Pharmacy Case Law Update

Roger Morris, R.Ph., J.D.
Quarles & Brady, LLP

William J. Stilling, B.S. Pharm., M.S., J.D.
Parsons Behle & Latimer

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Making an Impact in Patient Care

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I. ACA

A. Adequacy of Pleading


RELIEF SOUGHT: Repeat pro se plaintiff sought an order requiring a pharmacy and physician to split the cost of his insulin as he claimed was required under the Affordable Care Act (“ACA”).

ISSUE: Did the complaint state a claim for which relief can be granted based on an implied right of action under the ACA that allows a court to force private parties to subsidize medication costs?

FACTS AND PROCEDURAL HISTORY: In lieu of a complaint, pro se plaintiff filed a Motion for Insulin under the Affordable Care Act, asking the court to order two pharmacies and one physician to split the cost of his insulin. The case was assigned to a magistrate judge.

REASONING: The magistrate issued a Report and Recommendation in which he described the legal standard for the sufficiency of a civil complaint under Rule 12(b)(6) of the F.R.C.P and the standards the U.S. Supreme Court established in Bell Atlantic Corp. v. Twombly, 50 U.S. 544 (2007) and Ashcroft v. Iqbal, 556 U.S. 662 (2009). After reviewing the legal standards, the court explained:

In practice, consideration of the legal sufficiency of a complaint entails a three-step analysis: “First, the court must ‘take[e] note of the elements a party must plead to state a claim.’ Iqbal, 129 S.Ct. at 1947. Second, the court should identify allegations that, ‘because they are no more than conclusions, are not entitled to the assumption of truth.’ Id. at 1950. Finally, ‘where there are well- pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.’ Id.”

To the extent plaintiff was asserting a cause of action under the ACA, the court explained the two-step analysis for determining whether a federal law creates a private cause of action, “(1) Did Congress intend to create a personal right?; and (2) Did Congress intend to create a private remedy? Only if the answer to both of these questions is ‘yes’ may a court hold that an implied private right of action exists under a federal statute.” Some courts have found a private cause of action in limited circumstances under the ACA to remedy discrimination in access to health care. But, “no court has construed the statute as creating some freestanding right to sue pharmacies and doctors to force them to provide a private party medications free of charge, the relief which Walsh seeks here.”

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The plaintiff failed to meet the pleading requirements for sufficiently stating a cause of action upon which relief can be granted. The magistrate recommended dismissal without prejudice and, in an abundance of caution that the plaintiff could fix the defective motion to create a viable complaint, the court granted plaintiff 20 days to file an amended complaint. The district court issued an order incorporating the magistrate’s recommendations.

HOLDING: The court dismissed the motion (complaint) because it failed to demonstrate any private right of action under the ACA to require a pharmacy or physician to pay for medications.

II. ADMINISTRATIVE LAW
   A. Justification for Board Action

RELIEF SOUGHT: Jefferson City Apothecary and pharmacist Uldis Pironis appeal the judgement of the Circuit Court of Cole County affirming the joint decisions of the Administrative Hearing Commission (“AHC”) and the Missouri Board of Pharmacy (“Board”), which found cause to discipline and imposed discipline on Pironis and the Apothecary.

ISSUE: Did the Missouri Board of Pharmacy have justification for disciplining a pharmacist and his pharmacy for issuing orders to a technician to compound and dispense chemotherapy medications without a pharmacist on duty?

FACTS AND PROCEDURAL HISTORY: Pironis, a licensed pharmacist was the owner and pharmacist in charge of the Apothecary, a retail pharmacy. In April of 2011, Pironis traveled to Chicago for a continuing education seminar. Another pharmacist was scheduled to work at the Apothecary on the day Pironis was gone. However, the pharmacist did not report to work due to his wife’s illness. Pironis was informed by a pharmacy technician that the other pharmacist had not arrived. Pironis then instructed the technician to close the Apothecary but leave the front doors open so patients could be told that the pharmacy was closed due to there being no pharmacist on duty.

The technician also informed Pironis that a doctor had called in a compound chemotherapy prescription that was needed that day. Pironis initially instructed the technician not to make the medication. However, he eventually relented and instructed the technician to compound the medication and deliver it to the doctor’s office. The technician compounded the medication and delivered it to the physician on time. No evidence was presented that the patient suffered adverse effects from the medication.

The Board received an anonymous tip that the Apothecary was practicing pharmacy without a licensed pharmacist on duty. An investigator was sent to the Apothecary and the Board filed separate complaints with the AHC seeking orders granting authority to discipline Pironi’s license and the Apothecary’s permit. Ultimately, the AHC found cause to discipline Pironis and the Apothecary.

The Board later conducted formal disciplinary proceedings. At hearing, Pironis argued that he had done “the right thing” when directing his technician to compound and dispense needed chemotherapy drugs. Pironis admitted that he knew it was a violation of law, but contended that he would do the same thing again if presented with the same situation. Pironis argued that he used his professional judgement to violate the law when he believed it to be in the best interests of the patient.

The Board issued orders placing Pironis’s license and the Apothecary’s pharmacy permit on probation for one year, subject to various terms and conditions. Pironis and the Apothecary petitioned for judicial review of AHC’s decision and the Board’s disciplinary order. The circuit court affirmed the joint decision of both the AHC and the Board.
Pironis and the Apothecary appealed, arguing: (i) the AHC erred in determining the Board established cause to discipline because they did not violate any drug laws; (ii) the Board’s discipline was unsupported by competent and substantial evidence on the record; and (iii) the Board did not issue its order in accordance with statutory requirements, in that they were not sufficiently specific to show how the Board decided discipline to be imposed. The Missouri Court of Appeals affirmed the Circuit Court’s decision, rejecting Pironis’s arguments and finding there was cause to impose discipline.

**REASONING:** The Court of Appeals found that Pironis and the Apothecary cited no authority to support the proposition that professional judgement justified violation of the law. The court stated, “[s]imply put, the regulations in question are not suggestions for use, they are mandatory rules established and designed to protect the public. There is no excuse for Pironis’s flagrant disregard of the regulations.” Pironis attempted to justify his knowing violation of Board regulations by arguing that he was exercising his professional judgment as a pharmacist under extraordinary circumstances, that he had the cancer patient’s care in mind, and that he “knew” the medications would be properly compounded by the technician and checked by the doctor’s office. Nevertheless, the Court of Appeals found no legal support for his argument. The court concluded by stating that “Pironis’s decision to pick and choose which mandatory regulations he believes himself to be bound by in his expertise is nothing short of the sort of arrogance that the regulations are designed to guard the public against. . . . The reason professional license discipline laws exist is to protect the public served by those who have been granted such licenses.”

**HOLDING:** The Missouri Board of Pharmacy made sufficient findings of fact and conclusions of law to justify discipline against Pironis. Further, Pironis neglected his duties as pharmacist-in-charge and violated drug laws when ordering a prescription to be filled and compounded by a technician.

**B. Board Sanctions**


**RELIEF SOUGHT:** Pharmacist appealed pharmacy board revocation of his license, claiming excessive discipline not supported by substantial evidence.

**ISSUES:**

1. Did the Pennsylvania have sufficient evident to revoke a pharmacist’s license?
2. If so, was such revocation excessive?

**FACTS AND PROCEDURAL HISTORY:** In December 2014, the New Jersey Board of Pharmacy approved an Interim Consent Order of Voluntary Surrender of License for Frederick McLeish and ordered him to immediately cease and desist from engaging in the practice of pharmacy in New Jersey. The order was based on McLeish’s termination from his hospital employer following an admission that, over the course of two months, he had diverted IV morphine, fentanyl, and hydroxyzine tablets.

Pennsylvania’s Bureau of Professional and Occupational Affairs (“Bureau”) subsequently filed an order to show cause as to why the Pennsylvania Board of Pharmacy should not suspend, revoke, or restrict his license in the state (which had been inactive since 2002) based on McLeish’s discipline in New Jersey.

McLeish responded in a letter, requesting that his license be placed on inactive status because it had been inactive since 2002 and he had no future plans to practice in Pennsylvania. McLeish also noted that he was enrolled in the Professional Assistance Program of New Jersey and remained in good standing.

McLeish failed to appear before the subsequent hearing where the hearing examiner proposed that McLeish’s license in Pennsylvania be indefinitely suspended until the New Jersey Board had restored his New Jersey license to non-probationary, unrestricted status. It was also noted that in 2003, McLeish had
been subject to penalties in Pennsylvania for failing to comply with continuing education requirements and using non-approved courses in a fraudulent manner to falsely claim that he had completed continuing education credits. His license was reinstated in 2006. But, it was also noted that in 2006, McLeish’s license was suspended for three years based disciplinary action taken by the New Jersey Board in 2002. In 2008, the Board reinstated McLeish’s license after he completed the terms and conditions of the December 2006 probation.

The Board issued a notice of intent to review the record established before the hearing examiner. The Board then issued its final order, adopting the history, findings of fact, and conclusions of law of the hearing examiner’s proposed adjudication. The Board stated:

   The Board believes that the sanction imposed needs to send the appropriate message to [McLeish] that reciprocal discipline involving the diversion of drugs by members of the profession will not be tolerated and that the Board takes such matters very seriously in light of its role in protecting the safety of the public as well as the integrity of the profession.

On appeal, McLeish argued that the Board’s revocation of his license was excessive and not supported by substantial evidence because his Pennsylvania license had been inactive since 2002 and he had no intention of practicing in Pennsylvania. As a result, McLeish claimed that he was not in a position to harm the citizens of Pennsylvania and, thus, an indefinite suspension of his Pennsylvania license until his license in New Jersey has been restored to non-probationary, unrestricted status would be sufficient. The Commonwealth Court rejected this argument and affirmed the Board’s action.

REASONING: The court’s analysis was fairly straightforward. The court found the Board’s decision to be supported by substantial evidence and was not excessive. The court explained, “[g]iven McLeish’s licensure history in Pennsylvania in conjunction with his substance abuse issues, the disciplinary action taken against him by the New Jersey Board, the lack of mitigating evidence, and the state’s interest in protecting its citizenry, the Board’s revocation of McLeish’s license to practice pharmacy in Pennsylvania, as is its prerogative under Section 5(a)(10) of the Pharmacy Act, is not in error.”

HOLDINGS: The court affirmed the Board’s decision.

1. The Board had sufficient evident to revoke a pharmacist’s license.
2. The revocation was proper in light of the violations in the record.

III. ANTITRUST

A. Liability of Pharmacy Board Members


RELIEF SOUGHT: Pharmacy seeks declaratory judgment finding Nevada Board of Pharmacy engaged in activities in violation of state and federal anti-competition laws. Pharmacy also seeks permanent injunction against the Board and its members from attempting to exclude the pharmacy and its delivery model from the Nevada market.

ISSUE: Did Nevada Board of Pharmacy and its members violate the Sherman Act and Nevada State Unfair Competition Act by threatening disciplinary action against a non-resident pharmacy utilizing a direct-delivery model for veterinarians?

FACTS AND PROCEDURAL HISTORY: Non-resident pharmacy, VetSource Home Delivery, filed suit alleging that the Nevada State Board of Pharmacy engaged in anti-competitive actions. In its
complaint, VetSource alleged that the Board is controlled by private individual members licensed as pharmacists who actively compete in the market for pet medications in Nevada. VetSource further alleged that the Board is operating without state oversight and supervision, using its disciplinary authority to exclude VetSource from the Nevada market. Similar to plaintiffs in North Carolina State Board of Dental Examiners v. FTC, 135 S.Ct. 1011 (2015), VetSource alleged that the Nevada Board’s actions and make-up exclude it and its members from state-action immunity.

As outlined in VetSource’s complaint, it uses a “drop-shipping” model of distributing pet medications to veterinarians and pet owners and describes VetSource as an “outsourced pharmacy services provider for veterinarians that contract for VetSource to provide its services at fair market value.” Under VetSource’s model, veterinarians prescribe medications and obtain approval from pet owners that drugs will be “delivered to his/her home through Direct Shipping.” The veterinarian then contacts VetSource Wholesaler, which is validly licensed in Nevada. VetSource Wholesaler sells the applicable drug to the veterinarian. The veterinarian takes title to the drug but never takes possession of the drug. The veterinarian then consigns the medication to the pet owner at the veterinarian’s wholesale price although the veterinarian may choose to charge the pet owner a price that is more or less than the wholesale cost of the drug. The veterinarian then consigns the medication to VetSource’s pharmacy for “processing pursuant to an authorized prescription.” The VetSource pharmacy collects the retail cost, shipping costs, and sales tax, from the pet owner. All funds are deposited into an e-Merchant account for the veterinarian. The veterinarian is later charged by the pharmacy for “an agreed fair market price for the product and for the services provided by VetSource via separate charges by VetSource to the individual veterinarian’s e-Merchant account.” VetSource claims that the veterinarian or the pet owner may use any pharmacy to fill the prescriptions.

The complaint alleges that the Board has a “history of engaging in anticompetitive conduct under the guise of enforcing the state’s pharmacy regulations” and its members are “misusing their position to seek to exclude innovative competitors such as [VetSource] from the market.” Specifically, VetSource alleges that the Deputy Executive Secretary of the Board contacted VetSource’s pharmacy manager to solicit information regarding VetSource’s model. The Deputy Executive Secretary allegedly attempted to intimidate VetSource staff into ceasing VetSource operations, stating that the model likely violated the Board’s anti-kickback regulation. VetSource alleges that the Board’s assertion, and its suggestion that VetSource discontinue operations in Nevada, was made prior to any review of relevant documentation. The Board allegedly also issued an Accusation and Notice of Intended Action, beginning the proceedings for revocation or suspension of VetSource’s pharmacy license. Other alleged anticompetitive actions include Board communications with Nevada veterinarians suggesting that it was unlawful for them to conduct business with VetSource.

In support of its complaint, VetSource asserts that the Board’s actions are not in furtherance of any clearly articulated state policy and that the Board’s processes for rule-making or discipline are not reviewable by any other state official or body. Thus, the Board is not actively supervised by the state and the Board and its members do not qualify for state-action immunity.

**STATUS:** The parties, at least for the time being, settled the case. There was a concurrent state court case that had been appealed to the Nevada Supreme Court. The parties in the federal case stipulated to settle the case. Settlement would require legislative and regulatory changes that will take considerable time. Defendants would dismiss the case without prejudice. Plaintiff can reinstate the case after notice to the Nevada Board of Pharmacy.
IV. CONSCIENTIOUS OBJECTION

A. First Amendment (Emergency Contraception)


**RELIEF SOUGHT:** Pharmacy and pharmacists with religious objections to dispensing emergency contraceptives, brought action against Washington Pharmacy Quality Assurance Commission challenging the rules requiring a pharmacy to deliver or dispense drugs.

**ISSUE:** Are Washington’s pharmacy regulations, requiring pharmacies and pharmacists to deliver and dispense drugs, unconstitutional?

**HOLDING:** The delivery rules are constitutional. They are “rationally related to Washington’s legitimate interest in ensuring that its citizens have safe and timely access to their lawful and lawfully prescribed medications.”

**SUBSEQUENT ACTIVITY:** On June 28, 2016, the U.S. Supreme Court denied a petition for a writ of certiorari, which left the Ninth Circuit’s opinion in place. Justices Alito, Roberts, and Thomas wrote a scathing dissent, which read in part:

> This case is an ominous sign.

> At issue are Washington State regulations that are likely to make a pharmacist unemployable if he or she objects on religious grounds to dispensing certain prescription medications. There are strong reasons to doubt whether the regulations were adopted for—or that they actually serve—any legitimate purpose. And there is much evidence that the impetus for the adoption of the regulations was hostility to pharmacists whose religious beliefs regarding abortion and contraception are out of step with prevailing opinion in the State. Yet the Ninth Circuit held that the regulations do not violate the First Amendment, and this Court does not deem the case worthy of our time. If this is a sign of how religious liberty claims will be treated in the years ahead, those who value religious freedom have cause for great concern.

Given this dissent, it is likely the court will take a similar case in the future and this dissent seems to predict the outcome. In the context of current events, the quote above that “evidence that the impetus for the adoption of the regulations was hostility to pharmacists whose religious beliefs regarding abortion and contraception are out of step with prevailing opinion in the State” provides a glimmer of how some Justices view regulations that might be non-discriminatory on their face, but the motivation of religious discrimination might undermine the regulation’s constitutionality.

