

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF
MISSISSIPPI, SOUTHERN DIVISION

Vapor Technology Association, et al. v. Chris Graham, Mississippi
Commissioner of Revenue

Vapor Technology Association v. Graham, No. 1:25cv336-LG-BWR (S.D. Miss. Nov. 25, 2025) · No.
1:25cv336-LG-BWR · Decided November 25, 2025

SUMMARY

The United States District Court for the Southern District of Mississippi denies plaintiffs’ motions for a temporary restraining order and preliminary injunction challenging Mississippi HB 916. The court holds that plaintiffs have not shown entitlement to a TRO and are unlikely to succeed on their claim that the statute, which regulates the sale of electronic nicotine delivery systems and establishes a directory of FDA-authorized products, is preempted by the Federal Food, Drug, and Cosmetic Act. The opinion also addresses the federal enforcement authority and enforcement-discretion arguments raised by plaintiffs.

CASE DETAILS

COURT	United States District Court for the Southern District of Mississippi, Southern Division
WRITING FOR THE COURT	Louis Guirola, Jr.
JURISDICTION	United States District Court for the Southern District of Mississippi, Southern Division
DECIDED	November 25, 2025
DOCKET	1:25cv336-LG-BWR
DISPOSITION	other
PROCEDURAL POSTURE	Plaintiffs sought a temporary restraining order and preliminary injunction barring enforcement of Mississippi HB 916, and separately moved to strike defense exhibits. The district court denied all motions.
STANDARD OF REVIEW	A TRO without notice requires specific facts showing immediate and irreparable injury before the adverse party can be heard, together with the attorney certification required by Federal Rule of Civil Procedure 65(b)(1). A preliminary injunction requires a substantial likelihood of success on the merits, a substantial threat of irreparable injury, a balance of harms favoring relief, and consistency with the public

	interest. At the preliminary-injunction stage, the court may rely on otherwise inadmissible evidence, including hearsay.
PRECEDENTIAL VALUE	unpublished district court memorandum opinion; persuasive authority only
PARTIES	Vapor Technology Association, et al., One distributor of synthetic-nicotine ENDS products, Nine Mississippi retailers of synthetic-nicotine ENDS products v. Chris Graham, Mississippi Commissioner of Revenue

TOPICS

injunctions preemption equal protection fda regulation civil procedure

PRACTICE AREAS

health law constitutional law administrative law civil procedure remedies

QUESTIONS PRESENTED

1. Whether plaintiffs were entitled to a temporary restraining order under Federal Rule of Civil Procedure 65(b)(1).
2. Whether plaintiffs demonstrated a substantial likelihood of success on their claim that Mississippi HB 916 is conflict-preempted by the Federal Food, Drug, and Cosmetic Act and the Tobacco Control Act.
3. Whether plaintiffs demonstrated a substantial likelihood of success on their federal and state equal-protection claims based on HB 916's different treatment of tobacco-derived and synthetic nicotine products.
4. Whether defense exhibits should be stricken at the preliminary-injunction stage because they included hearsay evidence.

HOLDINGS

1. Plaintiffs were not entitled to a temporary restraining order because they did not demonstrate immediate and irreparable harm before the defendant could be heard in opposition.
2. Plaintiffs failed to show a substantial likelihood of success on their claim that HB 916 is preempted by federal law; the court concluded that HB 916 was unlikely to be an obstacle to the FDA's premarket authorization process or enforcement objectives.
3. Plaintiffs failed to show a substantial likelihood of success on their equal-protection claims because the challenged distinction between tobacco-derived and synthetic nicotine products had at least a conceivable rational basis.
4. The motion to strike was denied because, at the preliminary-injunction stage, the court may consider otherwise inadmissible evidence, including hearsay.

KEY QUOTATIONS

“State laws regulating health and safety are entitled to a presumption against preemption because those matters fall within the state’s traditional police powers.” (Discussion § II.A)

“The Supremacy Clause gives priority to ‘the Laws of the United States,’ not the criminal law enforcement priorities or preferences of federal officers.” (Discussion § II.A)

“Plaintiffs are not entitled to a preliminary injunction since they have not met their burden of demonstrating a substantial likelihood of success on the merits of either of their claims.” (Conclusion)

FACTUAL BACKGROUND

Mississippi enacted HB 916, effective July 1, 2025, requiring the Commissioner of Revenue to maintain a directory of electronic nicotine delivery systems authorized by the FDA and generally prohibiting the sale in Mississippi of products not listed in the directory. The statute contains an exception for certain tobacco-derived nicotine ENDS products marketed as of August 8, 2016, and submitted to and accepted for filing by the FDA by September 9, 2020. Plaintiffs, consisting of trade associations, a distributor, and retailers of synthetic-nicotine ENDS products, alleged that HB 916 was preempted by the Federal Food, Drug, and Cosmetic Act and violated equal protection by treating tobacco-derived and synthetic nicotine products differently.

