

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT

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No. 18-14934

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D.C. Docket No. 6:18-cv-00613-GAP-DCI

ROBERT DANIEL TAYLOR,

Plaintiff-Appellant,

versus

LEANNE POLHILL, solely in her official capacity as a Member of the Florida  
Board of Hearing Aid Specialists, et al.,

Defendants-Appellees.

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Appeal from the United States District Court  
for the Middle District of Florida

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(July 1, 2020)

Before MARCUS, ANDERSON, and EBEL,\* Circuit Judges.

EBEL, Circuit Judge:

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\* The Honorable David M. Ebel, Senior United States Circuit Judge for the United States Court of Appeals for the Tenth Circuit, sitting by designation.

Plaintiff-Appellant Robert Daniel Taylor sued Defendants-Appellees, the members of the Florida Board of Hearing Aid Specialists and the Secretary of the Florida Department of Health, each in their official capacities, alleging that three Florida statutes administered by the Defendants are preempted by federal law and/or violate Taylor's due process rights. The district court dismissed the case in its entirety, dismissing one of Taylor's claims for lack of standing and the others for failure to state a claim upon which relief could be granted. Taylor challenges the district court's dismissal of his claims. Having jurisdiction under 28 U.S.C. § 1291, we AFFIRM the district court's dismissals for failure to state a claim upon which relief could be granted and REVERSE the district court's dismissal for lack of standing and REMAND to the district court for further proceedings consistent with this opinion.

## **I. BACKGROUND**

In 1976, Congress amended the Federal Food, Drug, and Cosmetics Act through passage of the Medical Device Amendments ("MDA") which, together with regulations promulgated by the Food & Drug Administration ("FDA"), created a federal regulatory scheme for different kinds of medical devices, including hearing aids. The MDA contains an express preemption provision, 21 U.S.C. § 360k, which preempts state laws which are "different from, or in addition

to” the federal requirements and “which relate[] to the safety or effectiveness of the device or to any other matter included in a [federal] requirement applicable to the device.” § 360k(a). This same section also provides for the FDA to create a process through which states can request exemptions from express preemption. § 360k(b); see 21 C.F.R. pt. 808 (providing a procedure for requesting exemption).<sup>1</sup>

Florida, like most states, has enacted its own statutory scheme regulating professions and occupations, which includes statutes applicable to those who fit and dispense hearing aids. Fla. Stat. §§ 484.0401 et seq. Three of those statutes are at issue in this case. The first, Fla. Stat. § 484.0501 (the “Pre-Sale Testing Statute”), requires that when fitting and selling hearing aids, pre-sale audiometric testing be conducted following specific minimum procedures and using specified equipment. The second, Fla. Stat. § 484.053 (the “Licensing Statute”), prohibits dispensing hearing aids without a state hearing aid specialist license or through improper or fraudulent use of a state hearing aid specialist license. The third, Fla. Stat. § 484.054 (the “Mail Order Ban”), bans all sales of hearing aids through the mail.

Taylor has been selling hearing aids in Florida for over thirty years and, until

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<sup>1</sup> Neither the constitutionality nor the validity of the FDA’s promulgated regulations is at issue in this litigation.

2016, Taylor was a licensed hearing aid specialist. In 2016, based on his belief that the pre-sale testing requirements established by Florida's statutory scheme were preempted by the MDA, he did not renew his license. Taylor did not cease his business, but rather continued selling hearing aids utilizing the testing procedures he believes are necessary. Taylor was cited by Defendants for selling hearing aids without a license, and he was assessed a civil fine, which he paid.

Taylor then filed this suit against the members of the Florida Board of Hearing Aid Specialists and the Secretary of the Florida Board of Health, in their official capacities, alleging that the three aforementioned Florida statutes are unconstitutional because all three are preempted by federal law and because the Pre-Sale Testing Statute infringes on his due process rights. Taylor sought prospective declaratory and injunctive relief. The Defendants filed a motion to dismiss Taylor's complaint, which the district court granted.

