



# **LEGAL ISSUES IN HEALTHCARE: LESSONS LEARNED FROM THE TOYOTA RECALL**

Presented by:

**Melissa L. Markey, Esq.**

**Hall, Render, Killian, Heath & Lyman, PLLC  
201 West Big Beaver Rd, Suite 315  
Troy, Michigan  
(248) 740-7505**

**Christopher C. Eades, Esq.**

**Hall, Render, Killian, Heath & Lyman, PLLC  
One American Square, Suite 2000  
Indianapolis, IN 46282  
(317) 977-1460**





## Caveat:

This presentation is intended to provide general information. Please work closely with your lawyers to address specific situations.



# Causes of Healthcare Errors

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- Human Factors

- The caregiver

- Fatigue
    - Depression
    - Burn-out
    - Training
    - They are human...

- The patient

- They don't share all the information
    - They are non-compliant
    - They don't read the books...



# Causes of Healthcare Errors

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- The System:
  - Complicated technology, powerful drugs, and multiple co-morbidities
  - Fragmented systems with multiple hand-offs
  - Time pressures; staffing constraints
  - Similarity of drug names
  - Inadequate infrastructure
  - Communication failures
    - Between caregivers
    - Between patient and caregiver

# Healthcare's Reputation

- The reputation of healthcare as an industry has fallen
  - Estimated fatality rate from medical error: 100,000/ year
    - That's 1-747 airplane every day, for a year
  - 45% of nurses admit to medication error in last year
- Some recent examples
  - Radiation overdoses
  - Heparin overdoses
  - Wrong side/wrong site surgery
  - Retained objects

# Importance of Reputation



- 4<sup>th</sup> Annual "goodpurpose" Survey:
  - 86% of consumers globally believe that companies need to place at least equal weight on society's interests as they do on business' interests.
  - 2/3 of respondents say giving corporate money to solve societal problems isn't enough; good causes need to be integrated into everyday business.
  - Socially responsible companies appear to stimulate higher consumer loyalty – including in emerging markets
  - Translation for healthcare – be involved in the community and have visible presence



“It takes 20 years to build a reputation and five minutes to ruin it. If you think about that, you’ll do things differently.”

Warren Buffett

# The Toyota Recall

- Early in 2010: Toyota recalls millions of vehicles due to allegations of gas pedal failures
- July/August 2010: Toyota recalls 270,000 Lexus due to engine problems
- October 2010: Toyota recalls 1.5 million vehicles for brake and fuel pump problems

# Toyota Recall

- August 28, 2009 – A Lexus ES350 crashes at over 100 mph and bursts into flames, killing an off-duty California Highway Patrolman and three members of his family. The cause of the crash is determined to be a throttle that stuck open. At the time of the crash, the officer's brother-in-law, a passenger in the car, is on the phone with police frantically reporting that the car won't slow down.

# Toyota Recall

- September 29, 2009 – Toyota announces floor-mat “customer safety advisory”
- NHTSA calls for recall
- November 25, 2009 – Toyota recalls 3.8 million cars for floor-mat issues
- December, 2009 – Fatality, no floor mats involved
- January 21, 2010 – Toyota announces recall for non-floor-mat-related accelerator-sticking issues

# Toyota Recall

- January 26, 2010 – Sales of affected models suspended.
- January 27, 2010 – Recall expands to more cars
- February 1, 2010 - Fix for accelerator pedal proposed
- February 5, 2010 - Toyota president Akio Toyoda apologizes
- February 24, 2010 – Toyoda testifies before Congress

# Toyota Recall – Impact

- Early in the recall, Toyota:
  - Fell from No. 1 in customer loyalty to No. 3
  - Fell to No. 6 in a "perceived quality" study
  - 40% of consumers "would not buy" Toyota products
- Later:
  - 13.8% of visitors to Edmunds.com searched Toyota, compared to 16.1% the previous year

# Tylenol I: 1982

- Cyanide-laced capsules of Tylenol causes seven deaths in Chicago
- Tampering occurred after Tylenol reached retail shelves
- J&J recalled ALL Tylenol products, began broad publicity campaign about recall, and suspended all advertising
- J&J changed formulation (capsules to caplets), added tamper-resistant caps, developed advertising campaign
- Result: Tylenol was a trusted brand

## Tylenol II: 2010

- Consumer complaints about "musty" smelling pills increase in 2008.
  - Two years pass before McNeil Consumer Healthcare acts.
- April 2009, McNeil finds pills that do not dissolve properly
  - Tylenol attempts a "phantom recall"
- Between Sept. 2009 and Oct. 2010, 9 recalls
  - Tylenol's response to allegations that pediatric medications were tainted: "No real risk of harm."

# The FDA Warning Letter

- "...Your firm's quality management should have ensured the start of chemical testing far earlier. Failure to do so prolonged identification and resolution of the problem, resulting in continued consumer exposure. Quality problems must be thoroughly investigated, root cause determined, and appropriate corrective and preventive actions implemented as quickly as possible to limit exposure of the public to substandard drugs..."

## FDA Warning Letter

- "...The Agency is concerned about the response of Johnson & Johnson (J&J) to this matter... Corporate management has the responsibility to ensure the quality, safety, and integrity of its products. Neither upper management at J&J nor at McNeil Consumer Healthcare assured timely investigation and resolution of the issues..."



# Do The Right Thing

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- Sounds easy...
- Requires pre-work and planning
- And usually involves some hard decisions

# Before the Crisis



- Murphy's Law
  
- Be Prepared!
  - Plan ahead: What are the biggest reputational risks?

