



Criminal prosecution of human error: Dangerous consequences

In the past few months, three fatal medication errors have captured news headlines; according to these news reports, criminal investigations are being considered in each case. If the criminal investigations proceed, felony indictments could be levied against some or all of the practitioners involved in these errors. While each of these events resulted in a tragic loss of life, the representation of these events as criminal acts is likely to have an adverse effect on our healthcare system and its critical patient safety improvement initiatives.

In one case, a 44-year-old woman died in an emergency department after receiving 8,000 mg of phenytoin IV instead of 800 mg. The experienced nurse who administered the overdose (which required 32 vials [50 mg/mL, 5 mL] from several automated dispensing cabinets) has been targeted for criminal investigation.

In another case, a 2-year-old child died while undergoing chemotherapy after a pharmacy technician mistakenly prepared her infusion using 23.4% sodium chloride instead of 0.9%, and the pharmacist failed to notice the error. Criminal investigation of the event is under consideration.

In a third case, an elderly woman died after receiving an IV injection of potassium phosphate that was supposed to be given via a feeding tube. Court actions have been filed to request a change in the cause of death from an accident to homicide.

Though we cannot shed light on the causes of these errors, our experience with analyzing sentinel events and other errors strongly suggests that underlying system vulnerabilities played a role in each of the errors. While we are not in a position to judge the behavioral choices made by involved staff who were working within

these potentially flawed systems, we are deeply concerned about the recent events that have shed light on the criminalization of human errors in healthcare, including the criminal indictment of a Wisconsin nurse mentioned in prior newsletters.^{1,2}

Safety experts and the criminal justice system seem to be at odds regarding the proper course of action to take when a fatal error occurs. Safety experts advocate for a more just path for individuals involved in adverse events, arguing that punishment simply because the patient was harmed does not serve the public's interest.


Its deterrent effects on learning far outweigh its negligible impact on improving individual performance.

Even some professional associations and licensing boards have taken exception to the criminal prosecution of human error,³ citing that, if warranted, the licensing boards can adequately protect patients from reckless or incompetent healthcare practitioners by limiting or revoking their licenses. Safety experts and many licensing boards agree that the criminal system need only be invoked in rare cases of purposeful harm, such as a healthcare professional who molests a vulnerable patient, for individuals like this would pose a threat to both patients and society as a whole.

In the January/February 2007 issue of *The Just Culture Community News and Views*, David Marx, JD, provides valuable insight into how we have arrived at this impasse between healthcare providers and the criminal justice system.⁴ According to Marx, about 55 years ago, the US Supreme Court traced the birth of "criminal" human error, or what is now called "public wel-

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 **Error in drug references.** Incorrect dosing information for **DILAUDID** (hydromorphone) appears in several drug references, which could lead to serious overdoses. Monographs on page 815 in the 2006 *Nurse's Drug Guide* (Pearson-Prentice Hall) and page 138 in the 2006 *Nurse's POCKET Drug Guide* (McGraw-Hill Medical, 2nd edition) erroneously indicate that the dose ranges for hydromorphone are the same for oral, subcutaneous, IM, and IV routes of administration. **The same errors occur in the 2007 editions of these texts.** The usual oral dose in opioid-naïve patients is 2-4 mg every 3 or 6 hours prn; parenteral doses are typically one-fifth of oral doses, or 0.2 to 0.6 mg every 2 to 3 hours. The error was discovered by a resident after nurses questioned the doses of hydromorphone he had been prescribing using the above texts. Fortunately, no patients received the incorrect dose prescribed. The publishers for each handbook have been notified and have forwarded the information to the appropriate editors for correction in the 2008 editions. If you use either of these references, please correct the error directly in the publication and be sure to verify doses before administration. Visit www.ismp.org/Errata/default.asp for other reports of textbook errors.