V. CONTRACTS

A. Insurance Reimbursement for Pharmacy Services


**RELIEF SOUGHT:** A pharmacy appealed an Iowa district court’s determination that it failed to “provide covered services” and breached anti-assignment clauses under its contracts with a health insurance company.
ISSUES:

1. Did the pharmacy “provide covered services” to any of the insurance company’s beneficiaries such that it was entitled to reimbursement and recovery from the insurance company?

2. Did the pharmacy breach its contract with the insurance company by assigning its rights or delegating its duties in violation of an anti-assignment clause?

FACTS AND PROCEDURAL HISTORY: In July 2008, pharmacy-appellant entered into a contract pharmacy agreement with a pharmaceutical wholesaler to deliver Factor drugs to hemophilia patients across the country. Under the contract, the pharmaceutical wholesaler would deliver Factor drugs to its wholly-owned pharmacy, which would then assemble the patient-specific doses in compliance with the prescription, apply the appropriate label, package the drug, and deliver it to the pharmacy-appellant. The pharmacy-appellant would receive and store the Factor drugs, examine each prescription and label, affix its own labels, perform prospective drug utilization reviews, and repackage the Factor drugs for patient shipment. The pharmacy would then seek reimbursement from insurer-appellee, and pay 98.5% of its reimbursement to the pharmaceutical wholesaler.

In October 2008, the insurer began investigating the pharmacy after it noticed the pharmacy was submitting claims for a large volume of Factor drugs. The insurer denied the pharmacy’s pending and future reimbursement claims. In total, the insurance company declined to pay for 118 shipments of Factor drugs. Four of the 118 shipments were sent directly from the pharmaceutical wholesaler because the patients urgently needed the medication. The insurer reported that it denied these claims because the pharmacy was not performing “covered services.”

The pharmacy sued the insurance company after it declined to pay claims exceeding $7 million. The insurance company counterclaimed, arguing the pharmacy breached their contracts by failing to provide “covered services” to patients and by violating anti-assignment clauses. The district court agreed with the insurance company on both counts.

REASONING: The Iowa Court of Appeals found that the pharmacy provided covered services in 114 of the 118 shipments, and that the insurance company breached its contract with the pharmacy by denying payment. In the absence of a definition in the contract, the court broadly construed the term “provide” to include dispensation by packaging and labeling drugs for delivery. Additionally, the court acknowledged the contract defined “covered services” as “health care services or supplies,” but found that by dispensing the Factor drugs, the pharmacy was providing health care supplies and, by extension, “covered services.” The court noted that nothing in the contract required the pharmacy to provide the “whole constellation” of services required to manage the disease of hemophilia. Nothing in the insurance company’s contract prohibited a redundancy in the services the pharmacy provided, as long as reimbursement remained fixed.

However, the pharmacy did not provide covered services in the case of the four emergency shipments that passed directly from the pharmacy wholesaler to the patients. Regardless of the emergency circumstances, the court found that the pharmacy could not dispense drugs that never passed through its facilities. A pharmacist cannot dispense a drug simply by declaring that he is taking responsibility for the drug shipment. Accordingly, the pharmacy is not entitled to reimbursement for those four shipments.

The Court of Appeals found that the pharmacy did not violate any anti-assignment agreement contained in its contract with the insurance company. The “contract pharmacy agreement” the pharmacy and pharmaceutical wholesaler entered into did not mention any assignment or delegation of duties, and the pharmacy took sole responsibility for confirming, dispensing, and labeling all Factor products sold to customers. Although the insurance company’s provider guide included additional language prohibiting the type of relationship the pharmacy and pharmaceutical wholesaler shared, pharmacy was not a provider under the terms of the contract. Finally, the pharmacy and insurance company did not maintain a non-
delegable services contract because the pharmacy’s knowledge and expertise were not unique enough to prohibit delegation.

**HOLDINGS:**

1. The insurer breached its contract with the pharmacy by failing to reimburse because the pharmacy provided “covered services” by packaging and labeling drugs for delivery. However, the pharmacy did not provide “covered services” for four emergency shipments because the pharmacy could not dispense drugs that never passed through its facilities.

2. Because the pharmacy retained control over the products dispensed to customers, the pharmacy’s arrangement with a disease management company did not constitute an assignment. A provider guide’s warning regarding non-eligible practitioners filing claims using the status of an eligible practitioner did not, by its very terms, apply to the pharmacy. The pharmacy did not enter into a personal services contract.

**VI. CRIMINAL**

A. Prosecutorial Misconduct


**RELIEF SOUGHT:** Chain pharmacy owner asked the court to: (i) dismiss a new indictment, after a jury had previously convicted him of fraud, on the grounds that “the prosecutors were reckless and willfully blind in presenting false evidence on material issues to the jury at his trial in 2014;” (ii) disqualify “the prosecution team based on their misconduct; and/or (iii) compel the prosecutors to produce discovery on the issues discussed herein and hold an evidentiary hearing on those issues.”

**ISSUE:** Did prosecutors present materially false evidence to the jury in defendant’s criminal health care fraud trial in violation of his due process rights under the U.S. Constitution?

**FACTS AND PROCEDURAL HISTORY:** In July 2013, federal prosecutors filed an indictment against Reddy Annappareddy, alleging that Mr. Annappareddy’s chain of pharmacies, Pharmacare, operating in Pennsylvania, Maryland, and the District of Columbia, committed health care fraud. Specifically, prosecutors alleged that Annappareddy defrauded Medicare, Medicaid, and private insurers by submitting claims for prescription refills that were neither requested by patients nor picked up or delivered. One of the government’s most significant pieces of evidence was a calculation of the purported loss from Annappareddy’s alleged fraud. A federal jury convicted Annappareddy in December 2014. Annappareddy’s counsel subsequently filed a Motion for New Trial.

The Motion led to extensive discovery and depositions of trial counsel. The trial court scheduled a hearing on the motion for June 3, 2015. The day before the hearing, prosecutors filed a letter with the trial court conceding that the “inventory analysis” that had been presented to the jury was in substantial error. The analysis had been offered by the government to prove the significant government losses that had been suffered because of Annappareddy’s alleged fraud. In the letter, the government stated that it “concedes that the defendant’s due process rights were impacted and joins in defendant’s Motion for New Trial.”

A second trial was scheduled for September 19, 2016, which was to last eight weeks (three weeks longer than the first trial). In July of 2016, the government filed a motion to delay the second trial. The court denied the motion, stating that the government’s delay and postponement request, and the basis of such request, would be fundamentally unfair to the Annappareddy’s constitutional rights, and were not compelling enough to outweigh the public interest in a speedy trial.

In August 2016, Annappareddy filed a motion to dismiss the charges altogether, alleging that federal prosecutors had knowingly misinformed jurors, destroyed evidence, and presented false evidence.
Annappareddy argued that prosecutors misrepresented both the trial jury and the grand jury about the applicable laws for government claim reversals and automatic refills. Specifically, during the applicable time period of Annappareddy’s alleged criminal acts, there were no laws in Maryland or the District of Columbia that required a pharmacy to reverse a claim within a certain period of time (14 days) when a patient had not yet received the medication, or any law that prohibited automatic refills without a patient’s request. Nevertheless, Annappareddy argued, prosecutors represented or suggested to the trial jury and the grand jury that such laws were in effect and Annappareddy had been violated them.

Annappareddy presented trial transcripts that demonstrated the government’s misconduct on multiple occasions. Over objections, the government asked questions of defense witnesses inferring that it was fraud if “after 14 days” Pharmacare had not reversed the claim for a prescription that was not received by a patient. In another instance, the government stated in its closing argument that automatic refills are “really the basis for the fraud.” Annappareddy also argued that prosecutors intentionally destroyed exculpatory evidence, including boxes containing hundreds of files and claims data. The government argued that the destruction of the files was not done in bad faith and that Annappareddy had multiple occasions to review and make copies. Nevertheless, the court agreed with Annappareddy, calling the government’s actions “shocking” and granted Annappareddy’s motion to dismiss.

REASONING: The court agreed and dismissed the case with prejudice. In granting Annappareddy’s motion, the court ruled that the prosecutors’ mistakes violated Annappareddy’s constitutional due process rights. Specifically, the court found that prosecutors had presented false evidence and arguments to the jury. The court also questioned why prosecutors would destroy hundreds of files and not preserve evidence while a motion for a new trial was pending. The judge also found that the government had failed to turn over information about discrepancies in the amount of loss suffered by the government programs. Specifically, the judge found that a government witness’s opinions of the losses (which happened to be less than those of the government’s auditor), should have been shared with Annappareddy’s counsel.

HOLDING: The government violated Annappareddy’s due process rights by presenting false and misleading evidence at trial and by destroying and withholding evidence. Therefore, the court granted Annappareddy’s motion to dismiss.

B. Compounding (NECC)


RELIEF SOUGHT: Two pharmacists who were indicted for misbranding prescription drugs sought dismissal of criminal charges.

ISSUE: Did the indictment sufficiently put defendant pharmacists on notice that their activities of matching orders to packages prior to shipping constituted criminal misbranding under the FDCA?

FACTS AND PROCEDURAL HISTORY: A grand jury issued a 73-page, 145-paragraph indictment against fourteen defendants involved in the ownership, management, or operations of New England Compounding Center (“NECC”). The indictment claimed that the defendants’ criminal action allowed non-sterile methylprednisolone acetate compounded by NECC to be administered to patients and causing twenty-five deaths and hundreds of grave injuries.

Paragraphs 13 and 14 referenced Mss. Chin and Thomas as pharmacists who “worked in the packing area checking orders prior to shipment to NECC’s customers.” Aside from alleging these two defendants worked in the packaging area checking orders, the indictment claimed they “should have known from the improbable names of some of the ‘patients’ whose addresses they were presumably checking (which
included celebrities, star athletes, and fictional characters), that no medical practitioner had issued a valid prescription . . . .” The following chart summarizes the indictment.

<table>
<thead>
<tr>
<th>Counts</th>
<th>Violation</th>
<th>Facts</th>
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<tbody>
<tr>
<td>Chapter II (3)</td>
<td>“Klein” conspiracy to defraud the FDA under 21 U.S.C. § 371</td>
<td></td>
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<tr>
<td>Chapter III (4-56)</td>
<td>Racketeering under generic Mail Fraud Statute, 21 U.S.C. § 1341</td>
<td></td>
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<tr>
<td>Chapter IV (57-94)</td>
<td>Introducing adulterated or misbranded drugs into interstate commerce 21 U.S.C. § 331(a)</td>
<td>Chin (counts 104-107) &amp; Thomas (counts 108-109) (betamethasone and one case of triamcinolone)</td>
</tr>
<tr>
<td>Chapter V (95-109)</td>
<td>Violation of FDCA for dispensing drugs without a valid prescription</td>
<td></td>
</tr>
<tr>
<td>Chapter VI (110-131)</td>
<td>Criminal contempt of Bankruptcy Court Order 18 U.S.C. § 401(3) and unlawful structuring of banking withdrawals 31 U.S.C. § 5324</td>
<td>Previously closed</td>
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**REASONING.** The court noted the complex interplay of federal laws at issue. These defendants were charged with violating 21 U.S.C. § 353(b)(1), which requires prescription drugs to be dispensed only upon the order of a licensed practitioner and deems “[t]he act of dispensing a drug contrary to the provisions of this paragraph . . . to be an act which results in the drug being misbranded while held for sale.” The court explained that, “reduced to its essence, misbranding (as charged) means the dispensing of a toxic drug in interstate commerce without a (valid) prescription and with the specific intent to defraud and mislead the United States government by concealing or failing to disclose that no valid prescription had been issued.” (emphasis added).

In assessing a motion challenging the sufficiency of an indictment, “a court must determine whether the indictment “contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and . . . enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense.” The court focused on whether these defendants were dispensing drugs by checking orders in the packing room. Because the FDCA does not define dispensing, the court must look to the “meaning in common parlance” taken in the proper context, which here is “medical pharmacology.” Steadman’s Medical Dictionary defined dispense to mean, “fill[ing] a medical prescription.” Therefore, a pharmacist dispenses drugs only when acting in the role of a licensed professional “authorized to fill (put together) a medical prescription for delivery to a patient.” But, the indictment does not allege either of these defendants “engaged in any conduct meeting this definition.”

The court noted that the federal Controlled Substances Act does define dispense “broadly to mean ‘to deliver a controlled substance to an ultimate user or research subject by, or pursuant to lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery.’” 21 U.S.C. § 802(10).
While the federal CSA definition could encompass the factual allegations in the indictment, these defendants are not being charged under that law.

The issue here is whether these defendants received fair notice of the charges against them. The FDCA punishes a pharmacist who fills an invalid prescription” placed into interstate commerce with the intent to defraud or mislead the government.” The FDCA “does not reach” conduct incidental to the distribution of prescription drugs (e.g., “checking a package”). The court concluded a reasonable person would not understand from the indictment that she could be criminally liable for dispensing a misbranded drug by participating in the “filling of a prescription she had never approved (or is even alleged to have seen)” when her only alleged activity was matching orders to packages.

**HOLDING:** The court dismissed the charges against the two defendants because the indictment did not provide fair notice that their activities of matching orders to packages involved dispensing a prescription that could, under the circumstances of the case, constitute misbranding with intent to defraud and mislead the U.S. government.

**C. Controlled Substances Act—Ultimate User Defense**


**RELIEF SOUGHT:** Defendant seeks reversal of conviction for illegal possession of a controlled substance.

**ISSUES:** Does an affirmative defense exist for an “ultimate user” who possesses a controlled substance pursuant to a household member’s valid prescription?

**FACTS AND PROCEDURAL HISTORY:** On February 15, 2015, a police officer discovered Mary Yokel’s car parked in front of a motel. Yokel had an active arrest warrant. The officer knocked on the motel room door and made contact with and arrested Yokel. She was searched incident to arrest. During the search, the officer located one Vicodin pill in Yokel’s pants pocket. She was subsequently charged with possession of a controlled substance.

At trial, Yokel sought to introduce evidence that she possessed the Vicodin pursuant to her 16-year old daughter’s valid prescription. Yokel made an offer of proof that, on the day in question, she had taken two of the pills out of the bottle, gave one to her daughter, and put the other one in her pocket after determining that her daughter should not take two pills. The trial court denied Yokel’s motion to continue the case to allow her daughter to testify and granted the State’s motion in limine to exclude any evidence regarding Yokel’s daughter’s valid Vicodin prescription. In granting the State’s motion in limine, the trial court said:

> [M]aybe I would allow that as a defense if [the circumstances were that] the police broke down the door just as she was handing the medicine to her daughter at the appropriate time, and then maybe we would—you’d be able to present that, but not under the circumstances here.

At trial, Yokel testified in her defense, but she was not permitted to testify that she possessed the controlled substance for the purpose of administering it to her daughter. Yokel proposed a pattern form jury instruction directing the jury to find her not guilty of possession of a controlled substance if it found the substance was obtained directly from or pursuant to a valid prescription. The trial court refused to give this instruction.

The jury found Yokel guilty of one count of possession of a controlled substance (hydrocodone) and Yokel appealed.
REASONING: Ultimately, the court agreed with Yokel’s argument that the trial court misinterpreted former Wash. Rev. Code Ann. 69.50.4013(1) by concluding the statute’s affirmative defense did not apply to a person in possession of a controlled substance pursuant to a third party’s valid prescription because she had presented sufficient facts to entitle her to an ultimate user defense.

Former § 69.50.4013(1) provided an affirmative defense to a person who lawfully possesses a controlled substance obtained “directly from” or “pursuant to” a valid prescription. The court closely examined these undefined terms. It stated that the plain meaning of “directly from” a valid prescription relates to the possession of a controlled substance by the prescription holder. Lawful possession “pursuant to” a valid prescription, however, was less clear to the court because the plain language of the statute does not state who must hold the valid prescription; possession is arguably lawful if “pursuant to” a third party’s prescription as well as one’s own. Due to the ambiguity, the court looked to related statutes to determine whose valid prescription must be “pursuant to.”

Former § 69.50.308 (2013), of the state’s Uniform Controlled Substances Act, allows practitioners to dispense controlled substances to an ultimate user pursuant to a prescription. “Ultimate user” is defined as “an individual who lawfully possesses a controlled substance for the individual’s own use or for the use of a member of the individual’s household or for administering to an animal owned by the individual or by a member of the individual’s household.”

