Sales Representatives in the OR:

Navigating a Liability Minefield

Medmarc Webinar

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Introduction

- Medical device sales reps sometimes must be in the OR to provide surgeons with technical support when vendor's product is being used
- Part of larger challenge of “crowd control” in the OR, a popular place for everyone from residents and med students, to surgeon's children
- Worthwhile to have reps in OR guiding physician in terms of device with which physician might not be familiar
- Device may need some kind of baseline assessment and initial checking, so can be beneficial to have rep present
- When providing training on devices, companies engage in group lectures, whether live or online, small group practical training, and perhaps most importantly from litigation standpoint, one-on-one consultation with physicians or patients

Primary Role of a Sales Representative:

- Ensure all necessary surgical instruments, trial prosthetic components, and final prosthetic components available to surgeon on day of surgery
- Sales rep also expected to be familiar with intended use of each surgical instrument and component (of his/her company) during surgery to answer questions that may arise from OR personnel during course of operation.
- Such question may relate to any compatibility, of the device or sequence that instruments should be prepared for sugrgeon

Setting the Stage: The OR as Theater

- Reps – a cameo role only
- Regularly dealing with doctors/hospital staff to sell product
- Training sessions with doctors and staff
- Invested in product - financially and sometimes emotionally
- Often invited into OR by doctors
- Strive to be helpful - but not doctors
- Lessons from the Case Law ▪▪▪▪▪▪▪▪▶

Sales Representatives in the OR: What They Know May Be Dangerous

Zappola v. Leibinger (2006 App. Ohio), 2006 WL 1174448

- Plaintiff sued:
  - Stryker Corporation
  - Stryker sales representative, Brett Baird
  - Plaintiff's physician, Dr. Sawhny
- Sawhny was to perform craniotomy to remove Plaintiff's benign brain tumor *with Baird present in OR*
- During course of procedure, it was apparent that bone flap removed in order to get to tumor could not be replaced

Sales Representatives in the OR: What They Know May Be Dangerous!

- Original procedure required use of rigid fixation system designed by Stryker, but became clear that cranial opening would need to be closed by some other means
- Sawhny consulted with Baird, *in the OR*, who then observed opening in Plaintiff's skull (*approximately* 48 cm)

Sales Representatives in the OR: What They Know May Be Dangerous!

- Baird suggested Stryker product called Bonesource, which he then obtained from his car!!

Sales Representatives in the OR: What They Know May Be Dangerous!

- Baird failed to inform Sawhny that product was *not indicated for use* on openings of more than 25 cm
  - And, for openings of more than 4 cm, use of wire mesh for support and closed suction drainage of wound were suggested in IFU's

Sales Representatives in the OR: What They Know May Be Dangerous!

- Sawhny used Bonesource *without reading directions*
  - As result of improper application, Bonesource failed
- Plaintiff developed:
  - Leak of cerebrospinal fluid that required four additional surgeries to correct
  - Permanent disfiguration and damage to area where Sawhny applied Bonesource

Sales Representatives in the OR: What They Know May Be Dangerous!

- Alleged:
  - Failure to warn
  - Defective design
  - Common law negligence
  - Negligent preparation
  - Negligent representation
  - Fraud against Stryker and Baird

Sales Representatives in the OR: What They Know May Be Dangerous!

- According to Court:
  - It was Baird's duty to make sure product was properly used
  - Stryker and Baird did not "adequately" warn Sawhny about Bonesource, excluding Defendants from protection under *learned intermediary doctrine* (adequate warnings to physician preclude failure to warn liability to patient)

Sales Representatives in the OR: What They Know May Be Dangerous!

- Baird alleged that because written instructions came with Bonesource and Sawhny failed to read those instructions, Sawhny should be liable
- Court rejected this argument
  - Determined that written instructions did not adequately warn Sawhny, since Baird was in OR and should have informed Sawhny that he was not properly applying product

Case Impact and Recommendations

- Sales personnel are always problematic and making grandiose representations live in OR compounds that problem
- They are an added dimension in OR and can become part of the process
- This may obviate or supersede written warnings or eliminate learned intermediary protection (often becomes plaintiff's easiest claim to prove)
- If sales representatives take part in judgment and analysis that is reserved for licensed physicians, courts may impose liability on company for unauthorized practice of medicine

Case Impact and Recommendations

- Must instruct sales reps in informed consent
- Many hospital consent forms do not mention reps
  - Examples follow …

