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CONTROLLED SUBSTANCES

McKesson agrees to $150 million settlement for failing to report suspicious orders

The Department of Justice announced on January 17 a settlement with McKesson Corp. over alleged failures to follow its own plan agreed to in a 2008 settlement to screen for and report suspicious orders of controlled substances to the DEA. The DOJ press announcement notes, for example, that McKesson's Colorado distribution center shipped 1.6 million orders for controlled substances between 2008 and 2013, yet reported only 16 suspicious orders to the DEA during the period - all 16 related to a single previously terminated customer. The settlement, which requires McKesson to suspend controlled substances sales from distribution centers in Colorado, Ohio, Michigan, and Florida, also comes with a $150 million civil penalty, and a new and enhanced compliance agreement between McKesson and federal regulators. [USDOJ, Office of Public Affairs. McKesson agrees to pay record $150 million settlement for failure to report suspicious orders of pharmaceutical drugs. Justice News, 2017 Jan 17; http://bit.ly/2jywVxF] The McKesson settlement follows closely on the heels of a $44 million settlement with Cardinal Health announced in December by the DOJ. [Pharma-Law e-News 2016 Dec]

Ethical problems for lawyers who advise clients on marijuana laws

A post in the *ABA Journal* raises a question concerning whether an attorney may ethically advise a client on laws regarding cultivation, sale, or use of marijuana under state law, given that such practices

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violate federal law. The article cites an opinion issued earlier in the year by the Ohio Board of Professional Conduct, which concluded that under Rule 1.2(d), a lawyer may not assist a client in conduct the lawyer knows to be illegal, and that the "rule does not distinguish between illegal client conduct that will, or will not, be enforced by the federal government." The author concludes that under this opinion, Ohio attorneys may violate the RPCs by helping a client file an application for a marijuana license under Ohio law. The post notes that Ohio found its conclusion supported by similar opinions from Colorado, Connecticut, Hawaii, and Maine. The Ohio Supreme Court responded by amending Rule 1.2(d) to state that "a lawyer may counsel assist a client regarding conduct expressly permitted under ..." the state's marijuana law, but the lawyer under such circumstances shall also advise the client regarding federal law. Several states are reportedly amending or preparing to amend their equivalent of Rule 1.2, including Alaska, Colorado, Hawaii, Illinois, Nevada, Oregon, and Washington. [Hudson Jr. DL. Lawyers advising clients on marijuana laws may run afoul of ethics rules. ABA Journal 2017 Jan 1]

The City of Everett, Washington, sues Purdue Pharma for allowing black market distribution of OxyContin

On January 19, the City of Everett, Washington (located north of Seattle) filed a civil complaint in state court alleging that Purdue Pharma "knowingly, recklessly, and/or negligently suppl[ied] OxyContin to obviously suspicious physicians and pharmacies and enabl[ed] the illegal diversion of OxyContin into the black market, including to drug rings, pill mills, and other dealers for the highly addictive pills in Everett." The complaint also alleges that Purdue continued to ignore evidence of illegal distribution in spite of a 2007 settlement with the State of Washington in which the company agreed to design and maintain a system to disclose suspicious orders of OxyContin. The complaint alleges specific knowledge of diversion from a Los Angeles pharmacy and clinic by Purdue management in 2009 that was neither reported to the DEA nor stopped by Purdue into 2010, and a link to an Everett physician who pleaded guilty to diversion and to obtaining his OxyContin from the Los Angeles source.

The suit seeks damages due to costs incurred in dealing with an opioid

crisis in the City and for ongoing injury. The complaint is grounded in gross negligence, negligence, public nuisance, the Washington Consumer Protection Act, unjust enrichment, and punitive damages. [City of Everett (Wash.) v. Purdue Pharma, L.P. et al., No. 17-2-00469-31, Snohomish Co. Wash. Super. Ct., filed January 19, 2017; http://bit.ly/2lcDeYI]

Note: Other US cities, notably Chicago, have sued multiple opiate manufacturers alleging in part that the manufactures conspired or acted to mislead prescribers about the safety of long-acting opiates (see, e.g., City of Chicago v. Purdue Pharma L.P. et al., No. 1:2045-cv-04361, N.D. Ill., 2016); Purdue and other defendants have filed several motions in opposition, particularly objections that the City is trying to usurp the authority of the FDA. The Everett suit is, obviously, grounded in other bases.