According to the court, the definition of “ultimate user” indicates the legislature’s intent to allow an ultimate user to possess a controlled substance for the use of another household member. Therefore, the legislature intended to provide an affirmative defense to ultimate users who possess a controlled substance pursuant to a household member’s valid prescription. The court provided a final example for why its interpretation made practical sense.

Reading the statute to exclude an ultimate user defense “criminalizes behavior that may involve a common caretaking function. For example, a son who picks up his bedridden father’s prescription medication or a mother who administers a prescription medication to her infant daughter would be in violation of the statute. . . It cannot be presumed that the legislature intended this absurd result.”

HOLDING: Former Washington Rev. Code Ann. § 69.50.4013(1)’s plain language includes an affirmative defense for ultimate users who lawfully possess a controlled substance pursuant to a household member’s valid prescription. The plain language of the statute, taken with the statutory scheme, allows ultimate users to lawfully possess a household member’s prescription for a controlled substance and, as a result, provides ultimate users with a defense to the possession. Thus, the trial court misinterpreted former RCW 69.50.4013(1) in concluding it does not apply to ultimate users. Yokel’s conviction is reversed and remanded for a new trial.

VII. DEFAMATION

A. Physician against Pharmacist


RELIEF SOUGHT: The parties filed cross motions for summary judgment with CVS seeking to dismiss the case because any statements by its employees were opinions and not defamation and Dr. Mimms sought judgement that statements by CVS employees were defamatory per se.

ISSUES:

1. Did physician fail to plead defamation sufficiently by not identifying when the alleged statements were made, who made the statements, or to whom they were made?
2. Did the complaint fail because it lacked sufficient allegations of malice?
3. Was CVS entitled to dismissal because the alleged statements fell within a qualified privilege?

**FACTS AND PROCEDURAL HISTORY:** 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.

**REASONING:** “To prevail on a cause of action for defamation, a plaintiff must prove four elements: (1) a communication with defamatory imputation, (2) malice, (3) publication, and (4) damages. . . . A communication is defamatory per se if it imputes: (1) criminal conduct; (2) a loathsome disease; (3) misconduct in a ‘person’s trade, profession, office, or occupation; or (4) sexual misconduct.’ If a plaintiff prevails on a claim for defamation per se, damages are presumed.

CVS argued that the “excerpts” of statements in the complaint were not sufficient to state a claim because they were not full statements and did not identify who made the statements or to whom they were made. The court explained that while notice pleading requires the plaintiff to assert the operative facts of a claim, which include the defamatory statements, in this case, the physician plaintiff might not possess the precise details without discovery. Moreover, because he heard about the alleged defamatory statements from patients, plaintiff could not identify them without violating physician-patient confidentiality. Even if CVS was correct in arguing pharmacists have a legal duty to provide information regarding patients’ treatments, the affirmative defense of qualified privilege “depends on facts of the case that are not yet known to the Court.”

The court rejected CVS’s argument that plaintiff failed to plead “actual malice,” because the complaint alleged the allegations were “maliciously false.”

The court also rejected CVS’s argument the defamation claims fail because they are protected by a qualified privilege. A qualified privilege “rebuts the element of malice implied by law for the making of a defamatory statement.” To prove a qualified privilege the defendant must show: (i) the statement were made in good faith, (ii) there was an interest to be upheld, (iii) the statement was limited to this purpose, (iv) the occasion was proper, and (v) the statements were made in a proper manner only to the appropriate individuals.

**HOLDINGS:** The court denied the motion to dismiss.

1. The court found the defamation claim to be “plausible on its face” and therefore sufficient to withstand a Rule 12(b)(6) motion to dismiss.

2. The court concluded that plaintiff sufficiently pled actual malice.

3. CVS was not entitled to dismissal based on qualified privilege because privilege is an affirmative defense dependent on facts discovered during the case.

**VIII. EMPLOYMENT**

**A. American with Disabilities Act, Disparate Impact**


**RELIEF SOUGHT:** Pharmacist sued his former employer (for himself and a putative class) alleging Wal-Mart’s credentialing policy violated the Americans with Disabilities Act (“ADA”)
ISSUE: Did Wal-Mart’s policy of not employing pharmacists who have faced state board disciplinary action disproportionately affect recovering drug addicts, in violation of the ADA?

FACTS AND PROCEDURAL HISTORY: Pharmacist, James H. Bryan, filed suit against Wal-Mart in 2014, alleging that the retailer violated the ADA because it had implemented a policy of not employing pharmacists who had faced disciplinary action by a state pharmacy board. In 2002, Bryan lost his pharmacist license after he was charged with 17 counts of prescription forgery. He enrolled in a rehabilitation program and the charges were dismissed. He regained his license in 2007, and began working for Wal-Mart as an intern, then a staff pharmacist. In 2011, the company implemented a policy prohibiting the employment of a pharmacist with a history of adverse actions taken against their state licenses. Bryan was subsequently fired and brought suit.

At the trial court level, Bryan argued that the policy disparately impacts recovering drug addicts, including him, and that, under the ADA, an individual’s addiction “trumps” addiction-related misconduct. Wal-Mart asserted that Bryan was fired after the policy went into effect because he had been charged with forging prescriptions, not because he was a former addict. The trial court agreed, finding that Wal-Mart terminated Bryan because he had criminally forged prescriptions, and because that led to the suspension of his pharmacy license. The court further found that Bryan was not terminated “because he was a disabled, rehabilitated drug addict.” Bryan v. Wal-Mart Stores, Inc., No. C13-5934, 2014 WL 841532 (W.D. Wash. Mar. 4, 2014). Bryan appealed the decision.

On appeal, Bryan argued that he was fully rehabilitated before Wal-Mart employed him, and was required to disclose his record of addiction and rehabilitation. He further contended that Wal-Mart’s policy tends to screen out people with disabilities, including recovering addict.

REASONING: The Ninth Circuit reasoned that Bryan presented only a conclusory allegation that his pharmacy license was suspended due to his disability. Further, the court found that the record indicated that Bryan’s pharmacy license was actually suspended due to his history of adverse board action by the board of pharmacy. It was the court’s position that Wal-Mart implemented a neutral policy dismissing all employees with any history of adverse board action.

Because this case concerns a neutral policy affecting all those with any history of adverse board action, Bryan would have to allege a nexus between the policy, the forgery charges that resulted in his adverse board action, and his disability. Without establishing this causal nexus, this court cannot reasonably infer that Wal-Mart’s neutral policy screens out or tends to screen out Bryan on the basis of his disability.”

HOLDING: The Ninth Circuit held that it could not reasonably infer that Wal-Mart’s policy screened out plaintiffs on the basis of disability and there was no demonstrated nexus between plaintiff’s disability, his adverse board action, and his disability.

IX. FALSE CLAIMS

A. Usual and Customary Pricing


RELIEF SOUGHT: Relator filed qui tam suit on behalf of federal government alleging Kmart violated the False Claims Act (“FCA”).

ISSUE: Are pharmacy’s discount drug card prices for cash-paying patients to be considered usual and customary pricing for purposes of Medicare Part D?
FACTS AND PROCEDURAL HISTORY: In July 2008, pharmacist James Garbe filed a qui tam suit alleging Kmart violated the FCA by using higher U&C prices for Medicare Part D pricing purposes. Garbe alleged that Kmart charged cash-paying customers who signed up for one of the company’s discount programs lower prices and non-program cash customers higher cash prices. Garbe contended that Kmart used the higher non-program cash prices as its U&C pricing and that Kmart’s true U&C prices were the lower prices offered to cash customers participating in its discount programs, rather than the higher prices paid by non-program cash customers and third party payors. Conversely, Kmart argued that participants in these programs belonged to a particular group and thus should be distinguished from the general public.

At the close of discovery, Kmart filed several motions for partial summary judgment, arguing that Garbe’s allegations failed due to: (i) the lack of presentment and materiality on the theory that the government never actually received or paid any of its reimbursement requests since the requests were submitted to PBMs and plan sponsors; (ii) 2009 changes to the FCA brought the Fraud Enforcement and Recovery Act (“FERA”) meant that Garbe’s allegations were limited to requests for payment pending on or after June 7, 2008; and (iii) Garbe’s position on Kmart’s discount program participants and U&C. The district court denied Kmart’s motions for summary judgment and found that, as a matter of law, transactions under Kmart’s discount programs represented the U&C price.

Kmart then petitioned the district court to certify its summary judgment order for interlocutory appeal. The district court agreed and identified three key issues: (i) whether the FERA amendments only retroactively applied to all cases “pending on or after June 7, 2008,” as opposed to claims for payments; (ii) whether Medicare Part D PBMs and plan sponsors were “officers or employees of the U.S.” for purposes of presentment under the FCA; and (iii) whether Garbe had satisfied the materiality requirement under the FCA. The Seventh Circuit accepted Kmart’s petition and added a fourth question as to whether the district court correctly identified the U&C price.

REASONING: On the first three issues, the Seventh Circuit affirmed the district court’s earlier rulings holding: (i) that FERA applies to all cases pending on or after its effective date—not claims or requests for payment; (ii) that, post-FERA, there is no requirement for presentment to an officer or employee of the United States but that the FERA provision eliminating the presentment requirement could not be read to deem contractors implementing a government program to be “the government” prior to FERA’s effective date; and (iii) that, under another provision of the FCA, Garbe had presented evidence sufficient to create a genuine dispute of material fact as to whether Kmart knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim in violation of the FCA.

With respect to the U&C issue, the Seventh Circuit rejected Kmart’s argument that members of its discount programs “belong to a particular group” or “organization” and therefore represent a subset of its customer base that were not members of the general public. The Seventh Circuit rejected this argument, holding that this was the pharmacy’s U&C price. In particular, the Seventh Circuit stated that there was “no reason to think that there was any meaningful selectivity for the people who joined Kmart’s programs, and thus that they could be distinguished in any way from the ‘general public.’” The Seventh Circuit further stated that “few of Kmart’s customers would consider themselves as ‘belonging to a particular group’ […] just because they accepted Kmart’s offer of a discount.” Rather, “[c]ash customers walking into Kmart do not cease to be members of the general public the minute they are offered—or pushed into—‘membership’ in Kmart’s ‘discount program.’” The Seventh Circuit ultimately concluded that Kmart’s discount prices represented the company’s U&C charges because Kmart offered the terms of the discount programs to the general public and made such prices the, “lowest prices for which its drugs were widely and consistently available.”

HOLDING: The Seventh Circuit mostly affirmed a district court’s denial of Kmart’s motion for summary judgment. In doing so, the court affirmed that participants in the discount programs qualified as the
“general public” when determining “usual and customary” (“U&C”) prices under Medicare Part D. The Seventh Circuit then remanded the matter to the district court for further proceedings.

2. **Sheet Metal Workers Local No. 20 Welfare and Benefit Fund et al., v. CVS Health Corp., No. 16046 (S.D. RI Nov. 1 2016)**

**RELIEF SOUGHT:** Defendant filed a motion to dismiss claims by entities that providing prescription drug benefits (“TPPs”), which TPPs alleged CVS “perpetrated an eight-year fraud by reporting an inflated U&C price for generic drugs.

**ISSUES:**

1. Did the plaintiffs provide sufficient details in the complaint to satisfy the heightened specificity standards of specificity under Fed.R.Civ.P. Rule 9(b)?

2. Were third party payors “consumers” under the Indiana’s Deceptive Trade Sales Act (“Indiana DCSA”)?

**FACTS AND PROCEDURAL HISTORY:** The court explained that in response to other “big-box” retailers’ programs offering generic drugs at significantly reduced prices, CVS started its Health Savings Pass (“HSP”) in 2008. The HSP provided some 400 generic drugs at special pricing for individuals who paid an annual membership fee. “The U&C price is generally defined as the cash price to the general public, which is the amount charged cash customers for the prescription, exclusive of sales tax or other amounts claimed.” Plaintiffs claimed CVS offered HSP pricing to the general public, which made “HSP price is the most common price paid by CVS’s cash-paying customers.” However, according to plaintiffs CVS “reported U&C prices for generic drugs up to eleven times the U&C prices reported by some of its most significant competitors and its own HSP prices.” Plaintiff alleged CVS’s scheme resulted in “overcharging hundreds or thousands of TPPs.”

CVS filed a motion to dismiss arguing: (i) plaintiffs had not pled the fraudulent scheme with sufficient specificity under Fed.R.Civ.P. 9(b) and (ii) the plaintiffs were not “consumers” within the meaning of Indiana’s DCSA.

**REASONING:** Rule 9(b) requires a higher standard of specificity for fraud claims. Plaintiffs must allege “requires plaintiffs to allege the ‘who, what, when, where, and how’ of the alleged fraud.” Even though the complaint does not allege every detail, such as the specific amount of drugs purchased, a “complaint need not ‘allege specific shipments to specific customers at specific times with a specific dollar amount of improperly recognized revenue.’” The purpose of Rule 9(b) is to provide defendants with a fair notice of claims asserted and to discourage baseless claims. In this case, plaintiffs alleged a fraud occurred each time CVS submitted a claim to plaintiffs using the NCPDP reporting system and “misrepresented” the U&C price for generic prescription drugs when CVS had been charging cash-paying patients much lower prices.

As to CVS’s argument that plaintiffs allegations could not have violated the Indiana DCSA, the court explained the question was whether the TPPs suffered damages as “consumers” under the definition of that term in the law. The Indiana DCSA “prohibits deceptive acts ‘in connection with a consumer transaction,’ which is defined as a ‘sale . . . to a person for purposes that are primarily personal, familial, charitable, agricultural, or household, or a solicitation to supply any of these things.’” The term “person” encompasses individuals, various legal entities, and government entities. The court looked to two other cases alleging fraud in marketing practices for prescription drugs. See *In re Actiq Sales & Mktg. Practices Litig.*, 790 F.Supp.2d 313, 325-26 (E.D. Pa. 2011); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 495 F.Supp.2d 1027, 1036-37 (N.D. Cal. 2007). In both those cases, the courts concluded “consumer” includes TPPs.
The court concluded TPPs fall within the ambit of “consumer” under the Indiana DCSA because such interpretation was intended by the statute. “Consumer transaction” specifically included corporations, the Indiana DCSA states that it is to be “liberally construed” to promote its purposes and policies, and two federal courts have agreed with this conclusion.

**HOLDING:** The court denied the motion to dismiss.

1. The plaintiffs provided sufficient details in the complaint to satisfy the heightened specificity standards of specificity under Fed.R.Civ.P. Rule 9(b).
2. TPPs were “consumers” under the Indiana DCSA.


**RELIEF SOUGHT:** Safeway filed a motion to dismiss qui tam case alleging Safeway had fraudulently submitted higher U&C pricing to government programs than the $4 it charged the public or later to discount club members.

**ISSUES:**

1. Did the relator illegally obtain and use PHI it his complaint in violation of HIPAA?
2. Did the relator provide sufficient details in the complaint to satisfy the heightened specificity standards of specificity under Fed.R.Civ.P. Rule 9(b)?
3. Was the relator the original source of the facts in the complaint as required by the FCA?

**FACTS AND PROCEDURAL HISTORY:** Relator alleged Safeway, and subsidiaries, violated the FCA by routinely charging government health programs (Medicare, Medicaid, Tricare, and the Federal Employees Health Care Benefits Program (“FEHBP”)) more than the general public for the same drugs. Starting in 2008 in western states, Safeway began offering a free pharmacy “membership club” that matched competitors’ prices such as $4 generic. Around June 2008, Safeway announced and promoted an automatic $4 discount drug program in other areas of the country.

Safeway offered a formulary of approximately 300 generic drugs priced at $4 for a 30 days’ supply, $8 for a 60 days’ supply, and $12 for a 90 days’ supply. The formulary discount list and terms of the discounts offered were published and publicly available. Safeway continued to offer to price match any competitor’s price for a prescription drug not on its formulary list. All customers automatically received the reduced formulary pricing.

In 2010, Safeway discontinued the automatic $4 generic program and replaced it with the membership club.

The court explained that the relator provided examples of “Safeway’s own internal documents and communications” that revealed “Safeway corporate officials engineered the centrally controlled scheme which resulted in submission of false claims.” For example, in one email exchange between a corporate director and the CFO about the proposed plan, the CFO wrote: “I am still a bit hazy on a few pts [. . .] . . . look forward to discussing with you more . . . it seems like to me this whole thing revolves @ the insurance angle - to get the $10 per item from them vs the $4 cash price . . . am I off?”

