No. 16-50017

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

TELADOC, INC. ET AL.,
Plaintiffs-Appellees,

v.

TEXAS MEDICAL BOARD, ET AL.
Defendants-Appellants.

Appeal from the United States District Court
for the Western District of Texas
Case No. 1:15-cv-343

BRIEF OF AMERICAN MEDICAL ASSOCIATION AND TEXAS MEDICAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS, SEEKING REVERSAL

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RULE 26.1 DISCLOSURE STATEMENT

In compliance with Fed. R. App. P. 26.1, *amicus* the American Medical Association (AMA) is a nonprofit corporation organized and operating under the laws of the State of Illinois. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

Amicus the Texas Medical Association (TMA) is a nonprofit corporation operating under the laws of the State of Texas. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Regulations

Other Authorities

INTEREST OF THE *AMICI CURIAE*[1]

This Court is called upon to determine whether the Texas Medical Board ("TMB" or the "Board") may be subject to federal antitrust liability by virtue of its regulation of the practice of telemedicine. In particular, the Court must determine whether the Board may be held liable under the antitrust laws for its promulgation of a rule requiring a "defined physician-patient relationship" – *i.e.*, a relationship established through either an in-person examination or an examination by electronic means with a health care professional present with the patient – before a physician may prescribe dangerous or addictive drugs to the patient.

Telemedicine, a key innovation in support of health care delivery, is being used to improve access to care and reduce the growth in healthcare spending. Standards of care and practice guidelines relevant to telemedicine are evolving and vary based on specialty and service provided. Accordingly, the appropriate use of, and the

[1] All parties have consented to the filing of this brief and the source of authority for its filing is in Fed. R. App. P. 29(a). No counsel for any party authored this brief in whole or in part, and no party or counsel for any party made a monetary contribution intended to fund the preparation or submission of this brief.

appropriate limitations on, telemedicine are a subject of study and debate in the medical community. Health care practitioners and researchers are studying the results of the practice of telemedicine to date. They are seeking to determine how telemedicine can best be practiced in the future – to expand access to care while minimizing the risk of adverse effects for patients and the public. As associations of physicians dedicated to the improvement of medical care for patients and the advancement of the public health, *amici curiae* have a direct interest in this question.

Amicus curiae American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty area and in every state, including Texas. The AMA has devoted significant efforts to studying

telemedicine. *See* American Medical Association, *Connected Health*, online at www.ama-assn.org/ama/pub/advocacy/topics/digital-health/connected-health.page and http://www.ama-assn.org/ama/pub/news/news/2016/2016-06-13-new-ethical-guidance-telemedicine.page.

Amicus curiae Texas Medical Association ("TMA"; collectively with AMA, the "Medical Associations") is a private voluntary, nonprofit association of approximately 49,000 Texas physicians and medical students, in all fields of medical specialization. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, its mission is to "[i]mprove the health of all Texans." Consistent with its mission, TMA has an interest in ensuring that patients obtain safe, competent medical services and are not subject to care that may cause injury. Accordingly, TMA has worked to ensure fair and appropriate treatment of telemedicine in Texas.[2]

[2] The Medical Associations submit this brief on their own behalves and as representatives of the Litigation Center of the AMA and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in

The Medical Associations submit this Brief to inform the Court of the state of telemedicine in the health care field today. They believe this context will assist the Court in resolving the antitrust issues through appreciation of the State of Texas's reliance on the Board's medical expertise in regulating the practice of medicine, particularly telemedicine, and the State's chosen means of supervising the Board.

INTRODUCTION

The Texas Medical Board, the agency of the State of Texas charged by the State legislature with regulating the practice of medicine, has established minimum standards for the physician-patient relationship necessary to allow the prescription of dangerous drugs and controlled substances. Tex. Admin. Code § 190.8(L) ("Rule 190.8"). In the Board's judgment, prescription of such drugs requires a diagnosis established through "acceptable medical practices," including an in-person physical examination that is conducted either by the prescribing physician or by another medical professional. *Id.*; Tex. Admin. Code § 174.2(3), (4), § 174.8 ("Rule 174"). Thus, under the Board's rules, dangerous drugs and controlled substances – including, for example,

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the courts.

antibiotics and opiates – may not be prescribed by a physician who has not either physically examined a patient or examined a patient electronically with the assistance of a qualified medical professional who is physically present with the patient.[3] Plaintiffs, including a corporation that wants to have its physicians prescribe antibiotics and other dangerous drugs to patients solely on the basis of telephonic consultations, contend that this rule is anticompetitive and seek to hold the Texas Medical Board liable under federal antitrust laws.