 **Mucinex-Mucomyst mix-ups.** Numerous mix-ups have been reported between **MUCOMYST** (acetylcysteine), a drug used to treat acetaminophen toxicity, and **MUCINEX** (guaifenesin), a long-acting, over-the-counter expectorant. If Mucinex is administered instead of Mucomyst, serious consequences could occur in patients who should have received Mucomyst to treat acetaminophen toxicity, or for protection from contrast

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 fare offenses" to our industrial revolution. Before then, both an *evil hand* and an *evil mind* (intent to harm) were needed to label an activity as criminal. But since the advent of powerful machines that, through individual behaviors, could cause significant harm, an *evil mind* is no longer required for an action to be considered a crime. For example, automobile drivers who have been involved in an accident that caused the death of another individual might be prosecuted in most states for vehicular homicide, even if the death resulted from a human error such as failing to notice a stop sign. The reality is that mere human errors that randomly occur in well meaning people are now considered "criminal" in a number of circumstances where public safety is at issue. As noted in *The Just Culture Community News and Views*,⁴ "For whoever is unlucky enough to make one of these errors, criminal charges are only an indictment away."

Marx⁴ also contrasts the tenets of "criminal" human error with the notions of a Just Culture. In a Just Culture, human error is typically consoled as long as the individual's behavioral choices were not reckless. Thus, the quality of one's behavioral choices dictates accountability, not the human error itself and/or the severity of its outcome. In contrast to the criminal system, the question within a Just Culture is not whether harm occurred, but whether the individual consciously disregarded what he or she knew to be a substantial and unjustifiable risk.

The most recent wave of criminal investigations into errors made by healthcare practitioners is cause for concern. The law clearly allows for the criminal indictment of healthcare professionals who make errors that harm patients, despite the lack of intent to cause harm. But it will long be debated whether this course of action is required or beneficial. Its potential impact on patient safety is enormous, sending the wrong message to health-

care professionals about the importance of reporting and analyzing errors. Further, if this is just the beginning of an upward trend of criminal investigations and indictments in the wake of medical errors, it could also have a chilling effect on the recruitment and retention of an already depleted workforce of healthcare professionals.

Most healthcare professionals unwittingly put themselves at risk for criminal indictments when they enter the profession. They are fallible human beings destined to make mistakes along the way, as well as to drift away from safe behaviors as perceptions of risk fade when trying to do more in resource strapped professions.⁴ But it may not take long for practitioners to see that they have put themselves in harm's way, forced to accept punishment from the criminal (and civil) system for honest mistakes. Many practitioners already fear making that one error that could harm a patient. Escalating application of criminal error laws serves as a reminder that a harmful error—often similar in form to minor mistakes we all make daily—could also strip away a hard-earned and cherished livelihood and personal freedoms perhaps once taken for granted.

For more information on this important topic, please visit www.justculture.org/downloads/newsletter_jan-feb07.pdf to read the January/February 2007 issue of *The Just Culture Community News and Views*. Referred to as the "Criminal Edition" by its editors, the newsletter offers more in-depth discussion about this subject matter so critical to creating strong, safety cultures. Both ISMP (ismpinfo@ismp.org) and the Just Culture Community (info@justculture.org) welcome your feedback.

References: 1) *ISMP Medication Safety Alert!* Since when is it a crime to be human? 2006; 11(23):2. 2) *ISMP Medication Safety Alert!* News update: tragedy brings a measure of good. 2007; 12(1):2. 3) Wisconsin Nurses Association. Nurses stunned by criminal charges. November 3, 2006. Accessed at: www.wisconsinnurses.org/docs/AVNA%20Press%20Release%2011.3.06.pdf. 4) *The Just Culture Community News and Views*. The Criminal Edition. Marx D, Cassidy KM. Eds. January/February 2007.

