Case No. 16-50017

IN THE 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 her 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
Case No. 1:15-CV-343

BRIEF OF *AMICUS CURIAE* THE ERISA INDUSTRY COMMITTEE IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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The ERISA Industry Committee (ERIC) respectfully submits this brief as *amicus curiae* in support of Appellees Teladoc, Inc. et al. and affirmance. All parties consented to the filing of this *amicus* brief.[1]

INTEREST OF *AMICUS CURIAE*

ERIC is a nonprofit organization representing the Nation's largest employers that maintain health care, retirement, disability, and other employee benefit plans covered by the Employee Retirement Income Security Act of 1974 (ERISA), 88 Stat. 891. ERIC is the only national association that advocates for large employers on health, retirement, and compensation public policies at the federal, state, and local levels. Its members are leaders in every sector of the economy. ERIC seeks to enhance the ability of its members to provide high-quality health care benefits to millions of active employees, retired employees, and families. These benefits help ERIC members to attract and retain talent and maintain a healthy and productive workforce.

Employers are the primary source of health care benefits in the country.[2]

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[1] Pursuant to Federal Rule of Appellate Procedure 29(c)(5), the amicus curiae states that no party's counsel has authored this brief either in whole or in part; no party or its counsel contributed money that was intended to fund preparing or submitting the brief; and no person other than the amicus curiae or its members has contributed money intended to fund preparing or submitting the brief.

[2] *See* Hubert Janicki, *Employment-Based Health Insurance: 2010* (2013), https://www.census.gov/prod/2013pubs/p70-134.pdf.

ERIC offers this brief to provide the Court with the unique perspective of some of the Nation's largest health care plan sponsors on the issues in this case. ERIC also seeks to respond to and correct some of the misleading statements in the amicus briefs in favor of reversal filed by the American Medical Association ("AMA") and Texas Medical Association (collectively, "AMA brief") and the Federation of State Medical Boards ("FSMB").

INTRODUCTION AND SUMMARY OF ARGUMENT

Patients need to jump over numerous hurdles just to get access to basic medical care when they are sick—including investing large amounts of time, giving up productive work hours, and paying for the costs of care. Direct care telemedicine uses telecommunications technology to lower these hurdles. Telemedicine thus complements traditional office visits by providing patients with a convenient alternative channel for quickly obtaining high-quality medical care for minor, urgent complaints. Telemedicine provides these benefits with results comparable to in-person care, and often at lower cost. These features make telemedicine an attractive option for plan sponsors (employers) and for patients.

However, these same features also make direct care telemedicine a competitive threat to traditional office-based physician practices. The revised Rule 190.8 that the Texas Medical Board ("TMB") adopted in May 2015 ("New Rule

190.8")[3] is a market-protective rule designed to undermine the business model of direct care telemedicine. Contrary to the claims of the TMB, AMA, and FSMB briefs, New Rule 190.8 is not a "fair and considered" response to any credible increased "risks" associated with telemedicine. The evidence does not support the existence of these purported increased "risks" and, in any event, the rule bears no rational relationship to the claimed risks. What New Rule 190.8 actually does is remove the ability of telemedicine providers to offer basic treatment to patients, thereby making it difficult or impossible for telemedicine providers to compete with traditional office-based providers.

The district court correctly held that the TMB's actions are not entitled to immunity under *Parker v. Brown*, 317 U.S. 341 (1943). ERIC respectfully urges this Court to affirm the district court's order denying the TMB's motion to dismiss.

ARGUMENT

I. TELEMEDICINE HAS ENORMOUS POTENTIAL TO INCREASE PATIENT ACCESS TO HEALTH CARE WITHOUT COMPROMISING THE QUALITY OF CARE.

Patients need safe, high-quality, and effective health care. They also want to be able to access health care efficiently, when and where they need it. The traditional office-based model of primary care creates numerous barriers to

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[3] *See* 40 Tex. Reg. 3159 (May 29, 2015) (adopting revisions to 22 Tex. Admin. Code § 190).

efficient access to medical care, including the difficulty of getting an appointment (especially during evenings and weekends), the need to physically travel to the doctor, the wait at the doctor's office, and the high cost of care. For employed adults who may need to seek care for their children and elderly parents as well as themselves, these barriers quickly mount up.

