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Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

TN Board of Nursing's unjust decision to revoke nurse's license: Travesty on top of tragedy!

ISMP was shocked, discouraged, and deeply saddened to learn that the Tennessee (TN) Board of Nursing recently revoked RaDonda Vaught's professional nursing license indefinitely, fined her $3,000, and stipulated that she pay up to $60,000 in prosecution costs. RaDonda was involved in a fatal medication error after entering "ve" in an automated dispensing cabinet (ADC) search field, accidentally removing a vial of vecuronium instead of **VERSED** (midazolam) from the cabinet via override, and unknowingly administering the neuromuscular blocking agent to the patient. You can read the details of the error in three of our 2019 newsletters (www.ismp.org/node/1326, www.ismp.org/node/1389, www.ismp.org/node/26653). While the Board accepted the state prosecutor's recommendation to revoke RaDonda's nursing license, ISMP doubts that the Board's action was just, and we believe it set us back 25 years in patient safety.

Timeline of Events

In December 2017, RaDonda made a fatal medication error when administering vecuronium rather than Versed to a patient in radiology. Late in 2018, the hospital was investigated by the Centers for Medicare & Medicaid Services (CMS) after an anonymous whistleblower came forward to report the fatal error (www.ismp.org/ext/744). After CMS released its report (www.ismp.org/ext/738), RaDonda was indicted, arrested, and charged with criminal reckless homicide and impaired adult abuse. Disciplinary action against her license was then filed. Both the disciplinary hearing against her license and the criminal trial were delayed due to the coronavirus disease 2019 (COVID-19) pandemic. Last month, the TN Board of Nursing disciplinary hearing was held on July 22 (www.ismp.org/ext/741) and July 23, 2021 (www.ismp.org/ext/742). RaDonda's criminal trial is scheduled to begin on March 21, 2022. See **Table 1** (page 2) for a more detailed timeline of events.

Licensing Disciplinary Hearing

On September 27, 2019, in a stark reversal of a 2018 decision to take no licensing action against the nurse (www.ismp.org/ext/737), the TN Board of Nursing filed disciplinary action against RaDonda that focused on three violations (www.ismp.org/ext/740):

- Unprofessional conduct related to nursing practice and the five rights of medication administration
- Abandoning or neglecting a patient requiring nursing care
- Failure to maintain a record of interventions

The Board called for the revocation of RaDonda's nursing license and fines of up to $3,000.

During the hearing, RaDonda was given an opportunity to testify and defend herself; however, she never shrank from admitting her mistake. According to her defense attorney, her acceptance of responsibility for the error was immediate, extraordinary, and continuing. However, RaDonda also testified that the error was made because of flawed procedures at the hospital, particularly the lack of timely communication between the pharmacy computer system and the ADC, which led to significant delays in accessing medications and the hospital's permission to temporarily override the ADC to obtain prescribed medications that were not yet linked to the patient's profile in the ADC.

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Weapon of mass destruction? Recently, a pharmacy that was using a vial dispensing robot was in the process of refilling one of the cassettes (cells) with traZODone 50 mg tablets. The person refilling the machine retrieved two 500-count medication bottles from a storage shelf, but without realizing it, one of the containers held topiramate 50 mg, not traZODone 50 mg. Both medications are manufactured by Zydus Pharmaceuticals and look nearly identical (**Figure 1**), and one bottle was sitting right behind the other

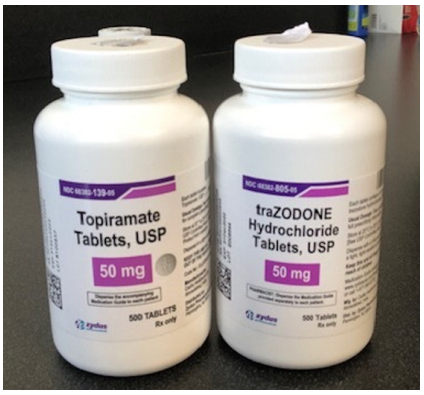

Figure 1. Look-alike containers of topiramate and traZODone from Zydus.

where they were stored on the shelf. Both tablets are round, white, and about the same size. The traZODone tablet is scored and has a tablet code on one side. However, the reverse side is smooth and without any markings. Topiramate tablets look very similar but are not scored (**Figure 2**). Thus, it is not only the bottles that look alike, but

Figure 2. Topiramate 50 mg and traZODone 50 mg tablets also look alike.

so do the tablets. Fortunately, before anyone received the wrong medication, a pharmacist caught the filling error while verifying a prescription for traZODone 50 mg when she

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Although many questions regarding RaDonda's alleged failures and the event remain unanswered (**Table 2**, page 5), the Board still voted unanimously to strip RaDonda of her nursing license and levy the full monetary penalties allowed, noting that there were just too many red flags that RaDonda "ignored" when administering the medication.