PROCEDURAL HISTORY

Plaintiffs filed suit and moved for emergency relief on November 13, 2025. The court ordered expedited briefing and heard oral argument on November 24, 2025. On November 25, 2025, the court denied the motions for a temporary restraining order, preliminary injunction, and to strike exhibits.

DISPOSITION

other

CASES CITED

- Shenzhen IVPS Tech. Co., Ltd. v. Food & Drug Admin., 148 F.4th 306 (5th Cir. 2025)
- Food & Drug Admin. v. R. J. Reynolds Vapor Co., 606 U.S. 226 (2025)
- Janvey v. Alguire, 647 F.3d 585 (5th Cir. 2011)
- Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ., 98 F.4th 220 (5th Cir. 2024)
- Bluefield Water Ass'n, Inc. v. City of Starkville, 577 F.3d 250 (5th Cir. 2009)
- City of El Cenizo v. Texas, 890 F.3d 164 (5th Cir. 2018)
- Arizona v. United States, 567 U.S. 387 (2012)
- CSX Transp., Inc. v. Easterwood, 507 U.S. 658 (1993)
- Zyla Life Scis., L.L.C. v. Wells Pharma of Houston, L.L.C., 134 F.4th 326 (5th Cir. 2025)
- AbbVie, Inc. v. Fitch, 152 F.4th 635 (5th Cir. 2025)
- Kansas v. Garcia, 589 U.S. 191 (2020)
- Oneok, Inc. v. Learjet, Inc., 575 U.S. 373 (2015)

- Lofton v. McNeil Consumer & Specialty Pharms., 672 F.3d 372 (5th Cir. 2012)
- Villas at Parkside Partners v. City of Farmers Branch, 726 F.3d 524 (5th Cir. 2013)
- Wisconsinites for Alts. to Smoking & Tobacco, Inc. v. Casey, No. 25-CV-552-WMC, 2025 WL 2582099 (W.D. Wis. Sept. 5, 2025)
- R.J. Reynolds Tobacco Co. v. County of Los Angeles, 29 F.4th 542 (9th Cir. 2022)
- U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 708 F.3d 428 (2d Cir. 2013)
- Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)
- Eckhardt v. Qualitest Pharms., Inc., 751 F.3d 674 (5th Cir. 2014)
- Morris v. PLIVA, Inc., 713 F.3d 774 (5th Cir. 2013)
- Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000)
- Williamson v. Mazda Motor of Am., Inc., 562 U.S. 323 (2011)
- Wyeth v. Levine, 555 U.S. 555 (2009)
- Heckler v. Chaney, 470 U.S. 821 (1985)
- City of Cleburne v. Cleburne Living Ctr., Inc., 473 U.S. 432 (1985)
- Gibson v. Tex. Dep't of Ins., 700 F.3d 227 (5th Cir. 2012)
- Vill. of Willowbrook v. Olech, 528 U.S. 562 (2000)
- Glass v. Paxton, 900 F.3d 233 (5th Cir. 2018)
- Integrity Collision Ctr. v. City of Fulshear, 837 F.3d 581 (5th Cir. 2016)
- Iowans for Alts. to Smoking & Tobacco, Inc. v. Iowa Dep't of Revenue, 781 F. Supp. 3d 724 (S.D. Iowa 2025)
- Sierra Club, Lone Star Chapter v. F.D.I.C., 992 F.2d 545 (5th Cir. 1993)
- Vapor Tech. Ass'n v. Wooten, No. 4:25-CV-00076-M-RJ, 2025 WL 1787420 (E.D.N.C. June 27, 2025)

OPINION

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI SOUTHERN DIVISION VAPOR TECHNOLOGY ASSOCIATION, et al. PLAINTIFFS v. CAUSE NO. 1:25cv336-LG-BWR CHRIS GRAHAM, Mississippi Commissioner of Revenue DEFENDANT MEMORANDUM OPINION AND ORDER DENYING PLAINTIFFS' MOTIONS FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION In this lawsuit Plaintiffs challenge a recently enacted Mississippi statute, HB 916.

On November 13, 2025, Plaintiffs filed an [2] Urgent and Necessitous Motion for Temporary Restraining Order pursuant to Fed. R. Civ. P. 65(b) and Preliminary Injunction pursuant to Fed. R. Civ. P. 65(a). The Court ordered expedited briefing and heard oral arguments on November 24, 2025.

In addition, Plaintiffs filed a [13] Motion to Strike several of Defendant's exhibits. After careful consideration of the Motions, briefs, legal authority and arguments of counsel, the Court finds that

Plaintiffs' Motions should be denied. BACKGROUND The Federal Food, Drug, and Cosmetic Act (FDCA) provides that certain products must be approved by the Food and Drug Administration (FDA) before they can be sold in the United States.