The appropriate requirements for telemedicine are a subject of study and debate among medical practitioners and researchers across the nation. It is evident that telemedicine offers significant potential benefits to patients, including expanded access to medical care. At the same time, telemedicine is inappropriate for certain medical conditions and it carries risks. Because a physician treating a patient remotely may be called upon to act with limited information, the quality of care may suffer, and a potential exists for fraud and abuse. Based on current

[3] If the only services provided are related to mental health services, a patient site presenter is not required, except in cases of behavioral emergencies, as defined by 25 Tex. Admin. Code §415.253 (relating to Definitions). Title 22, Part 9, Chapter 174, Rule 174.6

knowledge, the manner of practicing telemedicine that will best advance public health and welfare remains unsettled. As explained *infra*, researchers, physician associations, and State medical boards have reached different conclusions as they examine the rapidly evolving information about telemedicine's benefits and risks. No reasonable argument can be made, however, about the need for *some* regulation of this aspect of medical practice.

This background provides important context to the challenged Rules of the Texas Medical Board. The State of Texas has chosen to rely upon the medical expertise of the Texas Medical Board to regulate the practice of medicine to best promote Texans' health and safety. The Board consists of twelve practicing physicians, as well as seven non-physician members, all nineteen of whom are appointed by the Governor. Through the framework that Texas has adopted, the Board is expressly granted authority to use its expertise to establish medical policy – while other State actors retain the ability to take action in the event that Board members act in their own self-interest instead of in furtherance of public health. *See* Brief for Appellants at 36-44. Given the complex and evolving state of telemedicine, Texas's balance of

reliance on the expert Board to act in the first instance, with State supervision as needed, is entirely appropriate – and should not be subject to second-guessing under the federal antitrust laws.

To the contrary, a State may, consistent with the federal antitrust laws, exercise its authority to protect health and welfare by requiring an established physician-patient relationship for prescription of dangerous and addictive drugs. As the Supreme Court explained in *North Carolina State Board of Dental Examiners v. F.T.C.*, "the States …, when acting in their respective realm, need not adhere in all contexts to a model of unfettered competition." 135 S. Ct. 1101, 1109 (2015). The antitrust laws do not displace the States' traditional power to "impose restrictions on occupations" so as "to achieve public objectives." *Id.* "If every duly enacted state law or policy were required to conform to the mandates of the Sherman Act, thus promoting competition at the expense of other values a State may deem fundamental, federal antitrust law would impose an impermissible burden on the States' power to regulate." *Id.*

The only question before the Court on this appeal, therefore, is whether the Board's challenged Rules are "an exercise of the State's

sovereign power." *Id.* at 1110. The Supreme Court instructs that a regulation *is* an exercise of the State's sovereign power, and thus immune from antitrust liability, if it satisfies two requirements: "first that the challenged restraint be one clearly articulated and affirmatively expressed as state policy, and second that the policy be actively supervised by the State." *Id* (quoting *FTC v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003, 1010 (2013)) (internal quotation marks and ellipses omitted). The Supreme Court has explained that these requirements are designed to ensure that States "accept political responsibility for actions they intend to undertake" – particularly actions that may have the effect of restricting competition. *FTC v. Ticor Title Ins. Co.*, 504 U.S. 621, 636 (1992).

Here, the State has left no doubt that the Board's challenged Rule is an exercise of State policy-making in the complex and rapidly evolving area of medical practice – not a self-interested act of market participants. The State has clearly articulated that it wants the Texas Medical Board to regulate the practice of medicine, including telemedicine, to promote health and safety. Texas Occ. Code §§ 151.003, 152.001. The State has also retained ultimate control of the Board's

actions in a variety of ways: through the Governor's power to appoint all nineteen members of the Board, the legislature's obligation to review the Board's actions in determining whether the Board's authority should be preserved, and the judiciary's role in reviewing whether the Board's Rules and regulatory actions comport with the Board's authority under State law. For all of these reasons, the challenged Rules of the Board should be immune from federal antitrust liability.

ARGUMENT

I. The Board's Actions in Regulating Telemedicine to Promote Health and Safety Should Not Expose It to Antitrust Liability.

