No. 18-14934

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ROBERT DANIEL TAYLOR,

Plaintiff - Appellant,

v.

LEANNE POLHILL, solely in her official capacity as a Member of the Florida Board of Hearing Aid Specialists; RANDY ELLSWORTH, solely in his official capacity as a Member of the Florida Board of Hearing Aid Specialists; ROBERT PICKARD, M.D., solely in his official capacity as a Member of the Florida Board of Hearing Aid Specialists; JOHN FISCHER, solely in his official capacity as a Member of the Florida Board of Hearing Aid Specialists; DOUGLAS MOORE, solely in his official capacity as a Member of the Florida Board of Hearing Aid Specialists; et al.,

Defendants - Appellees.

On Appeal from the United States District Court
for the Middle District of Florida
Honorable Gregory A. Presnell, Senior District Judge

APPELLANT'S OPENING BRIEF

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STATEMENT OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Plaintiff-Appellant Robert Daniel Taylor, by his undersigned counsel and pursuant to Fed. R. App. P. 26.1 and 11th Cir. R. 26.1-1, files this Certificate of Interested Persons and Corporate Disclosure Statement.

Appellant is not a publicly held corporation and has no parent corporations, affiliates, or subsidiaries with an interest in the outcome of this case. Other identifiable interested parties to the action are:

Taylor v. Polhill, et al. **Docket No. 18-14934**

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

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STATEMENT REGARDING ORAL ARGUMENT

Plaintiff-Appellant requests oral argument pursuant to 11th Cir. R. 28-1(c). Oral argument is warranted because this case challenges the constitutionality of a state statute. The outcome of the case concerns the livelihood of hearing aid professionals and the availability and terms of sale of hearing aids to consumers in Florida, which is the nation's largest market for hearing aids.

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JURISDICTIONAL STATEMENT

Jurisdiction is proper in this case involving claims arising under the U.S. Constitution and 42 U.S.C. § 1983 pursuant to 28 U.S.C. § 1331 (federal question). This Court has appellate jurisdiction pursuant to 28 U.S.C. § 1291 (review of final decision dismissing Complaint). The district court filed an order on November 1, 2018, dismissing Plaintiff-Appellant's Complaint after a determination that Plaintiff-Appellant lacks standing and the Complaint failed to state a claim on which relief can be granted. Doc. 90. Plaintiff-Appellant filed a timely notice of appeal on November 27, 2018. Doc. 92.

STATEMENT OF ISSUES ON APPEAL

(1) Whether the district court erred in holding that Plaintiff-Appellant lacked standing to challenge Fla. Stat. § 484.0501, which prohibits the sale of hearing aids without conducting pre-sale audiometric testing using mandated procedures and equipment.

(2) Whether the district court erred in dismissing, pursuant to 12(b)(6), Plaintiff-Appellant's claims that Florida's occupational licensing requirement for hearing aid sellers (Fla. Stat. § 484.053) and ban on the mail order sale of hearing aids to consumers (Fla. Stat. § 484.054) are pre-empted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k, and related federal regulations.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

Plaintiff-Appellant Taylor earned his livelihood for more than 30 years selling hearing aids in Florida as a licensed Hearing Aid Specialist. Doc. 1, ¶ 3, 62-65. Florida law requires that sellers of hearing aids maintain a Hearing Aid Specialist license and perform pre-sale audiometric testing on customers using particular procedures and equipment as a condition of selling the devices. *See* Fla. Stat. §§ 484.053 & 484.0501.

In recent years, however, Taylor became frustrated that the state's nearly 40-year-old regulatory regime did not account for technological change in the hearing aid industry, which today produces devices containing sophisticated software and hardware that render the mandated testing procedures unnecessary. *Id*. ¶ 3. He also came to believe that Florida's hearing aid regulatory scheme was preempted by federal law, following a 2014 federal district court that invalidated Texas's similar hearing aid seller licensing and "fitting" requirements on preemption grounds. *See MeTX, LLC v. Wal-Mart Stores Texas, LLC*, 62 F. Supp. 3d 569 (E.D. Tex. 2014). That court held that Texas's pre-sale testing mandates were "different from, or in addition to" the federal regulatory regime for hearing aid sales established by the Medical Device Amendments (MDA) of 1976, 21 U.S.C. § 301, *et seq.*, and U.S. Food and Drug Administration regulations, and therefore expressly preempted.