Librax (chlordiazepoxide HCl and clidinium bromide capsules) is rediscovered as an approved drug

In a discussion of recently announced changes to the Orange Book, the FDA Law Blog reminded readers that as of late last year, the Orange Book listing for Librax (chlordiazepoxide and clidinium) was changed from a notice in the Preface that the drug was a drug marketed only on the basis of safety and was subject to ongoing DESI reviews to a full listing in the Orange Book as a drug approved prior to January 1, 1982. The FDA issued a statement in August that it had recently discovered that it was obligated by a stipulation for dismissal of *Hoffman-La Roche, Inc., v. Richardson, et al.,* C.A. 11-73 (D.N.J. 1973) to regard Librax as an approved drug not subject to DESI review. According to DEA's 2016 list of scheduling actions, Librax is an exempted prescription drug under the CSA, although chlordiazepoxide remains in Schedule IV. [USDHHS, FDA, CDER. Letter from CDER to Hyman Phelps and McNamara PC, August 22, 2016; http://bit.ly/2mhI0Bx]

Minnesota Federal District Court once again explains that exempted controlled substances, such as Fioricet, are still controlled substances when not distributed by prescription

Defendants in this criminal case have attempted for a second time to exclude evidence that dispensing of Fioricet® without a prescription violates the Controlled Substances Act. The motion was denied by the

court which patiently explained, again, that the exemption of Fioricet from certain requirements of the CSA was "for administrative purposes only," and the exemption does not operate to bar prosecution under the CSA for illegal distribution of a controlled substance. [United States of America v. Oz et al., Crim. No. 13-00273 (SRN/FLN), D. Minn., 2017 U.S. Dist. LEXIS 9208, January 23, 2017]

CRIMINAL LAW

Divided 4th Circuit panel upholds sentence enhancement based on "position of trust" for a defendant who was registered only as an intern pharmacist

The defendant/appellant in this case signed a written plea agreement in which he agreed to plead guilty to 2 counts of a third superseding indictment following his arrest for allegedly owning and managing a pharmacy that was reported to be the third largest distributor of oxycodone in West Virginia during 2014. The indictment charged him with participating in a conspiracy to distribute oxycodone outside of professional practice and not for a legitimate medical purpose, distributing and abetting the distribution of oxycodone, 40 counts of money laundering and 11 counts of structuring currency transactions to evade reporting requirements. The indictment contained a forfeiture notice informing him that his seized Lexus vehicle and $2.3 million in US currency were subject to forfeiture.

It was clear from the record that the pharmacy was owned by the defendant and his wife, however, he was a pharmacy school graduate who had never passed his licensure exams, and at all times relevant to this case was registered as a pharmacy intern in West Virginia. His wife was a pharmacist and regarded by the Board of Pharmacy as the pharmacy manager. Nevertheless, he acted as the CEO of the pharmacy, "controlling everything," according to his wife.

He pleaded guilty to structuring cash deposits and agreed not to contest judicial forfeiture, acknowledging that all property covered by the agreement was subject to forfeiture, and that the government could establish a forfeiture proceeding against him arising out of his

money laundering and illegal distribution of oxycodone.

In a presentencing report, a probation officer recommended a base offense level of 20, with several enhancements, 2 levels of which were based on his leadership role in the pharmacy, and 2 levels of which were for "abusing a position of public or private trust." The court overruled the defendant's objection to the enhancement levels based on abuse of trust, reasoning that he ran the pharmacy and "utilized the limited authority of a pharmacy and of a pharmacist ... to order huge quantities of controlled substances ..."

On appeal, the appellant argued that the leadership and trust enhancements were in error. He could not legally, he argued, be in charge of the pharmacy because he wasn't a pharmacist. The Court disagreed, finding that he was in fact the manager of the pharmacy as determined by the trial court which concluded that "'while there was a pharmacist [at the pharmacy] and she technically filled the prescriptions,' the evidence was that [defendant] actually 'ran the business' and directed her activities and the activities of the pharmacy." Thus, the Court affirmed the enhancement based on defendant's leadership role. Similarly, a majority of the panel affirmed the trial court's application of the enhancement based on abuse of a position of trust. The dissenting judge, however, concluded that the appellant "did not have the trust relationship necessary to support the imposition of an abuse of a position of trust enhancement with either the West Virginia Board of Pharmacy or the distributor from which [the] pharmacy purchased oxycodone." The dissent argued that the Board of Pharmacy entrusts pharmacists-in-charge, not interns for proper operation of the pharmacy. The wife may have abused her position of trust by allowing her husband to illegally distribute oxycodone from the pharmacy, but that is not a basis for enhancing his sentence; it is established law, the dissent noted, that a defendant's sentence cannot be enhanced on the grounds of a co-conspirator's abuse of a position of trust. [United States v. Agyekum, No. 15-4479, 4th Cir., 846 F.3d 744; 2017 U.S. App. LEXIS 1220, January 24, 2017]

