST ME!.

**NOW, MR BUCKLES INVALIDATES ALL MY EMAIL ADDRESSES SO I CANNOT SEND EMAILS TO THE FOLKS AT FDA! Please think about that!**

HIS ACTIONS WOULD HAVE BEEN MUCH, MUCH EASIER TO JUST CONTACT ME! I DO NOT BELIEVE THE ACTION HE TOOK IS HONORING HIS 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)'

SO, FINALLY, FINALLY, FINALLY AFTER 2 MONTHS SOME KIND OF COMMUNICATION FROM MR. BUCKLES, THE CDRH OMBUDSMAN. A SMALL EMAIL. THIS EMAIL CAME ON SEPTEMBER 5, 2011. THE EMAIL IN ITS ENTIRETY IS COPIED BELOW FOR YOUR REVIEW. IF YOU SEE ANYTHING IN QUOTES THEN THAT STATEMENT WAS IN HIS EMAIL!

I HOPE YOU UNDERSTAND HOW SURPRISED I WAS WHEN I RECEIVED MR. BUCKLES EMAIL SAYING 'Many individuals in FDA, including at CDRH, have received emails, faxes and telephone calls from you in the past week.'. WHEN ALL MR BUCKLES OR MR. ROMANELL NEEDED TO DO WAS ANSWER MY REQUEST TO PLEASE COMMUNICATE WITH ME. THAT REQUEST WAS MADE TO BOTH MR. BUCKLES AND MR ROMANELL ON JULY 5 2012. A FULL 2 MONTHS AGO WITH NO CONTACT FROM EITHER MAN. SO IN REALITY MR. BUCKLES AND MR. ROMANELL'S LACK OF CONTACT IS WHY I CONTACTED THE FDA.

I WAS ACTIVELY TRYING TO GET SOME CONTACT FROM THE DIRECTOR OFFICE OF CDRH SINCE JUNE 12, 2012. MS. LINDSAY LLOYD, ASSISTANT TO DR. WILLIAM MAISEL OR DR. WILLIAM MAISEL HIMSELF, OR MR. JEFFREY SHUREN, THE CENTER DIRECTOR OF CDRH.

SINCE I WAS IGNORED BY THE 3 PEOPLE ABOVE, I TRIED CALLING THE MAIN DEVICE NUMBER FOR THE DIRECTORS OFFICE AT 1-251-796-5900 AND I FOUND OUT MY COMMENT WAS NOT SENT TO 'exec sec'. AS MS. LLOYD HAD TOLD ME. SO WITH THAT KNOWLEDGE I STARTED CALLING Dr. David S. Buckles BECAUSE HE WAS THE 'Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' AT 301-796-5447 , BUT MR. BUCKLES NEVER RETURNED MY PHONE MESSAGES. AFTER A FEW DAYS I STARTED CALLING MR. ROMANELL PHONE NUMBER WITH THE SAME RESULTS.

NOW WHEN I CALL THE OMBUDSMAN AT 301-796-5447 OR THE DEPUTY OMBUDSMAN AT 301-796-5436 OR THE MAIN NUMBER FOR THE DIRECTORS OFFICE AT 301-796-5900, OR MS. LINDSAY LLOYD NUMBER AT 301-796-4866 ALL FOUR PHONES SAY 'the party you are trying to reach is not accepting calls at this time'

**SO THAT'S WHY I WAS TRYING TO GET A HOLD OF YOU BUT IT SEEMS THAT YOU WERE AVOIDING ME AS WELL! IS THAT WHAT THE 'Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' SUPPOSED TO DO???????**

I AM VERY SORRY IF MY ATTEMPT TO GET SOME CONTACT FROM MR. BUCKLES DISRUPTED THE GOVERNMENT! MY INTEND WAS ONLY FOR SOME KIND OF OMBUDSMAN RESPONSE!

**SO IN REALITY YOU MR. DAVID BUCKLES AS CDRH OMBUDSMAN AND MR LAWRENCE ROMANELLI AS CDRH DEPUTY OMBUDSMAN COULD HAVE PREVENTED ME FROM CONTACTING THE FDA BY SIMPLY CONTACTING ME!**

**MR. BUCKLES, I DO NOT UNDERSTAND HOW YOUR LACK OF CONTACT OF MYSELF CAN FORMULATE IN A COMPLAINT AGAINST ME!**

IN YOUR EMAIL TO ME YOU SAID 'I am writing to you in my capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' **MR. BUCKLES YOU DISABLED MY EMAIL ADDRESSES, ALL OF THEM!! ITS FUNNY BUT I DO NOT REMEMBER GOING IN FRONT OF A JUDGE! IN THE USA WE ARE SUPPOSED TO BE INNOCENT UNTIL PROVEN GUILTY**

WHAT YOU DID BY DISABLING ALL MY EMAILS WAS VERY PREMATURE! AND THERE ARE MANY OTHER WAYS, **1) THOSE FOLKS AT THE FDA CAN USE AN EMAIL FILTER TO PLACE MY EMAILS IN THE SPAM FOLDER OR 2) THEY CAN BYPASS MY EMAIL ALTOGETHER! SO THERE WAS NO IMMINENT DANGER!**

**I AM SORRY MR. BUCKLES IF YOU ARE YOU AFRAID OF WHAT I AM SAYING! EVERY EMAIL I HAVE EVER SENT THE FDA IS ABOUT FDA BUSINESS AND ALL MY EMAILS HAVE ONLY BEEN THE TRUTH! I AM VERY SORRY IF YOU WANT TO STOP THE TRUTH!**

WHAT HAS HAPPENED IS YOU FILED A COMPLAINT AGAINST ME TO THE US DEPARTMENT OF HOMELAND SECURITY AND I FILED A COUNTER COMPLAINT AGAINST YOU TO MR. R. BUCKANAN, POLICE OFFICER!

THE COUNTER COMPLAINT STATES THAT YOU WERE AVOIDING ME AS WELL AS AVOIDING YOUR CDRH OMBUDSMAN DUTIES! NOW I BELIEVE THE US DEPARTMENT OF HOMELAND SECURITY SHOULD COMPARE BOTH COMPLAINTS! AND DECIDE!

-----5-OF-25

**REASONS WHY I NEED TO BE ABLE TO EMAIL FOLKS AT FDA.**  
**CURRENTLY HAVE AN OUTSTANDING CITIZENS PETITION AT THE FDA,**  
**SO I NEED MY ABILITY TO EMAIL THE FDA. THE NUMBER ASSIGNED TO**  
**THE CITIZENS PETITION IS FDA-2012-O-0119-001/CP!**

**MY CITIZENS PETITION IS BEING HANDLED BY MS ELLEN MOLINARO**  
**HER EMAIL ADDRESS IS** ellen.molinaro@fda.hhs.gov , MS. MOLINARO IS A SUPERVISOR AT THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) I BELIEVE MS. MOLINARO IS IN REGULATORY HEALTH, HER TEL NO IS 301-796-2907

RECENTLY, AUGUST 1, 2012, I WAS INFORMED BY MS. JANE AXELRAD, HER EMAIL ADDRESS IS jane.axelrad@fda.hhs.gov, MS AXELRAD IS IN CDER AND IS THE DIRECTOR OF POLICY, HER TELEPHONE NUMBER IS 301-796-3600. MS AXELRAD'S LETTER TO ME IS BELOW FOR YOUR REVIEW.

AS YOU KNOW, AND IF YOU DO NOT KNOW, I HAVE MULTIPLE SCLEROSIS AND I'M IN A MOTORIZED WHEELCHAIR, I DO NOT DRIVE AS BOTH MY LEGS ARE PARALYZED AND MY RIGHT HAND IS IN A PERMANENT FIST POSITION! THAT IS THE REASON I TYPE USING MOSTLY CAPITAL LETTERS.

**SO, ASKING ME TO ONLY COMMUNICATE WITH THE FDA THRU THE MAIL**  
**AS YOU STATED IN YOUR EMAIL IS AN UNDUE HARSHIP ON ME. AS IT**  
**IS NOW, I MUST BRIBE MY PERSONAL CARE ATTENDANTS TO DO THESE**  
**MAILINGS FOR ME! . ALL TIME IS VALUABLE TO OTHER INDIVIDUALS!**  
**THUS I NEED MY EMAIL ADDRESSES BACK!**

IN YOUR ONLY COMMUNICATION TO ME, YOUR EMAIL YOU ALSO SAID 'I request that you direct your communications only to me, and only in writing. I can assure you that any written communications from you to me that pertain to the regulatory work of FDA will be handled appropriately.'

**SO HERE GOES IN REGARD TO 'regulatory work of FDA' THAT YOU SAID**  
**IN YOUR EMAIL 'will be handled appropriately.'**

**SO I WOULD LIKE YOU TO ACT AS STATED IN YOUR EMAIL IN YOUR**  
**'capacity as Ombudsman for the Center for Devices and Radiological**  
**Health (CDRH) of the Food and Drug Administration (FDA)'**

---

I SENT MY COMMENT ON, MON JUNE 11, 2012 AND THE COMMENT WAS CONFIRMED THAT MS. LINDSAY LLOYD RECEIVED THE EMAIL ON THE SAME DAY JUNE 11, 2012, PLEASE SEE EMAILS BELOW

-----6-OF-25

SO MY COMMENT HAS BEEN IN MS. LLOYD'S POSSESSION SINCE JUNE 11, 2012. NOW MS. LLOYD TOLD ME OVER THE PHONE THAT MY COMMENT WAS SENT TO 'exec sec' BUT I HAVE SINCE BEEN TOLD MY COMMENT WAS NOT RECEIVED BY 'exec sec' COULD YOU PLEASE ASSURE ME THAT MY COMMENT WAS SENT AND RECEIVED BY 'exec sec'. NOW SINCE THIS COMPLETE FIASCO HAS HAPPENED I WOULD LIKE TO VERIFY THAT IT IS THERE.

