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2 **In re National Prescription Opiate Litigation – A Federal Judge Talks to Us About DEA Red Flags, Dispensing as a Nuisance, and the Learned Intermediary Doctrine**

ACPE Program Number: 0487-0000-20-005-H03-P and 0487-0000-20-005-H03-T (knowledge-based activity)
Release Date: December 10, 2020
Expiration Date: December 10, 2023
Contact Hour(s): 1.0
Program Fee: $15.00

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Program Title: **In Re National Prescription Opiate Litigation – A Federal Judge Talks to Us About DEA Red Flags, Dispensing as a Nuisance, and the Learned Intermediary Doctrine**

Target Audience: Pharmacists and Pharmacy Technicians

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Accreditations:

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Objective: At the conclusion of this program, pharmacists and pharmacy technicians should be able to:
(a) restate the elements of the DEA's red flags,
(b) explain why dispensing can be a public nuisance, and
(c) explain the learned intermediary doctrine.

Important Note: Colleagues, this is a continuing education program. It is not legal advice. Do not rely on this CPE program as legal authority.

Contact Us: By phone (614) 481-8711 or email at patti@selectce.org.

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Introduction

This CE activity is the second in a series examining a federal judge's discussion about certain pharmacy responsibilities and the law. The federal judge in the National Prescription Opiate Litigation provides us with an analysis of the federal Controlled Substance Act (CSA) and other laws to answer the questions: "Who has a duty to spot DEA red flags?" and "Can dispensing prescriptions ever be seen as a public nuisance?" and "Does the learned intermediary doctrine protect a pharmacy from its obligation to prevent diversion?"

Question 1 (pre-test to get you thinking; please provide an answer but none will be graded as incorrect):

Persons with a duty to look for red flags which may indicate an illegitimate prescription include:

a. individual pharmacists;
b. pharmacy owners;
c. both a and b.

Background

Seeking to recover the costs of fighting the opioid epidemic, the National Prescription Opiate Litigation consolidated more than 2,000 pending lawsuits brought by thousands of the nation's cities, counties, state governments, tribal authorities, and individuals (the Plaintiffs) against hundreds of manufacturers, marketers, distributors, and dispensers of opioids. By some accounts, this is the most complex case in U.S. history.[1]

Plaintiffs (people bringing the case to court) allege that the manufacturers of prescription opioids grossly misrepresented the risks of long-term use of those drugs for persons with chronic pain, and distributors and dispensers failed to properly monitor suspicious orders of those prescription drugs--all of which contributed to the current opioid epidemic.[2]

This case was assigned to Judge Daniel Polster of the U.S. District Court for the Northern District of Ohio. For a complete and up-to-date list of court documents filed in this case, see the web page created specifically for it at https://www.ohnd.uscourts.gov/mdl-2804.

1 https://judicature.duke.edu/articles/the-negotiation-class/
2 https://www.ohnd.uscourts.gov/mdl-2804

In this CE activity, we are going to examine three sections of one opinion in this case. On pages 21-32 of the Opinion and Order dated August 6, 2020, the Judge addressed certain claims of 5 large pharmacy chains that the CSA requires only **individual pharmacists**, and not the **pharmacies**, to prevent diversion of controlled substances. Procedurally, this is not a finding of ultimate liability in this case; instead, this opinion is an initial step to determine as a threshold matter whether the law imposes any duties at all on pharmacies to prevent diversion. If so, then the Plaintiff's claims are viable and the lawsuit can proceed. If not, then the case is dismissed.

What follows is the relevant text of the court's decision, with some footnotes and citations removed for brevity and readability. The boxed questions are designed to test whether you are actively learning and meeting the objectives of this CE activity. We begin at Section B(2) of this Opinion and Order in which the judge is discussing certain pharmacy duties under the CSA.

B. Pharmacy Duties Under the CSA[3]

2. System Requirement.

Beyond the aforementioned statutory obligations, Plaintiffs assert the CSA also imposes duties on the Pharmacy Defendants[4] to maintain systems, policies, or procedures to identify prescriptions that bear indicia ("red flags") that the prescription is invalid, or that the prescribed drugs may be diverted for illegitimate use. The Pharmacy Defendants admit an equivalent duty exists for manufacturers and distributors with respect to suspicious ***orders***, but insist no such duty exists for pharmacies with respect to certain suspicious ***prescriptions.*** Defendants are wrong.

