Chapter 2

The Ombudsman

February – March 2012

During the week following my well-intentioned but poorly-executed activism at a meeting of the Neurological Devices Advisory Panel, I sought to "mend a fence" by sending a letter to Dr. Robert Hurst, chairman of the Panel. I apologized for disrupting the meeting. The letter did not try to justify my action. I assured him that I would not act so rashly in the future or attempt to contact any of the Panel members. In addition to providing Dr. Hurst this assurance, I hoped to head off any potential disciplinary action by the FDA, such as banning me from FDA meetings. There was no reply from Dr. Hurst. (Eighteen months later, I learned why. I sent Dr. Hurst another letter after CDRH revised Form 3429. When I again had no response, I telephoned him. He said he had received my letters and forwarded them to the FDA without reading them.)

I searched FDA regulations to better understand my rights and limitations at Panel meetings. That's how I came upon the rules regarding advisory committee meetings which give the Chairman sole discretion over who may speak. In addition, I found the full definitions of the three classes of medical devices, the Classification Questionnaire (Form FDA 3429) and information about the Ombudsman of the Center for Devices and Radiological Health (CDRH).

Role of CDRH Ombudsman

The website for the FDA (www.fda.gov) and more particularly, because of my interests, the many pages devoted to the Center for Devices and Radiological Health[1] proved to be a valuable source of information. It is a constantly changing, complex maze which takes some effort to master. Anyone who takes the time to browse the site will find they can retrieve data from many databases, including the organizational structure of the FDA, the law and regulations, the names, addresses and products of medical device companies. Chapter B6 contains some information about the CDRH website and how to use it.

Here's a quote from the page explaining the office of the 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. The Ombudsman can answer questions, follow up on a complaint, discuss appeal and dispute resolution options, or mediate a dispute. While providing this assistance, they maintain impartiality and neutrality. The Ombudsman advises the Center

Director, to whom they report, on ways to assure that our procedures, policies and decisions are of the highest quality and are fair and equitable.

The FDA has more than one Ombudsman. There is one for the entire agency, and one each for various components of FDA including CDRH, Drugs, Biologics, and Tobacco. Initially, I directed my attention to Dr. David Buckles, the CDRH Ombudsman at the time.

Emails

What follows are the contents of the email exchanges between David Buckles or Tim Marjenin and me during the period February 14 to March 20, 2012. You can read exactly what transpired between us as I sought to meet with Dr. Buckles and was eventually refused. I invite the reader to critique the interaction which took place.

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Message No. 1

From: Les Hamilton
Sent: Tuesday, February 14, 2012 11:07 PM
To: Buckles, David
Subject: Request for Meeting

Dr. Buckles,

Please consider my request to meet with you concerning an issue which may affect a number of medical device types. The issue I wish to discuss deals with FDA's interpretation of their authority and responsibility for putting devices into class III.

This problem, although not a new one, has recently gained importance as CDRH embarks seriously on setting dates by which PMAs for class III devices will be required.

I attended the Neurological Devices Panel meeting on February 10, 2012, where the sole agenda item was to consider reclassification petitions submitted by three manufacturers of cranial electrotherapy stimulator devices, known by the initials CES. (These are identified by Product Code JXK; they have been slated for class III for years.) The three petitions seek to have the devices reclassified into class II.

Prior to this meeting, I had no prior contact with any of the companies involved and no experience with their products. The only reason for attending was to observe the process for handling reclassification petitions, because of my long concern for another type of product in similar circumstances.

FDA policy as expressed in the FDA Presentation is at the heart of my request to meet with you. One slide contained a definition of classes II and III. My question, for which I made serious attempts to get an answer at the meeting, revolves on the interpretation of the definition of class III.

Here is the relevant information presented in the slide:

"21 CFR 860.3(c)(3): A device is in class III if

">> Insufficient information exists to determine that special controls would provide a reasonable assurance of safety and effectiveness, and

">> The device is life-supporting or life-sustaining, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury."

