

	2014	2015	2016	Mar-16
Administrative Filings	52	33	6	0
Criminal Filing/Felony	0	3	0	0
Letter of Concern	146	98	28	6
Referred to Diversion	2	0	0	0
PR/Outreach	4	1	1	0
Cases Received	567	666	93	78
Case Assigned	555	659	91	78
Closed Cases	595	624	113	97
Citations Issued	60	64	14	2
Pharmacy Inspections	335	316	40	70
Pharmacy Alerts	261	220	44	36
Dr. Shopper Letters	571	1251	604	496

**NOTES: Pharmacy Group**

PR Outreach

Lynn Hooper and Camille Farley presented at the Utah Animal Control Officers Association in St George, with approximately 75 attendees. The presentation covered the newly created Class E Pharmacy license that is now required for Animal Control/Animal Narcotic Detection Training facilities. They provided answers to questions, and handouts.

Citation

During a Random Inspection 46 medications were found in the pharmacy stock that were either expired or had indeterminate expiration dates, the oldest having expired on 07/2015. The pharmacy was issued a Citation with a fine of \$6,000.

Citation

During a Random Inspection it was found that Lorazepam 1mg and Hydrocodone w/APAP 7.5 mg/325 mg tablets were dispensed without being compliant to State and Federal Law. The pharmacy was issued a Citation with a fine of \$100.

## Previously Discussed

- Central Processing
- Licensing 3PL's
- Medication Therapy Management
- Prescription Misfills
- Veterinary Pharmaceutical Facility

## Legislative Changes

- HB 236 - Charitable Prescription Drug Recycling Program
- HB 186 - Volunteer Health Care Continuing Education Credit
- HB 375 - Prescription Drug Abuse Amendments

**CHARITABLE PRESCRIPTION DRUG RECYCLING  
PROGRAM**

2016 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: Gage Froerer**

Senate Sponsor: Evan J. Vickers

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**LONG TITLE**

**General Description:**

This bill creates a program that allows certain pharmacies to accept and dispense donated unused prescription medications to certain individuals.

**Highlighted Provisions:**

This bill:

- ▶ amends the Pharmacy Practice Act;
- ▶ defines terms;
- ▶ directs the Division of Occupational and Professional Licensing (DOPL) to make rules, in consultation with the Utah State Board of Pharmacy, to create a charitable prescription drug recycling program;
- ▶ establishes criteria for prescription drugs eligible for the program;
- ▶ establishes requirements for donors and pharmacies;
- ▶ limits the liability of program participants and drug manufacturers;
- ▶ directs DOPL to make rules establishing certain requirements, standards, procedures, and processes; and
- ▶ makes technical changes.

**Money Appropriated in this Bill:**

None

**Other Special Clauses:**

None

**Utah Code Sections Affected:**

30 AMENDS:

31 58-17b-502, as last amended by Laws of Utah 2015, Chapter 336

32 58-17b-503, as last amended by Laws of Utah 2011, Chapter 366

33 ENACTS:

34 58-17b-901, Utah Code Annotated 1953

35 58-17b-902, Utah Code Annotated 1953

36 58-17b-903, Utah Code Annotated 1953

37 58-17b-904, Utah Code Annotated 1953

38 58-17b-905, Utah Code Annotated 1953

39 58-17b-906, Utah Code Annotated 1953

40 58-17b-907, Utah Code Annotated 1953

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42 *Be it enacted by the Legislature of the state of Utah:*

43 Section 1. Section 58-17b-502 is amended to read:

44 **58-17b-502. Unprofessional conduct.**

45 "Unprofessional conduct" includes:

46 (1) willfully deceiving or attempting to deceive the division, the board, or their agents

47 as to any relevant matter regarding compliance under this chapter;

48 (2) (a) except as provided in Subsection (2)(b):

49 (i) paying or offering rebates to practitioners or any other health care providers, or

50 receiving or soliciting rebates from practitioners or any other health care provider; or

51 (ii) paying, offering, receiving, or soliciting compensation in the form of a commission,

52 bonus, rebate, kickback, or split fee arrangement with practitioners or any other health care

53 provider, for the purpose of obtaining referrals.

54 (b) Subsection (2)(a) does not apply to:

55 (i) giving or receiving price discounts based on purchase volume;

56 (ii) passing along pharmaceutical manufacturer's rebates; or

57 (iii) providing compensation for services to a veterinarian.

- 58 (3) misbranding or adulteration of any drug or device or the sale, distribution, or  
59 dispensing of any outdated, misbranded, or adulterated drug or device;
- 60 (4) engaging in the sale or purchase of drugs or devices that are samples or packages  
61 bearing the inscription "sample" or "not for resale" or similar words or phrases;
- 62 (5) except as provided in Section 58-17b-503 or Part 9, Charitable Prescription Drug  
63 Recycling Act, accepting back and redistributing [of] any unused drug, or a part of it, after it  
64 has left the premises of any pharmacy, unless the drug is in a unit pack, as defined in Section  
65 58-17b-503, or the manufacturer's sealed container, as defined in rule;
- 66 (6) an act in violation of this chapter committed by a person for any form of  
67 compensation if the act is incidental to the person's professional activities, including the  
68 activities of a pharmacist, pharmacy intern, or pharmacy technician;
- 69 (7) violating Federal Title II, P.L. 91, Controlled Substances Act, Title 58, Chapter 37,  
70 Utah Controlled Substances Act, or rules or regulations adopted under either act;
- 71 (8) requiring or permitting pharmacy interns or technicians to engage in activities  
72 outside the scope of practice for their respective license classifications, as defined in this  
73 chapter and division rules made in collaboration with the board, or beyond their scope of  
74 training and ability;
- 75 (9) administering:
- 76 (a) without appropriate training, as defined by rule;
- 77 (b) without a physician's order, when one is required by law; and
- 78 (c) in conflict with a practitioner's written guidelines or written protocol for  
79 administering;
- 80 (10) disclosing confidential patient information in violation of the provisions of the  
81 Health Insurance Portability and Accountability Act of 1996 or other applicable law;
- 82 (11) engaging in the practice of pharmacy without a licensed pharmacist designated as  
83 the pharmacist-in-charge;
- 84 (12) failing to report to the division any adverse action taken by another licensing  
85 jurisdiction, government agency, law enforcement agency, or court for conduct that in

86 substance would be considered unprofessional conduct under this section; and

87 (13) as a pharmacist or pharmacy intern, compounding a prescription drug in a dosage  
88 form which is regularly and commonly available from a manufacturer in quantities and  
89 strengths prescribed by a practitioner.

90 Section 2. Section **58-17b-503** is amended to read:

91 **58-17b-503. Exception to unprofessional conduct.**

92 (1) For purposes of this section:

93 (a) "Licensed intermediate care facility for people with an intellectual disability" means  
94 an intermediate care facility for people with an intellectual disability that is licensed as a  
95 nursing care facility or a small health care facility under Title 26, Chapter 21, Health Care  
96 Facility Licensing and Inspection Act.

97 (b) "Nursing care facility" [~~has the same definition as~~] means the same as that term is  
98 defined in Section 26-21-2.

99 (c) "Unit pack" means a tamper-resistant nonreusable single-dose single-drug package  
100 with identification that indicates the lot number and expiration date for the drug.

101 (2) [~~Notwithstanding the provisions of Subsection 58-17b-502(5), a~~] A pharmacist  
102 may;

103 (a) accept and redistribute an unused drug under Part 9, Charitable Prescription Drug  
104 Recycling Act; or

105 (b) accept back and redistribute any unused drug, or a part of it, after it has left the  
106 premises of the pharmacy if:

107 [~~(a)~~] (i) the drug was prescribed to a patient in a nursing care facility, [~~a~~] licensed  
108 intermediate care facility for people with an intellectual disability, or state prison facility,  
109 county jail, or state hospital;

110 [~~(b)~~] (ii) the drug was stored under the supervision of a licensed health care provider  
111 according to manufacturer recommendations;

112 [~~(c)~~] (iii) the drug is in a unit pack or in the manufacturer's sealed container;

113 [~~(d)~~] (iv) the drug was returned to the original dispensing pharmacy;



- 142 (d) has a licensed outpatient pharmacy.
- 143 (4) "Charitable pharmacy" means an eligible pharmacy that is operated by a charitable
- 144 clinic.
- 145 (5) "County health department" means the same as that term is defined in Section
- 146 26A-1-102.
- 147 (6) "Donated prescription drug" means a prescription drug that an eligible donor
- 148 donates to an eligible pharmacy under the program.
- 149 (7) "Eligible donor" means a donor that donates a prescription drug from within the
- 150 state and is:
  - 151 (a) a nursing care facility;
  - 152 (b) an assisted living facility;
  - 153 (c) a licensed intermediate care facility for people with an intellectual disability;
  - 154 (d) a manufacturer;
  - 155 (e) a pharmaceutical wholesale distributor;
  - 156 (f) an eligible pharmacy; or
  - 157 (g) a physician's office.
- 158 (8) "Eligible pharmacy" means a pharmacy that:
  - 159 (a) is registered by the division as eligible to participate in the program; and
  - 160 (b) is operated by:
    - 161 (i) a county;
    - 162 (ii) a county health department;
    - 163 (iii) a pharmacy under contract with a county health department;
    - 164 (iv) the Department of Health, created in Section 26-1-4;
    - 165 (v) the Division of Substance Abuse and Mental Health, created in Section
    - 166 62A-15-103; or
    - 167 (vi) a charitable clinic.
- 168 (9) "Eligible prescription drug" means a prescription drug, described in Section
- 169 58-17b-904, that is not:

*Application Process*

- 170           (a) a controlled substance; or  
171           (b) a drug that can only be dispensed to a patient registered with the drug's  
172 manufacturer in accordance with federal Food and Drug Administration requirements.  
173           (10) "Licensed intermediate care facility for people with an intellectual disability"  
174 means the same as that term is defined in Section 58-17b-503.  
175           (11) "Medically indigent individual" means an individual who:  
176           (a) (i) does not have health insurance; and  
177           (ii) lacks reasonable means to purchase prescribed medications; or  
178           (b) (i) is covered under Medicaid or Medicare; and  
179           (ii) lacks reasonable means to pay the insured's portion of the cost of the prescribed  
180 medications.  
181           (12) "Nursing care facility" means the same as that term is defined in Section  
182 26-18-501.  
183           (13) "Physician's office" means a fixed medical facility that:  
184           (a) is staffed by a physician, physician's assistant, nurse practitioner, or registered  
185 nurse, licensed under Title 58, Occupations and Professions; and  
186           (b) treats an individual who presents at, or is transported to, the facility.  
187           (14) "Program" means the Charitable Prescription Drug Recycling Program created in  
188 Section 58-17b-903.  
189           (15) "Unit pack" means the same as that term is defined in Section 58-17b-503.  
190           (16) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501  
191 and 58-17b-501.  
192           (17) "Unprofessional conduct" means the same as that term is defined in Sections  
193 58-1-501 and 58-17b-502.  
194           Section 5. Section **58-17b-903** is enacted to read:  
195           **58-17b-903. Charitable Prescription Drug Recycling Program -- Creation --**  
196 **Requirements.**  
197           (1) There is created the Charitable Prescription Drug Recycling Program.

- 198 (2) The division, in consultation with the board, shall:  
199 (a) implement the program, on a statewide basis, to permit an eligible donor to transfer  
200 an eligible prescription drug to an eligible pharmacy for dispensing to a medically indigent  
201 individual;  
202 (b) in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act,  
203 make rules necessary to implement the program; and  
204 (c) provide technical assistance to entities that desire to participate in the program.

205 Section 6. Section **58-17b-904** is enacted to read:

206 **58-17b-904. Criteria for eligible prescription drugs.**

207 An eligible pharmacy may not accept or dispense an unused prescription drug under the  
208 program unless the unused prescription drug:

- 209 (1) (a) is in a unit pack or the manufacturer's sealed container; or  
210 (b) is an injectable medication;  
211 (2) (a) is unopened; or  
212 (b) is a cancer drug packaged in an unopened single-unit dose that has been removed  
213 from a multi-dose package;  
214 (3) is accepted and dispensed by the eligible pharmacy before:  
215 (a) a beyond use date that appears on the label;  
216 (b) the expiration date recommended by the manufacturer; or  
217 (c) a date, established by division rule for a specific prescription drug, in accordance  
218 with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, that is later than the date in  
219 Subsection (3)(a) or (3)(b);  
220 (4) (a) is not adulterated or mislabeled; and  
221 (b) the pharmacist or licensed pharmacist technician accepting or dispensing the  
222 prescription drug does not have reason to believe that the prescription drug is adulterated or  
223 mislabeled.

