Chapter 10

The Law Has a Flaw (or is it a loophole?)

2013

In previous chapters, I've mentioned the Classification Questionnaire and the logic diagrams used by CDRH to graphically illustrate the classification process. **Obviously**, the logic diagram and the CQ are intimately related because they are supported by the same foundation: the definitions of the three device classes. In Chapter 3, I explained the logical flaw in the CQ I discovered in February 2012 which improperly led to Class III for some devices which do not satisfy the definition of Class III. In that chapter I promised to explain another problem with the CQ in this chapter.

At the May 21, 2013, meeting of the Orthopaedic and Rehabilitations Devices Panel, Marjorie Shulman gave her slide show which included the slide shown in Figure 10.1

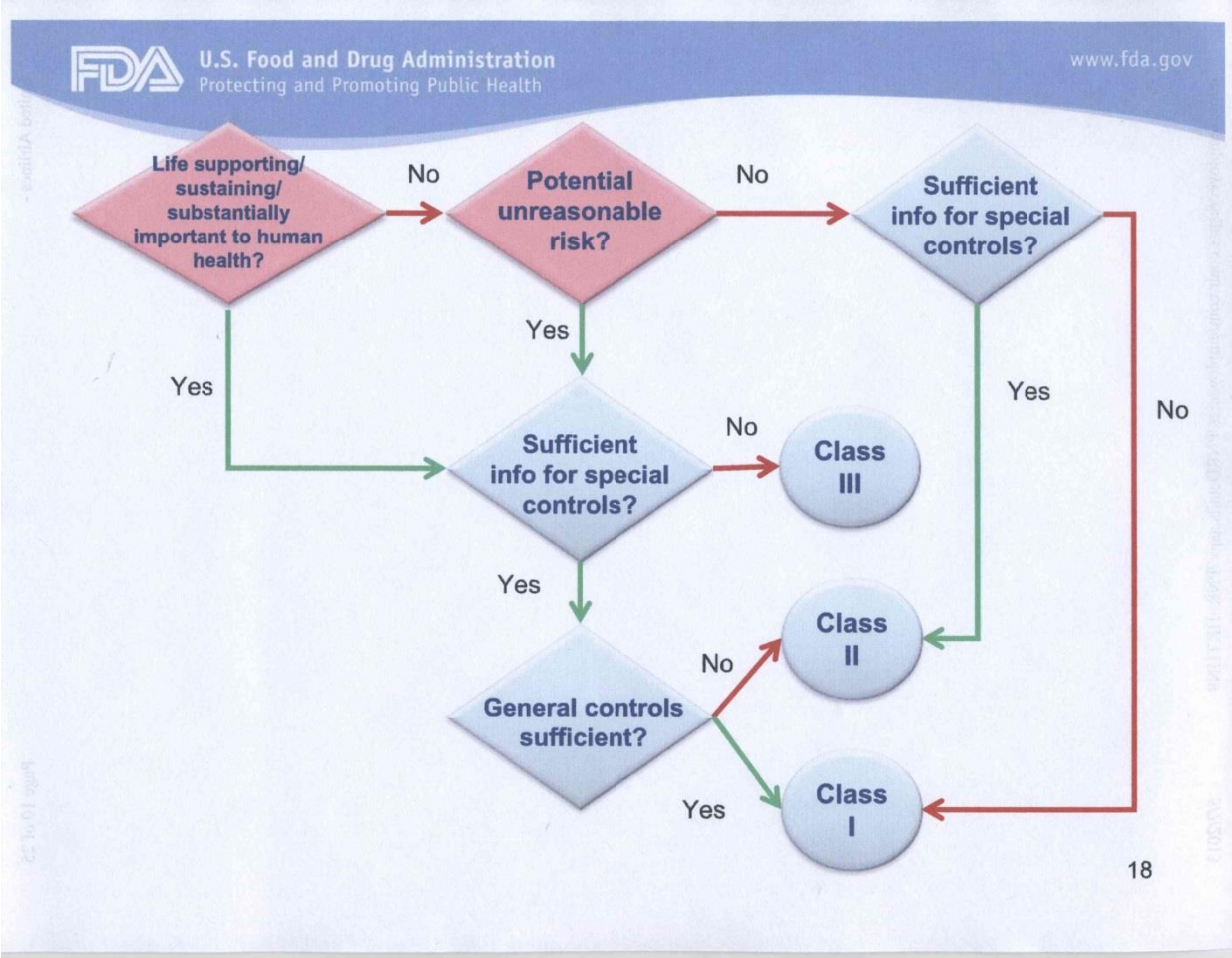

Figure 10.1 Classification Logic Diagram Shown at Panel Meeting on May 21, 2013.

Notice that there are two pathways to Class I. When I first looked at this slide (which was in the handouts available at the meeting), I was puzzled by the red line which goes from the block labelled "Sufficient info for special controls?" to Class I. (If Figure 10.1 appears in color, it accurately shows the slide from which it was copied.)

At the time and for another six months, I was absolutely convinced that the path from the question "General controls sufficient?" was the only valid path to Class I. I sent a rude email to Ms. Shulman pointing out that the red vertical line on the right side of the diagram didn't belong there. She didn't respond to my email. However, she revised the logic diagram (see Figure 10.2) for her next presentation in June but the "error" persisted. I made a nuisance of myself at two Panel meetings in June and another in September, trying to draw attention to this "error." I even complained to Laurie Lenkel, the FDA Ombudsman.

