

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

ROBERT DANIEL TAYLOR,

Plaintiff,

v.

Case No: 6:18-cv-613-Orl-31DCI

**LEANNE POLHILL, RANDY
ELLSWORTH, ROBERT PICKARD,
JOHN FISCHER, DOUGLAS MOORE,
PAMELA DECMEROWSKI, MARIA
HERNANDEZ, CELESTE PHILIP and
THOMAS HOLLERN,**

Defendants.

ORDER

This matter comes before the Court on the Motion to Dismiss (Doc. 67) filed by the Defendants, the members of the Florida Board of Hearing Aid Specialists and the Secretary of the Florida Department of Health, all in their professional capacities, and the Response in Opposition (Doc. 83) filed by the Plaintiff, Robert Daniel Taylor.

I. BACKGROUND

Plaintiff is engaged in the practice of selling hearing aids in Florida without the requisite license. (Doc. 1, ¶75.) Plaintiff allowed his previous license to lapse and, although he wishes to continue selling hearing aids, he has no intent to renew his license. *Id.* at ¶¶3,74,85. Plaintiff does not wish to renew his license because he would then be required to comply with Fla. Stat. § 484.0501, which he believes is antiquated. *Id.* at ¶¶3, 44, 49, 74.

II. PROCEDURAL HISTORY

In the three (comingled) counts Plaintiff argues that three sections of Florida's statutory scheme for the regulation of the sale of hearing aids are expressly preempted by federal law: § 484.0501, which imposes presale procedures on licensed hearing aid sellers, § 484.053, which penalizes unlicensed sellers of hearing aids, and § 484.054, which bans the sale of hearing aids through the mail. (*Id.* at ¶¶ 87-104.) Plaintiff also alleges that § 484.0501 breaches his due process rights under the Fourteenth Amendment. (*Id.* at ¶¶ 105-114.) By way of the instant motion, Defendants seek dismissal of the entire Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6). (Doc. 67, p. 1.)

III. LEGAL STANDARDS

A. Motion to Dismiss

In ruling on a motion to dismiss, the Court construes the complaint in the light most favorable to the plaintiff. *SEC v. ESM Group, Inc.*, 835 F.2d 270, 272 (11th Cir.1988). Dismissal of a complaint under Fed. R. Civ. P. 12(b)(6) will be granted where the allegations in a complaint, however true, do not raise a claim of entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007). "Conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts" will not prevent a complaint from being dismissed. *Davila v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir.2003).

B. Standing

Article III of the Constitution confines federal courts to adjudicating actual "cases" and "controversies." The case or controversy requirement defines for the judicial branch the idea of separation of powers, on which the Federal Government is founded. *Allen v. Wright*, 468 U.S. 737, 750, (1984). Establishing standing requires first a showing that the

plaintiff has suffered injury in fact: an invasion of a legally protected interest which is concrete and particularized, not conjectural or hypothetical. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). When a number of provisions of a statutory scheme are challenged, the plaintiff must establish standing to challenge each provision. *Camp Legal Def. Fund, Inc. v. City of Atlanta*, 451 F.3d 1257, 1273 (11th Cir. 2006).

C. Medical Device Amendments of 1976

The Medical Device Amendments of 1976 (“MDA”), along with regulations promulgated by the Food and Drug Administration (“FDA”), form a federal regulatory scheme for the sale of hearing aids (“Federal Scheme”). 21 U.S.C. § 301 *et seq.* State rules with respect to hearing aids are preempted when they relate to the “safety or effectiveness of the device” and are “different from, or in addition to” requirements under the Federal Scheme. 21 U.S.C. § 360k(a). State requirements that are not applicable to a device are not preempted, including state licensure rules which relate to the approval or sanction of “professions or occupations that administer, dispense, or sell devices.” 21 C.F.R. § 808.1(d)(3).

IV. DISCUSSION

A. Florida Statutes § 484.0501

Plaintiff challenges § 484.0501 on the basis that if he continues selling hearing aids without complying with § 484.0501 he risks future prosecution. (Doc. 1, ¶74); (Doc. 83, pp. 4-5.) Section 484.0501 imposes presale procedures on licensed hearing aid sellers and Plaintiff is not, nor does he intend to become, a licensed hearing aid seller. (Doc. 1, ¶3.) While Plaintiff remains unlicensed § 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. Plaintiff’s claims as to § 484.0501 will therefore be dismissed for lack of standing pursuant to Fed. R. Civ. P. 12(b)(1).