The Board is an agent of the State of Texas. Its members, primarily physicians, are charged by statute with regulating medical practice for the benefit of the people of Texas. In that regard, its telemedicine regulations were promulgated to fulfill that statutory duty. Its actions should not be subjected to plenary review, by non-physicians, under federal antitrust laws.

As the Supreme Court has explained, determining whether regulations like the Board's Rules are immune from antitrust liability is a "flexible and context-dependent" inquiry that "will depend on all the circumstances of a case." *N. Carolina State Bd. of Dental Examiners*,

135 S. Ct. at 1116. Accordingly, in assessing the Board's immunity, this Court should be mindful that the challenged Rules reflect the expert judgment of the Board, exercised with respect to complex subject matter based on rapidly evolving information. In this context, the State's regulatory scheme reflects an appropriate balance between reliance on the expertise of the Board while ultimate control is retained by other, non-expert State actors.

The State exercises its control – *i.e.*, "active supervision" – in a variety of ways. First, all nineteen members of the Board are appointed by the Governor. Tex. Occ. Code § 152.002(a). Vesting this power in the Governor allows the State executive both to harness the medical knowledge of the Board's physician-members (who make up twelve of the Board's total nineteen), while retaining the ability to steer the course of the Board's execution of Texas law. *Cf., e.g.*, *Myers v. United States*, 272 U.S. 52, 164 (1926) (under the federal Constitution, the President's power to appoint executive officers furthers "his obligation to take care that the laws be faithfully executed").

Second, all rules promulgated by the Board are subject to notice and comment under the Texas Administrative Procedure Act. *See* Tex.

Gov't Code § 2001.023 (requiring notice of proposed rules); *id.* § 2001.029 (requiring an opportunity for public comment). Texas law requires that the notice include a "statement of the statutory or other authority under which the rule is proposed to be adopted," including a "certification that the proposed rule has been reviewed by legal counsel and found to be within the state agency's authority to adopt." *Id.* § 2001.024(a)(3), (a)(3)(C). This requirement ensures that the public is made aware that the Board's authority to promulgate a rule is derived from the State and State law – thus leaving no doubt that regulations are "the State's own." *Ticor*, 504 U.S. at 635. Additionally, the opportunity for public comment ensures that the public, including all market participants, have an opportunity both to challenge the rule's substance and to question whether it fits within the agency's statutory authority.

The Board's actions are also subject to legislative review. Every proposed rule by the Board is referred by both houses of the Texas legislature to "the appropriate standing committee for review before the rule is adopted." Tex. Gov't Code § 2001.032(a). The standing committee may vote to support or oppose adoption of the rule. *Id.*

§ 2001.032(c). In addition, the legislature must periodically reenact the law granting the Board authority to make rules. *See* Tex. Occ. Code § 151.004; Tex. Gov't Code § 325.003. Before this periodic reenactment comes before the legislature, an advisory commission must review the Board—including identifying "any activities of the agency in addition to those granted by statute and of the authority of those activities," as well as "an assessment of the agency's rulemaking process." Tex. Gov't Code § 325.011(3)(A), (8). The commission must also hold public hearings regarding, among other things, the Board's compliance with its statutory authority. *Id.* § 325.009.

Finally, the Board's rules are subject to judicial review. Rules are subject to challenge under the Texas Administrative Procedure Act – including review to determine whether the rule is within the Board's authority to regulate medicine in furtherance of the public interest. Tex. Gov't Code § 2001.038. Judicial review of Board rules also exists through disciplinary proceedings. Any physician that the Board seeks to sanction under Rule 190.8 is free to challenge whether the Rule is an appropriate exercise of the Board's statutory authority to promote public health by promulgating rules. *See* Tex. Gov't Code

§ 2001.174(2)(B) (providing for judicial review of whether the agency acted "in excess of the agency's statutory authority").

Through the combination of all of these avenues, the State retains the ability to correct any action that amounts to self-interested rulemaking by market participants rather than Board action in furtherance of State policy. The Governor can appoint knowledgeable and well-motivated Board members and not reappoint members who subordinate the public interest to their own selfish preferences; stakeholders can provide input on rules through notice-and-comment proceedings; the State courts can strike down particular rules, and the legislature can decline to reauthorize the Board, if they find that the Board's rules exalt self-interest over the public health. At the same time, the system that Texas has established allows the Board sufficient flexibility to use its expertise to regulate in a timely fashion against the backdrop of complex and evolving subject matter.