Finding ways to lower barriers to patient access is a critical part of ensuring the efficient and effective delivery of health care—and, for employers, a healthy and productive workforce. Telemedicine (as the term is used in this brief) is the delivery of clinical health care services remotely through telecommunications technology. Direct care or direct-to-patient telemedicine is the use of telemedicine to provide direct patient care for common, uncomplicated, non-emergency medical conditions—*i.e.*, the types of conditions susceptible to remote diagnosis and treatment.[4] Examples of the conditions direct care telemedicine providers often

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[4] This brief focuses on direct care telemedicine because it appears to be the application of telemedicine that New Rule 190.8 directly targets. Telemedicine has numerous other uses and documented benefits, as well. Telemedicine has shown great promise, for example, when used to follow up with patients after hospital discharge, provide chronic care management, or provide acute care services to elderly patients in nursing homes. *See, e.g.*, Adam Darkins et al., *Care Coordination/Home Telehealth: The Systematic Implementation of Health Informatics, Home Telehealth, & Disease Management to Support the Care of Veteran Patients with Chronic Conditions*, Telemed. J. & E-Health, Dec. 2008, at 1118 (discussing the use of home health monitoring programs for patients recently discharged from the hospital or those with chronic conditions); David C.

encounter are sinus and respiratory infections, urinary tract infections, rashes, and pink eye.[5] The goal of this type of telemedicine is not to replace all in-person primary medical care, but rather to complement it by providing a convenient alternative channel for quickly obtaining care for minor, urgent complaints.[6] When used appropriately, direct care telemedicine can greatly improve patient access to basic medical care and lower costs without compromising the quality of care—making it a vital component in the evolution of our modern health care system, as the Nation's competition agencies have concluded.[7]

Grabowski & A. James O'Malley, *Use of Telemedicine Can Reduce Hospitalizations of Nursing Home Residents & Generate Savings for Medicare*, Health Aff., Feb. 2014, at 244 (describing benefits of switching from on-call to telemedicine physician coverage during off-hours in nursing homes). Because New Rule 190.8 is so broad, *see* Section II.A *infra*, it could also jeopardize other beneficial applications of telemedicine.

[5] *See* Am. Compl. ¶ 72; *see also* Caroline M. Poma, *Telemedicine: A Therapeutic Prescription for Our Health Care System Contaminated by Old Economy Rules & Regulations*, 17 N.C. J. L. & Tech. On. 74, 81 (2016) (explaining that telemedicine's purpose is "to meet the patient's acute care needs" and describing "minor medical needs such as 'allergies, sinus and bladder infections, bronchitis and other conditions'"); Manish N. Shah et al., *Potential of Telemedicine to Provide Acute Medical Care for Adults in Senior Living Communities*, Acad. Emergency Med., Feb. 2013, at 162 (identifying 38% of acute care episodes for adults in senior living communities as potentially appropriate for telemedicine-based care, including dermatologic conditions and respiratory and gastrointestinal illnesses).

[6] *See* Poma, *supra* note 5, at 104-05.

[7] *See, e.g.*, Fed. Trade Comm'n & Dep't of Justice, *Improving Health Care: A Dose of Competition* (2004) ("When used properly, telemedicine has considerable

A. Telemedicine Increases Patient Access to Medical Care.

The concept of a doctor providing remote medical care to a patient is hardly new. Doctors have been treating patients remotely for decades (*e.g.*, through "call coverage" arrangements with other doctors, programs to connect specialists with patients in rural and hard-to-reach areas, various Veterans Health Administration programs, etc.).[8] Telemedicine's reach has expanded significantly in recent years, however, due to technological improvements in network speed and video applications, wider availability and utilization of computer tablets and "smart" phones, favorable changes in reimbursement rules, and increased consumer demand.[9] As patients become more comfortable with using modern technology, they are increasingly open to interacting with doctors through "e-visits" for minor ailments. One survey in 2015 found that 64% of patients were willing to have a

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promise as a mechanism to broaden access, lower costs, and improve health care quality.").

[8] *See* Inst. of Med. Cmte. on Evaluating Clinical Applications of Telemed., *Telemedicine: A Guide to Assessing Telecommunications in Health Care* (M.J. Field, ed. 1996), http://www.ncbi.nlm.nih.gov/books/NBK45445/; Andrew Broderick, *The Veterans Health Administration: Taking Home Telehealth Services to Scale Nationally* (Jan. 2013), http://www.commonwealthfund.org/~/media/Files/Publications/Case%20Study/2013/Jan/1657_Broderick_telehealth_adoption_VHA_case_study.pdf.

[9] *See* Milt Freudenheim, *The Doctor Will See You Now. Please Log On*, N.Y. Times, May 29, 2010, http://www.nytimes.com/2010/05/30/business/30telemed.html?pagewanted=all.

video visit with a doctor,[10] and another survey found that 27% would actually opt for a telemedicine visit if given the choice.[11] In response to this growing interest, more employers are offering their employees a telemedicine benefit, usually as an add-on to existing benefit plans.[12]

By allowing patients to access basic acute care through "e-visits," telemedicine dramatically lowers the soft costs of obtaining health care, such as the time spent waiting for an appointment,[13] the physical and mental stress of traveling with children or elderly relatives or those with infectious conditions to a doctor's office, the time spent traveling to and waiting for the doctor, and the costs of

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[10] Am. Well, *Telehealth Index: 2015 Consumer Survey*, https://www.americanwell.com/infographic-telehealth-index-2015-consumer-survey/; *see also* Cisco, *Cisco Study Reveals 74 Percent of Consumers Open to Virtual Doctor Visit* (Mar. 4, 2013), https://newsroom.cisco.com/press-release-content?articleId=1148539.