MeTX, 62 F. Supp. 3d at 584. Federal law does not require audiometric testing of any kind prior to the sale of a hearing aid or that such testing be done using any particular methods or equipment. Moreover, Taylor concluded based on his experience and changes in technology that there was no longer a rational basis to require him to perform (or for consumers to be subjected to) unnecessary audiometric testing and that the mandate hindered his business.

Taylor's and the Texas district court's view on preemption is also embraced by the U.S. Food and Drug Administration, which administers the MDA. It has determined that "[t]here is no evidence that audiological evaluation reduces or eliminates any risk to health presented by a hearing aid," and therefore its regulations do not include an exam as a mandatory condition of sale. 45 Fed. Reg. 67,326, 67,327 (Oct. 10, 1980). Instead, the FDA has determined that state-mandated audiological exams "would interfere with the execution and accomplishment of the objectives of FDA's hearing aid regulation," are "in addition to" those requirements, and are therefore preempted. *Id*.; *see also* 45 Fed. Reg. 67,328 ("Because the FDA hearing aid regulation preempts State laws requiring audiological evaluation, the States may not require, as a condition to the purchase of a hearing aid, that the prospective purchaser receive an audiological evaluation."). Based on a survey of scientific literature, the FDA recently streamlined the sale of hearing aids further, allowing them to be sold "over-the-counter" without prior medical evaluation (or

written waiver of such an evaluation) on a finding that regulation "provides no clinically meaningful benefit" and presents "a barrier to [consumer] access" to hearing aids.[1]

The federal district court in *MeTX* also voided Texas's requirement that hearing aid sellers obtain an occupational license. It did so because it found that the terms of the licensing requirement effectively used an otherwise permissible licensing scheme to bootstrap the forbidden pre-sale testing mandate.

In 2016, on the basis of these factors, Taylor declined to renew his Florida Hearing Aid Specialist license and continued to offer hearing aids for sale in compliance with the requirements of the federal law. He was soon cited by the state for selling hearing aids without a license, subject to significant civil and criminal penalties. Doc. 1 ¶¶ 76-78. He paid a fine, closing the matter, Doc. 1 ¶ 79, and subsequently filed the instant action for prospective declaratory and injunctive relief challenging three relevant sections of Florida's hearing aid sales regulations. This appeal arises from the dismissal of that action under Fed. R. Civ. P. 12(b)(1) and 12(b)(6), for lack of standing and failure to state a claim on which relief can be granted. Doc. 90.

[1] U.S. Food and Drug Administration, *Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids*, Dec. 12, 2016, *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM531995.pdf (last visited Feb. 4, 2019).

First, Taylor challenged Florida's requirement that hearing aid sellers conduct pre-sale audiometric testing using mandated procedures and equipment (Pre-sale Testing Mandate) as preempted by federal law. *See* Fla. Stat. § 484.0501; Doc. 1 ¶¶ 87-95. He further alleged that advances in hearing aid technology present changed circumstances since the law's enactment, which render the Pre-sale Testing Mandate an irrational burden on his constitutional right to earn a living in violation of substantive due process. *Id*. ¶¶ 105-114. Second, following the reasoning of the *MeTX* case, he brought a preemption challenge to Fla. Stat. § 484.053, which makes it illegal to sell a hearing aid in Florida without obtaining and maintaining a Hearing Aid Specialists license (Licensure Requirement). *Id*. ¶¶ 87-95. A key reason why Taylor gave up his license is that adherence to the Board of Hearing Aid of Specialist rules requiring pre-sale audiometric testing is a legal condition of maintaining it. *See* Fla. Stat. § 484.047(2) (indicating conditions of license renewal). Third, Taylor brought a preemption challenge to Fla. Stat. § 484.054, which prohibits all mail order sales of hearing aids to consumers, on the grounds that the prohibition makes it impossible to sell hearing aids in Florida without obtaining a Hearing Aid Specialists license and conducting pre-sale audiometric tests. Doc. 1 ¶¶ 96-104.

According to the district court below, Taylor lacked standing for his preemption and due process challenges to the Pre-Sale Testing Mandate (Fla. Stat. § 484.0501). The court reasoned that because Taylor had not renewed his Hearing

Aid Specialist license, "§ 484.0501 will not apply to him and poses no threat of future injury to him, whether he continues to sell hearing aids or not." Doc. 90, at 3. In addition, the court held that Taylor "failed to state a claim for the preemption" of the Licensure Requirement, citing a savings clause element of the MDA that exempts certain licensing statutes from preemption. Doc. 90, at 5. The district court further assumed that the pre-sale audiometric testing requirement, even if preempted, could be severed from the remainder of the licensing statute. *Id*. Finally, the court dismissed the claim against the mail order ban (Fla. Stat. § 484.054) on the grounds that the challenge to the ban depended entirely on the rejected challenge to the Licensure Requirement. The court's order thereby disposed of all claims.