As I reflected upon the definition, it occurred to me there may be a serious question about the propriety of placing CES devices in class III. For the sake of discussion, consider the definition to consist of two parts: the first part begins with the words "Insufficient information" and the second part begins with "The device is life-supporting ...". The two parts are joined by the conjunction "and".

For a device to be in class III, both parts of the definition must be logically true.

Let us focus on the second part of the definition. The second part of the definition will be true if any of four conditions is satisfied. However, the second part of the definition will be false if all four conditions are false.

I would assert that for CES devices

1. They are not life-supporting;
2. They are not life-sustaining;
3. They are not for a use which is of substantial importance in preventing impairment of human health;
4. They do not present a potential unreasonable risk of illness or injury.

Thus, for CES devices, the second part of the definition is not satisfied, and they should not be classified in class III.

I realize this is at odds with FDA policy for many years. That is no reason to reject my argument out-of-hand. I have looked at the law as it was in 1979 and as currently presented on the CDRH website, and considered the legislative history.

If my analysis is correct and CDRH is unable to refute it, the agency would have to reexamine its policy for numerous devices types as well as the design of the classification questionnaire.

I'm not an unreasonable person, and I would welcome the opportunity to discuss this issue with knowledgeable CDRH people. I'm starting with you, as ombudsman, because you should be willing to examine the issue with an open mind.

I do not represent any company in this matter. I am a concerned citizen.

I look forward to your answer.

Leroy L. (Les) Hamilton, Ph.D.
[Address and contact information – omitted here]

Message No. 2

From: Buckles, David

To: 'Les Hamilton'
Cc: Romanell, Lawrence J.
Sent: Thursday, February 16, 2012 10:14 AM
Subject: RE: Request for Meeting

Dr. Hamilton,

I acknowledge receipt of your communication with my office. I am in the process of reviewing documents from the CES panel meeting and will respond to your inquiry after I have done so.

Regards,

David S. Buckles, PhD, FACC
CDRH Ombudsman
FDA/CDRH
[Address and contact information]

Message No. 3

From: Les Hamilton
To: Buckles, David
Sent: Tuesday, February 28, 2012 11:20 AM
Subject: Re: Request for Meeting

Dr. Buckles,

Please don't forget my request of February 14 to meet with you. The issue presented may be important as it relates to CDRH policy potentially affecting classification decisions on a number of device types. Although it was the Neurological Devices Panel meeting to consider the reclassification petitions of firms making cranial electrotherapy stimulator devices that triggered my concern, the issue is not limited to those devices.

I'm eager to have a meaningful discussion with you or someone else in CDRH who can understand the matter.

Just to be clear, I do not represent any company or organization. I am a concerned citizen, and a former employee of the Bureau of Medical Devices.

Please let me know when I can expect to have a meeting on the matter of class III devices.

Les Hamilton
[Contact information]

Message No. 4

From: Les Hamilton
Sent: Tuesday, February 28, 2012 3:57 PM
To: Buckles, David
Subject: Fw: Request for Meeting

Dr. Buckles,

This supplements my message of earlier today.

Since my name was mentioned in a blog by someone who attended the Neurological Devices Panel meeting, I supplied a correction. Here is a link to the blog and comments:

http://mdd.blogs.medicaldevicedaily.com/2012/02/21/fda-advisory-committees-is-there-a-problem/#comments

I do not wish to try in a public forum the issue that I raised with you. I think the matter is best resolved by direct discussion between the two of us with one or more other CDRH personnel competent to consider my viewpoint in a dispassionate way.

Obviously, I cannot force you to act in this matter, and I can't rest until it is resolved.

I hope you will be willing to respond affirmatively to my request for a meeting, or give me an estimate of when you might be prepared to reply, either affirmatively or negatively.

Thank you for your consideration.

