Chapter 4

Open Public Hearings

March – April 2012

Rebuffed in my efforts to establish a dialogue with someone in CDRH, I decided to follow Dr. Buckles' advice and present my concerns during the Open Public Hearing portion of medical device panel meetings. I checked the schedules for CDRH advisory committee meetings and learned how to get permission to speak. The regular email updates from the FDA included notices of upcoming advisory committee meetings. This chapter recounts my experience at three Panel meetings.

CDRH advisory committees are not standing committees, composed of a set of individuals who meet repeatedly. Instead, the Panel members are selected according to the topic of the meeting, their expertise, and their availability to serve. Some people serve more than once, depending on the agency's needs.

The Medical Devices Advisory Committee consists of 18 panels, each for a different medical specialty. The Medical Devices Advisory Committee is almost a fiction, it never holds a meeting, and the membership of its 18 panels is constantly changing. The people who serve on these panels come from all over the country. They are often affiliated with well-known institutions, and come with respectable credentials.

The FDA devotes a lot of resources to prepare for any panel meeting. FDA staff must decide who would be suitable, ensure that they would be able and willing to serve, coordinate the meeting arrangements, and prepare materials for the meeting. The meeting materials include a roster, an agenda, questions for the panel, and an Executive Summary which typically runs 50 pages or more. The Executive Summary provides a substantial amount of information about the device under consideration, its regulatory history, FDA's thinking about classification and the findings of a literature search.

According to the regulations[1], FDA advisory committee meetings consist of the following portions:

- The open public hearing (up to one hour)
- The open committee discussion
- The closed presentation of data
- The closed committee deliberations

In my experience, CDRH meetings are usually open to the public. Notices of CDRH advisory committee meetings are announced in the Federal Register weeks before the meeting date. They are also announced on the FDA website. They contain the following statement:

> FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting[2].

People who attend these meetings also expend time and energy preparing for them. Generally, they supply material to the FDA to be posted along with the FDA-generated materials.

Neurological Devices Panel – March 23, 2012

To my surprise, I found that another meeting of the Neurological Devices Panel was scheduled for March 23, 2012, only six weeks after the meeting described in Chapter 1. I had assumed that it would be months before the Panel would meet again. My email request to the Designated Federal Officer, Lt. Avena Russell, requested permission to speak during the Open Public Hearing. She soon replied granting permission and informing me that I was allocated five minutes.

Later the same day, another email from Lt. Russell withdrew permission. I telephoned to inquire the reason for the turnabout. She told me that my topic was not relevant to the Panel's business on March 23. As I explained that I wanted to address the Panel so they might better understand why I had made a scene at the February meeting, she told me that no one scheduled to attend the March Panel had been present at the February meeting. I brooded over the circumstances and decided to pressure her. By email, I advised her that I believed her behavior at the February meeting was contrary to the regulations as I understood them, and if she refused to allow me to speak I would file a complaint against her, charging that she had violated my right of free speech. She granted permission, and I prepared my statement for the meeting which was only a couple of days later. (I probably antagonized her by threatening her, but I didn't think about that at the time.)

When I compared the roster for the March meeting with that of the February meeting, I saw that Lt. Russell was correct. Not one person listed for the March Panel had attended the February meeting!

The day of the meeting, it became clear that Lt. Russell had been correct in another aspect: I would be speaking to the wrong people on a subject that was irrelevant to the agenda. Instead of withdrawing, I prefaced my remarks to the Panel with an apology. I said, "From what I've just heard from the other speakers in the open session, I think that you may find my presentation a little less than useful. However, I'd like to continue with it because it raises an issue that may extend to other devices you may consider in the future, and it certainly applies, I believe, to other devices considered by the FDA. … The device on the agenda today was placed in Class III, possibly years ago. However, I suggest there may be -- and I think, as I've already stated, I think it's unlikely in this case -- a legitimate question of whether this is the appropriate

class for this device. If it turns out that Class III is appropriate, I'll have egg on my face and I will apologize in advance, right now, for wasting your time."

Although I had practiced and timed my talk in the hours preceding the meeting, my ad libs and deliberate delivery caused me to run into the time limit. I was unable to complete my presentation before the red light came on, so my presentation was incomplete.

Chastened and a little wiser for the experience, I looked forward to doing a better job at another Panel meeting. I decided to pre-record the audio narration into the PowerPoint slide show to assure that I finished within the strict time limit.

Radiological Devices Panel – April 12, 2012

My next adventure was a meeting of the Radiological Devices Panel. The meeting announcement in the Federal Register[3] stated that the purpose of the meeting "On April 12, 2012, during session I, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 (74 FR 16214), for breast transilluminators, one of the remaining preamendments class III devices." I knew that these devices were in Class III. However, I questioned whether this was the appropriate class for them. I also knew that no devices of this type were approved for marketing in the U.S.