The district court dismissed Taylor's challenges to the Pre-Sale Testing Statute for lack of standing, and it dismissed Taylor's challenges to the Licensing Statute and the Mail Order Ban for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Taylor appeals the dismissal of all of his claims.

Because this appeal arises from a motion to dismiss, our review is de novo, "accepting the allegations in the complaint as true and construing them in the light most favorable to the plaintiff." Timson v. Sampson, 518 F.3d 870, 872 (11th Cir.

2008).

## II. DISCUSSION

The district court concluded that Taylor (1) did not have standing to challenge the Pre-Sale Testing Statute; (2) failed to state a claim as to the Licensing Statute; and (3) failed to state a claim as to the Mail Order Ban. We address these conclusions in turn.

### A. Standing to Challenge the Pre-Sale Testing Statute

The district court determined that, because the Pre-Sale Testing Statute imposes requirements on licensed hearing aid sellers, and because Taylor is not and does not intend to become a licensed hearing aid seller, the Pre-Sale Testing Statute neither applies to nor poses a threat of future injury to Taylor. Thus, the district court concluded that Taylor does not have standing to challenge the Pre-Sale Testing Statute.<sup>2</sup> We disagree.<sup>3</sup>

Article III, Section 2 of the United States Constitution limits our jurisdiction to cases and controversies; consequently, plaintiffs wishing to utilize the federal courts must establish that they have standing for each of their claims. U.S. Const.

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<sup>2</sup> The standing analysis applies equally to Taylor's preemption claim and his due process claim challenging the Pre-Sale Testing Statute.

<sup>3</sup> The court below did not reach the merits of Taylor's challenges to the Pre-Sale Testing Statute; thus, we limit our review to whether Taylor has standing to challenge the Pre-Sale Testing Statute, and we do not express an opinion as to the merits of either Taylor's preemption challenge or his due process challenge to the Pre-Sale Testing Statute.

art. III, § 2; Lujan v. Defs. of Wildlife, 504 U.S. 555, 559–60 (1992). Standing is a jurisdictional issue that we review de novo. Bochese v. Town of Ponce Inlet, 405 F.3d 964, 975 (11th Cir. 2005). “[W]hen a question about standing is raised at the motion to dismiss stage, ‘it may be sufficient to provide general factual allegations of injury resulting from the defendant’s conduct.’” Id. (quoting Fla. Pub. Interest Research Grp. Citizen Lobby, Inc. v. EPA, 386 F.3d 1070, 1083 (11th Cir. 2004)).

Standing consists of three elements: (1) injury in fact, (2) causation, and (3) redressability. Lujan, 504 U.S. at 560–61. To show an injury in fact, the plaintiff must show “an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” Id. at 560 (citations omitted). “A plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute’s operation or enforcement.” Babbitt v. United Farm Workers Nat’l Union, 442 U.S. 289, 298 (1979). “When a plaintiff has stated that he intends to engage in a specific course of conduct ‘arguably affected with a constitutional interest,’ however, he does not have to expose himself to enforcement to be able to challenge the law. ‘If the injury is certainly impending, that is enough.’” Am. Civil Liberties Union v. Fla. Bar, 999 F.2d 1486, 1492 (11th Cir. 1993) (quoting Babbitt, 442 U.S. at 298) (internal citation omitted).

Taking the factual allegations in the complaint as true, as we must, Taylor

has sufficiently alleged an injury in fact. Taylor challenges the Pre-Sale Testing Statute's constitutionality, arguing both that the statute violates his right to due process and that it is preempted by federal law. In his complaint, Taylor alleges that, prior to giving up his license, he was a state-licensed hearing aid specialist for thirty years and had operated his own hearing aid retail store for over twenty-six years. Taylor also alleges that "[b]ut for Florida's prohibition for dispensing hearing aids without using its required fitting procedures and equipment, [he] would immediately begin dispensing hearing aids." (Complaint ¶ 86.) In other words, the only thing keeping Taylor from dispensing hearing aids is the threat of enforcement of the allegedly unconstitutional Pre-Sale Testing Statute. And, as Florida's statutory scheme for dispensing hearing aids has been enforced against Taylor in the past, the chance that it will be enforced against him in the future is not speculative. Taylor is thus put in the position of either refraining from conduct he alleges to be unconstitutionally prohibited or engaging in such conduct and exposing himself to enforcement. The Constitution does not require that Taylor expose himself to enforcement of the statute before he can challenge the statute. Hence, Taylor has properly alleged an injury in fact.

