Chapter 7

The Ombudsman Strikes Again

February – April 2013

In February 2013, as my citizen petition FDA-2012-P-0747 languished and the meeting of the Orthopaedic and Rehabilitation Devices Panel approached, I again defied Dr. Buckles' edict that any communications with CDRH go through his office. I appealed to Dr. Buckles' boss Jeffrey Shuren[1], Director of the Center for Devices and Radiological Health in a letter requesting to meet with him; an email followed the letter. To my surprise, Dr. Shuren agreed to a meeting.

(As you proceed, you may wonder about the relevance of the title of this chapter – you may be surprised.)

Here is the initial email exchange:

From: Les Hamilton
Sent: Tuesday, February 12, 2013 10:18 AM
To: Shuren, Jeff
Subject: Request For Meeting Under 21 CFR 10.68

Dr. Shuren,

My letter formally requesting to meet with you was posted on February 7th. However, it was diverted, and may not reach your office for some time.

A copy of the letter is attached.

I request 15 minutes of your time as soon as possible to discuss an urgent matter, as explained in the letter.

Sincerely,

Leroy L. Hamilton, Ph.D.
[my phone number and email address redacted]

From: Shuren, Jeff
Sent: Thursday, February 14, 2013 8:58 AM
To: 'Les Hamilton' ; Lloyd, Lindsay
Cc: Camacho Lindsay
Subject: RE: Request For Meeting Under 21 CFR 10.68

Dr. Hamilton,

I would be happy to talk. Given my schedule we will try to squeeze in some time before March 1. Lindsay Lloyd can help coordinate it.

Jeff

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Foolishly, I thought this would be a meeting in person; before long, Ms. Lloyd[2] made clear to me that we would speak on the telephone.

Seizing the initiative, I decided to send Dr. Shuren a series of short email messages intended to lay a foundation for our meeting scheduled for February 28, 2013. Although we were barely acquainted, I addressed Dr. Shuren as "Jeff" since that was how he signed his first email to me.

The eight emails I sent to Dr. Shuren during the period February 18 to February 26 appear next. He did not respond to any of them; however, I did receive receipts that some of the messages were opened (by someone).

Email 1

From: Les Hamilton
Sent: Monday, February 18, 2013 4:53 AM
To: Shuren Jeffrey
Subject: Foundation for Understanding

Jeff,

I'm looking forward to our conversation on the 28th. I had much preferred to meet in person, but a telephone call will have to do for now.

To lay a foundation for that conversation, I plan to send you very brief emails spread over the next few days that I hope will make it easier for us to talk.

First, I want to let you know that I know yours is an extremely challenging job. You are responsible for the actions of far more people than one person can be expected to manage. There must be nearly a hundred people just in the Office of the Center Director, and certainly hundreds more in the entire CDRH. There is no way that you can be aware of the details of all that goes on in CDRH.

I appreciate the talent, training, and experience that you brought to your position in the FDA. I also appreciate the culture of the FDA with its dedication to protecting the American people. In addition to your knowledge of medicine and law, you need to work to bring out the best in your people.

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A receipt for this [message] is requested, simply to let me know that you (or possibly someone who works for you) has opened the message.

Over the next few days, I will send short messages of a range of topics that I would eventually like to discuss with you.

Thank you for your time.

Les Hamilton

P.S. I will not publicize the content of these messages until well after our conversation. I may be a "loose cannon" but I also have scruples.

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Email 2

From: Les Hamilton
Sent: Monday, February 18, 2013 3:42 PM
To: Shuren Jeffrey
Subject: Foundation for Understanding - Part 2

Jeff,

I've been a student of the FDA for a long time. My files fill quite a few crates.

Here's an excerpt from speech by Peter Barton Hutt given to members of the Health Industry Manufacturers Association at their annual meeting in Scottsdale, Arizona, in 1981. His words are as true today as they were then.

> "It would be foolish not to acknowledge that there is a special relationship between the regulated industry and the Food and Drug Administration. An FDA employee has enormous power, not only over industry as a whole, but indeed, at times, over specific companies and specific individuals. It may shock a corporate executive to realize that sometimes the lowest FDA employee will have a greater say over what happens in his company than will the president of the company. [Emphasis added]

Years before that, Hutt spoke at a conference with the intriguing title "Who regulates the regulator while the regulator regulates?"

