Chapter 14

Meeting with Ombudsmen

December 9, 2015 – March 2016

Meeting at FDA

Abiy Desta had sent me information about parking and said he would come to the security checkpoint about 10:45 am to escort my wife and me to the meeting room. His email said to telephone if we arrived early.

My wife and I drove the two miles down New Hampshire Avenue from our home to the FDA campus at White Oak. We found a place to park our car and took a shuttle bus to Building 1.

We were through security by 10:25 am, so I telephoned Mr. Desta, who came to meet us in just a few minutes. While we waited, we looked at historical exhibits in the lobby, including one on the Bjork-Shiley heart valve.

This was the first time to meet Abiy Desta in person. He was well dressed, cordial and welcoming; we chatted amiably as we walked to Building 32. The place was bustling with people. At one point, we were overlooking a large cafeteria, where a few people were seated.

Evelyn and I were fascinated by the architecture, the exhibits, and the artwork. There was one long wall decorated with small three-dimensional human figures, in a variety of colors, row upon row, stacked to perhaps 15 or 20 feet high and 100 feet long.

Eventually, we got to a vacant conference room where Abiy suggested we wait. Before long, his deputy, Melissa Sage, came in and introduced herself. We were grateful for the opportunity to talk with her. Just before 11 am, Abiy collected the three of us and we walked quite some distance to the conference room assigned for our meeting. Nancy Pirt was waiting in the hallway, and the introductions continued. As soon as our room was vacated by the prior group, we went in. I took a place at the head of the table, with my briefcase on the table in front of me. Abiy Desta and Melissa Sage took seats to my right. Nancy Pirt sat across from Abiy. Evelyn took the third seat on the left, leaving a vacant chair for Laurie Lenkel, who had not yet arrived.

Abiy suggested we get the meeting underway. I set a timer to 60 minutes on the table in front of me. I asked if anyone objected to my making an audio recording of the meeting. Abiy said they would prefer that I not do so and I complied.

I began by thanking everyone for attending the meeting, particularly Abiy Desta, for arranging the meeting.

I gave each person an envelope containing the exhibits to be discussed; I mentioned that page 2 had a list of the exhibits. I had just begun to discuss Exhibit 1 when Laurie Lenkel arrived. I introduced Evelyn and Laurie, and gave Laurie an envelope.

The cover sheet (reformatted) appears below.

Discussion Materials

for Meeting of

Leroy Leslie (Les) Hamilton, Ph.D.

with FDA Employees

Abiy Desta (CDRH Ombudsman)

Melissa Sage (CDRH Deputy Ombudsman)

Laurie Lenkel (FDA Ombudsman)

Nancy Pirt, J.D., M.P.H. (CDRH Regulations)

On December 9, 2015 – 11 am to noon

"Save the CQ"

Statement of Intent

To inform you of the importance of the Classification Questionnaire (Form FDA 3429), its current inadequacy, how it can be improved, and why it should be retained.

Introductory Remarks – Why I am concerned.

LIST OF DOCUMENTS

1. Federal Register Notice – June 12, 2015
   Obvious Errors in notice
   Less obvious but more important: misleading statement about industry consensus
2. Excerpt from AdvaMed comment August 25, 2014s
   Clearly, AdvaMed supports continued use of the Forms
3. FOI Request 2015-5582
   No response as yet

4. Federal Register Notice – July 23, 2015
   "Correction"
5. Comments to OMB from LLH – July 24, 2015
6. Letter from LLH to Leslie Kux – August 13, 2015
   With draft beginning of "Chapter XXXIX"
7. Letter from Lauren Silvis to Les Hamilton – November 13, 2015
8. Classification Logic Diagram
9. Form 3429 – June 2012
10. Form 3429 - July 2012
11. CDRH Memo to OMB – July 2012
12. FOI Request 2012-7617
13. Initial Response to FOI Request 2012-7617

* * *

The exhibits were a mix of FDA documents with others I generated.

Each discussion item is followed by my remarks (based upon my recollection).

1. Federal Register Notice – June 12, 2015

The Federal Register notice of June 12 was discussed at the beginning of Chapter 13.

You know that I've already cited the factual errors in the June 12 FR notice: the address and phone number for AdvaMed were incorrect, the contact listed at AdvaMed was unfamiliar with the subject matter, and the address for FDLI was incorrect.

