Chapter 9

FOIA Request 2012-7617

October 2012 – January 2014

The Freedom of Information Act became law in 1966. It can be an extremely valuable tool for news organizations and individuals to obtain vital information from the Government that might otherwise be inaccessible. I have used FOI requests sporadically since the early 1980s to obtain information from the FDA that is occasionally very useful. In particular, a request in 1984[1] provided me the names and addresses of hundreds of doctors whose Diapulse™ machines had been confiscated by the government. How I used this information is described in Part 2.

Too often, the response to requests has been that the information could not be located. When I sought documents more than a few years old, I was not surprised they weren't available because FDA policy sets retention times for various types of documents[2]. Delays in delivering requested information are the rule, despite the time limit for responses in the regulations. I've waited for nearly two years in some cases. At times, the material sent to me was so heavily redacted as to be virtually useless. (Human error can foil redaction; in one case, a company name was left in one place despite being blanked out numerous other places.)

* * * * *

FOIA Request 2012-7617 – Internal Memos Concerning Form 3429

Form FDA 3429 General Device Classification Questionnaire is the thread which binds Part 1 of this book together. As we have seen this Form was revised effective July 2012, just one month after it had been renewed for 37 months. I wanted to learn as much as I could about the people who participated in the decision to revise the Form and the reasons for doing so.

My email to Marjorie Shulman seeking answers had gone unanswered. My registered letter to Nancy Stade was also ignored. I was confident that they could not ignore a request made under the Freedom of Information Act, although I knew from experience that responses to my FOI requests were frequently delayed and often less than satisfactory.

In Chapter 6, I mentioned submitting an FOI request on October 17, 2012, seeking internal FDA memoranda pertaining to the revisions in Form FDA 3429 effective July, 2012. Now we'll get into the details and how it took considerable persistence on my part to get anything at all, let alone the actual documents requested.

My FOI request appears below; it was acknowledged as number 2012-7617 on Oct. 22, 2012.

> RE: FDA Memoranda concerning Changes to Form FDA 3429
>
> Please send me, under the Freedom of Information Act, the information described below:
>
> Internal FDA memoranda since May 1, 2012, concerning changes to or modifications of Form FDA 3429 General Device Classification Questionnaire. This request covers memoranda on this topic sent by or sent to any of the following CDRH personnel:
>
> Nancy Stade
> Marjorie Shulman
> Elizabeth Sands
> Pirambir "Paul" Gadiock
>
> This request is based on a comparison of the Form which expired May 30, 2012 and the subsequent Form which became effective July, 2012. A copy of the current Form FDA 3429 is made a part of this request and appears on the next page.
>
> Thank you for your assistance in this matter.
>
> Sincerely,
>
> /Signed/

I included the names of four FDA employees in my request because I felt that each of them was likely to have been involved in one or more steps of the process. Clearly, the end result – the revised Form 3429 posted on the CDRH website - didn't occur magically overnight. Someone had to recognize a need to revise the form. Someone had to design the revision. Someone had to approve the revision. Someone had to compose the request for approval of the change by OMB. Someone had to communicate the change to Elizabeth Sands so she could forward it to PSC. Someone had to receive the revised Form from PSC. Someone had to post the revised Form on the CDRH website. It is highly unlikely that all of these things were handled by one individual, acting alone.

The first indication that somebody was working on my request came on May 31, 2013, when I received a phone call from Michelle Bigesby[3], a clerk in the CDRH FOIA office. She asked whether I still wanted the information. When I told her I was still interested, she told me she was waiting for Paul Gadiock to return her call. She said she would call me again later that day. Months passed with no further word.

In August, 2013, I contacted William Holzerland[4], chief of FOI in CDRH, about the delay in response to request 2012-7617. He assigned Andrea Kirk[5] to the case. I telephoned Ms. Kirk a few days later when I had heard nothing further. Ms. Kirk said she had completed the search for records and forwarded a draft response to her supervisor. Alas, my expectation that meaningful information would soon be forthcoming was overly optimistic.

