Exclusion of FDA Evidence in Medical Device Trials

Wednesday, May 7, 2014

Presented By the IADC Drug, Device and Biotechnology Committee

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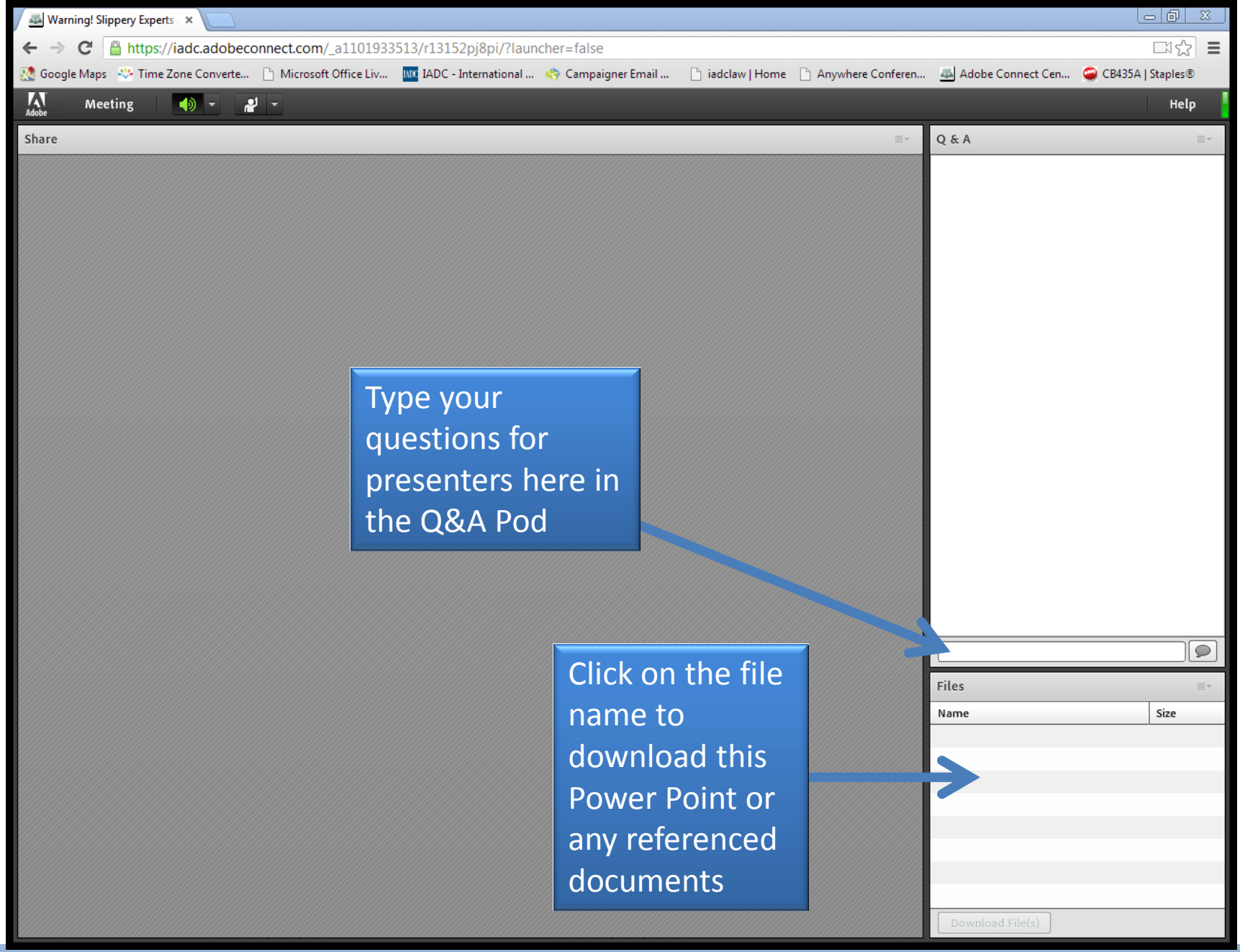
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FDA Evidence Is Under Attack

THE COURT: I think it goes directly back to the 510(k) process. And because it was a bellwether trial, you'll recall that I have ruled on that issue, and then I ruled on it again, and then I ruled on it again, and then I ruled on it again, and I'm ruling on it now. You may not use the 510(k) process tangentially, straightforwardly, backwardly, any way.