Far more important from my point of view, was the disingenuous assertion that the three organizations had a "consensus" of support for the CDRH program, particularly the proposal to discontinue use of Forms 3427 and 3429.

At this point, Nancy Pirt spoke up, saying something about the purpose of the notice. When it appeared she was about to launch into a lengthy speech, I interrupted her. I said my time was limited and there was a lot to cover; I'd be more than happy to hear her thoughts later.

2. Excerpt from AdvaMed comment August 25, 2014

This was also discussed in Chapter13; the relevant quote from the formal AdvaMed comment (Docket Number FDA-2013-N-1529-0007).

AdvaMed urged that CDRH continue to use Forms 3427 and 3429.

3. FOI Request 2015-5582

My request seeks information about the people who prepared the FR notices. If past experience is a guide, the answer will delayed by many months and will contain little of value.

4. Federal Register Notice – July 23, 2015

Again, I pointed out the July 23 notice corrected nothing.

5. Comments to OMB from LLH – July 24, 2015

This document speaks for itself.

6. Letter from LLH to Leslie Kux – August 13, 2015

I confessed to the group that my letter to Leslie Kux was an experiment designed to test the agency's response. I likened my action to the United States sending aircraft along the borders of unfriendly nations to probe for information about their radar systems.

7. Letter from Lauren Silvis to Les Hamilton – November 13, 2015

This was the letter sent in response to my letter to Leslie Kux. I pointed out that the letter dismissed all the errors in the June 12 FR notice as "inadvertent." How does one inadvertently use an address that's 30 years out of date? How does one inadvertently attribute to three organizations a "consensus" of support when one organization explicitly disagreed and the other two did not take a position? How could the July 23rd notice be considered a correction when in fact it simply deleted all the information about the three industry organizations?

8. Classification Logic Diagram

I pointed out that the diagram shows two paths to Class I. For about six months (May-December, 2013) I was convinced the one shown in red was a mistake. When I belatedly consulted the definition of Class I, I was quite embarrassed to find that I had been totally mistaken. I reminded Laurie Lenkel that I had made a nuisance of myself about the alleged error, and had apologized to her, to Marjorie Shulman and to others.

9. Form 3429 – June 2012

The form shows that a hypothetical device with "No" as the answer to the first six questions leads to Class III, even though "No" answers to the first three questions makes the device ineligible for Class III. The highlighted portion indicates what was removed in the version adopted in July 2012.

10. Form 3429 - July 2012

This version of the Form does not identify the appropriate Class for any device.

11. CDRH Memo to OMB – July 2012

This extraordinary document is an example of disingenuous presentation. My comments are appended to the memo to OMB.

12. FOI Request 2012-7617

This FOI request is similar to the one in item 3 above, in that it seeks information about the personnel or offices involved in CDRH decision-making.

13. Initial Response to FOI Request 2012-7617

I was running out of time by time we got to this document, so I didn't have time to explain that my appeal did bring forth a couple of minor items: an August 2013 email from Paul Gadiock to Marjorie Shulman and her response.

At some point during the hour, I told the group about my recent health issue. I said this was not intended to evoke pity but rather to explain why my preparation for the meeting was incomplete. I spoke the entire time with only the documents themselves for reference.

At the end of the meeting, Abiy assured me that my concerns would be conveyed to the agency, without identifying a person or an office. He said he could not anticipate what the response might be. He suggested I send him an email in a couple of weeks if I hadn't heard from him.

Follow-up to the Meeting

I sent the following emails during the two days following the meeting.

From: Les Hamilton
Sent: Thursday, December 10, 2015 6:38 AM
To: Desta Abiy ; Sage Melissa ; Lenkel Laurie
Cc: Hamilton Evelyn
Subject: Thank You

To : Abiy Desta, Melissa Sage, Laurie Lenkel, and Nancy Pirt
cc: : Evelyn Hamilton
Date : December 10, 2015
Subj : Thanks

My sincere thanks to all of you for your attendance at our meeting yesterday at the FDA. It was extremely important to me to have the opportunity to speak with human beings in person. Abiy Desta is no David Buckles, for which I am grateful.

The title I selected for the printed materials provided to you was "Save the CQ." I thank you for giving me your full attention during the 60 minutes allotted to me. I necessarily had to skim over much of the material, and omit relevant additional facts.

It occurs to me that my argument that CDRH should continue to use the Classification Questionnaire could have been bolstered by pointing out the value of checklists which commercial airline pilots are required to use.