Because the district court erroneously determined that Taylor did not show an injury in fact, it did not address whether Taylor satisfied the remaining standing requirements. However, as the question of Taylor's standing is reviewed de novo,

Bochese, 405 F.3d at 975, we address the remaining standing requirements here to conclude that Taylor has standing to challenge the Pre-Sale Testing Statute.

After properly alleging an injury in fact, the plaintiff must show causation and redressability to establish standing. Lujan, 504 U.S. at 560–61. To satisfy these elements, Taylor must allege that his injury in fact is “fairly traceable to the challenged conduct of the defendant” and is “likely to be redressed by a favorable judicial decision.” Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016). Here, Taylor’s alleged injury in fact is the impending imposition of a fine by Defendants in the course of their enforcement of the Pre-Sale Testing Statute. Because Taylor could not be fined were the Pre-Sale Testing Statute invalidated, Taylor has satisfied the causation requirement. And, because if Taylor were to succeed on any of his challenges to the Pre-Sale Testing Statute, the statute would not be enforced against him, and Taylor’s injury would be redressed by this litigation.

Thus, we conclude that Taylor has standing to challenge the Pre-Sale Testing Statute, and we therefore REVERSE the district court’s dismissal of Taylor’s claims for lack of standing as to the Pre-Sale Testing Statute and REMAND for further proceedings on that claim.<sup>4</sup>

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<sup>4</sup> Because we determine that Taylor has standing based on his assertion that he would become a licensed hearing aid seller but for the Pre-Sale Testing Statute, we do not address his additional standing argument that unlicensed hearing aid sellers are subject to enforcement of the Pre-Sale Testing Statute.



## **B. Failure to State a Claim Pertaining to the Licensing Statute and the Mail Order Ban**

The district court dismissed Taylor’s preemption challenges to the Licensing Statute and the Mail Order Ban for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Dismissal under Rule 12(b)(6) is proper when the facts alleged in the complaint fail “to state a claim to relief that is plausible on its face.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). On a motion to dismiss, we accept the plaintiff’s factual allegations as true. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). “However, conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal.” Davila v. Delta Air Lines, Inc., 326 F.3d 1183, 1185 (11th Cir. 2003).

### 1. Preemption and the MDA

“It is a familiar and well-established principle that the Supremacy Clause invalidates state laws that interfere with, or are contrary to, federal law.” Hillsborough Cty. v. Automated Med. Labs., Inc., 471 U.S. 707, 712 (1985) (internal citation, quotation omitted). “[W]hen acting within constitutional limits, Congress is empowered to pre-empt state law by so stating in express terms.” Id. at 713. In § 360k(a) of the MDA, Congress expressly preempted any state requirement “with respect to a device intended for human use . . . which is different from, or in addition to, any requirement applicable . . . to the device, and . . . relates to the safety or effectiveness of the device or to any other matter in a

requirement applicable to the device.” 21 U.S.C. § 360k(a). Thus, § 360k(a) acts to preempt a state requirement when (1) there is both a federal and a state requirement applicable to the same device, and (2) the state requirement is “different from, or in addition to,” the federal requirement and relates to the device’s safety or effectiveness. Riegel v. Medtronic, Inc., 552 U.S. 312, 321–22 (2008).