**REGULATORY REQUEST # 1**

**IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' WOULD YOU PLEASE SEND ME SOME CONTACT INFORMATION FOR 'exec sec'.**

**REGULATORY REQUEST # 2**

**ALSO IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' WOULD YOU PLEASE ASSURE THAT MY COMMENT SENT AND RECEIVED BY MS. LLOYD ON JUNE 11, 2012. IS PLACED IN THE FDA FOLDER FOR THE PROCEDURE KNOWN AS CCSVI. AGAIN I WOULD LIKE CONTACT INFORMATION FOR THE FOLDER FOLKS TO VERIFY IT WAS RECEIVED AND PLACED IN THE FOLDER!**

**BY THE WAY A COPY OF MY COMMENT IS BELLOW IF YOU SHOULD HAVE A HARD TIME FINDING A COPY**

---

**MY COMMENT REGARDING CCSVI WAS ASSIGNED THE TRACKING NUMBER 0807-2012-2513 BY THE CORRESPONDENCE DEPARTMENT OF MS. KATHLEEN SEBELIUS.**

**REGULATORY REQUEST # 3**

**ALSO IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' COULD YOU ASSURE THAT SOMEONE IN CDRH OR ANY ORGANIZATION WITHIN THE FDA ANSWERS MY COMMENT WITH TRACKING NUMBER 0807-2012-2513. I WOULD LIKE MY COMMENT ANSWERED BY PHONE!**

**REGULATORY REQUEST # 4**

**ALSO IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' I WOULD VERY MUCH LIKE MY DOCTOR TO PERFORM A FOLLOWUP PROCEDURE ON MYSELF, BUT BECAUSE OF THE FDA'S NEWS ANNOUNCEMENT HE WILL NOT! COULD YOU ASK THE FDA IF THEY COULD ISSUE ANOTHER NEWS ANNOUNCEMENT THAT WOULD ALLOW ME TO GET A FOLLOW-UP PROCEDURE FROM MY DOCTOR!**

**OMBUDSMAN REQUEST # 5**

ALSO IN YOUR EMAIL IT SAID 'I will be responding separately to you regarding CCSVI.' AGAIN IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' WOULD YOU PLEASE GIVE ME AN ESTIMATED DATE OF COMPLETION!

THANK YOU FOR YOUR TIME.

IF YOU HAVE ANY QUESTIONS OR CONCERNS PLEASE FEEL FREE TO CALL ME AT 978-252-4156 OR EMAIL ME AT [mariomorais8@gmail.com](mailto:mariomorais8@gmail.com).

SINCERELY YOURS,

MARIO MORAIS

FAXED TO MR. DAVID S. BUCKLES AT FAX NUMBER 301-847-8516 ALSO TO THE FINE FOLKS AT THE U.S. DEPARTMENT OF FOOD AND DRUG ADMINISTRATION (FDA) WHO RECEIVE THE LETTER MR. BUCKLES PERSONAL NUMBER IS 301-796-5447

ALSO

MAILED REGISTERED RETURN RECITE TO MR. BUCKLES CDRH OMBUDSMAN AT THE FDA

ALSO

MAILED REGISTERED RETURN RECITE TO MR. R. BUCKANAN, POLICE OFFICER, AT THE US DEPARTMENT OF HOMELAND SECURITY. MR. BUCKANAN PERSONAL NUMBER IS 619-257-4128.

ALSO

MAILED REGISTERED RETURN RECITE TO MR. JOSHUA HENRY, SPECIAL AGENT, AT THE US DEPARTMENT OF HOMELAND SECURITY. MAIN NUMBER IS 202-282-8000

ALSO

FAXED TO MS. MARGARET HAMBURG AT FAX NO 301-847-3531 ALSO TO THE FINE FOLKS AT THE U.S. DEPARTMENT OF FOOD AND DRUG ADMINISTRATION (FDA) WHO RECEIVE THE LETTER, MS. HAMBURG'S PERSONAL NUMBER IS 301-796-5000

ALSO

FAXED TO THE OFFICE OF CHIEF COUNCIL AT FAX NO 301-847-8618 ALSO TO THE FINE FOLKS AT THE U.S. DEPARTMENT OF FOOD AND DRUG ADMINISTRATION (FDA) WHO RECEIVE THE LETTER, MS. ANN WION'S PERSONAL NUMBER IS 301-796-8722

ALSO

FAXED TO THE OFFICE OF THE OMBUDSMAN AT FAX NO 301-847-8628, DIRECTOR IS MS. LAURIE LENKEL, MAIN NUMBER IS 301-796-8530. MS LENKEL'S PERSONAL NUMBER IS 301-796-8483.

ALSO

FAXED AND EMAILED TO THE FOLKS AT THE OFFICE OF THE SECRETARY FOR THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) AT FAX NO 202-690-7302, MS. KATHLEEN SEBELIUS THE SECRETARY OF HHS PERSON PHONE IS 202-690-7000

ALSO

FAXED AND EMAILED TO THE FOLKS AT THE OFFICE OF THE EXECUTIVE SECRETARIAT FOR THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) AT FAX NO 202-205-2135, MAIN NUMBER IS 202-690-5627. MS. JENNIFER M. CANNISTA SECRETARY. PERSONAL NUMBER IS 202-690-5627. MR. OLIVER POTTS DEPUTY SECRETARY, MR POTTS PERSONAL NUMBER IS 202-401-4273.

ALSO

FAXED AND EMAILED TO THE FOLKS AT THE OFFICE OF THE INSPECTOR GENERAL AT FAX NO 202-401-2596. MAIN NUMBER IS 202-619-2548 , MR. DANIEL R. LEVINSON, INSPECTOR GENERAL. MS. ROSE FOLSOM IS THE DIRECTOR OF THE EXECUTIVE SECRETARIAT. MS. FOLSOM PERSONAL NUMBER IS 202-619-3978

ALSO

FAXED TO THE OFFICE OF THE INTEGRITY COMMITTEE, PRESIDENTS INTEGRITY COMMITTEE AT 202-324-2043 CONTACT IS MS. MARY CONWAY, HER PERSONAL NUMBER IS 202-324-3768

ALSO

FAXED AND EMAILED TO THE OFFICE OF GOVERNMENT INFORMATION SERVICES (OGIS) AT FAX NO 301-837-0348. CONTACT IS MS. CANDACE BROWN –MAIN NUMBER FOR OFFICE IS 301-837-1996 CASE NO---- 20110177

ALSO

FAXED AND EMAILED TO CONGRESS MY REPRESENTATIVE IS THE HONORABLE CONGRESSWOMAN MS. NIKI TSONGAS REPRESENTING THE COMMONWEALTH OF THE FIFTH DISTRICT OF MASSACHUSETTS AT FAX NO 202-226-0771 BUT FAXED TO ALL OFFICES

ALSO

FAXED AND EMAILED TO THE SENATE MY SENATOR IS THE HONORABLE SENATOR JOHN F. KERRY REPRESENTING THE THE COMMONWEALTH OF MASSACHUSETTS AT FAX NO 202-224-8525, IN-HOUSE ATTORNEY IS MS. MEGAN LEAHY HER NO IS 617-565-8519.

ALSO

FAXED AND EMAILED TO THE SENATE MY OTHER SENATOR IS THE HONORABLE SENATOR SCOTT P. BROWN REPRESENTING THE COMMONWEALTH OF MASSACHUSETTS AT FAX NO 202-228-2646, IN-HOUSE ATTORNEY IS MR. JACK RICHARD HIS NO IS 617-565-2570.

-----9-OF-25

HERE IS THE ENTIRE EMAIL AND THE ONLY COMMUNICATION EVER  
THAT MR. DAVID BUCKLES SENT ME MR. BUCKLES ALSO CC'ED MR.  
ROMANELL

---

from:-----Buckles, David David.Buckles@fda.hhs.gov  
to:-----mario morais <anncartermjackbrown@gmail.com>  
cc:-----"Romanell, Lawrence J." <Lawrence.Romanell@fda.hhs.gov>  
date:-----Wed, Sep 5, 2012 at 4:31 PM  
subject:-----Communications with FDA

Mr. Morais:

I am writing to you in my capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA). Many individuals in FDA, including at CDRH, have received emails, faxes and telephone calls from you in the past week. As described in the August 10, 2012, letter to you from Mr. R. Buchanan, Federal Protective Service, which is part of the Department of Homeland Security, I request that you direct your communications only to me, and only in writing. I can assure you that any written communications from you to me that pertain to the regulatory work of FDA will be handled appropriately.

I will be responding separately to you regarding CCSVI.