Concerns with Board Deliberations and Decisions

Believing the best in everyone, ISMP has faith that the TN Board of Nursing likely had the right, albeit misguided, intention to protect the citizens of TN. Furthermore, we recognize how difficult it is to be conferred with the responsibility of protecting the public. However, was the Board's action fair and just in this situation? You can draw your own conclusions by viewing the 2-day hearing, but the following is what ISMP finds most disturbing and unjust about the Board's decision to revoke RaDonda's license:

Significant outcome bias. It seemed the Board was holding a disciplinary hearing primarily because the patient had died, so there was a significant outcome bias. In fact, the Board has not filed disciplinary action against all TN nurses who have not read a medication label carefully, obtained a nonurgent medication from an ADC via override, drawn an incorrect conclusion, failed to monitor a sedated patient, or failed to document a medication error in the patient's record. As ISMP knows well from the vast number of error reports received, even the most careful and competent practitioner might make these mistakes or drift into unsafe practice habits without recognizing the risks. An outcome bias often results in over-reacting to a singular event with unwarranted disciplinary action, or under-reacting to a system design flaw if the outcome is not harmful. We believe this is what happened here. As one Board member noted, "I feel like, as humans, every one of us make mistakes, none of us are perfect. But mistakes were made. And mistakes have consequences"…but apparently not for those lucky enough to avoid patient harm.

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Table 1. Timeline of important dates

Dates	Description
December 26, 2017	■ Nurse administers IV vecuronium instead of Versed (midazolam).
December 27, 2017	■ Patient involved in medication error is withdrawn from life support and dies.
January 3, 2018	■ Hospital fires nurse for not following the five rights of medication administration.
January 2018	■ Hospital settles with patient's family, requiring them to not speak about the error publicly.
October 3, 2018	■ Anonymous whistleblower alerts state/federal agencies about the fatal error (www.ismp.org/ext/744).
October 23, 2018	■ TN Department of Health (Nursing Board) decides not to pursue disciplinary action against the nurse and sends the hospital and nurse a letter affirming its decision (www.ismp.org/ext/737).
October/November 2018	■ In response to the whistleblower, CMS conducts a surprise hospital inspection.
November 2018	■ CMS releases details of the error, and the hospital submits a plan of correction (www.ismp.org/ext/738).
February 4, 2019	■ Nurse charged with criminal reckless homicide and impaired adult abuse.
March 27, 2019	■ State investigators allege nurse made 10 separate errors, including overlooking warning signs (www.ismp.org/ext/739).
September 27, 2019	■ TN Department of Health (Nursing Board) reverses its prior decision to not pursue discipline against the nurse and charges her with unprofessional conduct, abandoning/neglecting a patient, and failing to document the error (www.ismp.org/ext/740).
May 20-21, 2020	■ Nurse's disciplinary hearing is scheduled but delayed due to the pandemic.
July 13, 2020	■ Nurse's criminal trial is scheduled but delayed due to the pandemic.
July 22-23, 2021	■ Nurse's disciplinary licensing hearing is held. ■ Board revokes the nurse's professional license and fines her $3,000.
March 21, 2022	■ Nurse's criminal trial is scheduled to begin.

Adapted from: Kelman B. The RaDonda Vaught case is confusing. This timeline will help. *Nashville Tennessean*. July 23, 2021. www.ismp.org/ext/743

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recognized that the two drugs appeared to be mixed together in the prescription vial.

The pharmacist who reported this error told us that the software her pharmacy uses requires barcode scanning, but unless you scan each stock bottle individually, the technology can be bypassed by scanning just one bottle. That is, if you are trying to add 1,000 tablets and the medication comes in a 500-count bottle (which is how both above medications are supplied), you can just scan one of the bottles, then pour both bottles (one being the incorrect medication in the unscanned bottle) into the dispensing robot cell. Now, the pharmacy permits using only one bottle at a time to restock the robot.