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DEFAMATION

Indiana Federal District Court issues pre-trial rulings in physician's defamation suit against CVS

In an ongoing case first reviewed here in 2015, Dr. Anthony Mimms has sued CVS for defamation and tortious interference in business relationships. The instant opinion deals with cross-motions for summary judgment by the parties. Dr. Mimms alleges and has produced witnesses who aver that at various times in 2014, employees of CVS - mostly pharmacy technicians - had informed patients or patients' agents that Dr. Mimms' prescriptions for controlled substances could not or would not be filled for a variety of reasons including: "Dr. Mimms' license has been suspended or revoked;" "Dr. Mimms has been arrested, and if he hasn't been, he soon would be, therefore [] find a new doctor;" "CVS no longer fills prescriptions for Dr. Mimms because Dr. Mimms has been to jail, and is a bad doctor;" "Dr. Mimms is under DEA investigation;" and "CVS doesn't fill Dr. Mimms' prescriptions or prescriptions for any other pill mill." Dr. Mimms asserts that he has never been arrested, has never known of any investigation of him by DEA, and his license was never revoked or suspended.

Among the motions by the plaintiff for summary judgment were motions for declaratory judgment that one or more of the statements were defamatory *per se*; and motions to strike several of CVS' 13 affirmative defenses.

CVS moved to dismiss the claim of tortious interference as a matter of law, because no contract or business relationship was actually breached or interfered with, and, among other things, moved to dismiss his defamation claim because the statements were made by individuals with qualified privilege to discuss matters with Dr. Mimms' patients.

The Court found that pharmacy technicians, under Indiana law, are not expected to "exercise professional judgment in the best interests of the patient's health while engaging in the practice of pharmacy." Rather, those are expectations for pharmacists, which would arguably give pharmacists qualified privilege to discuss the validity of

prescriptions with patients seeking to fill them. Defamatory statements by technicians are not protected by qualified privilege.

The Court dismissed the tortious interference claim, agreeing with CVS.

The Court agreed with Dr. Mimms that the statement, "Dr. Mimms' license has been suspended or revoked is defamatory *per se.* It found that the following statements are defamatory: "Dr. Mimms is under DEA investigation," "CVS doesn't fill Dr. Mimms' prescriptions or prescriptions for any other pill mills," "CVS no longer fills prescriptions for Dr. Mimms because Dr. Mimms has been to jail," and "Dr. Mimms has been arrested, and if he hasn't been, he soon would be." However, a genuine issue of material fact exists as to whether the statements were made with malice, and whether, in fact some of the statements were actually uttered. [Mimms et al. v. CVS Pharmacy, Inc. et al., No. 1:15-cv-00970-TWP-MJD, S.D. Ind., 2017 U.S. Dist. LEXIS 166, January 3, 2017]

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FDA

Mithridates's invention of theriac (the universal antidote) in 1st century BCE may have paved the way for modern drug regulation
An interesting article in *The Atlantic* argues that the attempt to create a universal antidote by Mithridates VI in the mid-1st century BCE led to a profusion of various potions labeled as theriacs which ultimately led to regulation of pharmacy during and after the Renaissance. The article is an interesting review of the history of mithridatium and theriac and their ultimate elimination from the *London Pharmacopeia* in 1788 ending 18 centuries' use of that particular line of worthless cures. [Silver C. How ancient cure-alls paved the way for drug regulation. The Atlantic 2017 Jan 10; http://theatln.tc/2j15hsm]

FDA publishes memorandum on First Amendment considerations regarding manufacturer communications on off-label uses;

comments due April 19, 2017
On January 18, the FDA announced 2 draft guidances and a 63-page memorandum entitled "Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products." The memorandum explains that at its November public hearing on manufacturer communications regarding unlabeled uses, some commentators observed that little mention of First Amendment considerations was made in the Federal Register announcement of the public hearing or in the announcement's request for additional public comments by January 2017. As a result, the FDA has added this memorandum to the docket and has extended the deadline for public comments to April 19, 2017.