Exemplar Consent Forms

Procedure(s) Name of Description with NO Abbreviations

- ☐ Left
- ☒ Right
- ☐ Bilateral
- ☐ Not Applicable

Open reduction and internal fixation of nasal bone fracture

I understand that _____ **(print name and title)** is the attending physician or Licensed Independent Practitioner performing the procedure(s). I know that he/she may have assistants to help him/her during the procedure(s). These assistants may include other licensed physicians, doctors in training (residents), surgical assistants, nurses, medical students and students in other health care training programs (e.g., nursing, physician assistant, operating room technician). These assistants may perform a variety of significant tasks including but not limited to: opening and closing wounds, harvesting, dissecting, or implanting tissue, preparation of implanted devices and generally facilitating the operative procedure. If I want to know the names of those who assisted, I can obtain their names from the responsible practitioner after the procedure.

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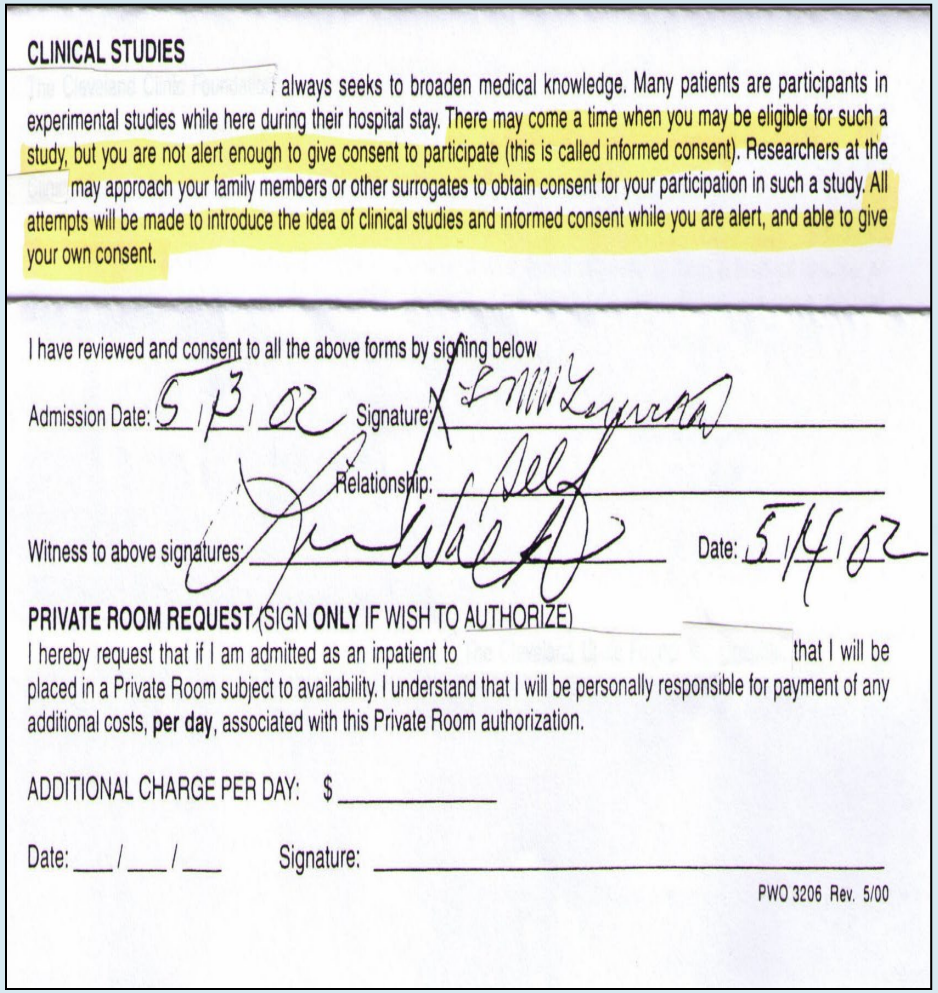
Exemplar Consent Forms



CLINICAL STUDIES

[redacted] always seeks to broaden medical knowledge. Many patients are participants in experimental studies while here during their hospital stay. There may come a time when you may be eligible for such a study, but you are not alert enough to give consent to participate (this is called informed consent). Researchers at the [redacted] may approach your family members or other surrogates to obtain consent for your participation in such a study. All attempts will be made to introduce the idea of clinical studies and informed consent while you are alert, and able to give your own consent.

