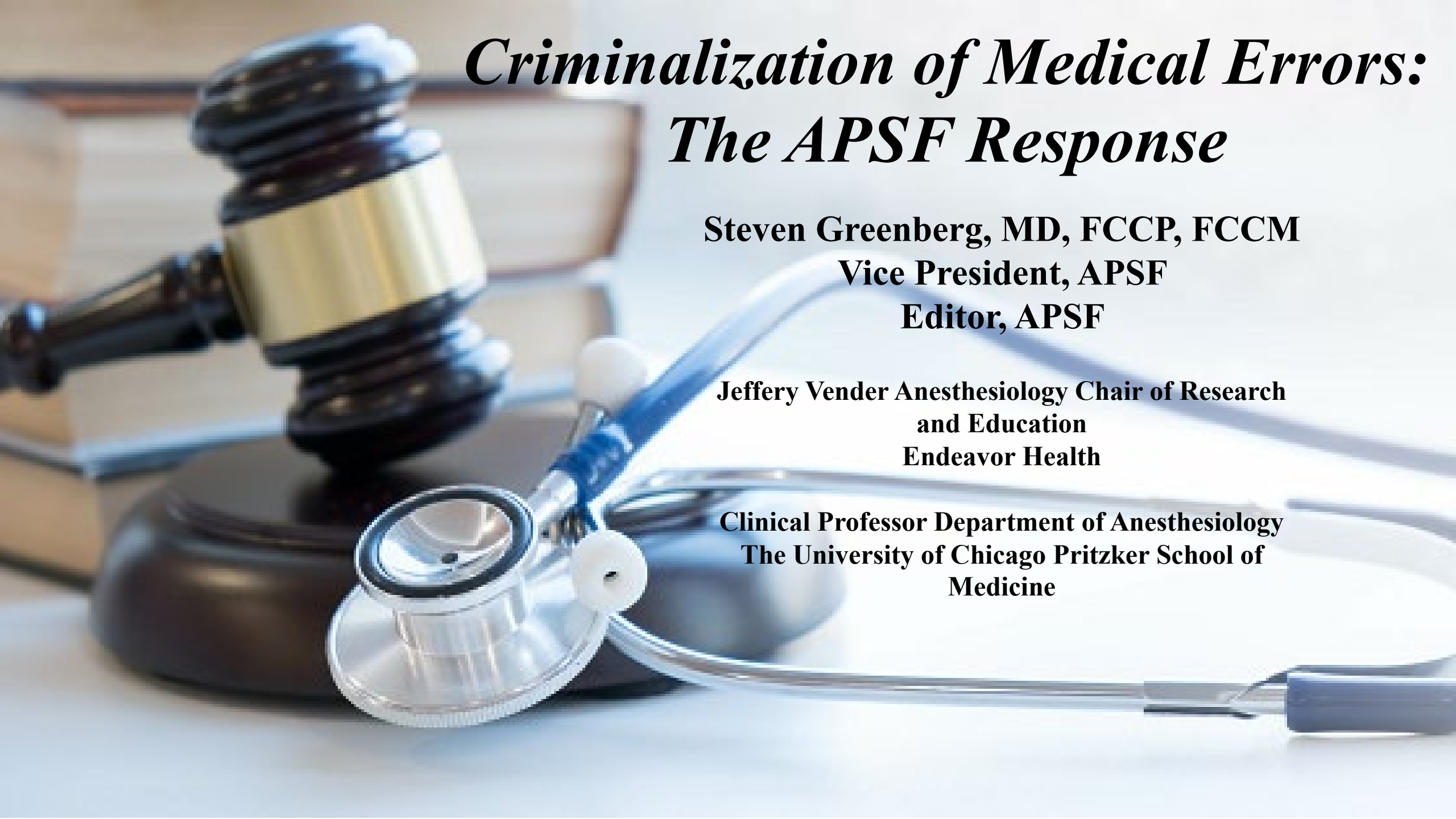


Criminalization of Medical Errors: The APSF Response

Steven Greenberg, MD, FCCP, FCCM
Vice President, APSF
Editor, APSF

Jeffery Vender Anesthesiology Chair of Research and Education
Endeavor Health

Clinical Professor Department of Anesthesiology
The University of Chicago Pritzker School of Medicine