This fits squarely within the form of "active supervision" endorsed by the Supreme Court. As that Court explained, "[a]ctive supervision need not entail day-to-day involvement in an agency's operations or micromanagement of its every decision," so long as "the State's review

mechanisms provide realistic assurance that a nonsovereign actor's anticompetitive conduct promotes state policy, rather than merely the party's individual interests." *N. Carolina Bd. of Dental Examiners*, 135 S. Ct. at 1116 (internal quotation marks and citation omitted). Considering "all the circumstances," as the Supreme Court has instructed, *id.* at 1117, the Board's rulemaking challenged here should be deemed immune from antitrust liability.

The district court's ruling rested on a crabbed reading of *North Carolina Board of Dental Examiners*. *See* Op. at 12-17. According to the district court, active supervision was not shown here on the ground that, in its view, other State actors could not "veto or modify" particular Board decisions that were not "in accord with state policy." *Id.* at 14-15. But the court failed to appreciate the extensive control that other State actors retain, as described above. And the court gave no weight whatsoever to the nature of the challenged Rules. It likewise ignored the fact that the Board's judgment as expressed in those Rules concerned complex and evolving subject matter, and landed in the middle of a broad spectrum of national responses to the challenge posed by regulation of telemedicine.

Contrary to the district court's decision, *North Carolina Board of Dental Examiners* does not call for such a wooden analysis. It does not compel States, as the district court seemed to think, to use agencies like the Texas Medical Board as no more than advisory councils whose decisions must be individually approved by some other State actor. *North Carolina Board of Dental Examiners* in fact dictates the opposite – a "flexible and context-dependent" analysis that considers "all the circumstances," including the State's interest in gaining the "substantial benefits" that come from "staffing their agencies with experts in complex and technical subjects." 135 S. Ct. at 1115-16; *see also Ticor*, 504 U.S. at 639 (emphasizing that the immunity analysis should be conducted "in light of the gravity of the antitrust offense" alleged).

Here, the State of Texas has expressly sought the Board's expert judgment in the regulation of the practice of medicine. The challenged Rules represent a fair and considered exercise of that expert judgment on the complex and evolving subject of telemedicine. They do not involve price fixing or any other per se violation of the antitrust laws, and there are ample considerations supporting the positions reflected in

those rules. If the Board's judgment were to prove objectionable, the Texas legislature, executive, and judiciary would have power to correct it. The antitrust laws should have no application here.

II. While the Appropriate Use of Telemedicine Is a Matter of Study and Debate in the Nationwide Medical Community, There is no Debate about the Need for Proper Regulation of Telemedicine Practices.

The provision of medical care remotely, through the use of technology, is a topic that has generated extensive study and discussion among physicians and medical researchers. Expanding the use of telemedicine has potential benefits for patients, including increased access to medical care and enhanced convenience. But those potential benefits come along with significant risks. Without the ability to conduct in-person physical examinations, treating physicians risk misdiagnosing or mistreating patients – including through over-prescription of antibiotics and other medications. Recognizing these benefits and risks, medical associations and State medical boards across the country have worked to determine what telemedicine practices will best serve patients and the public.

A. The Challenged Rules Reflect the Risk That Remote Treatment Without Adequate Precautions Can Cause Harm.

Rule 190.8 does not prohibit the practice of telemedicine in the State of Texas. Nor does it require that every physician meet in-person with a patient before engaging in any form of treatment. What the Rule *does* require is that a "defined physician-patient relationship" be created before a physician prescribes "any dangerous drug or controlled substance" to the patient. 22 Tex. Admin. Code § 190.8(1)(L).

The Board's Rules also do not mandate that an in-person encounter between physician and patient is the only means of establishing a defined physician-patient relationship. A physician may also establish such a relationship via telemedicine, using a patient site presenter (that is, a person licensed in any fashion as a healthcare provider) who is present at the site where the patient is located. 22 Tex. Admin. Code § 174.2(10); 22 Tex. Admin. Code § 174.6. The patient site presenter introduces the patient to the physician through telecommunications, and the physician may delegate tasks and activities to the patient site presenter in order to obtain objectively observed diagnostic data. *Id.* After the establishment of a physician-patient relationship – either through an in-person meeting between

physician and patient, or through the practice of telemedicine with another healthcare provider in-person with the patient – the physician may treat the patient remotely, and may prescribe any medication, without any patient site presenter, at the physician's discretion. 22 Tex. Admin. Code § 190.8(1)(L).