224 Section 7. Section **58-17b-905** is enacted to read:

225 **58-17b-905. Participation in program -- Requirements -- Fees.**

- 226 (1) An eligible donor or an eligible pharmacy may participate in the program.  
227 (2) An eligible pharmacy:  
228 (a) shall comply with all applicable federal and state laws related to the storage and  
229 distribution of a prescription drug;  
230 (b) shall comply with all applicable federal and state laws related to the acceptance and  
231 transfer of a prescription drug, including 21 U.S.C. Chapter 9, Subchapter V, Part H,  
232 Pharmaceutical Distribution Supply Chain;  
233 (c) shall, before accepting or dispensing a prescription drug under the program, inspect  
234 each prescription drug to determine whether the prescription drug is an eligible prescription  
235 drug;  
236 (d) may dispense an eligible prescription drug to a medically indigent individual who:  
237 (i) is a resident of the state; and  
238 (ii) has a prescription issued by a practitioner;  
239 (e) may charge a handling fee, adopted by the division under Section 63J-1-504; and  
240 (f) may not accept, transfer, or dispense a prescription drug in violation of the federal  
241 Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 301 et seq.

242 Section 8. Section **58-17b-906** is enacted to read:

243 **58-17b-906. Liability of participating organizations and manufacturers.**

244 In the absence of bad faith or gross negligence, a person is not criminally or civilly  
245 liable for injury, death, or loss of property based solely on the fact that the person  
246 manufactured, provided, donated, accepted, or dispensed an eligible prescription drug under  
247 this part.

248 Section 9. Section **58-17b-907** is enacted to read:

249 **58-17b-907. Rules made by the division.**

250 The rules made by the division under Subsection 58-17b-903(2)(b) shall include:

- 251 (1) registration requirements to establish the eligibility of a pharmacy to participate in  
252 the program;  
253 (2) a formulary that includes all eligible prescription drugs approved by the federal

- 254 Food and Drug Administration;
- 255 (3) standards and procedures for:
- 256 (a) verifying whether a pharmacy or pharmacist participating in the program is licensed
- 257 and in good standing with the board;
- 258 (b) handling of a donated eligible prescription drug, including:
- 259 (i) acceptance;
- 260 (ii) identification, including redundant criteria for verification;
- 261 (iii) documentation, under 21 U.S.C. Sec. 360eee-1, of transaction information, history,
- 262 and statements;
- 263 (iv) safe storage;
- 264 (v) security;
- 265 (vi) inspection;
- 266 (vii) transfer; and
- 267 (viii) dispensing;
- 268 (c) a pharmacist or licensed pharmacy technician working in or consulting with a
- 269 participating eligible donor;
- 270 (d) disposition of a donated prescription drug that is a controlled substance;
- 271 (e) record keeping regarding:
- 272 (i) the eligible donor that donated each prescription drug;
- 273 (ii) the identification and evaluation of a donated prescription drug by a pharmacist or
- 274 licensed pharmacy technician; and
- 275 (iii) the dispensing or disposition of a prescription drug;
- 276 (f) determining the status of a medically indigent individual;
- 277 (g) labeling requirements to:
- 278 (i) ensure compliance with patient privacy laws relating to:
- 279 (A) an individual who receives an eligible prescription drug; and
- 280 (B) patient information that may appear on a donated prescription drug;
- 281 (ii) clearly identify an eligible prescription drug dispensed under the program; and

282 (iii) communicate necessary information regarding the manufacturer's recommended  
283 expiration date or the beyond use date; and

284 (h) ensuring compliance with the requirements of this part;

285 (4) a process for seeking input from:

286 (a) the Department of Health, created in Section 26-1-4, to establish program standards  
287 and procedures for assisted living facilities and nursing care facilities; and

288 (b) the Division of Substance Abuse and Mental Health, created in Section  
289 62A-15-103, to establish program standards and procedures for mental health and substance  
290 abuse clients; and

291 (5) the creation of a special training program that a pharmacist and a licensed pharmacy  
292 technician at an eligible pharmacy must complete before participating in the program.

**VOLUNTEER HEALTH CARE CONTINUING EDUCATION CREDIT**

2016 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: David E. Lifferth**

Senate Sponsor: Brian E. Shiozawa

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**LONG TITLE**

**General Description:**

This bill addresses continuing education credit for a health care professional.

**Highlighted Provisions:**

This bill:

- ▶ defines terms;
- ▶ allows a health care professional to fulfill a portion of the health care professional's continuing education requirement, established by the Division of Occupational and Professional Licensing, by providing hours of uncompensated health care; and
- ▶ makes technical changes.

**Money Appropriated in this Bill:**

None

**Other Special Clauses:**

None

**Utah Code Sections Affected:**

**AMENDS:**

**58-13-3**, as last amended by Laws of Utah 2014, Chapter 400

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*Be it enacted by the Legislature of the state of Utah:*

Section 1. Section **58-13-3** is amended to read:

**58-13-3. Qualified immunity -- Health professionals -- Charity care.**

(1) (a) (i) The Legislature finds many residents of this state do not receive medical care and preventive health care because they lack health insurance or because of financial

30 difficulties or cost.

31 (ii) The Legislature also finds that many physicians, charity health care facilities, and  
32 other health care professionals in this state would be willing to volunteer medical and allied  
33 services without compensation if they were not subject to the high exposure of liability  
34 connected with providing these services.

35 (b) The Legislature therefore declares that its intention in enacting this section is to  
36 encourage the provision of uncompensated volunteer charity health care in exchange for a  
37 limitation on liability for the health care facilities and health care professionals who provide  
38 those volunteer services.

39 (2) As used in this section:

40 (a) "Continuing education requirement" means the requirement for hours of continuing  
41 education, established by the division, with which a health care professional must comply to  
42 renew the health care professional's license under the applicable chapter described in  
43 Subsection (2)(c).

44 [(a)] (b) "Health care facility" means any clinic or hospital, church, or organization  
45 whose primary purpose is to sponsor, promote, or organize uncompensated health care services  
46 for people unable to pay for health care services.

47 [(b)] (c) "Health care professional" means a person licensed under:

- 48 (i) Chapter 5a, Podiatric Physician Licensing Act;
- 49 (ii) Chapter 16a, Utah Optometry Practice Act;
- 50 (iii) Chapter 17b, Pharmacy Practice Act;
- 51 (iv) Chapter 24b, Physical Therapy Practice Act;
- 52 (v) Chapter 31b, Nurse Practice Act;
- 53 (vi) Chapter 40, Recreational Therapy Practice Act;
- 54 (vii) Chapter 41, Speech-Language Pathology and Audiology Licensing Act;
- 55 (viii) Chapter 42a, Occupational Therapy Practice Act;
- 56 (ix) Chapter 44a, Nurse Midwife Practice Act;
- 57 (x) Chapter 49, Dietitian Certification Act;

- 58 (xi) Chapter 60, Mental Health Professional Practice Act;
- 59 (xii) Chapter 67, Utah Medical Practice Act;
- 60 (xiii) Chapter 68, Utah Osteopathic Medical Practice Act;
- 61 (xiv) Chapter 69, Dentist and Dental Hygienist Practice Act;
- 62 (xv) Chapter 70a, Physician Assistant Act; and
- 63 (xvi) Chapter 73, Chiropractic Physician Practice Act.

64 [~~(c)~~] (d) "Remuneration or compensation":

65 (i) (A) means direct or indirect receipt of any payment by a health care professional or  
66 health care facility on behalf of the patient, including payment or reimbursement under  
67 Medicare or Medicaid, or under the state program for the medically indigent on behalf of the  
68 patient; and

69 (B) compensation, salary, or reimbursement to the health care professional from any  
70 source for the health care professional's services or time in volunteering to provide  
71 uncompensated health care; and

72 (ii) does not mean:

73 (A) any grant or donation to the health care facility used to offset direct costs  
74 associated with providing the uncompensated health care such as:

75 (I) medical supplies;

76 (II) drugs; or

77 (III) a charitable donation that is restricted for charitable services at the health care  
78 facility; or

79 (B) incidental reimbursements to the volunteer such as:

80 (I) food supplied to the volunteer;

81 (II) clothing supplied to the volunteer to help identify the volunteer during the time of  
82 volunteer services;

83 (III) mileage reimbursement to the volunteer; or

84 (IV) other similar support to the volunteer.

85 (3) A health care professional who provides health care treatment at or on behalf of a

86 health care facility is not liable in a medical malpractice action if:

87 (a) the treatment was within the scope of the health care professional's license under  
88 this title;

89 (b) neither the health care professional nor the health care facility received  
90 compensation or remuneration for the treatment;

91 (c) the acts or omissions of the health care professional were not grossly negligent or  
92 willful and wanton; and

93 (d) prior to rendering services:

94 (i) the health care professional disclosed in writing to the patient, or if a minor, to the  
95 patient's parent or legal guardian, that the health care professional is providing the services  
96 without receiving remuneration or compensation; and

97 (ii) the patient consented in writing to waive any right to sue for professional  
98 negligence except for acts or omissions which are grossly negligent or are willful and wanton.

99 (4) A health care facility which sponsors, promotes, or organizes the uncompensated  
100 care is not liable in a medical malpractice action for acts and omissions if:

101 (a) the health care facility meets the requirements in Subsection (3)(b);

102 (b) the acts and omissions of the health care facility were not grossly negligent or  
103 willful and wanton; and

104 (c) the health care facility has posted, in a conspicuous place, a notice that in  
105 accordance with this section the health care facility is not liable for any civil damages for acts  
106 or omissions except for those acts or omissions that are grossly negligent or are willful and  
107 wanton.

108 (5) A health care professional who provides health care treatment at a federally  
109 qualified health center, as defined in Subsection 1905(1)(2)(b) of the Social Security Act, or an  
110 Indian health clinic or Urban Indian Health Center, as defined in Title V of the Indian Health  
111 Care Improvement Act, is not liable in a medical malpractice action if:

112 (a) the treatment was within the scope of the health care professional's license under  
113 this title;

114 (b) the health care professional:

115 (i) does not receive compensation or remuneration for treatment provided to any  
116 patient that the provider treats at the federally qualified health center, the Indian health clinic,  
117 or the Urban Indian Health Center; and

118 (ii) is not eligible to be included in coverage under the Federal Tort Claims Act for the  
119 treatment provided at the federally qualified health center, the Indian health clinic, or the Urban  
120 Indian Health Center;

121 (c) the acts or omissions of the health care professional were not grossly negligent or  
122 willful and wanton; and

123 (d) prior to rendering services:

124 (i) the health care professional disclosed in writing to the patient, or if a minor, to the  
125 patient's parent or legal guardian, that the health care professional is providing the services  
126 without receiving remuneration or compensation; and

127 (ii) the patient consented in writing to waive any right to sue for professional  
128 negligence except for acts or omissions that are grossly negligent or are willful and wanton.

129 (6) Immunity from liability under this section does not extend to the use of general  
130 anesthesia or care that requires an overnight stay in a general acute or specialty hospital  
131 licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

132 (7) The provisions of Subsection (5) apply to treatment provided by a healthcare  
133 professional on or after May 13, 2014.

134 (8) A health care professional:

135 (a) may, in accordance with Subsection (8)(b), fulfill up to 15% of the health care  
136 professional's continuing education requirement with hours the health care professional spends  
137 providing health care treatment described in Subsection (3) or (5); and

138 (b) subject to Subsection (8)(a), earns one hour of the health care professional's  
139 continuing education requirement for every four documented hours of volunteer health care  
140 treatment.

1                                   **PRESCRIPTION DRUG ABUSE AMENDMENTS**

2   2016 GENERAL SESSION

3   STATE OF UTAH

4                                   **Chief Sponsor: LaVar Christensen**

5                                   Senate Sponsor: Brian E. Shiozawa

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7   **LONG TITLE**

8   **General Description:**

9           This bill requires prescribers and dispensers to use the controlled substance database to  
10 determine whether a patient may be abusing opioids.

11 **Highlighted Provisions:**

12       This bill:

- 13           ▶ defines terms;
- 14           ▶ amends the Controlled Substances Database Act to promote utilization of the  
15 controlled substances database to prevent opioid abuse;
- 16           ▶ requires a dispenser to contact the prescriber if the controlled substance database  
17 suggests potential prescription drug abuse;
- 18           ▶ limits liability for prescribers and dispensers who contribute to and use the  
19 database; and
- 20           ▶ makes technical changes.

