FDA Regulations v. Product Liability Law: Cleaning Up After an Adverse Event

Medmarc Webinar
August 27, 2015

Beth S. Rose, Esq.
Member

(973) 643-5877 | brose@sillscummis.com

One Riverfront Plaza
Newark, NJ 07102

Sills Cummis & Gross P.C.

Areas of Discussion

- Regulatory landscape
- Tension between FDA regulations and product liability law
- Selected case law
- Practice pointers

Regulatory Landscape: MDR Reportable Event

- Event that a manufacturer becomes aware of that reasonably suggests that one of its medical devices
  - may have caused or contributed to a death or serious injury; or
  - malfunctioned and the malfunction of the device or similar device would be likely to cause or contribute to a death or serious injury if malfunction were to recur
- Duty to investigate and evaluate the cause of each event

21 C.F.R. § 803.10(c); 21 C.F.R. § 803.50(a) & (b)(3)

Regulatory Landscape: MDR Reportable Event *(Cont'd.)*

- No requirement that device be
  - preserved or destroyed after reporting and investigation requirements met
  - maintained/stored for a certain period of time
- Time of retention – within the discretion of the manufacturer

Regulatory Landscape: Malfunction Defined

- The failure of a device to meet its performance specifications or otherwise perform as intended
  - 21 C.F.R. § 803.3
- "In regard to getting the actual device for analysis, although we cannot mandate that a user facility return a device to you for analysis, we strongly encourage them to do so."
  - Draft Guidance, *Medical Device Reporting for Manufacturers*, July 9, 2013 at p. 31, n. 15

Regulatory Landscape: Nonconforming Products

- Each manufacturer shall establish and maintain procedures:
  - that define the responsibility for review and the authority for the disposition of a nonconforming product
  - for rework, to include retesting and reevaluation of the nonconforming product after rework to ensure that the product meets its current approved specifications

21 C.F.R. § 820.90 (b) (1) & (2)

Regulatory Landscape: Corrective and Preventive Action (CAPA)

- Each manufacturer shall establish and maintain CAPA procedures
  - Procedures to include requirements for returned product
  - Investigation of cause of nonconformity
  - Actions needed to correct/prevent problem
  - CAPA broader than investigation for adverse event complaint

21 C.F.R. § 820.100

Tension Between Regulatory Environment and Product Liability Law

- Retention of device beyond time limits in standard operating procedure (SOP) for litigation purposes
  - Violation of company policy noted in Form 483
- Post-return investigation
  - Root cause/CAPA analysis – destructive testing - spoliation

Preservation Obligations

- Spoliation is the *destruction or material alteration* of evidence or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation.
  - *Silvestri v. General Motors Corp*., 271 F.3d 583, 590 (4th Cir. 2001)
- In pre-litigation situations, the duty to preserve material evidence exists where "a party reasonably should know that the evidence may be relevant to anticipated litigation." *Id*. at 591.
- "If a party cannot fulfill this duty to preserve because he does not own or control the evidence, he still has an obligation to give the opposing party notice of access to the evidence or of the possible destruction of the evidence if the party anticipates litigation involving that evidence." *Id.*

Preservation Obligations *(Cont'd.)*

- A plaintiff who brings an action alleging an injury as a result of a defective product has a duty to preserve the product for defense inspection.
  - *Bowman v. American Med. Sys.,* 1998 U.S. Dist. LEXIS 16082 (E.D. Pa. Oct. 9, 1998)
- A party has a duty to preserve evidence within its control that is essential to a claim or defense in litigation.
  - *Cooper v. United Vaccines, Inc*. 117 F. Supp. 864, 874 (E.D. WI. 2000)

Potential Consequences of Medical Device Spoliation

- Fines (party and counsel)
- Attorney's fees and costs
- Suppression of evidence
- Adverse Inference
- **Dismissal of specific claim or defense**
- **Judgment in favor of prejudiced party**

Case Law: Manufacturer's Destruction of Medical Device

- ***Burgos v. Satiety, Inc.*, 2013 U.S. Dist. LEXIS 31062 (E.D. N.Y. Mar. 5, 2013)** (Transoral Gastroplasty Stapling System (TOGA))
- Chronology
  - Nov. 2008 – Plaintiff sustains torn esophagus during TOGA surgery
  - Nov. 2008 – Apr. 2009 – TOGA device ultimately returned to the defendant; date of destruction unclear*

* Company SOP provides for destruction of returned non-commercial devices within 3 months

Case Law: Manufacturer's Destruction of Medical Device

(Cont'd.)

