

Pharmacy Law Update

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CPFI 2025 ANNUAL CONFERENCE
May 31, 2025
1:00PM - 2:15PM



Disclosures

Teri Miller declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Objectives

1. Describe the challenges encountered by the practice of pharmacy with the intersection of existing statutes and regulations.
2. Identify states that have set precedent which may be followed affecting pharmacy practice.
3. Compare the decisions across jurisdictions and how that may impact pharmacy practice.
4. Cite new or pending regulatory implication in the area of pharmacy practice.

Foundation

Current Practice: Pharmacists practice according to local jurisdiction without knowledge of what is happening legislatively on a comprehensive scale in the profession.

Best Practice: Pharmacists should have an awareness of what is affecting pharmacy practice on a national scale and be involved in local and national government pertaining to the profession.

Resulting Gap Strategy: Become more aware and involved in the state and local law-making process through state organizations and boards of pharmacy and remain informed about comprehensive strategies and nationwide perspectives in the continual evolution of pharmacy practice.

Who is to blame for the opioid crisis?

- CVS, Walmart and Walgreens ordered to pay \$650.6 million to Ohio counties in opioid case. (Aug 2022)
- Ohio's top court overturned a \$650.9 million judgment two local counties secured against Walgreens, CVS and Walmart in the first case to go to trial nationally over allegations the pharmacies contributed to the epidemic. (Dec 2024)
- United States v. Walgreens, et.al. (Jan 2025) DOJ says Walgreens
- Walgreens, et.al. v. DEA, DOJ, AG (Jan 2025) Walgreens says DEA/DOJ

Ohio Supreme Court: Opioid judgment against pharmacy chains not allowed under product liability law—Ohio Capital Journal

- “In 2022, \$650.9 million was awarded to Lake and Turnbull counties (Ohio) for a “public nuisance” perpetrated by national companies including CVS Health, Walmart, and retail pharmacy Walgreens Boot Alliance in exacerbating the opioid crisis in those counties.
- After a federal jury made their decision finding the chains responsible, U.S. District Judge Dan Polster ordered the \$650 million judgment, saying the companies’ actions brought on addiction, overdose and a strain on community resources related to the opioid crisis.
- The Sixth Circuit asked the Ohio Supreme Court to interpret state law regarding public nuisance claims and the Ohio Product Liability Act, and with the state’s highest court’s interpretation of state law leaning in favor of the pharmaceutical chains, those millions may be up in smoke.”

UNITED STATES OF AMERICA, Plaintiff, v. RIDLEY'S FAMILY MARKETS, INC. et. al, Defendants.

United States v. Ridley's Family Mkts., 525 F. Supp. 3d 1355 (D. Utah 2021)

- A DEA agent opened an investigation into a pharmacy after a physician reported forged prescriptions.
 - 167 prescriptions honored over several years
- Complaint: Violation of Federal Controlled Substance Act
 - “Red Flags”

Examples of “Red Flags” per DOJ

- Suspicious or stamped signatures
- Dangerous drug combinations
- Irregular dispensing intervals
- Odd dosages and pill quantities
- Cash payment
- Early fills
- Errors or missing information
- Brand name requests
- Patient calling in her own prescription
- Pattern prescribing
- Other odd behaviors

DOJ Moved for Summary Judgment

- Elements of Summary Judgment:

- #1 There is no genuine issue or dispute of material fact.
- #2 Moving party is entitled to judgment as a matter of law.

- DOJ was asserting that Ridley's had honored the prescriptions despite recognizing the "red flags" indicating their illegitimacy.

- The federal court judge in the District of Utah said not so fast.....

➤ 21 CFR 1306.04: Purpose of issue of prescription.

A prescription for a **controlled substance** to be effective must be issued for a **legitimate medical purpose** by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility rests with the pharmacist** who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the **person knowingly filling** such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

The court concluded that undisputed facts alone do not necessarily mean “knowingly”...