[11] UnitedHealthcare, *UnitedHealthcare Covers Virtual Care Physician Visits, Expanding Consumers' Access to Affordable Health Care Options* (Apr. 30, 2015), https://www.uhc.com/news-room/2015-news-release-archive/unitedhealthcare-covers-virtual-care-physician-visits.

[12] Willis Towers Watson, *Current Telemedicine Technology Could Mean Big Savings* (Aug. 11, 2014), https://www.towerswatson.com/en-US/Press/2014/08/current-telemedicine-technology-could-mean-big-savings (stating that 37% of surveyed employers expected to offer a telemedicine benefit by 2015, with another 34% considering adding such a benefit in 2016 or 2017).

[13] In a 2016 Texas survey, 23% of respondents reported having to wait 14 or more days to see their doctor. *See* Tex. Bus. Ass'n, *Telemedicine: The Pulse of Texans* (2016), http://www.txbiz.org/advocacy/telemedicine/ [hereinafter "TBA Survey"]; *see also* Am. Well, *supra* note 10 (reporting an 18.5 day average wait for an appointment).

travel. These may seem like minor inconveniences, but they carry significant social costs. One study that attempted to quantify the opportunity cost of a traditional office visit found that the average time required per visit was over two hours (including travel and waiting time), and that only about 20 minutes (or 17%) of that time was actually spent seeing the doctor.[14] The researchers calculated a mean opportunity cost for employed adults of $41 per visit—which added up across the population to "1.1 billion hours in time spent and $25 billion in opportunity costs" per year.[15]

Timely and efficient access to health care is especially challenging for patients who live in remote or under-resourced areas.[16] Texas has many such

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[14] Kristin N. Ray et al., *Opportunity Costs of Ambulatory Medical Care in the United States*, Am. J. Managed Care, Aug. 2015, at 567, 569; *see also id.* at 573 ("For every dollar of direct medical expenditures for ambulatory physician visits, 15 additional cents were spent on the indirect costs of patient time.").

[15] *Id.* at 570-71; *see also* Hilary Daniel & Louis Snyder Sulmasy, *Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper*, Annals Internal Med., Nov. 17, 2015, at 787, http://annals.org/article.aspx?articleid=2434625 ("Treating patients at home or outside the clinical setting, when applicable and appropriate, can yield cost savings by intervening before the development of more serious conditions, reducing hospital visits or readmissions, effectively managing chronic conditions, and reducing travel costs or lost productivity.").

[16] Am. Hosp. Ass'n, *The Promise of Telehealth for Hospitals, Heath Systems & Their Communities* 4 (Jan. 1, 2015), http://www.aha.org/research/reports/tw/15jan-tw-telehealth.pdf ("About 20% of Americas live in rural areas where they do

areas, with the "32-county border region and [] non-metropolitan" parts of the state having patient-to-provider ratios two to three times higher than other areas of the state.[17] The U.S. Department of Health and Human Services has designated 425 primary care physician Health Professional Shortage Areas in the state of Texas alone.[18]

Moreover, the alternative to a telemedicine "e-visit" is not necessarily missing work and waiting around for a regular office visit. Surveys show that a significant percentage of patients who obtain care through telemedicine would—if denied a telemedicine option—instead simply forego care altogether or seek care in a hospital emergency room.[19] Foregoing care means staying sick, which carries its own productivity costs, and sometimes means a potential early intervention is

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not have access to primary care or specialist services, or must travel hundreds of miles to reach a health care provider.").

[17] *See* Alexander Vo et al., *Benefits of Telemedicine in Remote Communities & Use of Mobile & Wireless Platforms in Healthcare* 3 (2011), http://telehealth.utmb.edu/presentations/benefits_of_telemedicine.pdf.

[18] *See* Health Res. & Srvs. Admin., U.S. Dep't Health & Human Srvs., *Data Warehouse: Map Tool*, https://datawarehouse.hrsa.gov/Topics/ShortageAreas.aspx (last visited Sept. 8, 2016). Twenty-four percent of rural Texans report having to drive 30 minutes or more to get to their doctor's office. TBA Survey, *supra* note 13.