Les Hamilton
[Telephone number]

Message No. 5

From: Buckles, David
To: 'Les Hamilton'
Cc: Romanell, Lawrence J.
Sent: Wednesday, February 29, 2012 11:13 AM
Subject: RE: Request for Meeting

Dr. Hamilton,

I acknowledge your communications. I am assessing the implications of your request for a meeting and I expect to have a response for you next week.

Regards,

David S. Buckles, PhD, FACC
CDRH Ombudsman

Message No. 6

From: Les Hamilton [mailto:les23hamilton@verizon.net]
Sent: Friday, March 09, 2012 7:06 AM
To: Buckles, David
Subject: Re: Request for Meeting

Dr. Buckles,

I hope you will honor my request for a meeting sometime soon. I promise to make my case succinctly. I don't want to waste your time or mine.

I think that my initial communication provided you enough information to understand the "burning question" which I want to discuss. Simply stated, what are the necessary and sufficient conditions that must be satisfied for a medical device to be eligible for assignment to class III?

I propose that we quickly discuss the issue hypothetically, then move to specific examples (ProdCodes JXK and ILX are of particular interest to me).

My patience with CDRH has been sorely tested over the years. During the past 30 months, responses to my FOIA requests have taken much longer than they should. In one case, obtaining a 510(k) on a CD took 22 months. Other simple requests remain unanswered after a year.

I gave a talk on predicate creep[2] at the CDRH meeting in February, 2010, which raised questions that remain unanswered, as far as I know. I identified a real case where the CDRH declared as "substantially equivalent" a series of shortwave diathermy devices where the peak power of the first predicate devices was 975 watts. In only a few steps, the peak power had declined to 0.043 watts! It is a real challenge to my common sense (and engineering background) to believe that the few devices involved are all substantially equivalent.

Providing you additional information at this point may help or hinder your decision if or when to meet with me, but I'll take the chance.

I was about the 45th employee of the new Bureau of Medical Devices when I was hired in May, 1974. My major assignment was to form the first Radiological Devices Classification Panel and to serve as its Executive Secretary. I did my work promptly and to the satisfaction of my superiors. However, I left the FDA in December, 1976, because of philosophical differences.

One factor that led me to resign was my concern about how FDA had dealt with a particular device (known as Diapulse). The FDA had declared it a quack device, despite favorable findings in published research, including double-blind studies. A federal injunction in July, 1972, prohibited the sale of that device. It took 15 years for the FDA to relent. It is a long sad story.

When Congress lambasted the FDA for failure to fully implement and enforce the medical device law, I wrote a thoughtful letter to Congressman Broyhill explaining why the law was overly broad and how it made the FDA's job nearly impossible. This letter led to my being invited by John Villforth then Director of CDRH to give a seminar about my concerns. There was a good turnout for the seminar. One of my recommendations was that CDRH establish the office of ombudsman which you now hold. (The seminar was videotaped and may be available from the CDRH office involved.)

I hope you will grant my request for a meeting. It may be useful to have Timothy Marjenin there, since he presented the slide that sparked my question in the first place.

You indicated you need to assess the implications of my request. If I'm wrong, let's put the matter to rest quickly, so we can all move on to other matters. If I'm right, it would not be good for you to be associated with protracted delay or the appearance of a cover-up.

I look forward to hearing from you.

Les Hamilton
[Telephone number]

Message No. 7

From: Buckles, David
To: 'Les Hamilton'
Cc: Romanell, Lawrence J.
Sent: Friday, March 09, 2012 11:09 AM
Subject: RE: Request for Meeting

Dr. Hamilton,

I have given careful consideration to your request for an in-person meeting, including records research and a review of events that transpired at a recent panel meeting. I have determined that the meeting you have requested is not an appropriate forum for the topics you wish to discuss.

There are various existing venues in which you may raise your concerns. The public session of an advisory panel meeting is one such venue, and I understand that you have recently availed yourself of this opportunity. Also, if you wish to make a case in writing that FDA change the way in which medical devices are regulated, then you may file a Citizen Petition as provided in the regulations in 21 CFR 10.30.