What the challenged Rules do not permit is unrestricted prescription of dangerous drugs based on telephonic consultations alone. With telephonic consultations, there is no observation or physical examination of the patient by the physician and no laboratory or other diagnostic work that the physician can utilize in determining a diagnosis and course of treatment. In such circumstances, under the Board's Rule 190.8(1)(L), no "defined physician-patient relationship" is established, and the physician is not permitted to prescribe dangerous or addictive medications.

The challenged Rules reflect the Board's judgment that telephonic consultations alone provide an inadequate basis for the prescription of dangerous drugs. An example, taken from allegations[4] in a pending

[4] The facts discussed are merely allegations that have not been proved or adjudicated. They are offered not to establish wrongdoing in any particular case, but to illustrate the potential for harm that the

complaint before the Texas State Office of Administrative Hearings, illustrates how telephonic consultation can lead to treatment errors. (*See* Dist. Ct. Dkt. 33-2.) The facts alleged in the complaint are as follows:

> 1. On August 31, 2010, the one-year-old patient was seen by his primary care physician ("PCP") for treatment of acute otitis media and the PCP prescribed Cefdinir. On September 13, 2010, the PCP felt the acute OM to be resolved, with some residual ear fluid.
>
> 2. On September 19, 2010, the patient's mother called TeleDoc [sic], a telephone service, because the patient developed a fever. The patient's mother reached Respondent, who practices in Pennsylvania and is primarily engaged in the practice of general surgery.
>
> 3. Respondent had no established relationship with the patient, had not examined the patient, and had not reviewed the patient's medical records.
>
> 4. Respondent diagnosed the patient with an upper respiratory infection and made a telephonic decision to prescribe Amoxil to the patient.
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> 5. The Amoxil dosage was improper because it was too low for the patient's body weight group.
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> 6. The following day, the patient had a fever of 104 degrees.

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challenged Rule seeks to address.

> 7. Respondent's medical records for the patient's encounter were inadequate, including but not limited to his failure to record a differential diagnosis.

(Dist. Ct. Dkt. 33-2 at 2.) As these allegations show, there can be real, material risk of harm from treatment without any physical examination. That risk is amplified where, as in this complaint, treatment is provided to a patient who cannot even communicate his or her own condition, but must instead rely on characterizations by a layperson.

Research confirms the risk of adverse effects from telemedicine. In one study, researchers determined that Teladoc provided overall poorer-quality care than physician offices. *See* Lori Uscher-Pines, *et al.*, *Access and Quality of Care in Direct-to-Consumer Telemedicine*, 22 Telemedicine & e-Health 282 (Apr. 2016). The researchers reviewed the care provided by Teladoc physicians to members of the California Public Employees' Retirement System, which offered Teladoc as a covered benefit for approximately 370,000 insureds. *Id.* at 283. The researchers noted that the "vast majority" of Teladoc visits they reviewed occurred by telephonic consultation, *id.* – meaning there was no "defined

physician-patient relationship" within the meaning of the Texas Rule at issue in this case.

The researchers found that "Teladoc visits are associated with less diagnostic testing and poorer performance on appropriate antibiotic prescribing for acute bronchitis compared with physician offices." *Id.* at 285. The higher rates of antibiotic prescriptions for bronchitis by Teladoc physicians were concerning because bronchitis is "a diagnosis for which antibiotics are never appropriate." *Id.* The researchers noted that, while less diagnostic testing was not necessarily problematic, patients who consult Teladoc rarely seek testing even when the Teladoc physician instructs them to – "and therefore treatment of conditions where testing is necessary may be inappropriate for DTC [direct-to-consumer] telemedicine at this time." *Id.*

The same researchers further found that the *type* of antibiotic prescribed by Teladoc physicians was a matter of concern:

> When antibiotics were prescribed, Teladoc used more broad-spectrum antibiotics. This is concerning because overuse increases costs and contributes to antibiotic resistance. Greater use of broad-spectrum antibiotics may be driven by the tendency for physicians serving DTC [direct-to-consumer] companies to practice

> conservatively, with limited diagnostic information.

Lori Uscher-Pines, et al., Research Letter: Antibiotic Prescribing for Acute Respiratory Infections in Direct-to-Consumer Telemedicine Visits, JAMA Internal Med. at E1-E2 (published online May 26, 2015).