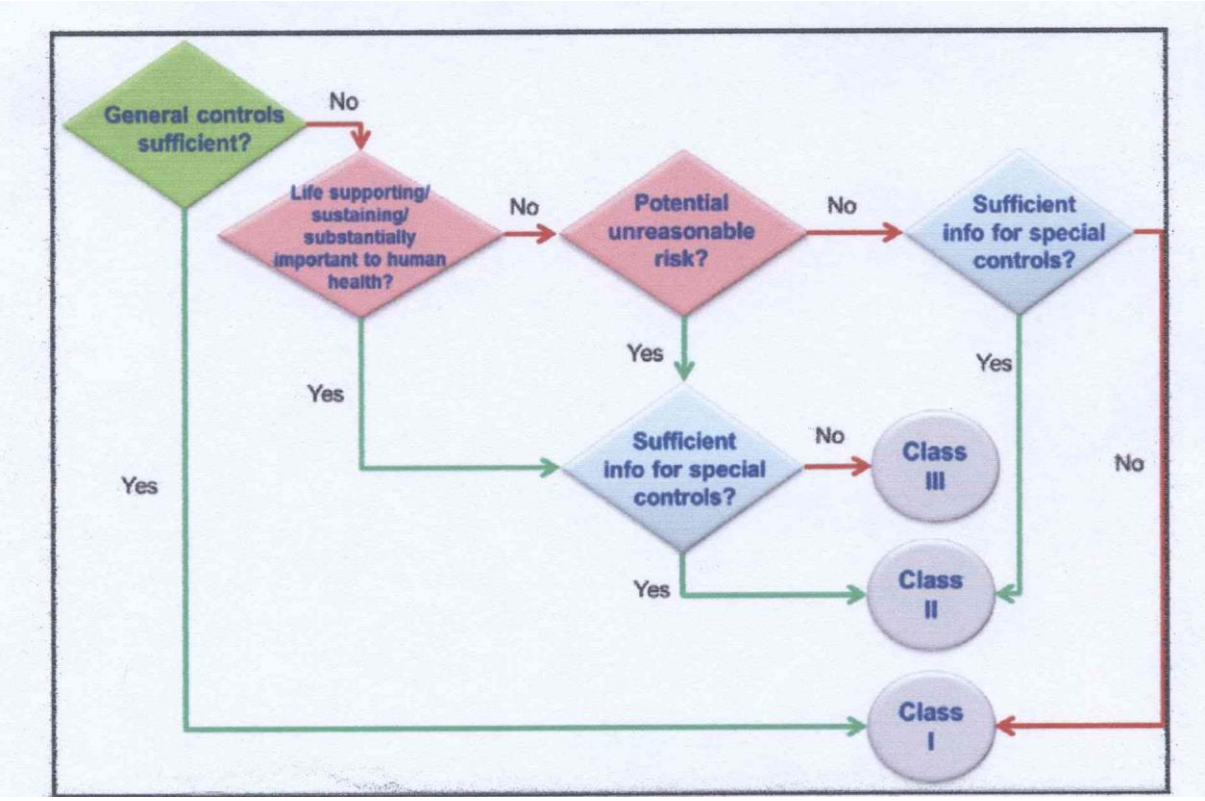

Figure 10.2 – Logic Diagram in June 2013

You can see that the logical blocks have been rearranged but there are still two paths to Class I. I don't know whether the change in the diagram was made because of my email to Ms. Shulman. In any case, the "error" persisted.

Ms. Shulman was scheduled to present to another Panel meeting in December and I was again prepared to call attention to her "mistake." As I read the FDA Executive Summary the day before the meeting, it finally dawned on me that I really needed to examine the definition of Class I in the law.

Full Definition of Class I

The full definition of Class I in the law[1] is as follows:

> (A) Class I. General Controls.-
>
> (i) a device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519 or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
>
> (ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard[2] [changed to special controls in 1990] to provide such insurance, but because it-
>
> (I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
>
> (II) does not present a potential unreasonable risk of illness or injury, is to be regulated by the controls referred to in clause (i).
>
> [End of quote]

We see there are indeed two independent paths to Class I. The first one simply states that if the General Controls provide reasonable assurance that the device is safe and effective, the device is in Class I. The second, more complicated path states that General Controls and Special Controls together cannot provide reasonable assurance of safety and effectiveness of the device BUT none of the conditions in the second clause of the definition of Class III is satisfied, the device is in Class I.

It was only then that I realized the mistake was all mine.

It had taken nearly seven months to do what I should have done immediately. It was December 2013 when I finally came to the realization that my misplaced confidence in my knowledge of the law had probably damaged my credibility, at least with people at CDRH.

I have little patience for ignorance in people in positions of authority who should know better. Further, I deplore arrogance in people who show little respect for others. Now, I realized I was guilty of both ignorance and arrogance in this instance, a deadly combination.

