Chapter 13

What is the Truth?

June 2015 – March 2016

To be persuasive we must be believable;
to be believable we must be credible;
to be credible we must be truthful.
Edward R. Murrow

When a federal agency prepares a notice for publication in the Federal Register, the public has a right to expect that the responsible agency has made a reasonable effort to ensure that the information contained is accurate and truthful. So what went wrong in the process when CDRH published a routine notice on June 12, 2015? Apparently, there was little or no fact checking. If someone had simply dialed a phone number listed in the notice they would have discovered "The number you dialed is not in service." Was this simply a typographical error, evidence of sabotage, another instance of "creative writing", or maybe a combination of factors?

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I've been on the "CDRH Update" distribution list for a few years now. These emails come out like clockwork nearly every weekday. Each email contains brief descriptions of the latest CDRH actions with links to the details. There may be a single item but there are usually a few and occasionally a dozen or more. Topics range from a list of PMAs approved in a recent month to recalls to Panel meeting items (meeting notice, availability of meeting agenda or meeting transcript). CDRH is a busy place.

The morning of June 15, 2015, I looked at the day's update. It announced that three items had been published in the Federal Register the previous Friday, June 12th. The second item "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices" caught my attention, so I clicked on the link.

The notice was intended to satisfy the requirement that agencies submit information to the Office of Management and Budget concerning the burden on the public associated with data collection activities, under the Paperwork Reduction Act (PRA). Since Forms 3427 and 3429 were set to expire on June 30, 2015, CDRH sent the notice to OMB. In it, CDRH stated their intention to retire Forms 3427 and 3429, but since that had not yet been done, they asked OMB for an extension.

As I perused the item, I found that it indeed was of interest to me. The notice had quite a bit of boilerplate; to read it, see the Federal Register for June 12, 2015, pages 33524-33525

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The excerpt I want you to see appears below:

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In the **Federal Register** of March 10, 2015 (80 FR 12642), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received.

The comment refers to changes to the form FDA 3429 as proposed by the commenter in a citizen petition (FDA–2014–P–0283–0001), which was subsequently denied by FDA in a final response letter to the petitioner (FDA–2014–P–0283–0003). Because the proposed changes have already been denied through the citizen petition process, we have not made changes to this information collection based on the comment.

The Center for Devices and Radiological Health (CDRH) has continually maintained contact with industry. Informal communications concerning the importance and effect of reclassification are provided primarily through trade organizations, and via CDRH's Web site. The consensus from the Agency's most recent contact with these trade organizations is that they are in favor of the program. The trade organizations involved are AdvaMed, the Food and Drug Law Institute (FDLI), and the National Electrical Manufacturers Assoc. Association (NEMA):

AdvaMed, Tara Federici, 1030 15th Street NW., suite 1100, Washington, DC 20005, 202–452–8240;

Food and Drug Law Institute (FDLI), 1000 Vermont Ave. NW., suite 1200, Washington, DC 20005, 202–371–1420; and National Electrical Manufacturers Association (NEMA), 1300 North 17th Street, suite 1847, Rosslyn, VA 22209, 703–841–3200

The comment mentioned in the first two paragraphs came from me. The cited citizen petition – also from me - proposed a revision of Form 3429 – Classification Questionnaire – which would correct the problem I had previously identified, and discussed in Chapter 12. (I now regret that I didn't promptly appeal the denial of my petition.)

Call me cynical, but I wondered whether the statement in the third paragraph ("The consensus from the Agency's most recent contact with these trade organizations is that they are in favor of the program.") would stand up to scrutiny. Because CDRH had provided phone numbers for all three organizations, and even the name of a contact person at AdvaMed, it should be easy to check.

THE TRUTH ABOUT ADVAMED

When I telephoned the number listed for AdvaMed, I heard the recorded announcement "The number you dialed is not in service." As I puzzled over that unexpected result, it suddenly came to me: the address and phone number listed for AdvaMed were actually those of the Health Industry Manufacturers Association (HIMA), where I had worked from 1976 to 1983. HIMA moved from the 15th Street address to a location on G Street many years ago, was renamed AdvaMed, and then moved again its present location on Pennsylvania Avenue. I wondered how CDRH had made such a careless mistake.

I looked up the number for AdvaMed and had Tara Federici on the line within minutes. When I told her why I was calling, she mentioned that someone else had told her that her name was in the Federal Register on June 12. She had no idea why her name was listed. She said she has worked at AdvaMed for 25 years and did not recognize the address on 15th Street.

