Chapter 6

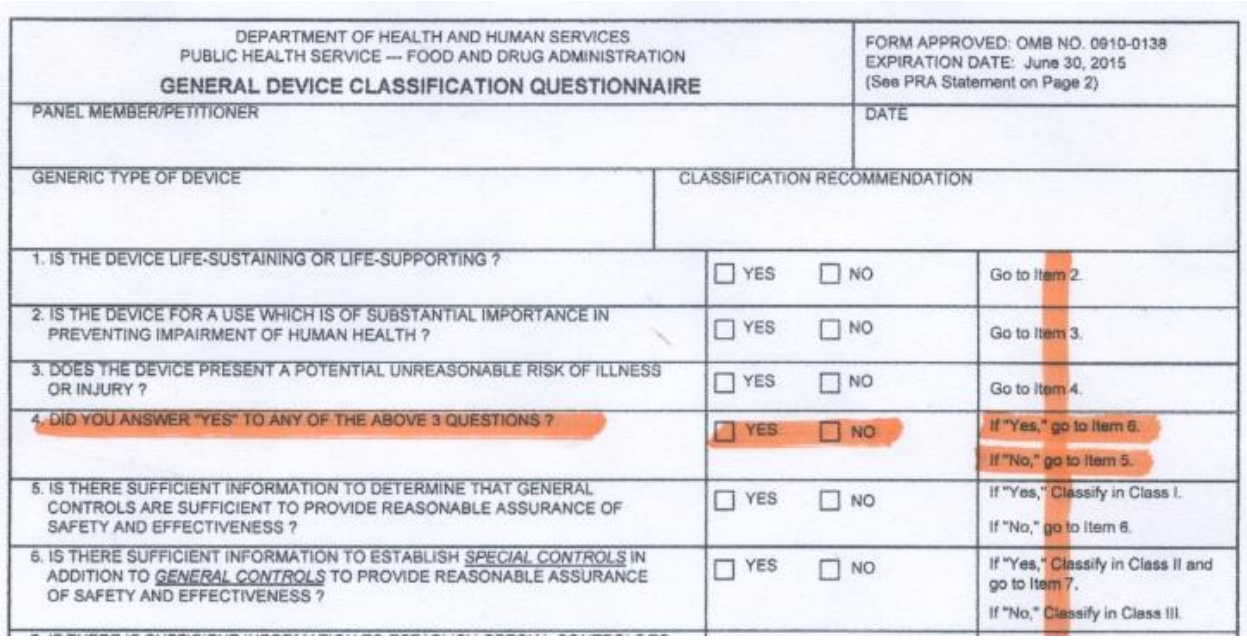
The Lobotomy

July to November 2012

Gentle reader, do not be taken aback at my choice of words for the title of this chapter.

We're talking about a paper document here, not a human being. At the same time, I feel lobotomy is not entirely inappropriate. CDRH cut out and discarded column 3 from Form 3429. It was the intelligent part of the Form, the part that made the Form whole and useful. Without it, the Form lacks logic.

Figure 6.1 shows the top of the form as it was renewed effective "6/12" – June 2012 – with an expiration date of June 30, 2015. (The Figure does not show the effective date; it is at the bottom of the form.) The highlighted area shows what material was removed from the Form for its next incarnation effective "7/12" – July 2012.



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 6.1 Top of Form 3429 renewed effective June 2012. Just one month later, the highlighted portions were removed effective July 2012.

CDRH had given the Form a clean bill of health and renewed it in June for another 37 months. Then, evidently, something changed. Mysteriously, without public notice, the Form was lobotomized; its logic removed and the remains posted on the CDRH website. Did anyone outside the FDA family notice? It's impossible to tell.

I accidentally discovered the lobotomized Form the following October. Something smelled bad to me. In this chapter and the next, you'll learn what steps I took in my efforts to understand what happened and who was responsible.

Consider this chapter as a whodunit as I take you through the process of attempting to unravel the mystery. Pretend you are a detective assigned to the case. Help me figure out who was involved, what happened and when.