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA). The TCA extended the FDA's regulatory authority to "new tobacco products." See 21 U.S.C. § 387j. Under the TCA, [t]obacco products that were not on the market as of February 15, 2007, must obtain marketing authorization from FDA. § 387j(a)(1)(A)– (a)(2)(A). FDA provides three pathways to obtain marketing authorization: (1) a premarket tobacco product application ("PMTA"); (2) a substantial equivalence report (only available if the applicant can show the tobacco product "is substantially equivalent" to one on the market as of February 15, 2007); and (3) a substantial equivalence exemption report. §§ 387j(a)(2)(A)–(B), 387e(j).

Shenzhen IVPS Tech. Co., Ltd. v. Food & Drug Admin., 148 F.4th 306, 310 (5th Cir. 2025). Initially, the FDA did not consider electronic nicotine delivery systems ("ENDS"), such as e-cigarettes, vape pens, and personal vaporizers, as "new tobacco products." However, in 2016, the FDA deemed these items "tobacco products" subject to the TCA. *Id.* at 309–10 (citing *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act*, 81 Fed.

Reg. 28,974, 29,028 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143)). Given the size of the e-cigarette market, pulling products from the shelves while manufacturers sought 'premarket' authorization to sell them would have been disruptive.

To mitigate the disruption, the FDA announced that it would defer enforcement of the TCA against e-cigarette manufacturers and retailers while the manufacturers sought FDA approval. *Food & Drug Admin. v. R. J. Reynolds Vapor Co.*, 606 U.S. 226, 230 (2025) (quoting 81 Fed. Reg. at 29009–15). It is undisputed that the deferred enforcement period has now expired.

Consequently, the FDA "may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period." 81 Fed. Reg. at 29010. In 2022 Congress amended the TCA defining "tobacco product" as: any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

21 U.S.C. § 321rr(2). As a result, synthetic nicotine products became subject to FDA's authority even though they are not derived from tobacco. On March 20, 2025, Mississippi Governor Tate Reeves signed HB 916. The law went into effect on July 1, 2025.

The statute is codified at Miss. Code Ann. § 75- 102-1 and § 75-102-2. It requires the Mississippi Commissioner of Revenue to create and maintain a state cigarette directory listing ENDS products that have been authorized by the FDA. Miss. Code Ann. § 75-102-2(7). HB 916 provides that

“ENDS product:” (i) Means any noncombustible product that employs a heating element, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size, to produce vapor from nicotine in a solution; (ii) Includes a consumable nicotine liquid solution suitable for use in an ENDS product, whether sold with the product or separately; and (iii) Does not include any product regulated as a drug or device under Chapter V of the Federal Food, Drug, and Cosmetic Act (21 USC Section 351 et seq.).

Miss. Code Ann. § 75-102-1(c). Generally, products not listed in the FDA directory cannot be sold in Mississippi. § 75-102-2(10)(a). However, HB 916 contains an exception for every “ENDS product containing nicotine derived from tobacco marketed in the United States as of August 8, 2016, that was submitted to the [FDA] or before September 9, 2020, and accepted for filing.” § 75-102-1(d).

The statute imposes both civil and criminal penalties for those violating its requirements. § 75-102-2(11)(a). The Plaintiffs consist of two industry trade associations whose members include manufacturers and sellers of synthetic nicotine ENDS products “that are the subject of timely[-]filed PMTAs pending before the FDA and are still undergoing FDA review”; one distributor “who exclusively sold ENDS products containing non- tobacco-derived nicotine to Mississippi retailers across the Mississippi Gulf Coast”; and nine retailers who sold ENDS synthetic nicotine products to Mississippi consumers prior to the enactment of HB 916.

Compl. [1] at 4–6. Plaintiffs seek a temporary restraining order (“TRO”) and a preliminary injunction to prohibit enforcement of HB 916. According to Plaintiffs, HB 916 is preempted by the FDCA. They further claim that HB 916 violates their right to equal protection under both federal and state law because the Mississippi statute treats tobacco-derived nicotine products differently than synthetic nicotine products.

In support of their preemption claim, Plaintiffs allege: HB 916 regulates unapproved ENDS products in different ways. It does not simply prohibit the sale of the same products that FDA prohibits. Instead, it prohibits the sale of some products that the FDA has not prohibited, namely, ENDS products which are the subject of still pending PMTAs filed after September 9, 2020.

The statute does interfere with the FDA’s exclusive enforcement authority because the FDA has already explained why it has decided to let unapproved ENDS products remain on the market. The FDA has explicitly announced its policy of addressing unapproved ENDS products on a case-by-case basis.... Pls.’ Mem.

[15] at 3. Plaintiffs cite the April 2020 FDA guidance that expresses its priority in enforcing premarket requirements for (1) “flavored, cartridge-based ENDS products,” (2) other ENDS products for which manufacturers fail to take adequate measures to protect minors; (3) ENDS products targeted to or marketed to minors; and (4) “any ENDS product that is offered for sale in

the United States after September 9, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).” Pls.’ Mot., Ex. B [2-2] at 10–11.