Disclosures:

- Vice President, APSF
- Editor-APSF Newsletter
- APSF Grant
- The speaker discloses the following relevant financial relationship with these companies:
  - Fresenius Kabi (received grant to investigate difference in safety among infusion pumps)
  - Senzime (received grant to perform pilot trial in ICU using quantitative monitoring device)
  - Merck Inc. (received grant to investigate outcomes in cardiac patients and sugammadex)
  - Astra-Zeneca (received grant to investigate outcomes in patients who receive Xa inhibitors)

Objectives:

- Define medical & medication errors
- Discuss APSF activity on topic
- Discuss historical/global perspectives of criminalization of medical error
- Describe unintended consequences of criminalization of error
- Discuss APSF response

Definition: Medical Error

- *"The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."*

Institute of Medicine (US) Committee on Quality of Health Care in America. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. National Academies Press (US); Washington (DC): 2000.

Definition: Medication Errors

- *"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer."*

https://cdn.who.int/media/docs/librariesprovider2/country-sites/medication-error-wpsd-final.pdf?sfvrsn=e5853e2a_1&download=true

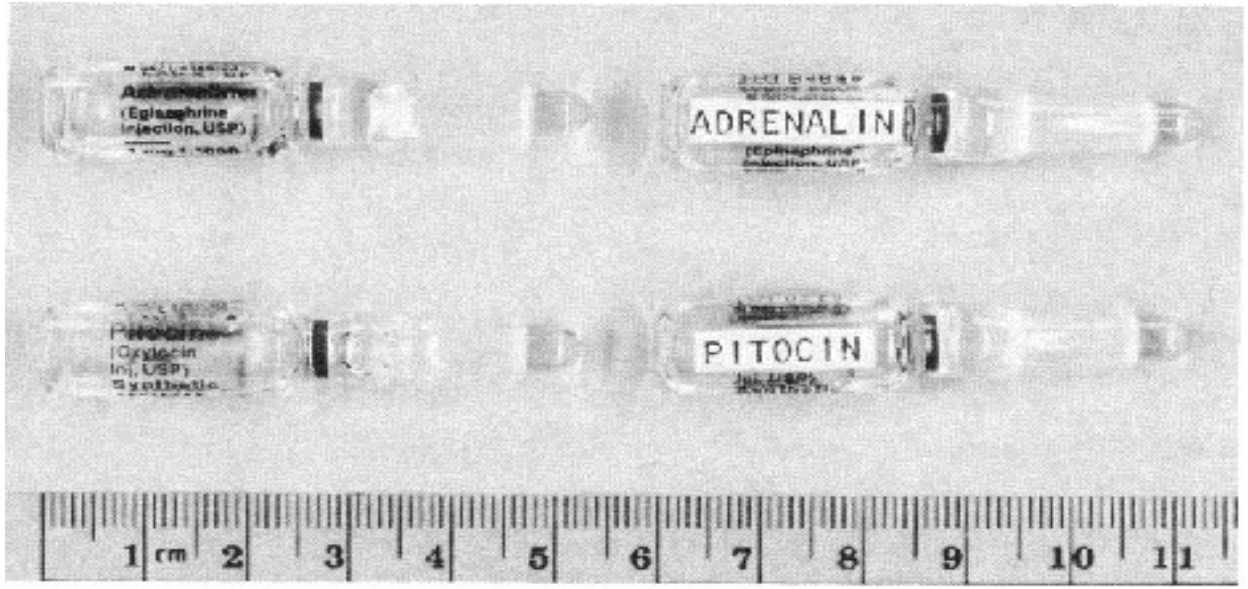
Medication Errors: Facts

- One of most common medical errors!
- Medication errors cost U.S. Healthcare System **$42 billion/yr.**
- Perioperative medication error incidence **1/20-1/274 anesthetics delivered.**
- **4% of Anesthesia Closed Claims Database** are medication error related.
- **"Substitution Error-"** most common error.
- Anesthesia departments should create culture of **"no blame."**
- **Bar code scanning** has been shown to **decrease medication errors.**

World Health Organization. Last updated 2022, https://www.who.int/initiatives/medication-without-harm., Webster CS. *Br J Anaesth*. 2021;127(3):346-349.