Moreover, she was not even acquainted with the subject matter of the Federal Register notice. I explained that the address and phone number belonged to HIMA; she knew of HIMA.
Tara said she would look into the matter. Three days later, she telephoned me with the news that AdvaMed had indeed submitted comments on the proposed changes in classification and reclassification and that an AdvaMed V.P. (Khaterei Calleja) was the contact person. In their 22-page comment[1] on the proposed rules; AdvaMed advocated that the two forms should be retained. At page 14, there was section heading "**D. FDA should not remove the definitions for, and use of, the Classification Questionnaire and Supplemental Data Sheet.**"

THE TRUTH ABOUT FDLI

My attempts to reach someone via email at the Food and Drug Law Institute were fruitless, so I sent a letter by snail mail to Amy Rick, the President. Ms. Rick telephoned in response to my letter. She explained the role of the FDLI as an educational organization that DOES NOT take a stand on FDA proposals. I also learned that the published address for FDLI was out-of-date.

THE TRUTH ABOUT NEMA

My emails to the National Electrical Manufacturers Association brought the response that NEMA had not taken a position on these particular proposed regulations because none of their members had asked NEMA to do so.

WHY FDA PUBLISHED A "CORRECTION"

On June 15, I had sent an email to the CDRH Ombudsman, Abiy Desta, about the errors in the address and phone number of AdvaMed, along with my preliminary comments I had faxed to OMB. Mr. Desta replied that he had informed CDRH management.
I heard that CDRH would be publishing a correction to the June 12 notice, so I was looking forward to it. It was published on July 23[2]. **The "correction" simply deleted the portion of the notice beginning "The trade organizations involved …" along with their addresses.**
In other words, the second notice was not really a correction, since it did not correct any of the errors in the June 12th notice. There was no correction for AdvaMed's address or phone number. No correction for the address of FDLI.
It would leave the casual reader with the impression that some unnamed trade organizations support the changes proposed by CDRH. I think this is intellectually dishonest.
Most FDA items published in the Federal Register these days end with a date along with the name and title of a high-ranking FDA official; in the case of these two notices it was **Leslie Kux, *Associate Commissioner for Policy.***

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[1] See page 14 of Docket Number FDA-2013-N-1529-0007 at Regulations.gov
[2] Federal Register Volume 80, Number 141, Thursday, July 23, 2015, Pages 43781

An Experiment

It seemed to me that Ms. Kux should have an interest in the accuracy and truthfulness of items submitted by the FDA to the Federal Register if only for the reason that her name – and presumably her reputation—are somehow involved.

On August 13 I sent a letter (certified-return receipt requested) to Ms. Kux with an early draft of this chapter. On a whim, I numbered the chapter XXXIX. My letter requested that Ms. Kux comment or explain the inconsistencies in the two Federal Register notices. She never replied, even though I followed up with an email entreating her to reply "No comment" if indeed that was her response. The green return receipt postcard finally came back to me on September 5, but only after I complained to the U.S. Postal Service that I hadn't received it. The postcard indicated the letter to Ms. Kux was received on August 18; the postcard wasn't mailed until September 4.

[CDRH responded to the letter in November after I was granted a meeting with the Ombudsman, as discussed in the Chapter 14.]

Frivolous Citizen Petition

The one method of reaching out to the FDA which seems to work best is by filing a Citizen Petition. Because I had sent several certified letters as well as one registered letter to persons in CDRH (all return receipt requested) in recent years and usually did not get the green return receipt postcard back, I filed a Citizen Petition to address this problem. The FDA acknowledged the Petition:

> Your petition to the Food and Drug Administration requests that the Commissioner direct employees of the Center for Devices and Radiological Health to complete and return "return receipt" postcards when they receive Certified or Registered letters with the green return receipt postcards attached. The Commissioner may conclude that other branches of the FDA need such direction; was received by this office on 09/11/2015.
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> It was assigned docket number FDA-2015-P-3364 and it was filed on 09/14/2015. Please refer to this docket number in future correspondence on this subject with the Agency.

As this is written, more than 180 days have elapsed since the FDA acknowledged receipt of my petition. Usually, that triggers a form letter explaining the delay. That letter has not yet arrived. I don't consider my petition "frivolous" but the lack of attention to it by the FDA may indicate their opinion in the matter. The pro forma letter indicating that my petition requires additional time came later.

Eventual Denial

By letter dated April 16, 2018, two years and seven months after the petition was filed, the FDA denied my petition. They claim that CDRH staff already return the postcard, so there is no need for the Director to issue an order.

Perhaps my experience is unique: maybe I am the one person who has sent a Certified or Registered letter to the FDA (return receipt requested), who didn't receive the postcard back. But I doubt that.