The Court's Opinion

United States v. Ridley's Family Mkts., Inc., No. 1:20-cv-173-TS-JCB,
2025 U.S. Dist. LEXIS 10692 (D. Utah Jan. 21, 2025)

- Since the moving party bears the burden of proof in a motion for summary judgment, the DOJ has not shown that the Ridley pharmacists ***subjectively*** believed the prescriptions were illegitimate.
- The quantity of red flags does not show by itself, as a matter of law, that the Ridley pharmacists actually recognized them.
 - Depends on Professional Judgment
 - Depends on Specific Circumstances of EACH prescription
- No codified standard for a “red flag”

The Court's Ruling

United States v. Ridley's Family Mkts., Inc., No. 1:20-cv-173-TS-JCB,
2025 U.S. Dist. LEXIS 10692 (D. Utah Jan. 21, 2025)

- #1-Lack of evidence as to the *subjective* knowledge of the pharmacists in filling and dispensing the controlled substances (i.e. “knowingly”)
- #2-Lack of clarity about what constitutes a “red flag”
- These two factors above leave enough doubt for a reasonable factfinder that a jury is necessary to decide this case....thus, summary judgment for the DOJ was **DENIED**.

Takeaways for Future Courts to Consider

- Pharmacists evaluate prescriptions one at a time. Each one has its own qualities that affect professional judgment. A report spreadsheet does not address this assessment.
- **SUBJECTIVE** standard adopted by this federal judge. “Knowingly” is up to the jury to decide based on the pharmacist’s subjective belief about EACH prescription.
- Ambiguity of “red flags” was recognized as well as the undefined and unexplained concept it creates.

RADONDA VAUGHT v. TENNESSEE BOARD OF NURSING

Vaught v. Tenn. Bd. of Nursing, No. M2023-01816-COA-R3-CV, 2025 Tenn. App. LEXIS 98 (Ct. App. Mar. 20, 2025)

- Nurse typed “VE” into automated dispensing unit in an effort to get “Versed” and mistakenly removed vecuronium. (Dec 2017)
- Nurse admitted she didn’t check the label.
- Nurse did not monitor the patient because another nurse told her monitoring midazolam was unnecessary.
- Patient died.

RADONDA VAUGHT v. TENNESSEE BOARD OF NURSING

➤ Charges:

- Criminal Prosecution
- Administrative Action to Revoke Nursing License
 - A medication safety pharmacist expertly testified at the revocation hearing explaining that nurses may override the automated dispensing unit, but that it comes with an **“expectation that the nurse or clinician is verifying the order.”**
 - The nurse admitted she had not met this expectation.
 - The board revoked the nurse’s license

➤ Nurse appealed...

RADONDA VAUGHT v. TENNESSEE BOARD OF NURSING

- While waiting on the appeal, the nurse was convicted of negligent homicide in a criminal court.
 - Many health care professionals had written letters of support for her to the judge...including the medication safety pharmacist
 - Urged “grace in sentencing”.... Why?
 - #1 Nurse’s error was not “intentional neglect.”
 - #2 “Confirmation bias” may have contributed to the administration of the wrong drug.
 - “Confirmation bias” was a “critical piece of evidence” that was never brought up at the hearing.....although the pharmacist desperately wanted it to be.
- Result: Nurse petitioned the licensure revocation court to send the case back to the board of nursing for reconsideration based on the letter...

The Court's Opinion....

- Information in the pharmacist's letter could have been elicited during the pharmacist's testimony at the license revocation hearing OR deposition.
- Nurse's attorneys had a full opportunity to question the pharmacist about nursing practices with the automated dispensing unit.
- Nurse's attorneys had a full opportunity to question the pharmacist's opinions concerning "confirmation bias."

BUT IT WASN'T AND THEY DIDN'T.

- **Ruling:** The license revocation hearing had NOT been unfairly prejudicial, and the nurse's petition was denied.

Takeaways for Pharmacists to Consider

- Testimony from pharmacists can be critical in criminal trials and licensure revocation hearings.
- In a formal legal proceeding, pharmacists must answer the question asked, but most judges will allow an expanded answer if the explanation does not stray far from the question asked.
- Pharmacists who are called to testify should insist on being adequately prepared for testimony by an attorney who represents the interests of the defendant health care institution or health care professional
- **NO DO-OVERS to clarify incomplete testimony if lawyers don't ask the right questions!!**
- **Explain the complications of the process to the lawyers as medication experts so they know the right questions to ask!!**



Chain Pharmacy Case- “Adequate Staffing”