However, we do not have the resources to meet with every individual who disagrees with FDA regulation of medical devices, and were I to agree to meet with some individuals but not others, that would present the appearance of preferential treatment. Given that there are already established means by which you can raise your concerns with the agency, I therefore cannot agree to your request.

Regards,

David S. Buckles, PhD, FACC
CDRH Ombudsman

After Dr. Buckles made it clear he was unwilling to discuss the issue, I turned to Timothy Marjenin, the man who presented slide no. 70 at the February 10 meeting.

Message No. 8

From: Les Hamilton
Sent: Sunday, March 11, 2012 9:05 AM
To: Marjenin, Timothy
Subject: Definition of Class III

Mr. Marjenin,

We met, however briefly, at the Neurological Devices Panel meeting on February 10, 2012. During the first afternoon break, I attempted to ask you about Slide 70, which you had presented earlier. Understandably, you had other matters which required your attention, so we did not engage in discussion.

As the meeting was about to end, I attempted, with limited success, to get my question into the record.

Following the meeting, I wrote to the Panel chairman to apologize for my dramatic, and for me atypical, foray into civil disobedience. I also contacted the CDRH ombudsman, hoping that he would facilitate the meaningful discussion about the issue which interested me and which I am now pursuing with you.

For now, I will not ask you to comment in the context of CES devices. Consider what follows as a theoretical discussion about the definition of class III presented in your Slide 70.

"21 CFR 860.3(c)(3): A device is in class III if

">> Insufficient information exists to determine that special controls would provide a reasonable assurance of safety and effectiveness, and

">> The device is life-supporting or life-sustaining, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury."

For the sake of discussion, consider the definition to consist of two parts: the first part begins with the words "Insufficient information" and the second part begins with "The device is life-supporting ...". The two parts are joined by the conjunction "and".

For a device to be in class III, both parts of the definition must be logically true.

Let us focus on the second part of the definition. The second part of the definition will be true if any of four conditions is satisfied. However, the second part of the definition will be false if all four conditions are false.

Suppose we have some hypothetical device for which the following statements are unequivocally true:
1. The device is NOT life-supporting;
2. The device is NOT life-sustaining;
3. The device is NOT for a use which is of substantial importance in preventing impairment of human health;
4. The device does NOT present a potential unreasonable risk of illness or injury.

The question is: can such a device be legitimately classified in class III?

I look forward to hearing from you.

Leroy L. (Les) Hamilton, Ph.D.
Silver Spring, Maryland USA

Message No. 9

From: Marjenin, Timothy
To: 'Les Hamilton'
Sent: Friday, March 16, 2012 8:36 AM
Subject: RE: Definition of Class III

Hello Dr. Hamilton,

Even though you state that your question is theoretical in nature, I'm unable to get into a discussion about these issues with you at this time. The CDRH Ombudsman is still your point of contact and your communications should be directed to him.

Thank you,
Tim

Timothy Marjenin
Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Ophthalmic, Neurological and ENT Devices
Neurodiagnostic and Neurotherapeutic Devices Branch
[CDRH/ODE/DONED/NNDB]

Message No. 10

From: Les Hamilton
To: Marjenin, Timothy
Sent: Friday, March 16, 2012 10:11 AM

Subject: Re: Definition of Class III

Thank you for replying to my message.

It appears that the issue I've raised is either too trivial or too sensitive for people in CDRH to be willing to discuss it. It is for that reason I am trying - some people might say I'm very trying :-) - to engage in a dialogue with someone at CDRH about the issue.

I too felt that the CDRH ombudsman would be the best point of contact. However, my repeated efforts to arrange a meeting with Dr. Buckles have been unsuccessful. His latest response explained why he decided not to meet with me, and provided options that I find less than satisfactory. Apparently, CDRH uses a different definition of ombudsman than I'm accustomed to. (Incidentally, I recommended creation of the position of ombudsman during a seminar I gave to CDRH staff on October 3, 1983. The seminar was video-taped and may be available from some department there.)

