

## LEGAL CAPSULES

By

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Hello again, and welcome to this issue's "Legal Capsules". Limitations. We all have them, but do you know what your limitations are as a pharmacist or pharmacy technician? How should you know? There is an ancient Chinese proverb that states, "May you live in interesting times", and while this saying is both a blessing and a curse, there is no doubt that we are living in those "interesting times" as this particular article will point out. I'll warn you at the outset, this case has raised more questions for me than I have answers for, and I definitely think it is headed down a slippery slope that none of us want to tread. Unfortunately, we may be forced to walk that path depending on the final outcome. If any of you have any comments or opinions after reading this, please let me know, as I would like some feedback on what you think. With that being said, let's get into it.

### ***WHEN DID THE COMMISSION OF AN ERROR BECOME A CRIME???***

This case involves an Ohio pharmacist who committed a dosing error that killed a 62-year-old chemotherapy patient. The pharmacist was to prepare an intravenous solution of Adriamycin® and vincristine that was supposed to be administered over a four-day period on an outpatient basis. Instead, the pharmacist dispensed a dosage that was four times as strong as what was intended and the patient died from the overdose. In addition to a civil suit filed on behalf of the decedent's estate, the pharmacist was charged by a grand jury with one count of involuntary manslaughter, and was fined \$1,500 (the maximum allowable under Ohio law) by the Ohio State Board of Pharmacy. In justifying its assessment of a fine, the Board of Pharmacy reported that the pharmacist was used to dispensing medications involving no more than a 24-hour dose and that he was not familiar with dispensing medications that are to be given over a longer period of time. Further, when the pharmacist was given the physician's order, which clearly stated what drug was needed and how much was to be given, he failed to look at the doctor's order but instead, read the nurse's transcription that could have been interpreted two ways. The record does not state whether the pharmacist contacted the physician for any clarification. In addition, the Board found that the drug was dispensed without the correct directions indicated on the label attached to the container. Lastly, the Board determined that the pharmacist had not conducted a prospective drug review.

So what does all this mean? I think a key insight into this case comes from the executive director of the Ohio Board who stated, "This is not just a medication error case. All pharmacists need to know their limitations because the general public holds pharmacists responsible and accountable for their actions, including those seen and proven as errors. If pharmacists are put into a position and expected to perform a specific task, they must say no if they feel unsure or unfamiliar with the task. *Pharmacists need to know what their capabilities are and how not to act outside them.*" [my emphasis]. Essentially, the executive director is saying that the Board did not fine him because he made an error, but because he acted outside of his "comfort zone". This begs the question of, "What should a pharmacist be expected to do?" When I graduated from pharmacy school some 25 years ago, a licensed pharmacist was expected to be able to do just

about anything that had to do with pharmacy, with the possible exception of compounding nuclear pharmaceuticals. It appears that the Ohio Board is stating this is no longer the case. Here was a pharmacist who was familiar with compounding chemotherapeutic agents, yet because he had only performed this function for 24-hour doses and not multiple-day doses, he is now being fined by the Board, and charged by a grand jury with involuntary manslaughter for not knowing his limitations. Perhaps our profession has become so specialized that there is no longer such a thing as a “general pharmacy practitioner”.

Another key issue this case brings up is competency. How detailed and specific does our competency documentation need to be now? Certainly from the looks of this pharmacist’s predicament, it is no longer acceptable to certify someone as being competent in preparing chemotherapeutic agents, but now it appears one must certify to the point of 24-hour doses versus multiple doses. What about when new drugs become available? Do we now need to document competency for each new drug product? How does this carry over to other inpatient or outpatient functions? How specific does competency certification need to be to avoid potential fines or criminal indictments?

A final aspect of this scenario that I find interesting is that a grand jury returned an involuntary manslaughter count against the pharmacist. In almost every case I have read, a negligence suit filed in a civil court is the remedy sought by a plaintiff when a medication error occurs. Rarely, if at all, does the state get involved in filing a criminal case unless the conduct causing the error was extremely egregious (such as working intoxicated), or fraudulent, and/or some other law or statute has been violated. An example would be the Kansas City pharmacist who diluted the chemotherapy regimens but billed the insurance companies/patients for the full amount. This is the first case I can think of where a pharmacist is being accused of manslaughter for a medication error that occurred without some other type of illegal activity. In essence, at least from my point of view, he committed an error of judgment, not of malice, yet he is being hammered with a criminal charge.

As you can see, this case poses a great deal more questions than I have answers for. There is an old saying in the legal profession that “bad cases make bad law”, and I definitely think this may be one of those cases. While this case has not gone to trial yet on the manslaughter charge, I believe that if this pharmacist is found guilty, it will profoundly affect the way we practice. Not only will we need to take a look at how we determine competency, but also each pharmacist or pharmacy technician will need to know his or her limitations. Supervisors will also need to be keenly aware of their staff’s limitations. Harder still is the issue that arises in a single pharmacist shop where, for instance, I may think one of my limitations is that I don’t know how to make an intravenous solution yet that is what a patient needs. Care may be denied or delayed which could cause an adverse outcome in itself and open up a whole new can of worms. It may also influence how we staff our pharmacies. If someone is being assigned to a one-pharmacist location, it may cause us to look closely at what skill set that pharmacist possesses instead of sending someone to a location simply because he or she is a pharmacist. The questions are many, but the answers are few. I’ll keep you posted when this case goes to trial. See you next issue!