II. STANDARD OF REVIEW

A district court's ruling on a motion to dismiss for failure to state a claim is reviewed de novo. *Castillo v. Allegro Resort Mktg.*, 603 F. App'x. 913, 915 (11th Cir. 2015). The same standard applies to a dismissal for lack of standing, which is equivalent to a dismissal for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). *See McElmurray v. Consol. Gov't of Augusta-Richmond Cnty.*, 501 F.3d 1244, 1250 (11th Cir. 2007). Under that standard, the Court must accept all factual allegations in the Complaint as true and make all inferences in the light most favorable to Plaintiff. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007).

A Complaint will survive a motion to dismiss where it contains "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted). Dismissal is improper "even if it appears that a recovery is very remote and unlikely." *Bell Atl. Corp. v. Twombly*, 550 U .S. 544, 556 (2007) (quotation omitted). The plausibility standard does not "impose a probability requirement at the pleading stage." *Id*. at 556. Nor does the plausibility standard require the Complaint to be a "model of the careful drafter's art" or meet the standard of laying out a "precise legal theory." *Skinner v. Switzer*, 562 U.S. 521, 530 (2011). The Supreme Court has said, rather, that the rules "do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *Johnson v. City of Shelby, Miss*., 135 S. Ct. 346 (2014); *see also Surtain v. Hamlin Terrace Found*., 789 F.3d 1239, 1245-46 (11th Cir. 2015) (finding district court abused discretion for failing to properly apply the *Iqbal*/*Twombly* plausibility standard).

SUMMARY OF ARGUMENT

The district court dismissed this case on Fed. R. Civ. Proc. 12(b)(1) and 12(b)(6) grounds after a determination that a) because Plaintiff-Appellant Taylor is not currently licensed to sell hearing aids in Florida, he lacks standing to pursue his his preemption and due process challenges to Florida's Pre-sale Testing Mandate for

hearing aid sales, and b) Taylor failed to state a claim for preemption of the state's Licensure Requirement and ban on selling hearing aids to consumers by mail.

The court's holding on standing was an error because the language of the Pre-sale Testing Mandate threatens punishment for noncompliance by any person, licensed or not. Further, even if Taylor were to lose on the merits of his Licensure Requirement challenge and had to renew his Hearing Aid License to resume his trade, he would face imminent risk of punishment from enforcement of the Pre-sale Testing Mandate. Taylor has standing because he is presently forced to choose between punishment and foregoing his constitutional right to earn a living as a hearing aid seller free of unconstitutional burdens. The court's holding that Taylor's Licensure Requirement and mail order sale ban challenge failed to state a claim on which relief can be granted is also in error. The holding depends on too expansive an interpretation of a clause of the MDA that saves some state licensing laws from preemption, and on impermissibly unfavorable inferences from the allegations in Taylor's Complaint. The lower court's decision should, therefore, be reversed, vacated, and remanded for further proceedings.

ARGUMENT

I. CONFLICTS BETWEEN THE FEDERAL MDA AND FLORIDA'S HEARING AID REGULATIONS MUST BE EVALUATED UNDER THE TEST FOR EXPRESS PREEMPTION

Federal laws and regulations are the "Supreme law of the land," and any state law that interferes with or is contrary to federal law is preempted and cannot be enforced. U.S. Const. art. VI, cl. 2. Preemption may be either express or implied. Preemption is express when Congress uses clear preemptive language in drafting the federal law. *Odebrecht Constr., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1274 (11th Cir. 2013). Under express preemption, Congress's language governs and "there is no need to infer Congressional intent." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). By contrast, preemption is implied where the statutory language indicates Congress's intent to occupy the field, or where state regulation conflicts with or frustrates federal law. *Id*.

The MDA includes an express preemption clause. Its language clearly preempts any state law pertaining to hearing aid devices: 1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and 2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device. 21 U.S.C. § 360k(a).

