Chapter 5

Two Citizen Petitions

May – October 2012

It had become clear that following Dr. Buckles' advice to present my concerns at Panel meetings probably wouldn't be effective, even if I polished my presentations to perfection. Moreover, as I perused the agendas for other Panel meetings, I realized that my topic would be appropriate for only the occasional meeting. It was only by a fortuitous -- and unanticipated -- coincidence that the Radiological Devices Panel had considered a petition to reclassify breast transilluminators from Class III to Class I. Most meetings dealt with other issues, such as Premarket Approval applications.

So I turned to the second option suggested by Dr. Buckles: submit a citizen petition. By this time, I was even more confident that Cranial Electrotherapy Stimulators did not belong in Class III, so this became my immediate objective. I really didn't have a vested interest in CES devices; I was not and never had been a stockholder in any of the companies, nor did I know anyone who used CES.

As reported in Chapter 1, the Orthopaedic and Rehabilitation Panel had voted overwhelmingly to keep CES devices in Class III, despite the petitions for reclassification submitted by the three manufacturers of CES.

The manufacturers' petitions had argued that there was sufficient information to establish special controls which would provide reasonable assurance that the devices would be safe and effective. Evidently, none of the manufacturers had examined the question of whether their devices actually satisfy the definition of Class III.

I knew that FDA has regulations[1] covering petitions to reclassify a device, so I considered using that approach. These regulations require the petitioner to include a completed Form 3429 Classification Questionnaire as part of their petition. But since I was convinced that Form 3429 had a logical flaw that would erroneously lead to Class III, I decided to instead follow the rules[2] for a Citizen Petition.

First Citizen Petition

In my petition, I explained that the petition was being submitted as a Citizen Petition instead of a petition to reclassify because of the (allegedly) faulty Form 3429.

In the petition, I argued that CES devices simply did not qualify for Class III because they do not satisfy the second part of the definition of Class III. What was needed was a persuasive argument that CES devices are NOT life-supporting or life-sustaining; they are NOT of substantial importance in preventing impairment of human health, and they do NOT present an unreasonable risk of illness or injury.

Let's follow the process for my Citizen Petition to reclassify CES devices. I submitted the Petition in a letter in May 2012 which I mailed to FDA's Documents Management Branch. FDA gave the Petition a cursory review and assigned a Docket Number: **FDA-2012-P-0493**. FDA prepared and mailed to me an acknowledgement letter informing me the date my Petition had been filed and it would be identified as FDA-2012-P-0493-0001. The petition was posted to regulations.gov along with the acknowledgement letter as FDA-2012-P-0493-0002.

A few weeks later, I received a letter signed by Nancy Stade[3], the CDRH Deputy Director for Policy, informing me that my petition was not accepted on the grounds that it should have been submitted as a petition to reclassify. Obviously, CDRH did not accept my reason for filing this as a Citizen Petition instead of a petition to reclassify, even though that made perfect sense to me.

[Ms. Stade's letter was not introduced into regulations.gov. As this is written over three years later, my petition and the acknowledgement letter are the only two items to appear under Docket FDA-2012-P-0493.]

The letter from Ms. Stade stated that I could contact Paul Gadiock[4] if I had any questions. I telephoned Mr. Gadiock and we had an extensive discussion. It seemed to me that he had a good understanding of my concern for the logical "flaw" in Form 3429 and that he agreed with me that there was a problem with the Form.

I subsequently wrote a certified letter to Ms. Stade pleading my case; she responded in a second letter reaffirming the position that my Citizen Petition was not acceptable since it was really a petition to reclassify. Chapter 15 explains what happened after CDRH decided that the CES devices could be in Class II.

Second Citizen Petition

My next step was to submit another Citizen Petition which requested the FDA Commissioner to initiate an impartial investigation into whether Form 3429 was in conformity with the definition of Class III in the statute. The petition included several additional requests in the event that the investigation determined that there was a problem with the Form.