Regards,

David S. Buckles, PhD, FACC  
CDRH Ombudsman  
10903 New Hampshire Ave, WO66-G414  
Silver Spring, MD 20993  
301-796-5447  
fax 301-847-8516

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-----10-OF-25

HERE IS A COPY OF THE LETTER FROM MS. KAREN KENNARD,  
DIRECTOR OF DOCKETS, TALKING ABOUT MY CITEZENS PETITION.

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service

Food and Drug Administration  
Rockville MD, 20857

FEB 3, 2012

MARIO MORAIS

DEAR MR. MORAIS,

YOUR PETITION TO FOOD AND DRUG ADMINISTRATION, THE CURRENT FDA RULES AND REGULATIONS ARE KILLING PEOPLES HUMAN RIGHTS AND HINDERING NEW TECHNOLOGY! THE CURRENT ACCESS LAW PROTECTS CLINICAL TRIALS, NOT HUMAN LIFE OR HUMAN RIGHTS, WAS RECIEVED BY THIS OFFICE ON 02/03/2012. IT WAS ASSIGNED DOCKET NUMBER FDA-2012-O-0119-001/CP, AN IT WAS FILED ON 02/03/2012. PLEASE REFER TO THIS DOCKET NUMBER IN THE FUTURE CORRESPONDENCE ON THIS SUBJECT WITH THE AGENCY.

PLEASE NOTE THAT THE ACCEPTENCE OF THE PETITION FOR FILLING IS A PROCEDURAL MATTER IN THAT IT IN NO WAY REFLECTS AN AGENCY DECISION ON THE SUBSTANTIVE MERITS OF THE PETITION.

SINCERELY,

KAREN KENNARD, DIRECTOR  
DIVISION OF DOCKETS MANAGEMENT  
OFFICE OF PUBLIC INFORMATION AND LIBRARY SERVICES  
OFFICE OF SHARED SERVICES  
OFFICE OF MANAGEMENT

-----11-OF-25

A COPY OF THE LETTER FROM MS. JANE AXELRAD STATING MY  
CITIZENS PETITION WILL BE DELAYED

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Rockville MD 20857

**AUG - 1 2012**

Mr. Mario Morais  
4 Glen Road, Apartment 103  
Hudson, 01749-1365

Re: Docket No. FDA-2012-P-0119

Dear Mario Morais

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition and supplement, received on February 3, 2012 and April 18, 2012, respectively. Your petition requests that the Agency: (1) issue a statement that "checking" (e.g., through imaging technology) and "fixing" blood flow to the brain (i.e., using "liberation therapy") may benefit patients who have neurological problems; (2) create an "unapproved drugs" category of drugs, to which patients could receive access at their own risk; (3) permit all interested patients to participate in clinical trials, and let all participants receive the drugs being tested; (4) make available the drug identified as BB:7075 to HIV patients, and ask the National Institutes of Health (NIH) to test it; (5) permit patients to have more influence in drug approval decisionmaking; and (6) provide safety information from investigational new drug trials.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

---

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

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-----12-OF-25

HERE IS A COPY OF AN EMAIL WHERE MS. LLOYD CONFIRMS RECEIVING MY LETTER REGARDING MY COMMENT ABOUT CCSVI

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from:-----Lloyd, Lindsay Lindsay.Lloyd@fda.hhs.gov  
to:-----mario morais <anncartermjackbrown@gmail.com>,  
-----"Maisel, William" <William.Maisel@fda.hhs.gov>,  
-----"Afia.Asamoah@fda.hhs.gov" <Afia.Asamoah@fda.hhs.gov>  
date:-----Mon, Jun 11, 2012 at 3:26 PM  
subject:-----RE: I WOULD LIKE TO EXPLAIN TO THE DEPARTMENT OF FOOD AND DRUG ADMINISTRATION THAT THE SIMPLE PROCEDURE KNOWN AS CCSVI, REALLY HELPED ME, AND I DO NOT UNDERSTAND THE FDA'S NEWS RELEASE OF THIS EASY NON-INVASIVE PROCEDURE THAT HELPS SICK FOLKS!

Mr. Morais,

This is to confirm receipt of your email.

Thank you,

Lindsay  
Lindsay Lloyd  
Office of the Center Director  
Center for Devices and Radiological Health  
Building 66, Room 5447  
301.796.4866

---

HERE IS MY RESPONSE TO MS. LINDSAY LLOYD

---

from:-----mario morais anncartermjackbrown@gmail.com  
to:-----"Lloyd, Lindsay" <Lindsay.Lloyd@fda.hhs.gov>,  
-----Afia.Asamoah@fda.hhs.gov  
date:-----Mon, Jun 11, 2012 at 6:17 PM  
subject:-----Re: I WOULD LIKE TO EXPLAIN TO THE DEPARTMENT OF FOOD AND DRUG ADMINISTRATION THAT THE SIMPLE PROCEDURE KNOWN AS CCSVI, REALLY HELPED ME, AND I DO NOT UNDERSTAND THE FDA'S NEWS RELEASE OF THIS EASY NON-INVASIVE PROCEDURE THAT HELPS SICK FOLKS!  
mailed-by:-----gmail.com

HI LINDSAY

THANK YOU FOR CONFIRMING MY EMAIL

-----13-OF-25

HERE IS THE LETTER SENT TO MS. LINDSAY LLOYD ON JUNE 11 TH, 2012 AND CONFIRMED THAT MS. LINDSAY LLOYD RECEIVED THIS EMAIL ON JUNE 11 TH, 2012. MS. LLOYD IS IN CDRH-THIS LETTER WAS ASSIGNED THE **TRACKING NUMBER 0807-2012-2513** BY THE CORRESPONDENCE DEPARTMENT OF MS. KATHLEEN SEBELIUS.

-----HERE-IS-THE-TITLE-----

Re: I WOULD LIKE TO EXPLAIN TO THE DEPARTMENT OF FOOD AND DRUG ADMINISTRATION THAT THE SIMPLE PROCEDURE KNOWN AS CCSVI, REALLY HELPED ME, AND I DO NOT UNDERSTAND THE FDA'S NEWS RELEASE OF THIS EASY NON-INVASIVE PROCEDURE THAT HELPS SICK FOLKS!

MARIO MORAIS  
4 GLEN ROAD, APARTMENT # 103  
HUDSON, MASS., 01749-1365  
PHONE: 978-252-5156 / Email: marioTTTmorais8@gmail.com

-----DATE JUNE 11, 2012

## The Department of Food and Drug Administration

MS. LINDSAY LLOYD / Dr. William Maisel, M.D., M.P.H., / ALSO  
Ms MARGARET HAMBURG / COMMISSIONER OF FDA  
WASHINGTON, DISTRICT OF COLUMBIA  
OFF # 301-796-5000 / FAX 301-796-9840 / [Margaret.Hamburg@fda.hhs.gov](mailto:Margaret.Hamburg@fda.hhs.gov)  
OFF # 301-796-4866 / [lindsay.lloyd@fda.hhs.gov](mailto:lindsay.lloyd@fda.hhs.gov) / [william.maisel@fda.hhs.gov](mailto:william.maisel@fda.hhs.gov)

#####  
RE: I WOULD LIKE TO EXPLAIN TO THE DEPARTMENT OF FOOD AND DRUG ADMINISTRATION THAT THE SIMPLE PROCEDURE KNOWN AS CCSVI, REALLY HELPED ME, AND I DO NOT UNDERSTAND THE FDA'S NEWS RELEASE OF THIS EASY NON-INVASIVE PROCEDURE THAT HELPS SICK FOLKS!  
#####

DEAR DR. WILLIAM MAISEL AND MS. LINDSAY LLOYD AND MEMBERS OF THE DEPARTMENT OF FOOD AND DRUG ADMINISTRATION:

I WOULD LIKE TO GIVE YOU DR. MAISEL AND MS. LLOYD AT THE FDA, MY EXPERIENCE AND KNOWLEDGE OF MULTIPLE SCLEROSIS --MS--! I HAVE HAD MS FOR ABOUT 25 YEARS NOW!

-----14-OF-25

MY EXPERIENCE HAS RE-ENFORCED THE FACT THAT I AM SURE THAT MS IS IN PART DUE TO A VIT B-1 DEFICIENCY --THE BODY CANNOT PRODUCE VIT B-1! THE INABILITY OF THE BODY TO PRODUCE THE VIT B-1 LEADS TO NO-ENERGY. AND NO-ENERGY IS A VERY COMMON TRAIT WITH MS PATIENTS. I INJECT VIT B-1 EVERYDAY AND I HAVE MUCH MORE ENERGY.

THE 2ND CAUSE FOR MS IS MS IS IN PART DUE TO A BLOOD VASCULAR PROBLEM, THE MAIN ARTERIES THAT DRAIN BLOOD FROM THE BRAIN GET EITHER CONSTRICTED OR CLOGGED, THE CONSTRICTED OR CLOGGED BLOOD VEINS WILL CREATE AN AUTOIMMUNE REACTION.

THE BRAIN USES THREE MAIN BLOOD VESSELS TO DRAIN BLOOD. THE THREE MAIN VEINS THAT DRAIN BLOOD FROM THE BRAIN ARE THE 2 JUGULAR VEINS AND THE AZYGOUS VEIN. IF THESE VEINS GET CONSTRICTED IT WILL CAUSE A BACK FLOW OF BLOOD BACK TO THE BRAIN. THIS CAUSES A LAYER OF BLOOD IN THE BRAIN. THAT LAYER OF BLOOD CAUSES IRON DEPOSITS AND IRON DEPOSITS IN THE BRAIN LEADS TO AN AUTO-IMMUNE REACTION, JUST LIKE IN MS!