When I see that the Commissioner stonewalls a Senator and members of Congress, I can readily understand why CDRH personnel feel they can ignore a nobody like me with impunity.

Indeed, who does regulate the regulator? [This is meant as a rhetorical question and not as a topic for our telephone call.]

Les Hamilton

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Email 3

From: Les Hamilton
Sent: Tuesday, February 19, 2013 6:03 AM
To: Shuren Jeffrey
Subject: Foundation for Understanding - Part 3

Jeff,

Foundation for Understanding - Part 3.

Perfection is a worthy goal, but unattainable in the real world. Human beings are fallible, as the Tacoma Narrows bridge collapse and the Challenger accident so graphically demonstrated. Some medical devices will fail despite best efforts to comply with GMPs, and FDA inspections.

I accept that CDRH employees are good people, dedicated to protecting the public health. I sympathize with you and other FDA leaders who must cope with occasional storms of adverse publicity when something goes wrong.

I also accept that device manufacturers are, by and large, good people who would not purposely set out to harm the public with unsafe or ineffective devices. To do otherwise would simply be bad business.

I accept that neither CDRH nor industry is infallible. Mistakes will be made. Despite layers of review, whether in design of a device or creation of a regulation, something can go wrong. People with integrity will admit their mistakes and strive not to repeat them.

The Medical Device Amendments granted FDA broad authority and responsibility. The law, while well-intended, was and is imperfect. FDA sometimes lacks the expertise to cope with innovative devices or the people assigned may be unable to understand a new technology.

FDA had 32 years to get the 510k process right, but the IOM committee asked to review it concluded the system was so broken it couldn't be fixed.

In *Free to Choose* Milton and Rose Friedman alleged that FDA employees would rather keep ten good drugs off the market than let one bad one through. Think about it.

Again, I do not expect you to reply. I'm simply trying to acquaint you with what I know and what I believe.

Les Hamilton

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Email 4

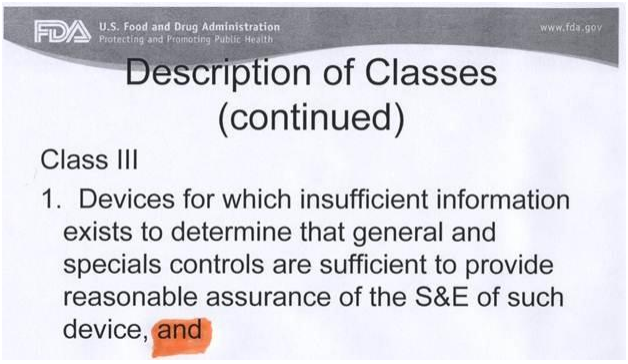
From: Les Hamilton
Sent: Wednesday, February 20, 2013 6:37 AM
To: Shuren Jeffrey
Subject: Foundation for Understanding - Part 4 of 7

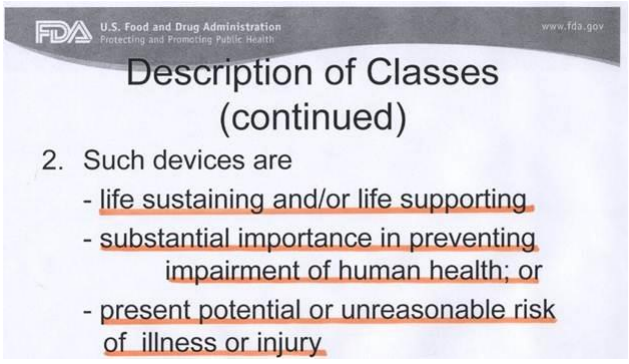
Jeff,

Part 4. – Definitions of Device Classes

The Medical Device Amendments included definitions for the three classes of medical devices as recommended by the Cooper Committee. I believe the definitions are applicable to both pre-enactment and post-enactment devices.

Here are two slides summarizing Class III which were shown at a Panel meeting in September, 2012:





As these slides suggest, there are two parts to the definition of Class III. Both parts are essential.

Again, I believe the definition applies to both pre-enactment and post-enactment medical devices regulated by the FDA.