There is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances. The DEA, in Agency decisions interpreting its regulations, routinely conducts a "red flag analysis." In fact, the Agency has even articulated the specific elements of a *prima facie* violation of a pharmacy-registrant's responsibility under 21 C.F.R. § 1306.04(a) using the term "red flag." See *Holiday CVS*, 77 FR at 62341 ("to show a violation of corresponding responsibility, the Government must establish that:

> (1) the Respondent (a pharmacy) dispensed a controlled substance;
> (2) a ***red flag*** was or should have been recognized at or before the time the controlled substance was dispensed; and
> (3) the question created by the ***red flag*** was not resolved conclusively prior to the dispensing of the controlled substance.") (emphasis added)(internal footnote 25).
>
> footnote 25: Regarding the second prong recited in *Holiday CVS* – whether "a red flag was or should have been recognized at or before the time the controlled substance was dispensed" – the DEA "has consistently interpreted [section 1306.04(A)] as prohibiting a pharmacist from filling a prescription for a controlled substance when he either ***knows or has reason to know*** that the prescription was not written for a legitimate medical purpose." *E. Main St. Pharmacy*, 75 FR 66149-01, 66163 (DEA Oct. 27, 2010)(citing agency and Sixth Circuit precedent)(internal quotations omitted). The Pharmacy Defendants assert that, absent identification by Plaintiffs of any specific prescription filled by Defendants that they knew or should have know was illegitimate, Plaintiffs do not state viable claims. Plaintiffs have alleged, however, that the Pharmacy Defendants had reason to know that at least some of the prescriptions they dispensed were

3 *In re* National Prescription Opiate Litigation, MDL No. 2804, No. 1:17-CV-2804 (N.D. Ohio August 6, 2020) Doc # 3403 Opinion and Order at page 21 – 33.
4 The "Pharmacies" or "Pharmacy Defendants" referred to by the court are Walmart, CVS, Rite Aid, Walgreens, and Giant Eagle; see Case 1:17-md-02804 Doc # 3403 at page 1.

illegitimate. At this motion to dismiss stage, with factual allegations in the complaint accepted as true and viewed in favor of the nonmoving party, the Court easily concludes that Plaintiff's allegations are plausible.)

Agency precedent, in analyzing whether a registrant identified and resolved red flags, uses a combination of factors (2) and (4) of 21 U.S.C. 823(f) as the statutory basis for the requirement. Those factors are:

> [2] The applicant's experience in dispensing…controlled substances," and
> [4] Compliance with applicable State, Federal, or local laws relating to controlled substances." 21 U.S.C. § 823(f)(2), (4).

Many of the red flags that the Agency examines (which a registrant should have at least identified and, if possible, resolved) include indicia that would be very difficult, if not impossible, for a human pharmacist to identify consistently absent a system to aggregate, analyze, and provide feedback to the pharmacist about the prescription. In other words, some prescriptions are not suspicious on their face but raise bright red flags when compared with other prescriptions in a database. One example of such a red flag is "pattern prescribing," defined as "prescriptions for the same drugs, same quantities[,] coming from the same doctor." *Holiday CVS*, 77 FR at 62344. Identifying prescriptions presented over time for the same drugs or combinations of drugs, in the same quantities, issued by the same doctor (and possibly presented to different pharmacists in different stores owned by the same pharmacy), would test the limits of human memory; this red flag would be nearly impossible for any individual pharmacist to discern absent some global mechanism for reference to other prescriptions. However, given that a ***pharmacy-registrant*** is required to collect the specific data needed to identify such a problem, the pharmacy – not the pharmacist – is in the best position to identify such a red flag (or at least provide the pharmacist with data reports to do so). Indeed, the fact that the DEA has revoked registrations of ***pharmacies*** for failure to identify such red flags necessarily means pharmacies are required to look for them, which can only be done by putting into place systems to identify them.

The Pharmacy Defendants assert they cannot be responsible for identifying red flags because they do not have the requisite "specialized knowledge, judgement, and skill" to engage in the practice of pharmacy. Doc. # 3340-1 at 15 (citing O.R.C. § 4729.01(B)). But the Pharmacy Defendants do have an obligation under the CSA to employ someone who does have and can exercise appropriate professional knowledge, judgement, and skill on their behalf. The same is expressly true under Ohio law. *See* O.R.C. § 4729.55(D). Pharmacies also have an obligation under Ohio law to "allow[] pharmacists…to practice pharmacy in a safe and effective manner." *Id.* These objectives are accomplished fully only when a pharmacy actually uses the data it is required to collect under 21 C.F.R. § 1304.22(c) to provide a tool otherwise unavailable to its pharmacists.