FDA seeks both (1) to avoid foreclosing, even if temporarily, one potential means by which some adult smokers might seek to transition completely away from combusted tobacco products to potentially less harmful tobacco products; and (2) to prevent minors’ access to ENDS products. FDA believes that this policy strikes an appropriate balance between restricting youth access to ENDS products and maintaining availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted tobacco products.

Id. at 24. The FDA has explained that it will make enforcement decisions on a case-by- case basis, “recognizing that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product, and that it needs to make the best use of Agency resources.” Id. at 11.

The FDA emphasized that “[t]his guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization, or to sell any tobacco product to minors.” Id. It “retains discretion to pursue enforcement action at any time against any deemed new tobacco product marketed without premarket authorization, regardless of whether it falls within one of these categories of enforcement priorities.” Id.¹ The FDA has also clarified that “it is illegal to sell or distribute new tobacco products that the FDA has not authorized,” regardless of whether the product contains tobacco-derived nicotine or synthetic nicotine.

Id. DISCUSSION I. PLAINTIFFS’ MOTION FOR A TRO The Federal Rules of Civil Procedure provide: The court may issue a temporary restraining order without written or oral notice to the adverse party or its attorney only if: (A) specific facts in an affidavit or a verified complaint clearly show that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition; and (B) the movant’s attorney certifies in writing any efforts made to give notice and the reasons why it should not be required.

Fed. R. Civ. P. 65(b)(1). Plaintiffs have not alleged or demonstrated they will suffer immediate and irreparable harm before Defendant “can be heard in opposition[.]” See id. Here, Plaintiffs served Defendant with the Complaint on November 13, 2025, and Defendant has conveyed opposition to the Motion by response, memorandum brief, and presentation of oral argument to the Court.

As a result, Plaintiffs are not entitled to a TRO. II. PLAINTIFFS’ MOTION FOR A PRELIMINARY INJUNCTION To obtain a preliminary injunction, a plaintiff must demonstrate the 1 In September 2021, the FDA issued an update on its review process, and it reiterated that all

new tobacco products on the market without premarket authorization are “marketed unlawfully and subject to enforcement at the FDA’s discretion.” See Pls.’ Mot., Ex. I [2-9] at 3.

The FDA expressed its commitment to “review the remaining products as quickly as possible to provide regulatory certainty....” *Id.* following four elements: (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.

Janvey v. Alguire, 647 F.3d 585, 595 (5th Cir. 2011). The first two elements “are the most critical.” *Career Colls. & Schs. of Tex. v. U.S. Dep’t of Educ.*, 98 F. 4th 220, 233 (5th Cir. 2024). “And there is authority that likelihood of success on the merits is the most important [element]....” *Id.* “[A] preliminary injunction is an extraordinary remedy which should not be granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements.” *Bluefield Water Ass’n, Inc. v. City of Starkville*, 577 F.3d 250, 253 (5th Cir.

2009) (citation modified). A. PLAINTIFFS’ PREEMPTION CLAIM Under the United States Constitution, “both the National and State Governments have elements of sovereignty the other is bound to respect.” *City of El Cenizo v. Texas*, 890 F.3d 164, 176 (5th Cir. 2018) (quoting *Arizona v. United States*, 567 U.S. 387, 398 (2012)).

However, the Constitution’s Supremacy Clause provides that federal legislation “shall be the supreme Law of the Land.” *Id.* (quoting U.S. Const. art. VI, cl. 2). Thus, “[w]here a state statute conflicts with, or frustrates, federal law, the former must give way.” *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663 (1993) (citing U.S. Const. art. VI, cl. 2). “But barring any contradiction, the States retain their sovereign prerogatives to regulate.” *Zyla Life Scis., L.L.C. v. Wells Pharma of Houston, L.L.C.*, 134 F.4th 326, 328 (5th Cir.

2025). State laws regulating health and safety are entitled to a presumption against preemption because those matters fall within the state’s traditional police powers. *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 646 (5th Cir. 2025). “In keeping with this presumption, when there is doubt about preemption, the tie goes to the state.” *Id.* at 645 (citation modified).² Since HB 916 regulates the health and safety of its citizens, the presumption against preemption applies here.

The Supreme Court has recognized two types of preemption—express and implied. *Zyla*, 134 F.4th at 328 (citing *Kansas v. Garcia*, 589 U.S. 191, 202–03 (2020)). “Implied preemption is further divided into two types: field preemption and conflict preemption.” *Id.* “[C]onflict preemption exists where compliance with both state and federal law is impossible, or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015) (citation modified). “In all these types of preemption, however, evidence of pre-emptive purpose must be sought in the text

and structure of the federal provision at issue.” *Id.* at 329 (citation modified) (quoting *Easterwood*, 507 U.S. at 664).

2 Plaintiffs cite *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012), for the proposition that “the validity of such a presumption is ‘uncertain.’” *Pls.’ Reply* [15] at 1 n.1. However, the *Lofton* decision is distinguishable here because the court merely held, “[W]hatever value or relevance a presumption against preemption of state tort law should play is uncertain.” 672 F.3d at 378 (emphasis added).