B. Florida Statutes § 484.053

Plaintiff argues that § 484.053, which penalizes the unlicensed sale of hearing aids (“**Licensure Requirement**”), is preempted by the Federal Scheme, which does not require hearing aid sellers be licensed. (Doc. 1, ¶¶38, 92.); 21 U.S.C. § 360k(a).¹ Section 360k(a) has been interpreted as requiring a two-step test to show preemption: there must be federal and state requirements that relate to the same device, and the state requirements must be “different from, or in addition to” the federal requirements. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). Section 360k(b) provides the FDA with the authority to exempt some state requirements from preemption, and pursuant to this authority the FDA promulgated 21 C.F.R. § 808.1(d)(3) which specifically exempts from preemption state statutes that require the licensing of hearing aid sellers.² This exemption of state licensing statutes from preemption is consistent with other federal guidance, which plainly envisions state licensing coexisting with the Federal Scheme. *See Exemption from Preemption of State & Local Hearing Aid Requirements; Applications For Exemptions*, 45 Fed. Reg. 67327 (Oct. 10, 1980) (codified at 21 C.F.R. pt. 808)(“The agency believes that the Federal

¹21 U.S.C.S. § 360k(a) provides:

(a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301 et seq.] 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 under this Act [21 USCS §§ 301 et seq.].

² 21 C.F.R. § 808.1(d)(3) provides in part:

(3) Section 521(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.

requirements along with stringent State and local licensing laws will adequately address abuses in the hearing aid industry.”)

Defendant argues, and this court agrees, that 21 C.F.R. § 808.1(d)(3) applies to exempt the Licensure Requirement from preemption under §360k(a). (Doc. 67, pp. 15-16.) Plaintiff has argued that the Licensure Requirement is preempted by federal law, but has failed to address, or mention, the federal law which exempts state licensing requirements from preemption. Plaintiff instead argues that the Licensure Requirement, though not preempted on its own, forms an improper licensing scheme in conjunction with §484.0501 which must be deemed preempted in its entirety. (Doc. 83, p. 14.) Such an 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. *Wollschlaeger v. Governor*, 848 F.3d 1293, 1317, 1319 (11th Cir. 2017) (applying Florida law to determine the severability of state statutory provisions and finding that general state practice in Florida favors severability). The cases cited by Plaintiff in support of the argument limit preemption in the same manner. *See Missouri Bd. of Exam’s for Hearing Instrument Specialists v. Hearing Help Exp., Inc.*, 447 F.3d 1033, 1036 (8th Cir. 2006) (limiting preemption to the subsection of Missouri’s hearing aid licensing regime that imposed an unwaivable presale test requirement); *N.J. Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 580 (1978) (Only the presale test requirement of the state licensing scheme was void due to preemption.)³

³ Plaintiff can only point to the nonbinding case of *MeTX v. Wal-Mart Stores* 62 F. Supp. 3d 569 (E.D. Tex. 2014) as precedent for invalidating an entire licensing scheme. (Doc. 83, p. 15.) *MeTX* is distinguishable because in the state scheme in question the unwaivable presale testing requirement was included in the definition of “fitting and dispensing,” a phrase which underpinned the entire scheme. *MeTX* 62 F. Supp. 3d at 580. Plaintiff has not made any arguments showing that Florida’s statutory scheme is analogous with that in *MeTX*.

Therefore, Plaintiff has failed to state a claim for the preemption of the Licensure Requirement that could be proven under any set of facts.

C. Florida Statutes § 484.054

Plaintiff's preemption argument against § 484.054, the mail order ban, rests entirely on his contention that the Licensure Requirement is preempted by the Federal Scheme. (Doc. 1, ¶¶54, 98, 101.) Plaintiff makes no effort to explain why § 484.054 is "different from, or in addition to" a federal requirement, nor has he argued that this provision relates to the "safety or effectiveness" of the device. He only argues it is invalid because it compels state licensed sale. Since Plaintiff has failed to state a claim for the preemption of the Licensure Requirement, his claim against § 484.054 necessarily fails.

Accordingly, it is **ORDERED** that Defendant's Motion to Dismiss (Doc. 67) is **GRANTED** and Plaintiff's Complaint is hereby **DISMISSED**.

DONE and **ORDERED** in Orlando, Florida on October 31, 2018.




GREGORY A. PRESNELL
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record