The Pharmacy Defendants also assert the CSA cannot impose an obligation on them to identify red flags because, as corporate-entity non-pharmacists, they cannot override the professional decisions of their pharmacists to determine the propriety of a prescription. *See* Doc. # 3340-1 at 16. But nothing about using data to identify a suspicious prescription would work to override a pharmacist's ability to determine if the prescription was proper. To the contrary, a data-driven analysis should assist and work in synergy with a pharmacist's expertise. Ultimately, pharmacists cannot best employ their "professional knowledge, judgment, and skill" to prevent diversion if their pharmacy-employer does not provide useful access to the "red-flag-revealing" data it has gathered.

Although the CSA is not perfectly clear about what a pharmacy-registrant must do with prescription data it must collect, what is clear is that a pharmacy is required to:

> (1) collect and maintain specific records and data regarding its dispensing activity;
> (2) employ a properly licensed pharmacist; and

Question 3:

a. prescription;
b. controlled substance;
c. opioid.

Question 4:

a. at the time;
b. at or before the time;
c. at any time after.

Question 5:

a. at the time of;
b. prior to the dispensing of;
c. within 48 hours of dispensing.

Question 6:

In the National Prescription Opiate Litigation, the Court stated that a data-driven analysis should work in synergy with:

a. a pharmacist's expertise;
b. ordering and dispensing activity;
c. the Controlled Substance Act (CSA).

Question 2:

In the National Prescription Opiate Litigation, the Court stated there is no question that dispensers of controlled substances are obligated to red flags of possible diversion prior to dispensing those substances.

a. investigate;
b. check for and conclusively resolve;
c. eliminate.

For Questions 3, 4 and 5:

The DEA, in Agency decisions interpreting its regulations, routinely conducts a "red flag analysis" which includes showing:

(1) the Respondent (a pharmacy) dispensed a _[Question 3]_;
(2) a ***red flag*** was or should have been recognized ___[Question 4]__ the controlled substance was dispensed; and
(3) the question created by the ***red flag*** was not resolved conclusively __[Question 5]___ the controlled substance.

(3) properly dispense controlled substances and avoid diversion.

Therefore, both the pharmacy and the pharmacist must cooperatively identify and resolve "red flags" prior to dispensing controlled substances. The Court concludes these requirements collectively mean that the Pharmacy Defendants cannot collect data as required by the statute, employ a licensed pharmacist as required by statute, identify red flags as required by Agency decisions, but then do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled. Possessing, yet doing nothing with, information about possible diversion would actually ***facilitate*** diversion, and thus violate the CSA's fundamental mandate that "***All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances***." 21 C.F.R. § 1301.71(a) (emphasis added).

In sum, the Court conclude the Pharmacy Defendants have failed to meet their burden of demonstrating there is no corporate-level obligation to design and implement systems, policies, or procedures to identify red-flag prescriptions. And the Pharmacy Defendants' ultimate argument – that they cannot be liable to Plaintiffs because only their pharmacist-employees are responsible for preventing diversion of opioids via illegitimate prescriptions – is premised upon a tortured reading of the CSA and its regulations. Because Defendants' reading of the CSA is antithetical to its very purpose, the Court rejects Defendants' positions.

Question 7:

Possessing, yet doing nothing with, information about possible diversion would actually _____ diversion.

a. facilitate;
b. prevent;
c. fulfill the duty under the CSA regarding controlled substances.

Question 8:

In the National Prescription Opiate Litigation, the Court stated both the _____must cooperatively identify and resolve "red flags" prior to dispensing controlled substances.

a. pharmacy and the pharmacist;
b. pharmacy and distributor;
c. pharmacist and pharmacy technician.

C. Ohio Absolute Public Nuisance

Plaintiffs allege common law tort claims for absolute public nuisance based on the Pharmacy Defendants' alleged intentional and unlawful misconduct involving both *distribution* and *dispensing* of opioid prescriptions. To the extent these claims are based on *dispensing* activities, the Pharmacy Defendants argue the claims are simply not cognizable under Ohio law of public nuisance. For the reasons set forth below, the Court rejects this argument.

A "public nuisance" is an unreasonable interference with a right common to the general public, including the rights to public health and safety. Ohio law recognized two categories of nuisance claims – "absolute" and "qualified" – and the distinction between the two depends on the conduct of the defendant. An "absolute" nuisance, also called a nuisance *per se*, is based on culpable and intentional or unlawful conduct by the defendant resulting in harm. A "qualified" nuisance, on the other hand, involves harm caused by the defendant's negligence.