Pharmacies with robotic dispensing capabilities need to address situations in which multiple bottles of tablets are used to refill a cassette. This should always require a scan of the cassette and the label of *each bottle* being added, with each scan documented. Two individuals need to be involved, each providing an independent double check and ensuring that all steps are followed. Visual checks are important, but as described above, cannot be solely relied upon for proper identification of bottle contents when more than one bottle is being used. Use only unopened stock bottles to ensure the national drug code (NDC) number, lot number, and expiration date match for all tablets (2D barcodes would be needed). Check with your robotics manufacturer to learn what is recommended to address situations in which multiple bottles are used to refill a cassette. Some systems allow for a final check for accuracy, comparing the pills in the vial with a computer screen image of the drug. Other systems require two independent barcode verifications and entry of a matching lot number and expiration date prior to unlocking the cell for refill. Finally, completing the entire process of filling one cell before moving to the next cell and corresponding drug bottle(s) is critical to ensure that bottles used to refill different cells are not mixed up after barcode verification. Two individuals are also needed to independently double check cassette assignment changes.

It is also undeniable that look-alike product labeling and packaging was a root cause of the mix-up. We always recommend read-

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Inability to differentiate between human error, at-risk behavior, and reckless behavior. According to the prosecutor, the Board has a policy that differentiates between human error, at-risk behavior, reckless behavior, and bad intent. While the prosecutor noted that RaDonda did not act with bad intent, he alleged that she did act recklessly. However, ISMP believes her actions were either unintentional (human error) or at-risk behaviors, not reckless behaviors. RaDonda could not have consciously disregarded a substantial and unjustifiable risk—a requirement for reckless behavior—because she had no idea that she had made a mistake. She did not read the front of the medication label due to either a momentary distraction (error) or an unsafe practice habit (at-risk behavior). Furthermore, the Board did not determine whether RaDonda saw the risk associated with her behavior as substantial and disregarded it, and whether her internal risk monitor fired—that little voice that creeps into our conscious thoughts and lets us know we are in danger. When an individual is engaged in at-risk behavior, their internal risk monitor is silent. And while RaDonda made a conscious decision to not monitor the patient or scan the medication's barcode, she was told that monitoring was not required, and barcode scanning technology was not available in radiology.

Lack of a thorough investigation. The Board relied on an incomplete investigation of the event, particularly related to the question, "What normally happens in similar circumstances?" For example, the investigation had failed to examine prior patients who were anxious about radiology scans due to claustrophobia to see what normally happens—did these patients receive oral anxiolytics or IV sedatives? Were they monitored and by whom and for how long? In addition, incorrect assumptions were made about the system capabilities based on present conditions rather than conditions at the time of the event. For example, the Board considered neuromuscular blocking agent warnings on the ADC screen and shrink wrap sleeves over the vials to be red flags overlooked by RaDonda, when both had been added to improve the warning system *after* the event occurred. Questions posed to witnesses were also misleading as they were directed at current conditions and not correlated to the conditions that existed in 2017. Furthermore, the answers to these questions at the time of the event appeared to be unknown to the prosecution.

Failure to consider the significant contribution of system failures. The prosecutor acknowledged that the hospital had various system failures that contributed to the error; however, he stressed that the Board is "not here to look at the system" and is instead looking at "individual conduct." Thus, the Board judged RaDonda's behavior in isolation of the contributing system failures. Yet, the primary way to determine the differences between at-risk and reckless behavior is to carefully consider the system-based causes that might have contributed to the behavioral choices. The Board seemed to hold RaDonda accountable for not overcoming any of the hospital system failures that, in turn, set her up for failure. In the end, the prosecutor made the statement that, "Nothing [the hospital] could have done would have made the respondent [RaDonda] meet the standards of nursing practice… She admitted to alarm and warning fatigue…. More warnings would not have changed her performance."