The victim: Form 3429, just one in the FDA's extensive inventory. The Form had been considered to be in good health for over a dozen years (at least since 1997) until someone outside the FDA family diagnosed an irregularity in the Form, a logical flaw that needed attention. That someone – I – had tried to discuss the ailment but no one at the FDA was willing to listen. I talked about it at Panel meetings and submitted a Citizen Petition (FDA-2012-P-0493) which was rejected. I submitted a second Citizen Petition (FDA-2012-P-0747) which was finally granted after eight months. A Freedom of Information request for documents about the revision yielded no information for ten months, followed by a letter denying there were any records in CDRH files about the matter. An appeal turned up a couple of minor documents over the next four months.

There were lots of questions and very few answers. Who had decided that the Form needed to be changed? Was it Marjorie Shulman, who is listed as the Form's custodian? Was it Paul Gadiock, who seemed to understand the problem with the Form when we discussed it in our phone conversations in June? Was it Nancy Stade? Somebody else? A committee?

Almost anything I thought would be pure speculation. I was eager to get the facts.

One fact was abundantly clear: the Form had been revised and the new version bore an effective date of July 2012. It was strange that the effective date was earlier than the petition that was most relevant: it wasn't filed until July 12.

Given the vast bureaucracy and separation of responsibilities within the FDA, it seemed likely that at least a few people were probably involved in some capacity. Some individual or group decided the Form should be altered. There should have been some oversight by management. That decision had to be communicated to the office where such changes are implemented. OMB approval for the change had to be sought and received. The updated Form had to be posted to the FDA website. And so on.

* * *

It seemed strange to me that the Form which had been renewed - unchanged - in June 2012 for 37 months was revised only one month later! For the FDA to move so quickly on anything may be a record.

The connection to my Citizen Petition FDA-2012-P-0747 seemed unmistakable, but that Petition wasn't filed until July 12. Had the FDA revised the Form and back-dated it? Further investigation would be needed to find out.

When I discovered in October 2012 that Form 3429 had been revised, apparently with no fanfare and certainly no notice to me, I struggled to find an explanation. I used a multi-pronged attack on the problem. In addition to emails, a Freedom of Information request and a registered letter, I also contacted a few people in government by telephone.

I sent the following email to Marjorie Shulman, custodian of Form 3429, to ask about the change.

From: Les Hamilton
Sent: Saturday, October 20, 2012 3:14 AM
To: Shulman Marjorie
Cc: Stade Nancy ; Buckles David ; Shuren Jeffrey ; Hamburg Margaret ; Pilot Larry ; Camacho Lindsay ; McCarty Mark
Subject: Revised Form 3429

Ms. Shulman,
In June, we had a brief telephone conversation regarding the Classification Questionnaire (Form FDA 3429) which expired on May 30, 2012. You told me the form would be renewed with no changes. I expressed my concern that the form contained a serious logical flaw which led to Class III for certain devices that do not meet the criteria contained in the definition of Class III in the statute. You suggested there may have been a change due to subsequent changes in the law. I subsequently sent you an email explaining my concern; there was no reply from you.

In July, I found that the renewed form had been posted on the CDRH website. As you had stated, there was no change in the form except for the effective and expiration dates.

On October 15, 2012, I happened to download Form 3429 from the CDRH website and was astonished to find that it has been modified significantly: question 4 was removed, and more importantly, **the column with the logic was entirely eliminated from Page 1.** In my opinion, this made the Form virtually useless for its intended purpose. An inquiry to the telephone number listed on the Form[1] elicited the information that the changes were requested sometime in August.

I have a few questions which I hope you will be able and willing to answer.

1) Why were the changes made?

2) When were the changes made?
3) When was the revised form posted on the CDRH website?
4) Who authorized the changes?
5) Was any notice given to the public, e.g., in the CDRH daily updates or by press release?

I look forward to hearing from you.

Leroy Leslie Hamilton, Ph.D.

* * *

You can see this email was sent in the middle of the night when I sometimes mull over current issues. I also cc-ed several people[2] to no avail. Despite this wide distribution, there was no response from Ms. Shulman or anyone else on the cc: list.

