Part 1

Save the CQ

Part 1 of this book deals extensively with the General Device Classification Questionnaire, a document which has been used for decades by the Food and Drug Administration. It is usually referred to as the Classification Questionnaire. I've abbreviated it to CQ for this book. The CQ is also known as Form FDA 3429.

The CQ's purpose is to identify to which of the three regulatory classes a medical device should assigned. The CQ consists of a series of questions, a list of the possible answers, and directions depending upon the answers. In 2012, I discovered a serious logical flaw in the CQ and petitioned the Commissioner of the FDA to correct the flaw. Instead, the FDA deleted the logical directions, arguing that the Form was confusing and needed to be simplified. In 2014, the FDA decided to discontinue use of the Form. However, they have not finalized that action, instead obtaining permission to extend the expiration date on the Form. Now, as of November 2018, the matter has not been resolved.

Part 1 also is concerned with devices that were misclassified into Class III by the FDA and were thus slated for Premarket Approval, even though they did not satisfy the definition of Class III. Chapter 1 deals with one of these devices.

Read on to learn why I am pleading to "Save the CQ."

Chapter 1

Call the Police

February - April 2012

I greeted Friday, February 10, 2012, with a mixture of anticipation and trepidation. Anticipation because I expected to witness first-hand an important part of the process by which the U.S. Food and Drug Administration regulates medical devices - trepidation because I was totally ignorant of the particular device to be discussed. Also, I might waste an entire day at a boring bureaucratic meeting. My anticipation did not include the possibility of being taken to jail. But I am getting ahead of the story.

For several weeks, I had been planning to attend a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. It had been 36 years since I had attended any FDA advisory committee meeting. The last time, in 1976, I was the Executive Secretary to the Radiological Devices Classification Panel. Now, I was just an interested party, a stranger to everyone else at the meeting except Larry Pilot[1], the man who had brought the meeting to my attention.

February 10, 2012: Neurological Devices Panel of the Medical Devices Advisory Committee Meeting Announcement

Center	Date	Time	Location
CDRH	February 10, 2012	8:00 a.m. - 6:00 p.m.	Hilton Washington DC North/Gaithersburg Salons A, B, C, and D 620 Perry Pkwy. Gaithersburg, MD 20877

I planned to drive to the meeting which was 17 miles from my home in Silver Spring, a suburb of Washington, D.C. I was no stranger to the meeting location. In fact, I had attended a national FDA meeting titled “Strengthening the Center for Devices and Radiological Health’s 510(k) Approval Program.” In my five-minute talk, I presented an extreme example of something called “predicate creep” which is explained in Chapter CXX.[2]

I decided to beat the rush and arrived at the Hilton around 7, early enough to have coffee and scope out the meeting room before the 8 am call to order.

The meeting room was arranged with a U-shaped table up front for the 14 Panel members and 2 FDA employees. Hundreds of chairs were provided for the audience, in rows of ten chairs on either side of a wide center aisle. Printed notices on many of the chairs announced who were permitted to occupy them. On the left side, two rows were reserved for each of the three companies whose petitions to the FDA provided the sole reason for the meeting. Another couple of rows were for presenters during the Open Public Hearing. On the right side, three rows (30 seats) were reserved for "CDRH" – employees of the Center for Devices and Radiological Health – the division of the FDA responsible for the regulation of medical devices.

On the left side of the room was a control panel where an operator managed the many microphones, the public address system, and the audio recording system used for the meeting transcript.

A separate microphone was provided for each person at the front table. Panelists were instructed to turn on their microphone when it was their turn to speak, and to announce their name each time they spoke to aid the transcriber. One microphone for public speakers was on a lectern (most people referred to is as a podium) between the front table and the audience.

Behind the last row of chairs for the audience, two private companies had set up commercial video cameras. I struck up a conversation with Bill Foster, the operator of one of these cameras, a spontaneous act that would prove useful later. Bill gave me his business card.

The meeting was organized by the FDA. Under law, the agency must seek advice of an advisory committee before ruling on particular issues, such as whether to grant a petition to reclassify a medical device, or approve a premarket approval application.

Classification of medical devices is a fundamental responsibility of the FDA in regulating medical devices. There are three classes: Class I General Controls, Class II Special Controls and Class III Premarket Approval. The class for a medical device determines the requirements to be satisfied by the manufacturer of the device. The three classes, their definitions and the requirements appear in Appendix R.

In this particular meeting, the device was a "cranial electrotherapy stimulator" – abbreviated CES. Three manufacturers of these devices had petitioned the FDA to reduce the class for CES devices from Class III to Class II.

At the time, I had no particular interest in, and little knowledge of, CES devices. My only reason for attending the meeting was to watch and learn. My motivation was my long-standing

interest in another type of device, known by the FDA as nonthermal shortwave diathermy, which was also in Class III and which I believed should be in Class II.

I wanted to see how the FDA and the Panel would interact when dealing with petitions to reclassify because I expected later petitions for nonthermal shortwave diathermy. Part 3 of this book deals with the nonthermal shortwave diathermy device.