Here, the Plaintiffs assert absolute public nuisance claims based on allegedly *intentional* and *unlawful* dispensing activities. The Pharmacy Defendants, however, contend the Plaintiff's allegations "fundamentally sound in negligence" and do not sufficiently describe intentional or unlawful conduct necessary to support an absolute nuisance action. More specifically, the Defendants content Plaintiffs merely allege that the Pharmacies engaged in lawful conduct and "should have innovated new ways to identify and prevent diversion."

Contrary to the Pharmacy Defendants' contention, Plaintiffs clearly allege Defendants engaged in *intentional* conduct to dispense opioids in a manner that caused an oversupply of highly addictive drugs in Plaintiffs' communities. Plaintiffs allege the Pharmacy Defendants:

(i) were "keenly aware of the oversupply of prescription opioids";
(ii) willfully and "systematically ignored red flags that they were fueling a black market";
(iii) required and rewarded speed and volume by opioid-dispensing employees, while minimizing standards of safety and care;
(vi) purposefully implemented performance metrics and prescription quotas to increase dispensing of opioids;
(v) "facilitated the supply of far more opioids than could have been justified to serve a legitimate market";

(iv) knowingly worked in concert with opioid manufacturers "to ensure that false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders";
(vii) "worked together to ensure that the opioid quotas allowed by the DEA remained artificially high"; and
(viii) falsely assured the public that Defendants were working to curb the opioid epidemic.

The Pharmacy Defendants contend these allegations are insufficient to show they intended to cause the harms allegedly suffered by the Plaintiffs. To meet the requisite intent for an absolute nuisance, however, a plaintiff only needs allege the defendant "intended to bring about the conditions which are in fact found to be a nuisance."

Here, Plaintiffs allege the conditions created by the Pharmacies' intentional conduct – that is, oversupply of opioids in Plaintiffs' communities – necessarily resulted in the devastating consequences that Plaintiffs allegedly suffered because of the opioid epidemic. Accepting these allegations as true and construing them in the light most favorable to the Plaintiffs, the Court finds Plaintiffs have fairly and sufficiently stated plausible claims for absolute nuisance based on the Pharmacy Defendants' alleged intentional conduct involving their dispensing activities. *See…Angerman*, 2003 WL 1524505, at 1-3 (where defendants intentionally built and operated a motocross track that generated a great deal of noise as an unavoidable byproduct of their intentional activity, the law of absolute public nuisance applied).

Additionally, as discussed in the previous section, Plaintiffs have sufficiently alleged the Pharmacy Defendants engaged in unlawful dispensing conduct by failing to comply with statutory and regulatory requirements to provide effective controls against diversion, including ensuring proper dispensing of controlled substances. These allegations provide an additional and alternative basis to support the absolute nuisance claims.

The Pharmacy Defendants also argue that, as a matter of law, an absolute immunity theory cannot apply because their dispensing conduct was licensed, authorized, and regulated under the CSA. This Court has previously rejected identical arguments, finding that, under Ohio law, "'safe harbor' immunity from absolute nuisance liability is available only to those who perform in accordance with their applicable licensing regulatory obligations. The same analysis applied here. As discussed, Plaintiffs allege the Pharmacy Defendants did not comply with the regulatory scheme but, rather, violated it. Accordingly, the Court declines to dismiss the absolute claims on this ground.

Lastly, the Pharmacy Defendants assert the Plaintiffs cannot pursue liability based on Defendants' First-Amendment-protected participation in trade groups that lobbied against additional regulation of the opioid supply chain. Completely aside from any alleged lobbying or trade group activity, however, Plaintiffs allege ample intentional and unlawful conduct by Defendants to support their absolute nuisance claims. Moreover, this Court has previously found that evidence of lobbying activities may be admissible for other purposes, such as to show motive or intent. On this record, the Court concludes Plaintiffs have sufficiently stated common law claims for absolute public nuisance based on the Pharmacy Defendants' alleged dispensing activities.

D. Proximate Causation – Learned Intermediary Doctrine

Finally, the Pharmacy Defendants argue that, under the learned intermediary doctrine, the intervening conduct of prescribing medical professionals breaks the causal chain between the Pharmacy Defendants' conduct and the Plaintiff's injuries.

The Court previously found allegations similar to Plaintiffs' here sufficient to overcome a motion to dismiss on proximate cause grounds. Specifically, the Court declined to find, under Florida and Oklahoma law, a doctor's prescribing decision breaks the causal chain between the Pharmacies' dispensing conduct and the plaintiffs' injuries as a matter of law. In each instance, the Court noted that causation should be left to the trier of fact (e.g., the jury).