Another PHS officer, Shanika Craig, was DFO[4] for the meeting. She granted me five minutes during the Open Public Hearing which was scheduled for a half hour beginning at 10:40 am. When I arrived at the meeting location, I asked an FDA staff person at the desk outside the meeting room how many people were scheduled for the Open Public Hearing and was told I was the only one so far.

The second row on the left side of the meeting room was reserved for Open Public Hearing speakers; as expected, I was the only person there. The first row was reserved for company representatives; I spoke to the only person in that row, a man from the United Kingdom named Russell Overend. He was there to represent a company which manufactures and markets a device called the BreastLight. We exchanged copies of our slide shows.

His slide show informed me that Overend's company had submitted a petition to reclassify breast transilluminators from Class III to Class I. The real reason for the meeting was for the Panel to discuss the petition. This fact was not mentioned in the Federal Register notice of the meeting or in the day's agenda.

It seemed that fate had smiled on me. This was the ideal setting for me to make my pitch that certain devices had been improperly classified into Class III. Indeed, this device, known as "breast transilluminator" or diaphanoscope, was on my short list of Class III devices which I suspected to have been overclassified.

Overend's presentation impressed me. The company had sponsored studies to assess whether women could use the device effectively. The company markets their device in Europe as a Class I over-the-counter device.

Essentially, the device is a specialized flashlight which can be used to transmit light of a particular wavelength through a woman's breasts. This enables a woman to visualize some of the internal structure of her own breasts. The idea is that she might detect changes over time and could seek medical advice in case she noticed something suspicious.

During the morning break, I spoke with Shanika Craig to inquire whether she would limit my presentation to five minutes since I would be the only speaker during the Open Public Hearing. She reacted sharply, asking "Who told you that?" It struck me as strange, as if I had been privy to a secret. It also struck me as peculiar that the meeting announcement and agenda had not alluded to the fact that a petition to reclassify was the reason for the meeting and now she wanted to know who had given me what I considered a trivial bit of information. I declined to answer her question, saying I didn't want to get anyone in trouble.

I had recorded my slide narration into the PowerPoint presentation. I gave a flash drive with the slide show on it to the staff person along with a printed request that the sound be patched into the public address system. This time, I felt confident I was fully prepared. All I would have to do is start the slide show using the laptop computer on the lectern.

When my turn came, I was in for a rude surprise. I started the slide show, but there was no sound. I was flustered and called out "where's the sound?" The staff person assured me there was sound, after a few silent slides. She was correct, so the Panel did not hear some of the basic information they needed to hear.

At the end of my talk, the Chairman (Dr. Rosenberg) asked "Are there any questions from the Panel?"

One panel member kindly said "I just wanted to say thank you for putting together your presentation and making the effort to come out and communicate your findings in public."

Later in the meeting, another panel member raised a question.[5]

> DR. HENDRICKS[6]: 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[7]: 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?
> [End of excerpt]

My comment: Dr. Hendricks seemed to appreciate that I had a concern relating to the definition of Class III devices, and she sought clarification. The real point of my presentation was that Form 3429 had a logical error which led to Class III for some devices which did not meet the statutory definition of Class III. Ms. Morris' answer suggested that she either didn't understand the point I was trying to make or she was evading the issue.

Ms. Morris' statement "we are actually not using the classification questionnaire" does not tell the whole story. The fact is that the regulations require anyone petitioning to reclassify a device must submit a completed CQ. This particular Panel meeting was scheduled so that the Panel could consider a petition to reclassify breast transilluminators from Class III to Class I, and the Panel should have been provided a copy of the petition from Mr. Overend's company prior to the meeting.

In years past, it was common practice for an FDA person to read the questions from the CQ at Panel meetings[8] and to tally the Panel's answers. This practice apparently went out of fashion, allowing Ms. Morris to say "we are actually not using the classification questionnaire (at Panel meetings).

However, CDRH regulations require anyone petitioning for reclassification to submit a completed questionnaire.

FDA's Regulation of This Device

Earlier in the meeting, Dr. Hendricks had sought some clarification about the device[9]. The transcript reads:

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. [Reads from regulation:}

> 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 [nanometers], transmitted through breasts to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.

Ms. Morris continued:

> Anything outside of that classification is not the topic of today's discussion, but there are other pathways in which products that could have a different indication for use go to market. But today we're focusing on this classification and whether or not devices with that indication for use and technological characteristics, whether or not there is safety and effectiveness information to support the appropriate classification.
> [End of transcript excerpt]

Dr. Hendricks raised a good question: there seemed to be a disconnect between the device that Mr. Overend described and the device as FDA defines it. How are Panel members to deal with this?

