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, and CELESTE PHILIP, M.D., all in their official capacity, **DISPOSITIVE MOTION**

Defendant.
_____/

DEFENDANTS' MOTION TO DISMISS AND MEMORANDUM OF LAW

Now come the Defendants and hereby move this Honorable Court, pursuant to Fed. R. Civ. P. 8(a)(2), 12(b)(1) and (12(b)(6), to dismiss Plaintiff's Complaint (Doc. 1), and state:

FACTUAL BACKGROUND

1. On April 19, 2018, Plaintiff filed his Complaint (Doc. 1), pursuant to 42 U.S.C. § 1983, against Defendants, members of the Florida Board of Hearing Aid Specialists, and Florida's Surgeon General and Secretary of the Florida Department of Health.

2. Plaintiff's Complaint alleges he was a Licensed Hearing Aid Specialist for over 30 years, but he decided not to renew his license and continue to sell hearing aids. (Doc. 1, p. 2, 19).

3. On October 11, 2017, after Plaintiff was discovered practicing without a Hearing Aid Specialists license and offering an exam for, fitting of and sale of a hearing aid, DOH issued Plaintiff a Cease and Desist notice and citation (Doc. 1, p. 19; Doc. 1-1, p. 2-4), which advised that practicing without a Hearing Aid Specialist license was a criminal offense. (Doc. 1, p. 19-20; Doc. 1-1, p. 2-4). Plaintiff paid the citation. (Doc. 1, p. 20; Doc. 1-1, p. 3-4). On November

6, 2017, Plaintiff received a letter from DOH confirming payment of the fine and stating "[t]his matter is now closed, effective today." (Doc. 1, p. 20; Doc. 1-1, p. 6).

4. Plaintiff claims he is "unable to pursue his livelihood," "unable to conduct his business," and cannot continue without a Hearing Aid Specialist license without using the state's mandated procedures and equipment, but as he states in ¶ 94 that he continues to practice. (Doc. 1, p. 20-21, 23). Unlike the usual case dealing with licensure issues and due process, Plaintiff could easily be licensed as he has for 30 years, but he refuses to renew.

5. Plaintiff alleges §§ 484.053, 484.054 and 484.0501, Fla. Stats., are different from, and in addition to, the MDA and FDA regulations and thus, expressly preempted. (Doc. 1, p. 10). Section 484.0501, Fla. Stat., provides for minimal procedures and equipment; § 484.054, Fla. Stats., prohibits the sale or distribution of hearing aids through mail; § 484.053, Fla. Stat., addresses licensing, prohibitions and penalties.

6. Plaintiff's Complaint sues for declaratory and injunctive relief, seeking §§ 484.053, 484.054 and 484.0501, Fla. Stats., to be declared unconstitutional on their face, as applied to the sale of Class I and Class II air-conduction hearing aids by Plaintiff and *others similarly situated*; and to permanently enjoin their enforcement. (Doc. 1, p. 27). Plaintiff also seeks attorneys' fees, costs and expenses, and all further legal and equitable relief as the Court deems appropriate.

MEMORANDUM OF LAW

I. THIS COURT LACKS SUBJECT MATTER JURISDICTION TO HEAR THIS CASE, PURSUANT TO FED. R. CIV. P. 12(b)(1)

The party invoking federal jurisdiction bears the burden of establishing standing and ripeness. *See Ralston v. LM Gen. Ins. Co.*, No. 616CV1723ORL37DCI, 2016 WL 6623728, at *3 (M.D. Fla. Nov. 9, 2016), *citing Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2342, 189 L. Ed. 2d 246 (2014). Because standing and ripeness are jurisdictional issues, a motion to

dismiss for lack of standing or ripeness may properly be brought under Rule 12(b)(1). *Abusaid v. Hillsborough Cty. Bd. of Cty. Comm'rs*, 637 F. Supp. 2d 1002, 1013 (M.D. Fla. 2007), *citing Region 8 Forest Serv. Timber Purchasers Council v. Alcock*, 993 F.2d 800, 807 (11th Cir.1993).

A. Plaintiff Lacks Standing

Article III of the U.S. Constitution limits the power of the federal courts to hear "cases" and "controversies." U.S. Const. Art. III, § 2; *see also Susan B. Anthony*, 134 S. Ct. at 2341. "In the absence of standing, a court is not free to opine in an advisory capacity about the merits of a plaintiff's claims." *Bochese v. Town of Ponce Inlet*, 405 F.3d 964, 974 (11th Cir. 2005). The doctrine of standing "serves to prevent the judicial process from being used to usurp the powers of the political branches." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408, 133 S. Ct. 1138, 1146, 185 L. Ed. 2d 264 (2013), *citing Summers v. Earth Island Institute,* 555 U.S. 488, 492–493, 129 S.Ct. 1142, 173 L.Ed.2d 1 (2009).

To establish Article III standing, a plaintiff must demonstrate: (1) injury-in-fact; (2) causal connection between alleged injury and the challenged action; and (3) a favorable decision will redress the injury. *Kennedy v. Solano*, No. 18-10250, 2018 WL 2411761, at *1 (11th Cir. May 29, 2018), *quoting Shotz v. Cates*, 256 F.3d 1077, 1081 (11th Cir. 2001). For purposes of Article III standing, "an injury must be concrete, particularized, and actual or imminent." *Clapper*, 568 U.S. 39; *see McCullum v. Orlando Reg'l,* 768 F.3d 1135, 1145 (11th Cir. 2014).