I have reviewed and consent to all the above forms by signing below

Admission Date: 5/3/02 Signature: [signature]

Relationship: [signature]

Witness to above signatures: [signature] Date: 5/4/02

PRIVATE ROOM REQUEST (SIGN **ONLY** IF WISH TO AUTHORIZE)

I hereby request that if I am admitted as an inpatient to [redacted] that I will be placed in a Private Room subject to availability. I understand that I will be personally responsible for payment of any additional costs, **per day**, associated with this Private Room authorization.

ADDITIONAL CHARGE PER DAY: $ _____

Date: ___/___/___ Signature: _____

PWO 3206 Rev. 5/00

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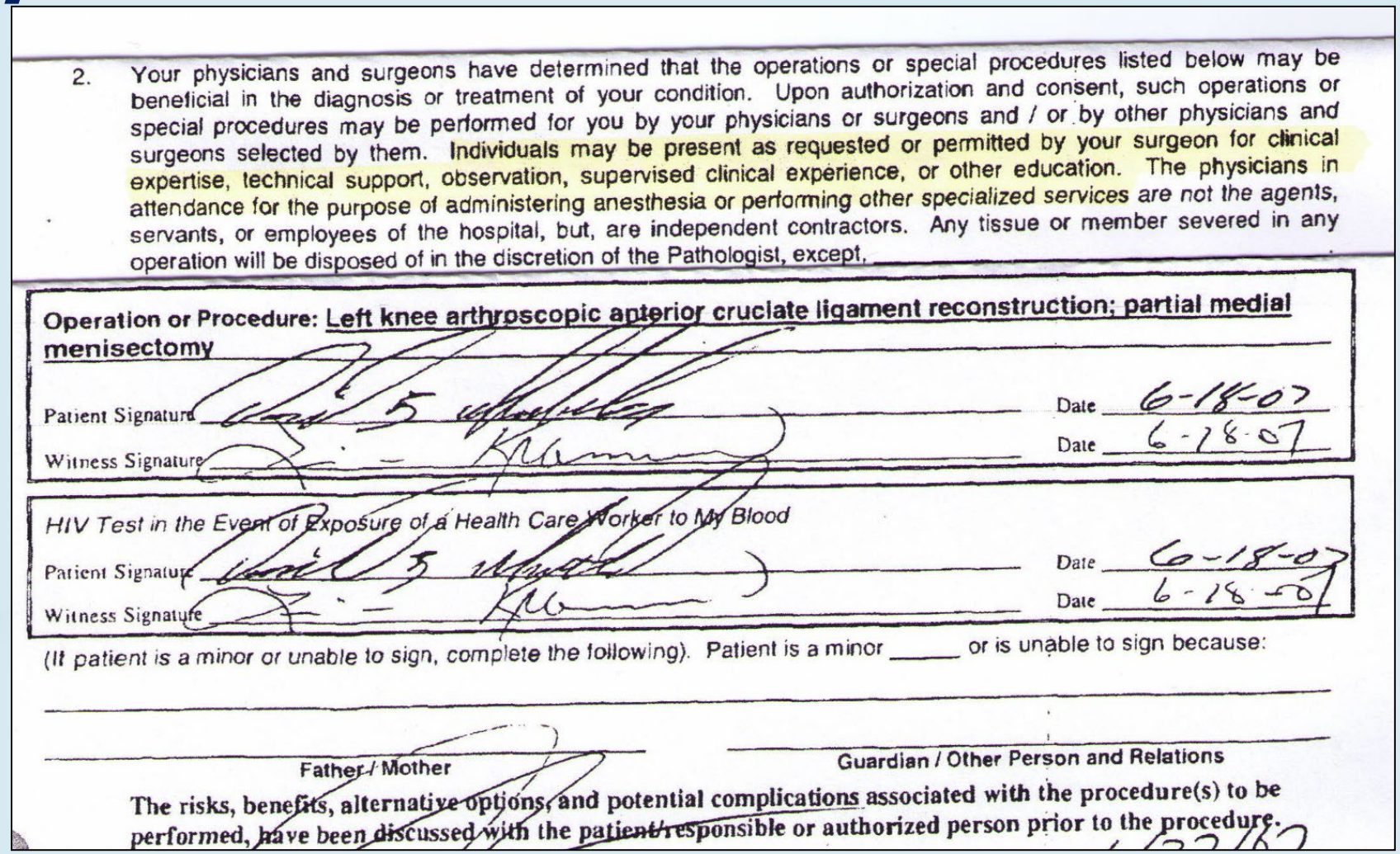
Exemplar Consent Forms