Unreasonable expectations. To determine what a "reasonable nurse" would do, the Board used a null hypothesis (suggesting no differences between nurses working in different systems) with a rigid lens in a vacuum, not actual nurses who were similarly situated, often leading to unreasonable expectations of a nurse. For example, one Board member suggested that a "reasonable nurse" would have transported the patient out of the radiology unit to a patient care unit that used barcode technology so she could scan the barcode on the medication prior to administration. What is NOT in dispute is that the hospital could have made barcode scanning technology a priority in radiology, given its high reliability for managing the risk of a competent, caring nurse showing up with the wrong drug in hand, as happened here. The same Board member said a "reasonable nurse" would have brought appropriate monitoring equipment and oxygen to radiology to monitor the patient, despite repeated discussions with the primary care nurse who

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ing medication labels three times—when obtaining a drug from storage, during use, and when discarding the container or returning it to stock. However, the need for companies to prevent container labels from looking similar across multiple items within a company's product line is among the topics included in draft guidance for industry from the US Food and Drug Administration (FDA), *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (www.ismp.org/ext/473). ISMP also has commented on the need for industry to step up their efforts to alleviate errors through premarket evaluation of pharmaceutical product labeling and packaging (www.ismp.org/node/24533). We asked Zydus to revise the product labeling that contributed to this error and also to look at all of their product labels for such safety issues.

It is important to share stories like this with staff who use this type of automation to emphasize the importance of scanning each bottle (rather than one bottle multiple times) and verifying the screen image of the markings on tablets contained in each bottle. Always keep in mind that automation is like nuclear energy; it can power your system and processes if managed appropriately, or it can be a weapon of mass destruction! So says pharmacist colleague Winson Soo-Hoo of Children's Hospital of Philadelphia, who is also an ISMP advisor.

Update on need for a pegfilgrastim formulation for pediatric dosing. A *Safety Brief* in our July 15, 2021, newsletter discussed error reports involving pediatric patients who required pegfilgrastim (**NEULASTA**) as outpatients. The product is only available in a 6 mg (0.6 mL) prefilled syringe from the sponsor, Amgen, and biosimilar manufacturers. Although the package insert includes a table for weight-based dosing of pediatric patients under 45 kg who need less than 0.6 mL, there is no vial to withdraw such a dose, and the prefilled syringe has no graduation marks to aid in measurement. Parents are often instructed to withdraw a partial dose from the prefilled syringe using an empty sterile syringe and needle. However, in some cases, this is not done correctly, and some children have been given the entire contents of the syringe.

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explicitly noted that no monitoring was required. To cite another example, the prosecutor stated that a "reasonable nurse" would have seen that the ADC defaulted to searching by the generic drug name, not the brand name (which was difficult to notice at the time), rather than recognizing that the capability of the ADC to simultaneously search by brand and generic names would have been so much more effective.

Accountability for not following the five rights. The prosecutor repeatedly referred to achieving the five rights of medication administration as "good nursing practice" and stated that, "Minimally competent nursing practice requires that all five rights… be followed." As presented, this appears to mean that nurses have a personal responsibility to produce the outcomes of the five rights, without error and irrespective of any system performance-shaping factors. But the five rights are merely broadly stated goals or desired outcomes of safe medication practices that offer no procedural guidance on how to achieve these goals. Yet, a "failure to follow the five rights" is often cited as a performance deficit when a medication error occurs, clearly perpetuating the mistaken belief that healthcare practitioners can be held individually accountable for achieving these goals. To be clear, nurses cannot be held accountable for achieving the five rights; they can only be held accountable for following the processes that their organizations have designed and held out as the best way to verify the five rights. If reading the front of the medication label was the best way to confirm the drug in hand, then RaDonda failed in that regard. But whether this happened due to human error or at-risk behavior, or reckless behavior as alleged by the Board, is at odds.

Failure to recognize self-blame in "second victims." During the hearing, RaDonda appeared to fall on the sword of guilt, remorse, self-doubt, loss of confidence, and a wish to make amends. These are all common symptoms of the deeply personal, social, spiritual, and professional crisis experienced by "second victims" of fatal errors (www.ismp.org/node/728). She said through tears at the hearing, "I won't ever be the same person. When I started being a nurse, I told myself that I wanted to take care of people the way I would want my grandmother to be taken care of. I would have never wanted something like this to happen to her, or anyone that I loved, or anyone that I don't even know. I know the reason that this patient is no longer here is because of me." Unfortunately, the Board members seemed to interpret this only as a clear admission of guilt and did not appear to acknowledge the psychological pain RaDonda is still experiencing as a "second victim" of a fatal error.