The morning session consisted of presentations by representatives of the three petitioners and by members of the audience during the Open Public Hearing.

I found the presentations very informative. I learned that CES devices are claimed to mitigate the symptoms of anxiety, insomnia, and depression. They have been regulated by the FDA since 1977, and have been around since the 1960s. They deliver low levels of pulsed electrical current by means of a pair of electrodes on the head or earlobes. Three U.S. companies are listed for CES devices in the FDA's Registration and Listing database: Electromedical Products International Inc., Fisher-Wallace Laboratories LLC, and Neuro-Fitness LLC. The Product Code[3] for CES devices is JXK.

The presentation by an Army Reserve psychologist, Col. Kathy Platoni, Psy.D., about her use of CES in private practice and by U.S. combat troops included the following statement.[4]

> In the wartime theaters of both Iraq and Afghanistan, and under the worst possible conditions that any human being should ever be forced to tolerate, Alpha-Stim CES was the single most effective form of treatment that our combat stress control team was able to provide to service members in our care.
>
> In terms of insomnia, CES was the best form of treatment we had to get soldiers to sleep where sleep is elusive. The use of CES spread to other practitioners once they viewed such positive results.
>
> In terms of anxiety, nothing worked better to treat anxiety than CES, and again under the most stressful conditions imaginable. In the face of desperately depressed soldiers consumed with overwhelming misery and despair, the rapid and progressive effects of CES made it possible for these soldiers not only to perform their missions but actually to exceed standards and expectations. And with respect to PTSD, most importantly, soldiers were able to remain on mission.

After the lunch break, there were presentations by FDA people. They covered the regulatory history of CES devices, which had been placed in Class III decades before, a literature survey, and questions the FDA had prepared for the Panel to consider.

One FDA speaker, a biomedical engineer named Timothy Marjenin, used a slide show to illustrate his talk. One particular slide that caught my attention is shown in Figure 1.1.

