New England Discussion Group

Current Compliance and Quality Issues

The
Case Study
U.S. v. Utah Medical Products, Inc.

Larry R. Pilot, Esq.
Partner
McKenna Long & Aldridge LLP
202-496-7561
lpilot@mckennalong.com

QSR Compliance

Introduction

– FFDCA/MDA – 1976

- GMP by Regulation, Force and Effect of Law

21 C.F.R. Part 820

– 1978 Good Manufacturing Practice (GMP) Regulation
– 1996 Quality System Regulation (QSR)

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Compliance Responsibility

- Finished Device Manufacturer
  - Implement Documented Procedures
  - Periodic Audits
- Food and Drug Administration
  - Periodic Inspections

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

FDA Inspection Process

- Investigator Appearance
  - Reasonable, time, limits, and manner
  - Investigations Operation Manual (IOM)
- Company Policy
  - Management Control
    - Document Access
    - Spokesperson/Interview Limits

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
Attorneys at Law
STAY AHEAD OF THE CURVE

QSR Compliance

Inspection Completion/Follow-up

- No FORM FDA 483
  - Good for FDA and Company
- FORM FDA 483 Issued
  - Management Conference
  - Written Reply
  - Request Establishment Inspection Report (EIR)
    - Granted
    - Denied
  - Warning Letter

McKenna Long & Aldridge LLP
Attorneys at Law
STAY AHEAD OF THE CURVE

QSR Compliance

Warning Letter Appeal Process

- Written Response
  - Acceptance
  - Rejection
- District Office Conference
- Center Review
  - Written Explanation/Conference
- Dispute Resolution

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Enforcement Review Process

- District Office Recommendation
- Center Review and Decision
- Office of Chief Counsel
- Department of Justice Civil Division
  - Sign or Sue Letter

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Sign or Sue Letter Litigation

- Options
  - Settle
  - DOJ Complaint

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Settlement Process

- – Discussions
- – Agreement
- – Draft Consent Decree
  - FDA Model Draft
  - Negotiation of Conditions

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Settlement Process *cont'd.*

- – Consent Decree (CD) Filed in Federal Court
  - FDA Confirms Compliance
  - Company Resumes Under CD Conditions
  - Remains Subject to CD Conditions

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Litigation
- DOJ Files Complaint in Federal Court
- Company/Individual Defendants Answer
- Discovery - Civil Rules of Civil Procedure
  - Interrogatories
  - Admissions
  - Document Production
  - Depositions
    - Fact/Expert Witnesses

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Litigation *cont'd.*
- Pre Trial Activities
  - Counterclaims
  - Motions
  - Settlement
  - Pre Trial Order, etc.

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Litigation *cont'd.*

- Trial
  - DOJ/FDA
    - Burden of Proof
    - Witness/Document Presentation/Cross Examination
  - Defendant
    - Witness/Document Presentation/Cross Examination

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

QSR Compliance

Litigation *cont'd.*

- Court Opinion
  - Appeal Options, Either Party
    - Appeal – Court of Appeals
    - Appeal – Supreme Court

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
Attorneys at Law
STAY AHEAD OF THE CURVE

The Case

Utah Medical History

- 1978 – Formation, Midvale, Utah
- 1995 – FDA Inspection, Warning Letter
- 1998 – FDA Confirms Corrections/QSR Compliance – No FORM FDA 483
- 2001, September – FDA Inspection, Warning Letter Recidivist
- 2001, December – Meeting Denver D.O. Barrell/Manresa

McKenna Long & Aldridge LLP
Attorneys at Law
STAY AHEAD OF THE CURVE

The Case

Utah Medical History *cont'd.*

- 2002, 2003 & 2004 – FDA Inspections and UTAH Medical Responses

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Federal District Court Litigation/DOJ

- June 2003 UTAH CFG Denial Complaint
- October 2003 DOJ Sign or Sue Letter
- January 2004 UTAH CFG Denial Complaint
- August 9, 2004 DOJ Files Permanent Injunction Complaint
  UTAH Answers

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

The Discovery Process

- Utah Medical
  - Interrogatories/Admissions
  - Document Production
  - Depositions of Witnesses
    - FRCP 30(b)(6) Barrell, Trautman, Spears, Lenkel
    - Fact
    - Expert

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

The Discovery Process

- DOJ/FDA
  - Same as Defendant Utah Medical Except 30(b)(6)

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Utah Medical Discovery Benefits

- Truth
- Comprehensive Analysis of FDA Performance
  - Administrative Failures
  - Careless Review Process District to Counsel
  - False/Misleading FDA Statements
  - Custer Mentality

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Utah Medical Discovery Benefits *cont'd.*

- Abuse of Process Claim
- Trial Focus

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

The Trial – 9/26/05 – 10/04/05

- DOJ/FDA Presentation
  - 3 Expert Witnesses – Trautman, Thibeault, and Olivier
- Utah Medical Presentation
  - 3 Fact Witnesses – Cornwell, Shirley, and Clawson
  - 2 Expert Witnesses – McDonnell and Driscoll

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

The Case

Trial Issues

The specific questions before the court, as set forth in the Pretrial Order, are three:

- *Issue No. 1(a): Whether Utah Medical has properly validated its extrusion and injection molding processes.*
- *Issue No. 1(b): Whether Utah Medical has properly validated the software programs used as part of production or the quality system.*
- *Issue No. 2: Whether Utah Medical properly processed complaints with regard to lookbacks and failure codes.*

*Utah Medical Decision, p. 4.