Ms. Morris stated "there are other pathways in which products that could have a different indication for use go to market." I wonder what these pathways might be. Mr. Overend's presentation made it clear that the company he represents makes no claim that their device is effective for diagnosing cancer or other conditions. It is simply a means for a woman to examine her own breasts and to look for changes over time that may signal a threat to her health.

An Inconsistency in the Regulations for Radiology Diagnostic Devices

The regulations for Radiology Devices appear in Part 892[10] of Title 21 of the Code of Federal Regulations. There are just a few subparts: Subpart A contains General Provisions, Subpart B deals with Diagnostic Devices, Subparts C, D, and E are reserved, Subpart F deals with Therapeutic Devices and finally, Subpart G is Miscellaneous Devices.

Transilluminators are listed in Subpart B Diagnostic Devices, along with 63 other devices, including x-ray, magnetic resonance, nuclear scanners and ultrasound.

Here is the entire entry for transilluminators:

> Subpart B--Diagnostic Devices
>
> Sec. 892.1990 Transilluminator for breast evaluation.
>
> (a)*Identification.* A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700-1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.
>
> [End of quote]

Examination of the "Identification" sections for the other 63 devices reveals an interesting inconsistency.

For 63 of the Diagnostic Devices, the "Identification" is a straight-forward description of the device's technical characteristics with no mention whatsoever of any disease condition it is intended to diagnose.

Transilluminators is the only category of diagnostic radiology device that mentions the word "cancer." Why are transilluminators singled out to specify "cancer, other conditions, diseases, or abnormalities" when not one of the other 63 devices in the Diagnostic Device section makes mention of any disease condition? I don't have an answer, but it does seem odd to me.

Do Transilluminators Belong in Class III?

The basic question is whether transilluminators satisfy the definition of Class III. Clearly, they are not life-sustaining or life-supporting. They are not for a purpose which is of significant importance in preventing impairment of human health. They do not present an unreasonable risk of illness or injury. I am forced to conclude that they do not belong in Class III because they do not satisfy any of the three conditions in the second part of the definition of Class III.

Postlogue: The FDA continues to believe that breast transilluminators belong in Class III. In a Federal Register notice published on January 17, 2014[11], FDA set April 17, 2014 as the date by which Premarket Approval Applications will be required for breast transilluminators. Is it any wonder that no manufacturer has taken the trouble to try to get one cleared for sale in the U.S.?

Lessons learned:

1. It seems to me that statements made during the Open Public Hearing of CDRH advisory committee meetings have little impact. (Based on my observations at several Panel meetings in recent years, even the testimonials of satisfied users of devices, no matter how dramatic, appear to have little if any effect on Panel deliberations.)

2. Questions by panel members may be misinterpreted or deflected. In the case mentioned above, Dr. Hendricks sought clarification about my issue about the Classification Questionnaire. The FDA response by Ms. Morris effectively brushed the question aside

3. It is vital to be well prepared for any presentation. One needs to be concise and on point with excellent communications skills.

4. The transcript of a meeting cannot do justice to what actually occurs. The transcript consists of the spoken words. Many speakers use slides or other visual aids. The content of diagrams, tables, and graphs are mostly absent from the transcripts. It is an almost hopeless situation. This is why there is a market for the video recordings of Panel meetings made by independent companies.

5. The CDRH website can be an excellent resource for anyone interested in the details of a particular Panel meeting. Generally, the materials include the roster, agenda, documents and slide shows prepared by the FDA along with material submitted by industry, and the transcript.

As an example, here is the link to the FDA slide show for the Radiological Device Panel discussed above.

http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/radiologicaldevicespanel/ucm300839.pdf

6. Transcripts may be purchased from the transcription company at a cost of over one dollar per page. They are also available for download free at www.fda.gov (if you have the patience and skills to locate the transcript of interest and it is still posted or archived on the CDRH website).

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I don't know whether Dr. Buckles appreciated how little effect Open Public Hearing presentations have on the proceedings. I don't begrudge the time I spent preparing for and making my presentations because I gained valuable experience and insights into how CDRH works.

In Chapter 5, you'll see how the other approach – citizen petition – was more successful.

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[1] 21 CFR 14.25
[2] Background material is available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm.

[3] 77 FR 12064, February 28, 2012
[4] Designated Federal Officer
[5] Transcript, page 83
[6] Carolyn B. Hendricks, M.D., medical oncologist, Bethesda, MD
[7] Janine Morris, a CDRH mechanical engineer, GS-15.
[8] I found an example in the transcript of a Panel meeting around 2002 in which Marjorie Shulman did exactly that. When and why the practice was abandoned, I can only guess.
[9] Transcript of April 12 2012 meeting of Radiological Devices Panel, Page 63.
[10] 21 CFR 892.
[11] Federal Register, Vol. 79, No. 12, Friday, January 17, 2014, pp 3088-3094