Conclusion

ISMP believes the TN Board of Nursing's disciplinary processes and judgment of RaDonda's actions during this event are NOT aligned with the tenets of a Just Culture. In a Just Culture, inadvertent behavior (human error) is not worthy of disciplinary sanction, regardless of the outcome, and the quality of behavioral choices made during an event are thoroughly examined to determine whether there was conscious disregard of significant risks. Also, disciplinary sanctions are not imposed for at-risk behaviors, including not following the rules; any system design failures that may have contributed to not following the rules must be examined and factored into the judgment of the behavior.

It is not our intent to embarrass or diminish the TN Board of Nursing by pointing out what we find disturbing or unjust in the deliberations of this complex matter, but rather to find a better way to achieve justice, learning, and improvement in safety. As RaDonda's defense attorney said during the hearing, "Rather than revoking this good nurse's license, there needs to be another… way." If we don't find it, we risk jeopardizing the opportunity to recruit talented people into the healthcare field—they won't want to join a profession where an unintended mistake could end in the loss of their license or even jail time. Also, healthcare practitioners, including nurses, will not want to speak up when they make an error, which will cripple learning, prevent the recognition of the need for system redesign, and set the healthcare culture back to when hiding mistakes and punitive responses to errors were the norm.

Table 2 appears on page 5 — Revoke nurse's license >

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We learned last week that, in October 2019, the US Food and Drug Administration (FDA) issued an "Order Letter" to the sponsor of Neulasta for a post-marketing requirement or commitment that includes the development of an appropriate formulation that can be used to administer Neulasta directly and accurately to pediatric patients who require doses less than 6 mg. FDA also sent similar letters to the pegfilgrastim biosimilar manufacturers. FDA called upon these companies to conduct any necessary human factors studies to evaluate the ability of practitioners and/or caregivers to measure the appropriate doses. In the letter, FDA stated that a pediatric presentation, such as a vial or a pediatric-sized, prefilled syringe (with a suitable concentration) would be an "appropriate formulation" alternative.

Special Announcements

Practitioner in Residence (PIR) program

Our next virtual Practitioner in Residence (PIR) program is scheduled for **August 23-27, 2021**. The PIR program is designed to meet the specific safety and planning needs for practitioners with oversight of medication safety in their organizations. Participants will learn to use ISMP's unique model for identifying and controlling areas of risk exposure, which can also help meet regulatory and accreditation requirements. Participants will also leave with comprehensive resources to support ongoing safety efforts at their organization. To learn more or to enroll, please call ISMP at 215-947-7797 or visit: www.ismp.org/node/872.

Accepting CHEERS AWARDS nominations

Each year, ISMP honors individuals, organizations, and groups from various healthcare disciplines that have demonstrated an exemplary commitment to medication safety through innovative projects with an **ISMP CHEERS AWARD**. The AWARDS will be presented in December—more to follow on the celebration! Nominations will be accepted through **September 10, 2021**. Please refer to a checklist of **DOs and DON'Ts** when submitting a nomination for a CHEERS AWARD. To submit a nomination, visit: www.ismp.org/node/1036.

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Table 2. Nurse's alleged failures and unanswered questions about the event