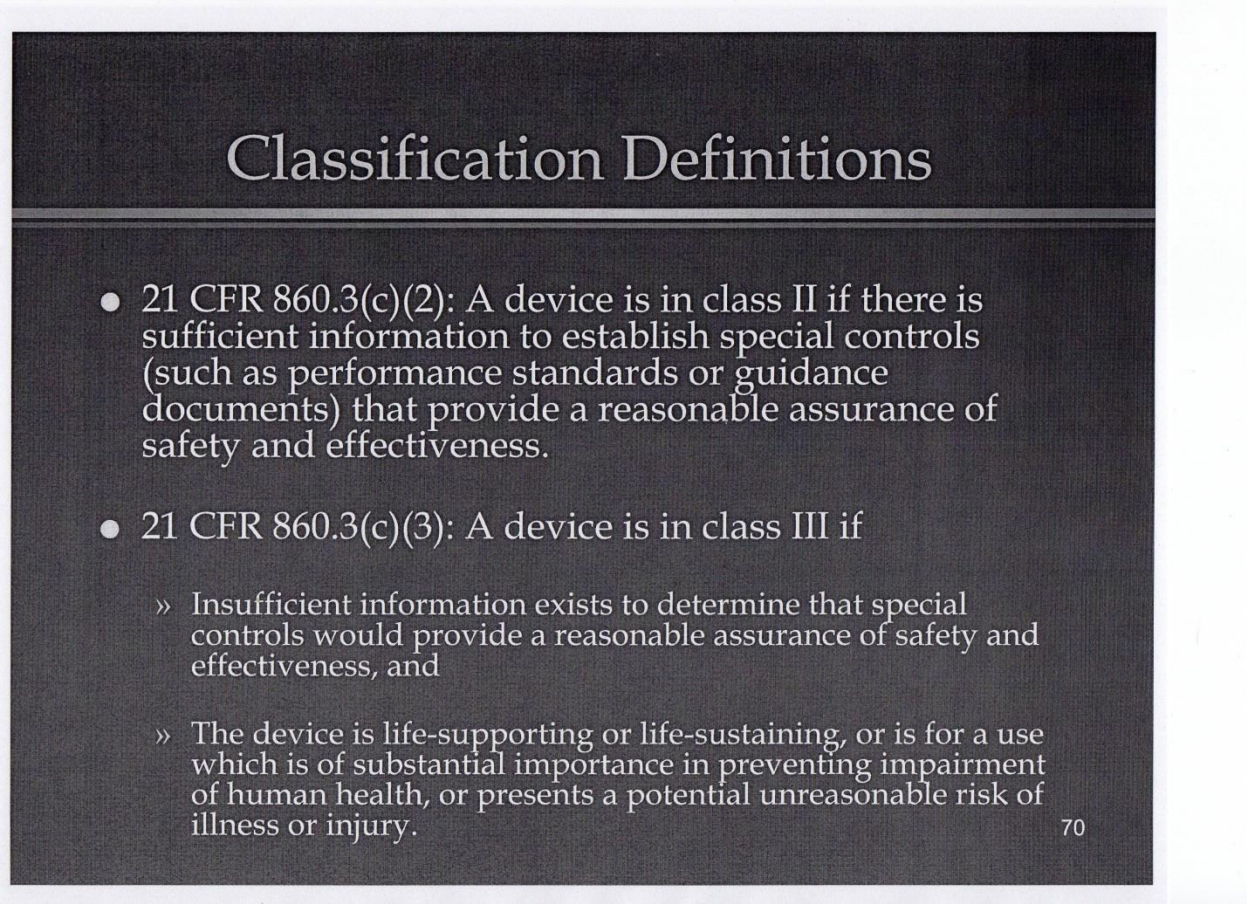

Figure 1.1 Slide 70 – Definitions of Class II and Class III

Hard copies of presentations by FDA and the companies were available at the desk outside the meeting room and I had taken a copy of Mr. Marjenin's slides. Slide No. 70 contains abbreviated forms of the definitions of Class II and Class III. As I mulled over the information contained in the slide, it occurred to me that there might be a serious question whether CES devices belonged in Class III. Based on what I had heard so far, It was clear to me that CES devices are not life-supporting or life-sustaining. There was nothing to suggest that they were important in preventing impairment of human health. And the Panel had indicated that CES devices did not present an unreasonable risk of illness or injury when used as directed.

Thus, in my estimation, none of the conditions in the second part of the (abbreviated) definition of Class III was satisfied. As I saw it, this would exclude CES devices from Class III. Was I missing something?

During the afternoon coffee break, I spoke briefly about my concern with Larry Pilot, who had first told me about the meeting. We discussed the definition of Class III. I also attempted to speak with Mr. Marjenin, who declined, saying he didn't have time.

After the break, I continued to mull over the issue. The more I thought about it, the more convinced I became that CES devices didn't meet any of the criteria in the second part of the definition of Class III.

The Panel Votes

Near the end of the meeting it was time for the individual Panel members to offer their opinions in response to a set of questions posed by the FDA. Panel members came from a who's who of American universities (including Harvard and Johns Hopkins) and medical institutions (Mayo Clinic). The roster[5] for this particular Panel consisted of the following people:

ROBERT W. HURST, M.D.	Univ. of Pennsylvania	Chair
EARL R. DORSEY, M.D., M.B.A.	Johns Hopkins Univ.	Standing Voting Member
SCOTT R. EVANS, Ph.D.	Harvard University	Standing Voting Member
KAREN E. ANDERSON, M.D., M.S.	Univ. of Maryland	Non-Voting Member
AMELIA M. ARRIA, Ph.D.	Univ. of Maryland	Non-Voting Member
RICHARD G. FESSLER, M.D., Ph.D.	Northwestern Univ.	Non-Voting Member
DAVID C. GOOD, M.D.	Penn State Univ.	Non-Voting Member
SURESH KOTAGAL, M.D.	Mayo Clinic	Non-Voting Member
KENNETH J. STEIER, D.O., M.P.H.	Touro College of Osteopathic Med.	Non-Voting Member
MURRAY B. STEIN, M.D., M.P.H.	Univ. of Calif. San Diego	Non-Voting Member
LYNDA J. YANG, M.D., Ph.D.	Univ. of Michigan	Non-Voting Member
MICHELLE CARRAS	Johns Hopkins Univ.	Patient Rep.
ANNE W. ALEXANDROV, Ph.D.	Univ. of Alabama Birmingham	Consumer Rep.
DAVID H. MUELLER, M.S.	American Medical Systems	Industry Rep.
LT AVENA RUSSELL, ABD, M.S.	CDRH	Designated Federal Officer

The FDA questions focused on the following indications for use of CES devices: insomnia, depression, and anxiety. The FDA had given the Panel six questions (spread over three pages) for the Panel members to discuss. Here is a brief summary of the questions.

Question 1 listed the risks which the FDA had identified; the Panel was asked if this is a complete and accurate list.

Question 2 dealt with the issue of reasonable assurance of effectiveness.

Question 3: "Based on the available scientific evidence, do the probable benefits to health from use of CES for these indications (treatment of insomnia, depression and anxiety) and conditions of use, outweigh the probable risks?"

Question 4: This dealt with petitioners' suggestions of the special controls which might be applied if the device were in Class II.

Question 5: Based on the available evidence and proposed special controls, what classification do you recommend for a. Insomnia, b. Depression and c. Anxiety.

Question 6: A lengthy question in connection with one petition for use of CES in treatment of patients with addiction.

Question 5, of course, was most important because it solicited the Panel members' opinions of what Class would be appropriate for CES devices for each of the three indications for use. The transcript[6] shows that Timothy Marjenin, the biomedical engineer mentioned earlier, asked the questions, and Dr. Hurst polled the Panel. The transcript excerpt which follows is confirmed by a video recording posted on YouTube.