# Before the Crisis

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- Prepare
  - Policies and plans for emergencies
  - Practice and training is critical
  - Establish a crisis response
  - Drill

# In the Midst of Crisis

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- Remain calm
- Get expert help when needed
- Gather facts
- Maintain perspective
- Maintain communications
  - Internal
  - External



# In the Midst of Crisis

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- Put Your Best Foot Forward – early!
- Think about the spokesperson

# In the Midst of Crisis

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- Respond quickly!
- Be vigilant for early warning signs
- Right-size the response

## In the Midst of Crisis

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- It is OK to not have all the facts early in the crisis.
- Develop an organized message that emphasizes concern and responsiveness
- Work with experts and regulators early and honestly
- Accept responsibility; be accountable

# Dealing with the Public

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- High exposure = high risk
- Demonstrate commitment to correction
- To the public, "no comment" means "we are hiding something".

# Social Media and Culture

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- Recognize the power of social media
- Consider the impact of culture
- Recognize the risks in aggressive growth



"...Quality control [means] daily vigilance.  
You can't coast on your reputation because it  
can fail very quickly..."

Ralph Nader

# Most Likely Risks in Healthcare

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- Malpractice
- Privacy Breach
- Leaked internal strife

# Cultural Commitment

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- Create a culture of quality and safety
- When quality and safety are your core promise, loss of quality or safety will quickly impact reputation
- Get rid of the John Wayne attitude!



# Publicity on Internal Issues

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- Have reasonable, enforceable, legal policies
- Review policies light of recent cases

# Breach of Privacy

- The question is not *whether* you will suffer a healthcare privacy breach, the question is *when, how severe, and why.*

# Disclosures/Apologies in Healthcare

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- Physician/Patient relationship is unique
- Disclosures/Apologies are both encouraged and required
- Many studies contrary to conventional wisdom – fear of litigation
- Concerns related to disclosure – litigation
- Conclusions

# Disclosures/Apologies in Healthcare

- Physician/Patient - the "good old days"



# Disclosures/Apologies in Healthcare

- Physician/Patient – current perception/fears



# Disclosures/Apologies in Healthcare

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- Physician/Patient relationship is unique
  - Need for apology
  - Expectation of apology
  - Studies appear to confirm these needs/expectations

# Disclosures/Apologies in Healthcare

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- Disclosures/Apologies are both encouraged and required
  - "Apology" Statutes
  - Accreditation
  - Ethics
  - State law requirements
  - Reimbursement

# Disclosures/Apologies in Healthcare

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- Disclosures/Apologies are both encouraged and required (cont.)
  - Statutes of Limitation (vary)
  - Fraudulent Concealment
    - Active Concealment - intention to mislead
    - Passive Concealment – negligent failure to disclose material facts

# Disclosures/Apologies in Healthcare

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- Many studies contrary to conventional wisdom – fear of litigation
  - Relate not only to the decision to disclose, but also the manner of disclosure
  - Suggest that disclosure/apology may lead to decreased litigation/cost/awards

# Disclosures/Apologies in Healthcare

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- Concerns related to disclosure
  - Peer Review Privilege/Confidentiality
    - many jurisdictions require non-disclosure of peer review
    - legislative intent appears to conflict
    - "final action taken" may be disclosed in some jurisdictions

# Disclosures/Apologies in Healthcare

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- Concerns related to disclosure (cont.)
  - Attorney-Client Privilege
    - communications made by a health care provider to the provider's attorney (or in some jurisdictions the provider's insurance contact in the context of litigation) are privileged and immune from disclosure.
  - Insurance Coverage Issues

# Disclosures/Apologies in Healthcare

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- Concerns related to disclosure (cont.)
  - Work Product Doctrine
    - Materials prepared by a party "in the anticipation of litigation" are often considered "work product" and are generally immune from production or disclosure

# Disclosures/Apologies in Healthcare

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- Concerns related to disclosure (cont.)
  - Potential Impacts on Litigation – "rules of evidence" where no legal "privilege"
    - Admissions of Liability (excluded by some "Apology Statutes")
    - Statements for Purposes of Medical Diagnosis/Treatment
    - Business Records
    - Disclosure creating "standard of care"
    - Disclosure equating to "expert testimony"
    - "Subsequent remedial measures" often protected



Jan 78 Obs of c. Abd. pain x 1 day  
Vomited x 1  
PE: Obs of c. malodorous breath  
dirty pig c poor dental hygiene  
Severe body odor, Hx of vom due to  
stench.

*[Signature]*

(Continue on reverse side)

IDENTIFICATION (For typed or written entries give Name - last, first, middle grade, rank, rate, hospital or medical facility)	REGISTER NO.	WARD NO.
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**PROGRESS NOTES**  
STANDARD FORM 509 (Rev. 11-77)  
Prescribed by GSA/OMB  
FPMR (41 CFR) 101-11.606-4  
509-110



MEDICAL RECORD	PROGRESS NOTES
DATE 100 matry	<p>The prognosis is not poor it is rotten. Talked with patients wife she expressed desire to have no more prolonging of patients life <del>she</del> She would like him to pass on as soon as possible because she needs the insurance money</p> <p style="text-align: right;">C. W.</p>

# Disclosures/Apologies in Healthcare

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## ■ Conclusions

- Patient safety should govern
- Consider/Discuss disclosure before it is made
  - Team approach often best
  - Avoid guessing
  - Recognize disclosure may be a process
- Be cognizant of language to be used
  - Consider coverage issues – coordinate
  - Apology vs. Admission – is there a distinction
  - Consider legal ramifications of language/word choice



**QUESTIONS?**



**THANK YOU!!!**