21 **Money Appropriated in this Bill:**

22       None

23 **Other Special Clauses:**

24       None

25 **Utah Code Sections Affected:**

26 AMENDS:

27       **58-37f-701**, as enacted by Laws of Utah 2010, Chapter 287

28 ENACTS:

29       **58-37f-303**, Utah Code Annotated 1953

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*Be it enacted by the Legislature of the state of Utah:*

Section 1. Section 58-37f-303 is enacted to read:

**Part 3. Access and Utilization**

**58-37f-303. Database utilization.**

(1) As used in this section:

(a) "Dispenser" means a licensed pharmacist, as described in Section 58-17b-303, or the pharmacist's licensed intern, as described in Section 58-17b-304, who is also licensed to dispense a controlled substance under Title 58, Chapter 37, Utah Controlled Substances Act.

(b) "Opioid" means those substances listed in Subsection 58-37-4(2)(b)(i) or (2)(b)(ii).

(c) "Outpatient" means a setting in which an individual visits a licensed healthcare facility or a healthcare provider's office for a diagnosis or treatment but is not admitted to a licensed healthcare facility for an overnight stay.

(d) "Prescriber" means an individual authorized to prescribe a controlled substance under Title 58, Chapter 37, Utah Controlled Substances Act.

(2) To address the serious public health concern of life-altering and life-threatening opioid abuse and overdose, and to achieve the purposes of this chapter and as described in Section 58-37f-201, which includes identifying and reducing the prescribing and dispensing of opioids in an unprofessional or unlawful manner or in quantities or frequencies inconsistent with generally recognized standards of dosage for an opioid, through utilization of the carefully developed and highly respected database:

(a) a prescriber or dispenser of an opioid for individual outpatient usage shall access and review the database as necessary in the prescriber's or dispenser's professional judgment and to achieve the purpose of this chapter as described in Section 58-37f-201;

(b) a prescriber may assign the access and review required under Subsection (2)(a) to an employee, in accordance with Subsections 58-37f-301(2)(g) and (h).

(3) The division shall, in collaboration with the licensing boards for prescribers and dispensers:

58 (a) develop a system that gathers and reports to prescribers and dispensers the progress  
59 and results of the prescriber's and dispenser's individual access and review of the database, as  
60 provided in this section; and

61 (b) reduce or waive the division's continuing education requirements regarding opioid  
62 prescriptions, described in Section 58-37-6.5, including the online tutorial and test relating to  
63 the database, for prescribers and dispensers whose individual utilization of the database  
64 contribute to the life-saving and public safety purposes of this section and as described in  
65 Subsection (2).

66 (4) If the dispenser's access and review of the database suggest that the individual  
67 seeking an opioid may be obtaining opioids in quantities or frequencies inconsistent with  
68 generally recognized standards as provided in this section and Section 58-37f-201, the  
69 dispenser shall reasonably attempt to contact the prescriber to obtain the prescriber's informed,  
70 current, and professional decision regarding whether the prescribed opioid is medically  
71 justified, notwithstanding the results of the database search.

72 Section 2. Section **58-37f-701** is amended to read:

73 **58-37f-701. Immunity from liability.**

74 (1) An individual who has submitted information to or accessed and reviewed the  
75 database in accordance with this [section] chapter may not be held civilly liable [for having  
76 submitted the information], including under Title 78B, Chapter 3, Part 4, Utah Health Care  
77 Malpractice Act, for such actions, or a lack of action, which are protected and are not subject to  
78 civil discovery, as provided in Section 58-37f-302.

79 (2) Notwithstanding any other provision of law, any action or lack of action by a  
80 prescriber or dispenser to meet the requirements of Section 58-37f-303 may not be used by the  
81 division in any action against the prescriber or dispenser.

82 (3) Nothing in Section 58-37f-303 establishes a minimum standard of care for  
83 prescribers and dispensers.

# **Abbreviated Case Law Update**

for

Utah Board of Pharmacy and Guests

April 26, 2016

Salt Lake City, Utah

William J. Stilling, BS Pharm, MS, JD



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## I. ANTITRUST

### A. Exclusion of Pharmacies

1. *Star Discount Pharmacy, Inc., et al v. MedImpact Healthcare Sys., Inc.*, 614 F. App'x 988 (11th Cir. June 11, 2015)

**RELIEF SOUGHT:** Pharmacy owner sued prescription drug program third party administrator of violating the Sherman Antitrust Act.

**ISSUE:** Does excluded pharmacy have a valid monopolization claim against third party administrator (or PBM)?

**FACTS AND PROCEDURAL HISTORY:**<sup>1</sup> Pharmacy owner and pharmacies sued MedImpact, administrator of prescription drug program for Alabama's Public Education Employees' Health Insurance Plan ("PEEHIP"), because MedImpact refused to allow them to participate as providers. The pharmacies were part of an association, American Pharmacy Network Solutions ("APNS"), which negotiated with PBMs on behalf of its member pharmacies. After negotiations between APNS and MedImpact failed to achieve a long-term agreement, the APNS pharmacies could not participate in the PEEHIP program. Plaintiffs sued MedImpact for violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO, violation of Alabama's antitrust laws, and negligence, wantonness, unjust enrichment, and intentional interference with a business relationship, pursuant to Alabama common law. Because "federal antitrust law 'prescribe[s] the terms of unlawful monopolies and restraints of trade as they should ... be administered in Alabama," plaintiffs' claims were essentially federal antitrust claims under sections 1 and 2 of the Sherman Act.

Plaintiffs claimed that because of MedImpact's refusal to include the pharmacies in PEEHIP's program: (i) excluded pharmacies "can no longer compete for the business of the defendants' enrollees"; (ii) "defendant's lower reimbursement rate reduces the profit that a pharmacy obtains from serving an additional customer, which profit incentivizes pharmacies to provide better point-of-sale services" and (iii) defendant's lower reimbursements rates can jeopardize a pharmacy's viability.

The district court granted summary judgment in favor of MedImpact on all claims. The only claims at issue on appeal were the antitrust claims.

**REASONING:** To prove a Sherman Act monopolization claim, a plaintiff must show harm to competition; harm solely to specific competitors is insufficient. The court determined that owner provided no evidence to support his claims of harm to competition among pharmacies. The court explained "the only arguably specific evidence of harm to competition" was in an expert report submitted late, after the briefing in the district court had been completed. Even considering that report, the court rejected plaintiffs' antitrust claims. The court addressed each of the harms in plaintiffs' expert report as follows.

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<sup>1</sup> Facts supplemented from the district court's opinion *Star Discount, et al v. MedImpact*, 2014 WL 4470720 (N.D. Ala. 9/10/14).

- *Excluded pharmacies can no longer compete for the business of the defendants' enrollees:* However, only plaintiffs' pharmacies declined joining the PEEHIP network while almost all other pharmacies joined.
- *Defendant's lower reimbursement rate reduces the profit that a pharmacy obtains from serving an additional customer, which profit incentivizes pharmacies to provide better point-of-sale services:* This was merely speculation.
- *Defendant's lower reimbursements rates can jeopardize a pharmacy's viability:* This too was speculative.

[I]t is clear that the instant defendant does not have monopsony power. It controls a mere five percent of the purchases in the market. The plaintiffs, and all other pharmacies which are not in defendant's network of providers, have the remaining ninety-five percent of the available purchases in the market, and plaintiffs are free to join networks of providers competing with the defendant.

**HOLDING:** The court affirmed the district court and held that plaintiffs provided no evidence of harm to competition among pharmacies due to lower reimbursement rates, as required under the Sherman Act.

**New Antitrust Lawsuit against PBM for Exclusion of Pharmacies:** On January 15, 2016 six compounding pharmacies sued Express Scripts, Inc. ("ESI") in the Eastern District of the U.S. District Court of Missouri alleging ESI and other PBMs are jointly boycotting compounding pharmacies and shifted patients to pharmacies in which ESI has an economic interest. *See Precision Rx Compounding, LLC, C & M Health Pro, LLC, Northern Va. Compounders, PLLC, Toth Enterprises II, PA, The Daily Dose, LP, and CPRX Pharmacy, LP, v. Express Scripts Holding Company,*) and *Express Scripts, Inc.*, Case No. 4:1-cv-0069.

## B. State Regulatory Boards Immunity

### 1. *North Carolina Bd. of Dental Examiners. v. Federal Trade Commission*, 135 S. Ct. 1101 (Feb. 25, 2015)

**RELIEF SOUGHT:** FTC sought injunctive relief against the North Carolina Board of Dental Examiners to stop Board from: (i) prohibiting non-dentists from providing teeth whitening services or products, (ii) discouraging the provision of such goods or services, and (iii) communicating to third parties that such provision violated state law.

#### ISSUES:

1. Were Board's actions anti-competitive?
2. Were Board's actions protected by state-action immunity?

**FACTS AND PROCEDURAL HISTORY:** North Carolina Dental Practice Act stated that Board was "the agency of the state for the regulation of the practice of dentistry," and that Board may file suit to enjoin any person from unlawfully practicing dentistry. Statute required an 8-member board: (i) 6

members to be licensed dentists; (ii) 1 to be a dental hygienist; and (iii) 1 to be a “consumer” appointed by Governor.

Board began to receive dentist complaints about non-dentists conducting teeth whitening services. Few of the complaints warned of potential harm to clients, but most focused on low prices charged by non-dentists. These individuals competed directly with teeth-whitening services from dentists. The Board opened an investigation in response to complaints. The dentist member led the inquiry while the hygienist and consumer members did not participate.

Board sent multiple “cease and desist” letters on Board letterhead to the unlicensed individuals seeking to impose fines or other liability for unlicensed practice of dentistry, a violation of the Dental Practice Act. Board also convinced the “North Carolina Board of Cosmetic Art Examiners to warn cosmetologists against providing teeth whitening services.”

The letters were effective. Non-dentists stopped offering teeth whitening in NC. No Board rule or regulation was developed, even though the Act did not specify that teeth whitening be considered dental practice. FTC challenged the Board’s actions, claiming actions to be anti-competitive and an unfair method of competition. Board argued it was operating under its state regulatory powers to protect the health and safety of North Carolina citizens (“State Action Doctrine”). Board sought immunity under doctrine.

An ALJ denied Board’s motion to dismiss, and concluded Board’s actions were anti-competitive, unreasonably restrained trade, and violated federal law. The Fourth Circuit affirmed.

**REASONING:** The U.S. Supreme Court explained that anti-trust laws are a “central safeguard” for a free market. However, states often pass laws and regulate economic activities that would normally run afoul of antitrust laws as restrictions on occupations or other restrictions on competition to further other public objectives. Therefore, states acting within their sovereign powers are not subject to antitrust laws. This is known as *Parker* immunity after the *Parker v. Brown*, 317 U.S. 341, 63 S.Ct. 307 (1943), the case that established state immunity from antitrust laws.

The N.C. Board argued the state gave its members the power of the state to regulate dentistry and the *Parker* immunity protected them from antitrust claims. The court rejected this argument because:

A nonsovereign actor controlled by active market participants—such as the Board—enjoys *Parker* immunity only if it satisfies two requirements: “first that ‘the challenged restraint ... be one clearly articulated and affirmatively expressed as state policy,’ and second that ‘the policy ... be actively supervised by the State.’”

The court and the parties assumed the first requirement for a clearly articulated and affirmatively expressed state policy had been met. The law prohibits the unlicensed practice of dentistry. However, the law does not address teeth whitening. However, the Board did not receive active supervision of the state when it interpreted the law to prohibit teeth whitening by non-dentists and issued cease-and-desist letters to non-dentists. Here, the dentist Board members were market participants who could gain financially from limiting competition by non-dentists, which the court noted is the “very risk of self-dealing” that the active supervision requirement was created to address.

The question that must be answered in evaluating sufficient state supervision “is whether the State’s review mechanisms provide ‘realistic assurance’ that a nonsovereign actor’s anticompetitive conduct ‘promotes state policy, rather than merely the party’s individual interests.’” The court noted a “few constant requirements of active supervision: [i] The supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it; [ii] the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy; and [iii] the “mere potential for state supervision is not an adequate substitute for a decision by the State[; and iv] . . . the state supervisor may not itself be an active market participant. In general, however, the adequacy of supervision otherwise will depend on all the circumstances of a case.” (citations omitted).

**HOLDINGS:** Supreme Court affirmed Fourth Circuit’s decision, finding:

1. Board’s actions were anti-competitive.
2. Board’s actions were not protected by state-action immunity.

**NOTE:** After the Supreme Court’s decision in *North Carolina Bd. of Dental Examiners*, the FTC issued *FTC Staff Guidance on Active Supervision of State Regulatory Boards Controlled by Market Participants* to help states’ evaluate whether their regulatory boards will receive *Parker* immunity. This guidance can be found at:

[https://www.ftc.gov/system/files/attachments/competition-policy-guidance/active\\_supervision\\_of\\_state\\_boards.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/active_supervision_of_state_boards.pdf)

See *Strategic Pharmaceutical Solutions, Inc. v. Nevada State Board of Pharmacy et al.*, No. 2:16-cv-00171-RFB-VCF, D. Nev., January 29, 2016

## II. CIVIL PROCEDURE

### A. Spoliation of Evidence–Pharmacy’s Duty to Retain Misfills

1. *Burton v. Walgreen Co.*, 2015 WL 4228854 (D. Nev. July 10, 2015)

**RELIEF SOUGHT:** Patient sought sanctions against pharmacy for willful spoliation of evidence after Walgreens destroyed bottle and pills returned after a misfill.