DR. HURST: Let's again begin with Dr. Stein, please.
DR. STEIN: So, I'd recommend Class III for all three of those.
DR. HURST: Thank you, Dr. Stein. Dr. Arria.
DR. ARRIA: Class III for all three.
DR. HURST: Dr. Yang.
DR. YANG: Class III for all three.
DR. HURST: Dr. Good.
DR. GOOD: Same. Class III for all three.
DR. HURST: Dr. Dorsey.
DR. DORSEY: Likewise, III.
DR. HURST: Dr. Kotagal.
DR. KOTAGAL: For insomnia and depression, Class III. For anxiety, Class II.
DR. HURST: Dr. Anderson.
DR. ANDERSON: Class III for all three.
DR. HURST: Dr. Steier.
DR. STEIER: Class II for all three.
DR. HURST: Dr. Evans.
DR. EVANS: Class III for each.
DR. HURST: Dr. Fessler.
DR. FESSLER: Class II for all.
DR. HURST: Ms. Carras.
MS. CARRAS: If we recommend Class III, we're going to be putting this in the same class as pulse generators, implantable pacemakers, breast implants, AEDs, and we seem to concur on the fact that there is no safety problem with it, so I don't understand how it could even go in Class III. It's not life threatening or life sustaining. So, I recommend Class II.
DR. HURST: Dr. Alexandrov.
DR. ALEXANDROV: Class III for all three, but I would also add that I think we need to come to some clarity about whether we're going to use this for symptoms or the primary diagnosis. I think that's still very, very unclear.
DR. HURST: Mr. Mueller.
MR. MUELLER: Dave Mueller. Class II for all three. And I would like to add that the -- I agree with our Patient Rep, that this -- I just can't see it being a Class III device.

DR. HURST: Thank you. My sense is that the Patient Representative, the Industry Representative, and two of the voting members of the Panel believe that all of the indications should be Class II. The remainder of the Panel believes that all of the indications should be Class III with one exception, who believes that anxiety should be Class II and depression and insomnia Class III.
[End of excerpt]

Dr. Hurst accurately summarized the vote except that he refers to "two of the voting members" who opted for Class II. This shows that he didn't not distinguish the "voting members" from the "non-voting members." Clearly, votes were solicited from all the Panel members regardless of their status. Again, it is unclear why the majority of Panel members are designated as Non-Voting, since they are treated no differently from those who are designated Permanent Voting Members.

The results of the vote are shown in Table 1.1, with Arabic numerals substituted for the Roman numerals for the classes.

Panel Member	Status	Anxiety	Insomnia	Depression
Hurst	Chairman	No vote	No vote	No vote
Stein	Non-Voting	3	3	3
Arria	Non-Voting	3	3	3
Yang	Non-Voting	3	3	3
Good	Non-Voting	3	3	3
Dorsey	Voting Member	3	3	3
Kotagal	Non-Voting	2	3	3
Anderson	Non-Voting	3	3	3
Steier	Non-Voting	2	2	2
Evans	Voting Member	3	3	3
Fessler	Non-Voting	2	2	2
Carras	Patient	2	2	2
Alexandrov	Consumer	3	3	3
Mueller	Industry	2	2	2

Table 1.1 Panel Votes for Classification of CES Devices for Three Indications for Use

Nine Panel members (including the Consumer Representative) voted for Class III for all three indications for use. Four Panel members (including the Patient and industry Reps) voted for Class II across the board. One non-voting member voted for Class III for insomnia and depression and Class II for anxiety.

Although Drs. Fessler and Steier had voted for Class II, Michelle Carras, the Patient Representative, was the first Panel member to make a speech questioning whether Class III was appropriate: her statement is repeated here:

"If we recommend Class III, we're going to be putting this in the same class as pulse generators, implantable pacemakers, breast implants, AEDs [automatic electronic defibrillators], and we seem to concur on the fact that there is no safety problem with it, so I don't understand how it could even go in Class III. It's not life threatening or life sustaining. So, I recommend Class II."

And the Industry Representative agreed with her.

I find it interesting that some members of FDA advisory committees are listed as "non-voting" yet they poll all the members on the questions. For this meeting, the Chairman did not voice his opinion. Since the Panel was overwhelmingly in favor of Class III, perhaps he didn't see a need to vote. It fell to the Patient Representative to apply some common sense; she clearly recognized that these devices, despite being in Class III for decades, did not belong there.

Insanity or Civil Disobedience?

As the meeting was about to adjourn, I decided on a rash course of action. I moved to a seat in the front row, closest to the public microphone. I would try to inveigle permission from the Panel chair[7] for me to speak briefly. I felt it was important to get a question into the record, because it might be many months before the Panel would meet again.

What follows is the dialogue and narrative comments about what occurred during these few minutes.

The Panel Chairman, Dr. Robert Hurst[8]: At this time, I would like to ask Dr. Ann Alexandrov, our Consumer Representative …

[The Designated Federal Officer, Lt. Avena Russell[9], nudges Dr. Hurst to let him know that someone has approached the public microphone.]

Dr. Hurst: [Looks at me] Oh … there's only two seconds left.

Dr. Leroy L. Hamilton: Mr. Chairman, I have sat patiently through the entire meeting. And I have a burning question …

Dr. Hurst: Sir, we don't …

Dr. Hamilton: Excuse me. Then call the police and have me arrested[10].