PREVIEW OF NEXT ITEMS

Part 5 - Classification Q'naire

Part 6 – Role of Ombudsman -
Part 7 - FOI

Unlike the earlier messages, this message is relevant to the discussion I wish to have with you on February 28th. If you have any questions, please let me know.

Les Hamilton

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Email 5

From: Les Hamilton
Sent: Wednesday, February 20, 2013 8:13 PM
To: Shuren Jeffrey
Subject: Foundation for Understanding - Part 5 of 7

Jeff,

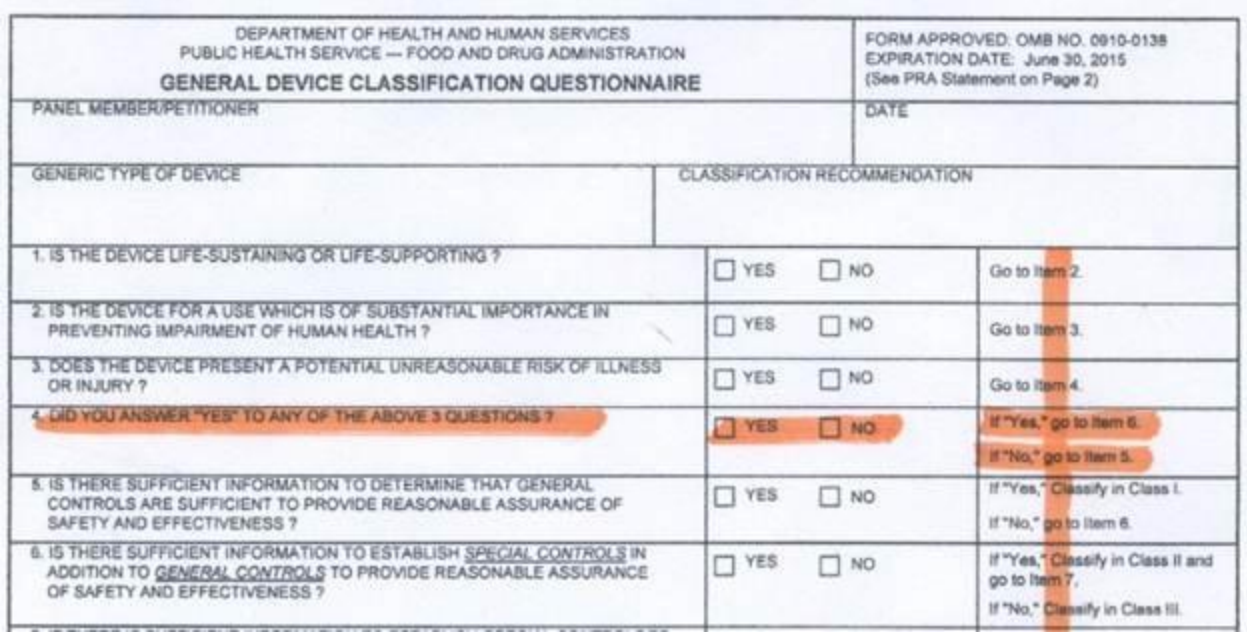
Perhaps you are out of the office or too busy to check your email. I have not received a receipt for any of the first four parts of this serial monologue. I don't expect you to necessarily reply to any of the seven parts, but it would be comforting to know that they do not reside in a spam folder someplace. Les

Foundation for Understanding - Part 5 - Classification Q'naire

From my own experience as Executive Secretary to the Radiological Devices Classification Panel in 1976, discussion with a co-worker who retired from CDRH in 2009, and by reading transcripts of Panel meetings during the past decade, I am certain that the Classification Questionnaire (now designated as Form 3429) has been an essential tool used to determine the appropriate classification of medical devices. I am just as certain that the Form has undergone changes which aggregate to a major transformation during the decades of its use.

The most recent revision (that I know about) took place during 2012. The version which expired on May 30, 2012, was renewed, unchanged, effective June 1, 2012 with an expiration date of June 30, 2015 (37 months). The Form was abruptly revised effective July 1, 2012, with an expiration date of June 30, 2015.

