

NO. 16-50017

**UNITED STATES COURT OF APPEALS FOR THE
FIFTH CIRCUIT**

TELADOC, INCORPORATED; TELADOC PHYSICIANS, PROFESSIONAL
ASSOCIATION; KYON HOOD; EMMETTE A. CLARK,
Plaintiffs-Appellees

v.

TEXAS MEDICAL BOARD; MICHAEL ARAMBULA, M.D., Pharm. D., in his
official capacity; MANUEL G. GUAJARDO, M.D., in his official capacity; JOHN
R. GUERRA, D.O., M.B.A., in his official capacity; J. SCOTT HOLLIDAY, D.O.,
M.B.A., in his official capacity; MARGARET MCNEESE, M.D., in his official
capacity; ALLAN N. SHULKIN, M.D., in his official capacity; ROBERT B.
SIMONSON, D.O., in his official capacity; WYNNE M. SNOOTS, M.D., in his
official capacity; KARL SWANN, M.D., in his official capacity; SURENDRA K.
VARMA, M.D., in her official capacity; STANLEY WANG, M.D., J.D., MPH, in
his official capacity; GEORGE WILLEFORD, III, M.D., in his official capacity;
JULIE K. ATTEBURY, M.B.A., in her official capacity; PAULETTE BARKER
SOUTHARD, in her official capacity, ,

Defendants-Appellants,

On Appeal from the United States District Court
For the Western District of Texas, Austin Division, Hon. Robert Pitman
Case No. 1:15-cv-343

**BRIEF OF *AMICI CURIAE* TEXAS NEURODIAGNOSTIC ASSOCIATES,
INC. AND WILLIAM L. HIGH, M.D., PH.D. IN SUPPORT OF
AFFIRMANCE OF DISTRICT COURT ORDER**

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CERTIFICATE OF INTERESTED PERSONS

1. In addition to the Plaintiffs-Appellees and Defendants-Appellants, as identified in Appellants' Brief and *Amici Curiae* briefs filed in support of reversal of the district court's order, *Amici Curiae* in support of Plaintiffs-Appellees and in support of upholding the district court's order are:

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CORPORATE DISCLOSURE STATEMENT AND CONSENT

Amicus Curiae Texas Neurodiagnostic Associates, Inc., is a Texas incorporated health-related company. Texas Neurodiagnostic Associates, Inc. does not have any parent corporation and is not owned by any publicly held corporations. All parties consented to this filing.

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STATEMENT OF THE ISSUE

The issue in this case is whether the Texas Medical Board (“TMB”), a board comprised of practicing physicians, may impose anticompetitive rules that harm physicians with whom they compete, reduce access to care for patients, and increase healthcare costs, all without active state oversight.

INTEREST OF *AMICUS CURIAE*

Texas Neurodiagnostic Associates, Inc. (“TNA”) is a Texas incorporated health related company, providing innovative remote or off-site electrodiagnostic testing to patients mostly within Texas. TNA has professional services agreements with neurologists within the State of Texas to provide remote off-site electrodiagnostic tests to Texans and some out-of-state patients of physicians. TNA operates under a standard of care provided by the TMB to Board Certified Neurologists with whom it works under TMB directives. (TMB File #09-3361 and TMB Remedial Plan #12-442).

William L. High, M.D., Ph.D. (“Dr. High”) is a Board-Certified Neurologist, who performs innovative off-site neurodiagnostic testing through electromyographs (“EMGs”) and other electrodiagnostic tests using the standard of care.

TNA and Dr. High are interested in the continued development and innovation of telehealth. With the ever-evolving regulatory landscape and

increased utilization of regulatory boards comprised of market participants,¹ it is imperative to ensure telehealth is properly regulated with state oversight to lead to increased patient safety, and not for the illegitimate purpose of diminishing competition. Consistent with this interest, TNA and Dr. High seek to prevent TMB's unsupervised implementation of unnecessary, irrational, and detrimental telehealth rules.

All parties have consented to this filing.

INTRODUCTION

TNA is a leader in telehealth innovation. TNA provides technical services for remote electrodiagnostic testing through EMG's in Texas, with more than half of its remote testings performed in cities of populations less than 77,000. Dr. High, a board-certified neurologist, interprets these off-site tests monitored in real time by a TNA physician. TNA's business model has significantly increased access to critical healthcare and treatment for Texans (particularly for those in rural areas), substantially decreased healthcare cost for Texans, and enabled economic and technological growth in the telehealth industry.