The memorandum emphasizes that significant public health interests anchor the statutory authority of the FDA to require evidence of safety and effectiveness for intended uses of marketed drug products, citing not only classic problems such as sulfanilamide elixir and thalidomide, but studies released in late 2015 demonstrating a higher risk of adverse events associated with unapproved uses of approved drugs than with approved uses of those drugs. The memorandum also discusses a need to protect against fraud, misrepresentation, bias, and diversion of health care resources toward ineffective treatments. FDA notes the results of the DESI review, which found that 70 percent of 16,500 claimed uses for drugs marketed in 1962 were found to be unsubstantiated.

In contrast to these concerns, the FDA acknowledges that certain communications from manufacturers regarding unapproved uses can advance public or individual health interests, particularly in populations which differ in important ways from the general population studied to obtain approval for drug indications. Key to this understanding is recognizing that "there is widespread agreement that no government interests are served by firm communications that do not fairly present reliable scientific information."

The memorandum summarizes several ways in which FDA has allowed for certain forms of communication concerning unapproved uses, particularly in truthfully responding to unsolicited requests for

information about the manufacturer's product. However, the memorandum explains in light of *Amarin Pharma* and *Caronia* that while the 2nd Circuit has foreclosed reliance "on the use of speech as evidence of intended use in the context of an FDA enforcement action where the misbranding was based solely on truthful, non-misleading speech regarding the unapproved use of an approved drug," the 2nd Circuit has "left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for" an unapproved use.

The memorandum also discusses alternative approaches that have been suggested, and seeks comment on its review of these approaches, noting that "FDA is concerned that none of them appear to integrate the complex mix of numerous, and sometimes competing, interests at plan and thus do not best advance those multiple interests." The bulk of the remaining portion of the memorandum then discusses these various alternatives.

The memorandum concludes with 3 appendices: (A) - summary of statutory and regulatory authority by product category; (B) - examples where commonly accepted unapproved uses have led to patient harm; and (C) - examples of products marketed for unapproved uses that caused harm

Examples in Appendix B include erythropoiesis stimulating agents used in cancer; atypical antipsychotics used in elderly patients with dementia; conjugated estrogens for protection against coronary heart disease in post-menopausal women; and flecainide and encainide for asymptomatic ventricular arrhythmias.

Examples in Appendix C include Aranesp to treat cancer-caused anemia; Seprafilm "slurries" in laparoscopic surgeries; Depakote to treat agitation and aggression in dementia patients, or for schizophrenia; Neurontin for monotherapy in seizures and multiple other unapproved uses; Zyprexa for multiple unapproved uses in the elderly; Geodon for unapproved uses in children; Seroquel for multiple unapproved uses based on ghostwritten articles; Abilify for dementia-related psychosis; Metacam (veterinary meloxicam) for use in species other than dogs, particularly in cats, leading to acute renal failure.

[DHHS, FDA. Memorandum: Public health interests and First Amendment considerations related to manufacture communications regarding unapproved uses of approved or cleared medical products. 2017 January; http://bit.ly/2lj19C4]

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FRAUD, WASTE AND ABUSE

HHS final rule provides flexibility for federal beneficiaries to participate in pharmacies' customer rewards or loyalty programs
Effective January 6, the HHS OIG has published a final rule that provides for safe harbors related to beneficiary inducements, of which 2 are of great interest to pharmacies:

- Waivers or reductions in co-pays or other cost-sharing amounts owed to pharmacies by financially-needy federal beneficiaries if
  - The waiver or reduction is not offered as part of an advertisement or solicitation;
  - The pharmacy does not routinely waive or reduce cost-sharing amounts;
  - The reduction or waiver is made only after a good faith determination that the individual is in financial need or after making reasonable failed efforts to collect the owed amount
- Offering of coupons, rebates, or other rewards from a retailer if
  - The rewards are offered on equal terms available to the general public, regardless of health insurance status; and
  - The rewards are not tied to the provision of other items or services reimbursed in whole or in part by federal funds

This would appear to allow Medicare Part D patients, for example, to participate in loyalty programs by a grocery chain which provides points for purchases in the pharmacy; it would not likely allow giving of coupons or rebates to a Medicare Part D patient or Medicaid patient for transferring prescriptions to the pharmacy. [DHHS, OIG. 42 CFR Parts 1001 and 1003. Medicare and State Health Care Programs ...