- April 6, 2009 – letter to plaintiff offering to pay for lost wages, medical expenses and future surgery
- September 27, 2010 – response from plaintiff's counsel requesting preservation and demand for inspection
- Manufacturing defect alleged

Case Law: Manufacturer's Destruction of Medical Device

(Cont'd.)

- Plaintiff moves for summary judgment based (in part) on defendant's destruction and disposal of device
  - Defendant should have known litigation was imminent because the TOGA device failed during surgery, defendant took possession of it and offered to pay medical bill and lost wages.

Case Law: Manufacturer's Destruction of Medical Device

(Cont'd.)

- Court denies motion
  - Even if defendant destroyed the TOGA in violation of SOP, there was no evidence of willful (as opposed to negligent) destruction
  - Consent form listed torn esophagus as potential injury
  - Plaintiff did not file complaint until June 2010 and did not request device until September 2010 well over a year after it was defendant's policy to destroy the device.

Case Law: Sales Reps in the Operating Room

- ***Evans v. Medtronic, Inc*. 2005 U.S. Dist. LEXIS 38405 (W. Dis. Va. Dec. 27, 2005)**
- Relevant facts
  - Medtronic Itrel 3 Spinal Cord Stimulation System
  - Medtronic sales reps present during the second revision surgery
  - Surgeon determines that “lead” is unsalvageable, removes it and hands it to scrub nurse who throws it away
  - Plaintiff claims that sale reps had a duty to preserve the explanted lead and/or notify her of its immediate destruction

Case Law: Sales Reps in the Operating Room *(Cont'd.)*

- Plaintiff's motion for adverse inference denied
  - Sales reps had no reason to anticipate future litigation surrounding the damaged lead
    - "Although the lead had been damaged, the record does not indicate that anyone related this to a product defect."
    - No reason to know that plaintiff had been injured during surgery

Case Law: Sales Reps in the Operating Room *(Cont'd.)*

- Sales reps never had possession, custody or control of the explanted lead
- No duty to retrieve lead based on FDA reporting requirement *(21 C.F.R. § 803.50)*
- Time-frame mitigates against finding of willful destruction of evidence.

Case Law: Spoliation as Potential Basis for a Parallel Claim

- ***Estate of LeMay v. Eli Lilly & Co*., 960 F. Supp. 183 (E.D. WI. 1997)**
- Relevant facts
  - Product liability case based on fracture of Class III pacemaker leads
  - Surgeon and nurse testify that they gave a broken portion of a lead to the defense sales representatives present at the surgery
  - Sales reps do not remember receiving the lead
  - Manufacturer says it did not receive the lead, but former employee, who examined products removed from patients, initially stated that she recalled examining plaintiff's lead. Changes her testimony after review of company records.

Case Law: Spoliation as Potential Basis for a Parallel Claim *(Cont'd.)*

- Court grants motion to dismiss on preemption grounds, but finds that plaintiff can sue for defendant's negligence in failing to manufacture the device in accordance with FDA regulations
- Allows case to proceed on potential parallel claim
  - If the defendant intentionally destroyed the lead, a jury could infer that an examination of the lead would have revealed the defendant's failure to meet FDA regulations
  - If the jury accepted plaintiff's spoliation allegations, it could infer that defendant received the lead and intentionally destroyed it
  - Once the defendant had possession of the lead, federal law required it to preserve the device. *21 C.F.R. § 820.162*.

Case Law: Whose Preservation Duty is it Anyway?

- ***Bowman v. American Med. Sys*., 998 U.S. Dist. LEXIS 16082 (E.D. Pa. Oct. 9, 1998)**
  - Penile implant malfunctions; explant surgery scheduled
  - Two months prior to the explant surgery, plaintiff's counsel writes to the surgeon asking that the prosthesis be preserved after removal so that "it can be examined by appropriate engineers to determine the cause of breaking."
  - Surgeon discards the prosthesis following surgery and has since died
  - Court affirms judgment on the pleadings for defendant as a sanction for spoliation of evidence

Case Law: Whose Preservation Duty is it Anyway? *(Cont'd.)*

- Third Circuit *Schmid* test applied:
  - The degree of fault of the party who altered or destroyed the evidence
    - *Fact that plaintiffs requested preservation and that the evidence was discarded by the surgeon in contravention of their instructions does not relieve them of preservation obligation*