A few weeks later, I received a letter dated September 13, 2013 signed by Candace Boston[6] with the bad news:

> In response to your information request, we have performed a diligent search of the following record sources:
>
> Image 2000 Plus
>
> Unfortunately, our search did not uncover any documents pertinent to your request.
>
> 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. According to the Regulations Staff, changes to forms, if they occur on the center level, would go through that office and that office would be in possession of the administrative record. The Regulations Staff suggested that changes to this form took place on the FDA departmental level or Health and Human Services, and the regulatory staff of the department would be in possession of the administrative record. This is because a significant change to the form would have required approval of the Office of Management and Budget pursuant to the Administrative Procedure Act.

This was not what I was expecting. Could there be no memo to or from Marjorie Shulman on this matter? After all, she is listed as the contact person for Form 3429. It seemed unlikely that she wouldn't at least be notified of a change. Paul Gadiock and I had discussed the issue at some length (in phone calls initiated by me) in May and June 2012. I brought the issue to Nancy Stade in our phone call in July, 2012.

I had been told by William Wragg (of the PSC staff) that Elizabeth Sands was the FDA person who transmitted the revisions to PSC; in a phone call, she confirmed her role as intermediary, and she identified Marjorie Shulman as the person responsible for the revision, assisted by Paul Gadiock. Was everything done verbally? Was there no paper trail? If not, why not?

The people of the Regulations Staff – presumably Nancy Pirt and/or Paul Gadiock - "suggested that changes to this form took place on the FDA departmental level or Health and Human Services" which does not seem likely to me. In any event, wouldn't they have communicated their decision and actions to Marjorie Shulman?

The letter suggested that I might receive additional information from the Office of the Commissioner. This never happened.

THERE APPEARS TO BE NO PAPER TRAIL.

It seemed incredible that a change in a Form under the control of CDRH could be made with no documentation to explain or support the change. Was there nothing to indicate why the change was made? Nothing to explain what was actually changed? Nothing to identify any official who had initiated or authorized the change? Nothing to support the logistics of the change which obviously involved other offices of FDA and even the PSC in HHS? Frustrated, I considered filing an appeal as suggested in the letter.

I also spoke with Mr. Holzerland and Ms. Kirk who agreed to renew the search. During the phone call with Ms. Kirk, she mentioned that she had uncovered a memo from Paul Gadiock to Marjorie Shulman which was pertinent.

On the advice of Mr. Holzerland, I filed an appeal with the Department of Health and Human Services concerning my request. It was assigned the number PSC/FOIA-14-0044-AA on October 31.

The matter languished for nearly two more months. On December 27, 2013, an email came from Andrea Kirk with five attachments: 1) cover letter signed by Candace Boston, 2) and 3) irrelevant copies of Form FDA 3427, 4) and 5) copies of the before and after versions of Form FDA 3429. This was quite unsatisfactory so I sent Andrea Kirk an email reminding her of the memo from Paul Gadiock she had mentioned in a phone call several weeks before.

On December 30, she sent me two emails provided to her by Marjorie Shulman on October 30. One was Paul Gadiock's email to Shulman dated August 2, 2012 which stated

> Hi Marjie,
>
> Per our discussion last month, CDRH's Classification Questionnaire, FDA Form 3429 is being revised. OMB recently approved the change and I'm hoping you can approve the attached docs (both the same content) so that we can get the updated form posted on the internet and implemented soon. There is also an open citizen petition that can be resolved once this form is posted.
>
> Please let me know if you approve. Thanks!
>
> Paul

I'm sure that the "open citizen petition" he mentions is my FDA-2012-P-0747.

Marjorie Shulman responded on August 8 with the following memo:

> Hi Paul,
>
> I am sorry for the delay. I was off last week and am catching up. I do agree with the forms as revised.
>
> Please let me know if you need anything else.
>
> Thanks.
>
> Marjie

At last, here was something concrete and relevant, clearly contradicting statements in Candace Boston's letter of September 13, 2013.