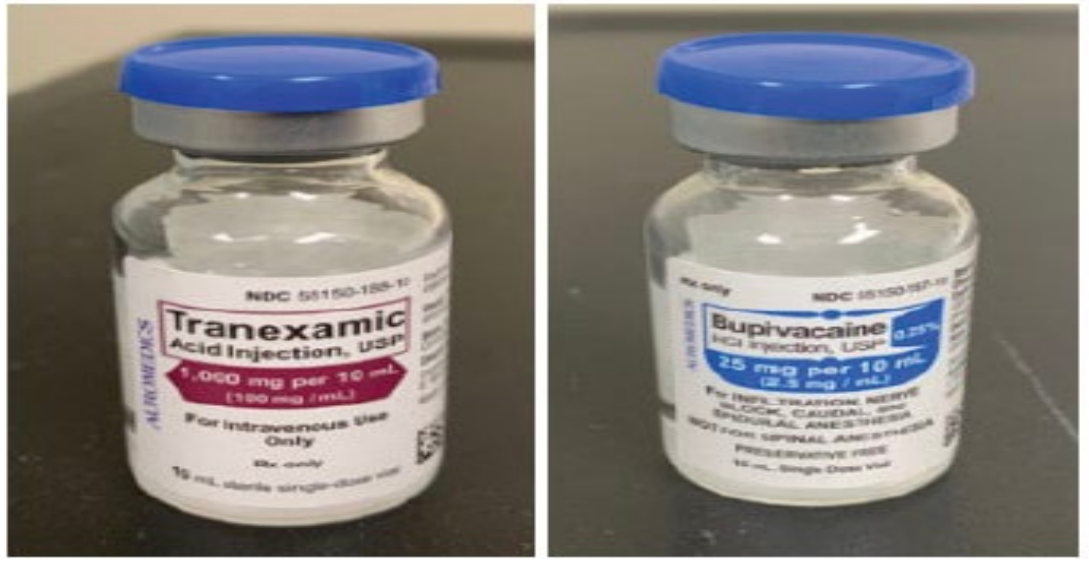
Accidental Look-A-Like Errors: APSF Newsletter

APSF Newsletter 1987;Winter issue



"Mother dies when given two ampules of adrenalin in mistake for pitocin."

APSF Newsletter 2024; 39: 37.

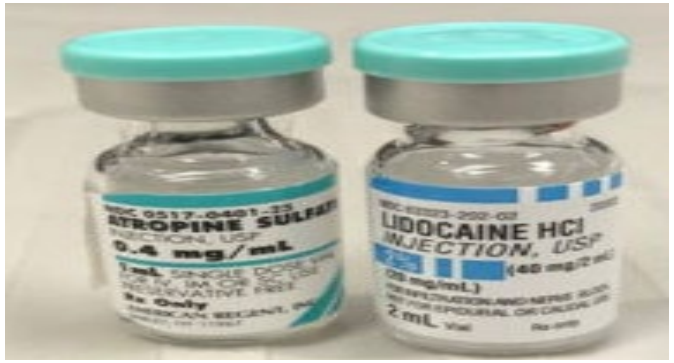


Unraveling a Recurrent Wrong Drug-Wrong Route Error—Tranexamic Acid in Place of Bupivacaine.

