Specimen Collection

Whither the Class III Lancet?

Anna Longwell MS, JD
9 October, 2015

Longwell & Associates
Attorneys Serving the Healthcare Industry

Outline

Reclassification

Concerns with blood sample collection using lancets

FDA response

The panel meeting of June 2013

Next Steps

Longwell & Associates
Attorneys Serving the Healthcare Industry

How to Reclassify

- Then: by regulation
  - Can start with a petition, or FDA can on their own
  - "May" obtain a panel recommendation
  - Publish proposed, Elicit comments
  - Final regulation
  - de novo different, but still requires regulation
- Now: by order
  - Three things required: panel meeting, proposed order published, final order published
  - Law: specific requirements for downclassifying, not so for upclassifying
  - Difference? Faster, more latitude for FDA-speed downclassifying
- Few products down classified since 2012, only 1 up classified

Longwell & Associates
Attorneys Serving the Healthcare Industry

Reclassification to date

- Eight since the Law was enacted
- Seven are Down Classifications, One Up Classification
- A large range between Panel date and Intent to Order
  - 16 years, to -3 months (Intent to Order published first)
- A shorter range between Intent to Order and Order
  - 13 to 4 months
- The next few slides are FYI: You can find all the data at
- http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378724.htm

Longwell & Associates
Attorneys Serving the Healthcare Industry

Classified By Order

- Temporal mandibular condyle plate
  - Panel: Feb.12 1997
  - Intent to Order: Feb 7 2013
  - Order: Dec. 30, 20213
  - Down classified
- Intraaortic baloon and control system
  - Panel:Dec. 5 2012
  - Intent to Order: June 19,2013
  - Order: May 21 2013
  - Order: Dec 30 20213
  - Some indications down classified

Longwell & Associates
Attorneys Serving the Healthcare Industry

Classified by Order

- External counter pulsating device
  - Panel: Dec. 5, 2012
  - Intent to Order: May 21, 2013
  - Order: Dec. 30, 2013
  - Down classified (some indications)
- Transilluminator
  - Panel: July 27, 2013
  - Intent to Order: April 4, 2013
  - Order: 1/17/2014
  - Down classified (some indications)

Longwell & Associates
Attorneys Serving the Healthcare Industry

Classified by Order

- Stair climbing wheelchair
  - Panel: Dec 12, 2013
  - Intent to Order: June 12 2013
  - Order: April 14, 2014
  - Down classified
- **Sunlamp, UV lamps**
  - **Panel: March 25 2010**
  - **Intent to Order: May 9, 2013**
  - **Order: Sept 2, 2014**
  - **Up Classified!**

Longwell & Associates
Attorneys Serving the Healthcare Industry

Classified by Order

- Endosseous dental implant
  - Panel: July 18, 2013
  - Intent to Order: Jan 14, 2013
  - Order: June 18, 2014
  - Down classified(some indications formerly III)
- Implanted blood access
  - Panel: June 27, 2013
  - Intent to Order: June 28, 2013
  - Order: July 25, 2014
  - Down classified

Longwell & Associates
Attorneys Serving the Healthcare Industry

Classified by Order

- Non-roller blood pumps
  - Panel: Dec. 6, 2012
  - Intent to Order: Jan 7, 2014
  - Order: June 8, 2015
  - Down classified (some indications)
- Lancets for Blood Drawing
  - Panel: June 26, 2013
  - Intent to Order: ?
  - Order: ?

Longwell & Associates
Attorneys Serving the Healthcare Industry

Lancets-What is the Safety Issue?

- Transmission of infection
  - Contamination of lancet
  - Subsequent infection by transmission to other handlers, users
- A number of tests require simple, rapid POC testing
  - Emergency room-Troponin I
    - Overburdened staff may not observe all safety protocols
  - Nursing home- blood glucose monitoring
    - Same issue, plus often not enough training of staff
    - Blood glucose has become the archetype of problems with with blood transmission involving lancets

.

Longwell & Associates
Attorneys Serving the Healthcare Industry

An Example: Glucose Monitoring

Over the decade glucose monitoring has increased as diagnosed diabetes has increased.

Statistics:

- Rise in both prevalence and incidence from 1900 till 2008
- Rise in incidence of over 65 up to 20% (nursing homes, extended care facilities, etc.)

Patient blog: Use and re-use of lancet blades

- "I change once a week", "I still have most of the original packet that came with my monitor"

Longwell & Associates
Attorneys Serving the Healthcare Industry

Concern is transmission of Hep B

Major sources of infection in nursing homes,

- Urinary infection (catherization)
- Surgical wound infection
- Infection associated with long-term infusion
- NOT infection associated with blood draw or fingerstick

Outbreaks of Hep B have been reported here and in Europe, since 1990 .

