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## 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:

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The Anesthesia Patient Safety Foundation (APSF) is the first organization created to focus solely on patient safety. For more than 35 years, the APSF has played a significant role in the dramatic reduction of harm from anesthesia and has advocated for perioperative patient safety. We are deeply saddened and concerned 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.<sup>1,2,3</sup> 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 supervised probation.<sup>4</sup> We believe the prosecution and conviction of the nurse involved was counterproductive to the pursuit of prevention of harm to future patients and health care professionals. However, we strongly advocate for systemic changes that will enhance health care's culture of safety and will reject the acceptance of "normalization of deviance" that enables unsafe medical practices.<sup>5</sup>

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.

While the APSF focuses on perioperative safety, the issues addressed here apply to all health care delivery. In addition, the APSF will take action to reduce medication errors and to advocate and support those health care professionals who are treated unfairly when they have acted in good faith in caring for their patients.



### Why does the APSF believe this criminal prosecution was unjust and counterproductive?

Based on the facts that have been reported, this most recent case represents how a combination of system and human failures combine to cause a tragic outcome. While the health care professional's responsibility for her role in this event may require education, monitoring of medication management competencies and discipline, her prosecution does not align with principles of "just culture" that are now widely accepted and improve health care.<sup>6,7</sup> This prosecution may lead to greater risk for patients when health care professionals' fear of significant retribution causes errors to go unreported and unaddressed, thus allowing the unidentified error to continue to harm more patients in the future.

Criminal prosecution provides no comprehensive mechanism for exploring the underlying causes of patient harm, including policy failures, implementation hurdles, or the impact of human factors to mitigate the risk of future error. There are no criminal mechanisms for health care to gather best practices, develop consensus statements, ideate, innovate, or deliver meaningful policy recommendations. Organizations, institutions, and individual health care professionals must instead work together to solve complex and often challenging medical issues to assure the safety of systems of care for patient best outcomes and safety.

**This type of criminal prosecution of health care professionals is fortunately very unusual and rare:**

It is rare for health care professionals to be criminally prosecuted for errors, and there is no indication the Tennessee case is representative of a trend. Specifically, the anesthesia data we have suggests that there are almost no events, with the few exceptions of truly egregious actions or inactions. Yet, many health care professionals have voiced concern that they may be similarly prosecuted for actions they have taken in good faith that led to an adverse outcome in part as a result of their error. This understandable fear could lead to health care professionals leaving the profession or failing to report errors as needed to identify and address causes of error and possible patient harm.

### Why is the APSF speaking out about this now?

Numerous health care organizations concerned about patient safety have spoken out about the injustice, unfairness, and harm caused by criminalization of medical errors. The APSF is adding its voice to this issue because of its history of advocacy for patient safety. More importantly, the APSF is going beyond criticism of the prosecution of this nurse. What is equally and more important about this event is that it illustrates the harm that is being done far too often by faulty systems of care.

The APSF was founded during a time when the focus of attention on adverse outcomes was generally to pursue tort reform to prevent unreasonable malpractice awards. Dr. Ellison C. Pierce, Jr., as President of the American Society of Anesthesiologists in 1984, took the path of calling for prevention of errors that cause adverse events as the major focus for action. Dr. Pierce was the driving force behind the creation of the APSF. We are, via this position statement, continuing in that mission by calling on actions to promote patient safety and prevent errors as the way to prevent criminalization of medical error.

If the prosecution of the nurse in this case were to prompt copycat prosecutions, that would pose a grave danger to patient safety. Equally, if not more important, this case illustrates how serious errors and adverse outcomes continue to occur and that there does not yet appear to be a nationwide safe and just culture among health care institutions that fos-

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ters reporting of poor systems of care, near misses, or errors to prevent future error and patient harm. For that reason, the APSF is urging that cases like this never be pursued by prosecutors, who should have the best interests of patients and society at heart. And we are calling to action all stakeholders to proactively assess their systems of care to identify and prevent similar events from happening across all health care settings.

### When is it appropriate to prosecute health care professionals for errors?

We acknowledge that there are some instances where criminal prosecution may be warranted, such as when a health care professional engages in a pattern of reckless behavior in providing care, commits errors that lead to harm while under the influence of substances that impair performance, or intends to harm (by definition, this is not an "error").