### ISSUES:

1. Did Walgreens have a duty to preserve evidence (bottle/pills)?
2. Was Walgreen on notice of potential litigation due to misfill?

**FACTS AND PROCEDURAL HISTORY:** Walgreens’ patient received a prescription for an antihypertensive prescription (Diovan). The prescription instructed patient to take one tablet of Diovan by mouth daily. A Walgreens’ pharmacist misfiled patient’s prescription with a mix of Diovan and Lithium pills (same color, but differently shaped pills). Patient took as instructed. Wife noticed two differently shaped pills, reported it to Walgreens, and returned pills/bottle to pharmacy. Patient experienced numbness and weakness in left hand and was later hospitalized. Hospital records showed

patient took approximately one 300 mg lithium pill per day for 5 days. Patient claimed hospital learned of lithium intake from communication with Walgreens' pharmacists.

As patient's symptoms worsened over time, he was diagnosed with carpal tunnel syndrome and polyneuropathy as result of improper ingestion of lithium. Patient underwent surgery on hand/arm, but suffered residual pain and stiffness. Patient sued Walgreen alleging various claims of negligence. During the initial discovery, patient asked for Walgreen policies for dealing with misfills and for the returned medications and original bottle so the suspect pills could be tested to determine if they were actually lithium. Walgreen informed patient that bottle and pills were destroyed in accordance with store policy.

Plaintiff filed a motion for spoliation sanctions and asked the court to strike defendant's answer and affirmative defenses on liability and causation. Plaintiff also sought a bench trial to determine the sole remaining issue of plaintiff's damages. As an alternative, plaintiff requested an adverse inference jury instruction, which would have allowed the jury to presume the missing evidence would have supported plaintiff's negligence claim. Plaintiff further asked the court to exclude any evidence that would controvert the adverse inference. Finally, plaintiff sought attorneys' fees and costs expended to prepare the motion for sanctions.

**REASONING:** "Spoliation is the destruction or significant alteration of evidence or the failure to preserve property for another's use as evidence pending or reasonably foreseeable litigation." The court reasoned, "[w]hen a defendant destroys evidence according to its internal policies or the normal course of business, that defendant has not engaged in the spoliation of evidence if the defendant had no notice of the evidence's potential relevance in future litigation." No evidence showed Walgreens' pharmacist purposefully and willfully destroyed evidence. Medication was destroyed as directed by store policy.

Further, Walgreens was on notice of potential litigation due to its error. Return of incorrectly filled medication by patient, triggered duty to preserve evidence. Walgreens had duty to preserve, but plaintiff faced no prejudice from spoliation because Walgreens admitted the misfill. Plaintiff had ample evidence to show lithium caused harm.

**HOLDINGS:** Court denied plaintiff's motion because Walgreens admitted error and there was no prejudice from destruction of prescription.

1. Walgreen did not have a duty to preserve evidence because the evidence was destroyed in accordance with its internal policies. The evidence was not destroyed purposefully or willfully.

### III. CONSTITUTIONAL LAW

#### A. First Amendment—Off-Label Use

1. *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, No. 15 Civ. 3588, 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015)

**RELIEF SOUGHT:** Pharmaceutical manufacturer sought an injunction against the FDA to prohibit FDA from deeming Vascepa as misbranded because the First Amendment protected its promotion of the drug for "off-label" use.

**ISSUE:** Does the First Amendment protect a drug manufacturer that promotes a drug for “off-label” use when such promotion is truthful and non-misleading?

**FACTS AND PROCEDURAL HISTORY:** Amarin Pharma, Inc. manufactures a triglyceride-lowering drug, Vascepa—a pure eicosapentaenoic acid, which is an omega-3 fatty acid. Amarin sought FDA approval for two separate uses of Vascepa, but the FDA rejected one indication and claimed promoting the drug for that use would make the drug misbranded. The court succinctly described the facts as follows:

Amarin wishes to make truthful statements to doctors relating to Vascepa's off-label use. The specific statements Amarin seeks to make are derived largely from an FDA-approved study of Vascepa's off-label use, and from writings by the FDA itself on that subject. Amarin therefore contends, and the FDA largely but not wholly concedes, that the statements Amarin seeks to make are truthful and non-misleading. However, the FDA, recognizing that Amarin's purpose in making these statements would be to promote an unapproved use of Vascepa, has threatened to bring misbranding charges against Amarin (and, presumably, its employees) if it does so.

In July 2012, Amarin received FDA approval to market Vascepa to treat adults with severe hypertriglyceridemia (i.e., triglyceride (“TG”) levels above 500 mg/dL of blood). Amarin sought FDA approval to market Vascepa for patients with persistently high TGs (i.e., TG levels between 200 and 499 mg/dL of blood) who are already take a statin. “This second use is the off-label use at issue in this case.”

Amarin conducted three studies: (i) MARINE study, which demonstrated Vascepa effectively lowered TG levels in patients with severe hypertriglyceridemia; (ii) ANCHOR study, which demonstrated Vascepa effectively lowered TGs in patients with persistently high TGs (21.5% lowering within 12 weeks); and (iii) REDUCE-IT study, which is still in progress to determine whether lowering TGs with Vascepa affects the risk of cardiovascular events. These latter two studies were subjects of special protocol assessment (“SPA”) agreements with the FDA. Under an SPA, if a drug meets the endpoint measurements for effectiveness, the FDA must approve the indication unless “a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.”

Despite the fact that Vascepa achieved the endpoint measurements in the ANCHOR study by reducing TGs in patients with persistently high TGs, the FDA refused to approve that indication. In its Complete Response Letter (“CRL”), the FDA stated that a “substantial scientific issue” arose because studies for other TG lowering drugs (fenofibrates or niacin) did not reduce the risk of cardiovascular events. In the penultimate paragraph of the CRL, the FDA stated: “This product [Vascepa] may be considered to be misbranded under the [FDCA] if it is marketed with this change before approval of this supplemental application.”

Amarin claimed FDA’s misbranding action would chill its constitutionally protected truthful speech. Thus, Amarin sought preliminary injunctive relief allowing it to continue promoting Vascepa for use in reducing TGs in patients with persistently high TGs free from potential FDA misbranding action.

**REASONING:** In constitutional pre-enforcement challenges, a plaintiff “must demonstrate a genuine threat that the alleged unconstitutional law is about to be enforced against him.” In First Amendment cases, such challenges are assessed “under somewhat relaxed standing and ripeness rules.” The court

determined that Amarin had standing to challenge FDA's threatened action to deem Vascepa as misbranded.

Amarin established "substantial likelihood of success on the merits" in its First Amendment claim to be "free from a misbranding action based on truthful speech promoting the off-label use of an FDA-approved drug." The court determined that "[w]here the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under *Caronia*<sup>2</sup>, cannot be the act upon which an action for misbranding is based."

**HOLDING:** The court granted Amarin's request for a preliminary injunction, holding that Amarin had standing to bring First Amendment claim and that truthful and non-misleading speech cannot form the basis for the prosecution of a misbranding claim.

**Settlement:** The parties settled this case on March 8, 2016. Amarin continues to market Vascepa for patients with persistently high TGs.

#### IV. CONTROLLED SUBSTANCES

##### A. Duty to Verify DEA Registration

1. *Farmacia, Yani*, 80 Fed. Reg. 29,053 (May 20, 2015)
2. *JM Pharmacy Group Inc., d/b/a/ Farmacia Nueva and Best Pharma Corp.*, 80 Fed. Reg. 28,667 (May 19, 2015)

**RELIEF SOUGHT:** In two separate DEA actions against pharmacies, each pharmacy appealed the decision of an administrative law judge ("ALJ") to deny applications for DEA registration.

**ISSUE:** Does a pharmacy have a duty to verify the DEA registration of prescribers under the DEA corresponding liability regulation?

**FACTS AND PROCEDURAL HISTORY:** In *JM Pharmacy*, the DEA claimed two pharmacies filled more than 170 prescriptions for a physician whose DEA registration had been revoked. *Farmacia Yani* involved allegations that the pharmacy filled more than 200 prescriptions for controlled substances for a physician whose DEA registration had been revoked. Both cases involved additional, detailed facts that the ALJ used as bases for denying the registrations. The most important basis for denial for purposes of this summary is ALJ finding that the pharmacies could have checked the prescribers' registration on the DEA diversion website, contacted the local DEA office, or contracted with a private service to obtain DEA verifications.

**REASONING:** The DEA Administrator (Administrator) reviewed the ALJ's decision and analyzed the corresponding liability section of the DEA regulations and other applicable laws and regulations.

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<sup>2</sup> *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

§ 1306.04 Purpose of issue of prescription.

(a) 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.

The Administrator noted that under this section, the pharmacist must act knowingly or intentionally. Moreover, there is no requirement in the Controlled Substances Act or DEA regulations that requires a pharmacist to verify a prescriber's DEA registration before dispensing a controlled substance prescription. To meet this requirement, a pharmacist must have knowledge or reason to know a prescription is not valid. The Administrator explained the pharmacists violated a duty to periodically check whether a prescriber had retained authority to practice medicine and dispense controlled substances. The Administrator further noted that the DEA must provide some guidance on the scope of this duty before the DEA will do anything more than give "nominal weight" to such a duty. The Administrator concluded that a pharmacist must have knowledge that a prescription is not valid, but also mentioned an amorphous duty to verify DEA registration. In *JM Pharmacy*, the Administrator denied registration case because pharmacy had falsified its application for registration.

**HOLDING:** In the *Farmacia Yani* case, the Administrator afforded minimal weight to the failure to verify DEA registrations and held the DEA application in abeyance for six months until the pharmacy personnel completed a course on controlled substances dispensing and corresponding liability. In *JM Pharmacy Group*, the Administrator likewise gave nominal weight to the pharmacists not ensuring the DEA numbers were current, but denied the registration because the pharmacy falsified its renewal application.

## V. DEFAMATION

### A. Physician against Pharmacist

#### 1. *LeFrock v. Walgreen Co.*, 77 F.Supp.3d 1199 (M.D. Fla. Jan. 16, 2015)

**RELIEF SOUGHT:** Physician sued Walgreens for alleged defamatory statements made by Walgreens pharmacists.

#### ISSUES:

1. Did pharmacists commit slander against physician during consultation with patient?
2. Were comments made during the consultation privileged?

**FACTS AND PROCEDURAL HISTORY:** Physician brought defamation claim against pharmacy. Physician claimed pharmacists at Walgreens made defamatory statements to patients regarding his medical reputation and ethics when they attempted to fill prescriptions. “[T]he apparent purpose of the statement was to inform customers about the physician who wrote the prescription.”

Plaintiff claimed Walgreens’ employees committed slander per se when they “conveyed defamatory statements” regarding his qualifications as a medical doctor. Walgreens moved for summary judgment.

**REASONING:** In order to prevail in a claim for slander under Florida law, a plaintiff must prove: (i) a false and defamatory statement; (ii) an unprivileged publication to a third party; (iii) fault amounting to at least negligence by the publisher; (iv) either an actionable statement irrespective of harm or the existence of special harm caused by the publication. Malice is an essential element of slander. Malice is presumed when a false statement states or suggests a person committed a dishonest or illegal act. When a statement is privileged, the presumption of malice does not apply.

Statements are privileged if: “(1) made in good faith, (2) with an interest to be upheld, (3) made on a proper occasion, and (4) made in a proper manner.”

Pharmacists acted in good faith and were upholding a legitimate interest because statements were made while filling scripts, and giving advice required by law. Pharmacists have duty to provide competent advice to customers “beyond merely following the doctor’s instructions robotically.”

Pharmacists exercised due diligence by informing customers of relevant information regarding the prescribing physician. Statements were made in proper location and manner. Statements were limited in scope to the specific prescriptions and were not mere generalizations. Therefore, pharmacists’ statements were protected by privilege; plaintiff cannot overcome qualified privilege because he failed to present evidence that statements were made with express malice.

**HOLDINGS:**

1. Pharmacists did not commit slander against physician during consultation with patient.
2. Comments made during the consultation were privileged.