- Long drive-through lines; lobby sign: “Pharmacy Closed”
- **Limited access:** only vaccine window open (20-minute wait to be acknowledged)
- **Security concerns:** open drug totes accessible; unsecured pharmacy area
- **Staffing issues:** 1 pharmacist, 1 tech, 1 concierge—overwhelmed
- **High workload:** 960 prescriptions in production; 75 in verification
- **Storage violations:** medications on floor; 48 wholesale totes (some needing refrigeration)
- **Staffing shortages:** 7 employees left; no extra help received
- **Facility concerns:** broken air conditioner, nonfunctional issues

Inspection Findings With Many Concerns (September 2021)

Follow-Up Inspections Not Much Better (October 2021)

- Staff from initial visit quit or are transferred
- **Backlog:** 1 month behind on filling prescriptions
- Trying to triage life-saving and life-sustaining medications

- After notice letter, request for hearing made
- **3-day hearing with witnesses:** board considered evidence and ruled pharmacy posed a public health risk
- **Indefinite probation**
 - Can request release after 3 years if compliant
 - Must prove all violations are remedied

Board Actions & Hearing Outcome

Historic Settlement Over Understaffing (February 2024)

- Chain & Ohio Board settled for **\$1.25 million fine + \$250,000 for monitoring**
- Covers **20+ Ohio pharmacies** over understaffing concerns
- **Largest settlement in board history**

Ohio State Board of Pharmacy v Chain Pharmacy #2063. A-2021-0567 (2024). <https://www.pharmacy.ohio.gov/documents/pubs/minutes/2024/202402%20-%20february%205,%206,%20and%207,%202024%20board%20meeting%20minutes.pdf>; Ohio Board of Pharmacy. News release. February 29, 2024. Accessed March 26, 2025. <https://www.pharmacy.ohio.gov/documents/pubs/newsreleases/2024/state%20of%20ohio%20board%20of%20pharmacy%20reaches%20settlement%20agreement%20with%2022%20ohio%20cvs%20stores%20to%20resolve%2027%20cases.pdf>.

Ohio BOP Rules to Address Workload Concerns



Board of
Pharmacy

[Pharmacy.Ohio.gov](https://www.pharmacy.ohio.gov)

Mike DeWine, Governor Jon Husted, Lt. Governor Steven W. Schierholt, Executive Director

Outpatient Pharmacy Minimum Standards

Updated: 5/1/2024

*All updates are notated in red (i.e. **UPDATED 4.26.2024**)*

Effective 5/1/2024, the following rules on outpatient pharmacy minimum standards go into effect. These rules are the result of the work of the Ohio Pharmacist Workload Advisory Committee and feedback provided by pharmacy professionals through various surveys. For more information on the Pharmacist Workload Advisory Committee, please visit: www.pharmacy.ohio.gov/PWAC.

Rule No.	Title
4729:5-5-02	Minimum Standards for the Operation of an Outpatient Pharmacy.
4729:5-5-02.1	Provision of Ancillary Services in an Outpatient Pharmacy.
4729:5-5-02.2	Mandatory Rest Breaks for Pharmacy Personnel.
4729:5-5-02.3	Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy.
4729:5-5-02.4	Significant Delays in the Provision of Pharmacy Services.
4729:5-5-02.5	Outpatient Pharmacy Access Points.

(Click on the rule number to access the full text of the rule)

HANHART v. LOUISIANA CVS PHARMACY LLC CVS LLC

Hanhart v. La. CVS Pharmacy LLC, 2024-0479 (La. App. 4 Cir. 09/20/24); 399 So. 3d 785

- **Patient requested a refill** of tirzepatide and **received a text 3 days** later saying it was ready, but that the prescriber had transmitted a new Rx with an increased strength.
- Patient called pharmacy and was advised by the pharmacist that the refill would be cancelled and the new Rx obtained for her.
- **6 days passed**....patient called pharmacy and was allegedly “left on hold and was unable to reach an employee.” Later that same day, she arrived at the pharmacy in person...admittedly “aggravated, irritated, and frustrated for what she had suffered.”
- According to the patient, employee “rolled her eyes at her and physically and audibly expressed derision toward her.” The two “engaged in heated verbal barbs and the employee made an offensive hand signal toward her.”
- Employee left the counter. No one else assisted.