Safeway filed a motion to dismiss the FCA claims. Among other arguments, Safeway contended: (i) the complaint was based on illegally obtained information because the relator violated HIPAA by disclosing PHI illegally; (ii) the allegations were not specific enough to satisfy Fed.R.Civ.P. 9(b) requirements that
“a party must state with particularity the circumstances constituting fraud”; and (iii) the relator was not the original source because the allegations were similar to an FCA suit brought in Colorado in 2014 and unsealed in March 2016.

REASONING: The court rejected the argument that relator violated HIPAA by providing PHI to the government as part of the sealed complaint. HIPAA rules contain an exception that exempts “[d]isclosures by whistleblowers” from the privacy rules prohibition on disclosing PHI without authorization. 21 C.F.R. § 164.502(j). Moreover, relator used codes to replace patient information in the complaint so individual patients could not be identified.

As to the heightened specificity requirements of Fed.R.Civ.P. 9(b), the court recited the standard for Rule 9 (b) that the complaint must describe the who, what, when, where, and how of the alleged fraudulent scheme. The relator had “alleged no less than 31 individualized pharmacy transactions as representative examples of the false claims.” The Rule (9)(b) does not require redundant examples of specific conduct or an enumeration of every specific fraud.

In response to Safeway’s argument that relator was not the original source, the court pointed out that to determine whether a person is the original source, the court needs to evaluate whether the allegations had been publically disclosed, if the lawsuit is based on such public disclosures, and whether the relator is an original source of the information. In this case, the other qui tam action against Safeway based on similar allegations was filed on August 5, 2014. Law 360 publicized the case on March 13, 2016, shortly after the complaint was unsealed... However, relator in this case filed the original complaint in November 2011. On March 31, 2016, relator filed an amended complaint with more detail, some of which overlapped with the Colorado case. Because relator’s complaint alleged the fraud in 2011, he was an original source. Moreover, the court deemed the relator to be an “independent source” because he had knowledge independent from the Colorado qui tam relator. Finally, this relator “‘materially adds’ to the alleged publically disclosed transactions” in the Colorado case.

HOLDINGS: Court denied Safeway’s motion to dismiss.

1. Relator did not violate HIPAA because any disclosed PHI was exempted by HIPAA rules permitting disclosure by whistleblowers.

2. Realtor provided multiple specific examples of alleged false claims that were sufficient to meet the who, what, when, where, and how specificity requirements of Fed.R.Civ.P. Rule 9(b).

3. The relator was the original source of the facts in the complaint and materially added to the transactions disclosed prior to filing an amended complaint.


RELIEF SOUGHT: Defendants filed a motion to dismiss FCA claims that alleged defendants did not include price-matching discounts when they submitted U&C prices to government health care programs.

ISSUE: Did relators sufficiently allege facts supporting the elements of “falsity,” “knowledge,” and “materiality” as required by the FCA?

FACTS AND PROCEDURAL HISTORY: Relator Tracy Schutte worked as a pharmacist briefly for Supervalu. Michael Yarberry worked as a pharmacist since 1992. Supervalu operated some 2,500 grocery stores with more than 800 pharmacies in 25 states under various names (e.g., Albertsons Save-On, Osco, and Jewel). Supervalu managed defendant pharmacies and directed all billing policies and practices. Relators alleged that in 2006 to 2007, defendants:
Implemented a “Price Matching” program to match certain competitors’ prices for generic drugs. The Relators claim that the matched competitor prices—rather than the cash prices—became the usual and customary prices that should have been passed on to government payers. The Relators assert that by not including price-match discounts in their usual and customary calculations, the Defendants knowingly submitted false claims for reimbursement to federal healthcare programs.

Relators provided computer printouts of purchases from defendants’ claims processing system that showed lower prices charged to the general public and higher prices charged to government programs.

Defendants moved to dismiss the complaint because realtors did not sufficiently plead “falsity,” “knowledge,” and “materiality” as required by the FCA.

**REASONING:** “The FCA provides, in part, that ‘any person who . . . (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,’ is liable to the federal government. 31 U.S.C. § 3729(a)(1).” (emphasis added).

**Falsity.** Defendants argued that relators did not sufficiently plead falsity for Illinois Medicaid or for Medicare Part D. But, relators recited federal Medicaid regulations that require the lower of AAC plus a dispensing fee or U&C charged to the general public. Relators also alleged that: (i) state Medicaid programs incorporate the federal rules for pricing and that the same pricing applies to Tricare and FEHBP, (ii) defendants unfairly profited from not offering Part D beneficiaries the discounted matching prices. Thus, relators sufficiently pled falsity.

**Knowledge and Materiality.** Rule 9(b) permits the state of mind to be pled generally. Relators met this standard by alleging defendants knowingly submitted fraudulent claims based on inflated prices. Realtors also alleged that reporting inflated prices was material because it resulted in overpayment by the government programs. Government health care programs require annual certifications of the accuracy and truthfulness of data that determines payment. Accordingly, relators sufficiently pled knowledge and materiality.

**HOLDING:** The court denied the motion to dismiss because relators adequately alleged facts to support the falsity, knowledge, and materiality requirements of the FCA.

**B. Fraudulent Billing**


**RELIEF SOUGHT:** United States sought criminal charges against a pharmacist, alleging fraudulent billing to a government run health care program.

**ISSUE:** Did pharmacist conduct fraudulent billing after submitting claims to Medicare and Medicaid for prescriptions that were never filled or authorized?

**FACTS AND PROCEDURAL HISTORY:** From January 2011 to December 2012, pharmacist Andrew Barrett operated pharmacies in Bronx, Rockland, and Queens counties in New York State. From his Queens pharmacy, Barrett fraudulently billed Medicare and Medicaid approximately $2.7 million for prescription medications that he never dispensed. According to the court filings and facts presented, from his Queens pharmacy, Barrett falsely billed government health care programs for drug products, including a substantial number of HIV-AIDs medications that he never dispensed to patients. Barrett’s scheme involved billing for refills of costly medications even though patients never requested or received them, and doctors had not authorized the refills to be dispensed.
Barrett also wrote checks for over $2.6 million to himself to pay for his personal expenses from the Bronx and Rockland pharmacy accounts while falsely claiming those funds as business expenses on his personal and corporate tax returns.

Barrett’s bail was revoked on May 17, 2016 after the judge in the case determined there was probable cause to believe that Barrett had violated his release terms by continuing to submit claims to Medicare and Medicaid. The judge also found that Barrett had performed a bogus transaction involving the purported sale of one of his pharmacies. Barrett agreed to a plea deal with the government days later, pleading guilty to one count each of healthcare fraud and tax fraud.

**PLEA DEAL:** Barrett was ordered to serve 43 months (3½ years) in prison and pay $2.7 million in restitution to the government, as well as about $736,000 to the IRS. Barrett also agreed to forfeit $2.7 million, some of which may be used to satisfy the restitution order, pending a future determination by the Department of Justice.

C. **Sufficiency of Claim**


**RELIEF SOUGHT:** Defendant filed a motion to dismiss because *qui tam* relator’s allegations were not sufficiently connected to specific false claims for payment.

**ISSUE:** Can relator’s claims proceed despite the fact that he does not allege specific instances of mislabeling, misbranding, or false billing?

**FACTS AND PROCEDURAL HISTORY:** The underlying case was filed by a *qui tam* relator who worked at all three of the defendants’ pharmacies at various times. In particular, relator alleged that the defendants submitted various false claims to Medicare or Medicaid, including: (i) claims for prescriptions that expired before the dates printed on the prescription vial label and before the patient could consume the medication as directed by her doctor; (ii) claims for dispensing fees that inflated the number of unexpired doses dispensed; and (iii) claims (by one defendant only) for the reimbursement of generic drugs using a false NDC number for more expensive drugs. The Government declined to intervene, and the defendants moved to dismiss the allegations for failure to connect the allegations to specific false claims for payment.

**REASONING:** The relator did not specifically identify a single false claim submitted by all three defendants. In particular, the court noted that “[w]hile the relator [] allege[d] that the prescription vials were mislabeled or misbranded because they contained a false expiration date, he d[id] not plead one claim submitted to the government which billed for expired drugs or contained a false date in the claim itself.” The court also noted that because the relator was a pharmacist at each of the pharmacies, “this knowledge was not peculiarly within the alleged perpetrators’ [i.e., pharmacists’] knowledge.”

**HOLDING:** The court dismissed the expiration date and dispensing fee claims with prejudice. Notably, however, the court explained that relator’s generic drug pricing allegations did contain some specific facts, gave the relator 30 days to refile this particular claim, along with facts regarding a specific false claim made to Medicare or Medicaid.
D. Implied Certification


RELIEF SOUGHT: Petitioner appealed the First Circuit’s denial of its motion to dismiss, claiming that respondents had failed to state a claim when they relied on the “implied false certification” theory of liability.

ISSUE: Can the implied false certification theory provide a basis for liability under the False Claims Act?

FACTS AND PROCEDURAL HISTORY: In 2009, a Medicaid patient undergoing treatment at a Massachusetts mental health clinic died of a seizure. In 2011, her parents filed a qui tam lawsuit under the FCA in federal district court, alleging that the staff members treating their daughter were not properly licensed or supervised, in violation of Massachusetts health regulations. They contended that, by submitting Medicaid invoices for services performed in violation of those regulations, the clinic submitted false and fraudulent claims to the Medicaid program. Because the claims for government payment did not expressly certify that the services were performed in compliance with state regulations, the complaint rested on the theory that the clinic impliedly certified its regulatory compliance when it submitted the claims.

The district court granted the ‘defendants’ motion to dismiss, concluding that the complaint did not state any implied falsity because it relied on noncompliance with regulations that were conditions of participation in ‘Massachusetts’ Medicaid program, rather than conditions of payment by the program. The U.S. Court of Appeals for the First Circuit reversed, holding that conditions of payment may be found in statutes, regulations, and contracts, and do not need to be expressly designated.

REASONING: The Supreme Court emphasized that the clinic’s claims were clearly misleading in context because they used specific billing codes and identifiers concerning types of treatment and specific job titles, implying that the ‘clinic’s personnel had the requisite training and qualifications for their jobs. Such misrepresentations fall within the rule that “half-truths” that state the truth while omitting critical qualifying information, can be actionable misrepresentations.

The court noted that the fact that a legal requirement is labeled as a condition of payment is not automatically dispositive, and elaborated on what kind of nondisclosure gives rise to material falsehood. Relevant materiality considerations include whether the government consistently refuses to pay claims based on noncompliance with the particular statutory, regulatory, or contractual requirement, or whether the government pays a particular claim in full despite its actual knowledge that certain requirements were violated.

HOLDING: The court unanimously held that the implied false certification theory can be a basis for False Claims Act liability. Because common-law fraud encompasses misrepresentations by omission, the court concluded that misrepresentations by omission can give rise to liability.

X. NEGLIGENCE

A. Human Research–Sovereign Immunity Defense


RELIEF SOUGHT: University of Texas appealed the trial court’s denial of its sovereign immunity defense.
ISSUE: Did the University of Texas waive its sovereign immunity by causing plaintiff’s personal injury through a “condition or use of tangible personal property [such that] the government unit would, were it a private person, be liable to the claimant?”

FACTS AND PROCEDURAL HISTORY: Plaintiff voluntarily signed up for defendant’s smoking cessation study, which investigated the effectiveness of using Chantix while taking Zyban. Plaintiff notified the study’s candidate screener that she was taking Zyban for depression and had a previous adverse reaction to Chantix. As part of the study, plaintiff was prescribed Chantix and a Zyban placebo. Several weeks later, plaintiff attempted to commit suicide.

Plaintiff filed suit, alleging that the defendant negligently screened her, and prescribed and dispensed Chantix when it knew that she should not be given the drug due to her history of depression. Defendant filed a plea for sovereign immunity based on its status as a government institution. The trial court denied defendant’s plea, citing Texas’ limited waiver of sovereign immunity, which applies when a plaintiff’s personal injury was “caused by a condition or use of tangible personal property if the governmental unit would, were it a private person, be liable to the claimant according to Texas law.” Defendant then filed an interlocutory appeal.

REASONING: Defendant’s actions in prescribing and dispensing Chantix to plaintiff were a sufficient “use of tangible personal property” to satisfy Texas’ waiver requirement. The court had previously held that tangible personal property includes medications that a patient administers to herself. Accordingly, the defendant waived its sovereign immunity when it directed its employees to administer or dispense the drugs that allegedly caused the plaintiff’s damage.

A sufficient causal nexus exists between defendant’s use of tangible property and plaintiff’s injuries. Plaintiff offered expert evidence that her suicide attempt was proximately caused by the Chantix that defendant’s employees prescribed. Defendant responded that the general proximate cause standard does not apply, and that the use of tangible personal property must be the direct cause of plaintiff’s injuries. The court determined that proximate cause was the appropriate standard, and that plaintiff’s evidence showed a nexus between the defendants’ dispensing Chantix and the plaintiff’s injuries.

HOLDING: Plaintiff’s pleadings and evidence trigger the defendant’s waiver of governmental immunity as a matter of law. Defendant used tangible personal property by prescribing and dispensing medication to plaintiff, and plaintiff’s allegations show a nexus between defendant’s use of property and her injuries.

B. Duty to Fill


RELIEF SOUGHT: Plaintiff appealed decision to recover damages arising from breach of pharmacist’s duty to fill prescription.

ISSUE: Can a pharmacist be held liable for failing to exercise independent professional judgment when there is no evidence of a failure to fill the prescription as directed, and the prescription was not clearly contraindicated?

FACTS AND PROCEDURAL HISTORY: In October 2007, patient John Abrams underwent a hemorrhoid surgery. While he was hospitalized, staff administered approximately 6 mg. of hydromorphone for pain. As part of his discharge, Mr. Abrams’ treating physician wrote a prescription for hydromorphone with an instruction to take up to 8 mg. every 3 to 4 hours as needed for pain. Mr. Abrams’ wife then had the prescription filled at CVS Pharmacy. Upon returning home, Mrs. Abrams gave Mr. Abrams an 8 mg. dosage. Approximately an hour later, Mrs. Abrams found her husband gasping for
air and called for an ambulance. Mr. Abrams died of apparent acute hydromorphone intoxication before
the ambulance arrived.

Mrs. Abrams then sued the treating physician alleging he was negligent for: (i) prescribing 8 mg. doses of
hydromorphone because such a dose was dangerous for an opioid-naive patient and (ii) allowing Mr. Abrams
to take an 8 mg. dose so soon after he received a similar dose at the hospital. Mrs. Abrams also
brought suit against CVS Pharmacy and the pharmacist that filled the prescription alleging the dosage was
so high that CVS and the pharmacist had a duty to take steps to confirm the prescription was appropriate.
CVS and the pharmacist moved for summary judgment on the claims against them arguing they did not
breach any duty of care. Mrs. Abrams filed a cross motion for summary judgment. The trial court denied
both motions concluding that there were material issues of fact as to whether the defendants breached a
duty owed to Mr. Abrams.

On appeal, CVS and the pharmacist contended that it had no duty to warn of the dangers of taking the
prescribed dosage of hydromorphone or to otherwise take steps to ensure the prescription was appropriate
for Mr. Abrams under the circumstances. Instead, CVS and the pharmacist argued that the prescribing
physician is solely responsible for determining whether the prescription is appropriate for a particular
patient. Requiring the pharmacist to otherwise verify the appropriateness of the prescription would
undermine the physician-patient relationship and intrude into the physician’s exclusive professional
sphere. Mrs. Abrams countered by arguing that the expert evidence she submitted demonstrated that the
defendants departed from the appropriate standard of care and that they failed to rebut her showing.

REASONING: The Appellate Division rejected the defendants’ categorical argument that a pharmacist’s
duty to their patients never extends beyond accurately filling a prescription. The court explained that a
pharmacist does not have a general duty to independently evaluate the propriety of a physician’s
prescription because such a rule would place an undue burden on pharmacists and likely create
antagonistic relations between pharmacists and physicians, and interfere with the patient-physician
relationship. Nonetheless, pharmacists owe a duty to patients in the presence of additional factors, such
as known contraindications, that would alert a reasonably prudent pharmacist to a potential problem.