**RELATED CASES:**

2. *Mimms v. CVS Pharmacy, Inc.*, No. 1:15-cv-00970 (N.N. Ind. Oct. 1, 2015)

**BRIEF SUMMARY:** Physician, who specialized in physical and rehabilitation medicine, sued CVS claiming that CVS employees committed per se defamation based on alleged statements including: (i) he “he operates a pill mill”; (ii) is a “murderer”; (iii) is “under DEA investigation”; and (iv) “had been or would soon be arrested” and the patients “should find another doctor.” CVS moved to dismiss the defamation claim because plaintiff did not sufficiently plead details such as who made the statements or when they were made and because the statements were protected by a qualified privilege. Court denied the motion because plaintiff would need to conduct discovery about the person and time of the statements. Court also said the question of whether a qualified privilege applied required discovery. Thus, the case would go forward so the parties could conduct discovery.

3. **Yarus v. Walgreen Co., No. 14-1656 (E.D. Penn. Oct. 9, 2015)**

**BRIEF SUMMARY:** Orthopedic surgeon who focused on pain management sued Walgreen for alleged defamatory statements from May 1, 2009 through December 9, 2013. Plaintiff claimed Walgreen had put a warning in his profile on its computer was “red flagged” with a message “BEING INVESTIGATED BY THE DEA!!!” Plaintiff also claimed Walgreen employees told patients, “Dr. Yarus is an irresponsible doctor who just writes scripts and probably does very little treating” and he “passes out too many pills,” among other statements. Walgreen sought summary judgment based on running of the statute of limitation and qualified immunity. The court dismissed claims based on statements made prior to 2012 because they were time-barred. The court also ruled that the warnings on the Walgreen computer were not defamatory because they were not “published” to third parties. The court denied defendants motion for several claims because a jury could find: (i) the statements could be construed as defamatory; (ii) they were made with malice because the statements implicated criminal activity; and (iii) the qualified privilege did not apply.

4. **Goulmamine v. CVS Pharmacy, Inc., 3:15-cv-370 (E.D. Vir. October 9, 2015)**

**BRIEF SUMMARY:** CVS sought to dismiss Dr. Goulmamine’s complaint alleging CVS employees told his patients they would not loner fill prescriptions he wrote. The complaint was based on alleged factually incorrect statements (e.g., he was “in jail,” overprescribed to pregnant patient, one patient died of Xanax overdose, government agencies were investigating him or revoked his license); opinions (e.g., “he fills [sic] too many prescriptions,” he won’t be in business much longer); and statements about patients (e.g., “you shouldn’t be taking these pain pill,” “you are probably a drug addict”) that were defamatory. **Court denied the motion to dismiss the defamation claim because:** (i) Dr. Goulmamine had pled statements that could be defamantory; (ii) statements are not necessarily protected by privilege (as in *LeFrock*); and (iii) even if communications were protected by a qualified privilege, there is a question of fact for the jury as to whether the privilege was lost because the statements were made with malice. The court granted the motion to dismiss the claim whether certain statements were actionable under Virginia’s insulting words statute, but allowed Dr. Goulmamine to amend his complaint.

**B. Duty to Fill**

1. **Kadambi v. Express Scripts, 2015 WL 475373 (N.D. Ind. February 5, 2015)**

**RELIEF SOUGHT:** Physician and eight patients sued mail-order pharmacies for breach of duty to honor prescriptions and to fill as written. Physician sued for defamation.

**ISSUES:**

1. Does Indiana pharmacy law, purportedly requiring pharmacists to honor all prescriptions from a physician, create a private cause of action?
2. Does Indiana anti-SLAP (strategic lawsuit against public participation) statute bar plaintiff’s defamation claim?
3. Are pharmacist statements to patients regarding reason for refusal to dispense protected by qualified privilege?

**FACTS AND PROCEDURAL HISTORY:** Dr. Kadambi, an endocrinologist, prescribed HGH for patients claiming HGH was medically necessary and approved by insurance companies. Defendant pharmacies refused to fill HGH prescriptions from Dr. Kadambi. Pharmacies claimed refusal was based on concern of violating 21 U.S.C. § 333(e). Section 333(e) makes distributing HGH for off-label use a felony. Pharmacists claimed they learned Dr. Kadambi prescribed HGH for off-label use or he was associated with organizations advocating for off-label use. Pharmacies explained to patients their refusal was based on suspect prescribing. Plaintiffs first alleged pharmacy violated Indiana Code § 25-26-13-16 requiring pharmacists to “exercise his professional judgment in the best interest of the patient’s health” and that “a pharmacist has a duty to honor all prescriptions from a practitioner.” Pharmacists must take “reasonable steps” to determine whether a prescription has complied with applicable law.

Patients sued pharmacies alleging (i) violation of Indiana pharmacy law/breach of duty to honor prescription and (ii) defamation.

Indiana Code § 25-26-13-16 granted immunity for criminal and civil liability for refusing to honor prescription if: (i) it would be contrary to law, (ii) be in best interest of patient, (iii) aid or abet an addiction or habit, or (iv) is contrary to health and safety of patient. Plaintiffs argued that because the code provided civil immunity for failure to honor prescriptions, the logical implication is that immunity would not be necessary if there was not private right of action.

Defendants moved to dismiss under state anti-SLAP law (designed to reduce lawsuits brought to chill freedom of speech—used as defense against a plaintiff’s defamation claim. Pharmacies argued that statements made to patients regarding refusal to honor HGH prescriptions were in furtherance of free speech on a public issue. Defendants argued statements were too narrow and patient-specific for anti-SLAP protection and statements were not made in public interest. Defendants also argued defamation claim was barred by qualified privilege. Under Indiana law, a statement is privileged if: (i) made in good faith; (ii) with an interest to be upheld (iii) made on a proper occasion; (iv) made in a proper manner.

Defendants claimed Dr. Kadambi: (i) wrote prescriptions for cosmetic reasons; (ii) is a plastic surgeon; (iii) is on a list of physicians involved with sports medicine and anti-aging medicine; and (iv) issued fraudulent and illegal prescriptions.

Dr. Kadambi alleged statements were not made in good faith because they turned a blind eye to key information that defendant had discovered about Dr. Kadambi in a previous suit. Pharmacies argued statements were made in good faith after investigations regarding HGH prescriptions by Dr. Kadambi.

**REASONING:** The court reasoned Indiana Code § 25-26-13-16 did not provide a private right of action. The law benefits the public at large, not any specific individual.

The court also held the anti-SLAP law did not protect pharmacies. There was no public interest in statements made to patients regarding Dr. Kadambi’s prescribing of HGH. Statements were not in furtherance of free speech, but were communicated to patients about reasons for not dispensing and to protect pharmacy from liability under federal law. Genuine issue of material fact existed as to whether defendant’s statements were made in good faith.

**HOLDINGS:**

1. As to claim under Indiana pharmacy law, court granted pharmacies' motion to dismiss on the pleadings.
2. Court denied motion to dismiss under anti-SLAP law because the law did not afford protection to pharmacies.
3. Court denied defendant's motion for summary judgment on qualified privilege because fact question existed about whether statements to patients were made in good faith.

## VI. EMPLOYMENT

### A. American with Disabilities Act

#### 1. *Stevens v. Rite Aid Corp., et al.*, 6:13-cv-00783 (N.D.N.Y., September 23, 2015)

**RELIEF SOUGHT:** Pharmacist sued former employer for violation of the Americans with Disabilities Act (ADA) and the New York State Human Rights Law (NYSHRL).

#### ISSUES:

1. Did employer violate the ADA and the NYSHRL after terminating a pharmacist who refused to provide vaccinations because of trypanophobia (needle phobia)?
2. Is trypanophobia a recognized disability?
3. Did Rite Aid fail to provide reasonable accommodations to the employee?
4. Where awarded damages excessive?

**FACTS AND PROCEDURAL HISTORY:** Pharmacist Christopher Stevens was a pharmacist at Eckerd Pharmacy in upstate New York. Rite Aid purchased the pharmacy in 2007. Rite Aid required all pharmacists to undergo mandatory immunization training. Stevens had never undergone such training. Stevens provided HR and district managers with letters from physician stating he has trypanophobia—needle phobia. Stevens contended that it would be unsafe for him to provide immunizations to patients.

Rite Aid warned Stevens he would be terminated if he did not undergo immunization training. Stevens refused and was fired days later. Stevens filed complaint with the EEOC. During the investigation, Rite Aid admitted Stevens was fired because he refused to administer flu shots.

Rite Aid argued that trypanophobia was not a disability defined by the ADA and firing was on a "legitimate, nondiscriminatory" basis. A jury found:

- (1) [Stevens] was discharged because of a disability in violation of the ADA; (2) Rite Aid failed to provide a reasonable accommodation in violation of the ADA; (3) [Stevens] was retaliated against in violation of the ADA; (4) [Stevens] was discharged because of a disability in violation of the NYSHRL; (5) Rite Aid failed to provide a reasonable

accommodation in violation of the NYSHRL; and (6) [Stevens] was retaliated against in violation of the NYSHRL. The Jury awarded Plaintiff \$485,633.00 in back-pay damages; \$1,227,188.00 in front-pay damages (encompassing 4.75 years from the date of the verdict, *i.e.*, January 22, 2015); and \$900,000.00 in non-pecuniary damages.

Pharmacy filed motions for judgment as a matter of law seeking to overturn jury verdict, or, in the alternative, seeking a new trial.

**REASONING:** The court first addressed whether the pharmacist had a *physiological or psychological disability*. The EEOC defines physical or mental impairment to mean:

Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more body systems, such as neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, Immune, circulatory, hemic, lymphatic, skin, and endocrine . . . .

A physician testified the pharmacist exhibited an “unprepared, spontaneous reaction . . . that could not be rehearsed” that included turning white, looking annoyed, and almost fainting when the physician pierced his own skin with an insulin syringe and drew blood.

The court concluded there was sufficient evidence that the *impairment was a “substantial limitation,”* which means the impairment substantially limits the ability of an individual to perform a major life activity as compare to most people.” However, an impairment “need not prevent, or significantly or severely restrict, the individual from performing a major life activity in order to be considered substantially limiting.” A physician testified that the trypanophobia significantly restricted the pharmacist from performing any job involving administration of injections.

The court also found sufficient evidence that *trypanophobia is a neurological impairment* based on expert testimony that the impairment impacted the pharmacist’s neurological function through the “sympathetic branch of the nervous system,” which caused anxiety, which in turn caused the pharmacist to avoid the thing he was phobic about.

The court then evaluated whether giving immunizations was an *essential job function*. If an employee cannot perform an essential job function with or without reasonable accommodation, the employer is not required to eliminate the function. Rite Aid District Manager did not include immunizations in his description of plaintiff’s duties. None of the 16 “essential duties and responsibilities” in the job description included immunization. Thus, there was sufficient evidence that immunization was not an essential job function. However, the court found that the pharmacist did not present sufficient evidence that Rite Aid failed to reasonably accommodate his disability by providing desensitization therapy, hiring a nurse, giving him technician position, or assigning him to a dual-pharmacist store.

The court turned to damages and sustained all damages except for the \$900,000 of compensatory damages based largely on emotional distress because such damages would shock the judicial conscience.

Type of Damages	Jury	Court's Decision
Back Pay	\$485,633	Same
Front Pay	\$1,227,188	Same
Non-pecuniary	\$900,00	\$125,000
Total	\$2,612,821	\$1,837,821 (or new trial)

**HOLDINGS:**

1. The court held there was sufficient evidence to support each of the jury's findings except for the finding that Rite Aid failed to provide reasonable accommodation by not allowing time off for "desensitization."
2. The jury's damages award was proper except for the non-pecuniary award for \$900,000, which the court reduced to \$125,000, or plaintiff could try the case again.

**VII. FRAUD AND ABUSE**

**A. False Claims--Generic Substitutions**

1. *Doe v. Houchens Indus., Inc.*, No. 1:13-CV-00196-RLY, 2015 WL 133706 (S.D. Ind. Jan. 9, 2015)

**RELIEF SOUGHT:** Relator brought *qui tam* claims under the federal FCA and the Indiana false claims act alleging defendant misrepresented drug prices.

**ISSUE:** Did relator sufficiently allege a FCA claim by claiming pharmacy's reward program allowed patients to purchase prescriptions at a lower price than the pharmacy used for usual and customary price calculations?

**FACTS AND PROCEDURAL HISTORY:** Defendant developed a pharmacy rewards program permitting cash-paying customers to pay a small fee to participate in the program, which offered flat discounted fees for hundreds of generic medications.