Agenda

- Brief review of FDA regulatory framework
- Common attacks on FDA evidence
- Presenting FDA evidence at trial
- Strategies when FDA evidence is excluded
- What the company and in-house counsel can do to protect company's FDA evidence

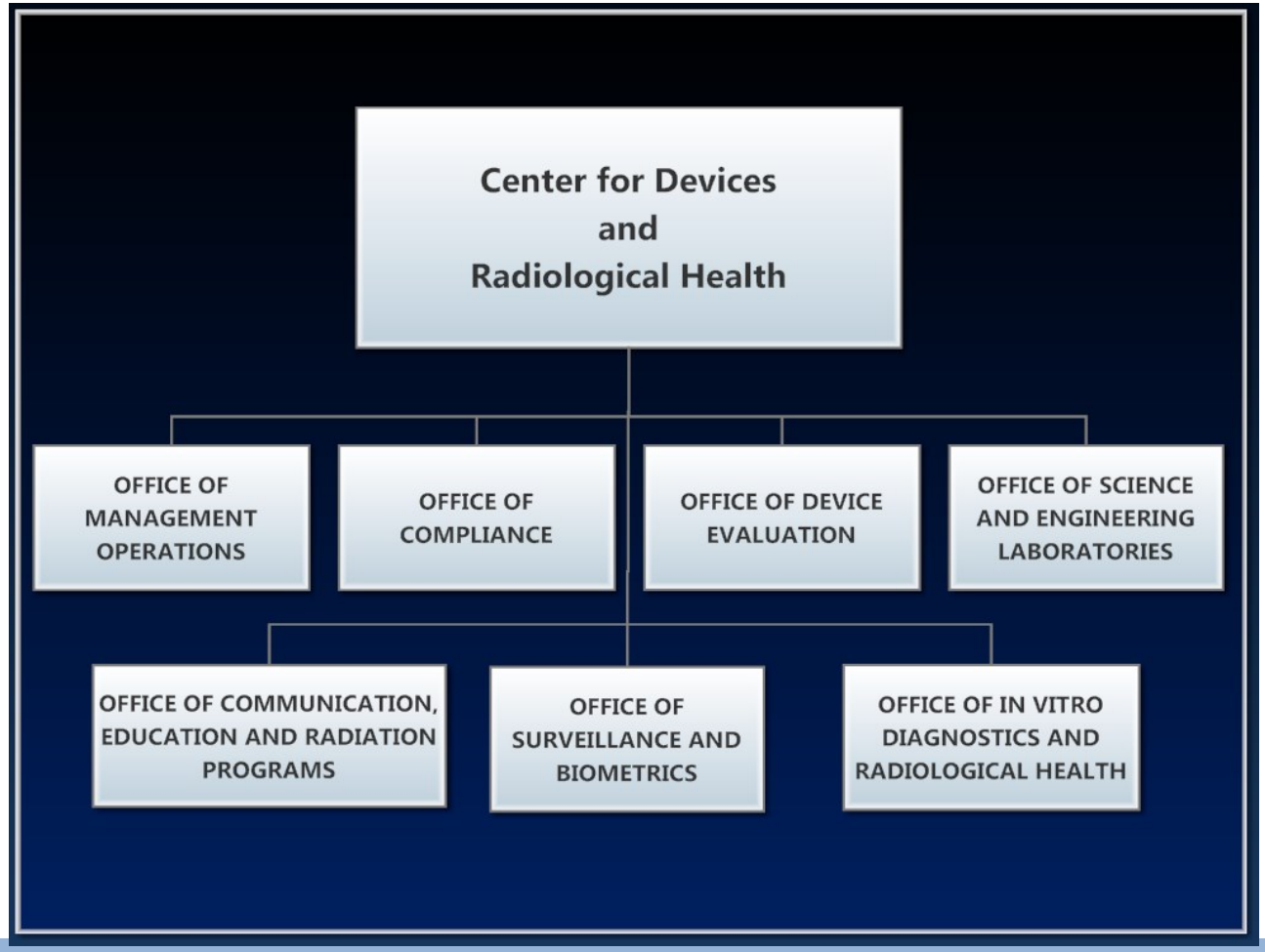
FDA Regulatory Framework

- Federal agency with sole authority to regulate the introduction of medical devices in the U.S. marketplace
  - Authority delegated to Office for Device Evaluation in Center for Devices and Radiological Health