I sent an email to Ms. Shulman to acknowledge and apologize for my mistake and reprehensible behavior. She responded with a very gracious note. I also communicated my apologies to staff at the meetings where I had raised the issue and to others in FDA, including Laurie Lenkel, to whom I had appealed for help. It was a humbling experience and a lesson well-learned.

The good news was that I finally understood the “flaw in the law” well enough to write the rest of this chapter.

The Anomaly in the Definition of Class I

The authors of the MDA76 adopted the three classes recommended by the Cooper committee, as did many of the people who supported the idea that the entire medical device industry needed to be regulated. Faced with the need to create a regulatory framework, the authors of the legislation knew it would be necessary to establish definitions for each of the three classes of devices, with Class I being the lowest or least demanding and Class III being the highest or most stringent. [I wondered why they used Roman numerals for the classes and why Class I wasn't the most demanding. My cynical thought for the second part is that they could later add even more demanding classes, e.g., Class IV, V, etc.] They created the definitions of the three classes with this in mind, incorporating into the definitions the requirements of the three classes embedded into the law. (That is why the full definitions are so wordy.)

Examining the definition of Class I in the law and the logic diagram in Figure 10.2, we see that there are two pathways to Class I. It should also be clear that the two pathways to Class I are mutually exclusive.

I say mutually exclusive because the preferred pathway is when the initial question is answered "Yes". This is obviously the preferred pathway because General Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness. The other pathway explicitly says that General Controls ARE NOT sufficient to provide reasonable assurance of the device's safety and effectiveness, but we get to Class I anyway.

What follows is my speculation of how the drafters of the law arrived at this anomaly in the definitions or a "flaw in the law" the catchy title of this chapter.

They were content with the three class structure. However, they struggled to craft the definitions for the three classes.

Class I was the easiest: these are the devices for which General Controls would be sufficient to provide reasonable assurance that the device is safe and effective.