HERE IS THE DEFINITION OF THIS PROCEDURE!

[http://en.wikipedia.org/wiki/Chronic\\_cerebrospinal\\_venous\\_insufficiency](http://en.wikipedia.org/wiki/Chronic_cerebrospinal_venous_insufficiency)

**CURRENTLY, WE HAVE A HEALTH CARE SYSTEM THAT ROUTINELY CHECKS AND FIXES THE ARTERY'S AND VEINS TO THE HEART.**

THE BLOOD FLOW TO THE HEART IS IMPAIRED, AND SOMEONE CAN GET A HEART ATTACK! NOW I'M SURE SOME PROBLEMS ARE SELF INFILCTED. WE EAT MORE FATTY FOODS. WE EAT A HIGHER CHOLESTEROL DIET. AND THE LIST GOES ON!

**LET ME ASK YOU A VERY SIMPLE QUESTION, WHAT ARE THE CHANCES THAT ANOTHER VEIN OR ARTERY IS ALSO RESTRICTED! THE CHANCES ARE VERY HIGH!**

I WANTED TO KNOW IF MY VEINS WERE CONSTRICTED, I FIRST TYRED THE CLINICAL TRIALS BUT THEY WERE FOR '**education purposes only**' THEY WOULD CHECK YOUR VEINS AND THEN TELL YOU YOUR PERCENTAGE BLOCKED, BUT THEN THE CLINICAL TRIALS WOULD NOT FIX THE CONSTRICTED VEIN....

THE **EDUCATION** THE CLINICAL TRIALS WERE OFFERING IS NOT WHAT I WANTED...**I WANTED IT FIXED BUT THE CLINICAL TRIALS JUST WANTED TO ASSOCIATE CONSTRICTED VEINS TO MS.** AND ALSO THE CLINICAL TRIALS ONLY CHECK THE NECK VEINS NOT REPEAT NOT THE 2 JUGULAR VEINS AND THE AZYGOUS VEIN, THOSE 3 VEINS ARE

-----15-OF-25

PROTECTED BY HARD TISSUE AND NEED ANOTHER TEST, LIKE AN MRI, TO GET PICTURES OF THEM. AND FINALLY THE CLINICAL TRIALS WANTED THIS PROCEDURE TO CURE MS... NOTHING KNOWN TO MANKIND CURES MS, NOT EVEN THIS SIMPLE PROCEDURE. I HAD THE PROCEDURE AND I HAVE A BETTER QUALITY OF LIFE BUT I STILL HAVE MS!

=====

I BELIEVE THE CLINICAL TRIALS WERE DESIGNED TO FAIL. THE HURDLE THE CLINICAL TRIALS ARE ASKING FOR A SIMPLE OUT-PATIENT PROCEDURE IS SET WAY TO HIGH, NOTHING KNOW TO MANKIND CURES MULTIPLE SCLEROSIS!

=====

+++++  
BUT A BETTER QUALITY OF LIFE IS ALL WE SICK FOLKS WANT!  
+++++

ON MY OWN, I TYRED TO GET A VASCULAR DOCTOR TO CHECK MY VEINS, BOY WHAT A TASK THAT WAS, THE DOCTOR SCHEDULED A TEST TO CHECK MY NECK VEINS ONLY, UNFORTUNATELY NOT THE CORRECT VEINS. I BELIEVE THOSE ARE THE VEINS THE CLINICAL TRIALS ARE CHECKING, THE TEST SHOWED MY NECK WAS FINE.

BUT I WANTED BOTH MY JUGULAR VEINS AND MY AZYGOUS VEIN CHECKED. BUT I FOUND ANOTHER DOCTOR AND HE AGREED TO PHOTO THE 3 MAIN VEINS. I TOLD HIM THAT IF PICTURES SHOWED RESTRICTIONS, I WOULD GO TO A SPECIAL CLINIC AND ASSURED HIM HE WOULD NOT NEED TO DO THE FIX. THE PHOTOS SHOWED THAT ALL 3 OF MY MAIN VEINS WERE RESTRICTED.

I HAD THIS PROCEDURE DONE, IT WAS A 2 HOUR OUT-PATIENT PROCEDURE, I WAS AWAKE THRU THE WHOLE PROCEDURE AND I SLEPT THAT NIGHT IN MY HOTEL ROOM!

THE RIDE TO THE VASCULAR CLINIC WAS MORE DANGEROUS THAN THE PROCEDURE ITSELF! THIS PROCEDURE WAS VERY SAFE AND EVERY PERSON I HAVE EVER TALKED TO WAS VERY HAPPY WITH THE PROCEDURE RESULTS, MYSELF INCLUDED!

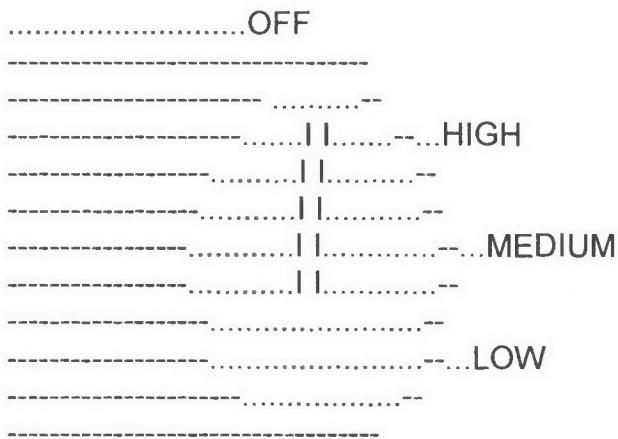
SINCE I HAVE HAD THIS PROCEDURE, THE CLINIC I WENT-ON TO NO LONGER PERFORM THIS PROCEDURE. THE FDA STOPPED THEM FROM PERFORMING THIS SIMPLE AND EFFECTIVE PROCEDURE. **IT APPEARS**

-----16-OF-25

**THE FDA CAN PROTECT THE SICK PERSON FROM A SIMPLE BENEFICIAL PROCEDURE, AND MAINTAIN YOUR DISEASE!**

LET ME GIVE YOU MY EXPERIENCE, AFTER THE PROCEDURE, THE DIFFERENCES WERE POSITIVE AND AUTOMATIC. I CAN NOW OPEN MY OWN WINDOW! THE WINDOW OPERATES WITH A CRANK, AND I FOUND IT TOO DIFFICULT, BEFORE THE PROCEDURE, TO MOVE THE CRANK. I FIND THAT NOW I CAN TURN THE CRANK BOTH CLOCKWISE AND COUNTER CLOCKWISE, AFTER THE PROCEDURE. MY STRENGTH HAS GREATLY IMPROVED

I CAN NOW TURN MY A/C ON AND OFF, EASILY! I HAVE A KNOB WITH 3 SETTINGS, I TYRED TO ILLUSTRATE THE A/C KNOB BELOW;



NOW I CAN EASILY CHANGE THE A/C UNIT BETWEEN HIGH/MEDIUM/LOW.

BEFORE THE PROCEDURE I TYRED SO HARD THAT THE PAINT AND EVEN THE OFF/HIGH/MEDIUM/LOW SETTINGS HAVE FADED AND ARE ALMOST GONE. I RUBBED MY FINGERS AGAINST THE A/C UNIT, BECAUSE I HAD A VERY HARD TURNING JUST THE NOBE.

THE REASON IS MY FEELINGS AT THE FINGERS ARE MUCH BETTER. I CAN NOW DISTINGUISH BETWEEN THE KNOB AND THE A/C UNIT, IN OTHER WORDS I KNOW LONGER PUT ANY PRESSURE ON THE A/C INDICATORS! I JUST TURN THE ONLY THE NOBE.

AND THE LIST GOES ON BUT I WILL STOP BY SAYING THAT THE PROCEDURE WAS THE BEST THING I'VE DONE AFTER THE VIT B-1!

**BUT NEITHER OF THOSE 2 THINGS CAN BE PATENTED BY AN ORGANIZATION! IN OTHER WORDS IT IS NOT FINANCIALLY**

-----17-OF-25

**FEASIBLE TO SPEND HUNDREDS OF MILLIONS OF DOLLARS TO PROVE TO THE FDA THAT SOMETHING SO SIMPLE MAY HELP A PATIENT.**

HERE IS MONTEL WILLIAMS EXPERIENCE REGARDING CCSVI  
<http://www.doctoroz.com/videos/montels-own-procedure?mid=51>

THE FDA ANNOUNCEMENT SAYS 'studies exploring a link between MS and CCSVI are inconclusive, and the criteria used to diagnose CCSVI have not been adequately established.' WHY MUST A LINK EXIST BETWEEN MS AND THIS PROCEDURE. THIS IS A HUMAN ISSUE NOT AN MS ISSUE!

MS CAN BE A REASON TO CHECK THE LEVEL OF RESTRICTION! THEN ITS THE PATIENTS DECISION IF HE/SHE WOULD LIKE IT FIXED!