[19] *See* Dale H. Yamamoto, *Assessment of the Feasibility & Cost of Replacing In-Person Care with Acute Care Telehealth Services* 5 (Dec. 2014), http://www.connectwithcare.org/wp-content/uploads/2014/12/Medicare-Acute-Care-Telehealth-Feasibility.pdf.

missed. Emergency room visits are expensive. They also mean patients with minor issues are clogging up emergency rooms with non-emergency cases.[20] In a recent Texas survey, 25% responded that they or someone in their households had visited an emergency room to obtain treatment for non-emergency conditions such as sinus infections, rashes, urinary tract infections, or pink eye.[21] By making basic medical care more accessible, telemedicine can also help to alleviate pressures on the emergency care system.

Telemedicine also has the potential to lower economic barriers to obtaining care. Though the cost savings of telemedicine would depend on how it is reimbursed, telemedicine's efficiencies offer promising opportunities for managing costs. A 2014 actuarial study of the Medicare program concluded that an expansion of the Medicare telemedicine benefit (*i.e.*, to remove rural and facility restrictions) could save the Medicare program an estimated $45 per visit—even if

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[20] *See* Truven Health Analytics, *Avoidable Emergency Department Usage Analysis* (2013), http://averytelehealth.com/wp-content/uploads/2013/03/Avoidable-Emergency-Department-Usage-Analysis-Truven-Health-Analytics.pdf. *See generally* Robert A. Barish et al., *Emergency Room Crowding: A Marker of Hospital Health*, Transactions Am. Clinical & Climatological Ass'n, 2012, at 304, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3540619/ (discussing emergency room overcrowding).

[21] *See* TBA Survey, *supra* note 13.

telemedicine visits were reimbursed at the same rate as traditional office visits.[22] Two studies of large employers (Home Depot and Rent-a-Center) found that adding a telemedicine benefit led to significant health plan savings overall—more than $450 per claim.[23] These potential cost savings can be critical for plan sponsors as well as beneficiaries (who usually must shoulder part of the cost burden of their care).[24] In 2015, 16% of adults nationwide (and 18% of adults in Texas) went without care because of cost.[25] The potential cost savings of telemedicine can help to break down the financial barriers to obtaining care.[26]

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[22] *See* Yamamoto, *supra* note 19, at 1.

[23] *See* Niteesh K. Choudhry et al., *Impact of Teladoc Use on Resource Utilization & Health Spending for the Home Depot Beneficiaries* (Feb. 2015) [hereinafter "Home Depot Study"] (finding an estimated average savings-per-claim of $673); Niteesh K. Choudhry et al., *Impact of Teladoc Use on Resource Utilization & Health Spending for Rent-a-Center Beneficiaries* (Feb. 2015) [hereinafter "Rent-a-Center Study"] (finding an estimated average savings-per-claim of $460).

[24] *See* Christopher S. Girod et al., *2016 Milliman Medical Index* (May 24, 2016), http://us.milliman.com/mmi/ (noting that the cost of health care for the typical American family of four pushed past $25,000 a year, and that employees pay on average about 43% of the cost of their care).

[25] Commonwealth Fund, *Health System Data Center: Texas State Health System Ranking* (2015), http://datacenter.commonwealthfund.org/scorecard/state/45/texas/.

[26] Telemedicine also shows promise for addressing other access barriers, including the barriers to health care system entry and cultural barriers. *See* Lori Uscher-Pines & Ateev Mehrotra, *Analysis of Teladoc Use Seems to Indicate Expanded Access to Care for Patients without Prior Connection to a Provider*, Health Aff., Feb. 2014, at 258, 263; Daniel & Sulmasy, *supra* note 15

B. Telemedicine Can Provide High-Quality Care Consistent with the Relevant Standards of Care.

ERIC's members are sophisticated health care consumers with a strong interest in keeping their beneficiaries healthy. They understand that improving patient access to care at the expense of the quality of care is a poor trade-off. With respect to telemedicine, however, the evidence shows that this trade-off does not exist. Direct care telemedicine can provide care that is accessible *and* consistent with the relevant standards of care.

"Resolution rate" is one rough proxy for health care quality. The resolution rate measures the percentage of patients who did *not* require follow-up care after the initial physician-patient encounter (*i.e.*, those who had their issues adequately addressed). One California study found that patients who had telemedicine encounters were *less* likely to require follow-up care compared to patients who received initial consultations for similar conditions in an emergency room or a traditional doctor's office.[27] In other words, telemedicine had a resolution rate that was comparable to (and actually slightly better than) in-person care. The Home

("Telemedicine may aid in facilitating care for underserved patients in both rural and urban settings. Two thirds of the patients who participated in the Extension for Community Healthcare Outcomes program were part of minority groups[.]").

[27] *See* Uscher-Pines & Mehrotra, *supra* note 26 (finding that only 6% of e-visits resulted in follow-up care, in contrast to 13% of office visits and 20% of emergency room visits).