Relator (a former employee) was instructed to "collect a small fee from the enrollees and give them a gift card in the same amount to offset the fee." Defendant also instructed relator "when billing Medicare Part

D and other third parties for a generic drug on the program list,” *not* to “change the price to the discounted price unless the co-pay exceeded \$3.99.” Relator claimed defendant overcharged the government by seeking reimbursement for the generic drug in an amount in excess of the “usual and customary” price it typically charged cash-paying customers. Relator alleged that this violated the FCA and the Indiana FCA. Defendant moved to dismiss.

**REASONING:** The FCA imposes liability on anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” Pharmacies who “contract with Medicare Part D plan sponsors are required to price prescriptions *at the contracted rate or U & C rate, whichever is lower.*” U&C price is the amount a provider would charge cash customers for a prescription, exclusive of sales tax.

Defendant argued that the special pricing it offered members who enroll in the Rewards program was not the U & C price because that price was not offered to the general public, but only to those who enrolled. However, this argument was rejected in *United States ex rel. Garbe v. Kmart Corp.*, 968 F.Supp.2d 978, 982–83 (S.D. Ill. 2013).

In *Garbe*, the court found that members of Kmart’s generic discount program were considered a part of the general public because anyone can join. Here, the enrollment process was simple and open to anyone who filled prescriptions at the pharmacy.

**HOLDING:** Court denied motion to dismiss because relator stated plausible claims under the FCA.

## VIII. MEDICAID

### A. Reimbursement Challenges (cuts to reimbursement)

#### 1. *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378 (2015)

**RELIEF SOUGHT:** Medicaid providers sued Idaho’s Department of Health and Welfare (“IDHW”) for failing to amend Medicaid reimbursement rates.

**ISSUE:** Can Medicaid providers sue a state in federal court to obtain injunctive relief for inadequate reimbursement under the Medicaid Act?

**FACTS AND PROCEDURAL HISTORY:** Plaintiffs, providers of “habilitation services,” are reimbursed by the Idaho Department of Health and Welfare through Idaho’s Medicaid plan. Section 30(A) of the Medicaid Act requires the Idaho's plan to “assure that payments are consistent with efficiency, economy, and quality of care” while “safeguard[ing] against unnecessary utilization of ... care and services.” Plaintiffs claimed Idaho reimbursed them at rates below the section 30(A) requirements and sought to enjoin the state to increase rates. The trial court and Ninth Circuit found in favor of the providers. The Ninth Circuit reasoned that the Supremacy Clause gave the providers a cause of action. The state appealed.

**REASONING:** The Supreme Court determined that the Supremacy Clause is not the source of federal rights, and thus does not create a cause of action. Instead, Congress has broad discretion in implementing its enumerated powers and has the authority to “make all Laws which shall be necessary and proper for carrying [them] into Execution.”

Spending Clause legislation like Medicaid “is much in the nature of a contract.” The notion that respondents have a right to sue derives, perhaps, from the fact that they are beneficiaries of the federal-state Medicaid agreement, and that intended beneficiaries, in modern times at least, can sue to enforce the obligations of private contracting parties. We doubt, to begin with, that providers are intended beneficiaries (as opposed to mere incidental beneficiaries) of the Medicaid agreement, which was concluded for the benefit of the infirm whom the providers were to serve, rather than for the benefit of the providers themselves. More fundamentally, however, the modern jurisprudence permitting intended beneficiaries to sue does not generally apply to contracts between a private party and the government—much less to contracts between two governments. Our precedents establish that a private right of action under federal law is not created by mere implication, but must be “unambiguously conferred.” Nothing in the Medicaid Act suggests that Congress meant to change that for the commitments made under § 30(A).

**HOLDING:** The U.S. Supreme Court reversed the Ninth Circuit. Medicaid providers do not have a private right of action to challenge inadequate reimbursements under the Medicaid Act.

## **IX. MEDICAL MARIJUANA**

### **A. DEA Authority to Enforce Controlled Substances Act**

1. *United States of America v. Marin Alliance For Medical Marijuana (“MAMM”), and Lynette Shaw*, No. C 98-00086 N.D. Cal. Ot. 19, 2015)

**RELIEF SOUGHT:** Medical marijuana dispensary asked the court to dissolve a permanent injunction that prohibited it from dispensing medical marijuana under California’s Compassionate Use Act because Congress prohibited the Department of Justice (“DOJ”) from using any resources to interfere with a state’s ability to implement its own medical marijuana laws.

**ISSUE:** Does Congress’s ban on DOJ’s interference with implementation of state medical marijuana laws warrant lifting the permanent injunction against MAMM?

**FACTS AND PROCEDURAL HISTORY:** In 2002, after four years of litigation, the U.S. District Court, Northern Division a permanent injunction against MAMM and five other dispensaries in Marin County. MAMM continued to operate its dispensary after the entry of the injunction, but the U.S. Attorney’s Office waited until 2011 to send cease and desist notices to the dispensaries. The mayor of Fairfax wrote to the U.S. Attorney explaining Marin County had the “the highest documented rate of breast cancer in the United States,” and the closure of legal marijuana dispensaries would be contrary to public safety by pushing the sale underground and that denying patients medical marijuana would needlessly increase the

suffering of patients. The DOJ nevertheless initiated a forfeiture proceeding to seize the property where MAMM operated.

In 2014, Congress passed the 2015 Appropriations Act, which in relevant part reads:

*None of the funds made available in this Act to the Department of Justice may be used, with respect to the States of Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, and Wisconsin, to prevent such States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana.*

Section 538 of the Consolidated and Further Continuing Appropriations Act of 2015, Pub. L. 113-235, 128 Stat. 2130 (2014) (“§ 538”). Section 538 was included in the Appropriations Act of 2016.

**REASONING:** The court began with its clear conclusion: “The plain reading of the text of Section 538 forbids the Department of Justice from enforcing this injunction against MAMM to the extent that MAMM operates in compliance with California law.” The court’s language is so emphatic that it warrants an extensive excerpt.

*The Government's contrary reading so tortures the plain meaning of the statute that it must be quoted to ensure credible articulation.* Specifically, the Government contends that Section 538 proscribes

"the use of appropriated funds to `prevent' states from `implementing their own' medical marijuana laws. Such prohibited uses could include, for example, federal actions that interfered with a state's promulgation of regulations implementing its statutory provisions, or with its establishment of a state licensing scheme. However, such uses do not include CSA enforcement actions against individuals or private businesses because such actions do not prevent a State from implementing its own laws. . . . [T]here is no evidence in the record that California has been impeded in any way in implementing its own State laws during the thirteen years the permanent injunction at issue has been in effect."

Where to start? An initial matter, perhaps, is the contradiction inherent in the Government's assertion that enjoining any one medical marijuana dispensary—here, MAMM—does not impede California's implementation of its medical marijuana laws.

(emphasis added). The court explained that the government’s “drop-in-the-bucket is at odds with fundamental notions of the rule of law.” Section 538 does not allow a little bit of enforcement. Congress chose to ban enforcement of federal laws by prohibiting the use of funds for such efforts.

The court further reasoned that California has chosen its own legal framework for allowing private dispensaries to operate under an intricate legal framework that “‘implements’ California’s medical marijuana laws by allowing licensed patients to obtain medical marijuana from highly regulated non-profit cooperative dispensaries.” Section 538 states: “None of the funds made available in this Act to the Department of Justice may be used, with respect to the States of . . . California [and 32 other states], *to prevent such States from implementing their own State laws* that authorize the use, distribution, possession, or cultivation of medical marijuana.” (emphasis added).

It defies language and logic for the Government to argue that it does not “prevent” California from “implementing” its medical marijuana laws by shutting down these same heavily-regulated medical marijuana dispensaries; whether it shuts down one, some, or all, the difference is of degree, not of kind.

In fact, contrary to the DOJ’s position, the court found that governments closing of dispensaries like MAMM substantially impeded Californians’ access to legal medical marijuana. With exceptionally high rates of breast and prostate cancer and a population of over 250,000, the government’s closure of these clinics has left those patients that can most benefit from medical marijuana without safe access in their local community.

The comments of lawmakers during the passage of §538 further undermine the DOJ’s position. Representative Alcee Hastings stated: “Specifically, the bill is a bipartisan appropriations measure that looks to prohibit the DEA from spending funds to arrest state-licensed medical marijuana patients and providers.” Lead Sponsor, Dana Rohrabacher, explained:

The harassment from the [DEA] is something that should not be tolerated in the land of the free. Businesspeople who are licensed and certified to provide doctor recommended medicine within their own States have seen their businesses locked down, their assets seized, their customers driven away, and their financial lives ruined by very, very aggressive and energetic Federal law enforcers enforcing a law

....

In April 2015, the drafters of §538 responded to the DOJ’s “recent statements indicating that the [DOJ] does not believe a spending restriction designed to protect [the medical marijuana laws of 35 states] applies to specific ongoing cases against individuals and businesses engaged in medical marijuana activity:”

As the authors of the provision in question, *we write to inform you that this interpretation of our amendment is emphatically wrong*. Rest assured, the purpose of our amendment was to prevent the Department from wasting its limited law enforcement resources on prosecutions and asset forfeiture actions against medical marijuana patients and providers, including businesses that operate legally under state law. . . . Even those who argued against the amendment agreed with the proponents’ interpretation of their amendment.

(emphasis added).

**HOLDING:** As long as §538 is in place, the DOJ can only enforce federal controlled substances laws against MAMM and other dispensaries if they are not in compliance with California laws.

## **X. NEGLIGENCE**

### **A. Duty Not to Dispense**

#### **1. *Oleckna v. Daytona Disc. Pharmacy*, 162 So. 3d 178 (Fla. Dist. Ct. App. 2015)**

**RELIEF SOUGHT:** Patient's widow appealed dismissal of her claims against pharmacy and pharmacist for filling controlled substances too often, which she claimed resulted in husband's death.

**ISSUE:** Did the pharmacy and its pharmacists have duty to inquire into or refuse to fill prescriptions being prescribed too often?

**FACTS AND PROCEDURAL HISTORY:** Patient (decedent) was diagnosed with stress syndrome and treating physician prescribed Xanax and hydrocodone or oxycodone. Complaint alleged that for two years the doctor repeatedly prescribed the drugs before patient was due for a refill and the pharmacy filled at least 30 of these prescriptions even though the prescriptions were issued too frequently. Patient died due to combined drug intoxication of Xanax and hydrocodone. Plaintiff sued pharmacy for negligence, alleging pharmacy owed several duties to the patient, including a duty not to dispense or fill prescriptions that were unreasonable on their face or in light of the circumstances. Trial court granted motion to dismiss for the failure to allege facts to support violation of the duty of care. Plaintiff appealed.

**REASONING:** A pharmacist's duty to use due and proper care in filling a prescription extends beyond simply following the prescribing physician's directions. The pharmacy unquestioningly filled numerous prescriptions that were so close together that the pharmacy should have been put on notice that the patient was getting too many pills within a short period. "[T]he prescriptions here were alleged to be unreasonable on their face because they were written in a quantity, frequency, dosage, or combination that a reasonable pharmacist would either have checked with the prescribing doctor or warned the patient." Court refused to "interpret a pharmacist's duty to use 'due and proper care in filling the prescription' as being satisfied by 'robotic compliance'" with the prescribing physician's instructions.

**HOLDING:** Court reversed the dismissal because a fact question existed as to whether the pharmacy and its pharmacists breached their duty to inquire into or refuse to fill prescriptions being prescribed too often.

#### **2. *Hernandez v. Walgreen Co.*, 2015 IL App. (1<sup>st</sup>) 142990 ( Dec. 28, 2015)**

**RELIEF SOUGHT:** Patient's estate appealed dismissal of complaint in which estate alleged pharmacies negligently failed to monitor and act on excessive methadone prescriptions.

**ISSUE:** Does a pharmacy have a duty to monitor a patient's prescription history for excessive and abnormal prescriptions, or to communicate a corresponding warning to the patient or prescribing physician?

**FACTS AND PROCEDURAL HISTORY:** Estate originally sued the prescribing physician for negligence because he prescribed methadone despite his knowledge that patient had a “propensity to overuse methadone.” Estate amended its complaint to name the pharmacies that filled the methadone prescriptions claiming breached their duty of care by dispensing methadone, “in quantities and time frames that were not appropriate.” The complaint further alleged the pharmacies were negligent by:

filling prescriptions “in excess quantities and for a time frame shorter than recommended on dosage prescribed for refills”; failing to “evaluate and control the dispensation of medication . . . in a manner to prevent an increased risk of injury and death from methadone intoxication”; and filling prescriptions for the decedent “when [they] knew or should have known the dispensing of said medication . . . would cause injury.”