The revisions were to omit question 4 and column 3. This is illustrated by a markup of the top portion of the June Form:



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: June 30, 2015
(See PRA Statement on Page 2)

PANEL MEMBER/PETITIONER

DATE

GENERIC TYPE OF DEVICE

CLASSIFICATION RECOMMENDATION

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☐ YES ☐ NO	Go to Item 2.
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☐ YES ☐ NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☐ NO	Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	☐ YES ☐ NO	If "Yes," go to Item 6. If "No," go to Item 5.
5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class II and go to Item 7. If "No," Classify in Class III.

The changes were explained to OMB as a minor revision to remove redundant and confusing information.

I vehemently disagree with this characterization. The Form has been gutted, rendering it useless for its intended purpose and in direct violation of the regulation defining the Classification Questionnaire.

What do you have to say about this revision and the reasons for the changes made?

THIS IS ONE OF THE MOST IMPORTANT TOPICS FOR OUR DISCUSSION.

Thank you.

Les Hamilton

Coming soon ...

Part 6 – Role of Ombudsman -
Part 7 - FOI

* * * * * *

Email 6

From: Les Hamilton
Sent: Thursday, February 21, 2013 10:49 PM
To: Shuren Jeffrey
Subject: Foundation for Understanding - Part 6 of 7

Part 6 – Role of Ombudsman

Jeff,

Strange but true: I may have been the first person to recommend that CDRH have an Ombudsman. The occasion was a seminar I gave for CDRH employees on October 3, 1983, at the invitation of then-Director John Villforth.

Imagine my disappointment to find that the current occupant of that office was not just unwilling to meet with me concerning the issue I've brought to you. Dr. Buckles' emails also document his refusal to answer any questions and how he tried to block communications with anyone else in CDRH. Evidently "ombudsman" in CDRH means something quite different from what I understand it to mean outside the FDA.

There is a fundamental question I've asked Dr. Buckles, Nancy Stade, Marjorie Shulman and Tim Marjenin; none of them was willing to answer.

Consider a hypothetical device with the following characteristics:

1. The device is NOT life-supporting or life-sustaining, AND
2. The device is NOT for a use which is of substantial importance in preventing impairment of human health, AND
3. The device does NOT present a potential unreasonable risk of illness or injury.

Can such a device be in Class III?

This is a question which I intend ask during our phone conversation on February 28, and I hope you will be able to answer with a simple Yes or No. If your answer is Yes, I will refer you to Part 4 of this serial monologue and to the definition of Class III in the law and in the regulations.

I am indebted to Dr. Buckles for his suggestion that I present my concerns during the Open Public Hearing of a Panel meeting or in a Citizen Petition. Both provided valuable experiences with lessons well learned.

The real issue remains: The Classification Questionnaire was burdened with flawed logic for decades. It directed devices into Class III which do not meet the requirements for Class III in the law. I believe a few devices were misclassified into Class III because of this flaw. Because petitioners for reclassification were required to submit a completed Classification Questionnaire, the flaw was a trap.

The manufacturers of those devices for which PMA dates have not been set are entitled to be relieved of this onerous burden. FDA needs to bite the bullet and admit the problem existed, rather than try to cover it up or pretend it never existed.

As Director of CDRH, I beg you: Please call a halt to this exasperating charade.

Almost done.

Les

Sent High Priority – read receipt

Next - Part 7 - FOI

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From: Les Hamilton
Sent: Saturday, February 23, 2013 7:08 AM
To: Shuren Jeffrey
Subject: Foundation for Understanding - Part 7 of 7

Part 7 – FOI (and other topics)

Jeff,

The Freedom of Information Act is a vital tool intended to provide concerned citizens timely access to government documents. In my experience, the ability or willingness of CDRH people to respond to FOIA requests has deteriorated significantly over the years. A request for a 510k in October, 2009, took 21 months. My request for the Position Description of the Ombudsman, submitted nearly a year ago, has never been filled. Several other requests were acknowledged but not filled.

When I requested followup, I was told all my requests had been closed. The most important open requests are 2012-2363, 2012-4061, and 2012-7617.

Often, CDRH is unable to fill a request because a document has already been removed from the files. For example, the completed Classification Questionnaires for devices I believe to be misclassified into Class III evidently are no longer available. Perhaps 428 forms took up too much file space.