While § 360k(a) preempts state requirements, § 360k(b) gives the FDA the authority to grant states, upon their application, exemptions from preemption. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 (1996). The FDA promulgated regulations which “prescribe[] procedures for the submission, review, and approval of applications for exemption.” 21 C.F.R. § 808.1. The regulations also set forth examples of types of state requirements “that are not preempted by [§ 360k(a)] because they are not ‘requirements applicable to a device’ within the meaning of [§ 360k(a)],” including licensing schemes.<sup>5</sup> Id. Thus, if a state requirement falls

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<sup>5</sup> Specifically, 21 C.F.R. § 808.1(d)(3) states that

Section [360k(a)] does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices.

Thus, by issuing these regulations, the FDA is not creating blanket exemptions from preemption for licensing schemes; rather, the FDA is explaining that such laws (specifically including licensing laws for the practice of dispensing hearing aids) did not fall within § 360k(a)’s preemptive scope to begin with.

within the purview of § 360k(a), and it has not been exempted pursuant to § 360k(b), that state requirement is preempted.

## 2. The Licensing Statute

When promulgating regulations to administer the MDA, the FDA stated “that strong State and local licensing laws are needed to establish and maintain minimum competency requirements for those persons who test for hearing loss and select and fit hearing aids.” Professional and Patent Labeling and Conditions for Sale, 42 Fed. Reg. 9,286, 9,287 (Feb. 15, 1977); see also Medical Devices; Applications for Exemption From Federal Preemption of State and Local Hearing Aid Requirements, 45 Fed. Reg. 67,325 (Oct. 10, 1980) (“Problems regarding the competency of hearing aid dealers to measure hearing loss will be adequately addressed by strong State and local licensing provisions.”). In that vein, the promulgated regulations explain that state licensing requirements are an example of “State or local requirements that affect devices that are not preempted by section [§ 360k(a)] because they are not ‘requirements applicable to a device’ within the

meaning of [§ 360k(a)].” 21 C.F.R. § 808.1(d), (d)(3) (quoting § 360k(a)(2)).<sup>6</sup>

Thus, the Licensing Statute is not a “requirement applicable to a device” and is not expressly preempted by § 360k(a).

Taylor’s challenge to the Licensing Statute is really premised on a more indirect attack, asserting that the Pre-Sale Testing Statute is preempted and those pre-sale testing requirements are embedded into the qualifying elements to obtain a license under the Licensing Statute, thus resulting in the Licensing Statute being preempted as well. Taylor concedes that “[a] licensing scheme that does not enforce the Pre-Sale Testing Mandate would be unobjectionable,” but he argues that “at the very least, elements of the Licensure Requirement are pre-empted.” (Appellant’s Br. at 14, 22.)<sup>7</sup> We disagree.

The Pre-Sale Testing Statute’s requirements are not “embedded” into the elements of the Licensing Statute. The Licensing Statute is short and

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<sup>6</sup> Section 808.1(d)(3) provides that there are two types of federal requirements which, should they conflict with state licensing requirements, would preempt such state licensing requirements: (1) requirements enacted when the Secretary has restricted the sale of a device under 21 U.S.C. § 360j(e), and (2) requirements enacted exempting devices from federal requirements in order to encourage scientific investigation under 21 U.S.C. § 360j(g). However, the Licensing Statute is a state law which addresses “the competency of hearing aid dealers to measure hearing loss,” 45 Fed. Reg. at 67,325, and Taylor has not alleged that either excepted federal requirement is applicable here. Therefore, neither of these provisions are relevant to our case.

<sup>7</sup> Taylor states that he “challenges the licensing requirements that impose conditions of sale that are ‘different’ from and ‘in addition to’ federal law and which relate to the ‘safety and effectiveness’ of hearings aids,” (Appellant’s Br. at 22); he does not, however, tell the court which elements of the Licensing Statute impose such conditions, nor does the court find any such elements in the Licensing Statute.

straightforward, first providing a list of prohibited acts:

- (1) A person may not:
  - (a) Practice dispensing hearing aids unless the person is a licensed hearing aid specialist;
  - (b) Use the name or title “hearing aid specialist” when the person has not been licensed under this part;
  - (c) Present as her or his own the license of another;
  - (d) Give false, incomplete, or forged evidence to the board or a member thereof for the purposes of obtaining a license;
  - (e) Use or attempt to use a hearing aid specialist license that is delinquent or has been suspended, revoked, or placed on inactive status;
  - (f) Knowingly employ unlicensed persons in the practice of dispensing hearing aids; or
  - (g) Knowingly conceal information relative to violations of this part.