**ITS A HUMAN ISSUE! REPEAT, IT'S A HUMAN ISSUE!**

I BELIEVE THE FDA IS MAKING FOLKS GO TO PERFORM UNSAFE PROCEDURES SOMETIMES EVEN OUTSIDE THE USA, THEN THE FDA STOPS THE PROCEDURE BECAUSE OF THOSE FOLKS THAT WERE FORCED TO GET DANGEROUS PROCEDURES! THAT LOGIC MAKES NO SENSE TO ME.

I BELIEVE THE MOST DANGERS RESULT, IS NOT ALLOWING THIS SIMPLE PROCEDURE, AND THUS ALLOWING THIS AUTO-IMMUNE DISEASE TO PROGRESS, ALLOWING DISEASE PROGRESSION IS MUCH MORE DANGEROUS THAN THIS SIMPLE PROCEDURE, KNOW AS CCSVI!

HERE IS AN ARTICLE THAT DESCRIBES CCSVI BY DR. ZAMBONI  
<http://singularityhub.com/2010/07/13/cure-for-multiple-sclerosis-controversial-liberation-procedure-moves-forward/>

THE ARTICLE SAYS 'Zamboni – whose own wife has MS – recognized that in many patients, the three veins responsible for draining blood from the brain (the two jugulars and the azygos) are tangled or constricted. He named this symptom "chronic cerebrospinal venous insufficiency," or CCSVI.'

SO THE THREE VEINS ARE LISTED. WHAT 'proof' DOES THE FDA NEED. WHY IS FDA UNSURE WHICH VIENS NEED TO BE CHECKED. THE NEWS RELEASE SAID 'the criteria used to diagnose CCSVI have not been adequately established.'

I DO FEEL THAT THE FDA WAITING FOR 'proof' WILL BE A MISTAKE! NO ORGANIZATION WILL SPEND 1 BILLION DOLLARS TO PROVE TO THE FDA THAT A SIMPLE PROCEDURE WILL HELP THE PATIENT AND WAITING FOR 'proof' WILL NOT HELP THE PATIENTS OF THE U.S.

### The Complete Theory

Zamboni – whose own wife has MS – recognized that in many patients, the three veins responsible for draining blood from the brain (the two jugulars and the azygos) are tangled or constricted. He named this symptom “chronic cerebrospinal venous insufficiency,” or CCSVI. In a healthy adult, blood vessels in the brain are impermeable to many of the blood’s contents – the blood brain barrier protects the brain from potential harm (e.g. bacterial cells) and only gives passage to smaller molecules like oxygen, carbon dioxide, hormones, and so on. Zamboni hypothesizes that poor drainage caused by CCSVI might cause a reflux of blood into the brain that increases blood pressure. The results of this pressure are twofold. First, iron is deposited out of the blood and into the brain. Second, if blood vessels are stretched out, they can tear microscopically and leak immune cells into the brain. The immune system then attacks the iron deposits, and MS results.

This is where the liberation procedure comes in. Zamboni proposed that balloon angioplasty, a common technique for widening blood vessels, should alleviate the symptoms of MS. Last year, he published a study of 65 MS patients who underwent the surgery; two years after the procedure, 73% of the subjects had no symptoms. Since his research was initially reported, many MS patients throughout the world have sought the liberation treatment from angioplasty surgeons.

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A COMPANY OR ORGANIZATION MUST PROVE TO THE FDA THAT A SIMPLE NON-INVASIVE PROCEDURE CAN HELP THE PATIENT TREMENDOUSLY BUT THAT COMPANY OR ORGANIZATION WILL NOT BE ABLE TO RECOUP THE BILLION DOLLARS NEEDED TO GET FDA ‘approval’ . SO THERE IS NO FINANCIAL INCENTIVE. THE CURRENT CHECKS AND BALANCES ARE VERY MUCH AGAINST THE SICK PERSON. THE SYSTEM DOES NOT PRODUCE REVENUE BY BENEFITING THE SICK PERSON!

I HAVE DONE A TREMENDOUS AMOUNT OF RESEARCH BUT THIS INFORMATION I WILL SHARE WITH EVERYONE AND I GOT THIS INFORMATION FROM THE WEB SITE:  
<http://www.youtube.com/watch?v=s2UJ3Hbm6ql>

I DID THE BEST I COULD AT TRANSLATING WHAT THE DOCTOR WAS SAYING BUT IT WAS IN BROKEN ENGLISH:

-----19-OF-25

### **Dr. Marian Simka from Poland talks about CCSVI**

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CCSVI THE VENUS PATHOLOGY WHICH HAS BEEN FOUND BY PROFESSOR ZAMBONI FROM ITALY, THIS LOOKS LIKE A REAL VASCULAR PROBLEM AND IT WAS FOUND TO BE HIGHLY CORRECTED WITH MUSCULAR SCLEROSIS AND MOST LIKELY IT GIVES A NEW CHANCE FOR THOSE PATIENTS AND TREATMENTS WHICH WAS NOT VERY GOOD IN THE PAST, AND NOW WE ARE SEEING ALLOT OF IMPROVEMENTS IN THOSE PATIENTS AND WE THINK THAT THIS DISCOVERY OPENS A NEW CHAPTER IN TREATING THIS INCURABLE DISEASE.

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**I BELIEVE THE CLINICAL TRIALS ARE CREATED TO FAIL! AND FDA'S DESIRE FOR ONLY CLINICAL TRIALS CAN PERFORM THIS PROCEDURE IS STOPPING SCIENCE, THE FDA IS ACCOMPLISHING THE OPPOSITE OF THE FDA'S STATED DESIRE!**

THE FDA FEELS THAT EVERYBODY IS DUMB AND NEEDS THE PROTECTION OF THE FDA. EVEN IF THE FDA'S PROTECT LEADS TO THE PERSONS DISEASE GETTING WORSE!

**PLEASE WILL THE FDA JUST HELP SICK FOLKS! INSTEAD OF PROTECTING SICK FOLKS TO MAINTAIN DISEASE AND EVEN PROTECTING THEM TO ALLOW THEIR DISEASE TO PROGRESS!**

**PLEASE STOP PROTECTING SICK FOLKS TO DEATH!**

MARIO MORAIS

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I INCLUDED THIS ARTICAL WITH MY LETTER. I FOUND THIS NEWS ARTICLE AS WELL, THE ARTICLE STATES THE BENEFITS OF THIS PROCEDURE, KNOWN AS CCSVI..

# The Clinics of the Heart statement after the FDA warning for "high risk" procedure

- Posted by Rafael Moguel on May 21, 2012 at 11:01pm

Dear patients with multiple sclerosis, relatives and caregivers.

This is a statement from The Clinics of the Heart staff about the recent FDA news released this may 10<sup>th</sup> alerting from injuries and death after the liberation treatment for CCSVI.

We, The Clinics of the Heart started an initial experience to test this procedure with ten patients suffering Multiple Sclerosis (MS) on diverse stages of the disease, based on the paper from Dr. Zamboni which resulted on slowing the progression and reducing the relapses on the majority of the patients.

We started this way because the published results sounded too good to be true. So we proposed a protocol that had the IRB authorization and we invited these ten patients that came to Los Cabos and received the treatment. We found that all of them had immediate changes to justify continuing doing the liberation treatment. I have to say that the operators at The Clinics of the Heart are Interventional Cardiologists and this is our most extreme experience looking improvements never seen before with any previous endovascular treatment for cardiovascular diseases, including the coronary intervention.

All patients signed the IRB approved informed consent form after the understanding of the characteristics of the procedure and the possible risks and we completed the analysis on the first 400 patients. The interim results were exposed as oral presentations in the last Congress of the Latin-American Society of Interventional Cardiology in Santiago (SOLACI), Chile 2011 and in the M3 Course of the Society for Cardiac Angiography and Intervention (SCAI) held in Miami on October 2011.

The results were as follows:

- N = 390 patients from June/2010 through Jan/2011
- (51±11 years old, male/women 31.6/68.4%)
- Average time from diagnosis 17 years

Type of MS:

Relapsing-remitting 29.9% / Primary progressive 24.1% / Secondary progressive 46%

- Left jugular was treated in 93.5% of patients
- Right jugular in 96.4% of patients
- Azygous in 20.4% of patients
- Objective clinical improvement in 91.2% of patients

pre and post Expanded disability status (EDSS) scale (5.46 Vs 5.06)

- Multiple sclerosis functional composite (MSFC) scale (0.07 Vs 0.15)
- Instability (60 Vs 2%)
- Hypoacusis (31.8 Vs 16.1%)
- Tinnitus (35 Vs 5.5%)  
all p<0.01

Fourteen self expanding stents were implanted to improve results.

Complications:

1.4% severe complications

- Thrombosis of jugular or azygous veins
- Femoral artery pseudo-aneurysm
- Balloon rupture
- Allergic reactions

As noted above we initially treated few azygous veins in order to avoid complications in this vein that is not accessible for surgery because it is behind the heart but there is clear that +90% of the patients had neurological improvements. Note also the very few complications rate even when we accepted patients on EDSS up to 8-9 and we found many patients with other diseases not previously diagnosed, such as symptomatic carotid obstructions, cardiac blockages (two of them requiring temporary pacemaker during treatment), severe coronary obstructions and one patient with thrombocytopenia. None of these complications terminated in death or more inability.

What the people against the liberation treatment have only seen is the unfortunate very few deaths but after looking at the results, the benefit/risk ratio is amazing. The (p value) at the end of the results means that they are not causal ( $p < 0.05$  gives a true statistical significance).