Case Law: Whose Preservation Duty is it Anyway? *(Cont'd.)*

- The degree of prejudice suffered by the opposing party
  - *The prejudice to the defendant from spoliation of evidence is greater in a manufacturing defect action where the alleged defect is unique to a particular product and which is also the primary source of evidence*
  - *Without ability to examine implant, manufacturer is left to guess at alternate theories of causation*
  - *No ability to question surgeon who is now dead*

Case Law: Whose Preservation Duty is it Anyway? *(Cont'd.)*

- Whether there is a lesser sanction that will avoid substantial unfairness to the opposing party, and where the offending party is seriously at fault, will serve to deter such conduct by others in the future.
  - Lesser sanction not appropriate given the severe prejudice.

Case Law: Whose Preservation Duty is it Anyway? *(Cont'd.)*

- ***Creazzo v. Medtronic*, 903 A.2d. 24 (Pa. Super. Ct. 2006)**
- Relevant facts
  - Explantation of Itrel 3 because of malfunction
  - Litigation commenced before the explant surgery
  - Prior to explant surgery, defense counsel requests preservation of device and proposes a stipulation for its examination and inspection to avoid potential spoliation issues
  - Plaintiff's counsel declines stipulation, but asks hospital to retain the device for examination
  - Plaintiffs do not try to retrieve explanted device from hospital for two years by which time it had been lost

Case Law: Whose Preservation Duty is it Anyway? *(Cont'd.)*

- Appellate court affirmed dismissal of plaintiff's product and manufacture defect claims based on spoliation
  - Plaintiffs bore substantial responsibility for the loss of the device despite conduct of third party hospital
  - Loss of device caused substantial prejudice to defendant as a claim of a manufacturing defect requires the inspection of the actual device
  - Court rejects argument that plaintiff's claim sounds in design defect

Case Law: Manufacture v. Design Defect

- ***See Creazzo*, 903 A.2d at 30** ("Unlike the claim for design defect in *Big Yank*, which could be investigated with reference to other products of the same design . . . a claim of manufacturing defect is untenable in the absence of the product itself. Where as in this case, the actual device has not been examined even by the plaintiff's own expert[,] both proof and defense of the claim are severely compromised.)
- ***But see Fleury v. Biomet*, 865 So.2d 537,539-40 (Fla. Dist. Ct. App. 2d Dist. 2003)** (summary judgment based on spoliation of artificial knee immediately following surgery reversed; appellate court finds neither party was at fault for loss of the evidence and both parties are in the same position in so far as their inability to examine the knee in question)

Case Law: Destructive Testing

- ***Cooper v. United Vaccines, Inc.* 117 F. Supp. 864 (E.D. WI. 2000)**
- Court finds that plaintiffs' *ex parte* destructive testing of the left over vaccine one year prior to commencement of lawsuit and without notice to defendant constitutes intentional destruction of crucial evidence which warrants a dismissal sanction. By the time plaintiff filed its complaint, the left over vaccine had been destroyed and any retained samples by the company has passed their expiration date

Case Law: Preservation Issues at Trial

- ***Huskey v. Ethicon, Inc.* 2014 U.S. Dist. 107887 (S.D. W. Va. Aug. 6, 2014)**
- Court denies plaintiff's *in limine* motion to exclude failure to preserve explanted mesh material as such evidence may be relevant; however, defense counsel may not blame plaintiff's counsel for destruction

SOP Practice Pointers

1. Address preservation of returned product for litigation purposes
   - Build in flexibility of retention periods to address different factual scenarios
   - Provide for consultation with in-counsel
   - Address disposition of returned goods after preservation obligation terminates
2. Ensure appropriate storage of retained samples

SOP Practice Pointers *(Cont'd.)*

3. Proper documentation for receipt of all returned goods, including contacts with potential plaintiff/counsel
4. Train sales representatives, complaint handlers and regulatory personnel on SOPs and preservation obligations
5. Develop protocol for destructive and non-destructive testing
   - Do not conduct destructive testing in the absence of notification/consent/participation of potential adversary

?

Questions

Beth S. Rose, Esq.
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102
Tel: (973) 643-5877
Fax: (973) 643-6500
brose@sillscummis.com

Sills Cummis & Gross P.C.