Surely there must be someone at CDRH with whom I can discuss the matter. The question is who? Your suggestions would be appreciated.

My behavior at the Neurological Devices Panel meeting on February 10, 2012, was an impetuous attempt to get the question on the record. It was not a total failure, despite the efforts of the Executive Secretary [Designated Federal Officer] to the Panel to try to silence me. One company with a vested interest in the matter has chosen to go public on YouTube, even posting an excerpt from the meeting video containing my brief dialogue with Dr. Hurst. I doubt that airing complaints in such a public way has a positive impact on the FDA's image.

I'm involved in this matter simply as an interested party. Until a few months ago, I had not even heard of CES devices. I attended the meeting on February 10 because I wanted to see how CDRH and one Panel would deal with reclassification petitions. I had no intention of speaking out until late in the day.

It has been my conviction for decades that another class of devices in class III does not belong there. Now, my conviction is growing that there is a fundamental flaw in the construction of the classification questionnaire and that numerous devices may have been improperly classified.

If no one at CDRH is willing to speak with me, even off the record, I feel compelled to air the issue in other venues. This has already begun via my comments (posted under the moniker TAM5CD) in response to Mark McCarty's blog which mentions me.

http://mdd.blogs.medicaldevicedaily.com/2012/02/21/fda-advisory-committees-is-there-a-problem/#comments

I'm contemplating letters to the editor of prominent medical journals and other publications. Of course, there's no guarantee of getting them published.

I'm sorry if I'm putting you in a difficult position on this matter. I will be even sorrier if it turns out that I've deluded myself into thinking there is a legitimate issue here and I'm wrong. But I have to let it play out, at least until someone explains why my analysis is flawed or flat-out wrong.

Thank you for reading, if you've gotten this far.

Les Hamilton

* * * * *

[Marjenin did not respond to my second email to him. Instead, I received Message No. 11 from Dr. Buckles.]

Message No. 11

From: Buckles, David
To: 'Les Hamilton'
Cc: Romanell, Lawrence J.
Sent: Friday, March 16, 2012 10:51 AM
Subject: RE: Definition of Class III

Dr. Hamilton,

You may in future direct any communications regarding medical devices to my office. However, I wish to clarify that we do not have the resources to engage in debate or argument; neither do we have the luxury of responding to repetitive communications or inquiries. I have therefore instructed CDRH employees to forward messages from you to me without replying. Also, please be advised that communications that do not contain information that is both new and significant will likely not receive a response.

David S. Buckles, PhD, FACC
CDRH Ombudsman

[Fwd: copy of Message 10 to Tim Marjenin]

Message No. 12

From: Les Hamilton
To: Buckles, David
Sent: Saturday, March 17, 2012 2:37 AM
Subject: Re: Definition of Class III

Dr. Buckles,

Since I mean you no disrespect, I will, at least for the immediate future, direct my communications regarding medical devices to your office. However, some clarification may be in order.

From time to time, I submit Freedom of Information requests to CDRH (five of them this week). Should FOIA requests go through your office?

Just hours ago, I learned that the Neurological Devices Panel is scheduled to meet on Friday, March 23. Following your suggestion that my question or comment be submitted at Panel meetings, I plan to request the opportunity to speak during the open public session of the meeting. Must I submit this request through your office, or may I address it directly to the Executive Secretary of the Panel?

I look forward to your reply.

Leroy L. (Les) Hamilton, Ph.D.
Silver Spring, Maryland USA

Message No. 13

From: Buckles, David
To: 'Les Hamilton'
Cc: Romanell, Lawrence J.
Sent: Tuesday, March 20, 2012 10:41 AM
Subject: RE: Definition of Class III

Dr. Hamilton,

You may use existing procedures for filing requests under the Freedom of Information Act and for requesting time to speak at public meetings of medical devices advisory panels.