Depot and Rent-a-Center studies discussed above also showed high resolution rates (92%) for the patients utilizing telemedicine.[28] A number of studies have similarly found that telemedicine can deliver clinical outcomes (*e.g.*, diagnoses and health results) comparable to in-person care.[29]

In short, direct care telemedicine allows patients to obtain treatment for minor ailments quickly and conveniently, with results similar to traditional office-based care. For employers and employees and their families, these characteristics make telemedicine highly attractive.

C. Plan Sponsors and Patients Will Never Reap the Full Benefits of Telemedicine If Market Participants Are Permitted to Create Unjustified Market-Protective Restrictions on Telemedicine.

Telemedicine offers clear benefits to plan sponsors and patients. To physicians with traditional office-based practices, however, telemedicine represents a source of competition. By allowing physicians to serve patients who are not located near them, telemedicine creates new competitive pressures on

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[28] *See* Home Depot Study & Rent-a-Center Study, *supra* note 23.

[29] *See* Daniel & Sulmasy, *supra* note 15 ("Sample studies of telemedicine used in the treatment of medical conditions and in various settings suggest that efficient use of telemedicine technologies can improve overall health outcomes."); Sonia Lamel et al., *Impact of Live Interactive Teledermatology on Diagnosis, Disease Management, & Clinical Outcomes*, Archives of Dermatology, Jan. 2012, at 61 (analyzing clinical outcomes for teledermatology); Patrick H. Brunett et al., *Use of a Voice & Video Internet Technology as an Alternative to In-Person Urgent Care Clinic Visits*, J. of Telemed. & Telecare, 2015, at 219.

physicians with traditional office-based practices who are accustomed to being the main providers of basic acute care to patients in their service areas.

The state medical boards that control the standards for medical licensing in each state are all comprised at least partially of practicing physicians, and some (like the TMB) are dominated by practicing physicians. Given the circumstances, there is a grave "structural risk" of such boards taking market protective actions against telemedicine. *See N.C. State Bd. of Dental Examiners v. FTC,* 135 S. Ct. 1101, 1114 (2015).[30] If self-interested market participants in each state can raise barriers to keep out their competition, the public will never reap the full benefits of telemedicine. Such unjustified restrictions would not only prevent patients in the affected states from using telemedicine, but could also stifle the growth of telemedicine nationally. Large employers want to be able to offer their workers uniform company benefits regardless of where they live and work, and the business

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[30] This is not to suggest that any board member would engage in unethical conduct, but merely acknowledges that self-interested market participants cannot always untangle their own self-interest from the public interest. As the Supreme Court has observed: "[E]stablished ethical standards may blend with private anticompetitive motives in a way difficult even for market participants to discern. Dual allegiances are not always apparent to an actor." *N.C. Dental Bd.*, 135 S. Ct. at 1111.

model of direct care telemedicine depends in large part on its scalability.[31]

Though many states have embraced telemedicine, a few state medical boards, like the TMB, have proposed or enacted market-protective rules limiting direct care telemedicine, such as the boards in Alabama and Mississippi.[32] In 2013, for example, the Alabama Board of Medical Examiners enacted a rule limiting telemedicine providers from seeing a patient outside of an established medical site, unless the provider had previously seen the patient in a "face-to-face visit" or was seeing the patient based on a referral from a doctor who had.[33] The Alabama board ended up withdrawing this rule in August 2015 in light of the Supreme Court's decision in the *N.C. Dental Board* case.[34] Even among its peers,

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[31] *See* Fed. Trade Comm'n & Dep't of Justice, *supra* note 7 (recommending that states consider "implementing uniform licensure standards or reciprocity compacts" in order to fully support the benefits of telemedicine).

[32] In 2015, the Mississippi Board of Medical Licensure proposed a rule to limit the practice of telemedicine to physicians with an office in the state or a contractual relationship with an in-state provider. The Mississippi Board later withdrew the rule from consideration but may reintroduce it. *See also* MississippiWatchdog.org, *Proposed Mississippi Telemedicine Rule Goes Temporarily Offline* (July 17, 2015), http://watchdog.org/229825/proposed-mississippi-telemedicine-rule-goes-temporarily-offline/.

[33] *See* Ala. Admin. Code r.540-X-15-.10 (2013), *available at* https://www.albme.org/Documents/Rules/540-X-15.pdf.

[34] *See* Am. Acad. of PAs, *Breaking: Alabama Board of Medical Examiners Repeals Telehealth Rules Based on U.S. Supreme Court Ruling* (Sept. 14, 2015), https://www.aapa.org/twocolumn.aspx?id=2147486506.

however, the TMB's anti-telemedicine position is extreme.[35] By eliminating the ability of telemedicine providers to treat patients with therapeutic medications, New Rule 190.8 imposes a practical "ban" on direct care telemedicine in Texas—to the detriment of plan sponsors and patients.