Look-Alike Medications-2023

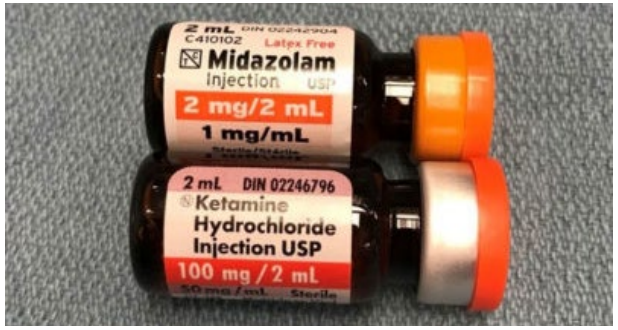
Ondansetron & Phenylephrine & Atropine

Lidocaine & Atropine



Tranexamic acid & Ropivacaine

Midazolam & Ketamine



Verapamil & Naloxone

Ondansetron & Oxytocin & Metoclopramide

https://www.apsf.org/look-alike-drugs/#alert

APSF Medication Safety Conferences

APSF Conference 2010: STPC	APSF Stoelting Conference 2018
Standardization APSF Newsletter 2010; 25:1. **High alert drugs** **Ready to use syringes/infusions**-machine readable labels **Standardize placement**-drugs, infusion libraries/protocols	**Drug Safety:** https://www.apsf.org/medication-safety-recommendations/ Identify and promote safer anesthetics
Technology Mechanism to **identify medications** **Technology training/device** education Improved/standardized user interfaces **Mandatory safety checklists** in all ORs	**Reducing Drug Administration Errors:** Standardize procedures and doses, carefully document administration, and simplify preparation.
Pharmacy Routine provider prepared meds should be discontinued Pharmacists should be part of OR team **Standardized pre-prepared meds** Deploy automated dispensing machines	**Drug Shortages:** Share information, simplify ordering and establish contingency plans.
Culture Establish a **"Just Culture"** Establish culture of education, understanding, accountability	**Standardization and Innovation:** Collaborate across specialties and establish consensus for refined standards.

Despite Our Best-Efforts Medical Errors Still Occur…….

https://healthjournalism.org/blog/2023/07/medical-errors-are-the-third-leading-cause-of-death-and-other-statistics-you-should-question/