[At this point, the public microphone was disabled.]

Dr. Hamilton: That's your option. That's the option. Allow me to take five minutes of the time of these people. That's your choice.

[Brief silence]

Dr. Hamilton: My name is Leroy L. Hamilton. I have a Ph.D. from Case Western Reserve University in Biomedical Engineering. I have a very simple, but very basic, question that really needs to be addressed. That is, the definition of Class III devices. Slide number 70 shows that there are two clauses associated with the definition of Class III.

[Dr. Hurst leans toward Lt. Russell – whispers something]

Dr. Hamilton: Those clauses are joined by the conjunction "and."

[Lt. Russell whispers in Dr. Hurst's ear.]

Dr. Hurst: Sir, I'm sorry but the Panel is not going to address your question.

Dr. Hamilton: That's fine.

Dr. Hurst: You just want to ask your question?

Dr. Hamilton: I want to go on the record. That will satisfy me. I'll make this very brief.

Dr. Hurst: Please do so.

Lt. Russell: I'm sorry sir, but we must ask you to have a seat, please. The Panel … You may not come and address the Panel.

Dr. Hamilton: If I cannot address the Panel, then I will address the audience.

[Dr. Hamilton turns to face the audience where company representatives occupy the first few rows.]

Lt. Russell: Sir, you may not address the Panel. Please have a seat. We …

Dr. Hamilton: (barely audible) [reads text from slide 70 – two clauses, joined by "and."]

Lt. Russell: Sir. [Stands and faces in the direction of Dr. Malvina Eydelman[11] – mouths something inaudible.]

Dr. Hamilton: (continues, barely audible)

Dr. Eydelman: Just to let you know, this …

Dr. Hamilton: … life-supporting or life-sustaining. Which of you makes a device which is life-supporting or life-sustaining?

Dr. Hamilton: I don't see any hands. [reading] Is it for a use which is of substantial importance in the preventing impairment of human health? Now, if the answer to that question is "Yes" then it's efficacious. If the answer to that question is "no" then it's not efficacious.

Finally, does it present an unreasonable – a potential unreasonable risk of injury or death? I think the Panel has shown by their words today that they do not …

Lt. Russell: Sir, we have asked you to please have a seat.

[Dr. Hamilton steps away from the lectern and faces Lt. Russell.]

Dr. Hamilton: If you want to call the police and arrest me, please do so. I'm willing to make a stand here because I've been … watching, working with … I was an FDA employee for two and a half years. I know how it works inside the agency. And they tend to take …

Unknown party[12]: [whispering]: Take a ten minute break.

Lt. Russell: At this time, we'll take a ten minute break.

Dr. Hurst: [Obviously directed to Dr. Hamilton] **Thank you for your input, sir.**

[Scattered applause from the audience.]

> **[Important note: you can view a video of this portion of the meeting on YouTube by following this link: https://www.youtube.com/watch?v=hv7T2A3s7Lk.**
> **It is also cited in the endnote 13.[13] FDA omitted this section from the transcript, and explained the omission in a transcript addendum, discussed later.]**

I won't apologize for how unprepared I was for this impromptu speech. I acted on impulse, bolstered by a deep-seated conviction that the majority of people involved in the day's activities had overlooked the possibility that CES devices had been misclassified, and that this option should be made part of the official record. In retrospect, my first words should have pointed out the likelihood that CES devices do not satisfy the definition of Class III, and if that were indeed the case, they had been improperly put into Class III.

During the ten-minute recess, I went to the back of the room to ask Bill Foster – who was operating one of the video recorders - if he had recorded my "presentation." He said he had, but he had no audio. I quipped "I could lip-sync it." Then I added that I would really like to get a copy of that portion of the video. He said his boss would have to approve[14].

Mending a Fence

Within a couple of days, I wrote to Dr. Hurst to apologize for disrupting the meeting. I was concerned that the FDA might bar me from attending future meetings and I wanted to show that I am really a responsible individual, not a raving lunatic. Dr. Hurst didn't respond to my letter.

"Creative" Writing

When the official transcript[15] was released a few weeks after the meeting, I found that the incident was "off the record." The transcript addendum[16] explained the omission as follows:

> " [page 281] At this time, a member of the audience approached the podium and spoke without being recognized by the Chair. He had not elected to address the Panel during the Open Public Hearing portion of the meeting and was not a presenter for any of the petitioners. He was instructed to stop and return to his seat by the Panel Chair since this portion of the meeting was not open for public participation, except at the specific request of the Panel Chair. His comments were not recorded, nor captured in the transcript."

There is little correlation between the contents of the transcript addendum and what actually occurred. Taking the addendum point by point:

1. "… without being recognized by the Chair" As the video shows, Dr. Hurst did recognize me and gave permission (albeit reluctantly) for me to speak.
2. "He had elected not to address the Panel during the Open Public Hearing." It is true that I didn't speak during the Open Public Hearing. The notion that CES devices did not satisfy the definition of Class III did not occur to me until after the Open Public Hearing was over.
3. "He was instructed to stop and return to his seat by the Panel Chair." Dr. Hurst never instructed me to stop and return to my seat. It was Lt. Russell who used her very authoritative voice and uniform in an attempt to control and intimidate me.