A separate study conducted through the University of Pittsburgh Medical Center Health System likewise found greater use of antibiotics in e-visits than in office visits for both sinusitis and urinary tract infections. Ateev Mehorotra, *et al.*, *A Comparison of Care at E-Visits and Physician Office Visits for Sinusitis and Urinary Tract Infection*, 173 JAMA Internal Med. 72 (Jan. 14, 2013). The researchers again theorized that "[w]hen physicians cannot directly examine the patient, physicians may use a 'conservative' approach and order antibiotics." *Id.* at 73. This is a concern – particularly "given the unclear benefit of antibiotic therapy for sinusitis." *Id.*

B. Appropriate Limitations on the Prescription of Dangerous Drugs through Telemedicine Can Mitigate the Risk of Adverse Effects.

The risk that improperly practiced telemedicine will cause harm to patients has spurred debate throughout the medical community nationwide. State medical boards across the country have adopted

various forms of regulation of telemedicine, and in particular, have limited the prescription of drugs without some form of physical examination. *See generally* Centers for Disease Control & Prevention, *Prescription Drug Physical Examination Requirements*, online at http://www.cdc.gov/phlp/docs/pdpe-requirements.pdf (Jan. 29, 2015); Federation of State Medical Boards, *Telemedicine Policies: Board by Board Overview*, online at http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/GRPOL_Telemedicine_Licensure.pdf.

Like the TMB, several state medical boards, have adopted restrictions on the ability to prescribe medications without a prior physical examination by the prescribing physician or a patient site presenter. In this respect they mimic the Federal Controlled Substances Act, which requires that a physician have conducted at least one in-person medical history and physical examination sufficient to establish a diagnosis prior to prescribing a controlled substance. 21 U.S.C. § 829(e).

Thus, for example, Delaware requires that a physician have "conducted at least 1 in-person medical history and physical

examination sufficient to establish a diagnosis…" Del. Code Ann. Tit. 16 § 4701(31). Further, Delaware prohibits prescriptions from being made solely in response to an internet questionnaire, an internet consult, or a telephone consult unless the provider has previously established a proper patient-provider relationship through steps outlined by statute. Del. Code Ann. Tit. 24 § 1769D.

Missouri likewise requires that the prescribing physician have "performed a sufficient physical examination and clinical assessment of the patient" before prescribing controlled substances and specifies that "a questionnaire completed by the patient, whether via the internet or telephone, does not constitute an acceptable medical interview and examination for the provision of treatment by telehealth." 20 Mo. Code Regs. Ann. 2220-2.020(9)(K). The state also prohibits prescribing of any controlled substance based solely on an internet request or an internet questionnaire. Mo. Rev. Stat. § 208.686.

Many other states have similar requirements. *See* Dist. Ct. Dkt. 64-1 (listing 27 states that, by statute and/or regulation, require a physical examination before medicine may be prescribed).[5]

[5] Some states, like Texas, authorize some treatment without a physical

Several medical societies have also reviewed the risks and potential benefits of telemedicine and offered recommendations for standards of remote medical care within their specialty. For example, the American College of Physicians ("ACP") noted that telemedicine had "expanded rapidly to solidify a place in the modern health care conversation," and accordingly undertook to prepare recommendations for best practices in telemedicine. Hilary Daniel, *et al.*, *Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper*, Annals of Internal Med. (published online Sept. 8, 2015). While ACP "supports the expanded role of telemedicine," it cautioned that "ACP believes that a valid patient-physician relationship must be established for a professionally responsible telemedicine service to take place." *Id.* at 2. ACP accordingly stated that "[a] physician using telemedicine who has

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examination, but require a physical examination before drugs may be prescribed. *See, e.g.*, State Medical Board of Ohio, Position Statement on Telemedicine (May 10, 2012) (authorizing treatment with any "appropriate examination," and noting that "this examination need not be in-person if the technology is sufficient to provide the same information to the [physician] as if the exam had been performed face-to-face," but requiring that physicians "personally physically examine a patient prior to prescribing drugs"), online at http://tinyurl.com/hhysvfm.

no direct previous contact or existing relationship with a patient must" do one of two things: "(a) Take appropriate steps to establish a relationship based on the standard of care required for an in-person visit, or (b) Consult with another physician who does have a relationship with the patient and oversees his or her care." *Id.*