Revisions to Safe Harbors ..., 81 Fed. Reg. 88368, December 7, 2016.]

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MEDICAID PHARMACIST PRESCRIBING

CMS tells states they may be flexible in facilitating access to drug therapy by recognizing the expanded scope of pharmacists
On January 17, the Center for Medicaid and CHIP Services (CMCS) within CMS, announced to states that in CMCS' view, they have "flexibilities" to "facilitate timely access to specific drugs by expanding the scope of practice and services that can be provided by pharmacists, including dispensing drugs based on their own independently initiated prescriptions, collaborative practice agreements ... 'standing orders' issued by the state, or other predetermined protocols" for Medicaid beneficiaries.

The announcement cites naloxone distribution, tobacco cessation therapy, immunizations, and emergency contraception as examples of options that states could choose to pay for when delivered by pharmacists to Medicaid beneficiaries. [USDHHS, CMS, CMCS. State flexibility to facilitate timely access to drug therapy by expanding the scope of pharmacy practice using collaborative practice agreements, standing orders, or other predetermined protocols. CMCS Informational Bulletin 2017 Jan 17.]

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NEGLIGENCE

5th Circuit overturns judgment against Safeway in indemnification action by PDX
This case arose from a negligence suit against Safeway and PDX in 2011 and 2012 filed by Kathleen and Dane Hardin, in which plaintiffs alleged that Safeway failed to provide them with a full patient information leaflet. Safeway was dismissed based on California's

statute of limitations, and the action proceeded solely against PDX.

The alleged negligence arose when PDX in 2006 modified its prescription dispensing software to eliminate an option for its customers to choose not to print 3 paragraphs of PDX-generated PILs entitled "overdose," "before using," and "additional information." This was done in response to the publication by DHHS of the so-called "Keystone Criteria" recommendations for information on prescription drugs that should be disseminated to patients.

Safeway then requested PDX to provide it with a customized version that would allow Safeway to continue to omit printing these paragraphs in PILs it distributed to patients. PDX agreed, but sought an indemnification agreement from Safeway, which read: "[Safeway] hereby expressly waives any claims against PDX with respect to such Program and the use of such and further agrees to indemnify and hold PDX harmless from any and all loss, damage, or expense (or claims of damage or liability) asserted against PDX arising from [Safeway's] use of the Program, including, without limitation, claims that the Program or the purpose for which this Program is used by [Safeway] includes a violation of [the statute directing the HHS Secretary to develop the Keystone Criteria]."

Subsequent to the Hardin litigation, PDX sought indemnification from Safeway, which refused to provide it. Safeway brought suit in the Northern District of Texas seeking a declaratory judgment that it owed no indemnification to PDX because the agreement "does not specifically reference negligence or strict liability as required under Texas law to indemnify a party for its own negligence or strict liability." PDX counterclaimed, and the district court denied Safeway's motion, granted PDX's motion, and entered judgment in favor of PDX, and awarded attorneys' fees to PDX.

On appeal, the 5th Circuit reversed, holding that under *Ethyl Corp. v. Daniel Construction Co.,* 725 S.W.2d 705 (Tex. 1987), "contracting parties seeking to indemnify one party from the consequences of its own negligence must express that intent in specific terms, within the four corners of the document." Citing its own jurisprudence, the Court noted that "we have previously stressed that 'broad statements of indemnity' are insufficient to satisfy the express negligence rule. In

fact, Texas courts have held insufficient even clauses that provide indemnification 'from and against all claims, damages, losses, ane expenses' '[t]o the fullest extent permitted by law.' Moreover, where the intent to indemnify a party for its own negligence can be gleaned from a contract only by implication or deduction, the agreement is not enforceable." [Safeway, Inc., v. PDX, Inc. et al., No. 15-10552, 5th Cir., 2017 US. App. LEXIS 1000, January 19, 2017]

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NONPRESCRIPTION MEDICATIONS

FDA issues guidances for OTC labeling of aspirin and acetaminophen

On January 10, the FDA issued 2 guidances relating to OTC aspirin and acetaminophen products.