As to preenforcement constitutional challenges, the injury requirement may be satisfied by establishing a *realistic danger of sustaining direct injury as a result of the statute's operation or enforcement*." *Georgia Latino All. for Human Rights v. Governor of Georgia*, 691 F.3d 1250 (11th Cir. 2012) (emphasis added). A plaintiff may demonstrate the "realistic danger" in any of three ways: "(1) *plaintiff was threatened with application* of the statute; (2) *application is likely*;

or (3) there is a *credible threat of application*." *Id, quoting Babbitt v. United Farm Workers Nat'l Union,* 442 U.S. 289, 298, 99 S.Ct. 2301, 2309, 60 L.Ed.2d 895 (1979) (emphasis added).

1. Plaintiff's Complaint Demonstrates the Investigation Against Him Was Closed, and That He Has Not Been Disciplined About the Matters for Which He Sues

Plaintiff was disciplined in October 2017, for practicing without a license, in violation of §§ 484.053(1)(e), 456.065 and 456.072(1)(k)(dd), Fla. Stat. (Doc. 1, p. 19-20; Doc. 1-1, p. 2-4), but not for selling hearing aids over the internet, in violation of § 484.054, Fla. Stat.; for failure to use minimum procedures and equipment, in violation of § 484.0501, Fla. Stat., or for § 484.053, Fla. Stat., other than § 484.053(1)(e), Fla. Stat.[1] *Id.* Nevertheless, Plaintiff seeks to strike down all sections of §§ 484.0501, 484.053 and 484.054, Fla. Stat., without challenging specific sections, and even though he was disciplined only under §484.053(1)(e), Fla. Stat.[2]

Of the statutes Plaintiff challenges, the Complaint fails to demonstrate he is threatened by the application of anything other than § 484.053(1)(e), Fla. Stat., which involves using his delinquent hearing aid specialist license. (Doc. 1, p. 19-20; Doc. 1-1, p. 2-4). In fact, Plaintiff paid a fine and the matter was closed. (Doc. 1, p. 19; Doc. 1-1, p. 6). Plaintiff currently practices without a license (Doc. 1, p. 23), so he is not currently being impacted by the challenged laws.

Plaintiff failed to demonstrate that either application of, or a credible threat of application of, anything other than § 484.053(1)(e), Fla. Stat., is likely. As Plaintiff's Complaint fails to demonstrate a realistic danger of direct injury, his challenges are exceedingly overbroad[3].

2. Requests for Relief on Behalf of "Others Similarly Situated"

A plaintiff "who wishes to bring a lawsuit on behalf of a class of *individuals similarly*

[1] § 484.053(1)(e), Fla. Stat. concerns "[u]se or attempt to use a hearing aid specialist license that is delinquent."
[2] As well as statutes Plaintiff does not challenge in this case
[3] To the extent Plaintiff relies upon his Declaration (Doc. 52, 52-1), such reliance is impermissibly outside the four corners of his Complaint; and Doc. 52-1 does not demonstrate a risk of being charged with violations of §§ 484.054 and 484.0501, Fla. Stats.

situated must first satisfy two prerequisites: '(1) the named plaintiff must have standing to bring the claim, and (2) the requirements of Rule 23 must be fulfilled.'" *City of Hialeah, Fla. v. Rojas*, 311 F.3d 1096, 1101 (11th Cir. 2002), *citing Carter v. West Publ'g Co.*, 225 F.3d 1258, 1262 (11th Cir. 2000) (emphasis added); *see also Cummings v. Baker*, 130 F. App'x 446, 449 (11th Cir. 2005) (to the extent a plaintiff seeks relief for other, similarly situated defendants, he must have standing to bring the claim).

In Plaintiff's Complaint, he seeks as relief a declaration that §§ 484.053, 484.054 and 484.0501, Fla. Stats. "are unconstitutional on their face and as applied to the sale of Class I and Class II air-conduction hearing aids by Plaintiff *and others similarly situated*"; and an injunction permanently enjoining Defendants from enforcing §§ 484.053, 484.054 and 484.0501, Fla. Stats." (Doc. 1, p. 27). Plaintiff does not specify whether he seeks an injunction only as to him or also as to the "similarly situated" others he references for declaratory relief, but notably, he does not limit the request to enjoin enforcement only as to Plaintiff.

As Plaintiff does not have, and cannot meet his burden of demonstrating, standing to seek declaratory and injunctive relief on behalf of "others similarly situated," and cannot demonstrate standing to make his constitutional challenges, this Court lacks subject matter jurisdiction over this case, pursuant to Fed. R Civ. P. 12(b)(1), and the Complaint should be dismissed.