In another example, the American Academy of Neurology ("AAN") assessed the use of telemedicine in the treatment of strokes, epilepsy, and other neurologic conditions. In its report, the Telemedicine Work Group of the AAN recognized that "performing a complete neurologic examination" through telemedicine would be "difficult to achieve" for persons untrained in neurology. Lawrence R. Wechsler, *et al.*, *Teleneurology Applications: Report of the Telemedicine Work Group of the American Academy of Neurology*, 80 Neurology 670, 673 (2013). Still, given the potential for telemedicine to "increase access to neurologic care in underserved rural areas," the Telemedicine Work Group advised that "[f]urther study of the application of teleneurology to stroke and other common and uncommon neurologic conditions is warranted. Process measures, reliability of consultation, and outcomes

should be monitored to define the limits of telemedicine in this setting." *Id.*[6]

As these and other examples demonstrate, the medical community at large is grappling with the appropriate regulation of telemedicine – regulation that will both allow for the benefits of increased access that telemedicine can offer and limit the risk of poor-quality treatment. Given the complexity and rapidly evolving facts at issue, different medical boards and medical societies have taken different approaches – and the existing research cannot yet declare one approach the "right" one. Research indicates, however, that *unrestricted* practice of telemedicine – in particular, allowing the prescription of dangerous drugs without any physical examination by any health professional – leads to poorer care. Some regulation of telemedicine, therefore, is important for protection of the public health.

Such regulation is precisely what the Texas Medical Board undertook with the Rules that Teladoc challenges here. Rule 190.8 requires a "defined physician-patient relationship" – established

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[6] *See also, e.g.*, American Academy of Dermatology & AAD Association, *Position Statement on Teledermatology*, online at https://www.aad.org/Forms/Policies/Uploads/PS/PS-Teledermatology.pdf (amended Mar. 7, 2016).

through an in-person physical examination, either by the prescribing physician or a patient site presenter – before dangerous drugs such as antibiotics may be prescribed. The risks addressed by Rule 190.8 – inappropriate prescription of antibiotics and, more broadly, lower-quality care – are real and have been empirically observed in studies of telemedicine. The Board's regulation of telemedicine is a reasonable implementation of the statutory mandate to regulate the practice of medicine generally and the practice of telemedicine specifically. *See* Brief for Appellants at 12-13.

III. In the Alternative, if This Court Declines to Order Dismissal of This Case it Should Provide Guidance to the Lower Court to Provide a "Rule of Reason" Antitrust Analysis, with Consideration to be Given to the Public Health Benefits of the Board's Telemedicine Regulations.

Although the Medical Associations believe this Court should reverse the order denying the motion to dismiss, if this case is to proceed it should follow a "rule of reason" analysis. That analysis should consider not only the mechanisms for active supervision of the Texas Medical Board, as described herein and in the Brief for Appellants at 36-52, but also the public health benefits arising from

telemedicine regulation. Telemedicine should not be left to the open market.

Medicine is characterized by a disparity between the information reasonably available to consumers and the information available to professionals, not to mention the practical inability of consumers, in many instances, to make informed judgements about that information. *California Dental Assoc. v. FTC*, 526 U.S. 756, 772 (1999) observed: "the quality of professional services tends to resist ether calibration or monitoring by individual patients …, partly because of the specialized knowledge required to evaluate the services."

Furthermore, when ill-informed consumers receive low-quality health care, the effects fall beyond those who receive the care. Repercussions of poor care are felt from emergency rooms and inner-city clinics to schools and the workplace – not to mention on government agencies that may themselves have to pay for the bad outcomes. The practice of medicine fairly screams for government regulation.

As noted in *Parker v. Brown*, 317 U.S. 341,362 (1943), states may regulate their economies "in the interest of the safety, health, and well-

being" of their residents. If this case is to proceed, that interest should be given due weight under a rule of reason antitrust analysis.

CONCLUSION

For the foregoing reasons, the decision of the district court denying immunity should be reversed. In the alternative, however, the district court should apply a rule of reason antitrust analysis, giving proper weight to public health considerations.

Respectfully submitted,

/s/ Donald P. Wilcox
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Date: June 24, 2016

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) and 29(d) because it contains 5,546 words according to Microsoft Word, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it is in Century Schoolbook 14-point font.

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Date: June 24, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on June 24, 2016, I caused the foregoing Brief of American Medical Association and Texas Medical Association as Amici Curiae in Support of Defendants-Appellants to be electronically filed with the Clerk of Court using the CM/ECF filing system, which will send notice of such filing to all registered CM/ECF users.

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