HANHART v. LOUISIANA CVS PHARMACY LLC CVS LLC

➤ Legal Ramifications

- The day after the altercation, the patient obtained her medication at a different pharmacy.
- Patient filed an Intentional Infliction of Emotional Distress claim (IIED) for “extreme and outrageous” conduct by the pharmacy’s employees.
- Pharmacy moved for dismissal.
- Motion was denied.
- Pharmacy appealed.

The Appellate Court's Opinion

- Elements of IIED in Louisiana:
 - Extreme and outrageous conduct was committed causing severe emotional distress
 - Such conduct was intended
- Pharmacy's service "may well have involved conduct that was inconsiderate and discourteous."
- "Persons must necessarily be expected to be hardened to a certain amount of rough language, and to occasional acts that are definitely inconsiderate and unkind." — but.. "Not every verbal encounter may be converted into a tort."
- **Ruling: The patient's lawsuit was dismissed.**

Takeaways for Pharmacists to Consider

- There is an expectation of civility of patients AND pharmacy team members in professional interactions.
- Pharmacy Personnel: **Defy Newton's 3rd Law of Motion**
 - For every action there is an equal but opposite reaction.
- Incivility must be treated with civility....where do we draw the line??
- **STANDARD: Mutual respect is the standard for professional interactions.**
 - Discontinue the relationship.
 - Adopt and enforce a policy of patients' rights and responsibilities reflecting mutual expectations for civility.
 - **Unusual or strange behavior** vs. **Threats and abuse**
- **No Effective Legal Remedies for Incivility**
 - Civility is an essential aspect of **professionalism**....**not of law.**

Presidential Actions- Executive Orders
DELIVERING MOST-FAVORED-NATION PRESCRIPTION DRUG
PRICING TO AMERICAN PATIENTS
May 12, 2025

- President Trump has directed the Department of Health and Human Services (HHS) to secure for U.S. patients the lowest price a drug manufacturer offers in any comparable nation, referred to as the “most-favored-nation” (MFN) price.
- Within 30 days, HHS must tell each manufacturer what that MFN price looks like.
- If companies do not move promptly toward those targets, the agency is instructed to:
 - prepare a rule that would impose MFN pricing,
 - consider certifying large-scale drug importation under section 804 of the Food, Drug, and Cosmetic Act, and
 - coordinate antitrust enforcement with the Justice Department and the Federal Trade Commission.
- The order also asks HHS to create pathways for manufacturers to sell directly to American patients at MFN prices.

Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability **Effective January 1, 2026**

- The law authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare drugs covered under Part B or Part D, meaning only those drugs for which there is no generic or biosimilar competition.
- 1st Year: CMS will select up to 10 high expenditure, single source drugs for negotiation. For the drug companies of selected drugs that elect to participate in the Negotiation Program, the maximum fair prices that are negotiated will apply beginning January 2026.
- 2nd Year: CMS will select up to an additional 15 drugs for negotiation effective 2027,
- 3rd Year: CMS will select up to an additional 15 drugs (including drugs covered under Part B) for 2028, and up to an additional 20 drugs for 2029 and subsequent years.

Drug Name	Commonly Treated Conditions	Total Part D Gross Covered Prescription Drug Costs from June 2022-May 2023	Number of Medicare Part D Enrollees Who Used the Drug from June 2022-May 2023
Eliquis	Prevention and treatment of blood clots	\$16,482,621,000	3,706,000
Jardiance	Diabetes; Heart failure	\$7,057,707,000	1,573,000
Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	\$6,031,393,000	1,337,000
Januvia	Diabetes	\$4,087,081,000	869,000
Farxiga	Diabetes; Heart failure; Chronic kidney disease	\$3,268,329,000	799,000
Entresto	Heart failure	\$2,884,877,000	587,000
Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	\$2,791,105,000	48,000
Imbruvica	Blood cancers	\$2,663,560,000	20,000
Stelara	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	\$2,638,929,000	22,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Diabetes	\$2,576,586,000	777,000

Note: Numbers are rounded to the nearest thousands.