In arriving at this rule, the court took a page from the treatment of hospital staff liability when following
physician orders. Notably, New York case law recognizes that the principal duty of hospital staff is to
follow a physician’s orders and that a hospital is normally protected from tort liability if its staff carries
out those orders. Hospital staff, however, can be liable for carrying out a physician’s order where the staff
knows the order is “so clearly contraindicated by normal practice that ordinary prudence requires inquiry
into the correctness of orders.”

The court held that a similar rule applies to pharmacists. Specifically, when a pharmacist did not exercise
any independent professional judgment in filling and dispensing a prescription, the pharmacist cannot be
held liable for negligence absent evidence that the pharmacist: (i) failed to fill the prescription precisely
as directed by the prescription or (ii) the prescription was so clearly contraindicated that ordinary prudence
required the pharmacist to take additional measures prior to dispensing the prescription.

In the instant case, the court found that the defendants submitted expert evidence that demonstrated they
did not render any professional judgment in filling Mr. Abrams’s prescription and that the prescription
was filled precisely as directed. Further, with respect to contraindications, the defendants demonstrated
that the prescribed dosage did not exceed the manufacturer’s maximum recommended dosage and that,
given the information available to them, the generally accepted community practice standards did not
require the pharmacist to take any additional actions. Lastly, the court found that Mrs. Abrams’s expert
evidence to the contrary was based on facts not supported by evidence and insufficient to raise an issue of
fact on whether the prescription was “so clearly contraindicated.”
**HOLDING:** The court held that pharmacists cannot be held liable for negligence when the pharmacist did not exercise independent professional judgment and absent evidence that: (i) the pharmacist’s failure to fill a prescription as directed, or (ii) a prescription was clearly contraindicated so as to require the pharmacist to take additional measures before dispensing the medication. Accordingly, the court reversed part of the trial court’s order and granted summary judgment to CVS and the pharmacist.

**C. Prescription Errors and Wrongful Death**


**RELIEF SOUGHT:** Plaintiff sued pharmacy for the wrongful death of a family member.

**ISSUE:** Is a pharmacy liable for delivering the wrong prescription to a patient, resulting in the patient’s death?

**FACTS AND PROCEDURAL HISTORY:** Family of Joyce Oyler filed wrongful death lawsuit against pharmacy Hy-Vee, alleging the pharmacy’s delivery of the wrong prescription drug led to Oyler’s death. In 2013, Oyler had been discharged from the hospital with multiple changes to her medications. The hospital called in eleven prescriptions to Oyler’s pharmacy, where a pharmacy technician received the orders. Under Missouri pharmacy rules, certified pharmacy technicians are permitted to receive oral prescriptions.

Plaintiffs alleged that the technician transcribing the prescription had erred, writing “methotrexate 2.5 mg daily” instead of the actual prescription order for “metolazone 2.5 mg daily.” Methotrexate is typically used to treat certain types of cancer, including cancer of the breast, skin, head, neck, or lungs. It can also be used to treat psoriasis and rheumatoid arthritis. Importantly, the drug is usually taken once or twice per week, not every day.

At trial, the pharmacy had claimed that a DUR and a final prescription check were performed. However, the pharmacy did not contest that the patient received methotrexate without counseling. Plaintiffs presented testimony that methotrexate is a high-alert medication that requires that certain precautions be taken. This includes segregation of the drug from normal pharmacy stock, mandatory patient counseling, and use of a hard stop in dispensing software to prevent dosage instructions for “one-tablet daily.” Plaintiffs argued that Hy-Vee had taken none of these precautions prior to dispensing the drug and the erroneous instructions to Oyler. Plaintiffs were also able to present testimony that the pharmacy’s technicians were not adequately trained to take oral prescriptions.

**VERDICT:** A jury found in favor of the plaintiffs, awarding $1.4 million for past non-economic damages and $600,000 for future non-economic damages.

**D. Excessive Dose & Negligence Per Se**


**RELIEF SOUGHT:** Decedent’s estate brought a wrongful death suit against the pharmacist that filled decedent’s prescription for negligent preparation and dispensing of hydromorphone.

**ISSUES:**

1. Did the pharmacist breach his duty of care by dispensing a prescription order that was unreasonable on its face due to the dosage and strength?

2. Was there a private cause of action for negligence per se against the pharmacist for filling an unreasonable prescription without being registered or licensed in Florida?
FACTS AND PROCEDURAL HISTORY: Decedent, an Ohio resident, suffered from chronic pain and took hydromorphone through a pain pump inserted in his spinal canal. While in Florida, decedent visited a pain management center, where he received a prescription order substantially increasing his hydromorphone concentration. The compounding pharmacist had no active license to compound drugs in Florida, but compounded and released the order to decedent’s Florida physician, who then administered it to the decedent through his pain pump. Patient died that same day.

The trial court dismissed the estate’s claims for failing to allege that the compounding pharmacists owed decedent a duty to use proper care that extended beyond simply filling his prescription as written. The trial court also found no statutory language creating a private cause of action for negligence per se when a pharmacy fills a prescription without being registered or licensed to do so.

REASONING: The Florida Court of Appeals found that the duty to use due and proper care involves more than merely filling a prescription as written. A pharmacist may breach this duty of care even when he or she fills a prescription in accordance with the instructions, if the prescription is unreasonable on its face. Quoting the court in Oleckna v. Daytona Disc. Pharmacy, 162 So.3d 178 (Fla. 5th DCA 2015), “‘robotic compliance’ with a prescribing physician’s instructions does not shield a pharmacist from liability when the prescription is unreasonable on its face.”

The Florida Court of Appeals also believed that a failure to be licensed or permitted may be evidence of negligence, but evidence of legislative intent is necessary to create a private cause of action for negligence per se. The court was unable to find evidence of legislative intent in the Florida Pharmacy Act or any other law.

HOLDINGS:
1. The Florida Court of Appeals reversed the trial court and held that a pharmacist may breach the duty of care even when he or she fills a prescription in accordance with the instructions, if the prescription is unreasonable on its face.

2. The court affirmed the trial court’s dismissal of the plaintiff’s negligence per se cause of action because there was no legislative intent to create a private cause of action for negligence.

E. Pharmacist on Rounds Failure to Correct


RELIEF SOUGHT: Defendant filed a motion to dismiss on the ground that the pharmacist was not sufficiently responsible for decedent’s care.

ISSUE: May a decedent’s estate bring malpractice and negligence claims against a hospital pharmacist who rounded with physicians and failed to correct the prescription order that contributed to his cause of death?

FACTS AND PROCEDURAL HISTORY: Decedent was admitted to a hospital for treatment of abdominal pain. A physician diagnosed septic shock, and two blood cultures tested positive for Staphylococcus aureus. The medical team allegedly did not order or administer vancomycin “although it would have been appropriately prescribed for him given the nature of the infection.” The infection allegedly resulted in bacterial growth on one of the decedent’s heart valves, causing severe damage to his circulatory system and his death.

Decedent’s estate filed a lawsuit alleging malpractice of decedent’s attending physician, medical fellow, and the pharmacist who accompanied the physicians on their patient rounds every day. The lawsuit alleged that the pharmacist “should have known that the drugs being given to [the patient] did not properly
‘match up’ with his condition, and the pharmacist should have known the results of the culture, and therefore should have known that [decedent] was receiving the wrong drugs for his condition.”

Decedent’s estate claimed that the pharmacist’s “failure to spot the problem and warn the treating physicians lengthened the time required for a proper diagnosis and thus allowed [decedent’s] condition to worsen.”

Defendants filed a motion to dismiss the case arguing that the patient had never requested the pharmacist to provide care, the pharmacist never agreed to provide care for the patient, and the pharmacist had no control over the attending physician.

REASONING: The court rejected all arguments related to the traditional limited role of pharmacists, particularly when a pharmacist accompanies physicians on their daily rounds and reviews specific patients’ charts. After taking note of previous cases that had refused to adopt expanded malpractice exposure for pharmacists on the basis of pharmacists’ incomplete knowledge of the patient, the court distinguished this case because the pharmacist here may have been aware of decedent’s medical history and condition. The court concluded that the pharmacist’s proximity to the decedent and the prescribing physician set this case apart from cases in which a pharmacist “mechanically fills a prescription.”

HOLDING: The court denied the motion to dismiss but left open the possibility that subsequent testimony of expert witnesses would clarify “the role of a pharmacist who accompanies a hospital physician on his or her rounds.”

F. Duty to Ensure Prior Authorization Was Submitted


RELIEF SOUGHT: Carmen Correa, administratrix for decedent Yarushka Rivera sued for compensatory and punitive damages for wrongful death against Ms. Rivera’s doctor and Walgreens for failing to submit prior authorization for an anti-epileptic drug Topamax.

ISSUE: Did pharmacists have a duty to submit prior authorization to decedent’s doctor?

FACTS AND PROCEDURAL HISTORY: In 2009, decedent Yarushka Rivera began seeing Dr. Andreas Schoeck after suffering a seizure and she was prescribed Topamax to treat her seizure disorder. On June 13, 2009, Ms. Rivera filled her Topamax prescription at a Walgreens pharmacy in Massachusetts. She filled another Topamax prescription at Walgreens on July 26, 2009. At that time, a Walgreens pharmacist informed Ms. Rivera that MassHealth, her insurer, would not cover additional prescriptions for Topamax without “prior authorization” from her doctor. She was told to contact Dr. Schoeck to obtain this required authorization.

Ms. Rivera suffered a second seizure in September of 2009. Six days later, Walgreens informed her that her insurance had denied coverage for a Topamax prescription for lack of prior authorization. As such, Walgreens could not fill the prescription unless it was paid in full by Ms. Rivera. Ms. Rivera and her family attempted to fill the Topamax prescriptions four more times over the next two months. Family also attempted to obtain the prior authorization by calling Dr. Schoeck’s office. Of note, the pharmacy computer system at Walgreens permitted the pharmacist to send a courtesy fax to the prescribing physician whenever there was a denial in coverage due to a lack of prior authorization. However, Walgreens pharmacists were not required to send these faxes, the pharmacy did not maintain a record of these faxes, and it did not monitor whether the prescribing physicians actually received these faxes. Correa alleged that Walgreens pharmacists told Ms. Rivera and her family that they would send Dr. Schoeck a fax and telephone his office about the required prior authorization. Rivera died after suffering a third seizure on October 29, 2009.
Administratrix of Rivera’s estate, Carmen Correa brought suit against Rivera’s physician and Walgreens. Walgreens moved for summary judgment on all claims. The court allowed the motion in a margin endorsement in June 2016 and invited Walgreens to file a motion for the entry of a separate and final judgement. The trial court granted the motion in relevant part.

**REASONING:** Walgreens argued that, as a matter of law, it neither owed Ms. Rivera a duty to ensure that she received her Topamax prescription, nor voluntarily assumed a duty to notify Dr. Schoeck that Rivera’s insurance required prior authorization before it would cover the prescription. Correa argued that when the pharmacy told her it would fax and phone her doctor with a request for a refill, it had assumed a duty to ensure that she receive her refill.

The court concluded that merely telling Rivera they would do so did not create a legal duty because the pharmacist also told the plaintiff’s family to contact the doctor, something they attempted to do to no avail. Thus, the court ruled that “the plaintiff has not demonstrated that she will be able to prove at trial that Walgreens offer to contact the doctor would reduce the risk of harm.” Thus, the court rejected Correa’s argument that it was not onerous to place a duty on Walgreens to notify the physician when prior authorization is required for a refill. It stated that such a duty “would place an onerous burden on” pharmacies, obligating them to monitor or supervise the prescribing physicians, and, in essence, to share in the responsibility to provide MassHealth with the necessary prior authorizations.

Correa also argued that Walgreens owed her a duty because it had “specific knowledge of an increased danger to” her from not taking Topamax and from taking a “sub-therapeutic dosage” of Lamictal, which, in high doses, may be used to treat epilepsy. Correa argued that such “special knowledge” was obtained by the pharmacy due to information readily available in its electronic claims submission system. However, the court rejected this argument as well, holding that there was no “special knowledge of an increased danger” because such a conclusion “required a speculative leap beyond a reasonable inference” given the facts. The court concluded by stating that “the plaintiff’s particular leap, unsupported by additional probative evidence, direct or circumstantial, . . . would not permit a reasonable inference to a sufficient degree of probability and would, in effect, impose liability on the basis of unacceptable speculation on the part of a jury.”

**HOLDING:** Walgreens did not voluntarily assume a duty to contact Rivera’s doctor to ensure she received the medication and did not have special knowledge of an increased danger. Therefore, the pharmacy was not held liable.

**XI. PBMS**

A. ERISA Challenges against PBMs

1. **Grasso Enterprises, LLC, et al., v. Express Scripts, Inc., 809 F.3d 1033 (8th Cir. 2016)**

**RELIEF SOUGHT:** Compounding pharmacies (“Compounders”) appealed the district court’s denial of their request for a preliminary injunction against Express Scripts, Inc. (“ESI”) based on the pharmacies’ allegations that ESI was in violation of the ERISA Claims Regulations under 29 C.F.R. § 250.503-1 and the Affordable Care Act by not affording plan beneficiaries a means to access compounded drugs.

**ISSUES:**

1. Do the Compounders have standing to sue under ERISA as assignees of beneficiaries?
2. Do the Compounders have standing to sue under ERISA on their own behalf?
3. Are the pharmacies entitled to injunctive relief declaring ESI must pay all compounded drug claims until it complies with the Claims Regulations?
FACTS AND PROCEDURAL HISTORY: The Compounders had executed provider agreements with ESI. In June 2014, ESI announced it would be reducing costs of compounded drugs to health plans and began denying claims for compounded drugs in July. ESI fully implemented the program by the end of the year. The Compounders asserted claims under two of ERISA’s remedial sections. 29 U.S.C. § 1132(a)(1)(B) (ERISA § 502(a)(1)(B)) provides “a participant or beneficiary” may sue “to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan.” Under § 29 U.S.C. § 1132(a)(3) (ERISA § 502(a)(3)) “a participant, beneficiary, or fiduciary” may sue “(A) to enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief” to redress violations or enforce the provisions of ERISA or the terms of the plan.

The substantive relief that the Compounders sought was: (i) a declaration ESI must pay compounded drug claims until in compliance with the Claims Regulation; (ii) require ESI to issue compliant explanation of benefits forms; and (iii) a declaration requiring ESI to provide a procedure for beneficiaries to request access to compounded drugs as required by the Affordable Care Act 42 U.S.C. § 300gg-6. The district court denied the relief sought.

REASONING: The Eighth Circuit explained that ERISA requires every benefit plan to: (i) provide adequate written notice of benefit denial to beneficiaries with the specific reason for denial and (ii) afford a full and fair review for any participant whose claim had been denied. 29 U.S.C. § 1133. The Claims Regulations provide that if a plan fails to establish or follow claims procedures, a claimant will be deemed to have exhausted administrative remedies under the plan. The claimant can then seek judicial relief as permitted by Section 29 U.S.C. § 1132(a) on the basis “the plan failed to provide reasonable claims procedure that would yield a decision on the merits of the claim.” (emphasis in original quote).

Claims under 502(a)(1)(B) and 502(a)(3) as assignees: The court explained the Compounders had standing to sue under § 502(a)(1)(B) for a legal remedy for wrongful denial of benefits based on assignment of benefits from plan participants. However, the proper judicial remedy for a plan participant under 29 U.S.C. § 1133 and for the Claims Regulation is not to award the benefits sought. Instead, a court would “remand [the dispute] to the plan administrator so the claimant gets the benefit of a full and fair review.” The Compounders likewise had standing under 502(a)(3) for equitable relief, but such relief would not have been proper given an adequate legal remedy under 502(a)(1)(B). The Eighth Circuit agreed with the district court’s decision to deny the injunction and explained it would have been an error for the district court to have granted an injunction requiring ESI to pay for compounded drugs as a benefit.

Claims under 502(a)(1) or (3) on behalf of the pharmacies themselves: The court rejected the Compounders argument that they have standing under 502(a)(1) or (3) to sue based on their own assertions that they were “plan-designated beneficiaries” in light of the summary plan descriptions detailing how ESI will implement the pharmacy benefit program. ERISA defines “beneficiary” as “a person designated by a [plan] participant, or by the terms of an employee benefit plan, who is or may become entitled to a benefit thereunder.” 29 U.S.C. § 1002(8). The Compounders’ “right to payment [directly from ESI] does not a beneficiary make.” The pharmacies had no standing in their own right under these sections because they were not beneficiaries.