B. Plaintiff's Constitutional Challenge Is Not Ripe for Review

"There is a considerable overlap between the doctrine[s] of ripeness and standing, and in practice, these two justiciability doctrines present similar inquiries." *Women's Emergency Network v. Bush*, 323 F.3d 937, 945–46, n. 10 (11th Cir. 2003). This is particularly so in cases involving pre-enforcement review, such as the instant case, "because these claims 'involve the possibility of wholly prospective future injury.'" *Dermer v. Miami-Dade Cty.*, 599 F.3d 1217,

1220 (11th Cir. 2010). Before a court can exercise subject matter jurisdiction over a case, it must determine whether a plaintiff's claims are ripe, and whether he has standing. *Abusaid*, 637 F. Supp. 2d at 1014–15, *citing Midrash Sephardi, Inc. v. Town of Surfside*, 366 F.3d 1214, 1223 (11th Cir. 2004).

Ripeness is "designed to prevent courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect agencies from judicial interference *until administrative decision has been formalized and its effects felt in concrete way by challenging parties*." *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 123 S. Ct. 2026, 155 L. Ed. 2d 1017 (2003) (emphasis added). Ripeness concerns "*whether the case involves uncertain and contingent future events that may not occur as anticipated, or indeed may not occur at all*." *Warner Cable Commc'ns, Inc. v. City of Niceville*, 911 F.2d 634, 642 (11th Cir. 1990) (emphasis added), *citing* 13A C. Wright, A. Miller, & E. Cooper, Federal Practice & Procedure § 3532.1, at 112 (2d ed. 1984); *see also Texas v. United States*, 523 U.S. 296, 296, 118 S. Ct. 1257, 1258, 140 L. Ed. 2d 406 (1998).

As with standing, the doctrine of ripeness does provide for "early review when, for example, the legal question is 'fit' for resolution and delay means hardship" *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13, 120 S. Ct. 1084, 1093, 146 L. Ed. 2d 1 (2000), *citing McCarthy v. Madigan*, 503 U.S. 140, 147–148, 112 S.Ct. 1081, 117 L.Ed.2d 291 (1992).

In addition to the reasons stated in Section I(A)(1) for Plaintiff's lack of standing, Plaintiffs constitutional challenges are not ripe, as they are not fit for resolution and Plaintiff's Complaint failed to sufficiently demonstrate any hardship if he does not receive early review. Plaintiff was disciplined in October 2017, for practicing without a license, but not for selling hearing aids over the internet, failure to use minimum procedures and equipment, or for sections

§ 484.053, Fla. Stat., other than § 484.053(1)(e), Fla. Stat. (Doc. 1, p. 19-20; Doc. 1-1, p. 2-4). Yet Plaintiff seeks to strike down all sections of §§ 484.0501, 484.053 and 484.054, Fla. Stat., regardless of their application to him and without specificity as to sections challenged. Plaintiff's claims involve "uncertain and contingent future events that may not occur as anticipated, or indeed may not occur at all." *Warner Cable*, 911 F.2d at 642.

As Plaintiff does not and cannot meet his burden of demonstrating ripeness for review, this Court lacks subject matter jurisdiction over this case, pursuant to Fed. R Civ. P. 12(b)(1), and the Complaint should be dismissed.

II. FAILURE TO STATE A CLAIM; INSUFFICIENCY OF PLEADING

A. Standard of Review for Sufficiency of Complaint

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). As to 42 U.S.C. § 1983 cases, courts require specificity of the facts upon which a claim is based "to weed out nonmeritorious claims." *Cabbil v. McKenzie*, No. 14-12661, 2014 WL 6804315, at *3 (11th Cir. 2014) (citation omitted).

"In considering a motion to dismiss, the Court must "accept well-pleaded facts and reasonable inferences drawn from those facts." *Carter v. Frito-Lay, Inc.*, 144 F. App'x 815, 818 (11th Cir. 2005), *quoting Gonzalez v. Reno*, 325 F.3d 1228, 1235 (11th Cir. 2003). However, "conclusory" statements and "[t]hreadbare" allegations will not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009); *see also Ziglar v. Abbasi*, 137 S. Ct. 1843, 1883, 198 L. Ed. 2d 290 (2017). Courts need not credit "conclusory allegations, unwarranted deductions of facts or legal conclusions masquerading as facts." *Rankin v. Bd. of Regents of Univ. Sys. of Georgia*, No. 17-14483, 2018 WL 1974995, at *1 (11th Cir. Apr. 26, 2018), *citing Oxford Asset Mgmt. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002). Additionally,

unwarranted deductions of fact *made upon information and belief* are not admitted as true for the purpose of testing the sufficiency of the allegations. *Daisy, Inc. v. Pollo Operations, Inc.*, No. 2:14-cv-564-FtM-38CM, 2015 WL 1418607, at *6 (M.D. Fla. Mar. 27, 2015), *citing Sinaltrainal v. Coca-Cola Co.*, 578 F.3d 1252, 1268 (11th Cir. 2009).

B. The Complaint Violates Minimum Pleading Requirements of Fed. R. Civ. P. 8

Plaintiff's Complaint violates the minimum pleading requirements of Fed.R.Civ.P. 8, as it is a shotgun pleading, fails to show "that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), and contains conclusory allegations and allegations based "upon information and belief."