The aspirin guidance was issued as a draft for comments over the next 60 days, and dealt with a recommended statement when the aspirin product is labeled with "cardiovascular related imagery," such as a stethoscope surrounding a heart. OTC aspirin products are marketed under the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for OTC Human Use, issued in 1988. The TFM does not envision labeling for use in secondary prevention of cardiovascular events, although the approved professional labeling (21 CFR 343.80) does so. In the guidance, the FDA notes that §343.80 contains indications for "reducing the risk of a second heart attack or stroke in patients who have already experienced a cardiovascular or cerebrovascular event or for patients with existing coronary artery disease ..." However, such use also has side effects including GI bleeding, cerebral bleeding, kidney failure, and hemorrhagic strokes. Although the FDA has never formalized rulemaking requiring OTC aspirin products to contain information on cardiovascular use, it does believe that placing cardiovascular related imagery on the product label implies a use not authorized in the TFM. In the proposed guidance, the FDA asserts it will not act against a manufacturer of OTC aspirin products with cardiovascular related

imagery if the labeling also includes the statement, "Consult your healthcare provider before using this product for your heart." [USDHHS, FDA. Recommended statement for over-the-counter aspirin-containing drug products labeled with cardiovascular related imagery. Guidance for industry. 2017 Jan 10; http://bit.ly/2iGovjU]

The FDA published a final guidance recommending a warning on acetaminophen OTC labels concerning serious skin reactions (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis). In 2013, FDA required manufactures holding NDAs or ANDAs for acetaminophen-containing products to include warnings about serious skin reactions in their labeling, and the guidance notes that those changes have now been made. This guidance is directed at manufacturers who are marketing acetaminophen-containing products under the 1988 TFM, and informs them that FDA will not act against them if their labeling contains the following language in the Warnings section of the DRUG FACTS label: "Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may contain [bullet] skin reddening [bullet] blisters [bullet] rash. If a skin reaction occurs, stop use and seek medical help right away." [DHHS, FDA. Recommended warning for over-the-counter acetaminophen-containing drug products and labeling statements regarding serious skin reactions. Guidance for industry. 2017 Jan 10; http://bit.ly/2j6OPqm]

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PBMs

The 8th Circuit invalidates Iowa's PBM law

The Pharmaceutical Care Management Association (PCMA) sued the State of Iowa over §510B.8 of the Iowa Code, which was enacted in 2014 as an "Act Relating to the Regulation of Pharmacy Benefits Managers." Among its various provisions, the Act requires PBMs to submit to the insurance commissioner information on their methodology for calculating MACs, and requiring inclusion in contracts with network pharmacies information about which sources were used

in calculating MAC prices, and provisions which allow pharmacies to comment on, contest, or appeal the MAC rates. The PCMA averred that the Act is preempted by ERISA. The trial court dismissed the case and PCMA appealed.

On appeal, the 8th Circuit agreed with PCMA, finding that the Act defines a PBM as " a person who performs pharmacy benefits management services," and defines PBM services as "the administration or management of prescription drug benefits provided by a covered entity under the terms and conditions of the contract between the pharmacy benefits manager and the covered entity." Likely key to the Court's findings, a "covered entity" is defined, in part, by excluding "a self-funded health coverage plan that is exempt from state regulation pursuant to the federal Employment Retirement Income Security Act of 1974 (ERISA); ..." By excluding ERISA plans, the Court opined, the Act "by its express terms, ... cannot reach PBMs who manage benefits for certain exempted ERISA plans, §510B.8 specifically exempts certain ERISA plans from its otherwise general application. If the effect of a State law is to exclude some employee benefit plans from its coverage, that law has a prohibited reference to ERISA and is preempted. ..." Additionally, the Court concluded that the Act's requirement that PBMs disclose their price determination methodology necessarily regulated the PBMs reporting, disclosure, and recordkeeping for ERISA clients. [PCMA v. Gerhart et al., No. 15-3292, 8th Cir., 2017 U.S. App. LEXIS 476, January 11, 2017]

Eastern District of Missouri denies ESI's motion to dismiss compounding pharmacies' lawsuit