TMB's new rules would destroy each of these advances and harm competition in the name of protecting traditional office-based physicians. The

¹ In the 1950s, only about five percent of Americans were subject to licensing requirements. Now, nearly a third of American workers need a state license to legally perform their jobs. *See Patel v. Tex. Dep't of Licensing & Regulation*, 469 S.W.3d 69, 102-03 (Tex. 2015) (WILLETT, J., concurring). This is most pronounced in the service sector. *See id.*

proposed new TMB Rules create a “face-to-face” component to telehealth not previously required and certainly not medically necessary. The new rules will substantially increase the costs of off-site electrodiagnostic testing. In fact, TNA and Dr. High will lose approximately 40 percent of their billings due to these new, unprecedented requirements. In addition, the new rules would force TNA and Dr. High to lay off a significant number of employees as a result of decreased revenue. Further, and most important, since TNA provides 60 percent of its EMG’s to rural areas of the State, the new rules would render health care more costlier to rural residents and deny some patients care altogether.

The current rules under which TNA and Dr. High operate are more than sufficient to ensure patient safety. TMB offers no legitimate reason for the anticompetitive rules at issue, and the only real reason for the rules is to protect traditional brick-and-mortar physicians from competition. These types of self-preserving regulations have, as courts have warned, “morphed into protecting the public from unqualified providers to protecting practitioners from unwanted competition.” *Patel v. Tex. Dep’t of Licensing & Regulation*, 469 S.W.3d 69, 105 (Tex. 2015) (WILLETT, J., concurring).

ARGUMENT

I. TNA and Dr. High’s Offsite Neurodiagnostic Testing is Safe and More Than Satisfies the Standard of Care.

As Nobel Prize-winning economist Milton Friedman accurately observed, the “*justification*” for regulatory restriction is always to protect the public, but the “*reason*” for the restrictions is revealed by who advocates for it—typically those representing vested, licensed market participants, not consumers. M. FRIEDMAN & R. FRIEDMAN, FREE TO CHOOSE 240 (1980); *Patel*, 469 S.W.3d at 104. This observation rings glaringly true in this case.

Exhibits 1 and 2 (TMB Rulings File No. 09-3361 and Remedial Plan 12-442, respectively) to this brief consist of rulings obtained on behalf of Charles D. Marable, M.D., a board-certified neurologist who worked under a Professional Services Agreement with TNA. Dr. Marable died in May 2014, but Exhibits 1 and 2 established a codified standard of care for remote off-site neurodiagnostic testing utilized by TNA. This standard of care is universally accepted by nationally accredited neurodiagnostic technician groups. Compliance with this standard of care is required by Medicare for purposes of reimbursing the technical and professional components of the remote off-site testing.

Dr. High associates with TNA on many of its remote off-site neurodiagnostic procedures. Like TNA, a large portion of his practice (approximately 40 percent) consists of providing remote EMG services to patients

at off-site locations. He provides the physician portion of the total service required to successfully complete an EMG. These off-site services provided through tested telehealth technology to patients in rural areas are difficult for patients to obtain when the population center is insufficient to support a board-certified neurologist. The TMB rules at issue will diminish services to rural Texans and increase their costs. As courts have warned about these self-protectionist regulations, “societal benefits are being subordinated to the financial benefits of those lucky enough to be licensed.” *Patel*, 469 S.W.3d at 105 (Tex. 2015) (WILLETT, J., concurring).

II. New Rule 190.8 Substantially Increases Patient Costs, Reduces Healthcare Access to Rural Patients, and Does Not Increase Patient Safety.