However, I believe one blank copy of each version of the Classification Questionnaire should have been maintained. The Classification Questionnaire (now known as Form FDA 3429) is defined at 21 CFR 21 CFR 860.3:

"(f)Classification questionnaire means a specific series of questions prepared by the Commissioner for use as guidelines by classification panels preparing recommendations to the Commissioner regarding classification and by petitioners submitting petitions for reclassification. The questions relate to the safety and effectiveness characteristics of a device and the answers are designed to help the Commissioner determine the proper classification of the device."

The Classification Questionnaire in use today bears little resemblance to the document published in the Federal Register in 1977. I think there should be available to the public a copy of every version of the Classification Questionnaire used since the law was enacted. Is that too much to ask?

My Citizen Petition (Docket No. FDA-2012-P-0747) is straight-forward, yet it languishes unresolved. I've been told "significant resources" are being devoted to it, and a response should be out soon.

But CDRH operates on its own time-scale. It's been only 8 months since my petition was submitted. Jim Dickinson's petition (Docket No. FDA-2009-P-0500-0001) has been around for over three years and Betty Martini's petition to ban aspartame has languished for over ten years!

Over a year ago, I tried to work with the CDRH Ombudsman to deal with a real issue – the logical flaw in the Classification Questionnaire and the consequent alleged misclassification of a few devices - but he refused. He knows the reason for his refusal. I can guess it was because he was too busy, the issue was too hot to handle, or he really didn't understand how important it was to me. He may have hoped that I'd give up and go away. I didn't give up and I know the value of persistence.

"American traditions and the American ethic require us to be truthful, but the most important reason is that truth is the best propaganda and lies are the worst. To be persuasive we must be believable; to be believable we must be credible; to be credible we must be truthful. It is as simple as that."

— Edward R. Murrow, Director, United States Information Agency, May 1963

I will follow up with one more Part which lists the explicit questions I hope you will answer, in addition to the one in Part 6. I look forward to speaking with you, and thank you for your time and attention.

Les Hamilton

P.S. I received the read receipt for Part 6. Thank you.

* * * * * *

Email 8

From: Les Hamilton
Sent: Tuesday, February 26, 2013 7:17 AM
To: Shuren Jeffrey
Subject: Closing Thoughts

Jeff,

I'm looking forward to your telephone call less than 48 hours from now.

I hope that my efforts to provide you a foundation for understanding have helped to promote a meaningful dialogue.

This email contains the questions I hope you can respond to in the limited time allotted for our conversation.

From Part 6:

There is a fundamental question I've asked Dr. Buckles, Nancy Stade, Marjorie Shulman and Tim Marjenin; none of them was willing to answer.

Consider a hypothetical device with the following characteristics:
1. The device is NOT life-supporting or life-sustaining, AND
2. The device is NOT for a use which is of substantial importance in preventing impairment of human health, AND
3. The device does NOT present a potential unreasonable risk of illness or injury.

QUESTION 1: Can such a device be in Class III?
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This gets at the heart of what I've been trying to communicate to CDRH personnel for over a year. I've promised to keep these emails brief, but there is a big story behind them. Because my pleas to communicate with the CDRH Ombudsman, your Deputy Director for Policy, and others have been fruitless, I've begun a sophomoric but very public effort to get the story out. I'm using a website, www.loosecannon.name as the vehicle.

Here is a link to a description of the incident which started this whole brouhaha:

http://www.loosecannon.name/files/CES2012.html

QUESTION 2: Have you read my letter to Nancy Stade? If so, can we discuss the issues it contained?

QUESTION 3: Do you see the revisions to Form 3429 made effective in July, 2012, as an improvement?

QUESTION 4: Why is it taking so long to reach a decision on my Citizen Petition (Docket No. FDA-2012-P-0747)?

It is my hope that you will see the necessity to calm the situation before it escalates further. I do not want to file suit in federal court because that would simply harden the lines, drag on for years, and to do it right, probably bankrupt me and break up my marriage. But I am adamant that CDRH either acknowledge that some few devices were inadvertently put into Class III because of a logical flaw (=serious mistake) in the Classification Questionnaire or explain to me why my analysis is incorrect.