The % discount for the negotiated prices:

Apixaban (**Eliquis**; Bristol Myers Squibb): **56%**

Empagliflozin (**Jardiance**; Boehringer Ingelheim): **66%**

Rivaroxaban (**Xarelto**; Janssen Pharms): **62%**

Sitagliptin (**Januvia**; Merck Sharp Dohme): **79%**

Dapagliflozin (**Farxiga**; AstraZeneca AB): **68%**

Sacubitril/valsartan (**Entresto**; Novartis Pharms Corp): **53%**

Etanercept (**Enbrel**; Immunex Corporation): **67%**

Ibrutinib (**Imbruvica**; Pharmacyclics LLC): **38%**

Ustekinumab (**Stelara**; Janssen Biotech Inc): **66%**

Insulin aspart: **76%**

(including Fiasp, Fiasp FlexTouch, Fiasp PenFill, **NovoLog**, NovoLog Flexen, NovoLog PenFill; Novo Nordisk)

Pharmacy Times

The Bottom Line....

Congressional budget estimators (Congressional Budget Office) predicted:

- about \$100 **billion** savings over 10 years from drug negotiations, and
- a \$3.7 **billion** savings in the first year alone.

In the first year of negotiations, we are saving Medicare an estimated \$6 **billion** and Americans who pay out of pocket will be saving another \$1.5 **billion** moving forward.¹

1. Negotiating for Lower Drug Prices Works, Saves Billions. News release. CMS. August 15, 2024. Accessed August 15, 2024. <https://www.cms.gov/newsroom/press-releases/negotiating-lower-drug-prices-works-saves-billions>

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

- On February 15, 2016, Leonhartt began working for MedStar Health as a pharmacist.
- MedStar Health maintained a mandatory influenza vaccine policy. Plaintiff received and provided documentation of her annual influenza vaccination and never sought a religious accommodation to avoid Defendant's mandate.
- Plaintiff's supervisor described her as a “very good pharmacist,” “detail-oriented,” and “very by the book for safety.”
- At the beginning of the COVID-19 pandemic, before the wide-spread availability of vaccines, Plaintiff continued to work in-person and complied with masking and social-distancing requirements.
- Plaintiff worked in a “closed-door” facility where she had no interaction with patients or the public.

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

- On August 30, 2021, Kenneth Samet, Defendant's President/CEO, emailed that all MedStar personnel were required to be fully vaccinated against COVID-19 by November 1, 2021. Under Defendant's policy, "fully vaccinated" was defined as "receiving both doses of a two-dose COVID-19 vaccine (Pfizer or Moderna) or the single-dose COVID-19 vaccine (Johnson & Johnson)." In the August 30 email, Mr. Samet wrote "we will offer medical and religious exemptions."
- The policy allowed exemptions for a sincerely held religious belief, practice or observance.
- "If you are granted an exemption, you will not be required to receive the COVID-19 vaccine, **however you will be required to comply with alternative safety measures** to be determined by the Executive Vice President and Chief Medical Officer based on community prevalence, **which will include requirements for distancing, masking, and interval testing, among others** to reduce the risk of COVID-19 transmission to you, our patients, visitors, and fellow Associates."

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

- The religious exemption request required the following:
 - personally identifiable information,
 - identify their sincerely held religious belief, practice, or observance;
 - to explain how their sincerely held religious belief, practice, or observance applies in their daily life;
 - an explanation of how their religious belief, practice, or observance prevents them from complying with the Mandatory COVID-19 Vaccination Policy; and
 - explain if such religious belief, practice, or observance applies to all vaccines or just the COVID-19 Vaccine; and
 - an explanation as to why their religious beliefs apply to one vaccine but not others, if applicable.

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

- September 7, 2021: Plaintiff submitted a religious exemption request including:
 - a notarized affidavit of her “Religious Belief for Exemption from Mandatory COVID-19 Vaccination
 - a letter from her priest
 - two documents containing guidance from the Catholic Church
 - Congregation for the Doctrine of Faith's (“CDF”) “Note on the Morality of Using Some Anti-COVID-19 Vaccines”
 - CDF's “Instruction Dignitas Personae on Certain Bioethical Questions.”

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

- In her affidavit, Plaintiff declared: “I, Amy Leonhartt, am a practicing Catholic, and my belief is sincere and meaningful.”
- She proceeded to lay out three “moral objections to a mandatory covid vaccine program.”
 - **Objection #1:** “the moral aspects of the use of the vaccines that have been developed from cell lines derived from tissues obtained from two fetuses that were not spontaneously aborted;”
 - **Objection #2:** the use of “gene therapy” in the vaccines; and
 - **Objection #3:** the potential of facing the same moral quandary repeatedly, given the likelihood of mandatory booster shots.