Criminalization of Medical Errors:
Nothing New


A Mistake, a Rare Prosecution, And a Doctor Is Headed for Jail

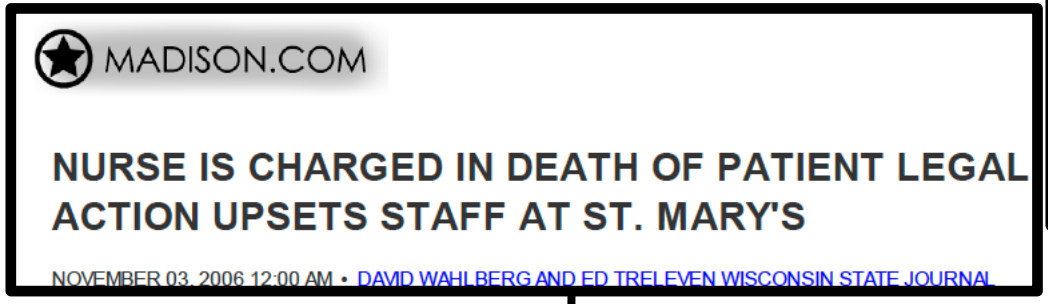
1990


Medication error

Nurses

Three Denver nurses may face prison in

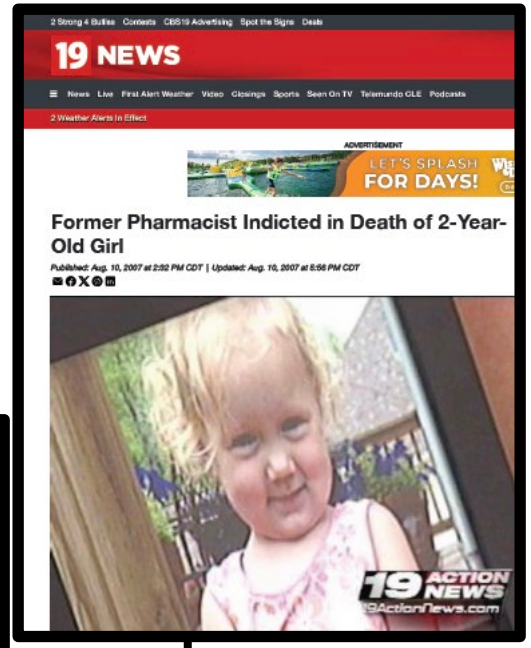
Late 1990's


MADISON.COM

NURSE IS CHARGED IN DEATH OF PATIENT LEGAL ACTION UPSETS STAFF AT ST. MARY'S

NOVEMBER 03, 2006 12:00 AM • DAVID WAHLBERG AND ED TRELEVEN WISCONSIN STATE JOURNAL

2006

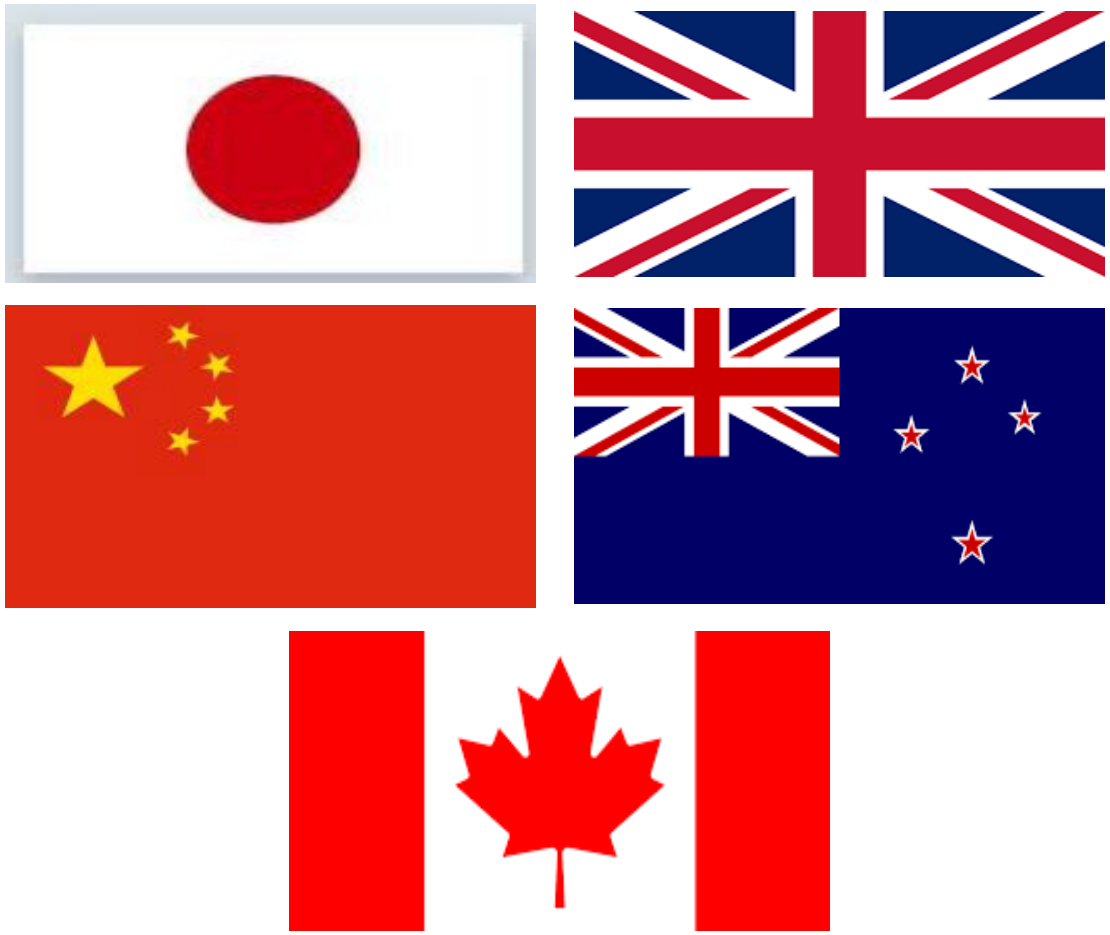


Late 2000's

Filkins, J. A., "With no evil intent": The criminal prosecution of physicians for medical negligence, *The Journal of Legal Medicine, 22*(4), 467-499 (2001)
Hurley, S.P. & Berghahn, M.J., Medication errors and criminal negligence: Lessons from two cases, *Journal of Nursing Regulation, 1*(1), 39-43 (2010),
https://wcca.wicourts.gov/caseDetail.html?caseNo=2006CF002512&countyNo=13
State of Ohio v. Eric Cropp, CR-07-499690-B, https://cpdocket.cp.cuyahogacounty.us/CR_CaseInformation_Summary.aspx?q=NFF-hcrbIWmBPLabKnGDsw2;