QSR Compliance

Industry Standards/Current GMP

- – General FDA Opportunity
  - Performance Standards – FFDCA Section 514
  - Recognition of Existing – Federal Register
  - Guidelines – FDA
  - QSR Revision – FR Notice and Comment
- – Utah Trial
  - FDA Recognized Experts

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Industry Standards/ Current GMP *cont'd.*

- Pre Trial FDA Testimony
- Expert Thibeault

Q. In your view, if a particular industry practice develops, such that it's generally accepted throughout the industry, even if it's not written down, at the point that it becomes generally accepted throughout the industry, it becomes a regulatory requirement such that failure to comply with the industry practice is a failure to comply with the regulation?

A. Yes.

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Industry Standards/Current GMP *cont'd.*

- Pre Trial FDA
- Expert Trautman

Q. And at what point in that evolution of a new good manufacturing practice does it become a legally binding requirement?

A. I don't think there is any magical date or magical time line. I think it's what we, in situations, teach, what we have been able to provide, what's known by the industry, what the industry acknowledges.

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Industry Standards/Current GMP *cont'd.*

– Expert Thibeault

Q. So if a practice has broad geographic distribution throughout the United States, it can become an industry standard that in turn becomes a regulatory requirement, even if a majority of the firms in the industry don't follow the practice; is that correct?

A. Yes, yes, that's my understanding

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Industry Standards/Current GMP *cont'd.*

– Expert Thibeault *cont'd.*

Q. And can you provide any more specifics about how broadly distributed geographically the practice has to be in order for it to become an industry standard that in turn becomes a regulatory requirement?

A. That's very, very difficult to identify.

Q. Has FDA ever provided guidance on that issue?

A. None that I've seen.

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Industry Standards/Current GMP *cont'd.*

- Expert Thibeault *cont'd.*
  Maintaining Knowledge of Industry Standards

The only way a company can keep up is to either participate in these committees [at certain industry conferences] or these [industry] organizations or again, to just keep their ears open to what's going on around them.

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Court Opinion

–Validation Industry Standards

*The United States asserts that the best source of validation information as to "current good manufacturing practice" is found in two publications: (1) The Quality System Compendium, (Assoc. for the Advancement of Medical Instrumentation, 1998) (Pl.'s Exh. 47); and (2) Quality Management Systems – Process Validation Guidance, 2d. ed. (The Global Harmonization Task Force, January 2004) (Pl.'s Exh. 99), and assert that such have been incorporated by the regulations.**

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Court Opinion *cont'd.*
Validation Industry Standards *cont'd.*

*The regulations were effective in 1997. They do not expressly incorporate any industry publication, nor have they been amended to expressly include "future practices" which may be of benefit.**

*Utah Medical Decision, p. 6.

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Court Opinion
– Selected Comments*

This is an unusual case. The safety of the products manufactured by Utah Medical has never been at issue.

"Edge of failure" testing to demonstrate what does not work makes no sense when engineers have specified what does work and what has worked over years of operation.

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Selected Comments *cont'd.*

The undisputed hands-on testimony confirmed that the intended use of the software used by Utah Medical is adequately documented and the software is tested properly.

Utah Medical is in compliance with Quality System regulations as to complaint handling under 21 C.F.R. Section 820.90(a) and Section 820.198(a).

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Selected Comments *cont'd.*

The court has been impressed as well by the Utah Medical's design of product, its record-keeping of each step along the way, the acceptance in the market of its products, the Company's uniform processing of complaints, and the manner in which change is made in practice and procedure as a result of complaint handling.

Product safety is not an issue in this case.

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Selected Comments *cont'd.*

The fact that the road chosen by Utah Medical may be different in degree than that thought to be appropriate by a regulator, does not mean that it is wrong, or in violation of the regulations.

It makes no sense for the court to order Utah Medical to do something they are already doing.

*Utah Medical Decision, pp. 4, 11, 12, 13, 14.

McKenna Long & Aldridge LLP
STAY AHEAD OF THE CURVE

The Case

Selected Comments *cont'd.*

*Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation.**

* * *

*. . . it is fundamental that the regulations state the applicable law.***

**21 C.F.R. Section 820.1(a) (emphasis added).*
***Utah Medical Decision, p. 14.*

ATLANTA BRUSSELS DENVER LOS ANGELES PHILADELPHIA SAN DIEGO SAN FRANCISCO WASHINGTON, DC

The Case

*Petition DENIED, and case DISMISSED.**

SO ORDERED.

Let judgment be entered accordingly.

DATED this 21 day of October, 2005.

BY THE COURT:

_____
Bruce S. Jenkins
United States Senior District Judge

**Utah Medical Decision – p. 15.*