Nearly 40 years ago, the Fifth Circuit considered 21 U.S.C. § 360k(a) and upheld against a preemption challenge a portion of Florida's hearing aid sales

regulations that required fittings to occur in a Commission-approved room. *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. 1981). The court's analysis in that case hinged on its application of an "implied preemption" standard of review. *Id.* at 1024. But subsequent case law demonstrates that the application of the looser implied preemption test was in error and courts must use the express preemption test.

In *Riegel v. Medtronic, Inc*., 552 U.S. 312, 316 (2008), the Supreme Court held that Section 360k(a) expressly preempts state laws regulating the sale of medical devices. *See also Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 352 (2001) (MDA includes express preemption statement); *see also Missouri Bd. of Exam'rs for Hearing Instrument Specialists v. Hearing Help Express, Inc.*, 447 F.3d 1033 (8th Cir. 2006) (MDA expressly preempts state conditions on sale of hearing aids); *Massachusetts v. Hayes*, 691 F.2d 57, 59 (1st Cir. 1982) (MDA "expressly preempt[s]" state law governing the sale of hearing aids); *MeTX*, 62 F. Supp. 3d 569 (same). Because Congress used clear language in the preemption statement, whether a state regulation of the sale of medical devices is preempted depends on a comparison between the terms of MDA and the terms of the challenged state statute.

As argued below, Taylor has standing to pursue his challenges to the Pre-sale Testing Mandate. Moreover, applying the preemption standards indicated above, he set out a plausible case for preemption of the Pre-sale Testing Mandate (Fla. Stat. § 484.0501), the Licensure Requirement (Fla. Stat. § 484.053), and mail order sales

ban (Fla. Stat § 484.054) through allegations making it clear that Florida's laws condition the sale of hearing aids in a manner that is "different from, or in addition to" the MDA and "relate[] to the safety or effectiveness of the device[s]."

II. TAYLOR HAS STANDING TO PURSUE HIS CLAIM AGAINST FLA. STAT. § 484.0501

Section 484.0501 prohibits the sale of hearing aids without a "fitting" of the device, by which a hearing aid seller must use proscribed procedures and equipment to ensure the effectiveness of the hearing aid. Doc. 1 ¶ 39. A fitting includes pre-sale audiometric testing. Taylor does not want to conduct such tests, believing them to be unreasonable burdens on his constitutional right to earn a living and to dissuade consumers from purchasing hearing aids. *Id*. ¶¶ 73-74. He challenged this provision of Florida's hearing aid sales regulatory scheme on two grounds.

First, he contends the Pre-sale Testing Mandate is pre-empted by federal law, alleging that "[n]either federal law nor FDA regulations requires a 'fitting' of a hearing aid or require audiometric testing prior to sale." Doc. 1 ¶ 40. Therefore, he asserts that "Florida's requirement of a pre-sale fitting, and the particular minimum procedures [and equipment] mandated by [Section 484.0501] are different from and in addition to rules promulgated [under the MDA] and are expressly preempted by them." *Id*. ¶ 40-41.

Second, he contends that the Pre-sale Testing Mandate "serve[s] no useful purpose in light of current hearing aid technology [and] irrationally burden[] sellers'

constitutional right to earn a living. . . .” *Id*. ¶ 51. Taylor avers that “[b]ut for Florida’s penalties for dispensing hearing aids without using its required fitting procedures and equipment,” he “would immediately begin dispensing hearing aids in the state using the modern techniques and equipment that he believes provide superior service to consumers.” *Id.* ¶ 86.

Taylor’s Complaint seeks pre-enforcement review of the Pre-Sale Testing Mandate to avoid future prosecution under Section 484.0501, before he engages in his desired course of conduct. *See Elend v. Basham*, 471 F.3d 1199, 1205 (11th Cir. 2006) (explaining pre-enforcement review as involving “the possibility of wholly prospective future injury). “A plaintiff stating that he ‘intends to engage in a specific course of conduct arguably affected with a constitutional interest . . . does not have to expose himself to enforcement to be able to challenge the law.” *Jacobs v. The Florida Bar*, 50 F.3d 901, 904 (11th Cir. 1995); *Chicago v. Atchison, Topeka & Santa Fe Ry. Co.*, 357 U.S. 77, 89 (1958) (company blocked from engaging in business by permit requirement “was not obligated to apply for [the permission] and submit to the administrative procedures incident thereto before” challenging them).