Criminalization: Worldwide Problem

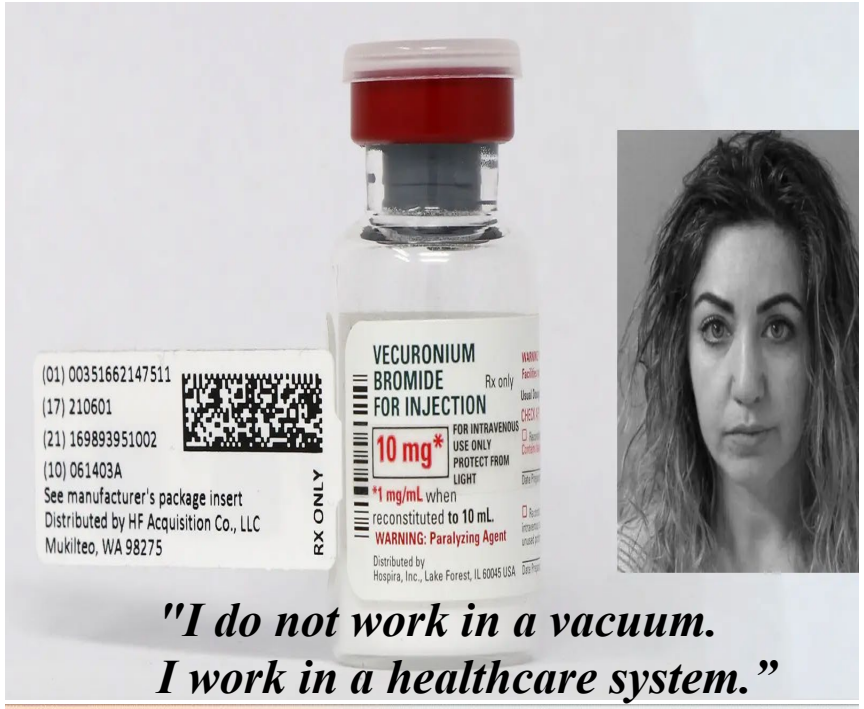
- Jail time
- Probation
- Overturned conviction
- Plea deals
- Dropped charges
- Not guilty verdicts

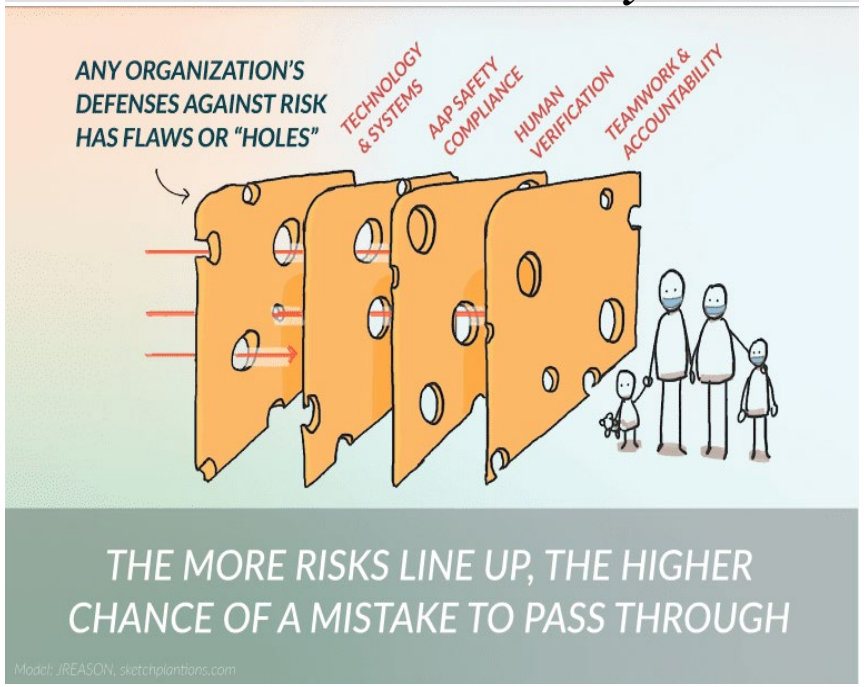


https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2021-2022/july-2022/criminalization-of-human-errors-in-healthcare/