In Count One, Plaintiff realleges and incorporates the prior 86 paragraphs; in Count Two, Plaintiff realleges and incorporates the prior 95 paragraphs; and in Count Three, Plaintiff realleges and incorporates the prior 104 paragraphs (Doc. 1, p. 22, 24, 25); as a result, each count adopts the allegations of all preceding counts. This is the most common type of shotgun pleading. *See Weiland v. Palm Beach Cty. Sheriff's Office*, 792 F.3d 1313, 1321 (11th Cir. 2015) (most common shotgun pleading contains multiple counts "where each count adopts the allegations of all preceding counts, causing each successive count to carry all that came before and the last count to be a combination of the entire complaint"). With this type of shotgun pleading, "allegations of fact that may be material to a determination of count one, but not count four, are nonetheless made a part of count four...it is virtually impossible to know which allegations of fact are intended to support which claim(s) for relief." *Paylor v. Hartford Fire Ins. Co.*, 748 F.3d 1117, 1126 (11th Cir. 2014); *see also Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp.*, 305 F.3d 1293, 1295 (11th Cir. 2002).

The Eleventh Circuit "has been roundly, repeatedly, and consistently condemning [shotgun pleadings] for years." *Davis v. Coca–Cola Bottling Co.*, 516 F.3d 955, 979 (11th Cir.

2008). It is appropriate for a defendant served with a shotgun complaint to move to dismiss under Fed. R. Civ. P. 12(b)(6). *See Weiland*, 792 F.3d at 1320; *Terry v. Interim Healthcare Gulf Coast, Inc*., No. 8:18-CV-692-T-33JSS, 2018 WL 1992276, at *1 (M.D. Fla. Apr. 27, 2018).

The Complaint also fails to meet the *Iqbal* and *Twombly* pleading standards, as it does not contain statements showing entitlement to relief and does not raise reasonable inferences of a risk of him being charged with violations of §§ 484.053, 484.054 and 484.0501, Fla. Stats. "[A]n inference is not reasonable if it is only a guess or a possibility, for such an inference is not based on the evidence but is pure conjecture and speculation." *Carlson v. United States*, 754 F.3d 1223, 1229 (11th Cir. 2014), *quoting Daniels v. Twin Oaks Nursing Home*, 692 F.2d 1321, 1324 (11th Cir. 1982). Plaintiff's allegations do not permit the Court to infer more than a possibility that he is at risk of being charged with violations of §§ 484.053, 484.054 and 484.0501, Fla. Stats.

Plaintiff's Complaint makes numerous conclusory claims:

> ¶ 2 - Hearing loss affects an estimated 30-million people across America. Yet many of those people lack access to hearing aids, because onerous, outdated, and unconstitutional regulations limit who may sell them and impose conditions on their sale, which decreases their availability and increases the cost of obtaining them.
>
> ¶ 4 - Florida's mandated procedures and equipment are unreasonable in light of advances in technology since its statutes.
>
> ¶ 5- Florida's regulations require Dan to suspend his business to avoid punishment by the state. He will suffer lost business and the deprivation of his constitutional rights unless the state laws challenged herein are declared unconstitutional and Defendants are enjoined from enforcing them.
>
> ¶ 18 - A significant reason why so few benefit from needed hearing aids is state regulation of hearing aid sales, which impose burdensome or unnecessary "conditions of sale," making it more difficult for consumers to access hearing aids, restrict who may sell the devices, and tend to increase the price of them to end consumers.
>
> ¶ 39 - Florida law prohibits the sale of hearing aids without a "fitting," using particular procedures and equipment prescribed by statute and regulation *to*

> *ensure the effectiveness of the hearing aid*. Fla. Stat. § 484.0501. (emphasis added).
>
> ¶ 40 - Florida's requirement of a presale fitting, and the particular minimum procedures mandated by Fla. Stat. § 484.0501, are different from and in addition to rules promulgated by the MDA and related FDA regulations and are expressly preempted by them.
>
> ¶ 51 Requiring sellers of hearing aids to engage in unnecessary testing or use procedures that serve no useful purpose in light of current hearing aid technology irrationally burdens sellers' constitutional right to earn a living in the occupation of their choice.
>
> ¶¶ 54, 98 The mail order sales ban has the purpose and effect of prohibiting the sale of hearing aid devices in Florida by a person unlicensed by the state as a Hearing Aid Specialist;
>
> ¶¶ 55, 99 - The 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
>
> ¶¶ 56 - prohibition on mail order sales to Florida consumers serves the purpose of protecting hearing aid dispensers licensed by the Board of Hearing Aid Specialists from competition from unlicensed sellers.
>
> ¶ 60 - Section 484.054 is also expressly preempted by the MDA and related FDA regulations because it prohibits sale of hearing aids *without performing state-mandated presale 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.
>
> ¶ 73 The more intrusive and time-consuming sales and fitting procedures mandated by Florida law tend to dissuade consumers from seeking information or engaging in the process to select a hearing aid.

(Doc. 1, p. 1-3, 5, 11-12, 14-16, 19).

Conclusory allegations are insufficient pleading, *Iqbal*, 556 U.S. at 678; *see also Ziglar*, 137 S. Ct. at 1883. The Court need not credit the above "conclusory allegations, unwarranted deductions of facts or legal conclusions masquerading as facts." *Rankin*, 2018 WL 1974995, at *1, *citing Oxford*, 297 F.3d at 1188.