- Many Associated with blood collection via lancet
- Source traced to lancet use by multiple individuals
- Studies in nursing homes: some show high probability of fingerstick as transmission agent

Longwell & Associates
Attorneys Serving the Healthcare Industry

Background: Expressions of Concern

- CDC practice reminder 2010:
  - Fingerstick devices should never be used on more than one person
  - Glucose monitors should be disinfected if used on more than one person
- FDA initiated a series of communications
  - Initial communication Aug 2010, updated Nov
  - Letters to manufacturers, 1 GSDB, 1 Chem/Toxx. OIR
  - Labeling guidance 2010
  - Public meeting about meter disinfection 2011

Longwell & Associates
Attorneys Serving the Healthcare Industry

The 2013 General and Plastic Surgery Panel

- FDA announces it will call panel on May 2013

to discuss whether or not it should re-classify lancets for blood collection

From Class I to Class II:

Single user, single use blade locked unusable after use

Single user, single use, blade not locked after use

Single user, multiple uses, (some provision for replacement of blades by user)

From Class I to Class III

Multiple users, multiple use

Longwell & Associates
Attorneys Serving the Healthcare Industry

FDA rationale

- Since 1990, studies by State and Federal heath authorities have indicated that blood collection lancet play a part in the transmission of blood borne infection when they are used improperly
- Other hazards
  - Sharp object injuries (mostly with non retractable blade models)
  - Transmission of local skin borne microorganisms into the puncture lesion left by blade
  - Adverse skin reaction: inflammation, irritation or rashes

Longwell & Associates
Attorneys Serving the Healthcare Industry

FDA rationale, continued

- "FDA is recommending reclassifying (from Class I to Class III-(Al note) multiple use *capable* (italics mine) blood lancets with a single use blade inserted into a solid reusable base which is *used* (AL note, not labeled-used) for multiple patients to puncture the skin to obtain a drop of blood for diagnostic purposes"

Are there any multi use, multi patient lancets available in US?

- There were in 2013, according to FDA "at least one"
- Presently, no (I can't find) lancets with that labelled indication on the market
- Some multi-use lancets without a warning about multi patient use, or with warning hard to find

Questions from the panel

- Why not ban-we all agree multi use lancets should not be used on more than one patient.
  - FDA staff believes they may not have enough evidence to ban-its not done very often
  - FDA staff believes that PMA approval very difficult since current expectations for a multi patient product are
    - Lancet must provide means of complete disinfection after each use (external plus internal)
    - Means of disinfection must be easy to use
    - Means of disinfection must be effective on blood borne virus such as HepB

Longwell & Associates
Attorneys Serving the Healthcare Industry

Questions from the panel, cont.

- We have a lot of evidence that health care workers, in nursing homes, hospitals and extended care facilities, are ignoring present labeling. Why do you think that more labeling will help solve the problem?
  - Not Just labeling, but the fact that we will be able to demand labeling for Class II and Class III, what to say and where to put it.
  - For better consiousness

Longwell & Associates
Attorneys Serving the Healthcare Industry

Questions from the FDA

- FDA asked if the panel thought special controls are necessary and complete for the single patient products, single use with disabling after use, single use without disabling, single patient with provision for multi use.
  - Labeling
  - Biocompatibility
  - Sterilization
  - Verification of design, performance testing
  - And, for multi use, disinfection procedures
- Panel answer: OK

Questions from the FDA

- FDA asked if they thought that special controls would suffice to make the multi patient, multi use lancets safe for use
  - Panel response-a definite no. Panel does not think anything will make these products safe

What does FDA need to do next?

- Panel meeting? Done, as we have seen
  - At the panel meeting, FDA stated they were already working on the Order
- Publish intent to publish an Order, not yet
- Publish the Order, need to publish intent first
- Inquiries to FDA
  - "we are working on it"
  - "we can't say when we will publish"
  - Yes, the Class III lancet is still included

Longwell & Associates
Attorneys Serving the Healthcare Industry

What will the effect likely be?

- A lot of 510(k)'s for single patient lancets
  - Labeling will be the big item,
  - Disinfection of multi use will be an ongoing issue
    - Given the prevalence of multi use for at-home, respect for patient's opinions/desire may require different special controls for at-home, vs. health care facility.
  - Most lancet makers have biocompatibility, sterilization and performance testing already, as part of their idea of general controls QSR (admitted by FDA at panel)
- No PMAs for multi patient lancets:

Longwell & Associates
Attorneys Serving the Healthcare Industry

Questions?

Longwell & Associates
Attorneys Serving the Healthcare Industry