2. Your physicians and surgeons have determined that the operations or special procedures listed below may be beneficial in the diagnosis or treatment of your condition. Upon authorization and consent, such operations or special procedures may be performed for you by your physicians or surgeons and / or by other physicians and surgeons selected by them. Individuals may be present as requested or permitted by your surgeon for clinical expertise, technical support, observation, supervised clinical experience, or other education. The physicians in attendance for the purpose of administering anesthesia or performing other specialized services are not the agents, servants, or employees of the hospital, but, are independent contractors. Any tissue or member severed in any operation will be disposed of in the discretion of the Pathologist, except,

Operation or Procedure: Left knee arthroscopic anterior cruciate ligament reconstruction; partial medial menisectomy

Patient Signature _____ Date 6-18-07

Witness Signature _____ Date 6-18-07

HIV Test in the Event of Exposure of a Health Care Worker to My Blood

Patient Signature _____ Date 6-18-07

Witness Signature _____ Date 6-18-07

(If patient is a minor or unable to sign, complete the following). Patient is a minor _____ or is unable to sign because:

_____

_____ _____

Father / Mother Guardian / Other Person and Relations

The risks, benefits, alternative options, and potential complications associated with the procedure(s) to be performed, have been discussed with the patient/responsible or authorized person prior to the procedure.

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More Case Impact and Recommendations

- Should have a consistent policy regarding rep conduct in the OR
  - Physician consult – deference to the Captain
  - Patient contact dangerous! – Defer to doctor; maybe even wait until anesthetized
  - Don't make suggestions unless physician has time to review *written* warnings; rep should recommend review
- Train the reps!

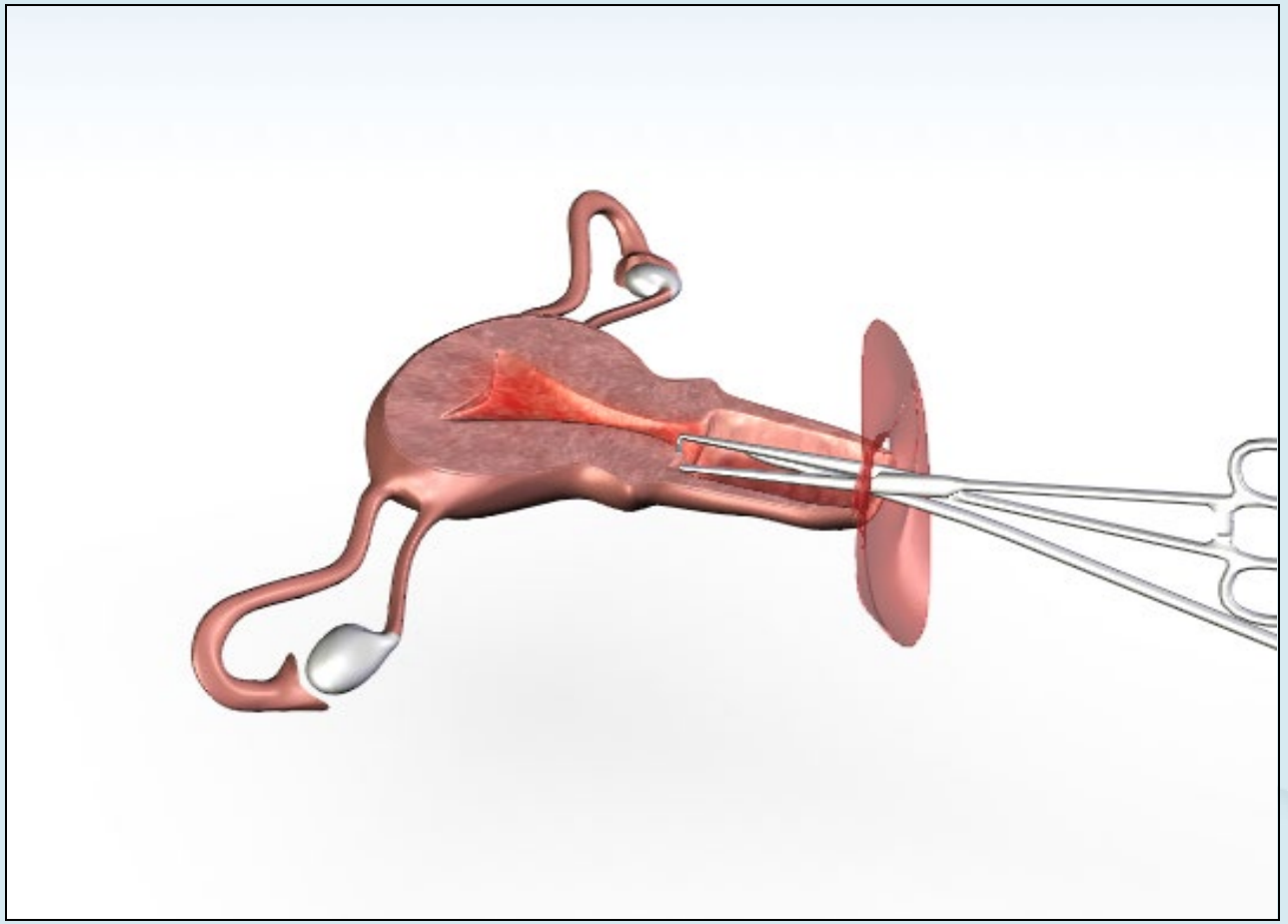
Stay Out of the Trunk During Surgery!