This petition was filed on **July 12, 2012** and assigned docket number FDA-2012-P-0747. The petition was posted at www.regulations.gov as FDA-2012-P-0747-0001 and the acknowledgement letter as FDA-2012-P-0747-0002.

At the time, I was pretty well convinced that the (alleged) flaw in the CQ may have been responsible for misclassification of an unknown number of devices into Class III. After all, it was largely on the basis of the CQ in the years immediately following the enactment of the Medical Device Amendments of 1976 that the various Panels arrived at their recommendations to FDA for the devices each Panel considered. I imagined the same would have been true over the succeeding years.

I went so far as to peruse the current list of devices in Class III – about 430 in all – to see which might be excluded on the basis of the "risk" criteria. My tentative list was fewer than 20 devices. As we'll see in Chapter 7, that list would be requested by the Director of CDRH, Jeffrey Shuren. But I am getting ahead of the story.

Convinced by this time that CES devices[5] and the shortwave diathermy devices[6] including Diapulse™ definitely did not belong in Class III and that others probably did not as well, I pushed for a meeting with Nancy Stade, J.D., the CDRH Deputy Director for Policy. Her email informed me that we could have a telephone "meeting" on Monday, July 23, 2012, and that Paul Gadiock and Jean Olson would also be on the line.

A few days prior to the meeting, I sent Ms. Stade an email – with copies to Gadiock and Olson – requesting that they review the attachments (my petition 0747 and Form 3429) prior to the phone call and be prepared to advise me of any problems they saw with my petition, either in form or content.

When Ms. Stade telephoned at 2:00 PM on Monday, July 23, 2012, I was relaxed and prepared. It soon became evident that she was not going to commit herself on anything. They were not going to comment about my petition or the issues it raised. Ms. Stade assured me that my petition would be promptly reviewed and that I should expect a response before "too long." I questioned – rhetorically – the phrase "too long." I stated that to a company whose business prospects hang on an FDA decision, a day, a week, a month may be "too long." I seem to recall saying hello to Paul Gadiock and hearing his reply, but aside from that, Ms. Stade and I were the only ones who spoke during the call.

Of course, I didn't know it at the time, but it would be six months before CDRH would send me an interim response explaining why it was taking so long to process my petition, and another three months before I would receive the letter granting my petition – sort of. These events are covered in Chapter 8.

I had no reason to suspect that CDRH was already moving with uncharacteristic speed to deal with the logical "flaw" in Form 3429. In light of subsequent events, Ms. Stade, Mr. Gadiock, and Ms. Olson probably knew at the time of our telephone call that the decision had already been made to revise the Form. But they wouldn't (or couldn't) hint at what was going on behind the scenes.

A Shocking Discovery

In **October 2012**, I decided to show my son John a copy of Form 3429 to illustrate the logical error I had discovered. Instead of retrieving a paper copy from my files, I downloaded the form[7] from www.fda.gov. As I began to explain the problem to John, I suddenly realized that the entirety of column 3 was missing from the form! I was astonished, as I had no idea until that moment that the form had already been revised.

With column 3 removed, the Form no longer indicates the appropriate classification for the device; in my opinion the Form was rendered useless for its intended purpose.

The butchering of Form 3429 is the topic of Chapter 6.

END NOTES FOR CHAPTER 5

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[1] 21CFR860.123 prescribes the content and form of a petition to reclassify a medical device.
[2] 21CFR10.30 states who may file a Citizen Petition and what such a petition must contain.
[3] In 2012, Nancy Stade was an ES 00 earning $149,747. An ES employee is Executive, Senior Level.
[4] Parambir "Paul" Gadiock is an attorney. In 2012, he was a GS-12, earning $105,211; in addition he received a $750 bonus. After Nancy Stade moved to a different division of FDA CDRH in 2014, Gadiock was promoted to become the Associate Director for Policy in CDRH.
[5] Cranial Electrotherapy Stimulators; Product Code JXK, covered in 21CFR882.5800.
[6] Shortwave diathermy for other uses; Product Code ILX, covered in 21CFR890.5290(b).
[7] Document identifier: ucm080858.pdf