Also, Plaintiff's Complaint contains the following claims "upon information and belief":

> ¶ 31 - Upon information and belief, and according to the FDA and the National Academies of Sciences, Engineering and Medicine, the medical evaluation requirement "provides no clinically meaningful benefit [to consumers]" and the need to affirmatively waive the requirement "presents a barrier to access with no substantial enhancement of patient safety."
>
> ¶ 47 Upon information and belief, hearing aid dispensers violate Florida state law even when selling lawfully under federal law, pursuant to procedures promulgated by the MDA and related FDA regulations.
>
> ¶ 49 Upon information and belief, the procedures and equipment for presale audiometric testing mandated by Fla. Stat. § 484.0501 are antiquated. They no longer represent the state of the art, and in fact, require procedures rendered wholly unnecessary by modern technology. Whatever rational basis may have existed for the regulation at the time of its enactment has been superseded by changes in hearing aid technology that render the particular procedures and equipment mandated by the law unnecessary or irrational.
>
> ¶ 58 - Upon information and belief, Florida's ban on mail order sales is aimed at ensuring the safety and effectiveness of hearing aids purchased by Florida consumers.

(Doc. 1, p. 9, 13-14, 16).

"When a plaintiff sets out allegations on information and belief, he is representing that he has a good-faith reason for believing what he is saying, but acknowledging that his allegations are 'based on secondhand information that [he] believes to be true.'" *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011), *quoting* Black's Law Dictionary 783 (7th ed. 1999). "'Information and belief' does not mean pure speculation." *Menard v. CSX Transp., Inc.*, 698 F.3d 40, 44 (1st Cir. 2012). Unwarranted deductions of fact *made upon information and belief* are not admitted as true for the purpose of testing the sufficiency of the allegations. *Daisy, Inc.*, 2015 WL 1418607, at *6, *citing Sinaltrainal*, 578 F.3d at 1268. Plaintiff has no good faith basis for these allegations, and they amount to mere speculation that should not be assumed true in deciding this motion to dismiss.

Plaintiff's Complaint should be dismissed, pursuant to Fed. R Civ. P. 8(a).

C. The Complaint Fails to State a Claim Upon Which Relief Can Be Granted

Fed. R. Civ. P. 12(b)(6) provides for dismissal of a pleading or portion of a pleading which fails to state a claim upon which relief can be granted.

Plaintiff's Complaint is rife with conclusory claims and claims "upon information and belief," which the Court need not credit[4],[5], *Rankin*, 2018 WL 1974995, at *1, *citing Oxford*, 297 F.3d at 1188, and unwarranted deductions of fact *made upon information and belief* are not admitted as true for the purpose of testing the sufficiency of the allegations. *Daisy, Inc.*, 2015 WL 1418607, at *6, *citing Sinaltrainal*, 578 F.3d at 1268.

[4] See ¶ 2 – "[P]eople lack access to hearing aids, because onerous, outdated, and unconstitutional regulations limit who may sell them and impose conditions on their sale, which decreases their availability and increases the cost of obtaining them"; ¶ 4 – "Florida's mandated procedures and equipment are unreasonable in light of advances in technology since its statutes";¶ 18 – "A significant reason why so few benefit from needed hearing aids is state regulation of hearing aid sales, which impose burdensome or unnecessary "conditions of sale," making it more difficult for consumers to access hearing aids, restrict who may sell the devices, and tend to increase the price of them to end consumers"; ¶ 39 - Florida law prohibits the sale of hearing aids without a "fitting," using particular procedures and equipment prescribed by statute and regulation *to ensure the effectiveness of the hearing aid*. Fla. Stat. § 484.0501 (emphasis added); ¶ 51 "Requiring sellers of hearing aids to engage in unnecessary testing or use procedures that serve no useful purpose in light of current hearing aid technology irrationally burdens sellers' constitutional right to earn a living in the occupation of their choice"; ¶¶ 54, 98 The mail order sales ban has the purpose and effect of prohibiting the sale of hearing aid devices in Florida by a person unlicensed by the state as a Hearing Aid Specialist; ¶¶ 55, 99 - The 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; ¶¶ 56 - prohibition on mail order sales to Florida consumers serves the purpose of protecting hearing aid dispensers licensed by the Board of Hearing Aid Specialists from competition from unlicensed sellers; ¶ 60 – "Section 484.054 is also expressly preempted by the MDA and related FDA regulations because it prohibits sale of hearing aids *without performing state-mandated presale 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"; ¶ 73 "The more intrusive and time-consuming sales and fitting procedures mandated by Florida law tend to dissuade consumers from seeking information or engaging in the process to select a hearing aid."(Doc. 1, p. 1-5, 11-16, 19).

[5] ¶¶31 – "[u]pon information and belief … the medical evaluation requirement "provides no clinically meaningful benefit [to consumers]"); ¶ 49 "[u]pon information and belief, the procedures and equipment for presale audiometric testing mandated by Fla. Stat. § 484.0501 are antiquated. They no longer represent the state of the art, and in fact, require procedures rendered wholly unnecessary by modern technology. Whatever rational basis may have existed for the regulation at the time of its enactment has been superseded by changes in hearing aid technology that render the particular procedures and equipment mandated by the law unnecessary or irrational"; ¶ 58 - "[u]pon information and belief, Florida's ban on mail order sales is aimed at ensuring the safety and effectiveness of hearing aids purchased by Florida consumers." (Doc. 1, p. 9, 13-14, 16).

