

# Challenges for Refusal to Fill – Legal Perspectives

Presented by:

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# About Our Speaker

Stephanie Eckerle devotes her practice to representing businesses in an array of healthcare matters. This includes representation of entrepreneurs as well as established and national companies with everyday operational and legal

issues as well as complex transactions. Within the healthcare industry, Ms. Eckerle focuses her practice on providing regulatory, compliance and corporate advice to physicians, practice groups, pharmacies, on-site employer healthcare clinics and other healthcare institutions. She counsels these clients on an array of regulatory matters, including pharmaceutical matters, reimbursement issues, fraud and abuse issues and licensure matters. In addition, Ms. Eckerle counsels healthcare providers and health plans on HIPAA and state privacy laws, including the identification, investigation and remediation of breach incidents, compliance programs and health information technology issues. She also works with providers on physician employment agreements, non-competition issues and telemedicine and telepharmacy issues. Within the healthcare arena, Ms. Eckerle also works with employers to implement health and wellness programs for their employees which includes counseling on occupational health and wellness initiatives, worker's compensation issues and the implementation of on-site employer clinics.



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# Legal Resources

- The Controlled Substances Act
- DEA Practitioner's Manual
- Red Flag Rules
- DEA Enforcement Actions
- State Law
  - Indiana
  - Wisconsin
  - Michigan
  - Ohio
  - Illinois

# Legitimate Medical Purpose

- To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.
- An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA (21 U.S.C. § 829).
- 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.
- A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed.

# Legitimate Medical

## Purpose

- The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.
- Such action is a felony offense, which may result in the loss of one's business or professional license (see United States v. Kershman, 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977]).

**“Pharmacists have a personal responsibility to protect their practice from becoming a target for drug diversion.”**

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# Red

## Flags

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area.
- The patient appears to be returning too frequently. A prescription which should last for a month in legitimate use is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for “uppers and downers” at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.

# Prevention Techniques

- Know the prescriber and his/her signature.
- Know the prescriber's DEA registration number.
- Know the patient.
- Check the date on the prescription order to determine if it has been presented in a reasonable length of time since being issued by the prescriber.

## Prevention Techniques

“If a pharmacist believes the prescription is forged or altered, he/she should not dispense it and call the local police.

If a pharmacist believes he/she has discovered a pattern of prescription abuse, he/she should contact the state Board of Pharmacy or the local DEA Diversion Field Office (Appendix K). Both DEA and state authorities consider retail-level diversion a priority issue.”

# Indiana Law

A pharmacist has a duty to honor all prescriptions from a practitioner...[.] Before honoring a prescription, the pharmacist shall take reasonable steps to determine whether the prescription has been issued in compliance with the laws of the state where it

originated. The pharmacist is immune from criminal prosecution or civil liability if he, in good faith, refuses to honor a prescription because, in his professional judgment, the honoring of the prescription would:

- (1) be contrary to law;
- (2) be against the best interest of the patient;
- (3) aid or abet an addiction or habit; or
- (4) be contrary to the health and safety of the patient.

# Case Studies: Indiana Law

## Kadambi, M.D. v. Express Scripts, Inc.

### Facts:

- Dr. Kadambi prescribed human growth hormone (HGH).
- Express Scripts refused to fill the prescriptions on the belief that the prescriptions were not medically necessary.
- Dr. Kadambi sued Express Scripts and alleged that (1) they violated Ind. Code 25-26-13-16; and (2) that Ind. Code 25-26-13-16 gave him a private right of action.

And the court concluded?

# Case Studies: Indiana Law

## Hooks SuperX, Inc. v. McLaughlin

### Facts:

- McLaughlin injured his back and was prescribed drugs containing propoxyphene.
- McLaughlin consumed the drugs at a much faster rate than prescribed.
- McLaughlin sued Hooks on the basis that it breached its duty of care by failing to stop filling the prescriptions because the pharmacist knew or should have known McLaughlin was consuming the drugs so frequently that it posed a threat to his health.

And the court concluded?

# Michigan

## Law

“Application of good faith to a pharmacist means the dispensing of a controlled substance pursuant to a prescriber's order which, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment: (a) Lack of consistency in the doctor- patient relationship; (b) Frequency of prescriptions for the same drug by 1 prescriber for larger numbers of patients; (c) Quantities beyond those normally prescribed for the same drug; (d) Unusual dosages; or (e) Unusual geographic distances between patient, pharmacist, and prescriber. Except as otherwise provided in this section, a practitioner, in good faith, may dispense a controlled substance included in schedule 2 upon receipt of a prescription of a practitioner licensed under section 7303 on a prescription form. A practitioner may issue more than 1 prescription for a controlled substance included in schedule 2 on a single prescription form.”

# Michigan Law

“A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply: (a) The prescription appears to be improperly written;... (c) The pharmacist has reason to believe that the prescription could cause harm to the patient; or (d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.”

Mich. Admin Code 338.490