### What health care organizations must do to prevent errors and acknowledge those that occur:

The type of event that occurred in Tennessee is not unique among health care organizations. Despite the many successful efforts by some organizations to address patient safety issues, there is still an egregious rate of preventable harm in health care that has been hampered by a failure of all stakeholders to work collaboratively and aggressively to innovate to ensure that safety procedures, technologies, and practices are widely deployed and continuously improved. To advance patient safety, the APSF believes that health care systems and health care professionals should:

- Ensure patients and family are treated with compassion and transparency.
- Disclose to the appropriate authority (e.g., local or state) when harm resulted during the delivery of care.
- Operate on the principles of a "Just Culture" and "Culture of Safety."<sup>6,8</sup>
- Employ medication safety techniques and technologies that prevent the types of errors represented in the case in Tennessee and others nationwide. These technologies force safe function and mitigate errors contributed by human factors, and include the following:
  - Use prefilled syringes when possible.

- The use of barcode/RFID technology for removal of medications from an automated dispensing cabinet (ADC).
- Develop a multidisciplinary medication safety committee that meets regularly to evaluate all safety threats in your system.
- Create a culture, reflected in policy, where all providers have a defined mechanism to report near misses and medication errors and are encouraged to speak up without fear of retaliation and provide actionable change when patient safety threats are observed. This culture change may involve having a medication safety officer who assists providers in difficult situations involving medication administration.
- Review and consider for implementation the items in the plan of correction<sup>9</sup> submitted by the organization involved in this event with special attention to
  - transport policies
  - communication during vulnerable hand-offs.

### What can/should health care professionals do now to combat medication error and failure to monitor, and improve their organization's safety culture?

- Take action in your organization to identify and address the types of system flaws that were exposed in the case in Tennessee to prevent error.<sup>3</sup> These might include
  - Evaluate medication dispensing methods for high-risk drugs, e.g., generic vs. brand name, therapeutic area and location of use, and consider evaluation of current workflow to enhance safety checks prior to medication administration.
  - Only use a medication dispensing override when required in urgent or emergent situations.<sup>10</sup>
  - Except in case of emergency, institute double medication verification systems for all override pathways when removing medication from automated dispensing cabinets.
  - Ensure appropriate monitoring of patients receiving high-alert medications
  - Deter a culture where "normalization of deviance" and the associated practices occur.<sup>5</sup>

- Empower others and yourself to report actions that may put patients at risk and remediate those actions.<sup>7</sup>

### APSF POLICY ON CRIMINALIZATION OF MEDICAL ERROR

#### What the APSF will do if a perioperative professional is prosecuted for an error unjustly:

- Learn as much as possible about the circumstances of that event.
- If warranted, provide information to a prosecutor about system issues and the harm that would be done by prosecuting a 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 in prosecuting health care professionals.
- Provide comfort to the health care professional.

#### What the APSF will do to foster patient safety prompted by events such as this recent one:

- Make public statements about efforts by organizations and government agencies to improve patient safety, specifically medication error, which is still being given too little focus based on its frequency and the continued extent of injuries.
- Make best practices available to all health care practices and professionals that can be used to reduce medical error.
- Make information available to patients so they can actively contribute to and monitor their care plan to optimize safety.
- Work collaboratively with professional organizations and advocacy groups to enhance awareness of the problem of medical errors and system failures that lead to adverse events to identify and implement best solutions.
- Continue to convene consensus processes for recommendations on medication safety.

The APSF believes that national, state, and facility policy should hold leadership and health care providers responsible for continuous systems of care evaluation and improvement to minimize risk of patient harm due to error. One opportunity to leverage policy across health care organizations is the Centers for Medicaid and Medicare Services Conditions of Participation, which include safety requirements in each

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## Anesthesia Professionals Should Take Action to Combat Medication Error and Failure to Monitor

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chapter.<sup>11</sup> Those requirements provide accrediting organizations with a framework to continuously evaluate facility safety practices to demand improvement when necessary and to share nationally best practices as they emerge.

The APSF will take a collaborative approach with multiple stakeholders including health care professionals, health care organizations, professional societies, policymakers, manufacturers, technology companies, legal professionals, and government agencies to foster the highest level of patient safety and to prevent errors that subsequently result in patient harm.

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