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

- October 1, 2021, Defendant requested “full responses” to two follow up questions by October 6...
 - 1. Describe how long you have held this belief that you cannot use any product that has been tested for efficacy and safety on cells propagated from fetal cell lines.
 - 2. Describe fully what other steps you have taken to observe this belief that you cannot use any product that has been tested for efficacy and safety on cells propagated from fetal cell lines.
- MedStar stated: “If you do not provide full responses, your request will be denied, and, in accordance with the MedStar Health Mandatory COVID-19 Vaccination Policy, you will be required to become fully vaccinated by the November 1, 2021, deadline to maintain employment with MedStar Health.”

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

➤ October 6, 2021: **Plaintiff's response to Defendant's first follow-up question read:**

- I am a strict supporter of life.
- I do not believe that abortion is morally acceptable.
- I have been a practicing Catholic since confirmation at youth.
- I have been a religious education instructor and confirmation teacher at my parish.
- I instruct the youth at my parish on the immortality of abortion.
- I do not wish to support abortion in any way.
- When the debate over covid vaccine initiated last year, I researched the topic thoroughly. I am aware that the vaccines are grown in or are tested using fetal cell lines. I am aware of this fact, and I object.
- Other products have not been hot topic issues like the current Covid-19 mRNA vaccines. To my best knowledge, other products have not been mandated for continued employment or societal participation. The mandatory nature of these new vaccine policies is an important distinction to consider. Vaccination by these specific Covid-19 mRNA products is not my individual choice. The vaccine is mandatory by MedStar Health Policy. **As stated in my notarized affidavit of religious belief my first moral objection is the mandatory nature of MedStar Health's vaccine policy.**
- In line 5 from the Note on the Morality of Using Some Anti-Covid-19 vaccines, the CDF states, "... practice reason make evident that vaccination is not, as a rule, a moral obligation and that, therefore, vaccination must be voluntary."
- **If I submit to your vaccine mandate, I will fail my moral conscience** regarding supporting products that have been tested for efficacy and safety on cells from fetal cell lines.

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

- **October 6, 2021: Plaintiff's response to Defendant's second follow-up question read:**
 - Again, my objection is the mandatory nature of your vaccination policy. I am unaware at this time of any other mandatory employment requirements that I have not already met. If new mandatory health requirements arise that invoke my moral objection to using products that are tested using cells propagated from fetal cell lines, I will inform MedStar Health in the appropriate way.
- **October 14, 2021: Defendant resubmitted the same two follow-up questions by email to Plaintiff.**
- **October 18, 2021: Plaintiff reiterated the same responses set forth in her October 6 email.**

AMY LEONHARTT, v. MEDSTAR HEALTH, INC., Case No. 1:23-CV-01211-JRR, Signed March 7, 2025

- **October 20, 2021:** Defendant issued Plaintiff a final denial of her religious exemption request saying that Plaintiff failed to sufficiently establish that her religious belief, practice or observance was sincerely held, and instructed Plaintiff that she must become fully vaccinated by November 1, 2021, to maintain employment with Defendant.
- **November 5, 2021:** Defendant notified Plaintiff that she was suspended, without pay, effective November 7 for failure to comply with the COVID-19 Vaccination Policy and that she would be terminated from her position if she did not provide proof of vaccination by November 14.
- **November 17, 2021:** MedStar terminated Plaintiff from her position.

The Complaint....

- Plaintiff filed a charge of discrimination with the Equal Employment Opportunity Commission (“EEOC”) alleging religious discrimination.
- The EEOC issued a Notice of Right to Sue on February 28, **2023**, and Plaintiff timely filed the instant action within 90 days of her receipt of the notice.
- **May 8, 2023:** Plaintiff filed the instant Complaint alleging:
 - failure to accommodate, and
 - wrongful termination claims under Title VII of the Civil Rights Act of 1964 and the Maryland Fair Employment Practices Act
- Defendant moved for summary judgment on all counts following the close of discovery.
- Plaintiff opposed the motion and cross-moved for partial summary judgment on liability.