Preemption: Conduct of Sales Reps may Prevent Complete Dismissal

- Why do we want it? How can reps defeat it?
  - *Adkins v. Cytyc Corp.*, 2008 WL 268474 (W.D.Va.)
- Claim against Cytyc sales representative for negligence in instructing operating physician on the use of Cytyc's medical device
- Was *not* preempted by federal law

Preemption: Conduct of Sales Reps May Prevent Complete Dismissal

- Lorraine Adkins underwent surgery in which physician used medical device called the NovaSure



Preemption: Conduct of Sales Reps May Prevent Complete Dismissal

- Defendants' sales rep was in OR during Adkins' surgery and instructed physician on proper way to measure size of Adkins' uterus and test integrity of uterine wall
- Results of examination indicated that Adkins *did not* have uterine perforations or uterine wall measuring less than 4 cm, which would preclude use of device

Preemption: Conduct of Sales Reps May Prevent Complete Dismissal

- During surgery, Adkins suffered thermal burn from NovaSure and was found to have perforated uterus (and uterus in fact measured 2 cm, i.e. < 4 cm)
- Adkins alleged negligent warnings or instruction to surgeon by Defendants' rep
- Court granted Defendants' motion to dismiss all claims, *but* allowed Plaintiff to amend complaint to allege specific facts relating only to Adkins' claim for negligent warnings or instructions to surgeon by sales rep

Preemption: Conduct of Sales Reps May Prevent Complete Dismissal

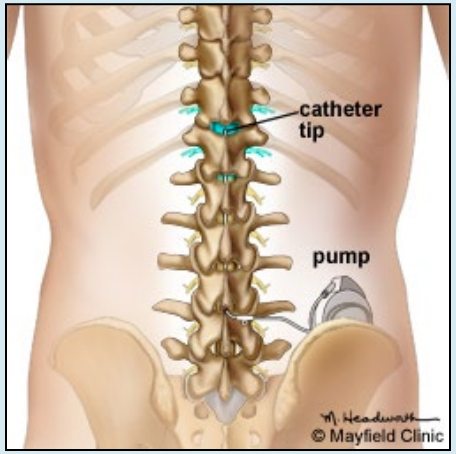
- Reasoned that Adkins' claims challenging safety or effectiveness of NovaSure were preempted by federal law under *Riegel v. Medtronic*, 128 S.Ct. 999 (2008)
  - But claims relating to conduct of sales representative were *not* preempted, so the case lived

Preemption: Case Impact and Recommendations

- Federal law may *not* preempt negligence claims against medical device manufacturer or rep for interactions between rep and physician during surgery
- They may be subject to liability under common law negligence when rep is “active as a *de facto* physician's assistant during surgery”
- Reps must be careful not to step into role of physician’s assistant when interacting with physician during surgery
- Also – claims against sales reps may defeat diversity jurisdiction

Liability of Sales Representative for Acts Occurring in the OR, Doing it Right!