Impromptu Investigation – October 2012

The letters PSC and a telephone number are printed at the bottom of Form 3429. I telephoned, and learned that PSC is the Program Support Center, a component of the Department of Health and Human Services. When I inquired about the recent update of Form 3429, I was referred to Mr. William Wragg. When he took my phone call, he was very helpful. He told me the request to revise the Form had been received in late August and had been completed in early September. He suggested I call Elizabeth Sands[3] in the FDA because the request to revise Form 3429 had come from her.

The HHS personnel directory provided the phone number for Ms. Sands and I telephoned her on November 5, 2012. She too was helpful when I inquired about Form 3429. Initially, she told me she didn't recall it because she deals with so many matters. She checked a database[4] she uses and told me that Marjorie Shulman was responsible for the revisions, assisted by Paul Gadiock.

When I asked for the name of Marjorie Shulman's supervisor; she said that according to inside.fda.gov, his name is Robert Gatling[5].

* * *

Gatling returned my call the same day. He said he is not really Majorie Shulman's supervisor due to a recent reorganization. He told me he did not sign off on the changes to the CQ and wasn't familiar with the details. His opinion is that CDRH does not need to publish for comment changes to the CQ.

Gatling said that my questions about the Form are more appropriate for the Office of General Counsel. He said my concerns are best handled by the Ombudsman. I suppose this was a

typical bureaucratic response. The email I sent to the Office of General Counsel – addressed to the individual listed for Devices - was not answered. Another dead-end.

* * *

FOI Request 2012-7617

On October 17, 2012 I submitted an FOI request[6] to FDA via Fax asking for internal memoranda since May 1, 2012, pertaining to the revision of Form 3429 originated by, or sent to, four FDA employees identified by name: Nancy Stade, Paul Gadiock, Marjorie Shulman and Elizabeth Sands.

This triggered a series of events that would drag on for another fourteen months. I will pick up that thread of the story in Chapter 9.

* * *

Notice to OMB

My efforts to gather information by other means proved to be more fruitful than the FOI route.

A Federal Register notice that FDA was sending a notice about Form 3429 to the Office of Management and Budget listed Daniel Gittleson as the contact person. I telephoned Mr. Gittleson to inquire about the revision to Form 3429. He volunteered that he had a relevant document, which he read to me over the phone. I asked if he would send it to me, or whether it would be necessary to submit an FOI request to obtain a copy. Mr. Gittleson surprised me by sending it immediately as an email attachment.

The document came as an attachment to the email that arrived within minutes. The document's information page stated the document was created on 7/23/2012 at 3:57 PM by "gittlesond" and last modified by "Gittleson, Daniel" on 7/25/2012 at 2:35 PM. Total editing time was 11 minutes. The document itself contained a wealth of (dis)information.

CDRH memo to Office of Management and Budget Explaining and Justifying the Revisions to Form FDA 3429 Which Became Effective July 2012.

What follows is the text in the document from Mr. Gittleson.

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"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.

* * *

My Comments on Memo to OMB:

The FDA memo trivializes the importance of the changes by using words and phrases such as "nonmaterial/non-substantive"; "slightly modify"; "unnecessary information"; "extraneous information has proven confusing to readers."

Although the question in row 4 may seem to be redundant, I think it served an important role as what I would call a "collector question." As I interpret the definition of Class III, at least one of the first three items in the second part of the definition must be answered "Yes" for the device to even be considered for Class III.

If the answer to question 4 is "No" then the device should be precluded from Class III!

Most importantly, removal of column 3 rendered the Form useless for its intended purpose which is described in the regulation[7] defining "Classification Questionnaire." It appears that the author of this document is purposely trying to conceal the existence of the logical flaw in the Form and to avoid acknowledging that there may have been consequences of that mistake.

The memo cites a Citizen Petition (Docket Number FDA-2012-P-0493) as the reason the agency re-evaluated the form. **This was my petition requesting FDA to reclassify cranial**

electrotherapy stimulators from Class III to Class II. This petition had been denied on the basis that it should have been filed instead as a petition to reclassify. It is interesting that this petition is cited as the reason CDRH revised Form 3429; I'm confident that the telephone conversations I had with Paul Gadiock had an impact too.

From the document I received from Mr. Gittleson, it would appear that he was the author of the notice to OMB. However, I think he was merely a link in the chain. It seems illogical that he would be in a position to originate the change. He may have created the document based on guidance provided to him orally or in a memo. When I spoke in October 2014 with Mr. Gittleson about the fact that his name appears in the metadata for the Word document which he sent to me, he did not offer any explanation.