STANDARD OF REVIEW FOR SUMMARY JUDGMENT

Sound familiar?.....

- The moving party must show that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”
 - A material fact is one that “might affect the outcome of the suit.”
 - A genuine dispute of material fact exists “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.”
- A judge's function is limited to determining whether sufficient evidence exists on a claimed factual dispute to warrant submission of the matter to a jury for resolution at trial

The Court's Analysis....

- Courts judge discrimination and retaliation claims brought under state law by the same standards as those same claims brought under Title VII.
- **Courts generally recognize two theories for asserting religious discrimination claims: failure to accommodate and disparate treatment.**
- The record presents no genuine dispute of material fact as to the sincerity of Plaintiff's Catholic belief and anti-abortion convictions.
- Courts in this particular District have found allegations of a religious objection to receiving the COVID-19 vaccine based on the use of aborted fetal tissue in the vaccine's development sufficient to state a claim

The Court's Analysis....

- Plaintiff supported the religious nature of her opposition to the vaccine and to Defendant's policy by specific citation to her Church's guidance.
- The court disagrees with the Defendant that Plaintiff's exemption request amounts to a claim of a blanket privilege.
 - Plaintiff relied on the guidance from the Church to which she belongs regarding the religious quandary she perceived between her employer's vaccine policy and her personal opposition to the use of aborted fetal cells.
- Plaintiff did **not** object to Defendant's mandatory **influenza** vaccination policy. Her objection, therefore, to the COVID-19 vaccination policy is the mandatory requirement that she receive a vaccine that was developed using fetal cell lines, not to any mandatory health policy.

The Court's Analysis....

- Defendant repeatedly stated that Plaintiff failed to answer the follow-up questions; but this Court stated this assertion was not supported by the record.
- Considering the undisputed facts and the cited precedent, the court concluded there is no genuine dispute of material fact as to the religious nature of Plaintiff's stated opposition to the vaccine on the grounds that it was developed with fetal cell lines.
 - ✓ **Objection #1:** “the moral aspects of the use of the vaccines that have been developed from cell lines derived from tissues obtained from two fetuses that were not spontaneously aborted;”

The Court's Analysis....

- Plaintiff's objection #2 and #3 were based on the potential need to receive booster shots... which was not in conflict with her employer's policy and included the Johnson & Johnson vaccine as a means of compliance which doesn't use the same contested technology.
 - Plaintiff could've gotten the Johnson & Johnson vaccine.
 - **Plaintiff does not address or dispute this contention.**
- ❖ **Objection #2:** the use of “gene therapy” in the vaccines; and
- ❖ **Objection #3:** the potential of facing the same moral quandary repeatedly, given the likelihood of mandatory booster shots.

The Court's Analysis....

- Defendant declined to provide Plaintiff with her requested accommodation and submits no evidence to suggest that providing such accommodation would have posed an undue hardship; indeed, Defendant does not address the feasibility of accommodating Plaintiff...thus...
- Based on the undisputed facts and applicable law, Plaintiff has demonstrated that Defendant discriminated against her based on her religion by failing to accommodate her religious exemption request.
- However.....

The Court's Analysis....

- Plaintiff introduces no evidence to suggest, or on which a reasonable conclusion could be based, that other employees engaged in similar conduct—namely, refused to be vaccinated in violation of the policy—and were not fired or were treated less harshly.
- Plaintiff fails to generate a triable issue as to her disparate-treatment religious discrimination claim and Defendant is entitled to judgment on same.
 - Plaintiff didn't not respond to Defendant's argument that she failed to establish a disparate-treatment religious discrimination claim
- **So What Now??....Drum Roll....**

The Ruling:

- Defendant's Motion will be granted in part and denied in part, and Plaintiff's Motion for Partial Summary Judgment will be granted in part and denied in part.

The Bottom Line: In the quagmire of claims, the ones the court granted summary judgment on for either party will end, while the ones that were not will continue to trial for a jury to decide.

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Questions or Comments??

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**The moment you become more convinced about what is in you than afraid of what is against you,
then you are about to push the limits of what is possible for your life.**

(I Corinthians 6:19, Acts 1:8, Acts 2:38, Romans 15:13, John 14:16-17, John 14:26, Isaiah 11:2, Micah 3:8, Acts 2:4)