Question 9:

In the National Prescription Opiate Litigation, the Plaintiffs allege the Pharmacy Defendants:

a. willfully and systematically ignored red flags that they were fueling a black market;
b. required and rewarded speed and volume by opioid-dispensing employees, while minimizing standards of safety and care;
c. both of the above.

Question 10:

In the National Prescription Opiate Litigation, the "safe harbor" immunity from absolute nuisance liability is:

a. only available to those who perform in accordance with their applicable licensing regulations;
b. not available to the Pharmacy Defendants at this time;
c. both of the above.

Ohio law calls for the same result. Ohio courts apply the learned intermediary doctrine in strict liability cases to shift a prescription drug manufacturer's duty to warn onto the prescribing physician, if the manufacturer has adequately warned the physician. *Tracy v. Merrell Dow Pharms., Inc.,* 569 N.E.2d 875, 878 (Ohio 1991). This shift recognizes manufacturers and physicians have distinct relationships with product users and are in different positions to issue warnings regarding a product. *See id.* at 878. ("The rationale behind [the doctrine] is that the physician stands between the manufacturer and patient…."); *see also Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 840 (Ohio 1981)(" A direct relationship between the manufacturer and the patient does not arise as a result of the provision of [warning] brochures.").

These cases, on which the Pharmacy Defendants rely, confirm the learned intermediary doctrine is wholly inapplicable here. Plaintiffs are not seeking to hold the Defendants liable for personal injuries to opioid users for harms caused by products or related warnings. Plaintiffs' public nuisance claims instead pertain to broad harms to the public allegedly caused by the Pharmacies' dispensing conduct that implicates legal obligations independent of manufacturers, physicians, or any other participant in the opioid supply chain. The Pharmacy Defendants have not identified any legal authority that shifts their obligation to prevent diversion to any other person or entity, or that otherwise establishes that prescribers are an intervening or superseding cause of Plaintiffs' alleged injuries.

Finally, Ohio law instructs that proximate cause is ordinarily a question of fact for the jury. *Brondes Ford, Inc. v. Habitec Sec.*, 38 N.E.3d 1056, 1086 (Ohio Ct. App. 2015). Because Defendants have not demonstrated Plaintiffs' allegations of proximate cause fail as a matter of law, the Court declines to dismiss Plaintiffs' claims.

Question 11:

In the National Prescription Opiate Litigation, the Court tells us the learned intermediary doctrine:

a. shifts responsibility from the prescriber to pharmacist;
b. shifts responsibility from the pharmacist to prescriber;
c. shifts a prescription drug manufacturer's duty to warn onto the prescribing physician, if the manufacturer has adequately warned the physician.

Question 12:

In the National Prescription Opiate Litigation, the Court rules the learned intermediary doctrine does not apply to protect the Defendant Pharmacies because:

a. the opioid users suffered no personal injuries;
b. the individual pharmacists employed by the Pharmacies are responsible for every prescription they dispense;
c. there is no legal authority that shifts the Pharmacies' obligation to prevent diversion to anybody else.

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<u>ANSWERS: In re National Prescription Opiate Litigation – A Federal Judge Talks to Us About DEA Red Flags, Dispensing as a Nuisance, and the Learned Intermediary Doctrine</u>

(#0487-0000-20-005-H03; Expires December 10, 2023)

Circle the answer for each question (questions are imbedded in the program).

1.	a	b	c	7.	a	b	c
2.	a	b	c	8.	a	b	c
3.	a	b	c	9.	a	b	c
4.	a	b	c	10.	a	b	c
5.	a	b	c	11.	a	b	c
6.	a	b	c	12.	a	b	c

13. I am a pharmacist: Yes No
14. I am a pharmacy technician: : Yes No

After completing this CE activity, I am able to:

15. - restate the elements of the DEA's red flags Yes Maybe No
16. -explain why dispensing can be a public nuisance Yes Maybe No
17. – explain the learned intermediary doctrine Yes Maybe No
18. This CE activity <u>filled a learning gap of mine</u>: Yes Maybe No
19. The learning material was <u>useful</u>: Yes Maybe No
20. The teaching and learning methods (e.g., format; questions embedded in the program) <u>fostered active learning</u> and were effective: Yes Maybe No
21. The test questions were <u>relevant to the goals of the CE activity</u>: Yes No
22. The test questions were at an <u>appropriate level of difficulty</u>: Yes No
23. The CE activity was presented in a <u>fair and unbiased</u> manner: Yes No
24. If you perceived any <u>bias or commercialism</u>, please describe:

_____

25. How <u>long</u> did it take you to complete this CE activity? _____