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media-induced nephropathy. Both medications may be prescribed orally in doses of 600 mg every 12 hours, as in one of the most recent reports of potential mix-ups between these two products. In this case, a pharmacist found it unusual when he received a transcribed verbal order for Mucomyst 600 mg orally every 12 hours with no specified stop date or total number of doses. He also found that the patient, who was admitted for bronchitis, did not have an acetaminophen overdose and was not being prepped for renal protection prior to receiving IV contrast media. He called the physician and learned that the intended medication was Mucinex. Simple read-back of the verbal order might not have helped detect the error in this case, as the drug names sound so much alike when spoken and the doses and route of administration were the same. Spelling drug names can help avoid mistakes when reading back verbal orders. But in reality, most practitioners would not do this unless they were unsure of the drug being prescribed, which apparently was not the case in the above-cited error. However, it would be reasonable to make a habit of asking the prescriber for the drug's indication or communicating your understanding of its intended purpose to ensure the medication makes sense in the context of the patient's condition. Unless Mucomyst is ordered by nebulization, as a mucolytic, a stop date should always be included with the order. The nurse should also include the patient in the verification process whenever possible.



Report on reporting values.

Hospitals and clinical laboratories set "critical" laboratory values (also called panic values) to reflect results that imply a life-threatening situation, thus requiring immediate action. By protocol, these values should be brought to the immediate attention of the patient's primary physician or a licensed health professional designee,

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Pregnancy alert: Can't touch this!

A pregnant nurse was splitting a tablet of **TRACLEER** (bosentan) for a pediatric patient with pulmonary arterial hypertension. After she administered the medication, she learned that Tracleer is a pregnancy category X drug with a black box warning about the likelihood of serious birth defects if taken during pregnancy. She was concerned that contact with a broken tablet or inhalation of tablet dust could adversely affect her pregnancy. According to the FDA, studies in animals or pregnant women have demonstrated evidence of fetal abnormalities, thus the drug is contraindicated in women who are or may become pregnant.

Because of this risk and the potential for serious liver injury, Tracleer must be prescribed through a limited access program which requires patient screening. However, the package insert and medication guide distributed with the drug contain no special handling instructions for healthcare personnel, and no warnings about crushing or splitting tablets. When the manufacturer (Actelion Pharmaceuticals US) was called, a representative confirmed that gloves should be worn if female personnel handle broken tablets, as the safe limit for occupational exposure of Tracleer is very low.

In response to a request for precautions in writing, the manufacturer forwarded information about dissolving

and cutting tablets. The information stated: "It is not recommended to crush the tablets before dissolving them. Exposure to dust from crushed Tracleer tablets should be avoided and appropriate precautions should be taken (e.g., mask and gloves). Women of child-bearing potential, in particular, should avoid exposure to the dust." As for cutting tablets to prepare a 31.25 mg dose from the 62.5 mg tablet, pharmacy staff should adhere to precautions, use a commercial pill cutter, and then safely repackage, label, and dispense the drug. Pharmacies may also place warnings on the MAR to make practitioners aware of the risk to pregnant nurses.



Special handling information should always be included in the package insert so safety policies can be implemented. There is precedent for such labeling with **PROSCAR** (finasteride), which states, in part: "Women should not handle crushed or broken tablets of Proscar when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus." A phone call to the manufacturer should not be required to obtain this information. ISMP has notified the company and FDA about this concern. A complete list of teratogenic drugs can be found in the *Red Book, Pharmacy's Fundamental Reference*, found in most pharmacies.

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as required by Joint Commission's National Patient Safety Goal 2a (which also requires the recipient to read back values communicated verbally). Critical lab values should not be communicated to a non-licensed worker, as occurred in the following situation. A patient had morning labs drawn, and a critical potassium value was detected (6.8 mEq/L). Per policy, the lab technician immediately called the nursing unit to report the value. A unit secretary took the call and wrote down the lab value but became distracted and forgot to pass the information on to a nurse. Although eight physicians tended to the patient over the next day and a half, no one noticed the lab report on the chart, thus treatment for hyperkalemia was not ordered. Thirty-six hours later, the patient's routine labs showed a potassium level of 9.4 mEq/L. Medical staff were alerted this time, labs were redrawn, and the potassium level was confirmed. A hemolytic process was suspected, and treatment and monitoring was initiated. To prevent future incidents, the hospital has implemented a policy that all critical lab values MUST be communicated to a licensed healthcare professional. In addition, it is now hospital and lab policy that critical lab values must be documented as such in the patient's permanent record to alert all caregivers prior to posting of the final report.