In addition, this Court previously determined that “*Lofton’s* statements about the scope of the presumption against preemption do not mean that the presumption against preemption no longer applies.” *AbbVie Inc. v. Fitch*, No. 1:24-CV-184-HSO-BWR, 2024 WL 3503965, at *9 (S.D. Miss. July 22, 2024), *aff’d*, 152 F.4th 635 (5th Cir. 2025). Plaintiffs argue HB 916 is preempted because it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Pls.’ Mem.*

[3] at 16 (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). The question of whether a state statute is a sufficient obstacle “is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects.” *Villas at Parkside Partners v. City of Farmers Branch*, 726 F.3d 524, 528 (5th Cir.

2013) (emphasis added). The FDCA, as amended by the TCA, contains the following preservation clause: [N]othing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of... a State or political subdivision of a State... to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products.

21 U.S.C. § 387p(a)(1). This preservation clause is limited by the following preemption clause: No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products. § 387p(a)(2)(A).

However, Congress included a savings clause providing that the preemption clause “does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, the advertising and promotion of, or use of, tobacco products by individuals of

any age[.]” § 387p(a)(2)(B). “Courts have found that the inclusion of these three clauses in § 387p was a deliberate choice by Congress not to ‘broadly jettison the longstanding tradition of states and localities’ role in the regulation of sales of tobacco products when it enacted the TCA in 2009.” *Wisconsinites for Alts. to Smoking & Tobacco, Inc. v. Casey*, No. 25-CV-552-WMC, 2025 WL 2582099, at *5 (W.D.

Wis. Sept. 5, 2025) (citation modified) (quoting *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542, 549–50 (9th Cir. 2022)); see also *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013) (noting that Congress made an “explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco products”).

The Ninth Circuit explained that “the better understanding [of § 387p(a)’s trio of clauses] is that Congress intended to allow the federal government the sole authority to set tobacco product standards, while retaining for states and localities their longstanding authority to say: ‘not here.’” *County of Los Angeles*, 29 F.4th at 560.

For this reason, Plaintiffs’ reliance on cases in which a patient filed a lawsuit concerning some aspect of the FDA’s standards or approval process are distinguishable.³ See, e.g., *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341. Plaintiffs claim, “Implied preemption precludes state tort claims that ‘exist solely by virtue of’ the federal regulatory scheme.” Pls.’ Reply [15] at 3 (emphasis added) (quoting *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 868 n.6 (5th Cir.

2017)). But the (2001) (plaintiff sued manufacturer for making fraudulent statements to the FDA during the regulatory process); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674 (5th Cir. 2014) (plaintiff claimed manufacturer should have unilaterally changed label on drug even though prohibited by the FDA); *Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013) (plaintiff could not sue generic drug manufacturer for failing to use a label not required by the FDA).

Here, HB 916 does not interfere with FDA’s standards for approving products or labels. It merely adopts the FDA’s list of approved products. Moreover, the preservation clause likely applies to HB 916 inasmuch as it is a state law regulating tobacco product sales that was enacted “in addition to” the requirements established by the TCA. See § 387p(a)(l). Furthermore, the preemption clause does not apply since HB 916 concerns the sale of tobacco products.

See § 387p(a)(2)(B).⁴ Nevertheless, Plaintiffs argue that “neither the Savings Clause nor the express Preemption Clause affects Plaintiffs’ claim that 21 U.S.C. § 337(a) preempts HB 916 under the doctrine of implied conflict preemption” because those clauses do not “bar the ordinary working of conflict pre-emption principles.” Pls.’ Mem.

[3] at Zyla decision is more applicable to the present case than the tort cases cited by Plaintiffs because it addresses implied preemption of state statutes. See *Zyla*, 134 F.4th at 330. This case does not concern a state tort claim; it concerns a state statute. ⁴ Plaintiffs claim that the preemption

clause implemented by the TCA causes HB 916 to be preempted because it changes the FDA's premarket review process.

Assuming this is correct, the TCA's savings clause limits the scope of the preemption clause. Statutes regulating tobacco sales, like HB 916, are not preempted. 22. Plaintiffs rely on two Supreme Court opinions—*Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000), and *Buckman*, 531 U.S. at 352.

In *Geier*, the Supreme Court addressed the effect of a preemption clause and savings clause. *Geier*, 529 U.S. at 869. The preemption provision provided: Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment, any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.

Id. at 867 (emphasis added) (citation modified) (quoting 15 U.S.C. § 1392(d) (1988 ed.)). The savings clause provided that “compliance with a federal safety standard does not exempt any person from any liability under common law.” *Id.* at 868 (citation modified) (quoting 15 U.S.C. § 1397(k) (1988 ed.)).