- Two basic regulatory pathways for medical devices
  - 510(k) premarket notifications
  - Premarket approval applications (PMAs)

- Various enforcement mechanisms available:
  - Audits/inspections
  - 522 Studies
  - Safety communications, recalls, letters

FDA Organizational Structure: CDRH



Device Classifications

- Medical devices are classified into one of three classes:
  - Class I – enforcement of general controls can provide reasonable assurance of safety and effectiveness
    - » Tongue depressors, bed pans
  - Class II – device requires general controls as well as special controls
    - » The vast majority of devices introduced today are Class II
  - Class III – devices for supporting or sustaining life or that can have a significant impact on health

Bringing Medical Devices to Market

- Most Class III medical devices require a Premarket Approval (PMA) application to obtain market clearance
- PMA approval is based on a determination by FDA that the application contains sufficient valid scientific evidence that the device is safe and effective for its intended uses
- FDA regulations provide 180 days to review a PMA, but in reality, the review time is normally longer

Bringing Medical Devices to Market

- Most Class II medical devices are brought to market through the 510(k) Premarket Notification Process
- The inquiry under the 510(k) process: is the medical device to be marketed substantially equivalent to a legally marketed device (predicate device)
- “Substantial equivalence” – at least as safe and effective as the predicate device
- The 510(k) process is the workhorse of the medical device program as the vast majority of new devices are cleared through this process

Attacks on Admission of FDA Evidence at Trial

Plaintiffs' Counsel Are Aware of the Power of FDA Evidence

- Plaintiffs' counsel rely on FDA evidence when it benefits them…
    - Mandated label changes
    - Recalls, warning letters
- …and attack it when it hurts them.
    - 510(k) clearance
    - FDA inaction

Plaintiffs' Arguments for Excluding FDA Evidence

1) Evidence of 510(k) clearance is irrelevant

2) 510(k) regulation is not a safety regulation, so evidence of compliance is irrelevant

3) Evidence is unduly prejudicial and will mislead the jury and cause confusion

Evidence of 510(k) Clearance Is Irrelevant

Bard has argued to date that because the FDA cleared the Avaulta products through the 510(k) process and never took any enforcement action against the products, the products were safe and effective, and its warnings were adequate. Bard's argument is inaccurate and misleading. The issues of consequence in this case involve the alleged defectiveness of the Avaulta products in their manufacture, design and/or warnings, and whether the products were a cause of the Plaintiffs' injuries. The fact that the FDA cleared the Avaulta products for sale, and never took enforcement action relative to Avaulta devices, makes no such issue more or less probable.

In re: C.R. Bard, Inc. Pelvic Repair System Products Liability Litigation, MDL No. 2187 (Cisson, No. 2:11-cv-00195)

510(k) Regulation Is Not a Safety Regulation so Compliance Is Irrelevant

> Moreover, similar to the principles set forth in the Restatement (Third) and cited by this Court in its prior rulings, Illinois law only allows for the introduction of evidence of compliance with a "safety standard":
>
> > In *Rucker v. Norfolk & Western Ry. Co.* (1979), 77 Ill. 2d 434, 436-40, this court held that evidence of a product's compliance with governmental *safety standards* is relevant and admissible in a product liability case on the issues of whether the product is defective and whether a defect in the product is unreasonably dangerous.
>
> . . . There is no parallel that can be drawn between the safety standards at issue in *Rucker* and the (non-product-specific, non-safety related) requirements of the FDA 510(k) process. Plaintiffs are aware of no Illinois decision allowing the introduction of evidence relating to "compliance" with a non-safety related regulation such as the FDA 510(k) process.[18]

In re: Ethicon, Inc. Pelvic Repair Systems Products Liability Litigation, MDL No. 2327 (Huskey, No. 2:12-cv-05201)

Evidence Is Unduly Prejudicial and Will Mislead the Jury

Evidence of the FDA's 510(k) clearance is unduly prejudicial because jurors will likely be confused or misled to believe that the DePuy ASR was thought by the FDA to be safe and effective. *See e.g.*, *Zemaitatis v. Innovasive Devices, Inc.*, 90 F. Supp. 2d 631, 634 (E.D. Penn. 2000) ("Testimony of FDA [510(k)] approval was likely to lead the jury to believe the FDA conducted substantial testing of the suture anchors; it would give the product an unearned stamp of approval."). Defendants' clear intention with this testimony is that it will convey "proof" of the following syllogism: the ASR was approved through a regulatory process. Therefore, the product is safer. Plainly stated, the 510(k) review process will be used by Defendants to prove something that is beyond its logical probative force, *i.e.*, that 510(k) clearance means that the DePuy ASR is safe and effective and equates to FDA approval.

