PACIFIC LEGAL FOUNDATION

LITIGATION BACKGROUNDER

Federal Lawsuit Fights for Freedom in Hearing Care

Taylor v. Polhill

Entrepreneur files constitutional case challenging the Florida Board of Hearing Aid Specialists' antiquated and unlawful regulation of hearing aid sales.

Summary

Hearing loss affects an estimated 30 million Americans, yet the U.S. Food and Drug Administration has found that only about one in five persons who could benefit from a hearing aid actually use them. A significant reason why so many go without the devices is state licensing regulations, which impose burdensome and unnecessary "conditions of sale" that restrict who may sell the devices, how they may be sold, and tend to increase their price.

For more than 30 years, Dan Taylor has earned his livelihood as a licensed Hearing Aid Specialist in Florida. In recent years, he observed that while hearing aid technology has advanced remarkably during the past decades, the regulation of hearing aid sales has not. Florida law requires him to perform the same tests and use the same equipment in selling hearing aids that was customary in the 1970s, completely ignoring the fact that modern hearing aids contain sophisticated hardware and software that allows almost anyone to more effectively select the right hearing aid with such common tools as personal computers and smartphone apps. Moreover, the state rules flout federal hearing aid laws aimed at eliminating needless and burdensome state regulation. Sellers licensed by the Florida Board of Hearing Aid Specialists who fail to follow the state's antiquated procedures are guilty of a felony, and subject to ruinous fines or even jail time.

Dan became frustrated that Florida law subverted innovation in hearing care, making him perform unnecessary tests contrary to federal law and prohibiting him from

offering state of the art service and convenience to his customers. He did not want to risk punishment by selling hearing aids in a manner inconsistent with the Board's mandates. Instead, he gave up his Florida Hearing Aid Specialists license and filed this lawsuit in the U.S. District Court for the Middle District of Florida challenging the state's burdensome regulation of hearing aid sellers and hearing aid sales.[1] His lawsuit seeks to vindicate his right to sell hearing aids to Florida consumers, subject only to reasonable regulations not forbidden by federal law.

Florida's hearing aid seller regulations stifle innovation and frustrate federal law

The federal government has established a relatively simple set of rules governing the "conditions of sale" of hearing aids.[2] In authorizing those regulations, Congress expressly preempted state laws that impose conditions of sale on hearing aids that are "different from" or "in addition to" the federal rules.[3] The rules established by federal law are aimed at increasing access to hearing aids and eliminating state regulation that would needlessly burden their sale. No license is required to sell a hearing aid under federal law, for instance, nor is any testing by a doctor, audiologist, or seller. The FDA deems hearing aids whose manufacture it has approved as representing virtually no risk to public health, classified alongside tongue depressors and motorized wheelchairs in terms of safety.

Despite the federal rules, the Florida Board of Hearing Aid Specialists declares that the occupation of selling hearing aids in Florida is a "privilege granted by the state." Florida law makes it a felony crime to sell a hearing aid without a license, to sell a hearing aid by mail or over the internet, or to fail to use the state's mandated testing procedures and equipment as part of the sales process. It is likewise a crime to help a consumer select a hearing aid or counsel them on how to use it. Those procedures include hearing tests that were state of the art in the 1970s, but which are now made unnecessary by modern hearing aid technology—and even require hearing aid sellers to build an expensive and unnecessary sound-proofed room certified by the state in which to perform the tests. Further, Florida has enacted among the most onerous licensing requirements in the nation, including the highest application fee ($855) and a requirement that licensees apprentice for a total of 480 hours under the supervision of a licensed sponsor before selling a hearing aid on their own.

All of this regulation insulates the market for hearing aids from competition—making the business lucrative for those who have licenses, but at the expense of consumers and more innovative entrepreneurs. Worse, the state's mandated testing procedures waste the time of consumers and sellers because they take longer and are

[1] [[link to complaint]].
[2] See 21 C.F.R. §§ 801.420-21 (implementing FDA regulations authorized by the Medical Device Amendments of 1976, 21 U.S.C. § 321(h)).
[3] 21 U.S.C. § 360(a).

less effective than modern methods. During Dan's career, he has noted that many customers are unwilling to even be evaluated for a hearing aid—and forgo their benefits—simply due to the perceived inconvenience or stigma associated with traditional testing.