The *Geier* Court explained that the savings clause “remove[d] tort actions from the scope of the express pre-emption clause.” *Id.* at 869. It noted, “The two provisions, read together, reflect a neutral policy, not a specially favorable or unfavorable policy, toward the application of ordinary conflict pre-emption principles.” *Id.* at 870–71. That is not the situation presented here.

Unlike the statute at issue in *Geier*, the FDCA contains a preservation clause that cannot be said to “reflect a neutral policy... toward the application of ordinary conflict pre-emption principles.” See *id.* Rather, it clearly provides that, “[N]othing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of... a State... to enact... any law... relating to or prohibiting the sale... of tobacco products.” See 21 U.S.C. § 387p(a)(1) (emphasis added).

Furthermore, “[t]he majority and dissent in *Geier* agreed that ‘a court should not find pre-emption too readily in the absence of clear evidence of a conflict.’” *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 337 (2011) (Sotomayor, J., concurring) (quoting *Geier*, 529 U.S. at 885). Justice Sotomayor emphasized “the Court’s rejection of an overreading of *Geier* that has developed since that opinion was issued.” *Id.* Nevertheless, out of an abundance of caution, the Court will address whether HB 916 conflicts with the FDCA.

Plaintiffs claim there is a conflict because “Congress intends for the Federal Government to have the sole authority to enforce the FDCA’s tobacco, drug, medical device, and cosmetic provisions.” *Pls.’ Mem.* [3] at 16–17 (citation modified). They rely on the following provision of the FDCA in

support of this argument: “[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter, shall be by and in the name of the United States.” See 21 U.S.C. § 337(a).

Additionally, Plaintiffs cite *Buckman Co. v. Plaintiffs’ Legal Committee*, where the Supreme Court noted, “[T]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the chapter.” 531 U.S. at 349 n.4 (2001).

However, the Fifth Circuit recently cautioned that the *Buckman* decision “must be understood in context.” *Zyla*, 134 F.4th at 338. “[T]he plaintiffs in *Buckman*... sought to wield state law to vindicate a wrong committed against the Federal Government.

The plaintiffs were hurt by that wrongdoing only incidentally.” *Id.* at 337. “*Buckman* holds that the FDCA’s allocation of enforcement to the Federal Government forecloses non-federal actors from policing wrongdoing against the Federal Government.” *Id.* at 338 (citation modified). 5 The Fifth Circuit decision in *Zyla* concerned six state statutes that “mirror[ed] federal law by making it illegal to sell any new drug that has not been approved under [the FDCA].” *Id.* at 330.

Zyla Life Sciences sued its competitor, Wells Pharma, claiming it violated those state statutes. *Id.* at 331. The issue before the Fifth Circuit was “whether the state laws somehow conflict with the FDCA by incorporating it.” *Id.* The Fifth Circuit rejected Wells Pharma’s argument that “allowing States to enforce their own parallel laws would upset the discretion given to federal officials in enforcing the FDCA.” *Id.* at 334.

It held that States are not prevented “from regulating everything federal law touches.” *Id.* at 335. The Court explained, “Because the States’ laws recognize the supremacy of the national law,.. it would be anomalous to conclude the Supremacy Clause some-how preempts them.” *Id.* at 332 (citation modified). Plaintiffs claim the *Zyla* court “clarified that preemption applies when a state 5 Plaintiffs’ argument that *Buckman* applies because “HB 916 wrongs the Federal Government by interfering with FDA enforcement decisions” is not well taken.

See Pls.’ Mem. [3] at 20 n.9. In *Buckman*, a plaintiff injured by bone screws attempted to assert a state law “fraud on the FDA claims” against “a consulting company that assisted the screws’ manufacturer... in navigating the federal regulatory process.” 531 U.S. 341, 343 (2001).

The Supreme Court held, “Policing fraud against federal agencies is hardly a field which the States have traditionally occupied.” *Id.* at 347. The present case is not an attempt to obtain third-party damages that resulted from a fraudulent misrepresentation made to the FDA. regulates the same conduct ‘in different ways.’” Pls’ Mem.

[3] at 19–20 (quoting *Zyla*, 134 F.4th at 336). Actually, the Fifth Circuit stated, “The [Supreme] Court held that States could regulate concurrently with the Federal Government the same primary

conduct related to drug safety and effectiveness in different ways without interfering with FDA oversight.” Zyla, 134 F.4th at 336 (citing *Wyeth v. Levine*, 555 U.S. 555, 574–75 (2009)).

The Zyla court reasoned, “If regulating the same primary conduct in different ways does not upset federal enforcement prerogatives, it follows a fortiori that regulating it in parallel ways does not either.” *Id.* at 336–37. Plaintiffs also argue that the Zyla decision is distinguishable because: HB 916 regulates unapproved ENDS products in different ways. It does not simply prohibit the sale of the same products that FDA prohibits.

Instead, it prohibits the sale of some products that the FDA has not prohibited, namely, ENDS products which are the subject of still pending PMTAs filed after September 9, 2020. Pls.’ Mem. [3] at 20. Plaintiffs claim HB 916 interferes with FDA’s enforcement authority because “[t]he FDA has explicitly announced its policy of addressing unapproved ENDS products on a case-by-case basis.” *Id.* at 21.