Frivolous FOI Request

The obvious errors in the June 12 Federal Register notice really annoyed me. I filed a Freedom of Information request on July 11 (FOI number 2015-5582**)** in an attempt to learn how it came about. There were two parts to my request:

1. Name(s) of the individual(s) responsible for the preparation and approval of the content of the cited Federal Register notice. If the names are not releasable, I am seeking at least the job titles and the organizational information, down to the Branch level if appropriate.
2. The notice includes the following statement: "Informal communications concerning the importance and effect of reclassification are provided primarily through trade organizations, and via CDRH's Web site. The consensus from the Agency's most recent contact with these trade organizations is that they are in favor of the program."
   This is followed by the names, addresses, and phone numbers of three organizations: AdvaMed, Food and Drug Law Institute and National Electrical Manufacturers Association.
   THE ADDRESS AND PHONE NUMBER FOR ADVAMED ARE INCORRECT. [They in fact were the address and phone number for the Health Industry Manufacturers Association, predecessor of the organization now known as AdvaMed. The information is some 30 years out-of-date.]
   Please send me notes or memoranda or any information CDRH has to support the statement "The consensus from the Agency's most recent contact with these trade organizations is that they are in favor of the program." This seems at odds with other information, including a 22-page statement from AdvaMed (Docket No. FDA-2013-N-1529-0007).

The response to this request containing pleasant surprises arrived less than nine months later. To keep events in chronological order, this will be discussed in the next chapter.

Comment to OMB

On July 24, I faxed a two-page comment to the Office of Management and Budget documenting the errors we have been discussing. This supplemented my earlier comment to the OMB. Of course, there was no response from the OMB to either comment.

FDA Ombudsmen

I was committed to holding their feet to the fire on this, so I sought the assistance of the FDA Ombudsman, Laurie Lenkel, in an email to her. She replied that she would look into the matter. On October 26, she wrote that she was too busy to investigate and suggested that I ask the CDRH Ombudsman, Abiy Desta, for help.

I had sought Mr. Desta's help on a related issue in January 2015, and he had demurred, saying he preferred not to interfere with evolving regulations policy. This time, he agreed to meet with me. Before a date for our meeting was set, he informed me that the FDA was preparing a response to my letter to Leslie Kux, and he suggested we wait until we found out what the response contained. I countered that I was willing to wait, but not for months. He suggested we wait until November 20, and if I hadn't received the letter by then, to set a date for our meeting. I agreed. He also said he wanted his Deputy, Melissa Sage, and the FDA Ombudsman, Laurie Lenkel, to attend. I don't know, but I suspect it is highly unusual for three Ombudsmen to participate in a meeting with an individual seeking help.

The response to my letter to Leslie Kux arrived on November 20; the date - November 13, 2015 was stamped on the first page . Here is the body of the letter:

> Dear Dr. Hamilton:
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> Thank you for your letter of August 13, 2015, addressed to Ms. Leslie Kux, Associate Commissioner for Policy. In that letter, you discuss two Federal Register notices, both of which were notices that pertained to information collection renewals under the Paperwork Reduction Act. The first notice was "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Requested; Reclassification Petition for Medical Devices," (80 FR 33534, June 12, 2015). The second notice was "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Requested; Reclassification Petition for Medical Devices; Correction," (80 FR 42781, July 23, 2015).
>
> In your correspondence, you discussed the two Federal Register notices, the errors in the first notice, and the corrections published in the second notice. You stated, "[T]he second notice was not really a correction, since it did not address the fact that erroneous information has been published."
>
> As stated in the correction notice of July 23, 2015, the original notice inadvertently contained inaccurate information regarding communications with industry, including inaccurate contact information, which has since been corrected. The original notice was

intended to provide specific information on the means of submitting public comments. Following the routine process for renewing FDA information collections, public comments were carefully considered prior to extending the information collection authorized under OMB Control Number 0910-0138.

If you have any questions about this response, please contact Abiy Desta, Ombudsman, at our Center for Devices and Radiological Health, at (301) 796-0293.

Sincerely yours,
/signature/
Lauren Silvis, J.D.
Deputy Director for Policy
Center for Devices and
Radiological Health

* * * *

This letter is another example of what I have been calling "creative writing." It dismisses all the errors in the June 12 FR notice with a single word "inadvertently." The letter ignores completely my findings that the three organizations cited in the June 12 notice did NOT agree with the proposed changes in the regulations and in particular, the plan to discontinue use of Forms 3427 and 3429.

The July 23 FR notice is identified as a correction. In fact, the July 23 notice simply deletes the names and other information for the three organizations. What did it correct? It didn't correct the wrong addresses listed for AdvaMed or the FDLI. It didn't correct the wrong phone number for AdvaMed. Most egregious of all, it left the "consensus" statement intact, while deleting the names of the organizations. So which organizations were the basis for the "consensus" statement?

Whoever at the FDA handled this matter should be tested for their ability to draw reasonable conclusions for a set of facts (or maybe tested for what they have been smoking). I would like this matter to be investigated by a proper authority, such as the Inspector General of the Department of Health and Human Services.

As soon as I received the letter from Ms. Silvis, I informed Abiy Desta, and he set our meeting for Wednesday, December 9, from 11 am to noon. The meeting I had been seeking for nearly three years was finally scheduled.

As luck would have it, I nearly had to cancel the meeting because of a health issue.

I was adamant that I wanted to attend the FDA meeting. Fortunately, my body cooperated and the meeting went off as scheduled.

Chapter 14 describes the meeting.