Telehealth is a new and disruptive form of healthcare, and TNA is at the forefront of the industry. Telehealth companies, such as TNA and Teladoc, are attempting to utilize innovative technology to increase patient access to high-quality care, while reducing costs. In this regard, TNA provides technical services for off-site EMGs to almost 120 patients per month from areas having little or no access to board-certified neurologists. These approximately 1,440 patients come from rural counties such as Webb, Dummitt, Duval, Menard, Palo Pinto, San Saba, Llano, Loving, Hudspeth, Presidio, Pecos, and other rural areas too numerous to count. If the proposed TMB Rule becomes effective, rural Texans will have their ability to receive off-site neurodiagnostic testing completely cut off or severely

restricted. An elderly person living in Ballinger, Texas, for example, will find it difficult to travel the eighty (80) mile round-trip drive to San Angelo to obtain electrodiagnostic testing that could have been provided in his or her hometown through safe telehealth technology. As the Texas population becomes older, Texans need to rely on technology to prevent lengthy trips associated with higher out-of-pocket insurance costs and additional doctor bills when rules, such as those proposed by the TMB, require a redundant and, therefore, costlier medical visit.

For the last two years, TNA has provided remote diagnostic EMG's to populations of less than 77,000. The cities serviced are at least 50 miles from major population centers and many are a 100 or more miles from major population centers. Exhibit 3 shows EMG's were performed to 816 patients in 2014-2015 and 889 patients in 2015-2016. If the TMB's proposed rules would have been in effect in 2014, 1,705 patients would have had to travel at least 50 miles (and many more than 100 miles) to obtain these neurodiagnostic services prescribed by physicians. TMB's proposed rules unduly burden the patients provided this care.

Despite the tremendous cost savings and patient access provided by telehealth companies, TMB has worked tirelessly to interfere with their progress. And while TNA and many others submitted comments and objections to TMB's rules, they seem always to fall on deaf ears. Ironically, with respect to telehealth, TMB has completely abrogated its "Compact with Texans" to "serve and protect

the public's welfare by ensuring our licensed healthcare professionals are competent and provide quality patient health care.” <http://www.tmb.state.tx.us/page/compact-w-texans> Instead, TMB has operated through New Rule 190.8 to disservice the public's welfare by diminishing access to demonstrably safe, competent, and quality care while simultaneously imposing unnecessary healthcare costs on Texans. TMB's apparent “Compact to Destroy Innovative Competition” is exactly the type of unsupervised regulatory scheme the antitrust laws were designed to protect against, especially when devised by market participants with no state oversight.

In some respects, TMB's actions are unsurprising given the fact that “[l]icensing boards are largely dominated by active members of their respective industries who meet to agree on ways to limit the entry of new competitors.” A. EDLIN & R. HAW, *Cartels by Another Name: Should Licensed Occupations Face Antitrust Scrutiny?* 162 U. PA. L. REV. 1093, 1095 (2014) (“Many boards have abused their power to insulate incumbents from competition.”). As one court recently explained:

According to the academic literature, the real-world effects of steroidal regulation are everywhere: increased consumer cost; decreased consumer choice; increased practitioner income; decreased practitioner mobility—plus shrunk economic prospects for lower income, would-be entrepreneurs. Thomas Edison, with little formal schooling, likely could not be a licensed engineer

today, nor could Frank Lloyd Wright be a licensed architect.

Patel, 469 S.W.3d at 100-01 (internal citations omitted).

TNA and Dr. High perform their offsite neurodiagnostic testing, in part, with North American Spine, a Nobilis Health Corporation, in New Jersey, Texas, and Arizona. Thousands of patients have been treated with no malpractice claims filed. The TNA policies and procedures duplicate regulations in Arizona and New Jersey. The business model TNA seeks to keep is consistent with the regulatory schemes of these states. The safety record (with zero complaints after seven years and over 10,000 patients) is impeccable. Any increases in regulation from the TMB requiring a doctor to physically examine the patient, even though medically unnecessary, cannot increase safety, but it will increase costs to patients through travel and the cost of a hands-on visit.

TNA competes with at least four other companies (Aureus Medical Group, Frontera Strategies LP, NeuroConnect LLC, and Alliance Family of Companies) in Texas performing offsite neurodiagnostic tests utilizing the same or similar policies and procedures. These similarly situated companies would also be significantly harmed if the proposed TMB rules require an initial face-to-face examination when medically unnecessary. The proposed anti-competitive rules of the TMB would adversely affect our competitors with no benefit to patients.