Strum v. DePuy Orthopaedics, Inc., Case No. 2011 L 009352 (Cook County Circuit Court, Illinois)

Responding to Plaintiffs' Attacks

510(k) Clearance Is Relevant

The fact that the FDA accepted DePuy's § 510(k) application and found that the ASR™ XL was substantially equivalent to other legally marketed predicate devices is direct evidence that DePuy did what a reasonable manufacturer would do—the key inquiry under Plaintiff's negligence claim. Indeed, this evidence establishes that the ASR™ XL was properly marketed.

Strum v. DePuy Orthopaedics, Inc., Case No. 2011 L 009352 (Cook County Circuit Court, Illinois)

Morey v. Mentor Worldwide LLC, Case No. 11-cv-5065 (N.D. Ga.)

The District of Minnesota has held that a determination of what constitutes "reasonable care" with respect to negligence claims depends on the surrounding circumstances, including a company's interactions with FDA, *see Huggins v. Stryker Corp.*, No. 09-1250, 2013 U.S. Dist. LEXIS 41260, at *43 (D. Minn. Mar. 25, 2013), and has acknowledged the use of FDA evidence to both support and rebut a claim of negligence, *see In re Levaquin Prods. Liability Litig.*, No. 08-1943, 2010 U.S. Dist. LEXIS 124647, at *3-4 (D. Minn. Nov. 24, 2010).

FDA Evidence Is Relevant: Winning the Issue at Trial

- Plaintiffs frequently cite to a decision from the ObTape MDL for the proposition that FDA evidence should be excluded:

> A similar motion was filed on behalf of the plaintiffs by the undersigned in the Mentor ObTape MDL prior to the initial trial in that litigation, and the Court there granted the motion, and excluded any reference to the FDA's 510(k) process for that trial.

- Judge Land in fact ruled at trial that Defendant would be allowed to introduce evidence of FDA complaint reporting

FDA Evidence Is Relevant: Winning the Issue at Trial

- Defendant argued the evidence should be allowed to demonstrate reasonableness

MR. LEWIS: And may I just make one for the record? I want to make my --

THE COURT: Yes, sir.

MR. LEWIS: -- position clear.

What Dr. Ducheyne has said is that we were unreasonable in what we did before we brought the product to the market. My argument is, I want to be able to show to the jury that we had a reasonable belief, based upon the federal regulations that we followed, that we had done enough before we brought the product to the market.

FDA Evidence Is Relevant: Winning the Issue at Trial

THE COURT: And what you're trying to do is leave the implication that we followed all the regulations and therefore it must be -- well, we did all that we were reasonably required to do, therefore the product is not defective.

MR. LEWIS: I would even give -- I would allow the Court to give an instruction to the jury that the mere fact that we received 510(k) clearance does not prove the device is safe and effective. I'm okay with that. I don't want to assert that.

FDA Evidence Is Relevant: Winning the Issue at Trial

But the instruction requires me to show that we were reasonable in what we did, and we did things because there was a framework under which we were operating, both in bringing the product to the market and thereafter in being transparent. All of these complaints, the substantially similar incidents, we reported those to the FDA, and they were available for any physician look at on a data base. And that transparency is very important here, because the implication is, is that we were receiving complaints but we weren't telling anyone about it. And I need to be able to rebut that in this case, to say we reported that in there --

FDA Evidence Is Relevant: Winning the Issue at Trial

- The Court ultimately agreed that evidence of interaction with the FDA would be allowed

24 THE COURT: I think they should be permitted to put
25 into evidence that when they got these complications, when they

1 got this evidence of complications or reports of alleged
2 complications, they should be permitted to put into evidence
3 that they didn't just sit on it or hide it, that they passed it
4 along to the FDA.