II. NEW RULE 190.8 IS NOT A "FAIR AND CONSIDERED" RESPONSE TO ANY CREDIBLE RISK ASSOCIATED WITH TELEMEDICINE.

The AMA and FSMB briefs assert that New Rule 190.8 is the TMB's "fair and considered" response to certain increased "risks" to patient safety associated with telemedicine. *See* AMA Br. at 15; FSMB Br. at 3, 17. Even a cursory examination of the rule and the available scientific evidence shows this is false. The AMA and FSMB briefs do not cite any credible evidence of these purported increased "risks" of telemedicine. (The TMB's supposed "reasoned justification" for New Rule 190.8 also does not cite any credible evidence of such "risks.") Moreover, even if these "risks" did exist, New Rule 190.8 would not be a fair or reasonable response to them. The rule places an effective ban on direct care telemedicine in Texas. This is unreasonable and contrary to the guidelines that

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[35] *See* Am. Telemed. Ass'n, *State Telemedicine Gaps Analysis: Physician Practice Standards & Licensure* (Jan. 2016), http://www.americantelemed.org/docs/default-source/policy/2016_50-state-telehealth-gaps-analysis-md-physician-practices-licensure.pdf?sfvrsn=2; Jack McCarthy, *Texas Ranks Worst in Telehealth* (Jan. 11, 2016), http://www.healthcareitnews.com/news/texas-ranks-worst-telehealth.

various respected national medical organizations have issued concerning telemedicine—including the AMA and FSMB's *own* guidelines.

A. An Analysis of New Rule 190.8 Shows It Is Neither Fair Nor Reasonable.

The predecessor to New Rule 190.8 ("Old Rule 190.8") prohibited physicians from prescribing "any dangerous drug or controlled substance" without first "establishing a diagnosis through the use of acceptable medical practices."[36] The Old Rule then included a list of "medical practices" by which a physician could establish such a diagnosis (one of which was conducting a "physical examination" of the patient) prefaced by the phrase "such as."[37] New Rule 190.8 replaced the phrase "such as" with the phrase "which includes documenting and performing," and also specified that the "physical examination . . . must be performed by either a face-to-face visit or in-person evaluation as defined [elsewhere in the rules]."[38] By making these changes, New Rule 190.8 made every "medical practice" in the list mandatory for establishing a diagnosis—including the in-person physical examination—whether such a step is medically indicated or

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[36] *See* TMB, *TMB Adopts Rules Expanding Telemedicine Opportunities* (Apr. 14, 2015), https://www.pharmacy.texas.gov/files_pdf/BN/May15/Tab_28.pdf [hereinafter "TMB Press Release"].

[37] *Id.*

[38] *Id.*

not.[39]

New Rule 190.8 is a knockout blow against the direct care telemedicine model.[40] Because the term "dangerous drug" in the rule refers to *any* prescription drug other than a controlled substance (*e.g.*, antibiotics, anti-virals like Tamiflu, topical creams), New Rule 190.8 covers literally every prescription drug.[41] In other words, New Rule 190.8 bans telemedicine providers from prescribing any medication to patients in Texas (because they will not be able to satisfy the in-person physical examination requirement to do so). Not having the ability to prescribe is a serious problem. Drug therapy is one of the most common types of

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[39] The TMB also adopted a minor change to the rules to permit a "face-to-face" or "in-person" examination to occur through telemedicine when the patient is at an "established medical site" with a "site presenter," *i.e.*, a medical professional who is present with the patient. *See id.* But the TMB's allowance is not particularly meaningful, because it requires the patient to travel to an established medical site and be with a medical professional before he or she can access direct care telemedicine. This requirement obviates most of the access benefits of telemedicine discussed above.

[40] Given the history of the TMB's legal battles with Teladoc, this was evidently what the TMB was trying to achieve. *See* Am. Compl. ¶¶ 95-127.

[41] Under Texas law, "dangerous drug" means any drug, other than a controlled substance, that is dispensed only by prescription. Tex. Occ. Code § 551.003(12); *see also* Tex. Health & Safety Code § 483.001(2). By covering "any dangerous drug or controlled substance," New Rule 190.8 thus covers every prescription drug.

primary care treatment and is used in more than 67% of all office visits.[42] The business model of direct care telemedicine depends on the provider's ability to offer patients basic treatment. New Rule 190.8 takes away that ability.

At the same time, New Rule 190.8 carved out an illogical exception to this in-person examination requirement for physicians in traditional "call coverage" arrangements.[43] This exception makes no sense. "Call coverage" is just another type of remote diagnosis and treatment. The most obvious difference between "call coverage" and direct care telemedicine is that the former supports traditional office-based practices, and the latter competes with them.[44] Physicians on call may never see the patient in person or have knowledge of the patient's medical history, but the call coverage exception nevertheless applies.