Walgreen and Osco each filed motions for summary judgment. They argued: (i) under Illinois law, a “pharmacist has no duty to warn a customer/physician or to refuse to fill a prescription due to the excessive quantities of the medication”; (ii) the Learned Intermediary Doctrine protects pharmacists from liability for failure to warn; (iii) there is no duty to refuse to fill lawful prescriptions authorized by a prescriber; (iv) that imposing a duty to monitor for the proper dosage “would directly interfere with the patient-physician relationship” and imposing a duty to “second-guess” the physician or to question the dosage and amount prescribed would require the pharmacy to “interject itself directly into the patient-physician relationship and practice medicine by overseeing and altering Dr. Preston’s chosen course of therapy.” The trial court granted the pharmacies’ motion for summary judgment and dismissed the complaint and the patient’s estate appealed.

**REASONING:** The court explained that the issue before it was whether the trial court erred in ruling the pharmacies had no duty “” The estate conceded “Illinois authorities to date establish a rule establish a rule that a pharmacist has no duty to warn the patient or to notify the doctor that addictive drugs may be dangerous in high doses.” The court then reviewed a long line of Illinois cases that “declined to impose upon a pharmacy, any duty to monitor patients, make medical decisions, or to warn a physician or a patient of ‘excessive’ prescribed doses.”

The court then turned to the decision in *Happel v. Wal-Mart Stores, Inc.*, 766 N.E. 2d 1118 (Ill. 2002) in which the Illinois Supreme Court “recognized ‘a narrow duty to warn’ where ‘a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient.’” In *Happel*, the pharmacy knew a patient was allergic to aspirin, the patient came to the pharmacy with a prescription for Toradol, the computer would have produced a contraindication warning, and the patient suffered an anaphylactic reaction to the Toradol.

The plaintiff had argued this case is like *Happel* because the pharmacy has access to the patient’s history in its computer and that the Illinois Controlled Substances Act (“ICSA”) supports a duty to monitor for over usage of methadone. The court rejected the plaintiff’s argument because the ICSA requires pharmacies to report controlled substances prescriptions to a database, but does not require them to access the database when filling prescriptions. Moreover, the ICSA expressly disclaims any requirement for a pharmacist to “request any patient medication disclosure, report any patient activity, . . . or refuse to . . .

*dispense any medications.*” (emphasis in opinion). Thus, the court rejected the argument that the ILCSA created a duty in this case.

The court then concluded Happel did not apply because the Happel court recognized a “narrow” duty and “did *not* require the pharmacy to ‘monitor’ a patient or otherwise exercise medical judgment.” (emphasis in original).

**HOLDING:** The court affirmed the trial court and dismissed the complaint against the pharmacies because Illinois law does not require a pharmacy to monitor a patient’s prescription history for excessive and abnormal prescriptions, or to communicate a corresponding warning to the patient or prescribing physician.

## XI. PRIVACY

### A. Patient Privacy – Vicarious Liability

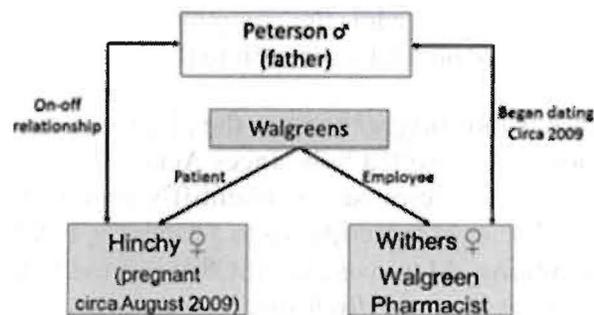
1. *Walgreen Co. v. Hinchy*, 25 N.E.3d 748 (Ind. Ct. App. Jan. 15, 2015) reh’g of, 21 N.E.3d 99 (Ind. Ct. App. Nov. 14, 2014)

**RELIEF SOUGHT:** Patient sued pharmacy and its employees for negligence, professional malpractice, and invasion of privacy.

### ISSUES:

1. Is pharmacy employer liable under theory of *respondeat superior* for pharmacist employee’s access and divulging of patient information?
2. Did Hinchy’s original complaint allege a viable claim of negligence/professional malpractice against Walgreen?

**FACTS AND PROCEDURAL HISTORY:** Peterson (♂) and Hinchy (♀) had an on-and-off again sexual relationship. Withers (♀), a Walgreen pharmacist, began dating Peterson in 2009. Hinchy was a pharmacy patient. Withers was notified by Peterson, her then-boyfriend that she may have been exposed to an STD. Fearful, Withers viewed Hinchy’s prescription profile to determine whether Hinchy had taken STD medication.



Withers revealed some of the information she discovered to Peterson. Peterson then sent Hinchy a series of text messages concerning her prescription records, accusing her of failing to refill her birth control and becoming pregnant. Excerpts from the text messages follow.

I'm not trying to start any crap but I have a print out showing that you didn't even refill ur birth control perscription for July or august. The last time you filled ur prescription was June. I know uve lied to ur mom and harmony and anybody willing to listen but the printout does not lie. I know you lied to me wth tears and curse words and misplaced righteousness. U really should think about what you did ... on ur own. You really should think about that FACT before you call me another name. What kind of person does something like that?

(internal spelling and grammatical errors original). Hinchy sent the following text to Peterson in response:

Print out. It's illegal for u to obtain any kind of information like that regarding me. And if u knew anything about my medical history u would know that I was on multiple types of birth control since I was 15[.]

(internal spelling and grammatical errors original). This prompted a reply from Peterson:

Abby, you ddnt refill ANYTHING at all. No type of birth control medication at all. June you did. You did NOT in july and august. Jeez ....r you really still trying to claim? Again, I'm not trying to start shit. What's done is done, but what's happening was totally avoidable. You are NOT a victim. You did something wrong abby. Very wrong. Ps ....it is not illigall for ME to have it. Ime being very technical here but I ddnt break any laws myself.

Hinchy filed a complaint against Withers for negligence and various theories of invasion of privacy, and against Walgreen under *respondeat superior*. Jury awarded \$1.4 million—Peterson 20% liable and Withers and Walgreen jointly responsible for 80% of the damages.

**REASONING:** Under *respondeat superior*, employer is responsible for actions of an employee acting within the scope of employment. The act must be incidental to the conduct authorized by the employer or it must further the employer's business. Conduct is within this scope if it is of the *same general nature* as that authorized or *incidental* to such conduct. As long as *some* of the employee's actions were authorized, the question of whether the actions were within the scope of employment is determined by the jury. Wither's actions were of the same general nature as those authorized by Walgreen. Wither's was authorized to use the computer system and printer, look up customer information, and review patient prescription histories.

Wither's actions were also incidental to authorized actions because she was on the job and using store equipment when the improper access occurred. Court of appeals affirmed \$1.4 million jury verdict finding Walgreen vicariously liable for pharmacist employee's illegal review of a patient's prescription profile and divulging such records to a third person. Walgreen filed a petition for rehearing challenging whether Hinchy had sufficiently raised a claim against it. The court reached the same conclusion.

**HOLDING:**

1. Walgreen was liable under theory of *respondeat superior* for pharmacist employee's accessing and divulging patient information.
2. The court determined that while Hinchy did not explicitly raise a precise negligence/professional malpractice claim, Hinchy stated a viable claim with supporting argument and evidence.

## ABBREVIATED CASE LAW UPDATE



William J. Stilling, BS Pharm, MS, JD  
for  
Utah Board of Pharmacy and Guests  
April 26, 2016  
Salt Lake City, Utah

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## Disclaimer

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## Background

- Twice each year Roger Morris and Bill Stilling present case law updates for
  - American Society for Pharmacy Law (“ASPL”)—November
  - American Pharmacists Association—March or April
- **ASPL was founded in 1974 with a purpose to:**
  - Further knowledge in Pharmacy Law;
  - Communicate accurate legal educational information; and
  - Provide educational opportunities for pharmacists, attorneys, and others interested in Pharmacy Law.
- Information about ASPL at <http://www.aspl.org/>

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## Background

- Cases are now compiled and updated in the *ASPL Case Law Compendium*
- ASPL funds a Biolaw Fellow at the University of Utah S.J. Quinney College of Law through the Center for Law and Biomedical Sciences
- *Today's presentation* is an abbreviated version of the Case Law Update presented at APhA in Baltimore on March 4, 2016

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## Overview of Cases

### ▪ Antitrust

- Exclusion of Pharmacies
  - *Star Discount Pharmacy, Inc., et al v. MedImpact Healthcare Sys., Inc.*, 614 F. App'x 988 (11th Cir. June 11, 2015)
- State Regulatory Boards Immunity
  - *North Carolina Bd. of Dental Examiners. v. Federal Trade Commission*, 135 S. Ct. 1101 (Feb. 25, 2015)

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## Overview of Cases

### ▪ Civil Procedure

- Spoliation of Evidence—Pharmacy's Duty to Retain Misfills
  - *Burton v. Walgreen Co.*, 2015 WL 4228854 (D. Nev. July 10, 2015)

### ▪ Constitutional Law

- First Amendment—Off-Label Use
  - *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, No. 15 Civ. 3588, 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015)

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## Overview of Cases

### ▪ Duty to Verify DEA Registration

- *Farmacia, Yani*, 80 Fed. Reg. 29,053 (May 20, 2015)
- *JM Pharmacy Group Inc., d/b/a/ Farmacia Nueva and Best Pharma Corp.*, 80 Fed. Reg. 28,667 (May 19, 2015)

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## Overview of Cases

### ▪ Defamation

- Physician against Pharmacist
  - *LeFrock v. Walgreen Co.*, 77 F.Supp.3d 1199 (M.D. Fla. Jan. 16, 2015)
- Duty to Fill
  - *Kadambi v. Express Scripts*, 2015 WL 475373 (N.D. Ind. February 5, 2015)

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## Overview of Cases

- **Employment**
  - ADA
    - *Stevens v. Rite Aid Corp., et al.*, 6:13-cv-00783 (N.D.N.Y., September 23, 2015)
- **False Claims—Generic Substitutions**
  - *Doe v. Houchens Indus., Inc.*, No. 1:13-CV-00196-RLY, 2015 WL 133706 (S.D. Ind. Jan. 9, 2015)



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## Overview of Cases

- **Medicaid**
  - Reimbursement Challenges (cuts to reimbursement)
    - *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378 (2015)
- **Medical Marijuana**
  - DEA Authority to Enforce Controlled Substances Act
    - *United States v. Marin Alliance For Medical Marijuana ("MAMM"), and Lynette Shaw*, No. C 98-00086 N.D. Cal. Ot. 19, 2015)



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## Overview of Cases

- **Negligence**
  - Duty Not to Dispense
    - *Oleckna v. Daytona Disc. Pharmacy*, 162 So. 3d 178 (Fla. Dist. Ct. App. 2015)
    - *Hernandez v. Walgreen Co.*, 2015 IL App. (1<sup>st</sup>) 142990 (Dec. 28, 2015)
- **Privacy**
  - Patient Privacy – Vicarious Liability
    - *Walgreen Co. v. Hinchy*, 25 N.E.3d 748 (Ind. Ct. App. Jan. 15, 2015) reh'g of, 21 N.E.3d 99 (Ind. Ct. App. Nov. 14, 2014)



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## Antitrust—Exclusion of Pharmacies

- *Star Discount Pharmacy, Inc., et al v. MedImpact Healthcare Sys., Inc.*, 614 F. App'x 988 (11th Cir. June 11, 2015)
  - RELIEF SOUGHT: Pharmacy owner sued prescription drug program third party administrator of violating the Sherman Antitrust Act.
  - ISSUE: Does excluded pharmacy have a valid monopolization claim against third party administrator (or PBM)?



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## Antitrust—Exclusion of Pharmacies

- ***Star Discount Pharmacy, Inc., et al v. MedImpact Healthcare Sys.***

- **HOLDING:** The circuit court affirmed the district court and held that plaintiffs (pharmacies) provided no evidence of harm to competition among pharmacies due to lower reimbursement rates, as required under the Sherman Act.

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## Antitrust—Exclusion of Pharmacies

- **New Antitrust Lawsuit against PBM for Exclusion of Pharmacies:**

- On January 15, 2016 six compounding pharmacies sued Express Scripts, Inc. ("ESI") in the Eastern District of the U.S. District Court of Missouri alleging ESI and other PBMs are jointly boycotting compounding pharmacies and shifted patients to pharmacies in which ESI has an economic interest.
- See *Precision Rx Compounding, LLC, C & M Health Pro, LLC, Northern Va. Compounders, PLLC, Toth Enterprises II, PA, The Daily Dose, LP, and CPRX Pharmacy, LP, v. Express Scripts Holding Company, and Express Scripts, Inc.* Case No. 4:1-cv-0069.