Similar licensing and "conditions of sale" regulations have been struck down by federal courts in recent years in Texas[4] and Missouri.[5] These laws were voided when the courts determined that the state regulation was "different from, or in addition to" federal requirements intended to expressly preempt state regulation of hearing aids, thereby violating the Supremacy Clause of the U.S. Constitution. The federal law holds that where "there is a conflict between [federal regulation of hearing aids] and State or local requirements, the Federal regulations shall prevail."[6]

In addition, economic regulations that do not have a "rational relationship" to a legitimate governmental objective, such as protecting public health and safety, are subject to challenge under the Due Process Clause of the Fourteenth Amendment. The Supreme Court has said that antiquated laws may sometimes be invalidated when "circumstances change" from the era in which they were enacted. That is the case here. To the extent that there may have ever been a rational justification for Florida's regulations on hearing aids, those regulations are now obsolete—a simple waste of time that needlessly restricts the sale of beneficial hearing aid devices that the FDA has said pose no, or the most minimal, risk to health or safety.

The technology involved in hearing aids has changed tremendously since Florida began regulating their sale in the 1970s. At that time, the mandated audiology equipment and audiometric testing was state of the art for fitting hearing aids. Today, however, software is more effective at helping to select a hearing aid and adjust them compared to old-style audiology exams—and can be done with a smartphone or personal computer. Technology has increased the range of devices that customers can try, and lowered their cost. In short, Florida's restrictions on hearing aid sellers and sales no longer benefit the public; they simply restrict opportunities for hearing aid sellers, stifle innovation in hearing care, and make it more difficult for consumers to access lower cost services that can benefit them.

Legal claims

Plaintiff Dan Taylor lives and works in Brevard County, Florida. He has earned his livelihood selling hearing aids to consumers in Florida for more than 30 years. The Defendants in the case are the members of the Florida Board of Hearing Aid Specialists,

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[4] *METX, LLC v. Wal-Mart Stores Texas, LLC,* 62 F. Supp. 3d 569, (E.D. Tex., 2014).

[5] *Mo. Bd. of Exam'rs for Hearing Instrument Specialists v. Hearing Help Express, Inc.*, 447 F.3d 1033, 1034–36 (8th Cir.2006);

[6] 21 C.F.R. § 808.1(d)(3).

which is responsible for the rules regulating the sale of hearing aids in the State of Florida. They are sued only in their official (not personal) capacity. No money damages are sought—only a declaration that Florida's hearing aid sales regulations are unconstitutional and an injunction prohibiting their future enforcement. The Secretary of the Florida Board of Health is also included as a defendant in her official capacity because she is charged with enforcing penalties for violations of the hearing aid seller rules.

Dan has brought three legal claims. First, that the conditions that Florida's licensing regulations impose on the sale of hearing aids violate the U.S. Constitution's Supremacy Clause because they are expressly preempted by federal law and FDA regulations; Second, that Florida's prohibition on mail-order/internet sales of hearing aids is similarly preempted by federal law and FDA regulations that permit such sales; and Third, that Florida's regulations violate the right to earn a living (protected by the Due Process Clause of the Fourteenth Amendment) because the antiquated tests and equipment that Florida law requires as part of the hearing aid sales process constitute unnecessary and unreasonable burden on the sale of hearing aids in light of advances in hearing aid technology during the past four decades.

Pacific Legal Foundation and the litigation team

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The litigation team for this case includes attorneys Anastasia Boden, Larry Salzman, Christina Martin, and Timothy Snowball.

For more information, visit www.pacificlegal.org/Taylor. To arrange interviews with Dan Taylor or PLF attorneys, please contact our media team at 202.465.8733 or media@pacificlegal.org.