The pertinent regulations[17] for such meetings state that during the **open committee discussion "No public participation is permissible during this portion of the meeting except with the consent of the committee chairman."** In my opinion, Lt. Russell violated the regulation when she intervened to counter Dr. Hurst's clear approval for me to speak. She infringed on my right of free speech. If I had been aware the regulations at the time, I would have appealed her orders to the Chair.

As the video [endnote 8] clearly shows, Dr. Hurst granted me permission to speak. Moreover, he uttered the words "Thank you for your input, sir" when I finished!!

The Transcript Addendum is an example of what I call "creative writing". I don't think it is too much to expect my government to take responsibility for its actions and to comply with reasonable requirements of honesty and accuracy. I know that many government employees

are hard-working and have high levels of integrity. I also know there is a culture of protecting the agency and the jobs of the people who work there. There is a cultural mindset. Of course, I too have a mindset rather different from most FDA employees.

Advisory committee meetings are open to the public, except during specified closed sessions. It seems to me this example shows one way the agency censors meeting transcripts. If they don't want someone's words to be recorded (or amplified through the public address system), they simply cut off the public microphone.

Thank goodness that commercial video recording companies are not contractors to the FDA. I don't know the details of any agreement between video recording companies and the government, but there probably is one. I hope that this source of information for the public does not come under censorship.

Although my intention at the beginning and during most of the meeting was simply to observe and to learn, my conclusion that CES devices might have been misclassified into Class III moved me to act. Indeed, this day was the occasion of my first public act of civil disobedience. In retrospect, it was also a very enlightening experience with some valuable lessons.

Lesson 1: The FDA doesn't like surprises. They plan their meetings in meticulous detail. They want to know in advance what each participant plans to say. And if someone intrudes on their meeting as I did, they are quick to squelch the intrusion by cutting off the public microphone, omitting the unwanted material from the transcript. I resolved to be better informed about the rules and work within them.

Lesson 2: Even though the rules say the Panel Chairman has sole discretion in deciding who may speak at a meeting, the Designated Federal Officer or other agency employee may overstep his/her authority in an effort to silence a speaker.

Lesson 3: My impromptu challenge to authority and the explicit invitation to call the police did not result in such a call. They probably want to avoid publicity which might invite closer scrutiny.

Lesson 4: The press may or may not get involved. After the meeting was over, a man named Mark McCarty approached me, introduced himself as a reporter and asked if he could call me the following Monday. I agreed and we exchanged cards. He didn't call. A few days after the meeting, a friend drew my attention to McCarty's online blog[18] because my name had been mentioned.

McCarty: FDA advisory committees: Is there a problem?

Just two days after the meeting, Mark McCarty's post to his blog included the following:

> I've attended more FDA advisory committee hearings than most and believe I have a decent grasp of how those hearings should go. It's true I'm no expert, but recent hearings for medical devices have gone in a direction that strikes me as odd. … Another example occurred at the advisory hearing dealing with the regulatory status of cranial electrotherapy stimulator (CES) units. As I wrote in the Feb. 14 edition of *Medical Device Daily*, the Feb. 10 hearing "was conspicuous for two events. At the conclusion of the hearing, a member of the audience approached the podium after the vote and criticized the panel's decision, but FDA staff instructed the audio team to kill the microphone before Les Hamilton of Silver Spring, Maryland, made his views known. … ."

When I learned of McCarty's blog, I added a series of comments under the user name tam5cd[19] to clarify my position and to describe subsequent events. What follows are the four comments I added over the next 28 months. The user name was not intended to obscure my identity: I included my name and city in the note.

- tam5cd

Posted February 26, 2012 at 5:00 PM |

I wish to correct Mark McCarty's description of my actions at the Neurological Devices Panel meeting on February 10, 2012.

I did not criticize the Panel's decision. Rather, I sought to get on the record what may be a basic issue of what devices may be placed in class III. Applying the definition of class III provided in slide 70 by the CDRH leads to a legitimate question of whether CES devices belong in class III, even though they have been there for 30 years. I hope to stimulate a meaningful dialogue on this issue.

Leroy L. Hamilton, Ph.D.
Silver Spring, Maryland

- tam5cd

Posted March 13, 2012 at 9:37 AM |

So far, my efforts to initiate a "meaningful dialogue" with the FDA on the issue I raised at the Neurological Devices Panel meeting on February 10, 2012, have been disappointing. I wrote to the CDRH ombudsman on February 14th, to request a meeting with him. He declined and suggested that I raise the issue at another Panel meeting or submit a citizen petition.

Here, for the record, is the issue as I see it.

The definition of class III appears at 21 CFR 860.3(c)(3). Slide 70 shown at the meeting accurately captured the essence of the definition, as follows:

"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 [emphasis added]

">> 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."

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".

As I read it, both parts of the definition must be logically true for a device to be eligible for class III.