The district court dismissed this claim, finding that “Section 484.0501 imposes pre-sale procedures on licensed hearing aid sellers and Plaintiff is not, nor does he intend to become, a licensed hearing aid seller.” Doc. 90, at 3 (citing Doc. 1 ¶ 3). Therefore, the court held, Taylor lacks standing to pursue a challenge to Section

484.0501 because the provision "will not apply to him and poses no threat of future injury to him." *Id.* The district court misconstrued both Section 484.0501 and Taylor's allegations resulting in error.

To begin, it is simply not true that Section 484.0501 exclusively imposes pre-sale procedures "on licensed sellers." The statute states that its proscribed procedures "shall be used in the fitting and selling of hearing aids" without exception or distinction concerning the status of sellers. Fla. Stat. § 484.0501. Taylor alleges that he "has sold, and wishes in the future to sell, state of the art hearing aids that use modern software and hardware" for which the fitting procedures are unnecessary. Doc.1 ¶ 3. To the extent that he sells or intends to sell hearing aids, licensed or not, Taylor "is subject to discipline for failing to dispense hearing aids using the procedures and equipment proscribed by Florida's Law . . . including citations and fines of up to $5,000." *See* Fla. Stat. § 456.065; Doc. 1 ¶ 45.

Moreover, a fair reading of Taylor's complaint does not support the district court's finding that Taylor does not "intend to become" a licensed hearing aid seller. He clearly alleged that he wishes to sell hearing aids in the future. Doc.1 ¶ 3. That paragraph, cited by the district court, only indicates that Taylor gave up his Hearing Aid Specialists license after 30 years of working as a licensed seller "because the state's requirement that he use antiquated procedures and equipment in the sale of

hearing aids" burdened his business in light of newer methods and technologies available. *Id.*

It is true that Taylor also challenged the validity of the Licensure Requirement (Fla. Stat. § 484.053), separately and in addition to his challenge to the Pre-sale Testing Mandate. But viewed in the full context of the complaint, with the allegations taken in the light most favorable to Taylor, one can see that Taylor gave up his license because maintaining it obligated him on threat of prosecution to conform his business to the objectionable mandates of Section 484.0501. For instance, Taylor alleged that "a licensed Hearing Aid Specialist is subject to discipline for failing to dispense hearing aids using the procedures and equipment" imposed by the Pre-sale Testing Mandate. Doc. 1 ¶ 45 (emphasis added).

Had Taylor's complaint proceeded in the district court and prevailed only on his challenge to the Pre-sale Testing Mandate, he would have been free to renew his Hearing Aid Specialists license and conduct business in the manner his complaint describes. A licensing scheme that does not enforce the Pre-Sale Testing Mandate would be unobjectionable, allowing him to renew his license and conduct his future business as a licensed seller without the burdens of the pre-sale requirements and without threat of further prosecution.

Taylor gave up his license based on the fear that if had he maintained it, and if he continued to offer hearing aids for sale in the manner he intended, he would be

prosecuted. Pursuant to Fla. Stat. § 484.047(2), one may not maintain a license unless one complies with all requirements of the state's regulatory scheme, including the Pre-sale Testing Mandate. Therefore, had Taylor maintained a license while attempting to sell hearing aids without abiding by Section 484.0501's requirements, he would subject himself to civil and criminal penalties. Indeed, he was previously cited by the Board for offering a hearing aid for sale without a license and he continues to be under investigation by the Florida Board of Health. Instead, Taylor gave up his license and sued for prospective declaratory relief, challenging both the Licensing Requirement and the Pre-sale Testing Mandate as imposing conditions on the sale of hearing aids different from or in addition to federal law.

The theory that both the License Requirement and the Pre-sale Testing Mandate should be challenged together and should fall together is not implausible: a similar claim prevailed in the *MeTX* case, where the Texas district court held that Texas's entire licensure scheme was preempted because it was bound up with preempted pre-sale testing requirements. The court there found that the license scheme as a whole was defective because it required persons "licensed under Texas law [to] perform an audiological exam on an adult customer before that customer may purchase a hearing aid." *MeTX*, 62 F. Supp. at 582.

The fact that Taylor is not presently licensed does not strip him of standing to challenge the Pre-sale Testing Mandate. If he prevailed on that claim and was

unsuccessful in his others, he would have to renew his Hearing Aid Specialists license before lawfully conducting business again. But he has a vital interest in doing so and not being subject to future prosecution for failing to conform his business to Section 484.0501 in that scenario. Were it not illegal to engage in his hearing sales without complying with the Pre-sale Testing Mandate, he would engage in the trade again.