1. Plaintiff's Supremacy Clause Preemption Claims

a. Binding Precedent in the Eleventh Circuit Precludes This Court from Deciding in Plaintiff's Favor

The Eleventh Circuit's precedent from *Smith v. Pingree,* 651 F.2d 1021 (5th Cir 1981)[6], holds that Florida's statutory requirements as to minimal procedure and equipment to be used in fitting and selling of hearing aids, then contained in § 468.135(7), Fla. Stat., are not preempted.

"[B]inding precedent . . . cannot . . . simply be ignored" by a district court. *Hand v. Scott*, 888 F.3d 1206, 1208 (11th Cir. 2018); *see also McGinley v. Houston*, 361 F.3d 1328, 1331 (11th Cir. 2004) (under the principle of *stare decisis*, "[a] circuit court's decision binds the district courts sitting within its jurisdiction"). The Eleventh Circuit is bound by prior precedent under the prior-panel-precedent rule, "unless and until it is overruled or undermined to the point of abrogation by the Supreme Court or by this court sitting *en banc.*'" *Fields v. Warden, FCC Coleman-USP II*, 641 F. App'x 863, 865 (11th Cir. 2016), *quoting In re Lambrix,* 776 F.3d 789, 794 (11th Cir. 2015) and *citing United States v. Archer,* 531 F.3d 1347, 1352 (11th Cir. 2008).

There is no clear abrogation and this Court is bound by the precedent of *Pingree*.

b. Plaintiff's Supremacy Clause Claims

21 U.S.C. § 360k(a), referred to as § 521, provides:

> 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 chapter 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 chapter.

The FDA is satisfied that "Congress intended section 521(1) to preempt only those State or local requirements *that relate directly to the safety or effectiveness of specific devices,"* and

[6] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), this court adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981.

not to peripheral areas involving devices." (Exhibit A, p. 1). The Defendants respectfully request this Court to take judicial notice of Exhibit A, an FDA Advisory Opinion[7].

When providing an opinion as to § 346.250.1, RSMo, Missouri's mail order requirement, which provided that no one could "sell, through the mails, directly to the consumer, hearing aids *without prior fitting and testing by a hearing aid fitter of licensed dealer*," the FDA concluded this was not a requirement with respect to a device under § 521 of 21 U.S.C. 360k(a). (Exhibit A, p. 1). In *Missouri Bd of Exam'rs,* 447 F.3d 1033, the Eighth Circuit addressed this issue, and found, contrary to the FDA's opinion, that the mail order statute was preempted. However, referring to the *Pingree* decision, the Eighth Circuit noted "significant distinctions" between Florida's law and the Missouri statute. In *Missouri Bd of Exam'rs,* 447 F.3d at 1036. "One element of the Florida law required that audiometric tests be conducted in a certified testing room with sound pressure levels at specified frequencies, *but unlike the Missouri statute it allowed consumers to waive the requirement*." *Id.* (emphasis added), *citing* §468.135(7), Fla. Stat. and *Pingree,* 651 F.2d at 1023. The Eighth Circuit also noted that "Florida law also had no mandatory testing requirement in contrast to the Missouri statute which mandates presale testing without exception.". *Id.* In *METX, LLC v. Wal-Mart Stores Texas, LLC,* 62 F. Supp. 3d 569 (E.D. Tex. 2014), the Texas statute concerning its mail order ban also required referenced a prefitting exam for a person ordering a hearing aid by mail.

[7] In deciding a motion to dismiss, a Court may consider facts that are within the public record and can be judicially noticed. See *Horne v. Potter*, 392 F. App'x 800, 802 (11th Cir. 2010)(district court took judicial notice of facts in public records without converting motion to dismiss into a motion for summary judgment); *Halmos v. Bomardier Aerospace Corp.*, 404 F. App'x 376, 377 (11th Cir. 2010)(a district court may take judicial notice of matters of public record without converting a Rule 12(b)(6) motion into a Rule 56 motion); *Universal Express, Inc. v. U.S. S.E.C.*, 177 F. App'x 52, 53 (11th Cir. 2006) (public records are among the permissible facts that a district court may consider without converting a motion to dismiss into a motion for summary judgment).

As the Eighth Circuit specifically noted in *Missouri*, Florida's mail order ban does not require state-mandated presale procedures to before hearing aids can be sold by mail, *Missouri Bd of Exam'rs*, 447 F.3d at 1036. In fact, §484.054, Fla. Stat., outright bans mail order hearing aid purchases, yet Plaintiff makes the conclusory and erroneous claim that §484.054, Fla. Stat., "it prohibits sale of hearing aids *without performing state-mandated presale procedures aimed* at assuring the effectiveness of the devices." As Florida's § 484.054, Fla. Stats., which prohibits the sale or distribution of hearing aids through mail, does not require presale fitting and testing, this is a significant distinction between *Missouri* and *METX*, and the instant case.