On August 2, 2012, Paul Gadiock forwarded the revised Form to Marjorie Shulman. Was this a mark-up or the Form after it was redone by PSC? He states that OMB has already approved the changes. Where was the communication to and from OMB? Was the OMB approval done via a phone call or mental telepathy?

These emails simply show that the revised form was reviewed by Marjorie Shulman and found to be acceptable. There was nothing to identify who had initiated or authorized the revisions. There was nothing to indicate who had originated or transmitted the memo to the OMB. It seems impossible to establish all the links in the chain. Were decisions conveyed orally?

Revisions to forms must be approved by OMB because of the Paperwork Reduction Act. From a Federal Register notice published In October, 2012, I obtained the name of a CDRH official. When I telephoned him to ask about the revisions to Form 3429, he read over the phone to me a document which explained and justified the changes to Form 3429. I immediately recognized the importance and relevance of the document and asked if he would send it to me (or would I have to submit an FOI request?). He agreed to send it, and I had it on my computer in short order. Here is the text of the document:

"Reclassification Petitions for Medical Devices"

(OMB Control Number 0910-0138)

Change Request (83-C)

July 24, 2012

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) in order to slightly modify a form associated with OMB control number 0910-0138.

FDA received a citizen petition prompting the agency to re-evaluate the information presented in FDA Form 3429 (FDA-2012-P-0493-0001/CCP). After careful consideration, FDA has determined that unnecessary information has been included in FDA Form 3429 and that the extraneous information has proven confusing to readers. The extraneous information in the last column and in row 4 describes merely one approach of understanding device classifications, albeit not the only approach, and has caused considerable confusion among FDA and stakeholders while providing little to no benefit. The information is being removed simply for clarity and does not bear on the underlying program or on the hour or cost burden associated with the collection of information. For consistency, we made minor conforming changes in the instructions on page 3.

[end of document]

This extraordinary document appears to be FDA's explanation and justification to OMB for the revisions. This document repeatedly hammers on the insignificance of the changes: "non-material/non-substantive", "slightly modify". The supposedly "extraneous" information in the last column and in row 4 was removed.

I STRONGLY DISAGREE WITH THE ASSESSMENT THAT THE REVISION WAS A SLIGHT MODIFICATION.

Row 4 is what I would call a "collector" question. It had been a part of the Form since at least 1997, and I think it was there to highlight the importance of the first three questions. **Unless at least one of the first three questions is answered "Yes", then the answer to number 4 must be "No." If the answer is "No" the device does not satisfy the second part of the definition of Class III and must excluded from Class III.**

More important, the right-hand column of the Form contained all the logic. It contained directions when questions were to be skipped. It also specified the appropriate class for a device according to the answers to the questions.

In my opinion, the form was rendered useless for its intended purpose!

Here is a snapshot of the upper portion of the form. The areas highlighted in orange were removed!

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION **GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE**		FORM APPROVED: OMB NO. 0910-0138 EXPIRATION DATE: June 30, 2015 (See PRA Statement on Page 2)
PANEL MEMBER/PETITIONER		DATE
GENERIC TYPE OF DEVICE	CLASSIFICATION RECOMMENDATION	
1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☐ YES ☐ NO	Go to Item 2.
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☐ YES ☐ NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☐ NO	Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	☐ YES ☐ NO	If "Yes," go to Item 6. If "No," go to Item 5.
5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class II and go to Item 7. If "No," Classify in Class III.

Figure 9.1 First six questions of Form 3429 Effective 6/12 (expiration June 30, 2015)

Based on these observations, I think it is fair to say that the author of the memo to the OMB was attempting to avoid any question or objection from the OMB about the revisions. He/she/they wanted to the OMB to rubber-stamp the request. This is another example of "creative writing" when in fact it is probably more appropriate to call it "spinning" or "cover up" or perhaps "obfuscation."

On January 16, 2014, I received two emails from Sarah Kotler with attachments. These were the following:

GET THESE

PROCESS

Decision to revise form.