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## Antitrust—State Regulatory Boards Immunity

- ***North Carolina Bd. of Dental Examiners. v. Federal Trade Commission*, 135 S. Ct. 1101 (Feb. 25, 2015)**

- **RELIEF SOUGHT:** FTC sought injunctive relief against the North Carolina Board of Dental Examiners to stop Board from: (i) prohibiting non-dentists from providing teeth whitening services or products, (ii) discouraging the provision of such goods or services, and (iii) communicating to third parties that such provision violated state law.

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## Antitrust—State Regulatory Boards Immunity

- ***North Carolina Bd. of Dental Examiners. v. Federal Trade Commission***

- **ISSUES:**
  1. Were Board's actions anti-competitive?
  2. Were Board's actions protected by state-action immunity?

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## Antitrust—State Regulatory Boards Immunity

- **North Carolina Bd. of Dental Examiners. v. Federal Trade Commission**
  - HOLDINGS: Supreme Court affirmed Fourth Circuit's decision, finding:
    1. Board's actions were anti-competitive.
    2. Board's actions were not protected by state-action immunity.

See Strategic Pharmaceutical Solutions, Inc. v. Nevada State Board of Pharmacy et al., No. 2:16-cv-00171-RFB-VCF, D. Nev., January 29, 2016

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## Civil Procedure Spoliation of Evidence & Pharmacy's Duty to Retain Misfills

- **Burton v. Walgreen Co.**, 2015 WL 4228854 (D. Nev. July 10, 2015)
  - RELIEF SOUGHT: Patient sought sanctions against pharmacy for willful spoliation of evidence after Walgreens destroyed bottle and pills returned after a misfill.
  - ISSUES:
    1. Did Walgreens have a duty to preserve evidence (bottle/pills)?
    2. Was Walgreen on notice of potential litigation due to misfill?

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## Civil Procedure Spoliation of Evidence & Pharmacy's Duty to Retain Misfills

- **Burton v. Walgreen Co.**
  - HOLDINGS: Court denied plaintiff's motion because Walgreens admitted error and there was no prejudice from destruction of prescription.
    1. Walgreen had a duty to preserve evidence. However, the evidence was destroyed in accordance with its internal policies and was not destroyed purposefully or willfully because.
    2. Walgreens was on notice of potential litigation.

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## Constitutional Law First Amendment—Off-Label Use

- **Amarin Pharma, Inc. v. U.S. Food & Drug Admin.**, 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015)
  - RELIEF SOUGHT: Pharmaceutical manufacturer sought an injunction against the FDA to prohibit FDA from deeming Vascepa as misbranded, arguing the First Amendment protected its promotion of the drug for "off-label" use.
  - ISSUE: Does the First Amendment protect a drug manufacturer that promotes a drug for "off-label" use when such promotion is truthful and non-misleading?

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## Constitutional Law First Amendment—Off-Label Use

- **Amarin Pharma, Inc. v. FDA**
  - **HOLDING:** The court granted Amarin's request for a preliminary injunction, holding that Amarin had standing to bring First Amendment claim and that truthful and non-misleading speech cannot form the basis for the prosecution of a misbranding claim.

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## Controlled Substances Duty to Verify DEA Registration

- **Farmacia, Yani**, 80 Fed. Reg. 29,053 (May 20, 2015)
- **JM Pharmacy Group Inc., d/b/a/ Farmacia Nueva and Best Pharma Corp.**, 80 Fed. Reg. 28,667 (May 19, 2015)
  - **RELIEF SOUGHT:** In two separate DEA actions against pharmacies, each pharmacy appealed the decision of an administrative law judge ("ALJ") to deny applications for DEA registration.
  - **ISSUE:** Does a pharmacy have a duty to verify the DEA registration of prescribers under the DEA corresponding liability regulation?

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## Controlled Substances Duty to Verify DEA Registration

- **HOLDINGS:**
  - In the *Farmacia Yani* case, the Administrator afforded minimal weight to the failure to verify DEA registrations and held the DEA application in abeyance for six months until the pharmacy personnel completed a course on controlled substances dispensing and corresponding liability.
  - In *JM Pharmacy Group*, the Administrator likewise gave nominal weight to the pharmacists not ensuring the DEA numbers were current, but denied the registration because the pharmacy falsified its renewal application.

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## Defamation Physician against Pharmacist

- **Lefrock v. Walgreen Co.**, 77 F.Supp.3d 1199 (M.D. Fla. Jan. 16, 2015)
  - **RELIEF SOUGHT:** Physician sued Walgreens for alleged defamatory statements made by Walgreens pharmacists.
  - **ISSUES:**
    1. Did pharmacists commit slander against physician during consultation with patient?
    2. Were comments made during the consultation privileged?

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## Defamation Physician against Pharmacist

### ▪ *Lefrock v. Walgreen Co.*

#### – HOLDINGS:

1. Pharmacists did not commit slander against physician during consultation with patient.
2. Comments made during the consultation were privileged.

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## Defamation—Duty to Fill

### • *Kadambi v. Express Scripts*, 2015 WL 475373 (N.D. Ind. February 5, 2015)

- RELIEF SOUGHT: Physician and eight patients sued mail-order pharmacies for breach of duty to honor prescriptions and to fill as written. Physician sued for defamation.

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## Defamation—Duty to Fill

### ▪ *Kadambi v. Express Scripts*

#### – ISSUES:

1. Does Indiana pharmacy law, purportedly requiring pharmacists to honor all prescriptions from a physician, create a private cause of action?
2. Does Indiana anti-SLAP (strategic lawsuit against public participation) statute bar plaintiff's defamation claim?
3. Are pharmacist statements to patients regarding reason for refusal to dispense protected by qualified privilege?

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## Defamation—Duty to Fill

### ▪ *Kadambi v. Express Scripts*

#### – HOLDINGS:

1. As to claim under Indiana pharmacy law, court granted pharmacies' motion to dismiss on the pleadings.
2. Court denied motion to dismiss under anti-SLAP law because the law did not afford protection to pharmacies.
3. Court denied defendant's motion for summary judgment on qualified privilege because fact question existed about whether statements to patients were made in good faith.

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## Employment--ADA

- *Stevens v. Rite Aid Corp., et al.*, 6:13-cv-00783 (N.D.N.Y., September 23, 2015)

– RELIEF SOUGHT: Pharmacist sued former employer for violation of the Americans with Disabilities Act (ADA) and the New York State Human Rights Law (NYSHRL).

## Employment--ADA

- *Stevens v. Rite Aid Corp.*

– ISSUES:

1. Did employer violate the ADA and the NYSHRL after terminating a pharmacist who refused to provide vaccinations because of trypanophobia (needle phobia)?
2. Is trypanophobia a recognized disability?
3. Did Rite Aid fail to provide reasonable accommodations to the employee?
4. Were the awarded damages excessive?

## Employment--ADA

- *Stevens v. Rite Aid Corp.*
- Differences in Damages by Jury and Court on Rehearing

Type of Damages	Jury	Court's Decision
Back Pay	\$485,633	Same
Front Pay	\$1,227,188	Same
Non-pecuniary	\$900,00	\$125,000
Total	\$2,612,821	\$1,837,821 (or new trial)

## Employment--ADA

- *Stevens v. Rite Aid Corp.*

– HOLDINGS:

1. The court held there was sufficient evidence to support each of the jury's findings except for the finding that Rite Aid failed to provide reasonable accommodation by not allowing time off for "desensitization."
2. The jury's damages award was proper except for the non-pecuniary award for \$900,000, which the court reduced to \$125,000. In the alternative, plaintiff could try the case again.

## Fraud and Abuse—False Claims Generic Substitutions

- *Doe v. Houchens Indus., Inc.*, No. 1:13-CV-00196-RLY, 2015 WL 133706 (S.D. Ind. Jan. 9, 2015)
  - RELIEF SOUGHT: Relator brought *qui tam* claims under the federal FCA and the Indiana false claims act alleging defendant misrepresented drug prices.
  - ISSUE: Did relator sufficiently allege a FCA claim by alleging pharmacy's reward program allowed patients to purchase prescriptions at a lower price than the pharmacy used for usual and customary price calculations?

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## Fraud and Abuse—False Claims Generic Substitutions

- *Doe v. Houchens Indus., Inc.*
  - HOLDING: Court denied motion to dismiss because relator stated plausible claims under the FCA.

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## Medicaid Reimbursement Challenges

- *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378 (2015)
  - RELIEF SOUGHT: Medicaid providers sued Idaho's Department of Health and Welfare ("IDHW") for failing to amend Medicaid reimbursement rates.
  - ISSUE: Can Medicaid providers sue a state in federal court to obtain injunctive relief for inadequate reimbursement under the Medicaid Act?

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## Medicaid Reimbursement Challenges

- *Armstrong v. Exceptional Child Ctr., Inc.*
  - HOLDING: The U.S. Supreme Court reversed the Ninth Circuit. Medicaid providers do not have a private right of action to challenge inadequate reimbursements under the Medicaid Act.

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**Medical Marijuana**  
DEA Authority to Enforce Controlled Substances Act

- *United States v. Marin Alliance For Medical Marijuana ("MAMM"), and Lynette Shaw, No. C 98-00086 N.D. Cal. Oct. 19, 2015)*
  - **RELIEF SOUGHT:** Medical marijuana dispensary asked the court to dissolve a permanent injunction that prohibited it from dispensing medical marijuana under California's Compassionate Use Act because Congress prohibited the Department of Justice ("DOJ") from using any resources to interfere with a state's ability to implement its own medical marijuana laws.

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**Medical Marijuana**  
DEA Authority to Enforce Controlled Substances Act

- *United States v. MAMM*
  - **ISSUE:** Does Congress's ban on DOJ's interference with implementation of state medical marijuana laws warrant lifting the permanent injunction against MAMM?
  - **HOLDING:** As long as §538 is in place, the DOJ can only enforce federal controlled substances laws against MAMM and other dispensaries if they are not in compliance with California laws.

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**Negligence**  
**Duty Not to Dispense**

- *Oleckna v. Daytona Disc. Pharmacy, 162 So. 3d 178 (Fla. Dist. Ct. App. 2015)*
  - **RELIEF SOUGHT:** Patient's widow appealed dismissal of her claims against pharmacy and pharmacist for filling controlled substances too often, which she claimed resulted in husband's death.
  - **ISSUE:** Did the pharmacy and its pharmacists have duty to inquire into or refuse to fill prescriptions being prescribed too often?

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**Negligence**  
**Duty Not to Dispense**

- *Oleckna v. Daytona Disc. Pharmacy*
  - **HOLDING:** Court reversed the dismissal because a fact question existed as to whether the pharmacy and its pharmacists breached their duty to inquire into or refuse to fill prescriptions being prescribed too often.

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## Negligence Duty Not to Dispense

- *Hernandez v. Walgreen Co.*, 2015 IL App. (1<sup>st</sup>) 142990 (Dec. 28, 2015)

- **RELIEF SOUGHT:** Patient's estate appealed dismissal of complaint in which estate alleged pharmacies negligently failed to monitor and act on excessive methadone prescriptions.
- **ISSUE:** Does a pharmacy have a duty to monitor a patient's prescription history for excessive and abnormal prescriptions, or to communicate a corresponding warning to the patient or prescribing physician?

## Negligence Duty Not to Dispense

- *Hernandez v. Walgreen Co.*

- **HOLDING:** The court affirmed the trial court and dismissed the complaint against the pharmacies because Illinois law does not require a pharmacy to monitor a patient's prescription history for excessive and abnormal prescriptions, or to communicate a corresponding warning to the patient or prescribing physician.

## Privacy Patient Privacy – Vicarious Liability

- *Walgreen Co. v. Hinchy*, 25 N.E.3d 748 (Ind. Ct. App. Jan. 15, 2015)

- **RELIEF SOUGHT:** Patient sued pharmacy and its employees for negligence, professional malpractice, and invasion of privacy.
- **ISSUES:**
  1. Is pharmacy employer liable under theory of *respondeat superior* for pharmacist employee's access and divulging of patient information?
  2. Did Hinchy's original complaint allege a viable claim of negligence/professional malpractice against Walgreen?

## Privacy Patient Privacy – Vicarious Liability

*Walgreen Co. v. Hinchy*



**Privacy**  
**Patient Privacy – Vicarious Liability**

▪ **Walgreen Co. v. Hinchy**

– HOLDING:

1. Walgreen was liable under theory of *respondeat superior* for pharmacist employee's accessing and divulging patient information.
2. The court determined that while Hinchy did not explicitly raise a precise negligence/professional malpractice claim, Hinchy stated a viable claim with supporting argument and evidence.

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**Questions?**

Contact info

Bill Stilling  
Parsons Behle & Latimer  
201 S. Main St., Ste. 1800  
(801) 536-6765  
[bstilling@parsonsbehle.com](mailto:bstilling@parsonsbehle.com)

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