Alleged Failures	Unanswered Questions
Unprofessional Conduct Related to Nursing Practice	
Nurse failed to verify the physician's order for Versed and administered the drug based on the primary nurse's oral directions.	Disputed failure. Nurse claims that after failing to find the order in the patient's profile in the ADC, she called the charge nurse to make sure the order had been placed, and then entered an empty room and checked the patient's electronic health record (EHR) to verify the physician's order before returning to the ADC to withdraw the drug via override.
Nurse retrieved a nonurgent medication from the ADC via override.	Undisputed failure but most likely at-risk, not reckless, behavior. At the time of the error, the EHR, ADC software, and pharmacy computer system were not communicating properly, leading to significant pharmacy order verification delays. Thus, the nurse obtained the drug via override, as all nurses did per hospital directives, to temporarily address the system issue. It is unlikely that the nurse perceived a significant or unjustifiable risk associated with obtaining medications via override. (The patient involved in the error received 20 different medications obtained by various nurses via ADC override during her hospitalization.)
Nurse was distracted while talking to an assigned orientee while retrieving the medication from the ADC.	Undisputed failure but most likely at-risk, not reckless, behavior. During the investigation, it was never determined whether other nurses would talk to an orientee while pulling medications from an ADC. Also, the degree to which distractions were tolerated by the nurse, as well as by other hospital nurses, was never determined. Nor did anyone consider if the nurse recognized the risk associated with talking to the orientee while pulling medications from the ADC at the time of the error.
Unprofessional Conduct Related to the Five Rights: Wrong Drug	
Nurse did not verify that the proper medication was removed from the ADC.	Undisputed failure but most likely human error, not reckless behavior. The nurse was surprised that the medication was a powder, so she turned the vial over quickly to look at the reconstitution directions on the back of the label, without looking at the front of the label (and product name). While the Board believed it was conscious disregard to not read the label, this is likely human error, as it happened inadvertently when she saw that the drug was a powder and quickly turned the vial over. If it was a choice to not read the front of the label, at worse, it would be an at-risk behavior since most decisions are made on the fly in the subconscious, without the risk monitor firing.
Nurse did not verify that the proper medication was administered to the patient.	Undisputed failure but most likely at-risk, not reckless, behavior. The nurse was distracted (talking to an orientee) while preparing the medication and failed to read the full medication label. Also, the nurse was used to scanning the barcode on drug labels for verification and tried to locate a scanner to do so while in radiology, but to no avail—barcode scanning technology was not available in radiology.
Nurse did not see or heed the warning on the vial cap/ferrule, "**Warning—Paralyzing Agent**," while reconstituting the drug.	Undisputed failure but most likely human error, not reckless behavior. "**Warning—Paralyzing Agent**" has been previously overlooked or misunderstood with other neuromuscular blocking agent errors. Given this, ISMP recommends placing bold auxiliary labels on storage bins, ADC pockets, and containers of neuromuscular blocking agents that state: "**Warning: Paralyzing Agent—Causes Respiratory Arrest—Patient Must Be Ventilated**" to clearly communicate that respiratory paralysis will occur and ventilation is required. Also, the nurse believed she had the intended medication in hand (Versed) and likely subconsciously screened out the warning (confirmation bias) while completing the task at hand, or processed the warning in her subconscious rather than conscious thoughts (inattentional blindness).
Unprofessional Conduct Related to the Five Rights: Wrong Dose	
Nurse could not know the dose of the drug she administered if she had not read the label and knew the concentration.	Disputed failure. The nurse believed she administered the prescribed dose of 1 mg (which was actually vecuronium, not Versed) after reading the directions for reconstitution on the label, correctly reconstituting the drug, and administering 1 mL of the reconstituted drug. However, this failure is substantively unimportant relative to the wrong drug error.
Abandoning or Neglecting the Patient	
Nurse did not monitor a patient who had received an IV sedative that is sometimes used for moderate sedation.	Disputed failure. The nurse claims that she questioned the need for monitoring the patient and was told that monitoring was not required. Also, hospital policy did not require monitoring after Versed administration, and the drug was not mentioned in the moderate sedation policy or the hospital's high-alert medication list. Investigation of the event did not include examination of recent sedation for claustrophobic patients in radiology or sedation with IV Versed to determine whether monitoring had occurred previously.
Nurse could not carry out the physician's order to repeat the first dose if "insufficient" because she did not monitor the effectiveness of the first dose.	Disputed failure. Adherence to the physician's order is oddly linked by the prosecutor to the nurse's alleged failure to monitor the patient. The nurse questioned the need to monitor the patient, which was framed around the need to bring monitoring equipment along for use in radiology. After discussions on this topic, the nurse did not think she had a duty to monitor the patient. Also, during investigation of the event, it was not determined whether previous patients in radiology had been monitored after receiving an IV sedative.
Failure to Maintain a Record of Interventions	
Nurse failed to document vecuronium administration to the patient in the EHR.	Undisputed failure. However, the nurse was unable to document medication administration in the EHR or electronic medication administration record (MAR) while in radiology. By the time she arrived back in the intensive care unit (ICU), she learned of her error and immediately reported it and completed an event report. Also, it cannot be asserted that the failure to document in the EHR contributed to the patient's harm or denied her any opportunity for recovery. RaDonda's immediate verbal disclosure to the team treating this patient far exceeded any benefit that would have been available through documentation.

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