Class II was also easy because the law initially specified that such devices would require a performance standard. Thus the actual controls to be applied to a Class II device would be General Controls and a standard whatrever it may be. (The change from Class II Standards to Class II Special Controls is discussed in the next chapter.)

With Class III things became a little sticky. First, they had to incorporate specific provisions into the definition. During the years before the bill was finalized, they considered ways to assess the risk of devices. For a time they considered implanted devices as one of the factors which would contribute to risk. In the end, they decided to include three risk factors in the definition. Here is a list of the factors:

- The device is life-supporting or life-sustaining, or
- The device is for a purpose which is of significant importance in preventing impairment of human health, or
- The device presents a potential unreasonable risk of illness or injury.

For a device to qualify for Class III, at least one of these conditions must be satisfied.

In the logic diagrams above, CDRH combined the first two factors into one question.

The other major consideration was whether there was sufficient information for the device to be adequately regulated with Class II controls in addition to the requirements of Class I.

All done? Not quite! They had to deal with every possibility. There was the problem of whether there was enough information to allow the creation of a performance standard. (The added complication of "special controls" wouldn't come up for years.) What if the device were excluded from Class III because none of the risk factors was satisfied AND there was insufficient information to establish a standard (or Special Controls)?

The Anomaly or Flaw

In both Figures 10.1 and 10.2, there are two pathways to class I. The preferred path is when Class I General Controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The second pathway – the red line extending from the bottom to the top of the diagram - was evidently included to solve a nasty problem. If the device does not satisfy any of the three risk conditions mentioned above the device is not eligible for Class III. If, in addition, there is insufficient information to establish special controls, it would seem logical to have a class higher than II but less than III. Class II+? The authors instead provided a safety net back to Class I. This is the anomaly. Clearly, the answers to the individual questions determine which class a particular device will be assigned. (And there will be cases in which reasonable people will disagree about those answers.)

Petitions to Reclassify

At times, the FDA moves with glacial speed while the rest of us wonder why it is taking so long to reach a decision. There were some 25 or 30 devices which had been put into Class III decades ago, but the FDA had not set dates by which Premarket Approval (PMA) Applications would be required. These were referred to by the FDA as "Class III 510(k) devices." In other words, the manufacturers were required to satisfy Class I General Controls without the burden of any Special Controls or of submitting a PMA (or of completing a Product Development Protocol[3] until the final order classifying the device into Class III and setting a date by which a PMA would be required). If an existing manufacturer wanted to introduce a new model, or if a new manufacturer wanted to enter the market, all that was required was a 510(k) notification establishing that their new device was substantially equivalent to a device already on the market. Essentially, these Class III devices were regulated as if they were Class I devices, except that the sword of Damocles hung over them: eventually, they would have to submit a PMA (or hope the FDA could be persuaded to downclassify the device).

As FDA published notices of intent to set a date by which PMAs would be required, they also offered manufacturers the option of submitting petitions to reclassify their devices. Many manufacturers did submit petitions to reclassify.

Although I am not a manufacturer, I also submitted petitions to reclassify two devices from Class III to Class II. My first petition was for the cranial electrotherapy devices discussed in Chapters 1 and 5. The second was for ILX devices in Part 3.) My petitions argued that the devices did not qualify for Class III because they did not meet the definition of Class III in the law and that the FDA had erred by putting them in Class III. Most

petitions to reclassify argued that the Class III devices should be in Class II, mine included. There was one exception of which I am aware: the British company petitioned that their Class III device called the "Breastlight" discussed in Chapter 4 should be in Class I on the basis of very limited claims made by the company. Their petition was denied. (CDRH eventually published a final regulation with the device in Class III.)

I see now that some of the petitioners to reclassify from Class III to Class II could have requested Class I. However, It's highly unlikely that such a request would have gained traction with the FDA.

END NOTES FOR CHAPTER 10

[1] Public Law 94-295.
[2] Performance standard was changed to special controls by the Safe Medical Devices Act of 1990.
[3] The Product Development Protocol or PDP is an alternative to a PreMarket Approval Application. PDP is not discussed in this book.