III. Implementation of Texas Medical Boards' Proposed Rules will Cause Significant Financial Injury to Texas Physicians

The New Rules proposed by TMB require a “face-to-face” meeting between a patient and a physician. (New Rule 190.8(1)(L)(i)(II)(c); New Rule 174.8(a)(2)) This is contrary to the previous rule of the TMB in File No. 09-3361 and Remedial Plan 12-442, under which TNA and Dr. High have operated that require:

- a) Monitoring EMGs in real time through telemonitoring;
- b) Ability to communicate with technician's office by way of cell phones, computer keyboarding, and microphone;
- c) Ability to instruct the technician on needle adjustments by way of above stated means of communication; and
- d) Using technicians who are certified or have passed the American Association of Electrodiagnostic Technologists (AAET) certification test.

Id.

Based on these previous rulings, TNA and Dr. High provide 200 or more remote EMGs per month to mostly rural Texans throughout the state. By eliminating forty percent (40%) or more of the their billings in 2014, this rule will create an irreparable economic harm to them.

The newly adopted rules restrict the EMG and other remote off-site services that can be provided by TNA. New Rule 190.8 (22 T.A.C. §190.8) now provides that the required physician-patient relationship must include, at a minimum (among other listed requirements), “physical examination that must be performed by either a face-to-face visit or in-person evaluation as defined in §174.2(3) and (4) of this title (relating to Definitions).” 22 T.A.C. §190.8 (1)(L)(i)(II)(c). Texas Medical Board Rules 174.2, 174.6 and 174.8 (22 T.A.C. §§174.2, 174.6 and 174.8) of

Chapter 174, which governs telemedicine, also incorporate this “face-to-face” or “in-person” requirement. The net effect of these rules is to prohibit the remote off-site physician monitored provision of these services, which may currently be provided without the newly mandated “face-to-face” or “in-person” component.

TMB argues that the Legislature has directed the TMB to “ensure that appropriate care, including quality of care, is provided to patients who receive telemedicine medical services.” Appellants’ Brief at 12. However, the rules proposed by the TMB do not allow telehealth to occur at all. Such rules are incongruent with the Texas Medicaid programs recent inclusion of reimbursement for telemedicine medical services. *See* Tex. Gov’t Code § 531.0216(a); *see also* Tex. Health & Safety Code § 62.1571(a).

TNA and Dr. High would like to expand their electrodiagnostic testing business. However, the proposed rules prevent their expansion by legally preventing the off-site testing without a “face-to-face” visit. The proposed rules will require a doctor visit by a qualified physician, which the doctor now provides through telehealth making the proposed rule cost an additional \$100.00 - \$200.00 per procedure for medical bills. Based on 200 EMGs per month, Texans who used to obtain diagnostic testing through TNA and Dr. High will pay another \$20,000.00 - \$40,000.00 per month for additional healthcare. Moreover, rural Texans (approximately 60 percent of the EMGs performed by TNA and Dr. High)

will now have the additional expense of travelling to areas where board-certified neurologists office to obtain the same results they can obtain using telehealth. This resultant loss of such a large percentage of its business and revenue may cause TNA to cease to operate. The proposed rules are anathema to the TMB's charge of "ensur[ing] that patients using telemedicine medical services receive appropriate, quality care. . ." (Tex. Occ. Code § 111.004(1)); where the net effect of the rules are to eliminate quality care.

IV. Implementation of Proposed Texas Medical Board's Rules will Cause Significant Injury to Employees in the Healthcare Industry.

As discussed *supra* in Section I, the New Rules would prohibit TNA from providing off-site EMG services. Because such EMG services provide such a large percentage of the business and revenue of TNA, losing the ability to perform these services would mandate that TNA drastically reduce its workforce. TNA currently employs 22 people, with plans to expand its workforce. The attendant loss of business and revenue caused by implementation and enforcement of the proposed rules would force TNA to lay off forty percent (40%) of its workforce. There remains the distinct possibility that all of TNA's employees would lose their positions and livelihood if TNA is forced to cease operations because of the substantial loss of business that the New Rules would cause.

CONCLUSION

For the foregoing reasons, the Court should affirm the ruling of the United

States District Court for the Western District of Texas, Austin Division.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that on this 6th day of September, 2016, a true and correct copy of the foregoing instrument was electronically filed by the Court's ECF system, and a true and correct copy was delivered ECF service to all counsel of record as follows:

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CERTIFICATE OF COMPLIANCE

This brief complies with: (1) the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 3204 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii); and (2) the type-face requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Equity) using Microsoft Word (the same program used to calculate the word count).

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