- *Wolicki-Gables v. Arrow International, Inc.*, 2009 WL 2190069 (M.D. Fla), *aff., 634 F.3d 1296 (2011)*
- Dr. Brian James performed surgery on Linda Wolicki-Gables to implant delivery pump and catheter to treat chronic pain



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Liability of Sales Representative for Acts Occurring in the OR; Doing it Right!

- Pump implant manufactured by Defendant Arrow International
  - Defendant Greg Nelson, rep for Arrow, sold the pump to Wolicki-Gables' physician
  - Greg Nelson was in OR during Linda's surgery
- After surgery, pump malfunctioned

Liability of Sales Representative for Acts Occurring in the OR; Doing it Right!

- Wolicki-Gables consented to surgery to replace pump
  - She *did not* consent to presence of people needed for technical support in OR
- Dr. James performed surgery on Wolicki-Gables to
  - Remove pump, replace connector, and reimplant same pump

Liability of Sales Representative for Acts Occurring in the OR; Doing it Right!

- On July 29, 2003, Wolicki-Gables was unable to move her lower back and was hospitalized
- Dr. Raymond Priewe removed pump and found skin infection – lawsuit resulted
- Court granted Nelson's motion for summary judgment on claim of negligence in relation to Nelson's alleged participation in operation to replace pump

Liability of Sales Representative for Acts Occurring in the OR; Doing it Right!

- Court reasoned that Nelson *did not* take part in decision-making during operation to replace the pump
  - His role was limited to carrying back-up products
  - He did not scrub-in for the procedure
  - He did not enter the sterile field

Liability of Sales Representative for Acts Occurring in the OR; Doing it Right!

- Plaintiffs alleged that Nelson had duty to verify Wolicki-Gables' consent to Nelson's presence in the OR
- Court rejected claim
  - Nelson did not know that Wolicki-Gables did not consent
  - Nelson *could not* have looked for himself to see if she consented due to privacy laws

Liability of Sales Representative for Acts Occurring in the OR; Doing it Right!

- Under Florida's medical consent statute, only medical practitioners could be liable for such a claim. *Nickell v. Gonzalez*, 17 Ohio St. 2d 136 (1985) (Same holding)
- Wolicki-Gables also claimed negligence based on Nelson's participation in an "off-label" use of the pump by providing replacement connector for pump, rather than suggesting replacement of entire pump or disallowing replacement of the connector

Liability of Sales Representative for Acts Occurring in the OR; Doing it Right!

- Court rejected claim:
  - Although FDA regulations prohibit off-label promotion by manufacturers, there is no private right of action for FDA violations
  - Plaintiff had no evidence establishing promotion of off-label uses of the pump by Nelson

Case Impact and Recommendations

- Factors court will consider in determining whether sales rep overstepped boundaries in OR:
  - Extent of interaction between physician and sales rep
  - Whether physician made own decisions relating to procedures (tactical vs. strategic)
  - Purpose of sales rep being in the OR
  - Whether sales rep promoted off-label uses

Case Impact and Recommendations

- Sales reps should discuss only information on medical device's label/IFU's
- Sales rep should never promote, suggest, or even imply that physician should act in a way that is not expressly stated on device's label
- Extreme example: Overt disregard of IFU's (Guidewire)

Learned Intermediary Doctrine

Harrington v. Biomet, No. CIV-07-25-R, 2008 WL 2329132 (June 3, 2008 W.D. Okla.)

John Harrington had hip replaced with Biomet hip in May 2004 and sub-sequently suffered eleven hip dislocations (within a period of weeks)

Learned Intermediary Doctrine

- Dr. Tompkins performed revision surgery in February 2005
  - He noted Biomet hip dislocation easily only during flexion to 80 to 90 degrees with moderate adduction, 30 degrees of inward rotation and axial loading (which rotation plaintiff was warned not to do) So – not abnormal
- Plaintiff had also fallen and injured ligaments holding hip in place before first dislocation, making subsequent dislocations more likely

Learned Intermediary Doctrine

- Plaintiff claimed design and manufacturing defect
- Court concluded that Plaintiff failed to allege facts sufficient to support claim – Design and manufacturing defects – tougher to prove
- Plaintiff also asserted that Biomet failed to warn that hip could repeatedly dislocate over short period of time
- Alleged that Biomet sales rep (who was present for Plaintiff's hip replacement) should have warned Plaintiff or Tompkins of implant's "hidden dangers" or possibility that implant had damaged acetabular cup