Furthermore, they argue that “HB 916 categorically forbids certain unapproved ENDS products while allowing other unapproved ENDS products to be sold.” *Id.* The Supreme Court has held, “[I]n the vast majority of cases where federal and state laws overlap, allowing the States to prosecute is entirely consistent with federal interests.” *Kansas*, 589 U.S. at 212.6 “[T]he possibility that federal 6 Plaintiffs’ reliance on *Heckler v. Chaney*, 470 U.S. 821 (1985), is misplaced.

Heckler held that the FDA’s decision not to enforce the FDCA’s requirements for lethal injection drugs was not subject to judicial review under the Administrative enforcement priorities might be upset is not enough to provide a basis for preemption.

The Supremacy Clause gives priority to ‘the Laws of the United States,’ not the criminal law enforcement priorities or preferences of federal officers.” *Id.* (quoting U.S. Const. art. VI, cl. 2). In Zyla, the Fifth Circuit reiterated this point while considering a preemption argument concerning the same FDCA provision at issue here—21 U.S.C. § 337. See Zyla, 134 F.4th at 334–36.

The Zyla court stated, “To preserve the federal system, we do not prevent the States from regulating everything federal law touches.” *Id.* at 335. 21 U.S.C. § 337(a) “only confers a cause of action upon the Federal Government to enforce the FDCA.” *Id.* at 338 n.8. It “says nothing about the States’ authority to provide remedies for violations of state law.” *Id.* Federal statutes that “grant the Executive Branch extensive enforcement discretion... do not preclude parallel or non-parallel state regulation of the same conduct.” *Id.* at 338 (emphasis added).

As a result, it follows that HB 916 is not preempted, regardless of whether it provides for parallel or non- parallel enforcement. Finally, Plaintiffs’ reliance on the 2020 FDA guidance⁷ and the 2023 FDA letter, which they have attached to their [2] Motion as Exhibits B and I respectively, is not persuasive. These exhibits merely express the FDA’s enforcement priorities Procedure Act because the FDCA grants the FDA complete enforcement discretion.

470 U.S. at 835, 838. 7 As Plaintiffs conceded at oral argument, Congress had not yet amended the FDCA to provide the FDA with jurisdiction over synthetic nicotine products when the FDA issued its 2020 guidance. As a result, the FDA likely did not contemplate the products at issue in this case when it issued the 2020 Guidance. in 2020 and 2023, not its current policies.

The priorities are temporary, and they were devised due to insufficient enforcement resources. Furthermore, the FDA cautioned that it is illegal to sell any products that have not been FDA-approved, and that it reserves the right of enforcement at any time regardless of its expressed priorities.

Finally, the FDA stated that it “is committed to the enforcement of federal laws, regulations, enforcement policy and priorities related to tobacco products, including disposable ENDS products” that contain synthetic nicotine and tobacco-derived nicotine. Pls.’ Mot., Ex. I [2-9] at 8. It is therefore unlikely that HB 916 constitutes an obstacle to the FDA’s premarket authorization process or its enforcement objectives.

For all these reasons, Plaintiffs have failed to meet their burden of demonstrating a substantial likelihood of success on the merits of their preemption claim.⁸ B. PLAINTIFFS’ EQUAL PROTECTION CLAIMS Plaintiffs claim that HB 916 violates their right to equal protection under both federal and state law. Plaintiffs note that HB 916 allows products on the market as of August 8, 2016, and for which a still pending premarket tobacco 8 Most sister courts that have considered whether similar state statutes are preempted have reached the same conclusion.

See, e.g., *Wisconsinites*, 2025 WL 2582099, at *8 (finding that plaintiffs did not show a reasonable likelihood of prevailing on the merits of their preemption claim); *Vapor Tech. Ass’n v. Wooten*, No. 4:25-CV-00076-M-RJ, 2025 WL 1787420, at *5 (E.D.N.C. June 27, 2025) (“Plaintiffs are highly unlikely to succeed on the merits of their preemption claim[.]”). But see *Iowans for Alts. to Smoking & Tobacco, Inc. v. Iowa Dep’t of Revenue*, 781 F. Supp. 3d 724, 741 (S.D.

Iowa 2025) (holding that a similar Iowa statute is preempted by federal law). application was filed by September 9, 2020, to be included in the state directory, and thus, protected from enforcement penalties. Plaintiffs claim the effect of this HB 916 provision is to protect some tobacco-derived ENDS products from enforcement while allowing enforcement for synthetic nicotine ENDS products.⁹ The Equal Protection Clause of the Fourteenth Amendment requires the government to treat all similarly situated people alike.