I cited the example of the Panel meeting on February 10, 2012 (the Neurological Devices Panel) in which all the medical members of the Panel recommended Class III for Cranial Electrotherapy Stimulators for the three indications for use (anxiety, insomnia, and depression) except one, who thought Class II was

appropriate for one of the indications. When the Patient Representative was asked for her opinion, she voted for Class II wisely stating why she did not believe the devices should be in Class III. (The Industry Representative agreed with her.)

The devices considered at the 2/10/12 meeting – Product Code JXK - had been in Class III for many years, but FDA had not set a date by which PMAs would be required. CDRH has since stated that, on the basis of "new information" these devices are slated for Class II. It is possible that my Citizen Petition FDA-2012-P-0493 precipitated the decision to downclassify JXK devices, just as it was a stimulus for the revision of the CQ effective July, 2012.

Nancy Stade, In her letter of March 4, 2013, responding to my Citizen Petition FDA-2012-P-0747, indicated that the Classification Questionnaire is only one of many ways the agency can arrive at a decision about the proper classification for a device.

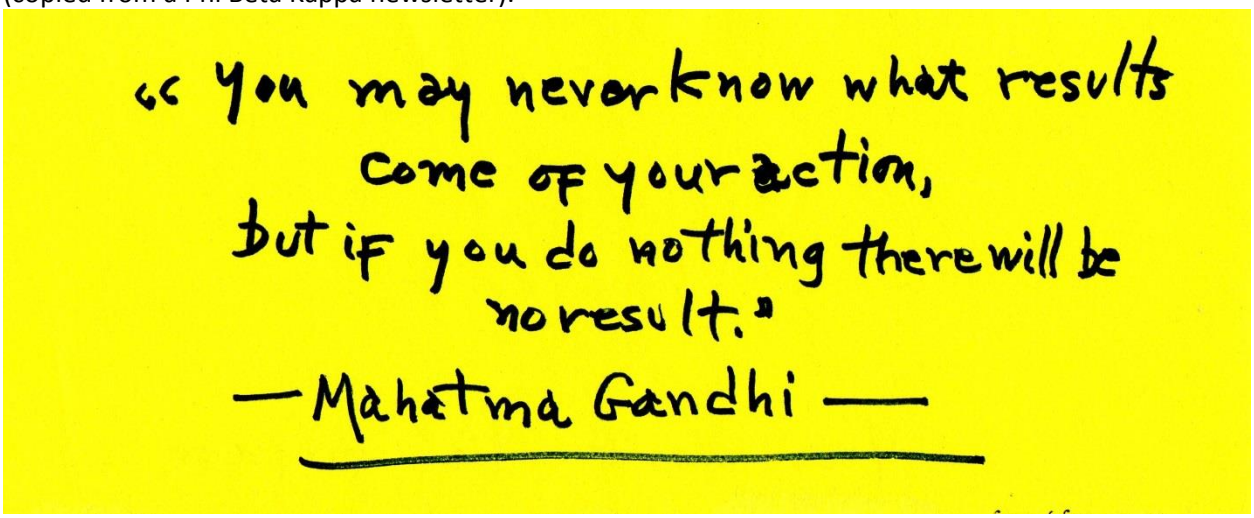
I believe a properly constructed Classification Questionnaire is ESSENTIAL to the process. Similar to the checklists that commercial aircraft pilots are required to use, the CQ would ensure that they follow the dictates of the definitions in the law.

* * *

I can understand that FDA personnel do not want the agency to get a black eye when the inevitable mistakes are made.

* * *

Two days ago, a dear friend who knew that I was preparing for our meeting gave me this quotation (copied from a Phi Beta Kappa newsletter):



I tried.

Again, my sincere thanks for your attendance and participation in the meeting. If my arguments fell on deaf ears or other considerations take precedence, I'll accept the outcome whatever it may be. Meanwhile, I will focus on completing my book.

Les Hamilton

[End of email]

* * *

The next day, I realized that I hadn't sent the above message to Nancy Pirt, so I forwarded the message to her with the following note:

From: Les Hamilton
Sent: Friday, December 11, 2015 2:53 AM
To: Pirt Nancy
Cc: Desta Abiy ; Sage Melissa ; Lenkel Laurie
Subject: Fw: Thank You

Nancy,

I am forwarding to you an email I sent yesterday. I intended it for the four FDA employees who attended the meeting hosted by Abiy Desta. I *inadvertently* neglected to include your email address. I apologize for the oversight.