Fla. Stat. § 484.053(1). The Licensing Statute then goes on to provide penalties for undertaking any aforementioned prohibited acts. Id. § 484.053(2), (3). None of these prohibited acts pertains to any device sold by a properly certified licensee or to any testing procedures that must be undertaken by a licensee when selling a particular device.

None of the prohibited acts in the Licensing Statute mention or reference either the Pre-Sale Testing Statute or its requirements. Id. § 484.053(1). Even subsection (1)(g) of the Licensing Statute, which references “violations of this part,” does not prohibit a person from violating another section; rather, it only prohibits a person from knowingly concealing information about such violations.

In other words, the Licensing Statute does not prohibit a licensed hearing aid specialist from selling hearing aids without performing pre-sale testing, even though it does prohibit him from knowingly concealing information about such sales. As is shown by its focus on the knowing concealment of a violation, the Licensing Statute properly addresses the truthfulness of the licensee, which is certainly a factor in a licensee's competency. But liability for underlying acts of selling hearing aids is addressed under other sections of Florida's statutory scheme rather than under the Licensing Statute, which is the basis for Taylor's claim.

As all of the Licensing Statute's prohibitions are properly aimed at ensuring a minimal level of competency and truthfulness for licensees, rather than creating requirements "applicable to the device," enforcement of the Pre-Sale Testing Statute's requirements is not embedded into the Licensing Statute, and the Licensing Statute cannot be attacked with an argument that the Pre-Sale Testing Statute is preempted.

Taylor's reliance on MeTX, LLC v. Wal-Mart Stores Texas, LLC, 62 F. Supp. 3d 569 (E.D. Tex. 2014), is unavailing. That case concerned a similar preemption challenge to Texas's hearing aid licensing scheme. Id. at 574. However, the Texas law clearly ties licensing to the "fitting and dispensing of hearing instruments." Id. at 584 (citing Tex. Occ. Code § 402.451); see also Tex. Occ. Code § 402.001(6) (defining "license" as "a license issued by the department

under this chapter to a person authorized to fit and dispense hearing instruments”). And, the Texas Code defines “fitting and dispensing hearing instruments” as “the measurement of human hearing by the use of an audiometer or other means to make selections, adaptations, or sales of hearing instruments.” MeTX, LLC, 62 F. Supp. 3d at 578 (quoting Tex. Occ. Code § 402.001). Thus, under the Texas law one could not become licensed without satisfying the pre-sale testing requirements.

Florida, by contrast, draws a distinction between those who must be licensed hearing aid dispensers and those who must perform pre-sale testing. For example, a licensee undertaking acts pertaining to the warranty of a previously sold hearing aid is, by statutory definition, “dispensing hearing aids”; however, because he has already sold the hearing aid and is addressing the device’s post-purchase warranty, he is not “fitting and selling” hearing aids and the Pre-Sale Testing Statute’s mandate would not be applicable. Fla. Stat. §§ 484.041(3)(b), 484.0501. Thus, unlike in Texas, it is possible to be a licensed hearing aid specialist in Florida without automatically being subject to the Pre-Sale Testing Statute.

Because any infirmity in the Pre-Sale Testing Statute is not inextricably linked to the Licensing Statute, and because state licensing schemes are not preempted by § 360k(a)’s express preemption provision, Taylor has failed to state a claim that the Licensing Statute is preempted by federal law.