"A plaintiff stating that he 'intends to engage in a specific course of conduct arguably affected with a constitutional interest . . . does not have to expose himself to enforcement to be able to challenge the law." *Jacobs*, 50 F.3d at 904. Taylor is suffering an injury-in-fact, and has standing, because he is forced by the Pre-sale Testing Mandate to choose between exercising his constitutional right to earn a living and facing serious penalties. *See Babbitt v. United Farm Worker Nat'l Union*, 442 U.S. 289, 298-00 (1979) ("[A]n intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and . . . a credible threat of prosecution" is an injury-in-fact under Article III.) The U.S. Supreme Court has said that,

> where threatened action by government is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat—for example, the constitutionality of a law threatened to be enforced. The plaintiff's own action (or inaction) in failing

> to violate the law eliminates the imminent threat of prosecution, but nonetheless does not eliminate Article III jurisdiction.

MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 128-29 (2007).

Seen in this light, Taylor has standing because his Complaint establishes an injury in fact that is traceable to the statute, which can be redressed by a favorable decision by the court. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992) (explaining the basic test for standing). He alleges that he would like to resume his livelihood by selling hearing aids, but he cannot do so without complying with the state's unconstitutional fitting procedures. Doc. 1 ¶ 81-86. This injures him because he must either cease his desired course of conduct, or subject himself to future fines and penalties. *Id.* ¶¶ 45-46, 53. That injury is attributable to the Board because it is tasked with enforcing the challenged law. *Id.* ¶¶ 10-11. A favorable decision by a court would redress his injury because it would allow him to earn a living free of the preempted and irrational mandates of Section 484.0501. *Id.* ¶¶ 5, 85-86. Taylor therefore has standing to bring his claim against the Pre-sale Testing Mandate (Fla. Stat. § 484.0501).

In summary, the district court's holding rests on an implicit premise that Taylor's injuries could not be redressed if the licensing requirement remained, even one shorn of the Pre-Sale Testing Mandate, because Taylor would refuse to become licensed. That speculative premise is not supported by the Complaint. In fact, the

Complaint clearly indicates Taylor's intention to remain active in the profession he thrived in for more than 30 years but for regulations that make it impossible for him to practice in the way he believes is lawful and consistent with his and his customers' interests.

III. THE DISTRICT COURT DISMISSED THE CLAIMS RELATING TO FLA. STAT. §§ 484.053 & 484.054 BY AN ERRONEOUS APPLICATION OF THE MDA'S SAVINGS CLAUSE, AND DID NOT VIEW TAYLOR'S ALLEGATIONS IN THE LIGHT MOST FAVORABLE TO HIM AS REQUIRED ON A 12(B)(6) MOTION

A. Section 484.053 is not categorically saved from preemption

Taylor alleged that the Licensure Requirement (Section 484.053), which prohibits the sale of hearing aids in the state by anyone other than a licensed seller, is preempted by 21 U.S.C. § 360k(a) of MDA. *See* Doc. 1 ¶ 38. The statute expressly preempts state laws that relate to the safety and effectiveness of hearing aid devices, where the state law imposes conditions on the sale of the devices that are "in addition to, or different from" the federal requirements. *See Riegel*, 552 U.S. at 321-22 (explaining that express preemption is the appropriate test under the MDA). In the district court, Taylor argued that the Licensure Requirement related to the safety and effectiveness of hearing aids because it is aimed at "protecting the public from physical and economic harm" from the sale of the devices. *See* Doc. 83 (Motion for Preliminary Injunction) at 13-15; *see also* 45 Fed. Reg. 67,327 (FDA opinion that pre-sale exams relate to safety and effectiveness of hearing aid devices.). His

complaint further alleged that the Licensure Requirement is "different from" and "in addition to" federal law because it requires licensed sellers to conduct a pre-sale audiological exam using minimum procedures and equipment while the MDA does not. Doc. 1 ¶ 38. Taylor therefore adequately pled a claim that Section 484.053 is preempted by the MDA.

The district court held, however, that this claim "could not be proven under any set of facts" and dismissed it pursuant to Fed. R. Civ. P. 12(b)(6). The court gave two reasons for its ruling. First, it addressed an FDA regulation that saves some types of licensing laws from preemption. Doc. 90 at 4 (citing 21 C.F.R. § 808.1(d)(3)). The savings clause permits "[s]tate or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine [. . .] or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices." 21 C.F.R. § 808.1(d)(3). The Court held that Florida's Hearing Aid Specialists license falls within that exemption, making it impossible for Taylor to prevail on a claim that the Licensure Requirement is preempted. *Id*. at 5.