U.S. Const. amend. XIV; *City of Cleburne v. Cleburne Living Ctr. Inc.*, 473 U.S. 432, 439 (1985). The parties agree that the Mississippi Constitution does not contain an equal protection clause, but Plaintiffs cite authority recognizing the right under Mississippi law.¹⁰ Plaintiffs assert that the same standards apply under both federal and Mississippi law.

To succeed on an equal protection claim, a plaintiff must show it has been “intentionally treated differently from others similarly situated and that there is no rational basis for the difference in treatment.” *Gibson v. Tex. Dep’t of Ins.*, 700 F.3d 227, 238 (5th Cir. 2012) (citing *Vill. of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000)). “Under this standard, a legislative classification must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification.” *Glass v. Paxton*, 900 F.3d 233, 244–45 (5th Cir.

2018) (citation modified). “Moreover, the State need not articulate 9 Defendant asserts that there is no evidence to support Plaintiffs’ argument that “no tobacco-derived products fall outside the ‘safe harbor’ and no synthetic products fall within.” Def.’s Mem.

[12] at 18 n.7. He reserves the right to challenge the factual basis for Plaintiffs’ equal protection argument. 10 See *Sinclair v. State*, 132 So. 581, 586–87 (Miss. 1931) (Ethridge, J. concurring); 3 J. Jackson, M. Miller, & D. Campbell, *Encyclopedia of Miss. L.* § 19:50 n.16 (3d ed. 2020). its reasoning at the moment a particular decision is made. Rather the burden is on the challenging party to negative any reasonably conceivable state of facts that could provide a rational basis.” *Integrity Collision Ctr. v. City of Fulshear*, 837 F.3d 581, 589 (5th Cir.

2016) (citation modified). Plaintiffs attempt to meet this burden by asserting that “nicotine derived from tobacco and nicotine derived from non-tobacco sources are chemically identical, produce the same physiological effects, and are held to the same FDA toxicological and aerosol-analysis standards in PMTA review.” Pls.’ Mem.

[3] at 25 (citing Ex. N to Pls.’ Mot. [2-14]).¹¹ Defendant responds that HB 916’s enforcement exception for products on the market as of August 8, 2016, is rational because it is derived from the FDA’s 2020 guidance. Specifically, in the 2020 guidance, the FDA states it will prioritize enforcement of “any ENDS product that is offered for sale in the United States after September 9, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).” Pls.’ Mot., Ex. B [2-2] at 10–11 (emphasis added).

Defendant also cites *Iowans for Alternatives to Smoking & Tobacco, Inc.*, a decision where the court found the following rational bases for the same statutory provision: (1) “research suggesting that nicotine products labeled ‘tobacco-free’ may increase consumption among young adults due to misconceptions about health 11 Plaintiffs cite testimony given by the President and Chief Scientific Officer of an e-liquid corporation that is a member of Plaintiff Vapor Technology. risks”; (2) “synthetic nicotine products often employ marketing approaches—such as labels proclaiming ‘clean nicotine’ or ‘putting the flavor back in vaping’—that may create misleading impressions about relative safety compared to tobacco-derived nicotine”; and (3) synthetic nicotine products

became subject to the FDCA requirements at a later date, which justifies taking “a more cautious approach toward the more recently regulated synthetic alternatives.” 781 F. Supp. 3d at 743.

Defendant has provided copies of the articles relied on by the Iowa court when making these findings.¹² Defendant relied on FDA guidance when it included the exception now challenged by Plaintiffs, and to the extent that the exception may cause tobacco- derived nicotine and synthetic nicotine to be treated differently under HB 916, Defendant has produced scholarly articles that arguably justify the different treatment.

As a result, it is unlikely Plaintiffs can meet their burden of proof by demonstrating that there is no rational basis for Mississippi’s alleged differing treatment of synthetic nicotine products. Thus, Plaintiffs have failed to show a substantial likelihood of success on the merits of their equal protection claims. CONCLUSION A TRO is inappropriate here because Plaintiffs did not show they would suffer irreparable harm before Defendant could be heard in opposition.

In addition, 12 Plaintiffs have filed a [13] Motion to Strike those articles as hearsay. The Fifth Circuit has held that, “at the preliminary injunction stage, the procedures in the district court are less formal, and the district court may rely on otherwise inadmissible evidence, including hearsay evidence.” *Sierra Club, Lone Star Chapter v. F.D.I.C.*, 992 F.2d 545, 551 (5th Cir.

1993). Plaintiffs are not entitled to a preliminary injunction since they have not met their burden of demonstrating a substantial likelihood of success on the merits of either of their claims. Consequently, it is not necessary for the Court to address the other preliminary-injunction elements. IT IS THEREFORE ORDERED AND ADJUDGED that Plaintiffs’ [2] Motion for Temporary Restraining Order and Preliminary Injunction is DENIED.

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs’ [13] Motion to Strike Defendant’s Exhibits is DENIED. SO ORDERED AND ADJUDGED this the 25th day of November, 2025.
Louis Guirola, Jr. s/ LOUIS GUIROLA, JR. UNITED STATES DISTRICT JUDGE