### 3. The Mail Order Ban

Florida's Mail Order Ban provides that: "It is unlawful for any person to sell or distribute hearing aids through the mail to the ultimate consumer." Fla. Stat. § 484.054. Taylor pursues his challenge to the Mail Order Ban through two theories. First, he asserts that the Mail Order Ban has the purpose and effect of prohibiting sales by unlicensed sellers. This theory rests on the assertion that Florida may not prohibit sales by unlicensed sellers, because any such restriction in the Licensing Statute would be prohibited by the MDA. Because we rejected this assertion above in concluding that Florida's Licensing Statute is not preempted, Taylor's first theory fails.

Taylor's second theory is that the Mail Order Ban has the purpose and effect of prohibiting sales conducted without complying with the Pre-Sale Testing Statute's requirements. This theory also fails.

We do not accept Taylor's conclusory allegation that the purpose and effect of the Mail Order Ban is to prohibit sales that do not comply with the Pre-Sale Testing Statute. See Iqbal, 556 U.S. at 678 ("[W]e are not bound to accept as true a legal conclusion couched as a factual allegation."). The plain text of the Mail Order Ban does not expressly require compliance with the Pre-Sale Testing Statute, as it categorically bans all mail order sales. Thus, although Taylor alleges that the Mail Order Ban prohibits sales that do not comply with the Pre-Sale Testing Statute, it would be just as accurate to allege that the Mail Order Ban



prohibits sales that do comply with the Pre-Sale Testing Statute. A comparison of Missouri’s ban on mail order sales, addressed in Missouri Board of Examiners for Hearing Instrument Specialists v. Hearing Help Express, Inc., 447 F.3d 1033, 1035 (8th Cir. 2006), highlights this difference.

That case upheld a preemption challenge to Missouri’s mail order ban, which “provides that ‘[n]o person shall (1) sell through the mails, hearing instruments without prior fitting and testing by a hearing instrument specialist.’” Id. at 1036–37 (quoting Mo. Rev. Stat. § 346.110 (subsequently amended)) (emphasis added). The court concluded that Missouri’s ban was preempted by § 360k(a) solely because the ban contained a mandatory pre-sale testing requirement. Id. at 1037. The same cannot be said for the Mail Order Ban at issue here, which does not contain such a requirement and works to ban even those mail order sales undertaken with pre-sale testing. Moreover, the only language common to both the Missouri and the Florida bans—“[n]o person shall (1) sell through the mails, hearing instruments”—was never discussed by the court in Missouri Board of Examiners. Hence, Florida’s ban does not contain the same incorporation of a pre-sale testing requirement as does Missouri’s ban, and Missouri Board of Examiners is distinguishable<sup>8</sup>

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<sup>8</sup> This is not to say that we endorse the court’s approach to pre-sale testing requirements in Missouri Board of Examiners, which was not informed by this circuit’s long-standing precedents. We merely hold that it is distinguishable.

Since we do not accept Taylor's conclusory legal assertion as to the Mail Order Ban's purpose and effect, we look to the plain language of the Mail Order Ban itself to determine whether it is preempted by § 360k(a): "It is unlawful for any person to sell or distribute hearing aids through the mail to the ultimate consumer." Fla. Stat. § 484.054. Under § 360k(a), the Mail Order Ban would be preempted if it is "different from, or in addition to," a federal requirement and if it relates to the safety or effectiveness of the device. Taylor's argument that the Mail Order Ban relates to the safety and effectiveness of the device is based not on the Mail Order Ban itself, but on the fact that pre-sale testing relates to safety and effectiveness. He makes no argument, nor could he, that prohibiting sales by mail, in and of itself, relates to the safety or effectiveness of the device.

Thus, because the Mail Order Ban does not embed the Pre-Sale Testing Statute within it, and because the Mail Order Ban does not relate to the safety or effectiveness of the device, Taylor has failed to state a claim that the Mail Order Ban is preempted by federal law.

### **III. CONCLUSION**

For the foregoing reasons, we **AFFIRM** the district court's dismissals for failure to state a preemption claim as to Florida's Licensing Statute and Mail Order Ban. We **REVERSE** the district court's dismissal for lack of standing as to Taylor's due process and preemption challenges to Florida's Pre-Sale Testing

Statute and REMAND to the district court for further proceedings consistent with this opinion.