HOLDINGS: The Eighth Circuit affirmed the district court’s denial of injunctive relief and held:

1. Compounders had standing to sue as assignees under ERISA §§ 502 (a)(1)(B) and 502 (a)(3).
2. Compounders had no standing under ERISA §§ 502(a)(1) or (3) because they were not beneficiaries under ERISA.
3. Compounders were not entitled to injunctive relieve under ERISA § 502(a)(3) because there was an adequate legal remedy under § 502(a)(3) for violation of the Claim Regulations.
B. Breach of Contract—Termination from Network


RELIEF SOUGHT: Prime Aid Pharmacy sued Express Scripts on seven grounds, and Express Scripts (“ESI”), sought to dismiss the following three: (1) fraudulent misrepresentation, (2) violation of the Missouri Prompt Pay Act, and (3) equitable accounting.

ISSUES:
1. Did Prime Aid provide enough details in its complaint to satisfy the specificity requirement so it could survive a motion to dismiss?
2. Did Prime Aid adequately state a claim for relief under Missouri’s Prompt Pay Act?
3. Did Prime Aid show that ESI had a fiduciary relationship such that Prime Aid was entitled to an equitable accounting?

FACTS AND PROCEDURAL HISTORY: Prime Aid operated as a licensed pharmacy in New Jersey since 2006 and entered into a “Provider Agreement” with ESI in 2011. During an audit, ESI issued a discrepancy report on July 31, 2014 that showed Prime Aid “submitted reimbursement claims for more syringe kits than it had received from its supplier resulting in $142,845.72 in overpayments.” On August 8, 2014, ESI notified Prime Aid that it would be terminated from the provider network on August 22, 2014. Prime Aid challenged the immediate termination claiming it violated New Jersey law and Prime Aid “demanded a hearing and a stay of termination for 90 days.” In addition, Prime Aid demanded to be paid “over $8 million in funds due and owing to” Prime Aid. ESI denied the request and stated that it did not owe Prime Aid any additional funds. This forced Prime Aid to lay off pharmacists, nurses, and a salesperson. But, on December 21, 2015, ESI forwarded Prime Aid a check for $845,002 for claims dating back to 2013. This check was accompanied with a letter that stated ESI continued to withhold $968,233.56 and refused to forward it to Prime Aid. Prime Aid sued ESI alleging the following claims:

- fraudulent misrepresentation (Count I);
- breach of contract (Count II);
- breach of covenant of good faith and fair dealing (Count III);
- violation of the Missouri Prompt Pay Act (Count IV);
- unjust enrichment (Count V);
- promissory estoppel (Count VI);
- and equitable accounting (Count VII).

Plaintiff seeks an award of compensatory damages and punitive damages.

ESI moved to dismiss Counts I, IV, and VII.

REASONING:

Fraudulent Misrepresentation. Prime Aid claimed that ESI “fraudulently misrepresented that it was not withholding any additional monies that belonged to plaintiff” and that “[i]n reliance on the misrepresentation, plaintiff laid off several employees.” Prime Aid needed to show that ESI made a knowing false representation of material fact and that Prime Aid acted upon those facts to its detriment. Prime Aid pled that “the process of submitting claims to and receiving payment from defendant is complex, and that as a result of the complexity and the volume of claims, plaintiff is unable to ascertain what amounts and claims are outstanding, what claims [defendant] is refusing to pay and/or what amounts and claims [defendant] has paid.” Along with the letter stating that ESI continued to withhold $968,233.56, the court found that Prime Aid met its burden to state a claim of fraudulent misrepresentation.

Missouri’s Prompt Pay Act. Prime Aid also alleged that ESI failed to “timely and properly pay, dispute or deny 104 claims that it submitted in violation of the Missouri Prompt Pay Act.” The Act requires:
“health carriers to notify a ‘claimant’ within 30 days whether a claim (1) is a ‘clean claim’ that does not require additional information before processing—in which case the carrier must pay or deny the claim—or (2) requires additional information.” ESI challenged this allegation, arguing that the Act “is not available to an out-of-state health care professional claiming reimbursement for services to non-Missouri residents” because it requires the health care provider to be “licensed, accredited, or certified by the state of Missouri.” The court was not persuaded by ESI’s argument because Prime Aid was licensed as a pharmacy in Missouri. Thus the Act applies, and Prime Aid sufficiently stated a claim for relief under the Act.

**Equitable Accounting.** Finally, Prime Aid’s claim for equitable accounting required Prime Aid to plead “(1) a need for discovery; (2) the nature of the accounts is complicated; (3) a fiduciary duty existed between the parties; and (4) plaintiff lacks an adequate remedy at law.” Missouri law does not provide, “a specific list of factors which must be present in order to determine that a fiduciary relationship exists[,]” but the Missouri courts have established five factors that help establish whether a fiduciary relationship exists:

1. one party must be subservient to the dominant mind and will of the other party as a result of age, state of health, illiteracy, mental disability, or ignorance;  
2. things of value such as land, monies, a business, or other things of value, which are the property of the subservient party, must be possessed or managed by the dominant party;  
3. there must be a surrender of independence by the subservient party to the dominant party;  
4. there must be an automatic and habitual manipulation of the actions of the subservient party by the dominant party; and  
5. there must be a showing that the subservient party places a trust and confidence in the dominant party.

Prime Aid supported the claim that a fiduciary relationship existed between Prime Aid and ESI by providing the complex nature of the “Provider Agreement” and the fact that Prime Aid had “submitted thousands of claims to defendant, of which some have been paid and some have been denied on pretextual grounds.” The court found that the complexity of the ESI claims process—which allows ESI to retain sole discretion as to whether to approve or deny a claim, as well as sole possession of records regarding amounts paid and withheld on claims—that Prime Aid sufficiently stated a claim for equitable accounting.

**HOLDING:** The court denied ESI’s motion to dismiss on all three challenged causes of action.

1. Prime Aid’s allegations regarding the complexity of ESI’s claims process, the volume of claims, and an ESI letter saying it would withhold nearly $1 million in claims provide enough details to state a claim for fraudulent misrepresentation

2. The Missouri Prompt Pay Act applied to Prime Aid even though it was an out-of-state pharmacy because Prime Aid was licensed in Missouri.

3. The complexity of ESI’s claims process and its control over information justified fining it had a fiduciary relationship with Prime Aid, which supported a claims for equitable accounting.

**C. PBM—Exclusion from Network**


**RELIEF SOUGHT:** Defendant moved to dismiss six counts the Freedom Pharmacy filed because defendant had terminated the pharmacy from defendant’s network.
ISSUES:
1. Did Freedom Pharmacy state a viable claim that Express Scripts’ termination of the pharmacy network agreement violated the covenant of good faith and fair dealing?
2. Did Freedom Pharmacy state a viable claim that Express Scripts’ termination of the pharmacy network agreement constituted unjust enrichment even though there was a written contract between the parties?
3. Did Freedom Pharmacy state a viable claim that Express Scripts’ termination of the pharmacy network agreement tortuously interfered with the relationship between the pharmacy and its patients?
4. Should Freedom Pharmacy’s claim for injunctive relief be dismissed?

FACTS AND PROCEDURAL HISTORY: On June 13, 2016, ESI terminate the provider agreement with Freedom Pharmacy because ESI claimed the pharmacy was a mail order pharmacy and was not properly licensed in some states where it was mailing prescriptions, which ESI asserted was a breach of the provider agreement. The termination was effective July 18, 2016 and ESI informed the pharmacy’s patients of the termination on July 8, 2016. Freedom Pharmacy sued ESI under various contract causes of action, for tortious interference with the pharmacy’s relationship with patients and with patients’ choice of pharmacy, for declaratory judgment asking the court to declare the parties’ rights under the agreement, and for an injunction against ESI.

REASONING:

Covenant of good faith and fair dealing. The court explained that all Missouri contracts contain an implied covenant of good faith and fair dealing. When a contract leaves a decision to a party, the party will violate the covenant if it makes the decision in bad faith or was arbitrary and capricious so as to abuse the discretion it has to make the decision. The pharmacy alleged ESI terminated the contract to engage in “anticompetitive and other unlawful behavior;” took steps to divert the pharmacy’s patients to ESI’s mail-order pharmacy, which was more economically adventitious to ESI; and failed to comply with the agreement’s notice and opportunity to cure requirements. Therefore, because the court must accept allegations as true for purposes of a motion to dismiss, the pharmacy stated claim that ESI violated the covenant of good faith and fair dealing.

Unjust Enrichment. Unjust enrichment is an equitable remedy that cannot be recovered under a contract. Plaintiff must prove: (i) defendant was enriched by receipt of a benefit; (ii) at the expense of plaintiff; and (iii) it would be unjust to let defendant keep the benefit. Here, the claimed defendant has unjustly diverted patients for its own benefit, which falls outside the contract.

Tortious Interference. Pharmacy asserted two tortious interference claims based on ESI’s interference with: (i) “its business relationships with its patient base” and (ii) “patient choice to obtain prescriptions for any source or medium.” To prove its case, the pharmacy must prove: (i) contract or valid business relationship; (ii) defendant’s knowledge of same; (iii) defendant’s intentional interference with relationship; (iv) no justification; (v) damages from the conduct. Pharmacy did not have a valid business interest in patients’ right to choose, therefore that basis is insufficient for a tortious interference claim. Pharmacy had a legitimate business relationship with its patients and alleged ESI wrongfully terminated without cause and failed to comply with the notice obligations under the contract. These actions could be construed as improper means of interference and the pharmacy’s claim survives.
**Declaratory Judgment.** Declaratory relief cannot be duplicative of another claim, such as breach of contract. But, because pharmacy’s request for the court to declare the parties’ rights and obligations is different than its breach of contract claim, the separate claim for declaratory relief survives.

**Injunctive Relief.** Because injunctive relief is a remedy for an underlying claim, it cannot stand alone as a separate cause of action.

**HOLDING:**

1. Court refused to dismiss Freedom Pharmacy’s claim for breach of the covenant of good faith and fair dealing.
2. Court denied the motion to dismiss unjust enrichment because the pharmacy did not rely on the contract as a basis for its unjust enrichment claim.
3. The court dismissed Freedom Pharmacy’s claim for tortious interference based on ESI’s alleged interference with patients’ right to choose their pharmacy, but the court denied the motion to dismiss tortious interference with Freedom Pharmacy’s business relationship with patients.
4. The court did not dismiss the declaratory judgment claim, but dismissed the claim for injunctive relief as a separate claim.

**XII. PRIVACY**

A. Disclosure of PDMP Records to DEA

1. *United States Dep’t of Justice, Drug Enforcement Administration v. Utah Department of Commerce and Utah Division of Occupational and Professional Licensing (“DOPL”), 2:16-cv-00611 (D. Utah June 14, 2016)*

**RELIEF SOUGHT:** DEA filed a petition to enforce an administrative subpoena for records from the Utah Controlled Substances Database (“Utah PMP”).

**ISSUE:** Does the DEA have the authority to obtain records from the Utah PMP with an administrative warrant under the requirements of Utah law and the Fourth Amendment to the U.S. Constitution?

**FACTS AND PROCEDURAL HISTORY:** The DEA issued an administrative subpoena for records from the Utah PMP to support an investigation of an individual prescriber registered to dispense controlled substances. The State refused to comply with the administrative subpoena because the Utah Controlled Substances Database Act and the Fourth Amendment to the U.S. Constitution require a search warrant issued by a magistrate based on probable cause.

The State argued that the Utah PMP statute provided limited exceptions to disclosure of records, including a patient’s prescriber and pharmacist, third party payors, and “Federal, state, and local law enforcement authorities, including state and local prosecutors, who have obtained a valid warrant regarding an individual suspected of an offense related to controlled substances.” (Emphasis in Memorandum, quoting Utah Code Ann. § 58-37f-301.) According to the State’s motion in opposition to the DEA’s petition, the Utah Legislature added the search warrant requirement “to more strictly limit access to the Database in recognition of Utah residents’ privacy interest in their prescription records and in response to incidents of law enforcement accessing records on the Database without judicial oversight.” The Utah PMP law makes it a 3rd degree felony to “improperly accesses or knowingly or intentionally releases Database information in violation of the Utah Controlled Substances Act.” Because the DEA did not present a valid search warrant, the Executive Director of the Dept. of Commerce, the Director of DOPL, and the Utah PMP manager would all be criminally liable if they provided the requested records. The State cited *Oregon Prescription Drug Monitoring Program v. U.S. Drug Enforcement Administration*, 998 F.Supp.2d 957
(D.Or. 2014) in which the federal court in Oregon refused to allow the DEA to obtain PMP records without a search warrant. That court concluded, “intervenors’ [patients] subjective expectation of privacy in their prescription information is objectively reasonable.” Accordingly, “the DEA’s use of administrative subpoenas to obtain prescription records from the PDMP violates the Fourth Amendment.

STATUS: On November 7, 2016, the court granted the ACLU’s motion to intervene. The parties continue to litigate.

B. Disclosure of PDMP Records in Litigation


RELIEF SOUGHT: Defendant (employer) in a sexual discrimination and harassment suit filed motion to compel production of employee’s prescription records from the Kansas Board of Pharmacy.

ISSUE: Is a plaintiff in a sexual discrimination case permitted to receive copies of his or her own prescription record from the Kansas Board of Pharmacy?

FACTS AND PROCEDURAL HISTORY: Martha Fox (employee) filed a sexual discrimination, harassment and retaliation action against her employer. Fox claimed her supervisor sexually harassed her, and once the action was reported her employer failed to discipline the supervisor. Fox claimed damages for include emotional distress (including stress, anxiety, depression, loss of sleep, and embarrassment). As to the specific discovery requests at issue, the employer requested all records of prescription medications filled by plaintiff as available through the Kansas Board of Pharmacy. The employer expressed concern that the records it had been able to compile leave a gap in which Fox did not fill a prescription.

The Federal Rules of Civil Procedure provide that the requested information must be both non-privileged and relevant to be discoverable. Plaintiff stated that she did not have possession, custody, or control of the documents at issue. Further, plaintiff contended that she requested the records from the Kansas Board of Pharmacy, but was informed that Kansas law prohibits disclosures of those records in civil proceedings. Specifically, the Board informed plaintiff:

K.S.A. 65-1685 provides, in part, that the PMP records shall be privileged and confidential, shall not be the subject to subpoena or discovery in civil proceedings and may only be used for investigatory or evidentiary purposes related to violations of state or federal law and regulatory activities charged with administrative oversight of those persons engaged in the prescribing or dispensing of scheduled substances and drugs of concern.

REASONING: Here, the employer expressed concern about a gap in which Fox did not fill a prescription, and this gap in records could only indicate that: (1) either Fox actually did not fill the prescription for almost a full year; or (2) other pharmaceutical records exist that would show that she was filling the prescription. Although the court agreed that the information is relevant given Fox’s claimed damages, the position of the Kansas Board does not provide Fox with access to the records at issue.

HOLDING: The court denied the motion to compel the prescription records from the Kansas Board of Pharmacy because the statute governing the PDMP prohibited disclosure of records pursuant to “subpoena or discovery in civil proceedings.”
C. Telephone Consumer Protection Act (“TCPA”)—Robocalls


RELIEF SOUGHT: Pharmacy sought to dismiss a TCPA lawsuit for excessive phone calls regarding prescription refills because the automated calls about prescription refills were subject to the “emergency purposes” exemption.

ISSUE: Are automated calls about prescription refills exempted from the TCPA under the “emergency purposes” exemption?

FACTS AND PROCEDURAL HISTORY: The plaintiff, St. Claire, sued CVS pharmacy for violation of the TCPA when he received excessive phone calls reminding him about his prescriptions after asking to be removed from the calling list. CVS claimed that they were not liable under the TCPA because the phone calls about prescriptions fell under the “emergency purposes” exemption.