Second, the court addressed Taylor's argument, following the reasoning in the *MeTX* case discussed above, that the Licensure Requirement is preempted because it effectively incorporates Section 484.0501's pre-sale testing requirements. The district court held that this argument is "not only inconsistent with 21 C.F.R.

§ 808.1(d)(3), but also with Eleventh Circuit case law, which requires severance of unconstitutional provisions in such situations." Doc. 90 at 5 (citing *Wollschlaeger v. Governor, Sate of Fla.*, 848 F.3d 1293, 1317, 1319 (11th Cir. 2017)).

The district court did not acknowledge that Taylor addressed the savings clause in his motion for a preliminary injunction. *See* Doc 51 at 18-19. In that motion, Taylor conceded that the exemption language states that the MDA does not preempt "licensing . . . or other requirements relating to the approval or sanction of the practice of medicine [. . .] or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices." 21 C.F.R. § 808.1(d)(3). However, he pointed out, the exemption also states that "[i]f there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail." *Id.*

Read as a whole, the meaning of this savings clause is clear: state laws imposing licensing, registration, certification or other requirements that relate to ensuring medical professionals are qualified to do their jobs are not preempted, but the MDA does preempt all laws, including licensing laws, to the extent they impose conditions of sale on hearing aids that conflict with the federal regulatory scheme.

Taylor analogized his Licensure Requirement claim to the challenge to hearing aid licensure raised in *MeTX*—the most similar case to the instant one on this point. There, the preemption challenge was brought defensively by a hearing aid

retailer when a group of licensed hearing aid sellers complained that the company was selling in Texas without a license. The Texas district court struck down the licensing requirement on the grounds that it forced licensed hearing aid sellers to perform preempted pre-sale audiological exams. *Id*. at 584. Contrary to the district court here, that court rejected the argument that the licensing requirement was saved from preemption by 21 C.F.R. § 808.1(d)(3). It reasoned that "licensure is only exempted from preemption to the extent it does not impose requirements applicable to a device different from, or in addition to specific FDA requirements." *MeTX*, 62 F. Supp. 3d at 580.

Florida's Section 484.053 is analogous to the Texas statute. What was legally relevant in *MeTX* is that the Texas license required that "fitters and dispensers" were the only persons who could sell hearing aids in the state and that those persons were obligated to perform "fitting services" (mainly consisting of pre-sale audiological testing). *MeTX*, 62 F. Supp. at 573. The district court noted that this federal trial-level case is non-binding, which is of course true. Doc. 90, at 5 n.3. But the cases are analogous on this point: a state may not bootstrap its way into preempted pre-sale testing requirements by embedding those preempted regulations within a "licensing" statute.

On the district court's next issue—that the Pre-Sale Testing Mandate can or must be severed from the License Requirement under Eleventh Circuit precedent—

the general concern is well taken. But again, Taylor at least indicated the answer to that concern in his pleadings. In the course of his argument for a preliminary injunction, Taylor stated that he does not contest the state's power to impose licensing that fits within the exemption. In particular, Taylor "does not challenge those licensing requirements related to ensuring the competency of hearing aid fitters." Doc. 51, at 19. Rather, "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 hearing aids." *Id*. It is true that ***some*** state licensing laws are permitted under the federal regulations; the point remains, however, that ***this particular*** licensing law impermissibly treads over the federal scheme by enforcing the Pre-sale Testing Mandate—at the very least, elements of the Licensure Requirement are pre-empted. To the extent that the Complaint was not clear on this point, or might have been amended to narrow the claim, the district court ought to have taken the allegations in the light most favorable to Taylor at the motion for dismissal stage and allowed the claim to proceed. *See Am. United Life Ins. Co. v. Martinez*, 480 F.3d 1043, 1057 (11th Cir. 2007) (allegations must to taken in the light most favorable to plaintiff at motion to dismiss stage).

Taylor's Complaint raised a plausible claim that the License Requirement, at least some aspect of it, is preempted by federal law. A full proof of that claim may require factual development in discovery; perhaps the severability concern means

his claim will be narrowed, or may even fail. But these are merits questions that were inappropriate to prejudge on a 12(b)(6) motion.