We are sure that this CCSVI experience is causing a groundbreaking point in Medicine as it was for the cardiac surgery and coronary angioplasty. Note that many doctors in the 60's hesitated about the relationship between the coronary obstructions and the heart attacks.

We are sure that the implementation of the jugular/azygous angioplasty into the treatment options for MS is a must in the next few years after the following evidence is confirmed:

Clear constant histopathological relationship between MS and blood vessels (Rindfleisch)

- Clear constant presence of blood elements out of the blood vessels in the brain
- Experimental reproducibility of MS lesions in animals (Putnam)
- Neurological improvements after treatment with very low complication rate (many publications are in progress from many treating centers in the world)
- Curative vs. palliative effect of treatment
- Future research to identify causes and risk factors for valve obstructions in veins
- Relationship of internal jugular/azygous valve veins obstructions with MS. Consider in this crucial point that:
  - There are several studies that excludes this relationship using non-invasive diagnostic methods such as ultrasound, computed tomography and magnetic resonance Angiography is the diagnostic gold standard
  - Not all patients presenting venous obstructions will develop symptoms. Please remember that not all patients having coronary obstructions develop angina

The majority of medical procedures in the world, including USA and Canada are off label. This is because every indication based on clinical evidence rises from inclusion/exclusion criteria and many patients are not represented in such trials. A clear example is when cardiovascular diagnostic and treatment procedures are done in women or aging population

- The angioplasty and stent placement in veins is regular practice to treat obstructions in coronary venous grafts, a-v fistulae for hemodialysis, proximal deep venous thrombosis, etc.

A special problem to resolve is related to restenosis. It means that after an angioplasty the vessel narrows again as an exaggerated response to trauma. It happens in all treated vessels and is cause of the return of symptoms in many patients.

Unfortunately all the CCSVI lovers (Doctors, patients and relatives) have some very hard obstacles to deal with:

- Opposing pharmacy, doctors and establishment
- Lack of follow up in the original countries (patients are treated abroad with the reluctance to be followed by local medical system) even after complications
- Low price war by competing centers pushed by patients. This will end in cheap medicine, lower efficacy and higher complications risk

We like to thank to all the patients, as well as to their relatives, caregivers and supporters for their trust in the liberation procedure.

Thank you very much

Rafael Moguel MD FSCAI

Director

The Clinics of the Heart

Cozumel, Los Cabos

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24-OF-25

HERE IS A COPY OF THE LETTER THAT I RECEIVED FROM R. BACHANAN  
-police officer IN FEDERAL PROTECTIVE SERVICES AT THE U.S.  
DEPARTMENT OF HOMELAND SECURITY

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*Federal Protective Service  
National Capital Region  
U.S. Department of Homeland Security  
National Protection and Programs Directorate  
1900 Half Street, SW  
Suite 5000  
Washington, DC 20536*

Mario Morais  
4 Glen Rd., Apt. 103  
Hudson, MA 01749-1364

**August 10, 2012**

Dear Mr. Morais,

This letter is in reference to your telephone contact with representatives from the Food and Drug Administration (FDA) over the past several years.

During your telephone contact with FDA representatives, you have been informed that the FDA has answered all your questions in relation to the experimental drug SF I0 19, as well as procedures intended to treat chronic cerebrospinal venous insufficiency (CCSVI) and they have nothing else to discuss with you in regard to these matters. The FDA has directed hundreds of personnel hours to your inquiries, which now have become disruptive to the productivity and the efficiency of the government.

This letter is to advise you that any further communications regarding experimental drug SF I 0 19 or procedures intended to treat CCSVI is prohibited. Further inquiry is unwarranted and unwelcome. You are to cease and desist in any further conduct, deemed harassing in nature, when communicating with the FDA. Failure to comply with this request could result in the filing of criminal charges for violations of the United States Code. It is strongly suggested that when, and if possible, you utilize methods not requiring direct contact with representatives of the FDA.

Should you have a different issue that has not already been addressed by the FDA, you are directed to contact the Ombudsman for the Center for Devices and Radiological Health (CDRH), preferably in writing. I have included the Ombudsman's information below:

David Buckles  
CDRH Ombudsman  
10903 New Hampshire Ave  
Bldg. 66, rm. G414Silver Spring, MD 20993

-----25-OF-25

If you feel any employee of the United States Department of Health and Human Services, Food and Drug Administration, has committed an act of gross misconduct or an infraction of federal law, please feel free to contact the Department of Health and Human Services, Office of the Inspector General directly. You may obtain the contact information through the online resources provided at <http://www.oig.hhs.gov>.

Should you have any questions or concerns, or require any clarifications, you may contact me utilizing the contact information below.

Sincerely,

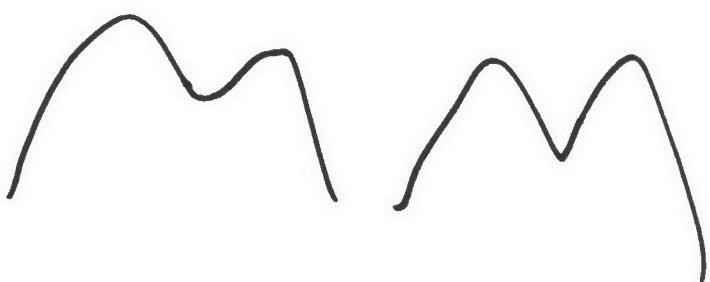
R. Buchanan, Police Officer  
Department of Homeland Security  
Federal Protective Service  
1900 Half Street, SW  
Washington DC 20536  
(619-257-4128)

-----  
**THE LETTER STOPS HERE AND HERE IS A PICTURE OF MYSELF:  
MONA LISA ZERO AND ME ONE! ----I WIN!----**



## **AMENDMENT TWO**

**MR. BUCKLES DID NOT PERFORM HIS  
REGULATORY DUTIES AS THIS LETTER  
SHOWES.**



-----2-OF-10

MARIO MORAIS  
4 GLEN ROAD, APARTMENT # 103  
HUDSON, MASS., 01749-1365  
PHONE: 978-92-4156 / Email: mariomorais8@gmail.com

-----TODAYS--DATE NOVEMBER 05, 2012  
-----LETTER—DATE SEPTEMBER 20, 2012

## The Department of Food and Drug Administration – Office of CDRH

TO; MR. DAVID S. BUCKLES, CDRH OMBUDSMAN AND MR. LAWRENCE ROMANELLI, CDRH DEPUTY OMBUDSMAN, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)  
10903 NEW HAMPSHIRE AVENUE, WO66-G414  
SILVER SPRINGS, MD 20993  
OFF # 301-796-5447 / FAX 301-847-8516 / EMAIL ADDRESS CDRHOmbudsman@fda.hhs.gov, david.buckles@fda.hhs.gov, lawrence.romanell@fda.hhs.gov,

#####  
RE; THIS IS MY COMMUNICATION TO MR. DAVID BUCKLES AND MR. LAWRENCE ROMANELLI SAYING THAT HE HAS NOT ANSWERED REGULATORY REQUEST #1 AND #2 AND #3!

ALSO  
I STILL WANT THE FDA TO FOLLOW ITS OWN RULES AND REGULATIONS AND ANSWER MY COMMENT WITH TRACKING NUMBER 0807-1012-2313!

#####  
DEAR MR. DAVID S. BUCKLES, CDRH OMBUDSMAN AND MR. LAWRENCE ROMANELLI, CDRH DEPUTY OMBUDSMAN, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH), AND THE FOLKS AT THE DEPARTMENT OF THE FOOD AND DRUG ADMINISTRATION;

MR. BUCKLES HAS SENT ME TWO EMAILS, BOTH EMAILS ARE BELOW IN THEIR ENTIRETY FOR YOUR REVIEW. THE FIRST EMAIL WAS SENT ON SEPTEMBER 05. 2012 AND THE SECOND EMAIL WAS SENT ON SEPTEMBER 15, 2012..

BOTH OF THESE EMAILS, ARE THE ONLY COMMUNICATIONS THAT I HAVE HAD FROM MR. BUCKLES OR MR. ROMANELLI!

IN MR. DAVID BUCKLES LATEST EMAIL HE STATES 'You ask for an estimated date of completion regarding the statement in my email message that I will respond separately regarding CCSVI. My response is below.

**I AM VERY SORRY MR. BUCKLES BUT YOU DID NOT REPEAT DID NOT ANSWER MY COMMENT, YOU ANSWERED ANOTHER QUESTION. YOU ANSWERED THE QUESTION WHY DID THE FDA HAVE THE LEGAL RIGHT TO ISSUE A NEWS ANNOUNCEMENT REGARDING CCSVI!**

THE FDA HAS A LEGAL RIGHT TO MAKE THE NEWS ANNOUNCEMENT ABOUT ASKING FOR CAUTION REGARDING THE PROCEDURE KNOW AS CCSVI AS YOU STATE IN YOUR EMAIL 'this is required by section 520(g) of the Federal Food, Drug, and Cosmetic Act and applicable regulations at 21 CFR part 812' **I HAVE NOT AND HAVE NEVER QUESTIONED THAT FACT!**

BUT MY **COMMENT** IS ALSO LEGAL AND NOT AS A 'personal anecdotes and testimonials are of extremely limited value in terms of objective, verifiable scientific evidence.' PLEASE REMEMBER THAT **I AM NOT PERFORMING A CLINICAL TRIAL, CLINICAL TRIALS DO NOT AQUIRE TRACKING NUMBERS** BUT AS A **COMMENT**! PLEASE REMEMBER THE FDA IS IMPARTIAL!