Request to PSC to make change

Notification/application to OMB

Update web page

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I have reason to believe that Marjorie Shulman and Paul Gadiock were principally responsible for the revisions to Form 3429. [Statement by Elizabeth Sands]

10/30/13 – Expected Andrea Kirk to telephone me at 10 am. No call. Around 10:07, JDRF fax came in.

Called Ms. Kirk about 10:10 am. She answered; she asked if I had seen her email. She said there was nothing new to report, as her email would explain.

Content of her email:

From: Kirk, Andrea
Sent: Wednesday, October 30, 2013 8:48 AM
To: 'Les Hamilton'
Subject: RE: Your Phone Call

Mr. Hamilton,

I have not received an answer or any additional documentation from Ms. Shulman. Until I do, I have no information or updates to relay on your request. In accordance with our procedures, I searched Image 2000 Plus for records associated with your request at the time I received it. Image 2000 Plus is an internal CDRH database that holds a repository of all approval and clearance records for devices. At that time I also sent out a records request to our regulatory staff here in the center. The regs staff had no records in their custody regarding your request.

Once I hear from Ms. Shulman, I will call and advise you of the existence of any additional records.

Sincerely,

Andrea

I kept her on the phone for quite awhile, trying to get her to understand the significance of my FOIA request. I suggested that Marjorie Shulman and Paul Gadiock may be stonewalling. I explained the Elizabeth Sands had given me their names as the parties involved in revision of Form 3429.

She did not recognize Sands' name so I looked her up in the HHS directory – when I told her Sands is in WO66, Room 4267A, she said that is right down the hall from her! Sands is assigned to Office of the Commissioner.

I told Kirk of my email in October 2012 to Marjorie Shulman. She asked if I still had a copy. When I said yes, she asked me to forward her a copy which I did.

Kirk said she would keep trying to contact Shulman and would get back to me.

Sent email to Bill Holzerland.

Telephoned Holzerland – "I was just reading your email." Talked for quite awhile. He was clearly sympathetic to my issue – and they have tried twice to dredge up the records. Mystery about who actually made the revision to Form 3429.

Strongly suggested that I file a brief appeal on FOI if only to preserve my rights. Had some experience with IG.

I filed a brief appeal via email. DHHS responded by email (which went into my spam folder! Where I discovered it weeks later.

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http://www.politico.com/news/stories/0311/52114.html

Story about William Holzerland when he was at the Department of Homeland Security in 2011.

> William Holzerland, the career employee charged with teaching the political appointees about FOIA, said Mary Ellen Callahan, the chief privacy officer at DHS, was "kicking me under the table, saying move [the presentation] along" because [Amy] Shlossman was "bored and looking at her BlackBerry."

Read more: http://www.politico.com/news/stories/0311/52114.html#ixzz3FhXG2U3V

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FOIA Request 2014-7707

This request, made in September 2014, was all too typical. Leon Snyder telephoned me over a year later to inquire whether I still wanted the information. I said I did, and explained what I was after.

On February 23, 2016, he telephoned to say his supervisor had helpfully supplied him a link to the requested information. We talked briefly: I asked if the link he was sending to me was for the specific meeting I had requested, or if it would lead to data for other meeting as well. He hadn't followed the link.

His follow-up email led to the meeting materials for the meeting, not to anything about the meeting expenses. I replied to his email explaining the disconnect. No response.

TBD 2/26/16 – call Leon Snyder. Left message.

END NOTES FOR CHAPTER 9

[1] FOI request F84-20421, filled on August 21, 1984. The cover memo signed by Dan Beardsley stated "Charges of $10 for 1 hr of search time [and] $41.10 for 411 copies and postage charges will be included in a monthly invoice from the FOI Staff if your request(s) total more than $5.00." The information was evidently photocopied from a set of 5 inch by 8 inch index cards.
[2] See the regulations in 21 CFR Part 20.
[3] 2013 data: GS-8, $57,649.

[4] 2013: GS-15, $136,134. Holzerland was formerly with the Department of Homeland Security where he fought a tough battle with political appointees who worked to subvert President Obama's directive for openness in connection with FOI practices.
[5] 2013: GS-13, $94,969.
[6] 2013: GS-14, $105,201.