The fact that Marjorie Shulman and others changed the Classification Questionnaire is tacit admission that something needed to be fixed in the Questionnaire. But their fix made matters worse!

I'll be waiting for your call at 8:30 am on February 28, 2013. I hope we can make some progress on the issue of devices inadvertently misclassified into Class III.

Les Hamilton
301-384-8949

* * * * *

Dr. Shuren telephoned me at the appointed time. He said that Nancy Stade was also in on the phone call. Our call lasted approximately 20 minutes.

After I reiterated the question from Part 6, he said "We agree with you." I felt this was a significant development.

We talked about devices which may have been misclassified into Class III. Dr. Shuren asked if I had a list of possible devices and I told him my list has fewer than 20 items on it. He asked me to send the list to Nancy Stade.

When I asked when I might expect a response to my Citizen Petition 0747, he said it would be within a week.

As we were about to conclude the call, I thanked Dr. Shuren for his time. I told him I appreciated the progress we had made towards resolving some of the issues and that I hoped we could continue the dialogue at another time.

* * * * * *

Later the same day, I sent Ms. Stade the following email:

From: Les Hamilton
Sent: Thursday, February 28, 2013 11:37 PM
To: Stade Nancy
Cc: Shuren Jeffrey
Subject: Class III devices which may be misclassified

Ms. Stade,

Thank you for your participation in the phone call with Dr. Shuren this morning.

In response to Dr. Shuren's request, I am sending you a list of seventeen devices which I think may have been misclassified into Class III. The two devices about which I am most confident are Product Codes JXK and ILX.

This is really a tentative list since I cannot claim expertise for most of these devices. I selected them because I think it is likely they do not satisfy any of the criteria in the second part of the definition of Class III in the statute.

In others words, I selected them on the basis that, in my opinion, all three of the following statements is true:

1. The device is NOT life-supporting or life-sustaining.
2. The device is NOT for a use which is of substantial importance in preventing impairment of human health.
3. The device does NOT present a potential unreasonable risk of illness or injury.

They are identified by the Product Code and device name.

Prod Code	**Device Name**
BWL	Apparatus, Electronanesthesia
LMY	Monitor, Skin Resistance Skin Temperature, For Insulin Reactions
MTV	Device, Needle Destruction
JXK	Stimulator, Cranial Electrotherapy
EGJ	Device, Iontophoresis, Other Uses
HPH	Diathermy, Microwave, For Use Other Than Applying Therapeutic Deep Heat
ILX	Diathermy, Shortwave, For Use Other Than Applying Therapeutic Deep Heat
IPO	Orthosis, Pneumatic Structure, Rigid
LXF	Diathermy, Ultrasonic, For Use Other Than Applying Therapeutic Deep Heat
LOE	Stimulator, Invasive Bone Growth
LOF	Stimulator, Bone Growth, Non-Invasive
MBQ	Peripheral Electromagnetic Field (Pemf) To Aid Wound Healing
LEK	Transilluminator (Diaphanoscope)
MJS	Contrast Media, Ultrasound

MYN Analyzer, Medical Image
NCL Imager, Breast, Electrical Impedance
LTD Paraquat Assay

I realize there may be differences of opinion. Certain general rules seem to be applicable. For example, I think it would be a tough argument to say that a laboratory instrument (e.g., EGJ or LTD) is life-supporting, etc.. And what about MTV, the needle destruction device?

All three Diathermy devices for use other than applying therapeutic deep heat are associated with higher power devices. The high power devices are in Class II, which suggests there is not a safety issue.

NON AVAILABILITY OF EARLIER RECORDS

It would be interesting to see exactly how the Classification Panels completed the Classification Questionnaires initially. The FDA was unable to provide completed Classification Questionnaires I requested under FOI. Were these not preserved?

In addition, my FOI request for all the versions of the Classification Questionnaire have met with little success. So far, I have not been able to obtain any questionnaire between 1977 and 1997. Weren't copies retained?

If any of these devices are considered in the future by a CDRH Panel, perhaps the Panel could be polled about the first three questions on Form 3429.