As to licensure, Plaintiff makes the unsupportable argument that licensure is preempted (Doc. 1, p. 10), but it is clearly not preempted. While Plaintiff states federal law does not require licensing (Doc. 1, p. 2, 10), it also does not prohibit licensure statutes. 21 C.F.R. § 808.1(d)(3), (5) specifically provides that *licensing and general enforcement are not pre-empted by Section 521(a)*. Also, as reported in the Federal Register at 45 FR 67321:

> [a]lthough FDA is denying exemption from preemption for many state requirements, *it encourages the States to remain active in regulating the hearing aid industry. FDA particularly encourages the States to adopt strict licensing laws to establish and maintain minimum competency requirements for persons who test for hearing loss and select and fit hearing aids*.

Demonstrating its support for strict licensing requirements, the FDA issued an advisory opinion to Connecticut as to Ct. Stat. § 20-396(4), which precluded a hearing aid dealer from selecting a hearing aid for the customer. See 53 FR 52789. The FDA concluded that, as Ct. Stat. § 20-396(4), "*is a licensing provision for hearing aid dealers. Therefore, it is not a requirement with respect to a device within the meaning of section 521 of the act and is not preempted*." *Id.* (emphasis added).

As the FDA itself supports licensing provisions for hearing aid dealers and found that licensing provisions are neither a requirement with respect to a device within the meaning of

section 521 of the act nor preempted, and 21 C.F.R. § 808.1(d)(3), (5) specifically provides that licensure and enforcement are not preempted, Plaintiff cannot demonstrate that the licensing requirements of § 484.053, Fla. Stat., are preempted.

The Defendants anticipate Plaintiff will cite in his response to this motion these cases in support his Complaint: *Missouri Bd of Exam'rs.*, 447 F .3d 1033; *METX*, 62 F. Supp. 3d 569; *Hayes*, 691 F.2d 573; and *New Jersey Guild*, 384 A.2d 795. However, as referenced *supra* at p. 1415, and below, these cases are inapplicable and/or distinguishable from the instant case.

In *Mass. v. Hayes*, 691 F.2d 573, the statute involved did not permit adults to waive exams, which the Court found to be preempted. No such allegation is made in Plaintiff's Complaint, so *Hayes* is inapplicable. In *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978), a state court case which has no binding on this Court, the New Jersey Supreme Court found everything that was challenged, except presale testing, not be preempted.

Plaintiff's Supremacy Clause challenges fail to demonstrate that the challenged Florida statutes, particularly as to licensure and mail order sales, relate to the safety and effectiveness of hearing aids. In addition, the precedential *Pingree* decision, which held that Florida's statutory requirements as to the minimal procedure and equipment for the fitting and selling of hearing aids, then contained in § 468.135(7), Fla. Stat., are not preempted, is binding on this Court. Plaintiff fails to state a claim and his Complaint should be dismissed, pursuant to Fed. R. Civ. P. 12(B)(6).

2. Plaintiff's Due Process Claim Fails

"Regulations on entry into a profession, as a general matter, are constitutional if they "have a *rational* connection with the applicant's fitness or capacity to practice" the profession. *Lowe v. S.E.C.*, 472 U.S. 181, 228, 105 S. Ct. 2557, 2582, 86 L. Ed. 2d 130 (1985), *quoting*

Schware v. Board of Bar Examiners, 353 U.S. 232, 239, 77 S.Ct. 752, 756, 1 L.Ed.2d 796 (1957) (state can require high standards of qualification "but any qualification must have a rational connection with the applicant's fitness or capacity to practice [the profession]"). "A state law will not be permitted to deny a person the right to pursue his occupation (including the physician class in this case) unless it is *rationally related to the achievement of a legitimate state interest*." *Margaret S. v. Treen*, 597 F. Supp. 636, 674 (E.D. La. 1984), *aff'd sub nom. Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986) (emphasis added), *citing Kelley v. Johnson*, 425 U.S. 238, 247, 96 S.Ct. 1440, 1445, 47 L.Ed.2d 708 (1976); *Weber v. Aetna Casualty & Surety Co.*, 406 U.S. 164, 172–73, 92 S.Ct. 1400, 1405, 31 L.Ed.2d 768 (1972).

In ¶ 25, Plaintiff notes that "the FDA regulations require hearing aid dispensers to be aware of eight 'red flags,'" (Doc. 1, p. 25), but without a state licensing scheme, the state is unable to ensure that those distributing hearing aids follow these important steps. Additionally, where the FDA itself does not deem bans of sales over the internet or licensure as preempted, and 21 C.F.R. § 808.1(d)(3), (5) specifically provides that *licensing and general enforcement are not pre-empted by Section 521(a)*, there cannot be said to be no rational basis for these provisions.

§ 484.0401, Fla. Stat., provides the Legislative purpose of the challenged statutes:

> The Legislature recognizes that the dispensing of hearing aids requires particularized knowledge and skill to *ensure that the interests of the hearing-impaired public will be adequately served and safely protected*. It recognizes that a *poorly selected or fitted hearing aid* not only will give little satisfaction but *may interfere with hearing ability* and, therefore, deems it *necessary in the interest of the public health, safety, and welfare to regulate the dispensing of hearing aids in this state*. Restrictions on the fitting and selling of hearing aids shall be *imposed only to the extent necessary to protect the public from physical and economic harm*, and restrictions shall not be imposed in a manner which will unreasonably affect the competitive market.