**USING FDA'S OWN RULES AND REGULATIONS, I AM SURE YOU UNDERSTAND THOSE RULES AND REGULATIONS BETTER THAN ME, I SHOULD BE ABLE TO ASK THAT MY COMMENT AS YOU STATED IN YOUR EMAIL 'submitted by you to FDA and assigned tracking number 0807-1012-2313' NEEDS TO BE ANSWERED! THOSE SAME RULES AND REGULATIONS ALLOW MY COMMENT TO GO TO 'exec sec' AND AGAIN THOSE SAME RULES AND REGULATIONS ALLOW MY COMMENT TO BE INCLUDED IN THE FDA'S FOLDER REGARDING THE PROCEDURE CCSVI. NOW MY COMMENT IS STILL NOT ANSWERED!**

**PLEASE REMEMBER THAT I HAVE NEVER QUESTIONED THE FDA'S LEGALITY TO MAKE THE NEWS ANNOUNCEMENT REGARDING CCSVI! I WAS MERELY SURPRISED THAT SUCH AN EASY PROCEDURE' AN OUT-PATIENT PROCEDURE THAT HELPED MY MULTIPLE SCLEROSIS SO MUCH WAS ISSUED A CAUTION ANNOUNCEMENT BY THE FDA!**

FIRST I WOULD LIKE TO THANK YOU FOR ACKNOWLEDGING MY LETTER. IN YOUR EMAIL, DATED SEPTEMBER 15, 2012, YOU STATE 'I acknowledge receipt of your fax dated September 12, 2012.

ALSO YOU SAID IN YOUR EMAIL 'I will respond to the questions posed beginning on Page 6'

**LETS SEE HOW YOU ANSWERED THE QUESTIONS;**

**REGULATORY REQUEST # 1**

**IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' WOULD YOU PLEASE SEND ME SOME CONTACT INFORMATION FOR 'exec sec'.**

MR BUCKLES ANSWER IN HIS EMAIL WAS 'You request contact information for 'exec sec'. As I have previously indicated, I request that you direct your communications to CDRH only to me, and only in writing.

SO MR. BUCKLES ONLY RESTATED MY LIMITATIONS HE DID NOT ANSWER THE REGULATORY REQUEST # 1! I KNOW WHAT MY LIMITATIONS ARE!

**THE QUESTION IS STILL NOT ANSWERED!**

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**REGULATORY REQUEST # 2**

**ALSO IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' WOULD YOU PLEASE ASSURE THAT MY COMMENT SENT AND RECEIVED BY MS. LLOYD ON JUNE 11, 2012. IS PLACED IN THE FDA FOLDER FOR THE PROCEDURE KNOWN AS CCSVI. AGAIN I WOULD LIKE CONTACT INFORMATION FOR THE FOLDER FOLKS TO VERIFY IT WAS RECEIVED AND PLACED IN THE FOLDER!**

MR BUCKLES ANSWER IS 'You ask whether your comment sent to Ms. Lloyd has been placed in an FDA folder. The information that you transmitted to Ms. Lloyd has been conveyed to me.'

SO MR. BUCKLES ONLY TOLD ME MY COMMENT 'has been conveyed to me.' SO HE DID NOT ANSWER THE REGULATORY REQUEST # 2! I AM GLAD THE COMMENT FINALLY REACHED MR. BUCKLES BUT THAT INFORMATION DOES NOT ANSWER MY QUESTION!

**THE QUESTION IS STILL NOT ANSWERED!**

**REGULATORY REQUEST # 3**

**ALSO IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' COULD YOU ASSURE THAT SOMEONE IN CDRH OR ANY ORGANIZATION WITHIN THE FDA ANSWERS MY COMMENT WITH TRACKING NUMBER 0807-1012-913. I WOULD LIKE MY COMMENT ANSWERED BY PHONE!**

MR BUCKLES ANSWER IS 'You ask that a comment submitted by you to FDA and assigned tracking number 0807-1012-2313 is answered by phone. As I have previously indicated, please direct your communications only to me, and only in writing. You should not expect to have direct telephone communication with the Center.'

AGAIN, MR. BUCKLES ONLY RESTATED MY LIMITATIONS HE DID NOT ANSWER THE REGULATORY REQUEST # 3! ALSO I HAVE MORE INFORMATION REGARDING MY COMMENT ABOVE!

**THE QUESTION IS STILL NOT ANSWERED!**

**REGULATORY REQUEST # 4**

**ALSO IN YOUR 'capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)' I WOULD VERY MUCH LIKE MY DOCTOR TO PERFORM A FOLLOWUP PROCEDURE ON MYSELF, BUT BECAUSE OF THE FDA'S NEWS ANNOUNCEMENT HE WILL NOT! COULD YOU ASK THE FDA IF THEY COULD ISSUE ANOTHER NEWS ANNOUNCEMENT THAT WOULD ALLOW ME TO GET A FOLLOW-UP PROCEDURE FROM MY DOCTOR!**

I BELIEVE MR. BUCKLES EMAIL ANSWERS THIS QUESTION. BUT IT IS A VERY FINE LINE BETWEEN THE FDA'S NEWS ANNOUNCEMENT AND THE DOCTOR'S DESIRE TO COMPLY WITH THE FDA NEWS ANNOUNCEMENT! DOCTOR'S ARE AFRAID OF THE FDA'S NEWS ANNOUNCEMENT. SO WITHOUT ANOTHER FDA NEWS ANNOUNCEMENT TO ALLOW A FOLLOW-UP, IT WILL BE VERY HARD FOR ME TO GET ONE! I WISH I COULD GET FOLLOW-UP PROCEDURE FROM MY DOCTOR!

**THE REGULATORY REQUEST #4 HAS BEEN ANSWERED!**

AGAIN, I NEED MY COMMENT INCLUDED IN THE FDA'S FOLDER, REGARDING CCSVI...AND SENT TO 'exec sec' AND ANSWERED BY THE FDA. THAT IS MY RIGHT UNDER FDA'S OWN RULES AND REGULATIONS. THE FDA NEEDS TO FOLLOW ITS OWN RULES!

-----6-OF-10

PLEASE ANSWER **REGULATORY REQUEST # 1 and # 2 and # 3 AND**  
**PLEASE ANSWER MY COMMENT WITH TRACKING NUMBER 0807-1012-2313!**

I AM SORRY BUT THE ANSWERS YOU HAVE GIVEN TO REGULATORY REQUESTS #1 and #2 and #3 AND THE ANSWER TO MY COMMENT ARE UNACCEPTABLE!

THANK YOU FOR YOUR TIME.

IF YOU HAVE ANY QUESTIONS OR CONCERNS PLEASE FEEL FREE TO CALL ME AT 978-92-4156 OR EMAIL ME AT [mariomorais8@gmail.com](mailto:mariomorais8@gmail.com).

SINCERELY YOURS,

MARIO MORAIS

FAXED AND MAILED TO MR. DAVID S. BUCKLES AND MR. LAWRENCE ROMANELLI AT FAX NO 301-947-9516 TO THE FINE FOLKS AT THE U.S. DEPARTMENT OF FOOD AND DRUG ADMINISTRATION (FDA) WHO RECEIVE THE LETTER MR. BUCKLES PERSONAL NUMBER IS 301-796-5447

ALSO

FAXED AND MAILED TO MS. MARGARET HAMBURG AT FAX NO 301-947-3531 ALSO TO THE FINE FOLKS AT THE U.S. DEPARTMENT OF FOOD AND DRUG ADMINISTRATION (FDA) WHO RECEIVE THE LETTER, MS. HAMBURG'S PERSONAL NUMBER IS 301-796-5000

ALSO FAXED AND MAILED TO THE OFFICE OF CHIEF COUNCIL AT FAX NO 301-947-9618 ALSO TO THE FINE FOLKS AT THE U.S. DEPARTMENT OF FOOD AND DRUG ADMINISTRATION (FDA) WHO RECEIVE THE LETTER, MS. ANN WION'S PERSONAL NUMBER IS 301-796-9722

ALSO

FAXED AND MAILED TO THE OFFICE OF THE OMBUDSMAN AT FAX NO 301-947-9628, DIRECTOR IS MS. LAURIE LENKEL, MAIN NUMBER IS 301-796-9530. MS LENKEL'S PERSONAL NUMBER IS 301-796-9483.