► Special Announcements

High-alert drug survey! We are reviewing our list of high-alert drugs and would appreciate your input by completing the short survey on page 4. Please submit your responses by **April 13** via our Web site at www.ismp.org/survey/survey200702.asp (or fax to 215-914-1492 if Internet access is unavailable). We encourage all readers to participate.

Join ISMP at the unSUMMIT! *Bedside Barcode Technology in Practice*, a 2-day conference, will be held on **May 9-11**. Basic and advanced tracks are available as well as a post-conference workshop by ISMP on using bar-code point-of-care data. For information, visit: www.unsummit.com.

Purchase discounted ISMP book! *Medication Errors* (2007) is now being offered with a month-long discount of \$10 in tribute to Patient Safety Awareness Week in March. For details, visit: www.ismp.org/products/medErrsEd2/default.asp.

ISMP Medication Safety Alert! *Nurse Advise-ERR* (ISSN 1550-6304) ©2007
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Report medication errors to ISMP at 1-800-FAIL-SAF(E).

2007 ISMP Survey on High-Alert Medications

Please take a few minutes to complete our short survey on high-alert medications (see definition below), and submit your responses by **April 13, 2007**, via our Web site at: www.ismp.org/survey/survey200702.asp (or fax to 215-914-1492 if Internet access is unavailable). High-alert medications are those that bear a heightened risk of causing significant patient harm when they are used in error. Although errors may or may not be more common with these medications, their consequences are often more devastating. For **Section A**, indicate whether YOU believe these drugs or class of drugs should be considered high-alert medications. For **Section B**, indicate whether YOUR PRACTICE SITE considers each drug or class of drugs a high-alert medication, with special precautions in place when using them. Under “Others,” please include drugs not on the list that YOU would consider high-alert medications.

Medication or Class of Medications	Section A		Section B		Comments
	Do <u>YOU</u> believe this is a high-alert medication?		Does <u>YOUR PRACTICE SITE</u> consider this a high-alert medication with special precautions in place?		
A. Current List	Yes	No	Yes	No	
1) adrenergic agonists, IV (e.g., epinephrine)					
2) adrenergic antagonists, IV (e.g., propranolol)					
3) anesthetic agents, general, inhaled and IV (e.g., propofol)					
4) cardioplegic solutions					
5) chemotherapeutic agents, parenteral					
6) chemotherapeutic agents, oral					
7) dextrose, hypertonic, 20% or greater					
8) dialysis solutions, peritoneal and hemodialysis					
9) epidural or intrathecal medications					
10) glycoprotein IIb, IIIa inhibitors (e.g., eptifibatide)					
11) hypoglycemics, oral					
12) inotropic medications, IV (e.g., digoxin, milrinone)					
13) liposomal forms of drugs (e.g., liposomal amphotericin B)					
14) moderate sedation agents, IV (e.g., midazolam)					
15) moderate sedation agents, oral, for children (e.g., midazolam, chloral hydrate)					
16) narcotics and opiates, IV, transdermal, transmucosal, oral liquid concentrates					
17) neuromuscular blocking agents (e.g., succinylcholine)					
18) radiocontrast agents, IV					
19) thrombolytics/fibrinolytics (e.g., tenecteplase)					
20) total parenteral nutrition solutions					
21) amiodarone, IV					
22) colchicine injection					
23) heparin, low molecular weight, injection					
24) heparin, unfractionated, IV					
25) insulin, subcutaneous					
26) insulin, IV					
27) lidocaine, IV					
28) magnesium sulfate injection					
29) methotrexate, oral, non-oncologic use					
30) nitroprusside, sodium, injection					
31) potassium chloride for injection					
32) potassium phosphates injection					
33) sodium chloride injection, hypertonic, more than 0.9% concentration					
34) warfarin					
B. New drugs/products to consider					
1) epoprostenol (FLOLAN)					
2) promethazine injection, IV					
3) oxytocin					
4) others: please list					

Please place a checkmark in the box that best describes your professional designation:

()Nurse ()Pharmacist ()Pharmacy Technician ()Physician ()Administrator ()Risk/Quality/Safety Manager ()Other