§ 484.0401, Fla. Stat. (emphasis added).

The challenged statutes are rationally related to the protection of the hearing aid consumers in Florida and do not violate Plaintiff's due process rights.

CONCLUSION

Based on the foregoing, the Defendants respectfully move this Honorable Court to dismiss Plaintiff's Complaint (Doc. 1).

Dated: July 13, 2018

Respectfully submitted,

PAMELA JO BONDI
ATTORNEY GENERAL

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, on the 13th day of July, 2018, I electronically caused the foregoing document to be filed with the Clerk of Court using CM/ECF, which will electronically serve copies of the foregoing upon the following:

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s/ Anne F. McDonough
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DOCKETS MANAGEMENT BRANCH
89 JAN -5 AM 10: 35

Mr. Q. Russell Hatchl, Esquire
Clohan, Adams & Dean
Attorneys at Law
Suite 400
1101 Vermont Avenue, N.W.
Washington, D.C. 20005

Re: Docket No. 88A-0213/AP

Dear Mr. Hatchl:

This is in response to your letter of May 25, 1988, requesting an advisory opinion as to whether the provisions of Section 346.250.1, RSMo are preempted by section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k(a)). This section prohibits the sale of a hearing aid through the mail directly to a consumer without prior fitting or testing by a licensed hearing aid fitter or dealer.

Section 521(a) of the act provides that no State or local government may establish or continue in effect any requirement with respect to the safety and effectiveness of a device or any other requirement applicable to the device under the act if such requirement is different from, or in addition to, a requirement which is applicable to the device under the act. Section 521(b) of the act provides that the Commissioner of Food and Drugs may, upon application of a State or local government, exempt a requirement from preemption, if the State or local requirement for the device is more stringent than the requirement under the act, or if the requirement is necessitated by compelling local conditions and compliance with it does not cause the device to be in violation of a requirement under the act.

Our examination of the legislative history of the act satisfies us that Congress intended section 521(a) to preempt only those State or local requirements that relate directly to the safety or effectiveness of specific devices. State or local requirements that are substantially identical to particular FDA requirements, however, are not preempted. Also, section 521(a) does not preempt State or local requirements relating to peripheral areas involving devices. Therefore, State or local requirements with respect to the practice of healing arts, general administrative procedures such as licensing, registration, fee collection and purchasing, and other requirements of general safety applicability such as fire and electrical safety codes, are not preempted by section 521.

We have reviewed Section 346.250.1, RSMo and have determined that it is not directly related to the safety or effectiveness of hearing aids. Therefore, it is not a requirement with respect to a device within the meaning of section 521 of the act and is not preempted. Section 808.1(d)(3) of FDA's regulations governing preemption of medical device requirements (21 CFR 808.1(d)(3)) provides in part: "Section 521(a) does

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not preempt State or local ... 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." We believe that Section 346.250.1, RSMo is such a requirement.

If you have any questions about this matter, please contact Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-4874. A copy of your letter and this advisory opinion are being sent to the State of Missouri, Council for Hearing Aid Dealers and Fitters.

Sincerely yours,

John M. Taylor
Associate Commissioner
for Regulatory Affairs

cc: Charlotte P. King
Executive Secretary
State of Missouri
Council for Hearing Aid Dealers and Fitters
3523 N. Ten Mile Drive
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bcc: HFC-1 (Taylor)
HFC-200 (Trujillo)
HFC-220 (Howard)
HFC-230 (Chron, r/f, ENF-1.6, Bender, #88-0661)
HFZ-100
HFZ-300 (Gundaker)
HFZ-80 (White)
HFZ-84 (Sheehan)
GCF-1 (Rothstein, Horton)
HFA-305 (88A-0213)

Drafted:JSheehan:06/23/88
Revised:BRothstein:10/05/88
Approved:LHorton:10/06/88
Redrafted:CBender:10/14/88
DT:10/18/88:BENDER#3:Doc#1.54:rr
Review:TNeprud:10/19/88
DT:10/19/88:rr
FT:10/20/88:rr

Kiren Mathews

From: cmecf_flmd_notification@flmd.uscourts.gov
Sent: Friday, July 13, 2018 3:24 PM
To: cmecf_flmd_notices@flmd.uscourts.gov
Subject: Activity in Case 6:18-cv-00613-GAP-DCI Taylor v. Polhill et al Motion to dismiss/lack of jurisdiction

U.S. District Court

Middle District of Florida

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The following transaction was entered by McDonough, Anne on 7/13/2018 at 6:24 PM EDT and filed on 7/13/2018

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Document Number: 67

Docket Text:
MOTION to dismiss for lack of jurisdiction , MOTION to dismiss for failure to state a claim by All Defendants. (Attachments: # (1) Exhibit FDA Advisory Opinion)(McDonough, Anne)

6:18-cv-00613-GAP-DCI Notice has been electronically mailed to:

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Document description: Exhibit FDA Advisory Opinion
Original filename:n/a
Electronic document Stamp:
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