ALSO

FAXED AND MAILED TO THE FOLKS AT THE OFFICE OF THE SECRETARY FOR THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) AT FAX NO 202-690-7302, MS. KATHLEEN SEBELIUS THE SECRETARY OF HHS PERSON PHONE IS 202-690-7000

ALSO NO ANSWER SO I AGAIN REFAXED ON WED SEP 26, 2012

ALSO NO ANSWER SO I AGAIN REFAXED ON FRI SEP 28, 2012

THE WEEK OF OCT 01 THRU OCT 05, 2012

ALSO NO ANSWER SO I AGAIN REFAXED ON MON OCT 01, 2012

ALSO NO ANSWER SO I AGAIN REFAXED ON TUE OCT 02, 2012

-----7-OF-10

ALSO NO ANSWER SO I AGAIN REFAXED ON WED OCT 03, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON THU OCT 04, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON FRI OCT 05, 2012

THE WEEK OF OCT 08 THRU OCT 12, 2012

HOLIDAY ON MON SO FAX WAS NOT SENT ON MON OCT 08, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON TUE OCT 09, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON WED OCT 10, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON THU OCT 11, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON FRI OCT 12, 2012

THE WEEK OF OCT 15 THRU OCT 20, 2012

ALSO NO ANSWER SO I AGAIN REFAXED ON MON OCT 15, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON TUE OCT 16, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON WED OCT 17, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON THU OCT 18, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON FRI OCT 19, 2012

I ALSO FAXED ON FRI OCT 9, 2012, MS. MARGARET HAMBURG AT 1-301-847-3531 AND MS. CAROL RADOS AT 1-301-847-8602

THE WEEK OF OCT 22 THRU OCT 27, 2012

ALSO NO ANSWER SO I AGAIN REFAXED ON MON OCT 22, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON TUE OCT 23, 2012  
ALSO NO ANSWER SO I AGAIN REFAXED ON WED OCT 24, 2012  
ALSO ON THU OCT 25, I COULD NOT FAX MR BUCKLES SO I FAXED LETTER TO THE OFFICE MANAGEMENT OPERATIONS AT 301-847-8524  
Again ON FRI OCT 26, I COULD NOT FAX MR BUCKLES SO I FAXED LETTER TO THE OFFICE SCIENCE AND ENGINNERING AT 301-796-9959  
I ALSO FAXED ON FRI OCT 26 2012, MS. MARGARET HAMBURG AT 1-301-847-3531 AND MS. CAROL RADOS AT 1-301-847-8602

THE WEEK OF OCT 29 THRU NOV 2 27, 2012

AGAIN, ON MON OCT 29, I COULD NOT FAX MR BUCKLES SO I FAXED LETTER TO THE OFFICE SERVEILLANCE AND BIO. AT 301-847-8125  
HURRICAN SANDY STRIKES, I HOPE ALL PEOPLE ARE FINE!  
AGAIN, ON TUE OCT 30, I COULD NOT FAX MR BUCKLES SO I FAXED THIS LETTER TO THE OFFICE COMPLIANCE AT 301-847-8136  
AGAIN, ON WED NOV 01, I COULD NOT FAX MR BUCKLES SO I FAXED THIS LETTER TO THE OFFICE ENFORCEMENTS A AT 301-847-8137  
AGAIN, ON THU NOV 02, I COULD NOT FAX MR BUCKLES SO I FAXED THIS LETTER TO THE OFFICE OF COMM, RAD, & EDU AT 301-847-8142  
AGAIN ON FRI OCT 26, I COULD NOT FAX MR BUCKLES SO I FAXED LETTER TO THE OFFICE THE CENTER DIRECTOR AT 301-847-8510  
I ALSO FAXED ON FRI OCT 26 2012, MS. MARGARET HAMBURG AT 1-301-847-3531 AND MS. CAROL RADOS AT 1-301-847-8602

THE WEEK OF NOV 05 THRU NOV 09, 2012

I WILL FROM NOW ON TRY MR.BUCKLES BUT IF, I COULD NOT FAX MR BUCKLES I WILL NOT ENTER IT HERE!  
I FAXED ON MON NOV 05 TO OFFICE OF VITRO EVAL AT 301-847-8513

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8-OF-10

SECOND AND FINAL EMAIL FROM MR. BUCKLES DATED SEPTEMBER 15,  
2012, WHERE HE ATTEMPS TO ANSWER MY QUESTIONS

---

from:-----Buckles, David David.Buckles@fda.hhs.gov  
to:-----"anncartermjackbrown@gmail.com"  
<anncartermjackbrown@gmail.com>  
cc:-----"Romanell, Lawrence J." <Lawrence.Romanell@fda.hhs.gov>  
date:-----Sat, Sep 15, 2012 at 11:08 AM  
subject:-----Communications with FDA

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Mr. Morais:

I acknowledge receipt of your fax dated September 12, 2012. In this message I will respond to the questions posed beginning on Page 6 and will provide additional information regarding the Center's position on procedures intended to treat the condition known as CCSVI.

You request contact information for 'exec sec'. As I have previously indicated, I request that you direct your communications to CDRH only to me, and only in writing.

You ask whether your comment sent to Ms. Lloyd has been placed in an FDA folder. The information that you transmitted to Ms. Lloyd has been conveyed to me.

You ask that a comment submitted by you to FDA and assigned tracking number 0807-1012-2313 is answered by phone. As I have previously indicated, please direct your communications only to me, and only in writing. You should not expect to have direct telephone communication with the Center.

You ask that the FDA issue a news announcement that would allow you to get a follow-up procedure from your doctor. I will address this item in this message. You ask for an estimated date of completion regarding the statement in my email message that I will respond separately regarding CCSVI. My response is below.

There are several points regarding the Center's position on procedures intended to treat CCSVI that I will clarify. Publication of information by CDRH regarding "liberation therapy" or "liberation procedure" is intended to call the attention of the public and of health care providers to information that has come to the attention of CDRH regarding reports received by the Center of serious adverse events, up to and including death, experienced by patients undergoing this procedure. Upon receipt of these reports, CDRH looked further into the matter and learned that there is very little credible, objective, scientific evidence of a therapeutic benefit associated with this procedure. In the interests of public health it is important for the Center to inform the public and health care providers that the risks are real but the benefits are unproven. Further, the Center learned that at least one

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medical facility in the United States was conducting a clinical trial of this procedure without having first obtained approval from FDA. Our communications were intended to inform clinical researchers in the US that they must obtain approval from FDA before conducting this type of clinical trial because the procedures can pose substantial risks to patients. This was not an arbitrary decision on the part of CDRH; this is required by section 520(g) of the Federal Food, Drug, and Cosmetic Act and applicable regulations at 21 CFR part 812. Please note that the Center has not forbidden clinical trials of this type, but rather has clarified that these trials constitute a significant risk to patients and therefore must first be approved by FDA.

Further, and specifically in response to your question #4, FDA has not prohibited health care providers from performing this procedure within their practice of medicine. Health care providers may prescribe or administer any legally marketed medical device for any condition or disease within a legitimate health care practitioner-patient relationship. FDA does not regulate the practice of medicine. With respect to the CCSVI procedures, if the stents, interventional catheters and other medical devices are legally marketed, licensed health care providers may use them to perform these procedures on their patients. It is up to the individual health care provider, in consultation with the patient, to determine whether and how to use legally marketed medical devices in a given procedure for a specific patient. We encourage both health care providers and patients to be aware of the risks and benefits and to make informed decisions, which is one of the reasons why we publish public health notices such as concerning CCSVI. If your health care provider has elected not to perform a given procedure then that is a medical practice decision that is strictly between you and your health care provider.

Finally, with respect to the information you have conveyed to us regarding your personal experience with CCSVI intervention, please be advised that, although we appreciate your position in the matter, personal anecdotes and testimonials are of extremely limited value in terms of objective, verifiable scientific evidence.

I hope this information is helpful. As before, you may communicate with me in writing. However, please be advised that communications that are essentially repetitive or argumentative in nature, or that do not contain information or inquiries that are both new and significant, will likely not receive a response.

Regards,

David S. Buckles, PhD, FACC  
CDRH Ombudsman  
10903 New Hampshire Ave, WO66-G414  
Silver Spring, MD 20993  
301-796-5447 / fax 301-947-9516

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FIRST EMAIL SENT TO ME ON SEPTEMBER 5, 2012, FROM MR. BUCKLES  
THE EMAIL IS IN ITS ENTIRETY

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from:-----Buckles, David David.Buckles@fda.hhs.gov  
to:-----mario morais <anncartermjackbrown@gmail.com>  
cc:-----"Romanell, Lawrence J." <Lawrence.Romanell@fda.hhs.gov>  
date:-----Wed, Sep 5, 2012 at 4:31 PM  
subject:-----Communications with FDA

Mr. Morais:

I am writing to you in my capacity as Ombudsman for the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA). Many individuals in FDA, including at CDRH, have received emails, faxes and telephone calls from you in the past week. As described in the August 10, 2012, letter to you from Mr. R. Buchanan, Federal Protective Service, which is part of the Department of Homeland Security, I request that you direct your communications only to me, and only in writing. I can assure you that any written communications from you to me that pertain to the regulatory work of FDA will be handled appropriately.

I will be responding separately to you regarding CCSVI.

Regards,

David S. Buckles, PhD, FACC  
CDRH Ombudsman  
10903 New Hampshire Ave, WO66-G414  
Silver Spring, MD 20993  
301-796-5447  
fax 301-947-9516

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FROM

MARIO MORAIS  
4 GLEN ROAD APT 103  
HUDSON, MASS. 01749-1365

TO

Division of Dockets Management,  
DOCKET MANAGEMENT BRANCH (HFA-305)  
FOOD AND DRUG ADMINISTRATION  
5630 FISHERS LANE, ROOM 1061  
ROCKVILLE, MD. 20852

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OF THE RETURN ADDRESS, FOLD AT DOTTED LINE

**CERTIFIED MAIL**



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