Learned Intermediary Doctrine

- Alleged that Biomet sales rep breached duty of care because he should have advised physician on what size and type of components to use and suggest that different implant might be more suitable for that age patient
- Court found no evidence that sales rep had duty to advise attending physician and breached it, or that rep volunteered to advise physician and breached duty

Learned Intermediary Doctrine

- Court stated that Biomet *did* provide *FDA approved* warning to Tompkins, through his physician – *i.e.*, the Learned Intermediary
  - Under learned intermediary doctrine there was no duty to provide *additional* warnings to patient
  - Even if warning could be considered inadequate, Biomet not liable because failure to warn did not result in Plaintiff's injuries
  - Plaintiff was warned before and after surgery of likelihood of dislocation if precautions were not taken to minimize risk by not engaging in certain movements or activities
  - Therefore, Biomet's broad warning in informational material was adequate to satisfy learned intermediary doctrine

Case Impact and Recommendations

- If relatively general, yet still inclusive (and FDA approved – which most are), warning is included with medical devices, learned intermediary doctrine offers protection to device manufacturers
- If sales rep is present in OR, make sure they interact with *physician* rather than patient
  - Direct warnings *to the physician*, to avoid appearance of "volunteering" which carries duty of care that could then be breached, leading to liability for device manufacturers under *respondeat superior*

Case Impact and Recommendations

- To keep learned intermediary status, target marketing to medical professionals rather than customers/patients (Ideally)
  - Following all FDA advertising regulations and consumer warnings should be considered adequate

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Lightning Round

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Lightning Round!
Chamian v. Sharplan Lasers, Inc.

- 18 Mass. L. Rptr. 308, 2004 WL 2341569 (Mass. Super. 2004)
- Physician's misuse of device standing alone was insufficient to establish that manufacturer breached duty to patient
- Less clear whether court would so hold had manufacturer more affirmatively "certified" physician on specific medical device

Lightning Round!
Disbrow v. Richards, Inc.

- 1996 Tex. App. LEXIS 4543 (Tx. Civ. App. 1996)
- Plaintiff brought suit against device manufacturer and sales rep for injuries sustained during hip replacement
- Rep had positioned equipment and assisted scrub nurse in preparing equipment
- Court found no evidence that rep had practiced medicine

Lightning Round!
Kennedy v. Medtronic

- 851 N.E.2d 778, 787 (Ill. App. 2006)
- Court held that device rep did not voluntarily assume duty of care by providing technical support and calibrating a cardiac lead before surgery
- Although rep had assisted with fifteen insertion surgeries per week, court determined that rep could not make judgment about whether lead was inserted correctly
- By taking on limited technical role, court held that manufacturer did not owe duty to patient to ensure that lead was correctly placed into patient's cardiac ventricle (tactical vs. strategic)
- Court also found that by verbally reassuring patient before surgery, representative did not assume duty to ensure patient's safety during procedure (*dangerous*!)

Duty To Train

- Generally, manufacturers and their sales representatives owe no duty to train physicians.
- *See Scott v. C.R. Bard, Inc.,* 180 Cal. Rptr. 3d 479, 490 (Cal. App. 2014) ("In general, there is no duty to take affirmative action to assist or protect another. . . [defendant] had no duty to train physicians on the use of its . . . products.");
- *Glennen v. Allergan, Inc*., 202 Cal. Rptr. 3d 68, 83-84 (Cal. App. 2016)
- "The manufacturer of a prescription medical device has no duty to train a physician in using its medical device . . . manufacturers are not responsible for the practice of medicine.").

Unauthorized Practice of Medicine

- In *Wilkerson v. Christian*, No. 1:06CV00871, 2008 WL 483445, at *11 (M.D.N.C. Feb. 19, 2008) court suggested that if plaintiff's claim was not barred by the statute of limitations, defendant sales rep's conduct in OR might constitute the unauthorized practice of medicine.
- "Plaintiff alleged facts, in good faith, that raise serious questions regarding the propriety of sales representatives in the operating room. The gravity of Plaintiff's allegation that a sales representative performed, or participated in, tumor ablation procedure is not lost on this court"
- But Court found no "quasi-physician/patient relationship"