* * *

Registered Letter to Nancy Stade

On November 23, 2012, I mailed a six-page Registered letter[8] via the US Postal Service to Nancy Stade, CDRH Deputy Director for Policy. The letter stated my concerns about the revised CQ and the memo to OMB justifying the revisions. Although I paid for a return postcard[9], none was received. In addition, no acknowledgement or response was ever received.

* * *

On July 23, 2012, I had a telephone conference call with Nancy Stade to discuss petition 0747. Paul Gadiock and Jean Olson listened in on the call. I think Ms. Stade may have known at that time of plans to revise Form 3429 but made no mention of that fact. The memo to OMB was created the very next day.

The revisions became effective July 2012 even though, according to Mr. Wragg of the PSC, he did not send the revised Form back to the FDA until September. Either Mr. Wragg's recollection was faulty or FDA essentially turned back the clock!

How Many Devices May Have Been Misclassified?

In my Citizen Petition 0747, I suggested that some devices in Class III had been placed in Class III because of the flaw in Form 3429. I reasoned that if the Panel was led to Class III by the CQ, they would have recommended Class III. I did so based upon my experience with the Radiological Devices Classification Panel in 1976. At that time, the Classification Panels relied heavily on the Classification Questionnaire employed then in use.

In the years immediately following the enactment of the Medical Device Amendments of 1976, the recommendations of the 19 device classification panels were considered by the FDA as the agency proceeded to formalize the regulations. This process culminated in the creation of the many device regulations in 21 CFR Parts 862 to 894.

When Petition 0493 was denied, I submitted another Citizen Petition (Docket Number FDA-2012-P-0747 filed July 10, 2012), which requested the Commissioner to initiate an impartial investigation into whether Form 3429 was in compliance with the definition of Class III in the law. Petition 0747 was finally granted by letter dated March 4, 2013. CDRH acknowledged that Form FDA 3429 needed to be revised and that it was revised. The March 4, 2013 letter neglects to mention that the effective date of the revised Form (July 2012) actually predates the filing of my Petition 0493 on July 10, 2012!

Why did it take so long for the FDA to formally grant my petition, given that the agency had instituted the revisions to Form 3429 - designed to nullify my argument that the Form was flawed - eight months earlier?

Is it reasonable to expect government employees to respond to inquiries from the public or is a total silence the normal response?

Chapter 7 recounts my experience with FOI request 2012-7617.

END NOTES FOR CHAPTER 6

[1] "PSC Publishing Services (301) 443-6740" appears at the bottom right corner of page 1 of Form 3429.
[2] Jeffrey Shuren, (CDRH Director), Margaret Hamburg (Secretary of Health and Human Services), David Buckles (CDRH Ombudsman), Larry Pilot (former FDA lawyer now in private practice), Mark McCarty (reporter), and Lindsay Camacho (in the Rockville office of Congressman Chris Van Hollen). It is probably a waste of resources and possibly counter-productive to share information in this way. From my experience, nothing appears to be accomplished by sending copies willy-nilly.
[3] Management Analyst (GS-13) in the Office of the FDA Commissioner. The size of the bureaucracy is enormous: there are about 1675 people (including over 400 contractors) assigned to the Office of the Commissioner in Silver Spring, Maryland.
[4] FDA has databases for internal use only as well as several databases which the public may access.
[5] Gatling (GS-15 in 2002) was employed in the Bureau of Medical Devices when I worked there in the 1970s. His retirement must have been imminent because his name does not appear in the salary database for 2013.
[6] FOI request 2012-7617.
[7] 21 CFR 860(f)
[8] See Appendix B for my letter to Nancy Stade.
[9] The postcard, attached to the back of the letter, is transferred from the Postal Service to the agency's mail unit. In my experience, these postcards are seldom executed and returned. A clerk at my post office said I can get a refund when the card doesn't come back. In September 2015, I submitted a Citizen Petition (Docket Number FDA-2015-P-3364) requesting the Commissioner to direct CDRH employees to complete and mail return receipt postcards.