The Catalyst: A Call to Action

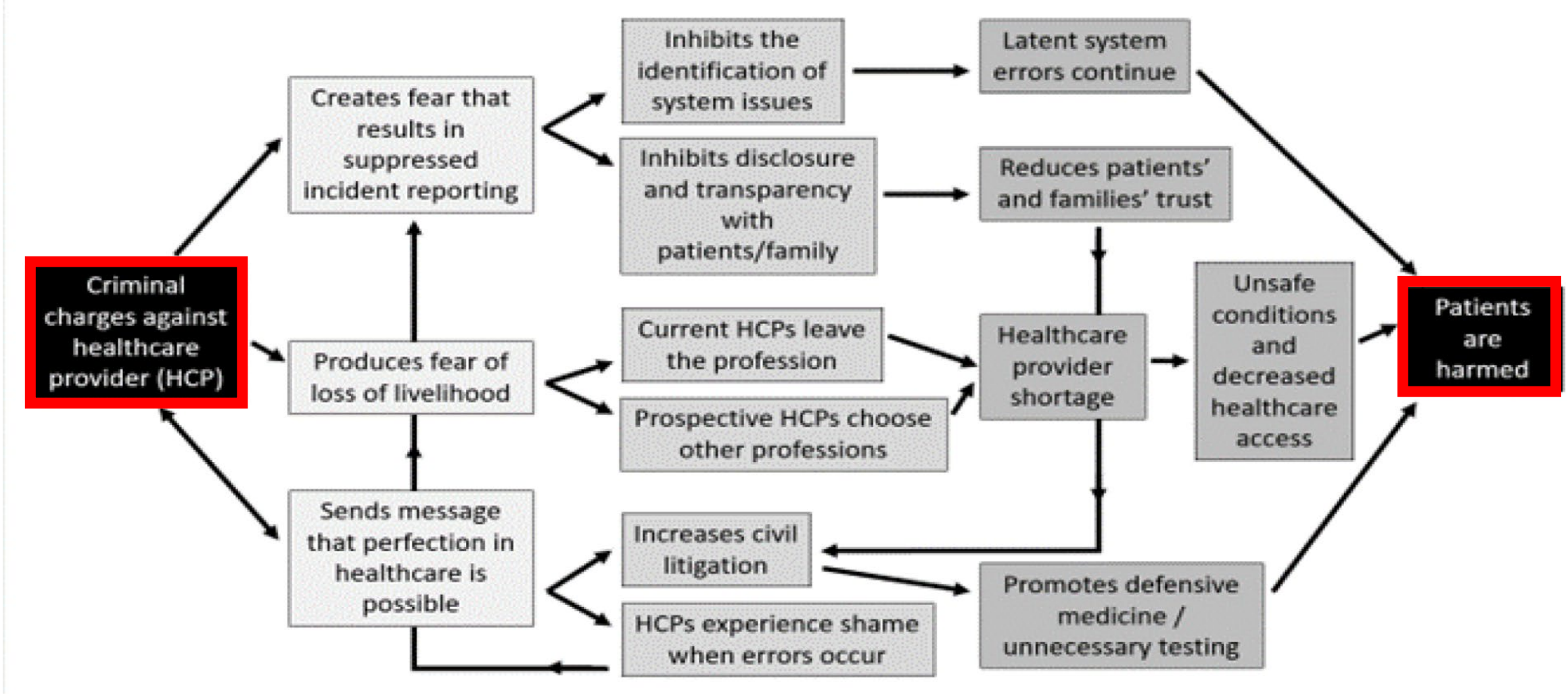
- **List of distractions/errors:**
  - Orienting a new nurse
  - Typing in VE: Receiving vecuronium
  - Issue with rollout of new EHR system
  - Culture of “normalization of deviance”
  - Overriding medication dispensing system
  - No visual checking of medication
  - Disregard of “Warning: Paralyzing Agent”
  - No double check of high-risk medication.
  - No monitoring of the reaction to drug
  - No reporting of unusual/unexpected death





BJA 2022; 129: e61-62.