In another suit by compounding pharmacies alleging that PBMs, including Express Scripts (ESI), have conspired to exclude them from the marketplace and to move business to entities owned by the PBMs, ESI failed to have the suit dismissed in Missouri Federal District Court. The claims and defenses are similar to other cases reported here recently, so this case is briefly reported for the record. [Grasso Enterprises, LLC, et al. v. Express Scripts, Inc., No. 4:14CV1932 HEA, E.D. Mo., 2017 U.S. Dist. LEXIS 9998, January 25, 2017]

Missouri Federal District Court denies ESI's motion to dismiss counts of specialty pharmacy's breach of contract suit

A New Jersey specialty pharmacy was excluded from ESI's provider network following a determination by CVS that a $143,000 discrepancy justified "immediate termination." This, alleges the plaintiff pharmacy, was in spite of documentation made available to ESI resolving the discrepancy. The plaintiff sued ESI and in the current action, the Court was asked to dismiss 3 counts of the plaintiff's complaint: fraudulent misrepresentation; violations of the Missouri Prompt Pay Act; and violation of a duty of equitable accounting. The Court found all 3 counts to be sufficiently pleaded and denied ESI's motion. [Prime Aid Pharmacy Corp. v. Express Scripts, Inc., No. 4:16-CV-1237 (CEJ), E.D. Mo., 2017 U.S. Dist. LEXIS 6692, January 18, 2017]

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PHARMACY EDUCATION

Federal District Court dismisses pharmacy student's discrimination suit against WVU and individual faculty members

The plaintiff is a Syrian of Arab descent and a practitioner of Islam. He enrolled in WVU School of Pharmacy following graduation from Marshall University in the fall of 2009. In his first semester, he received a "D" grade in physical pharmacy, which placed him on probation, which required no additional "D" grades and a minimum semester grade of 2.5. He was removed from probation at the end of the semester. However, in fall 2010, he received "D" grades in 2 additional courses, and a semester GPA of 2.07, prompting a review by the SOP's Academic Professional Standards Committee, which informed him that it would recommend to the dean that he be dismissed from the program. He appealed, and the committee denied the appeal based on "the objective academic data."

In early 2011, the plaintiff applied for readmission and presented the committee with a remedial plan. The committee recommended readmission with specific conditions, and the dean accepted the conditions with her own modifications. The conditions included the following: (1) he must retake all courses beginning with the P2 year

(modified by the dean from the committee's recommendation he restart as a P1); (2) he would re-enter on permanent academic probation; (3) he must earn at least a "C" grade in every required course (another modification by the dean; the committee recommended a minimum grade of "B" in all core courses); (4) he must complete all experiential rotations with a satisfactory evaluation for each required competency (i.e., 3 or greater out of a possible 5); and (5) he must submit a comprehensive study schedule 2 weeks prior to each didactic semester.

In fall 2011, spring 2012, and fall 2012, the plaintiff progress satisfactorily with GPAs of 3.2, 3.06, and 3.13. However, in spring 2013, he earned 3 "C" grades, lowering his GPA to 2.37, dropping below the 2.5 minimum for a student on probation. The committee again recommended dismissal, but recanted at the dean's request. His new remediation plan required study for and retakes of exams in a pharmacotherapeutics and a pharmacokinetics course, and his experiential preceptors would be advised of his need for close monitoring. The committee advised him further that failure to score at least 70% on his exam retakes, or a failure to pass any competency in any rotation, up to and including his final one, would result in his dismissal. He appealed the plan, "claiming that it would set him up to fail," and that it treated him unfairly. The committee denied his appeal. On appeal to the dean, the dean modified the plan by removing the requirement to retake pharmacotherapeutics exams, but otherwise upheld the requirements.

In his P4 year, the plaintiff was removed early from an acute care rotation, after his preceptor "began to notice what he considered to be substantial deficiencies in [his] academic performance and knowledge base" on the plaintiff's second day in the rotation. The preceptor's clinical supervisor advised the SOP that "based on his own 'observation as clinical director, supervising and evaluating [the plaintiff] is taking an undue amount of time and effort, and is preventing his preceptor from the efficient conduct of his responsibilities to [the medical center].'" The clinical supervisor requested the plaintiff's removal from the site and the SOP complied. The experiential director at the SOP treated the removal as a failure of the rotation and advised the plaintiff he would receive a failing

grade. This was ultimately appealed to a university-level vice president who found that the SOP's experiential rotation manual did not provide for early removal from a rotation, and ruled that the plaintiff should be given an "Incomplete" grade and allowed to retake the rotation. However, the VP advised the plaintiff that he remained subject to the remediation plan and could not fail any competency on any rotation.