16 THE COURT: Well, I think it is a slippery slope, but
17 I think if I prevent them, I think it's likely error.

Compliance with Government Regulations Is Relevant

This approach is consistent with the approach of courts across the country. *See* 3-18 Frumer & Friedman's Products Liability § 18.05 (2013) ("In most states, and in federal courts, proof of compliance with governmental statutes and governmental regulations is admissible but not conclusive on the issues of negligence, warranty, and strict liability"); *Salmon v. Parke Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) ("[C]ompliance with federal laws and regulations concerning a drug, though pertinent, does not in itself absolve a manufacturer of liability.").

In re: Ethicon, Inc. Pelvic Repair Systems Products Liability Litigation, MDL No. 2327 (Lewis, No. 2:12-cv-04301)

Jury Will Not Be Confused and Should Be Given the Complete Picture of Regulatory Process

It is clear from Plaintiffs' Motion that they intend to attack DePuy's decision to use the 510(k) process rather than the PMA process. (*See* Pls' Mot. at 8 ("FDA 510(k) clearance is merely a short-cut to get a product to market and avoid substantive investigation, review, and the risk of denial.").) If this Court were to enter the order Plaintiffs request, then Plaintiffs would be empowered to attack the ASR™ device's regulatory history without any ability on the part of DePuy to respond in defense of its product. Defendants should be allowed to present evidence and argument on the FDA's clearance of the ASR™ device to counterbalance Plaintiffs' slanted characterizations of the regulatory process and to provide the jury with all of the relevant information related to this specific device's regulatory history.

DePuy ASR™ Hip System Cases, JCCP No. 4649
(Kransky, LASC Case No. BC456086)

If Necessary, Limiting Instruction Will Curb Jury Confusion

A manufacturer of a medical device to be sold in the United States may use this 510(k) process to obtain clearance from the FDA to sell a product that it believes is substantially equivalent to another product that is presently on the market. To obtain clearance under this process, the manufacturer must convince the FDA that its product is substantially equivalent to one or more products that are presently being marketed in the United States. The manufacturer does not have to convince the FDA that its product is safe and effective to obtain clearance through the 510(k) process as long as the FDA finds that the product is substantially equivalent to another product that is presently on the market. Clearance by the FDA for the marketing of these types of devices does not necessarily mean that the FDA has approved them to be safe and effective, but it means that it has found them to be substantially equivalent to other devices that are presently on the market. You may consider the FDA's 510(k) process, along with all other evidence presented during the trial, in evaluating whether the plaintiff has proven her claim in this case.

Morey v. Mentor Worldwide LLC, Case No. 11-cv-5065 (N.D. Ga.)

Presenting FDA Evidence at Trial

Hitting FDA Highlights in Trial Presentation

- Provide overview of FDA structure – emphasize role as sole regulatory authority
- Discuss enforcement mechanisms
- Walk through company regulatory history/interaction
- Present FDA review process
  - Process flow/steps taken
  - Reviewer memos

Vehicles for FDA Evidence

- Expert witness (keys):
  - Former FDA
  - Pre-market and post-market experience best
- Fact witness (keys):
  - Establish importance of FDA at all levels: engineers, quality, regulatory, and marketing

Plan B:
When FDA Evidence Is Excluded

Present FDA Evidence Without FDA Evidence

- Walk through process to get product to market
  - Design
  - Testing
  - Labeling
- Discuss post-market actions
  - Complaint monitoring
  - Interaction with physicians/patients
- Consider expert witness lineup
  - Engineer with FDA experience permissible (?)

The Role of the In-house Lawyer in the FDA Litigation Strategy

The Role of the In-house Lawyer

- Be familiar with the regulatory process
  - Getting the medical device to market
  - Making modifications to the medical device
    - Proposed label changes
    - Product enhancements/line extensions
  - Understanding FDA oversight
    - Necessary reporting
    - Audit preparedness

The Role of the In-house Lawyer

- Consider being involved in the process
  - What level of involvement is appropriate?
    - Involvement, but not direction

The Role of the In-house Lawyer

- Provide litigation perspective
  - Counsel employees on appropriate interaction internally and with regulatory officials
  - Ensure employees properly documenting interaction with FDA
  - Find/nurture fact witnesses for litigation

Questions for Presenters?

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