



AND THE LAW

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CORRESPONDING RESPONSIBILITY

The opioid crisis, and the multitude of court cases around the country that followed from it, have placed additional scrutiny on the duty of Corresponding Responsibility for pharmacists.

This concept is not new. The regulation has been in effect for many years. The regulation states;

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the

*provisions of law relating to controlled substances."*¹
(emphasis added)

Recent activity in the Multi District Litigation (MDL) court in Ohio² focused on Corresponding Responsibility. Judge Dan Polster issued an order on August 6, 2020 denying the pharmacy defendants' motion to dismiss the complaint against them. The pharmacy defendants' motion to dismiss asserted that the duty of Corresponding Responsibility falls on the pharmacist, not on the pharmacy. Therefore, the pharmacies had no duty to take any action during the opioid crisis. The judge disagreed and denied the motion.

The judge then went on in his ruling to outline what steps the pharmacies should have taken and the information that should have been provided to their staffs. His opinion was very detailed and involved data mining and data analytics. The pharmacy defendants filed a motion to reconsider on August 25, 2020 because they believed the requirements outlined by the judge were excessive and beyond the requirements imposed by statute and DEA regulations. The motion to

1 21 C.F.R. Section 1306.04(a)

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https://www.ohnd.uscourts.gov/sites/ohnd/files/MDL2804_2709.pdf

reconsider was denied on September 22, 2020. However, the judge did acknowledge that his previous order was not intended to prescribe the actions that the pharmacy defendants should have taken. The question of whether the actions they did take were sufficient under the law is a question of fact for the jury to decide.

The Corresponding Responsibility regulation does specifically cite pharmacists. However, the assertion by the pharmacy defendants to say that they have no duty here seems to be an extreme position. Pharmacies are registrants too. As registrants under the Controlled Substances Act, pharmacies also have a duty to prevent abuse and diversion of controlled substances. The Administrator of the DEA has the authority to suspend or revoke a pharmacy's registration if it appears to create a danger to the public health or safety to allow the pharmacy to continue. While the Corresponding Responsibility regulation refers to pharmacists, it seems unrealistic to leave the dispensing pharmacist unsupported in the performance of their duty. The judge's initial ruling also seems to be an extreme position. As is many times the case, the best solution is somewhere in the middle.

Pharmacy owners need to be clear with their staff about diversion and addiction prevention. Establishing a culture of judicious and sensible dispensing of controlled substances starts with owners and managers of the pharmacy. Owners who concentrate on volume will get less discernment from their staff pharmacists as the staff will likely feel pressure to fill all controlled substance prescriptions. The DEA believes that the law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. The pharmacist is making a real-time decision with the conflicting pressures of prevention of diversion or addiction and patient care. It seems unreasonable that the pharmacy has no duty in this situation. Yes, the pharmacist is on the frontline and has to make the decision, but the pharmacy and its owner create the environment where this decision must be made. The pharmacists can't make these decisions in a vacuum. Discussion with the prescriber will probably be necessary. Perhaps discussions with the patient will also

be necessary. The pharmacist can then use this information in conjunction with their professional knowledge, experience and judgment.

Another portion of the filings in this case discussed the pharmacy's duty to train their staff pharmacists to properly handle prescriptions for opioids and to establish policies and procedures to prevent their pharmacies from facilitating the diversion of opioids. While this duty is not explicitly spelled out in the DEA regulations, it seems to be implied in the pharmacy's duty to protect public health and safety. The judge's initial ruling went into a lot of detail on what he thought was acceptable and went far beyond what someone could easily infer from the regulations. The judge stepped back from this initial position when he denied the motion for reconsideration.

What can we learn from this case? There will be a continued focus on the doctrine of Corresponding Responsibility going forward. The law continues to evolve and yesterday's solution will not be sufficient for tomorrow. Pharmacists have an independent duty to the patient and are not merely order takers for the physician. Following the physician's orders is no longer a sufficient defense when a patient is harmed by a prescription when the pharmacist could have intervened. The pharmacy needs to create a team atmosphere and assist their pharmacists as they make these important patient care decisions.

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