B. Taylor adequately alleged that Section 484.054, the ban on mail order sales, is preempted

Taylor's Complaint also challenged Fla. State. § 484.054, which prohibits all sales and distribution of hearing aids through the mail to consumers. Its effect is to limit competition from online sellers, among others, from competing with licensed Hearing Aid Specialists with a presence in the state. Taylor alleged that "[t]he mail order sales ban has the purpose and effect of prohibiting the sale of hearing aid devices in Florida without prior fitting and testing by a Florida licensed Hearing Aid Specialist." Doc. 1 ¶ 55. Taylor claims that the mail order ban is preempted by the "MDA and related FDA regulations because it prohibits [the] sale of hearing aids without performing state mandated pre-sale procedures aimed at assuring the effectiveness of the devices, which are conditions of sale different from and in addition to the conditions of sale established by federal law." Doc. 1 ¶ 60.

The district court dismissed this claim as a consequence of the dismissal of the challenge to the Licensure Requirement, on the grounds that the "argument against § 484.054 . . . rests entirely on [Taylor's] contention that the Licensure Requirement is preempted by the federal scheme." Doc. 90 at 6. "Since Plaintiff has failed to state a claim for the preemption of the License Requirement, his claim

against § 484.054 necessarily fails." *Id.* It's not true, however, that both claims necessarily fall together.

Although the district court stated that Taylor did not explain the mail order ban was "different from, or in addition to" a federal requirement or how it related to the safety and effectiveness of hearing aids, *Id.*, Taylor did address that matter and showed why the two claims are separate. *See* Doc. 51 at 16-19.

The Florida law is "different from and in addition to" federal conditions on the sale of hearing aids because the MDA permits sales of hearing aids through the mail so long as prospective purchasers undergo (or waive) a medical exam, and so long as the hearing aids are labeled and packaged with certain product information. *See* 21 C.F.R. § 801.421. By contrast, Florida categorically bans such sales. Further, the prohibition relates to the safety and effectiveness of devices because it is both intended and has the effect of requiring consumers to undergo in-person, audiometric testing as part of the purchase of a hearing aid. The FDA has opined that mandatory testing is a condition on the sale of the devices that relates to their safety and effectiveness because they are "intended to ensure that the purchaser is fitted properly with a hearing aid that will benefit his or her hearing ability." 45 Fed. Reg. 67,327. Every court that has considered the question agrees. *Missouri Bd. of Exam'rs for Hearing Instrument Specialists*, 447 F.3d at1036; *MeTX*, 62 F. Supp. 3d at 584;

Mass., 691 F.2d 63; *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795, 812 (N.J. 1978).

Like Florida, the state of Missouri once prohibited mail order sales without prior fitting by a licensed specialist. In *Missouri Bd. of Exam'rs*, the Eighth Circuit determined that Missouri's restrictions were different from, or in addition to, federal law and therefore preempted, allowing mail order companies to sell directly to consumers in that state. *Missouri Bd. of Exam'rs*, 447 F.3d at 1036. Florida's law is distinguished from Missouri only because it is worse, going one step further than Missouri to not merely condition mail order sales but to prohibit them entirely.

The obvious function of the mail order sales ban is to ensure that consumers only purchase hearing aids in Florida from licensed sellers who perform pre-sale audiometric tests. The purpose of those mandated fittings is an attempt to ensure the effectiveness of the devices. If there is another purpose or function of the mail order sales ban that is not subject to preemption, perhaps evidence of it might arise in discovery. But Taylor's Complaint made a plausible prima facie case that the ban exists to impose conditions on the sale of hearing aids different from, and in addition to, the federal scheme. Whatever the merits of that claim, it certainly has enough plausibility—particularly in light of another Circuit striking down mail order restrictions—to survive a 12(b)(6) challenge.

CONCLUSION

The district court erred in dismissing Plaintiff-Appellant's preemption and due process claims by failing to take his allegations in a light most favorable to him, and misconstruing both Fla. Stat. § 484.0501 and the MDA's preemption savings clause. For those reasons and those foregoing, this Court should vacate the district court's order of dismissal, reinstating Plaintiff's complaint and remanding the matter for further proceedings.

DATED: February 6, 2019.

Respectfully submitted,

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STATEMENT OF RELATED CASES

Plaintiff-Appellant is aware of no related cases within the meaning of Circuit Rule 28-2.6.

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DATED: February 6, 2019.

s/ Lawrence G. Salzman
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