I'm sorry that we did not have time to discuss your concerns. As it was, the hour allotted to me sped by, and I had to omit facts that I thought were important.

As but one example, Item 13 indicated that there were no documents in the CDRH files relevant to my FOI request. Your name was cited along with that of Paul Gadiock.

The response hinted that the decision to modify Form 3429 may have come from another level of government, e.g., the Commissioner's office or even the Department. I think this was smokescreen and that CDRH MUST have been involved at some level.

What I didn't get to say at Wednesday's meeting was that my appeal of item 13 was modestly successful, eventually yielding an August 2012 memo from Paul Gadiock to Marjorie Shulman along with her response, and another couple of minor items.

It amazes me that the changes made in Form 3429 do not have a paper trail to support them. Despite claims of transparency, it is difficult to determine which office did what. At the very least, Marjorie Shulman should have been made aware of the details since she is listed as the responsible party for the Form. I have been able to locate a few pieces of the puzzle. I know that Abigail Corbin was involved in the mechanics of the changes, Elizabeth Sands sent the request to PSC, and a little more.

Was everything done orally? Who actually initiated the plan to omit item 4 and column 3 from the Form? Who approved the changes? I think the memo to OMB (item 11) should have been included in FDA's response to my request.

I find the explanation and justification to OMB for the changes (Item 11) quite unsatisfactory. The fact is that Form 3429 contained a serious logical flaw, yet nowhere is there any hint that the FDA acknowledged the existence of the flaw. I suggest you might consider the quote at the beginning of my draft "Chapter XXXIX[1]."

I would welcome the opportunity to speak with you again.

Any comment?

Les Hamilton
[End of email]

There was no response from any of the four FDA officials to my emails of December 10 and 11.

* * *

Abiy Desta sent the following email to me on December 18:

Dear Les,

I hope this email finds you well. As promised [at the December 9 meeting] yesterday December 17, 2015 I spoke with Paul Gadiock (CDRH's Associate Directory [sic] for Policy) regarding the concern you raised at our December 9, 2015 meeting on how CDRH Classification Questionnaire (FDA 3429 rev 7/12) does not match up with Section 513 (a) of the FD&C act. At this time I am unable to communicate to you what if any action the Center is contemplating regarding FDA 3429.

Best regards
Abiy

* * *

I was grateful that Abiy identified the person with whom he spoke. Paul Gadiock has been involved in this matter at least since May 2012. Shortly after my May 2012 Citizen Petition[2] was denied, Paul and I had spoken at length about Form 3429 and the logical flaw it then contained. He was a party to the telephone call with Nancy Stade on July 23, 2012. He was cited by the FOI response letter (Item 13 in the handout for the December 9 meeting), etc. Is he a decision-maker in this whole brouhaha or just a link in the chain? The agency claims to be transparent, but it doesn't seem that way to me.

As of May 2016, the CDRH webpage has not updated Forms 3427 and 3429 to reflect their new expiration dates. It's been nearly two years since the agency announced its intention to abandon forms 3427 and 3429. The matter seems to be on hold.

I telephoned Abiy Desta a few weeks after the meeting to inquire whether he had any new information concerning CDRH plans for the two forms. He said he hadn't any news. When I asked about his own opinion concerning the matters discussed at the December 9th meeting, he said that he tries not to let his personal feelings intrude on his official responsibilities. I wanted

to tell him that from my viewpoint he is shirking his responsibility if he feels that my complaints have merit but he is unwilling to act. I wanted to tell him that he is part of the problem when he should be part of the solution. But I didn't say these things.

RESPONSE TO FOIA REQUEST FOI 2015-5582

On March 24, 2016, I received the following response to my FOI response:

> Dr. Hamilton:
>
> This letter is in response to your Freedom of Information Act (FOIA) request (copy attached) dated July 11, 2015, and received by the Food and Drug Administration (FDA) on July 14, 2015. Your request asked for information concerning Federal Register Notice by CDRH on June 12, 2015.
>
> The Center for Devices and Radiological Health (CDRH) conducted a reasonable search and provided the following information responsive to your request:
>
> 1. The titles of the individuals who prepared and approved the notice are as follows:
>
> a. Regulatory Policy Analyst, CDRH
> b. Management Analyst, OC
> c. Supervisory Management and Program Analyst, OC
> d. Program Support Specialist, OC
> e. Regulatory Policy Analyst, OC
>
> 2. We do not have any notes or memoranda or any information that supports the statement, "The consensus from the Agency's most recent contact with these trade organizations is that they are in favor of the program." Further, this statement was erroneously included in the published document.
>
> This completes the response from the FDA.
>
> X. The following charges will be included in a monthly invoice.
>
> **Reproduction: $0.00 Search: $11.50 Review: $0.00 Other: Total: $11.50**
>
> The above total may not reflect final charges for this request. Please **DO NOT** send payment unless you secure an invoice for the total monthly fee. Please contact the Government Information Specialist who processed this request at (301)796-5954 or by email at Susan.Weeks@fda.hhs.gov if you have any questions about your request.
>
> Sincerely,
> Jasmine Howard - eSignature
> Branch Chief

Division of Information Disclosure
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration

* * *

It is my understanding that under FOIA, requests should be limited to documents thought to be in the possession of the government. My request for the names, or alternatively, the job titles of the individuals involved in the creation and review of the Federal Register notice was probably beyond the required level of effort by the agency.

However, the response was notable for its completeness and candor. Let's take a look.

I had not expected the FDA to reveal the names of the people involved in the preparation and review of the Federal Register notice. But it doesn't take a great detective to glean a lot from the job titles. The DHHS personnel directory[3] allows easy access to a database of employees, which can be searched by any combination of search terms. You can narrow the search to a particular division, or duty station, etc. Thus, one can search for people with an exact job title, within the office of the FDA Commissioner and so forth. Another database provides the GS ratings and salaries

Regulatory Policy Analyst, CDRH.

There are eight names in CDRH listed with this title. All are GS-13 or GS-14 with salaries in the range of $98,913 to $131,053 (2014 data).

Management Analyst, OC

This is more of a problem because there are 138 names on the list. However, it seems likely that this person was a GS-13 or higher.

Supervisory Management and Program Analyst, OC

The DHHS Personnel Directory does not accommodate job titles this long. There are thirteen people with the title "Supervisory Management Anal" (presumably Analyst). Two are GS-13, four are GS-14, and five are GS-15. Their 2014 salaries ranged from $104,911 to $154,160.

Program Support Specialist, OC

There are 39 names in the Office of the Commissioner in Silver Spring with this job title.

Of these, most are GS-9 or higher, with salaries ranging from $52,000 to $79,000 in 2014.

Regulatory Policy Analyst, OC

There are six people with this job title. One is a GS-13, four are GS-14 and one is a GS-15. Their 2014 salaries ranged from $92,922 to $157,100.

It is impossible to know how much time each person devoted to their writing or reviewing of the June 12 Federal Register notice. What we do know is that the job was not done properly, and no one appears to be accountable for the mistakes in the notice. Even worse, the Ombudsmen for the agency seemed to lack any concern for the mistakes and misrepresentations.

The letter admits that no support for the statement concerning the "consensus" of industry was located.

* * *

This peek behind the curtain is revealing. Six highly paid individuals were involved in the drafting and reviewing a routine notice for the Federal Register. Yet none of them caught the obvious factual errors or the misleading statement concerning the "consensus" of industry. The letter from Lauren Silvis dismisses all the errors as "inadvertent." Where is the accountability?

* * *

Clearly, the evidence I presented to the three ombudsmen was insufficient to get their meaningful assistance with any of the issues presented to them. The fact the meeting was also attended by an attorney, Nancy Pirt, who was directly involved is the cover-up concerning the basis for the changes in Form 3429, probably had something to do with the outcome. (The response to my FOIA request discussed in Chapter 9 stated that "According to Nancy Pirt and Paul Gadiock of the Regulations Staff, there are no records in the custody of CDRH related to negotiations and modifications of FDA Form 3429. "

In my eagerness to get more issues on the table, I commanded the flow of the meeting. It might have been better to engage them in a dialogue, asking them explicit questions about fewer issues, e.g., "Do you think that revision of the CQ 3429 in 2012 improved the Form?" and "Why shouldn't the CQ provide the user the suggested class for the device?" And waited for them to express an opinion.

* * *

The next chapter concerns the next step in the classification of CES devices. CDRH springs another surprise.

End Notes for Chapter 14

[1] The draft Chapter XXXIX was expanded to become Chapter 13.
[2] Docket No. FDA-2012-P-0493
[3] http://directory.psc.gov/employee.htm