OBSERVATIONS RE: LEK – BREAST TRANSILLUMINATOR

I was present at the April 12, 2012, meeting of the Radiological Devices Panel when a petition to reclassify LEK Transilluminator from Class III to Class I was discussed. The petition was submitted by a British firm which markets in Europe and elsewhere in the world a relatively inexpensive illuminating device intended for home use by women. The company representative, Russell Overend, made what I thought was a rather clear and comprehensive about their BreastLight® device and its use. The company makes no claims that the device can diagnose any medical condition. It is offered as a means to assist a woman in the examination of her own breasts at home. Using it she can visualize the internal structure and perhaps notice when a change occurs.

It is treated as a Class I device in countries other than the U.S.

A Panel member wondered why the FDA presentation focused on the cancer diagnosis question when the petitioner made no medical claims for their device. Here is an excerpt from the transcript showing the question by Carolyn Hendricks, M.D., and the answer by Janine Morris, a CDRH mechanical engineer:

Radiological Devices Panel Meeting – excerpt from transcript

April 12, 2012

Pages 63-64

DR. HENDRICKS: Yeah, Carolyn Hendricks. I just need clarity, I think, for the information that I've heard this morning about whether we are addressing either a diagnostic or a non-diagnostic tool, because the information from the Petitioner appears to hinge on the whole issue of breast self-awareness, but all the information from the FDA relates to this device in the detection of breast cancer. And to me, there seems to be a significant disconnect, and I need better clarity on that as a charge to us as a panelist.
DR. ROSENBERG: FDA, please?
MS. MORRIS: Yes. So the subject of today's meeting is specific to what we see in the regulation for the reclassification. And if we could have the slides pulled back up quick enough -- otherwise I can read it out of the regulations. It should be under -- yes, 21 C.F.R. 892.1990, transilluminator for breast evaluation. The transilluminator, also known as the diaphanoscope or light scanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation, approximately 700 to 1050 nm, transmitted through breasts to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.

MY COMMENT: In this instance, the petitioner makes no claims that the device can be used for any medical diagnosis. The device in question of one of about 65 in Subpart B – Diagnostic Devices. IT IS THE ONLY WHICH MENTIONS SPECIFIC CONDITIONS TO BE DIAGNOSED. By the way, the CDRH online Registration and Listing database does not list a single manufacturer of LEK devices.

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The reason I attended this particular meeting was to present my argument about the "flaw" in Form 3429 during the Open Public Hearing. Dr. Hendricks asked a question about my presentation which was also answered by Janine Morris. Here is the excerpt from the meeting transcript:

Pages 82-83
DR. ROSENBERG: Dr. Hendricks?

DR. HENDRICKS: Question for the FDA. Just clarification on the issue raised in the Open Public Comment section, please.

MS. MORRIS: I'm sorry. I'm not quite --

DR. HENDRICKS: Well, as I understand it, in the Open Public Comment section, significant concerns were raised about some inconsistencies in the definition of a Class III device. I just wanted clarification on behalf of all the panelists.

MS. MORRIS: Okay. So I'm not familiar with the concern regarding the classification questionnaire, but for the sake of this discussion, we are actually not using the classification questionnaire that's being referred to in the Open Public Hearing. Does that answer your question?

My comment: I'm confused: since the petition to reclassify a device MUST be accompanied by a completed Form 3429, how can Ms. Morris say "we are actually not using" it?

Again, I would argue that the LEK device does not qualify for Class III because it does not satisfy any of the three conditions listed above.

I hope this information is helpful to you.

Les Hamilton

[end of email to Nancy Stade]

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There was no response, not even an acknowledgement, from Ms. Stade.

Encouraged by the seemingly meaningful meeting of the minds in the February 28 phone call, I requested another meeting with Dr. Shuren. The letter I sent him appears on the next page.

Leroy L. Hamilton, Ph.D.
13002 Autumn Drive
Silver Spring, MD 20904

March 22, 2013

Jeffrey Shuren, M.D., J.D., Director
Center for Devices and Radiological Health
Bldg WO66, Rm 5442
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

Thank you very much for taking the time for our phone call on February 28, 2013. I also appreciated that Nancy Stade was a party to the call.

It was a very welcome change to be able to speak with someone at CDRH at last.