REASONING: Under 47 U.S.C. § 227(b)(1) there are two exemptions to the TCPA: automated phone calls made for (i) emergency purposes or (ii) with prior express consent. CVS tried to argue that the Federal Communications Commission’s definition of “emergency”, “calls made necessary in any situation affecting the health and safety of consumers”, applied. The court disagreed, because cases surrounding “emergency purposes” related to service outages, such as long-term outages of water, gas, or electricity, which could pose a risk to public health. Other emergency purposes found in FCC cases were related to school calling lists, which are automated calls sent to parents and guardians regarding dangerous persons, fires, threats, or other health risks. The court also explained that the Ninth Circuit instructed courts to “take a common sense approach to TCPA liability.” The court found that it “defies common sense” to allow immunity from liability when the individual asked to be removed from the automated calls related to prescriptions, which do not pose a public health risk.

HOLDING: The court found that calls made for prescription refills, made an excessive number of times, especially after the individual requested to be taken off the calling list, did not fall under the “emergency purposes” definition under the TCPA or the FCC. The motion to dismiss was denied.


RELIEF SOUGHT: Jackson sued Safeway for violating the TCPA when she received prerecorded telephone messages promoting Safeway’s flu shots.

ISSUES:
1. Do the flu shot calls fall within the FCC’s 2015 safe harbor (the Exigent Healthcare Treatment Exemption)?

2. Do the flu shot calls fall within the exemption for healthcare messages under 47 C.F.R. § 64.1200(a)(2)?

FACTS AND PROCEDURAL HISTORY: The plaintiff brought a putative class action against Safeway alleging that the prerecorded telephone messages promoting Safeway’s flu shots violated the TCPA. The plaintiff received the telephone messages after completing a Consent and Release form that she was provided after receiving a flu shot from a Safeway pharmacy. On the Consent and Release form, the plaintiff provided her wireless phone number.

Around nine months later, in September 2014, Safeway entered into an agreement with MarkeTouch Media, Inc., “for purposes of contacting Safeway’s existing pharmacy patients through the use of prerecorded telephone calls to remind them to get a flu shot for the new flu season.” In order for the pharmacy patients to receive the calls the patients needed to satisfy three criteria:
(1) the patient was an existing Safeway patient who previously provided her telephone number to Safeway; (2) Safeway believed that the patient had received a flu shot at one of its pharmacies during the immediately preceding year’s flu season; and (3) Safeway’s records indicated that the patient had not yet received a flu shot during the current flu season.

Safeway provided records that indicated the plaintiff satisfied all three criteria. In November 2014, plaintiff received the prerecorded phone call and then visited a Safeway pharmacy the following day to receive a flu shot. The plaintiff received a second prerecorded flu shot reminder in January of 2015. The plaintiff sued Safeway in September 2015 for violating the TCPA.

**REASONING:**

**Exigent Healthcare Treatment Exemption.** Congress provided the FCC with the authority to regulate telemarketing. The FCC issued regulations that prohibited “calls made by automated telephone dialing systems and artificial prerecorded voice messages unless there was an emergency or the called party provided her prior express consent.” The FCC created a safe harbor in 2015, the Exigent Healthcare Treatment Exemption, that allowed “exigent” calls to wireless numbers that “have a ‘healthcare treatment purpose’ and ‘are not charged to the called party.’” These calls include:

- appointment and exam confirmations and reminders, wellness checkups,
- hospital pre-registration instructions, pre-operative instructions, lab results,
- post-discharge follow-up intended to prevent readmission, prescription notifications, and home healthcare instructions.

The court found that there was no “genuine dispute that the flu shot reminder calls, i.e., immunization reminders, [were] not telemarketing solicitations or advertising calls.” It was undisputed that the plaintiff provided her wireless phone number when she signed the Consent and Release form in 2014 when she received her flu shot at a Safeway pharmacy. It was also undisputed that the plaintiff was not charged for the phone message because she had an “unlimited talk, text, and data” plan with her phone company.

**Health Care Exemption.** The court also found that the Telemarketing Health Care Exception under 47 C.F.R. § 64.1200(a)(2) applied because the calls constituted “a call that deliver[ed] a ‘health care’ message made by, or on behalf of, a ‘covered entity’ or its ‘business associate’” which did not constitute telemarketing. Flu shots are “health care services that relate to the health of an individual.”

**HOLDINGS:** The court granted Safeway’s motion for summary judgment and Safeway was not liable for the prerecorded telephone messages promoting Safeway’s flu shots because

1. The flu shot calls fall within the FCC’s 2015 safe harbor (the Exigent Healthcare Treatment Exemption) because the patient provided her number and the calls were for healthcare treatment purposes and not for telemarketing.

2. The flu shot calls fall within the exemption for health care messages under 47 C.F.R. § 64.1200(a)(2) because the calls were made by a covered entity or business associate.
XIII. PRODUCT LIABILITY

   A. Former Brand Name Manufacture’s Liability for Subsequent Generic Company


RELIEF SOUGHT: Minors who claimed they were injured while in utero through their mothers’ use of generic asthma medication brought action against former manufacturer of brand name medication alleging negligence and negligent misrepresentation.

ISSUE: Could Novartis, a former manufacturer of a brand name asthma medication, be liable in negligence for injuries sustained in utero through a ‘mother’s use of a generic form of the medication?

FACTS AND PROCEDURAL HISTORY: In the 1970s, Novartis obtained a license to manufacture and market terbutaline (for use as a bronchodilator), and it owned the NDA for this brand name drug (Brethine) until 2001. Drug manufacturers allegedly perceived an opportunity to market terbutaline as a tocolytic to inhibit preterm labor. The original manufacturer promoted terbutaline as a tocolytic and its use for this purpose gained wide acceptance. However, neither the original manufacturer nor any of its successors or licensees sought FDA approval for this use.

In 1978, studies began to question the safety and efficacy of using terbutaline as a tocolytic, noting that the labor inhibitors are potentially dangerous. One study reported that terbutaline can injure the developing brain, and children exposed to tocolytic had higher rates of psychiatric disorders. In 1993, the FDA invited terbutaline manufacturers to submit applications for approval of tocolytic use and to review their labeling to clarify the uses and risks of the drug. The manufacturers allegedly decided not to voluntarily seek FDA review for tocolytic use.

Novartis divested its interest in the NDA in 2001. Another pharmaceutical company became the NDA holder for Brethine thereafter.

In 2007, a pregnant woman was prescribed terbutaline to inhibit preterm labor. She was given a generic version of terbutaline and continued to take the medication until her children (twins) were born. In 2012, the twins were diagnosed with autism. The minors sued Novartis asserting causes of action against Novartis for negligence, intentional misrepresentation, concealment, and negligent misrepresentation.

Novartis filed a demurrer, arguing that it had no duty to the minors because it did not manufacture the generic form the mother took and was not responsible for the warning label for generic versions as it sold the rights to the drug six years before the alleged injury. The trial court sustained the demurrer concluding that Novartis owed no duty as a matter of law for claims arising from the prescribing of terbutaline in 2007.

On appeal, the court determined whether Novartis can be held liable under a negligent failure to warn theory to minors allegedly injured as a result of their ‘mother’s ingestion of generic terbutaline for tocolysis years after Novartis divested itself of the NDA for Brethine. The minors claim that Novartis had sufficient information before it divested the NDA in 2001 to revise the drug label and package insert to include warnings of potential fetal harm. Essentially, if Novartis had provided such warnings when it owned the NDA, it is probable that the warnings would have remained in effect until 2007.

REASONING: The court concluded that, although Novartis did not own the NDA in 2007, it did own the NDA until 2001 and was responsible for the label information prior to that time. Its formulation of the product was biologically identical to the generic and the label was allegedly the same in 2007 as it was in 2001. If the minors can prove Novartis failed to adequately warn about fetal risks it knew or should have
known were associated with tocolytic use before it divested the product in 2001, they may be able to establish "Novartis’s conduct bore some direct relationship to the alleged harm.

The court applied common law principles of duty and foreseeability to conclude a brand name pharmaceutical manufacturer should “shoulder its share of responsibility for injuries caused, at least in part by its negligent…dissemination of inaccurate information” even though the patient consumed a generic version of the medication manufactured by another company.

**HOLDING:** The minors demonstrated they can amend their complaint to state a claim under California law for negligent failure to warn and negligent misrepresentation based on acts or omission by Novartis prior to 2001, which allegedly caused the minors' injuries in 2007. Therefore, the court reversed and remanded with directions with leave to amend the negligence and negligent misrepresentation causes of action.

**XIV. TORTS**

A. False Arrest--Expert Witness Affidavit


**RELIEF SOUGHT:** Plaintiff seeks reversal of trial court’s grant of a motion to dismiss her claim of negligence against her former doctor and his practice after she was arrested for altering a controlled substances prescription her doctor had actually altered.

**ISSUE:** Does plaintiff’s claim against her doctor and his practice sound in simple negligence or professional malpractice?

**FACTS AND PROCEDURAL HISTORY:** Plaintiff Tami Carter appeals the dismissal of her complaint against Dr. William Cornwell for negligence after she was arrested for altering a prescription to illegally obtain a controlled substance. Carter argued that the trial court had erred by granting Cornwell’s motion to dismiss because her claims were based in negligence, rather than professional malpractice. Thus, she argued, an expert affidavit was not required.

Cornwell had been Carter’s physician since 1998, treating her for chronic pain. In August 2014, Cornwell wrote Carter a prescription of 120 pills of hydrocodone. Before Carter left his office, Cornwell decided to change the quantity of pills on the prescription from 120 to 180, and altered the original prescription to reflect the change. Carter took the prescription to her local pharmacy. There, a pharmacy employee grew suspicious after noticing the alteration. The pharmacy employee called Cornwell’s practice and spoke with his partner and on-call physician. The physician was not aware that Cornwell had altered the prescription and did not attempt to contact Cornwell to verify that he had done so. When Carter arrived at the pharmacy the next day to pick up her prescription, she was arrested for altering a prescription to illegally obtain a controlled substance. She sued Cornwell and his practice for basic negligence and did not file an expert affidavit. Cornwell and his practice moved to dismiss and the trial court granted the motion, finding that claims sounded in professional malpractice and Carter had failed to file an expert affidavit. Carter appealed. The Court of Appeals affirmed in part and reversed in part.

**REASONING:** First, the Court of Appeals concluded that the claim Dr. Cornwell was negligent in altering the prescription from 120 to 180 pills sounded in professional negligence rather than ordinary negligence. The court reasoned, “[w]riting a prescription for a controlled substance is a decision which normally requires the evaluation of the medical condition of a particular patient and, therefore, the application of professional knowledge, skill, and experience.” *Carter v. Cornwell, 791 S.E.2d 447, 450 (2016) (quoting Dent. V. Mem. Hosp. of Adel, 509 S.E. 2d 908 (Ga. 1998). Therefore, an expert affidavit was required to proceed on Carter’s claim against Cornwell.
In contrast, for Carter’s claim against the practice, the court found that the practice’s on-call physician’s failure to make any attempt to contact Dr. Cornwell to verify whether he changed the prescription did not require the exercise of professional judgment or skill, and an expert affidavit was not required to proceed on an ordinary negligence claim against the practice. The court reasoned, “[N]ot every suit which calls into question the conduct of one who happens to be a medical professional is a medical malpractice action. We must look to the substance of an action against a medical professional in determining whether the action is one for professional or simple negligence.” *Id. (quoting Atl. Women’s Health Grp. v. Clemons, 651 S.E.2d 762 (Ga. App. 2007)).*

**HOLDING:** Carter’s claim against the physician’s practice for “failing to exercise ordinary care in handling on-call responsibilities for its patients” was for simple negligence, not professional malpractice. Thus, no expert affidavit was required. Carter’s claim against Cornwell, however, was grounded in professional malpractice. Thus, an expert affidavit was required.

XV. **SETTLEMENTS**

A. **Obstructing Medicare Audit**


**RELIEF SOUGHT:** U.S. Attorney for N.D. Alabama filed an Information against Logan, based on allegations that there was falsification of documents in an effort to defraud Medicare.

**FACTS AND PROCEDURAL HISTORY:** The U.S. attorney filed an Information and plea agreement concurrently. According to the Information, the pharmacies compounded prescriptions using bulk pharmaceutical substances, mostly pain creams, for Medicare Part D patients despite the fact that after February 1, 2009 Medicare Part D did not reimburse for such compounded prescriptions. In 2012, CVS/Caremark conducted audits of some compounded prescriptions and requested documents that identified ingredients used for the prescriptions. Allegedly, Logan provided documents indicating that manufacturers’ tablets and capsules had been dispensed rather than bulk ingredients compounded into a finished product. The Information charged Logan with one count of obstructing a federal audit under 18 U.S.C. § 1516.

**PELA AGREEMENT TERMS:** Defendant pled guilty and agreed to pay a fine of $2,499,000. Defendant also agreed that the maximum penalty could have been: (i) up to five years imprisonment and (ii) a fine of $250,000 or twice the pecuniary gain or loss under 18 U.S.C. § 3571(d) whichever is greater, which defendant acknowledged was more than $2,499,000. The DOJ agreed to recommend an appropriate reduction in sentencing based on defendant’s acceptance of responsibility and that the sentence be on the lower end of the range of imprisonment, probably about 12 months, based on 12-18 month range for level 13 adjusted offense level.

B. **Controlled Substances—Wholesalers’ Obligations to Report**

1. **McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs**

Excerpt from *Department of Justice Announcement* (Jan. 17, 2017):

McKesson Corporation (McKesson), one of the nation’s largest distributors of pharmaceutical drugs, agreed to pay a record $150 million civil penalty

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for alleged violations of the Controlled Substances Act (CSA), the Justice Department announced today.

The nationwide settlement requires McKesson to suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan and Florida for multiple years. The staged suspensions are among the most severe sanctions ever agreed to by a Drug Enforcement Administration (DEA) registered distributor. The settlement also imposes new and enhanced compliance obligations on McKesson’s distribution system.

In 2008, McKesson agreed to a $13.25 million civil penalty and administrative agreement for similar violations. In this case, the government alleged again that McKesson failed to design and implement an effective system to detect and report “suspicious orders” for controlled substances distributed to its independent and small chain pharmacy customers – i.e., orders that are unusual in their frequency, size, or other patterns. From 2008 until 2013, McKesson supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills . . .


Excerpt from Department of Justice Announcement (Jan. 17, 2017)²:

Cardinal Health has agreed to pay $34 million in civil penalties to resolve allegations that the Lakeland, Florida-based distributor failed to report to the DEA suspicious orders of Class II controlled substances by pharmacies located in central Florida and Maryland. The settlement also resolves a civil investigation in the Western District of Washington into Cardinal Health’s failure to maintain adequate records concerning Class II controlled substances in that district.

Separately, the United States Attorney for the Southern District of New York announced that Cardinal Health has agreed to pay an additional $10 million to resolve allegations that its subsidiary, Kinray, Inc., failed to report suspicious orders by pharmacies operating in the Kinray service area.

The settlement announced today imposes a civil monetary sanction for the conduct addressed in Cardinal Health’s administrative settlement executed with the DEA in 2012, which suspended Cardinal’s registration to distribute Class II narcotic medications for a period of two years. The DEA returned Cardinal’s registration in May 2014 while the civil penalty negotiations that led to today’s announcement were pending.

² [https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0]
C. Controlled Substances—Lax Controls

1. Costco Wholesale to Pay $11.75 Million to Settle Allegations of Lax Pharmacy Controls

Excerpt from Department of Justice Announcement (Jan. 19, 2017)3:

Costco Wholesale will pay $11.75 million to settle allegations that its pharmacies violated the Controlled Substances Act when they improperly filled prescriptions for controlled substances. The settlement resolves allegations that Costco pharmacies filled prescriptions that were incomplete, lacked valid Drug Enforcement Administration (DEA) numbers, or were for substances beyond various doctors’ scope of practice. Additionally, the settlement resolves allegations that Costco failed to keep and maintain accurate records for controlled substances at its pharmacies and centralized fill locations . . . .

Under the settlement reached Jan. 18, 2017, Costco acknowledges that between Jan. 1, 2012 and Dec. 31, 2015, certain Costco Pharmacies dispensed controlled substances inconsistent with their compliance obligations under the Controlled Substances Act (CSA) and its implementing regulations. The violations include: filling prescriptions from practitioners who did not have a valid DEA number; incorrectly recording the practitioner’s DEA number; filling prescriptions outside the scope of a practitioner’s DEA registration; filling prescriptions that did not contain all the required information; failing to maintain accurate dispensing records; and failing to maintain records for their central fill locations in Sacramento, California, and Everett, Washington . . . .