The dean then recommended that the plaintiff audit the pharmacotherapeutics course, and advised him that all his future preceptors would be full-time faculty members. This resulted in a delay to Summer 2014 for his resumption of rotations. He completed his first summer rotation successfully, but received evaluations of "2" on 3 competencies in his mid-rotation evaluation in his subsequent ambulatory care rotation. The course of the remainder of that rotation was uneven at best, and at the end of the rotation he received increased scores on 2 competencies, he remained at "2" for "collecting patient data," and declined to "2" in "professionalism." He failed the rotation and was ultimately dismissed from the program.

He sued the SOP, the WVU Board of Governors, and the dean and 7 other faculty members in their official and individual capacities. He asserted 7 causes of action: (I) violation of substantive due process under 42 USC § 1983 and the 4th Amendment; (II) violation of procedural due process under 42 USC § 1983 and the 4th Amendment; (III) violation of civil rights under 42 USC § 1981; (IV) violation of civil rights under 42 USC § 1985; (V) breach of contract; (VI) breach of contract; and (VII) promissory estoppel. He sought compensatory and punitive damages, damages for breach of contract and estoppel, attorney's fees and costs, and a declaratory judgment that defendants violated his procedural and substantive due process and civil rights.

The Court initially dismissed his claims against the SOP, which is not an entity that can be named as a subdivision of WVU. It dismissed counts I through IV against the WVU Board of Governors under 11th Amendment immunity, without prejudice. The Court found that defendants were subject to 11th Amendment immunity against suits in their official capacity, holding that *Ex Parte Young* was inapplicable to this suit, and dismissed counts I through IV without prejudice as to the

faculty defendants in their official capacity. The breach of contract and promissory estoppel claims are state claims subject to 11th Amendment immunity and beyond the subject matter of the federal court, so counts V, VI, and VII were also dismissed without prejudice.

As to the remaining counts against the faculty defendants in their individual capacity, it became clear that the plaintiff's history and subsequent claims fit fully in the mold of two signal academic dismissal cases: *Regents of the University of Michigan v. Ewing,* 474 U.S. 214 (1985), and *Board of Curators of Univ. of Missouri v. Horowitz,* 435 U.S. 798 (1978). *Ewing* limns the requirements of substantive due process, and *Horowitz* generally outlines procedural due process for academic dismissal cases, as opposed to discipline. Under *Ewing,* academic decisions will be generally given great deference by courts when a decision by the faculty to dismiss a student is "made conscientiously and with careful deliberation, based on an evaluation of the entirety of [a student's] academic career." Under *Horowitz* all the procedural due process required by the 4th Amendment will be satisfied when the faculty has at multiple times informed the student of their "dissatisfaction with her clinical progress," and warned the student that her continuation in the program was at risk, such that the student had "clear notice of her shortcomings." *Horowitz* commands courts to "give significant deference to academic decisions, reasoning that 'courts are particularly ill-equipped to evaluate academic performance' because they require 'an expert evaluation of cumulative information and [are] not readily adapted to the procedural tools of judicial or administrative decisionmaking.'" *Horowitz* also distinguished between the need for hearings in making disciplinary decisions, and the lack of need for hearings when academic judgments are made by faculty.

The Court found that "it is indisputable that [the dean's] decision to dismiss [the plaintiff] was made carefully and deliberately. As chronicled above, [the dean] was intimately familiar with the details of [plaintiff's] case, having been personally involved in his history at the SOP and the several attempts to resolve his academic problems." The Court dismissed counts I and II with prejudice.

As to the remaining civil rights claims, the Court found that the

plaintiff had failed to demonstrate any evidence that "the SOP's actions were based in whole or part on his race, ethnicity, or national origin," as required by § 1981 or § 1985(3). Counts III and IV were dismissed with prejudice. [Al-Asbahi v. WVU Board of Governors et al., No. 1:15CV144, N.D. W.Va., 207 U.S. Dist. LEXIS 12400, January 30, 2017]

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THANKS FOR TIPS FOR THIS EDITION GO TO:
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