The Hospital's Perspective

- Hospitals should designate area where reps wait until time for surgery, and area should *not* be physicians' lounge
- Reps should wear badges and, perhaps, different color scrubs (some examples: black, fuchsia, jailhouse orange)
- Reps should scrub in (wash hands and arms thoroughly), and stay out of OR until patient has been properly draped (and maybe even anesthetized)
- Reps must have proof of negative TB and hepatitis tests. Some hospitals require them to complete questionnaires about their health (*e.g.*, that they have no infectious diseases)
- From privacy perspective, "you don't want [vendor reps] knowing who's in the hospital." [Hospital Compliance Officer]
- Rep doesn't need to know name of patient on operating table, or at least there should be provision to prevent rep from writing down patient's name (some tension with MDR reporting)
- Some hospitals require vendors to sign statement in advance agreeing to comply with hospital's privacy and security policy

The Sales Rep's Perspective

- Examples of policies that device companies might consider for their sales representatives
- Wear name tag during the procedure, unless prohibited by the hospital
- Confirm where to stand during the procedure
- Comply with operating room decorum and other hospital policies
- Do not touch patient
- Do not enter sterile or semi sterile field
- Do not offer opinions on diagnosis and treatment of any condition or person
- Do not promote off-label use of a product

A Rep's Eye View on the OR: Actual Device Rep Testimony

Q. All right. And when you went into the room, you stood near the head of the patient? Is that fair?

A. I don't think we were at the head of the table. There were several people in the OR. There were, I think, some perfusion students. It was a pretty crowded OR. We stood kind of to the side, but I don't remember specifically were we stood.

Q. What was the reason for you to be in the room?

A. To be in the OR was – was a good opportunity to – to be around a surgeon doing a procedure.

Secondly, we wanted to get his feedback after using this product. We often wait until the surgeon has gone – completed the procedure. We like to find out his thoughts, his comments, positive or negative, about a product, so we were waiting to be able to get some time with him to discuss what he thought of the product.

A Rep's Eye View on the OR: Actual Device Rep Testimony

Q. *Were you in the room to offer guidance or instruction to the doctor on the use of the ADE?*

A. No.

Q. Did you offer guidance or instruction in the OR room to the doctor?

A. No.

Q. *Were you able to visualize the operative field from where you were standing in the OR room?*

A. Not really.

Q. Were you able to watch the procedure on a monitor or an echo screen?

A. I don't think so.

Top 10 Tips for Minimizing Liability for Reps in the OR

Sales Reps in
the OR

Top 10 Lessons

Top 10 Tips for Minimizing Liability in the OR

10. Reps should strive to stay out of ambit of sterile field and any actual physical assistance should be rudimentary and mundane - Handing a *nurse* something (tactical *vs*. strategic) – *Never* touch the patient!

9. Reps should have means to clearly, verbally and visually identify themselves as sales reps, and not *healthcare personnel* – scrubs, badges, verbal I.D.

8. Reps should confine *any* consult in OR to matters specifically relating to device

Top 10 Tips for Minimizing Liability in the OR

7. Have training program by reps for surgeons *before* actual surgery - with appropriate demonstrations, feedback and Q & A

6. In OR, do not give training instructions to surgeons that contravene IFU's. (Problem: if surgeon consciously disregards)

5. Minimize or eliminate all direct patient contact; wait until anesthetized. Avoid personal knowledge of patient (different system to track the surgery)

Top 10 Tips for Minimizing Liability in the OR

4. Interface with hospitals for inclusion of sales rep language in patient informed consent forms

3. Formulate a written policy for sales reps conduct in the OR

2. Enforce and abide by the policy—and document that!

1. Train the reps! Annual in house seminars - it sinks in!

One Last Buzz Word that Could Win Your Case

THE SURGEON IS THE CAPTAIN OF THE SHIP!

Actual surgeon quote:

"Well, it is my strong belief that the patient has a contract with the physician. *The physician has to take responsibility for everything that occurs there.* I am old fashioned in that I believe *the surgeon is the captain of the ship*, so regardless of what happens, the surgeon has a certain degree of responsibility."

Captain of the Ship Doctrine

- *O'Connell v. Biomet*, 250 P.3d 1278, (Colo. Ct. App. 2010).
- Sales rep who delivered the fixator was in the OR
- Dr. applied the fixator to the bone with bone screws, during application the drill bit of the bone screw pierced the radial nerve causing permanent damage.
- Court applied "captain of the ship" doctrine in the negligence claim to all persons in the OR, including those that did not work for the hospital (*i.e.* the sales rep)

Questions and Answers

Further questions?

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