“These are not just administrative or paperwork violations – Costco’s failure to have proper controls in place in its pharmacies played a role in prescription drugs reaching the black market,” said U.S. Attorney Decker.

To address issues uncovered in this investigation, Costco made improvements in its pharmacies. The company purchased a new pharmacy management system at a total budgeted five-year cost of approximately $127 million. Additionally, Costco implemented a three tier audit program of its pharmacy locations: Tier 1 done by pharmacy managers and regional pharmacy supervisors; Tier 2 completed by an Internal Audit group consisting of three auditors and an audit supervisor; and Tier 3 an External Audit of 40 annual audits.

D. Controlled Substances—Forged Prescriptions

1. CVS Settles for $3.5 Million over Allegations of Filling Forged Prescriptions

Excerpt from Department of Justice Announcement (June 30, 2016)4:

CVS Pharmacy, Inc. has agreed to pay $3.5 million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged

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prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014. In addition, CVS has entered into a three-year compliance agreement with the Drug Enforcement Administration (DEA) that requires CVS to maintain and enhance programs it has developed in recent years for detecting and preventing diversion of controlled substances.

“Pharmacies have a legal responsibility to ensure that controlled substances are dispensed only pursuant to valid prescriptions,” said United States Attorney Carmen M. Ortiz. “When pharmacies ignore red flags that a prescription is fraudulent, they miss a critical opportunity to prevent prescription drugs from entering the stream of illegal opiates on the black market. . . .”

This settlement resolves two investigations of CVS stores initiated by the DEA after it received an increased number of calls reporting forged oxycodone prescriptions. In the first investigation, the DEA identified forged prescriptions filled 403 times at 40 CVS stores in Massachusetts and New Hampshire. In the second investigation, the DEA identified 120 forged prescriptions filled at 10 CVS stores in and around Boston. The DEA estimated the street value of the diverted pills to be over $1 million. . . .

The forged prescriptions traced back to just a few individuals. One of the forgers, P.R., signed a dentist’s name on 56 of 59 oxycodone prescriptions that P.R. was then able to be filled at five CVS locations. CVS pharmacists filled these prescriptions even though CVS banned P.R. in 2011 and its computer system contained notes warning that P.R. had tried to fill forged prescriptions in the past. P.R. managed to circumvent the ban by opening a new patient profile using her own Arizona driver’s license number but with a different last name. . . . the government alleged, even if CVS had believed the prescriptions to be real, there were red flags that P.R. was “doctor shopping,” including the fact that P.R. presented oxycodone prescriptions from two different providers during a single week at one CVS store. [Click on press release link above for more details of the different forgers.]

E. Controlled Substance—Hospital Self-Disclosed Discrepancies

1. Abington Memorial Hospital to Pay $510,000 to Resolve Drug Diversion Allegations

Excerpt from Department of Justice Announcement (Jan. 9, 2017)

Abington Memorial Hospital (AMH) has agreed to pay the United States $510,000 to resolve allegations that failures in AMH’s controls and practices enabled its employee to divert controlled substances for illegal, non-medical uses. In addition to this monetary settlement, AMH has implemented a program to prevent, identify, and address future diversions.

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In 2013, an investigation was launched after AMH disclosed to the Drug Enforcement Administration (DEA) that a pharmacist at AMH’s inpatient pharmacy had stolen large volumes of controlled substances (prescription medications) from the hospital. Altogether, over the course of at least 85 different occasions between February 1, 2010 and August 20, 2013, the pharmacist stole more than 35,000 pills, including highly addictive painkillers such as oxycodone. DEA’s ensuing audit of AMH’s controlled substances revealed pill count discrepancies totaling over 35,000, missing or incomplete medication inventories, and altered or missing drug records, all in violation of AMH’s responsibilities under the Controlled Substances Act and federal regulations.

In 2015, the AMH pharmacist . . . pleaded guilty to 25 counts of possession with the intent to distribute oxycodone and was sentenced to six years of imprisonment and three years of supervised release.

AMH has worked cooperatively with the DEA and the U.S. Attorney’s Office to address the identified deficiencies in AMH’s handling of controlled substances.

Acting U.S. Attorney Lappen [stated:]. “. . . We commend Abington Memorial Hospital for disclosing its diversion problems and for working to improve its practices and address potential diversion by hospital personnel.”

F. Anti-kickback Statute—Loyalty Programs and Discounts

1. Manhattan U.S. Attorney Announces $50 Million Settlement with Walgreens for Paying Kickbacks to Induce Beneficiaries of Government Healthcare Programs to Fill Their Prescriptions at Walgreens Pharmacies

Excerpt From Department of Justice Announcement (Jan. 19, 2017):

[The United States Department of Health and Humans Services Office of Inspector General and Department of Defense Office of Inspector General] announced today a $50 million settlement in a civil fraud lawsuit against Walgreen Co. . . . a nationwide retail pharmacy chain that owns and operates thousands of retail pharmacies throughout the United States. The settlement resolves claims that Walgreens violated the federal Anti-Kickback Statute (“AKS”) and False Claims Act (“FCA”) by enrolling hundreds of thousands of beneficiaries of government healthcare programs (“government beneficiaries”) in its Prescription Savings Club program (“PSC program”). Specifically, the Government’s Complaint alleges that Walgreens violated the AKS and FCA by providing government beneficiaries with discounts and other monetary incentives under the PSC program, in order to induce them to patronize Walgreens’ pharmacies for all of their prescription drug needs. The Complaint further alleges that Walgreens understood that allowing government beneficiaries to participate in the PSC program was a violation of the AKS, but that it nevertheless marketed the program to government beneficiaries and paid its employees bonuses for each customer
they enrolled in the program, without verifying whether the customers were government beneficiaries. The settlement will also resolve numerous state law civil fraud claims.

Under the settlement, Walgreens is required to pay approximately $46.21 million to the United States, has admitted, and accepted responsibility for conduct alleged in the Government’s Complaint. Further, as part of the settlement, Walgreens will pay approximately $3.79 million to resolve the state law civil fraud claims. Walgreens launched the PSC program in 2007. Throughout the period January 2007 through December 2010, the PSC program provided members with discounts on thousands of brand-name and generic drugs, as well as a 10 percent rebate on all Walgreens’ branded products, including household products, baby-care products, most grocery items, and non-prescription medications. Walgreens intended these lower drug prices and other monetary benefits to be an inducement to its existing and potential customers to cause them to patronize Walgreens for all of their pharmacy needs. Walgreens hoped that by offering these significant benefits to its customers, it would prevent them from taking their pharmacy business to Walgreens’ competitors.

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2. **Forest Laboratories and Forest Pharmaceuticals to Pay $38 million to Resolve Kickback Allegations under the False Claims Act**


Forest Laboratories LLC, located in New York, New York, and its subsidiary, Forest Pharmaceuticals Inc., have agreed to pay $38 million to resolve allegations that they violated the False Claims Act by paying kickbacks to induce physicians to prescribe the drugs Bystolic®, Savella®, and Namenda®, the Department of Justice announced today. . . .

The settlement resolves allegations that Forest violated the Anti-Kickback Statute, which prohibits the payment of remuneration to induce referrals of items or services covered by federal health care programs, by providing payments and meals to certain physicians in connection with speaker programs about Bystolic®, Savella®, or Namenda® between Jan. 1, 2008

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and Dec. 31, 2011. The United States contends that the payments and meals were intended as improper inducements because Forest provided these benefits even when the programs were cancelled (and Forest provided no evidence of a bona fide reason for the cancellation), when no licensed health care professionals attended the programs, when the same attendees had attended multiple programs over a short period of time, or when the meals associated with the programs exceeded Forest’s internal cost limitations.

As a result of today’s $38 million settlement, the federal government will receive $35.5 million and state Medicaid programs will receive $2.5 million. The Medicaid program is funded jointly by the state and federal governments.

The settlement resolves allegations filed in a lawsuit by former Forest employee Kurt Kroening, in federal court in Milwaukee, Wisconsin. The lawsuit was filed under the *qui tam*, or whistleblower, provisions of the False Claims Act, which permit private individuals to sue on behalf of the government for false claims and to share in any recovery. Mr. Kroening will receive approximately $7.8 million.

G. Deceptive Trade Practices—Off-Label Promotion

1. **$19.5 Million Multi-State Agreement with Bristol-Myers Squibb to End Deceptive Advertising Practices and Off-Label Promotion of Drug Used to Treat Schizophrenia**

Excerpt from N.Y. Attorney General Press Release (Dec. 8, 2016):

Attorney General Eric T. Schneiderman announced today a $19.5 million multistate agreement with Bristol-Myers Squibb (“BMS”) arising from alleged improper marketing and promotion of the drug Abilify. New York’s share of the settlement is $788,774. Abilify is one of several second-generation antipsychotic prescription drugs, commonly referred to as “atypical antipsychotics,” that were originally used to treat schizophrenia. The agreement is signed with 41 other State Attorneys General and the District of Columbia.

In a complaint filed today in New York County Supreme Court, Attorney General Schneiderman alleges that BMS engaged in off-label marketing, which is the promotion of drugs for uses that are not FDA approved. BMS improperly promoted Abilify for pediatric use and for use in elderly patients with symptoms consistent with dementia and Alzheimer’s disease. In fact, in 2006, Abilify received a “black box” warning stating that elderly patients with dementia-related psychosis who are treated with antipsychotic drugs have an increased risk of death. The complaint further that BMS violated state consumer protection laws by misrepresenting and minimizing risks of the drug including metabolic and weight gain side effects and by misrepresenting the findings of scientific studies.

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H. Medicaid Rebates

1. United HealthCare to Pay $1.5 million to New York State for Rebates Retained by Express Scripts

Excerpt from the Office of the New York State Comptroller:9

According to Thomas DiNapoli said, New York State Comptroller, contractor Express Scripts collected rebates but failed to turn over a significant amount of them to the state. This money is intended to help hold down costs of the program and contractors are expected to make every effort to collect and turn over all rebates, . . . The Department of Civil Service and United HealthCare need to make sure this money is fully collected and remitted to the state.

Civil Service contracted with United HealthCare to administer the Empire Plan’s prescription drug program. Under the contract, United was responsible for agreements with drug manufacturers for rebates, discounts, and other considerations. United was required to pass 100 percent of the resulting revenues back to the prescription drug program. For the audit period Jan. 1, 2010 through Dec. 31, 2013, United remitted $862.9 million from such agreements with drug manufacturers.

United subcontracted key functions of the prescription drug program, including the negotiation, collection, and allocation of rebates offered by drug manufacturers. Express Scripts Holding Company took over those duties in 2012.

. . . auditors found that on a quarterly basis, Express Scripts invoiced drug manufacturers for rebates and, in accordance with its subcontract with United, made quarterly payments to United based on the rebates it estimated it would receive from the manufacturers. In turn, United transferred those rebates to Civil Service.

Express Scripts then performed reconciliations 450 days after the end of each quarter to compare the actual rebates received from drug manufacturers to the estimated payments made to United. Express Scripts officials said they retained all rebates collected from drug manufacturers after the 450-day reconciliation. That practice, however, is contrary to both Civil Service’s contract with United and the subcontract between United

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9 http://www.osc.state.ny.us/press/releases/nov16/110116.htm
and Express Scripts, which required all rebates to be passed through to the NYSHIP drug program.

. . . auditors analyzed data provided by Express Scripts for the audit period and identified $1,498,719 in NYSHIP rebates that Express Scripts did not remit. The audit recommended United work to get that money for the state.10

I. PBM Rebates

1. Horizon Pharma to Pay $65 Million to Settle Express Scripts Lawsuit Claiming Withheld Rebates

From APhA News September 30, 201611:

Horizon Pharma has settled a lawsuit with Express Scripts related to aftermarket rebates for three of its drugs. Express Scripts sued the company in November for a breach of contract, seeking about $166 million in rebates related to famotidine–ibuprofen (Duexis), prednisone (Rayos), and esomeprazole magnesium–naproxen (Vimovo). Horizon then countersued, saying Express Scripts had breached the rebate agreement. Horizon will pay $65 million to settle the lawsuit, and both companies will be released from claims related to the litigation without admitting any fault or wrongdoing. Horizon separately noted it has signed a rebate agreement with Prime Therapeutics that will start on October 1.

J. Marketing—Telephone Consumer Protection Act (“TCPA”) (Junk Faxes)


CVS subsidiary, Advanced Care Scripts, Inc. (“ACS”), settled a class action for $9.25 based on claims alleging violation of the TCPA by sending unsolicited faxes

Named class representative Jefferson Radiation Oncology, L.L.C. and other class members alleged ACS violated the Junk Fax Prevention Act, which is part of the TCPA, when it “blasted thousands of faxes nationwide” that advertised ACS’s services and products (e.g., notifying prescribers that ACS is part of Bayer’s limited network for dispensing Nexavar and Stivarga along with oncology referral forms).

Counsel received $1.85 million for fees and expenses and named plaintiff received $20,000 with the remainder distributed to other class members.

K. Antitrust—Pay-for-Delay (Provigil)


Plaintiffs in a ten-year old case alleging damages from an agreement between Mylan and Cephalon to delay the introduction of generic modafinil sought the court’s permission to settle the case for $96.5 million.

10 The entire audit report can be found at http://www.osc.state.ny.us/audits/allaudits/093017/16s7.pdf.


4846-2097-9779.v2
Plaintiffs were direct purchasers of Provigil who claimed Cephalon and Mylan entered into an agreement for a Hatch-Waxman reverse-payment settlement agreement that unlawfully postponed the entry of a generic form of Provigil into the market. Reverse payments are so named because a brand name drug company pays a generic drug company to settle a claim that the generic drug company would infringe the patent of the brand name drug. Under the proposed settlement, the settlement class would consist of all persons or entities in the U.S. who purchased Provigil directly from Cephalon (e.g., wholesalers) between June 24, 2006 and August 31, 2012.

L. Antitrust—Monopolizing

1. Mallinckrodt ARD Inc., and its parent, agreed to pay $100 million to settle charges that they violated the antitrust laws when Questcor acquired the rights to a drug that threatened its monopoly in the U.S. market for adrenocorticotropic hormone (ACTH) drugs

Excerpt from FTC Press Release January 18, 2017:  
Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., and its parent company, Mallinckrodt plc, agreed to pay $100 million to settle charges that they violated the antitrust laws when Questcor acquired the rights to a drug that threatened its monopoly in the U.S. market for adrenocorticotropic hormone (ACTH) drugs. Acthar is a specialty drug used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, as well a drug of last resort used to treat other serious medical conditions. The complaint alleges that, while benefitting from an existing monopoly over the only U.S. ACTH drug, Acthar, Questcor illegally acquired the U.S. rights to develop a competing drug, Synacthen Depot. The acquisition stifled competition by preventing any other company from using the Synacthen assets to develop a synthetic ACTH drug, preserving Questcor’s monopoly and allowing it to maintain extremely high prices for Acthar. In addition to the $100 million monetary payment, the proposed stipulated court order, which must be approved by the federal court, requires that Questcor grant a license to develop Synacthen Depot to treat infantile spasms and nephrotic syndrome to a licensee approved by the Commission.

According to court documents and other reports, Acthar (autoimmune diseases treatment), accounted for 95% of Questcor’s sales In 2001, Questcor bought Acthar rights and raised price from $40 to $34,000 per vial. In 2012, Mallinckrodt allegedly monopolized the market by purchasing Synacthen from Novartis for $135 million. The states of Alaska, Maryland, New York, and Washington were also plaintiffs and parties to the settlement.


M. Foreign Corrupt Practices Act (“FCPA”)

1. Teva Pharmaceutical Paying $519 Million to Settle FCPA Charges

Excerpt from SEC Press Release December 22, 201614:

The Securities and Exchange Commission today announced that Teva Pharmaceutical Industries Limited has agreed to pay more than $519 million to settle parallel civil and criminal charges that it violated the Foreign Corrupt Practices Act by paying bribes to foreign government officials in Russia, Ukraine, and Mexico.

The SEC’s complaint alleges that Teva made more than $214 million in illicit profits by making the influential payments to increase its market share and obtain regulatory and formulary approvals as well as favorable drug purchase and prescription decisions.

Under the settlement, Teva must pay more than $236 million in disgorgement and interest to the SEC plus a $283 million penalty in a deferred prosecution agreement with the U.S. Department of Justice. Teva must retain an independent corporate monitor for at least three years.