The second part of the definition will be true if any one of four conditions is satisfied, explicitly,
1. the device is life-supporting OR
2. the device is life-sustaining OR
3. the device is for a use which is of substantial importance in preventing impairment of human health OR
4. the device presents a potential unreasonable risk of illness or injury.

Admittedly, I am not expert on CES devices, but from the information presented at the Feb. 10 meeting, I am confident the CES devices

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

By my reasoning, the second part of the definition is not satisfied, and CES devices should NOT be eligible for class III.

I realize this is contrary to FDA policy for many years for CES devices. I believe the argument presented here applies to other devices.

If my analysis is correct and CDRH is unable to refute it, the agency needs to reexamine its policy for CES devices (and others). In addition, the classification questionnaire[20] should be revised.

I do not represent any company in this matter, nor do I have a financial interest in any CES company.

My hope is that by posting this analysis, anyone who finds fault will join in the discussion. If I'm wrong, please let me know, either in this forum, or directly.

Leroy L. (Les) Hamilton, Ph.D.
thinker20904 AT yahoo.com

This time, I even included my email address (modified in hopes that it wouldn't be harvested by a bot[21])

No one contacted me about the blog and my comments.

Most of the content in my comment on March 30, 2012, has already been covered above, so I won't repeat it here, except for the following additional comments:

-  tam5cd

Portion of post on March 30, 2012

Apparently, I am to be shunned by CDRH; this blog in one venue to set the record straight.

CDRH personnel seem unfazed by my sincere efforts to point out the material inconsistency between the definition of Class III and the logic of the Classification Questionnaire Form FDA 3429.

This is not, or at least it should not be, about me. It should be about the need for CDRH to respect and respond responsibly to legitimate questions from the public. It should be about the inherent problem in Form 3429[22].

CDRH personnel expect the rest of us to know and follow the rules. I suggest they need to abide by the rules, too.

Leroy Leslie Hamilton, Ph.D.
Silver Spring, Maryland

It was over two years later that I added my final comment to McCarty's blog. For the first time, I cited my loose cannon website.

-  tam5cd

Posted July 4, 2014 at 5:41 AM |

June 12, 2014. Much has happened in the two years since my prior comments were posted. My citizen petitions (Docket Nos. FDA-2012-P-0493 and FDA-2012-P-0747) led to a revision of the Classification Questionnaire (Form FDA 3429) and FDA's decision to reclassify CES devices [Product Code JXK] from Class III to Class II.

See http://www.loosecannon.name for more information.

* * *

I have no way to know who may have read McCarty's blog and my comments. I received one phone call a couple years after the first posting from a man who wanted to discuss an unreleated topic. No one else ever contacted me in connection with my comments.

Vindication

Skipping over the events between February 2012 and January 2016 for now, I'll close Chapter 1 with what I consider to be good news and a vindication of my position concerning the classification of CES devices. On June 12, 2014, FDA announced[23] that they were withdrawing their proposed order and proposed rule to set a date by which a Premarket Approval application would be required for CES devices. The next step would be to reclassify them from Class III to Class II.

On January 22, 2016, nearly four years after the Panel meeting which was the subject of this chapter, the FDA published the proposed final regulations for CES devices[24]. The notice contained a big surprise: instead of Class II for all three indications for use, they decided that Class II was okay for anxiety and insomnia, but Class III would be needed for depression. Comments were solicited by April 21, 2016. See Chapter 15 for details.

It is noteworthy that over two years after the meeting described above, the FDA bureaucrats finally decided to do what I thought was appropriate. However, I question the rationale for their decision. Yes, they did eventually realize that CES devices didn't belong in Class III but they didn't look at the fundamental question: do CES devices satisfy the definition of Class III in the law? Instead, they reasoned that there is sufficient information to establish Special Controls which, in addition to General Controls, would provide reasonable assurance that the devices are safe and effective. The effect may be the same, but the logic is quite different.

Furthermore, by ignoring the idea that these devices do not present an unreasonable risk, they are inclined to push for more "special" controls, thus imposing a heavier burden on the manufacturers. The regulators are constantly looking for the worst-case scenario, extending the list of real and imagined risks as far as the imaginations of themselves, Panel members, and anyone else can go. Reports in the MAUDE system[25] never go away, even if they are obviously irrelevant.

It took two years for FDA to announce their intention to reclassify CES devices. And it was many years later than it should have been, if only the agency had done its job properly in the first place. In the meantime, the manufacturers labored under the expectation that they would be required to submit Premarket Approval Applications at some point.

* * *

Months later, after the FDA had changed Form 3429 (Chapter 6), I wrote to Dr. Hurst to inform him of later developments. Again, no reply. Finally, I telephoned him to inquire if he had received my letters. He said he had, but turned them over to the FDA, unread.

* * *

At this point, the reader may wonder why I was willing to risk my freedom the afternoon of February 10, 2012 – to interrupt the meeting as it was about to adjourn. When I said the words "I'm willing to make a stand here," it was out of utter frustration with the FDA and the process, going back many years. My sense of fairness was deeply offended and I felt compelled to speak out.