Criminalization of Error:
Unintended Consequences



https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2021-2022/july-2022/criminalization-of-human-errors-in-healthcare/

Societal Organizations: Criminalization of Medical Error

APSF Criminalization Task Force

Brian Thomas, JD
Chair and Attorney

Lynn Reede, DNP, MBA
CRNA

Steven Greenberg, MD
Anesthesiologist/Intensivist

Seema Kumbhat, MD
Surgeon

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THE OFFICIAL JOURNAL OF THE ANESTHESIA PATIENT SAFETY FOUNDATION

Volume 37, No. 3, 78-107 | More than 1,000,000 readers annually worldwide | October 2022

Position Statement on Criminalization of Medical Error and Call for Action to Prevent Patient Harm from Error

by the APSF Criminalization of Error Task Force:
Jeffrey Cooper, PhD; Brian J. Thomas, JD; Elizabeth Rebello, MD; Paul Lefebvre, JD; Karen Wolk Feinstein, PhD; Lynn Reede, DNP, MBA, CRNA, FNAP; Seema Kumbhat, MD; and Steven Greenberg, MD, FCCP, FCCM

Criminal prosecution provides ***no comprehensive mechanism for exploring the underlying causes of patient harm.***

cerned by each patient adverse event that results in harm during any aspect of health care delivery, especially when the causes are preventable. We offer our heartfelt condolences to all patients and their loved ones who have been harmed by preventable adverse events. We recognize that errors occur and that health care professionals have responsibility for those errors, in particular, recognizing them and working to prevent them from reoccurring.

In the interest of patient safety, the APSF feels strongly compelled to comment on the issue of criminalization of medical error.[1,2,3] The issue recently received much attention due to the conviction of a Tennessee nurse for gross

neglect of an impaired adult and criminally negligent homicide after a patient died as the result of a medication error and failure to monitor. The Court granted judicial diversion and sentenced the nurse to three years of super-

acceptance or "normalization of deviance" that enables unsafe medical practices.[5]

In this position statement, we assert our reasons for these beliefs. Yet, we know that this recent event is representative of an incalculable number of similar events that occur in health care. It is thus equally important that we focus on preventing errors and system failures that lead to such tragic outcomes. We ***call to action*** all health care systems, professional societies, health care professionals, and appropriate government agencies to take energetic, collaborative action to create and continuously improve systems of care so that such errors are nearly impossible.

See "Position Statement," Page 80

When is it Appropriate to Prosecute HealthCare Professionals?

- Engaging in a pattern of reckless behavior
- Commits errors that lead to harm while under the influence of substances that impair performance
- Intends to harm (by definition, this is not an "error").

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See "Position Statement," Page 80

What Health Care Organizations Must do to Prevent Errors and Acknowledge Those That do Occur?

- Employ **medication safety techniques/technologies**
- Operate on the principles of a **"Just Culture"**
- **Disclose** to the appropriate authority
- Develop **multidisciplinary medication safety committee**
- Review/consider for implementation the items in the plan of correction submitted by the organization involved
- Ensure **compassionate treatment**

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See "Position Statement," Page 80

What Should Health Care Professionals Do?

- M***edication dispensing methods for high-risk drugs.***
- Only use medication dispensing unit override when required in **urgent /emergent situations**.
- Institute ***double medication verification systems***
- Ensure appropriate monitoring of patients receiving ***high-alert medications***.
- Do not contribute to **"normalization of deviance"**
- ***Empower others and yourself***

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See "Position Statement," Page 80

What the *APSF* will do if a Perioperative Professional is Unjustly Prosecuted For a Medical Error

Learn about the circumstances of event

Provide information to prosecutor about system issues and harm that would be done by prosecuting health care professional **who intended no harm and had helpful intent**.

Make public statements about **the harm of unreasonable retribution for medical error reporting to patient safety**.

Provide **comfort to the health care professional**.

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See "Position Statement," Page 80

The *APSF's Intention* to Foster Patient Safety

Make public statements about efforts by organizations/government to improve patient safety

Make best practices available to all health care practices and professionals

Make information available to patients (https://www.apsf.org/patient-guide/).

Work collaboratively with professional organizations/advocacy groups to enhance awareness of medical errors/system failures & identify and implement best solutions.

Continue to ***convene consensus processes recommendations on medication safety-***

(YOU ARE AT OUR 3rd CONFERENCE ON THIS TOPIC!).

Learning From Failure Leads to Success

- *"I've missed **more than 9000 shots in my career**. I've **lost almost 300 games**. **26 times**, I've been trusted to **take the game-winning shot and missed**. **I've failed over and over and over again in my life. <u>And that is why I succeed</u>**." — Michael Jordan*