During the phone call, you informed me that a response to my Citizen Petition (Docket Number FDA-2012-P-0747) would be forthcoming within a week. As you stated, FDA's response dated March 4, 2013 and signed by Nancy Stade arrived less than a week later.

The letter informed me that my petition had been granted and that Form FDA 3429 had been changed in response to my concerns. Ms. Stade's letter stated "FDA is aware of no devices that have been misclassified into class III as the result of Form FDA 3429." This statement may be technically correct, because other factors may have also contributed to the decision in each case to select Class III for the particular devices that I allege were misclassified. Her letter addresses two of these devices (Product Codes ILX and JXK), but does not address the fundamental issue of whether these devices satisfy the definition of Class III.

In my opinion, the revisions made to Form FDA 3429 are unsatisfactory because they rendered the Form useless for its intended purpose. In addition, I believe that certain medical devices were misclassified into Class III, regardless of the details in each case, because the devices do not satisfy the definition of Class III.

Since Dr. Buckles and Ms. Stade are unwilling to discuss these issues, I'm turning to you for assistance. I feel it is important to meet with you in person in an effort to reach an understanding of these issues and how they can be resolved. Please let me know when I can meet with you.

Sincerely,
Leroy L. Hamilton

As I had done before, I followed up with an email to Dr. Shuren. I was shocked by the response which came instead from the CDRH Ombudsman:

From: Buckles, David
Sent: Tuesday, April 09, 2013 2:03 PM
To: Les Hamilton
Cc: Romanell, Lawrence J.
Subject: Communications with CDRH

Dear Dr. Hamilton,

I am responding to your recent communications to CDRH, including emails, phone calls and a letter to Dr. Shuren's office as well as emails and letters to Ms. Stade and other CDRH employees. I understand that you have requested another meeting with Dr. Shuren so that you can continue your discussion regarding classification of medical devices.

I have looked further into this matter and my assessment is that the actions taken by the Center in response to your issues have been appropriate and complete. There is therefore no need for further meetings or teleconferences with you on these issues and your requests are declined.

You may continue to correspond with my office at your convenience. However, please be advised that communications that do not contain information that is both new and significant will likely not receive a reply. Similarly, requests for meetings and teleconferences will not receive a response as we have already addressed this request. You may continue to utilize existing means for requesting documents from FDA, such as via the provisions of the Freedom of Information Act (FOIA), and there are numerous sources of information on the agency's public Web site at www.fda.gov.

Regards,

David S. Buckles, PhD, FACC
CDRH Ombudsman
fax 301-847-8516

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Lessons learned and unanswered questions:

For whatever reasons, Dr. Buckles is unwilling to address the issues that I raised. He didn't answer direct questions and makes assertions with which I simply cannot agree.

My request to have a follow-up meeting with Dr. Shuren was answered by Dr. Buckles. Was he acting on orders from Dr. Shuren? Who's really in charge at CDRH?

The CDRH Ombudsman appears to serve as an enforcer instead of an advocate. His word is law. It would seem he is the final arbiter. He is unwilling to recognize that there are unresolved issues which

need to be addressed. He dismisses my concerns, and warns that if they are brought up again, they will be ignored.

How can Buckles claim that CDRH responses have been “appropriate” and “complete” ? Was it appropriate to revise Form 3429 by removing column 3? Was it appropriate to send a justification to the OMB for the revision characterizing it as inconsequential? Has the CDRH response to my questions been complete? No one at CDRH has responded to my complaint that the Form was rendered useless for its intended purpose by the changes made effective July 2012.

It seems that CDRH operates under a bubble (or in a parallel universe). Or am I being unrealistic?

To whom is the agency accountable?

END NOTES FOR CHAPTER 7

[1] Jeffrey Shuren, M.D., J.D. earned degrees in both medicine and law. Before he came to the FDA, he was a manager in the Centers for Medicare and Medicaid Services in Baltimore. His appointment under the Senior Executive Service is AD 00; in addition to his $270,000 salary in 2013, he was awarded a $3,375 bonus.
[2] Lindsay Lloyd is Dr. Shuren’s Executive Assistant. She is a GS-12; in addition to her $74,872 salary, she received a $3,500 bonus.