The AMA brief argues that telemedicine is not appropriate for "certain conditions" and that "*some* regulation" of telemedicine is necessary. AMA Br. at 5-6, 27. This is an attack on a straw man. No one disputes that medical care,

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42 *See* Ctrs. for Disease Control & Prevention: Nat'l Ctr. for Health Statistics, *Therapeutic Drug Use*, http://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm (last visited Sept. 8, 2016).

43 *See* 40 Tex. Reg. at 3161.

44 The TMB's "reasoned justification" for its "call coverage" exception was essentially just the assertion of a few individual physicians (including a member of the TMB) that "call coverage" is different from telemedicine, without a clear explanation as to *how* it is different. *See, e.g.*, *id.* at 3161-63, 3169.

including medical care provided through telemedicine, needs to be properly regulated. No one disputes that telemedicine is not appropriate for all conditions. However, telemedicine has *always* been regulated so that its use was limited to conditions appropriate for remote treatment.[45] Old Rule 190.8, for example, already required a physician to establish a diagnosis prior to writing a prescription, *including* conducting a physical examination of the patient where such an examination was medically indicated.[46] The change effected by New Rule 190.8 was to make a physical examination mandatory even when such an examination is *not* medically indicated. New rules that create specific barriers against telemedicine that are not tied to clinical appropriateness do not protect or improve the standard of care. They just create barriers to competition and add to the challenges of health care accessibility and affordability.

B. The AMA and FSMB Briefs Point to No Credible Evidence that Telemedicine Is Associated with Increased Patient Safety Risks.

The AMA and FSMB briefs mention three specific safety risks that they claim justify New Rule 190.8: (1) telemedicine increases the risks of misdiagnosis; (2) telemedicine increases the risks of over-prescription of antibiotics; and (3) telemedicine increases the possibility of abuse and diversion of opioids. *See* AMA

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45 *See* Poma, *supra* note 5, at 97-98.

46 *See* TMB Press Release, *supra* note 36.

Br. at 18-24; FSMB Br. at 3. However, the sources they cite do not actually show that telemedicine increases such risks in comparison with traditional office-based medical care. These purported "increased risks" are unfounded.

First, with respect to the purported increased risk of misdiagnosis, the AMA brief cites the facts alleged in a complaint that is pending before the Texas State Office of Administrative Hearings. *See* AMA Br. at 19-20. A complaint is not scientific evidence, and it certainly does not show an increased risk with telemedicine as compared to a control group. The risk of misdiagnosis is an issue with medical care generally; it is in no way unique to telemedicine.[47] Moreover, the mere existence of the complaint confirms that Old Rule 190.8 already embodied a prohibition against treating patients through telemedicine where an in-person physical examination is indicated. Effectively banning telemedicine cannot possibly be a "fair and considered" response to the general risk of misdiagnosis in modern medicine.

The same is true for the over-prescription of antibiotics. The article the FSMB cites states only that over-prescription of antibiotics is a general issue in

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[47] *See generally* Hardeep Singh et al., *The Frequency of Diagnostic Errors in Outpatient Care: Estimations from Three Large Observational Studies Involving US Adult Populations*, BMJ Quality & Safety, Sept. 2014, at 727 (discussing the frequency of diagnostic errors in medical care generally).

health care; it says nothing at all about telemedicine.[48] *See* FSMB Brief at 17. The AMA brief cites a study that is similarly not on point. *See* AMA Br. at 22. Though the AMA-cited study supposedly showed a greater use of antibiotics in "e-visits" compared to office visits for sinusitis and urinary tract infections, the "e-visits" discussed in the study involved diagnosis merely through *questionnaires*, with no real-time provider-patient interaction.[49] These are not the type of "e-visits" at issue in this case. Diagnosis by questionnaire was *already barred* under Old Rule 190.8, so there is no way the results of this study could justify New Rule 190.8.[50]

The AMA brief also cites a California study that it claims showed higher rates of antibiotic prescriptions by Teladoc providers. *See* AMA Br. at 20-22. However, as the California study itself notes, an earlier study by the same researchers found that the antibiotic prescribing rates for acute respiratory

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[48] Sumathi Reedy, *Your Health: Antibiotics Do's and Don'ts*, Wall St. J., Aug 20, 2013, at D1.

[49] Ateev Mehorotra et al., *A Comparison of Care at E-Visits & Physician Office Visits for Sinusitis & Urinary Tract Infection*, JAMA Internal Med., Jan. 14, 2013, at 72, 72 ("In e-visits, patients log into their secure personal health record internet portal and answer a series of questions about their condition. This written information is sent to the physicians, who make a diagnosis, order necessary care, put a note in the patients' electronic medical records, and reply to the patients via the secure portal within several hours.").