How had I come to the point that I was willing risk arrest in my desire to go on the record over what I thought was a regulatory foul-up for a device in which I had no prior interest? In Part II, I'll provide a glimpse into my life experiences that provided the foundation for my evolution from strong supporter of regulation by the FDA to passionate critic. It didn't happen overnight.

Before we get to that, the next few chapters detail what has happened since February 10, 2012, especially concerning Form 3429 – the General Device Classification Questionnaire. What should have been a simple matter to resolve took on a life of its own. NOTHING IS SIMPLE ANY MORE!

END NOTES FOR CHAPTER 1

[1] Larry Pilot and I first met when we were both employed In the Bureau of Medical Devices in the 1970s. I contacted him in 2009 when I decided to write a book about the regulation of medical devices. He has been helpful. Larry had been employed in the FDA beginning in 1969, eventually serving as Director of the Division of Compliance, Bureau of Medical Devices. He resigned in 1979 to enter private practice.

[2] February 18, 2010, "Strengthening the Center for Devices and Radiological Health's 510(k) Review Program." My topic was titled "predicate creep" and is discussed in Chapter XX.

[3] Product codes are simply three letters, used to identify specific types of devices. The letters have no intrinsic meaning; they were assigned many years ago and are widely used in FDA databases.

[4] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM296891.pdf

[5] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM291033.pdf

[6] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM296891.pdf, pages 259-262

[7] Robert W. Hurst, M.D., Hospital of the University of Pennsylvania, Philadelphia, where he is a Professor of Radiology and Professor of Neurosurgery. Board certified in Neurology, Diagnostic Radiology, and Neuroradiology. His name appears in various lists of Top doctors.

[8] Robert W. Hurst, M.D., Hospital of the University of Pennsylvania, Philadelphia, chaired this particular meeting of the Neurological Devices Panel.

[9] Avena Russell was the Designated Federal Officer for the meeting. She sat beside the Panel chairman and made various announcements during the meeting. She is a Lieutenant in the Public Health Service and was dressed in the PHS uniform. The ranks of PHS officers parallel those of the Navy: a Lieutenant is equivalent to a Captain in the Army.

[10] My inspiration to risk arrest probably arose from an incident a few days before the meeting. Josh Fox, who produced the documentaries *Gasland* and *Gasland* 2 was arrested when he tried to film an open meeting of a congressional committee. See http://www.politico.com/news/stories/0212/72298.html

[11] Eydelman is a supervisory medical officer. Her job title is Director, Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices, Office of Device Evaluation, Center for Devices and Radiological Health, FDA

[12] This was probably Dr. Eydelman.

[13] The description of events and the dialogue are based on the video recording of the incident which can be viewed at http://www.youtube.com/watch?v=hv7T2A3s7Lk. Although the FDA cut off the public microphone, my words were picked up by the video camera.

[14] A few days after the meeting, I arranged to meet with a representative of the company, and for a small consideration, was provided a DVD of the few minutes I wanted. In addition, for a fee, I obtained a copy of the audio recording of the last portion of the meeting from the company which prepared the official transcript. My first few words were recorded, followed only by the words of Dr. Hurst, Lt. Russell, and Dr. Eydelman with lengthy silences between their utterances. FDA acted quickly to turn off the public microphone. It is easy to imagine circumstances in which a recording of the missing audio might be very useful in any subsequent investigation.

[15] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM296891.pdf

[16] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM296892.pdf

[17] 21 CFR 14.25(b): *The open committee discussion.* A committee discusses any matter pending before it in an open portion of its meeting unless the meeting has been closed for that matter under 14.27. To the maximum extent feasible, consistent with the policy expressed in 14.27, a committee conducts its discussion of pending matters in an open portion. No public participation is permissible during this portion of the meeting except with the consent of the committee Chairperson.

[18] http://medicaldevicedaily.com/perspectives/2012/02/21/fda-advisory-committees-is-there-a-problem/

[19] TAM5CD is a moniker I sometimes use online. It derives from "TAM-5" the designation for a miniature airplane that set two world records in August 2003, and "CD" Contest Director, my title during the historic flight.

[20] The "Device classification logic system was first explained in detail in the Federal Register, volume 40, number 97, May 19, 1975, pages 21849-21850. "Each device subject to classification shall be sequentially carried through the device classification logic system to determine which of the following controls apply: General controls, performance standards, or premarket approval. The determination is made after the consideration of 18 logic system questions pertaining to the safety and effectiveness characteristics of the device under consideration."

[21] A bot is a program which searches the internet to harvest email addresses to be sold.

[22] Form 3429 will be discussed in Chapter 3.

[23] Federal Register Volume 79, Number 113, Thursday, June 12, 2014, page 33712.

[24] Federal Register vol. 81 No. 14, Friday, January 22, 2016, pp 3751-3762

[25] MAUDE – Manufacturer and User Facility Device Experience database – contains reports of problems associated with medical devices. The database is online and can be easily searched. The reports are generally redacted to remove information that identifies the injured party, the institution where the report originated, dates, etc.