Regards,

David S. Buckles, PhD, FACC
CDRH Ombudsman

* * * * *

Recap and Comments

I decided to limit my comments since the emails tell the story. Readers can draw their own conclusions.

Given the announced role of the Ombudsman, I thought my request to meet with him was reasonable and that he should have been willing to assist. In light of subsequent events, detailed later in this book, it should become clear that there was a solid foundation for my analysis: the Classification Questionnaire did contain a serious error in logic and that some medical devices did not belong in Class III.

If Dr. Buckles had granted me a meeting and mediated with the appropriate CDRH staff, we might have settled these issues in a matter of days or weeks instead of the years that ensued.

Some of Dr. Buckles' responses puzzled me and I wondered whether they were consistent with the authority conveyed with his appointment. In particular, I was curious about his statement "I have therefore instructed CDRH employees to forward messages from you to me without replying."

Freedom of Information Requests

Buckles not only denied my request to meet with him, he forbade me from communicating with anyone else in CDRH about my concerns. His email to me on March 16, 2012 stated:

> You may in future direct any communications regarding medical devices to my office. However, I wish to clarify that we do not have the resources to engage in debate or argument; neither do we have the luxury of responding to repetitive communications or inquiries. I have therefore instructed CDRH employees to forward messages from you to me without replying. Also, please be advised that communications that do not contain information that is both new and significant will likely not receive a response.

Several things about his message troubled me. First, he is the Ombudsman, a title that generally applies to people with some empathy and willingness to listen to complaints. He clearly states that "communications that do not contain information that is both new and significant will likely not receive a response." So … he is the judge of whether a request has merit. Even if I have brought to him a legitimate issue, he will thereafter ignore me.

I wondered what his Position Description might reveal about the scope of his authority and whether he should be able to deliver a sweeping directive to all other CDRH employees (except, presumably, his boss, the Center Director).

I believe it has become common practice for businesses and government to have written Position Descriptions for their employees. In March 2012, I faxed two FOI requests. One asked for a copy of the Position Description of the CDRH Ombudsman[3]; the other requested communications from Dr. Buckles to the CDRH staff which pertained to me[4].

The requests were promptly acknowledged and assigned numbers.

The first request included the statement:

> Please send me, under the Freedom of Information Act, the information described below:
>
> The full description for the position of CDRH ombudsman including, but not limited to, his authority to issue directives to CDRH personnel not under his direct supervision.

The first response from the FDA to both requests was that the requested information could not be located.

Months later, I complained to William Holzerland, the Director of the CDRH Freedom of Information office, about the lack of a Position Description. Mr. Holzerland later reported that at the time of my request the Position Description was held at the Department of Health and Human Services and was thus not available from CDRH. It was subsequently transferred to CDRH. On June 25, 2013, I received the Position Description. It was silent on the subject of authority to issue directives to CDRH personnel.

The response to the second request - asking for communications from the CDRH Ombudsman to CDRH personnel – came by email in July 2013, and, according to my notes, was "sort of complete." There was nothing concrete, however, so I do not know whether Dr. Buckles actually communicated to CDRH employees concerning communications from me. I suspect he was using this claim as a ploy to curtail my attempts to engage in a dialogue.

Chapter 3 explains the logical error in the Classification Questionnaire.

Although disappointed by Dr. Buckles' responses, I decided to take his advice. Chapter 4 reveals my experience with advisory committee meetings and Chapter 5 covers two Citizen Petitions I submitted.

END NOTES FOR CHAPTER 2

[1] http://www.fda.gov/MedicalDevices

[2] This endnote is provided for readers unfamiliar with the term "predicate creep." When a manufacturer submits a 510(k) notice to the FDA, the notice must identify a device already on the market to which the new device is "substantially equivalent." The older device is called the predicate device. "Predicate creep" is the incremental change in device performance associated with a series of 510(k) notices for a particular device type.

[3] FOI request 2012-2363

[4] FOI request 2012-2364