[50] *See* TMB Press Release, *supra* note 36.

infections were *similar* for Teladoc and physician's offices.[51] Though the pattern varied by diagnosis, the study concluded that *both* the in-person and telemedicine settings had high rates of inappropriate antibiotic prescribing for conditions such as bronchitis.[52] Effectively banning direct care telemedicine is not a fair or reasonable solution to the problem of over-prescription of antibiotics in the medical field at large.

Finally, the AMA and FSMB briefs contend that New Rule 190.8 is justified because telemedicine increases the risk of abuse and diversion of opioids and

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[51] Lori Uscher-Pines et al., *Access & Quality of Care in Direct-to-Consumer Telemedicine*, Telemed. & E-Health, Apr. 2016, at 282, 286.

[52] *See* Lori Uscher-Pines et al., *Research Letter: Antibiotic Prescribing for Acute Respiratory Infections in Direct-to-Consumer Telemedicine Visits*, JAMA Internal Med., May 26, 2015 (published online), at E1 ("Antibiotic prescribing rates for ARIs overall were similar for Teladoc and physician offices. However, both settings had high rates of inappropriate prescribing for conditions such as bronchitis; consistent with prior research that half of outpatient antibiotic prescriptions are not clinically indicated."). Though the study did note certain higher prescription rates, a noted weakness of the study was its failure to use a "case-control methodology" to adjust for risk. Rashid L. Bashshur et al., *The Empirical Foundations of Telemedicine Interventions in Primary Care*, Telemed. & E-Health, May 2016, at 342, 363. In other words, it was unclear if the study was comparing cases that were actually comparable at all. *See id.*

As for the AMA brief's claim that these researchers concluded Teladoc visits were associated with "less diagnostic testing," *see* AMA Br. at 21, this finding was in contrast to traditional outpatient settings, which are "typically criticized for *overtesting*" patients. *See* Uscher-Pines, *supra* note 51, at 286 (emphasis added). Diagnostic testing is also irrelevant to New Rule 190.8, which did not make any changes to the language in the Old Rule discussing "appropriate diagnostic and laboratory testing." *See* TMB Press Release, *supra* note 36.

controlled substances. *See* AMA Br. at 22-24; FSMB Br. at 17. However, neither brief cites to a source even tangentially supporting this claim. The FSMB brief cites an article that discusses the general risk of abuse and diversion of opioids that does not even mention "telemedicine."[53] *See* FSMB Br. at 17. The AMA brief cites to Delaware and Missouri laws limiting the prescription of "controlled substances." *See* AMA Br. at 23-24. Controlled substances were never really at issue in New Rule 190.8. Federal law already limits telemedicine providers from prescribing DEA-controlled substances,[54] and Teladoc providers do not prescribe them.[55] There is no rational connection between these facts and the TMB's actions.

The TMB's supposed "reasoned justification"[56] for New Rule 190.8 is similarly devoid of credible evidence of the purported increased "risks" of telemedicine. In fact, where the TMB provided *any* support for the rule, it offered only anecdotal support (*e.g.*, statements by a few individual physicians) or irrelevant studies or rules (*e.g.*, a study about the difficulty of diagnosing sepsis *in hospitals* and a rule requiring veterinarians to physically examine dogs and cats

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53 Josh Hicks, *Report Calls for Stricter Opioid Rules*, Wash. Post, Nov. 17, 2015, at B03.

54 *See* 21 U.S.C. § 829(e).

55 *See* Am. Compl. ¶ 82.

56 Tex. Gov't Code § 2001.033(a)(1).

before treating them).[57] This is hardly compelling scientific evidence. New Rule 190.8 is not an evidence-based rule. It imposes an overbroad restriction in response to non-existent risks.

C. New Rule 190.8 Is Inconsistent with the Telemedicine Guidelines of Numerous National Medical Organizations, including the AMA and FSMB's Own Guidelines.

In addition to being inconsistent with the evidence, New Rule 190.8 is *also* inconsistent with the guidelines that various respected national medical organizations have issued concerning telemedicine—including the AMA and FSMB's *own* guidelines.

New Rule 190.8 requires an in-person physical examination of the patient (either directly by the provider or indirectly through a site presenter at an established medical site) before any drug can be prescribed. In contrast, the AMA's own guidelines (which the AMA brief cites but neglects to discuss, *see* AMA Br. at 2-3) require an in-person physical examination to establish a diagnosis

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[57] *See, e.g.*, 40 Tex. Reg. at 3162-63, 3165, 3169. The TMB actually cited only *one* study relating to telemedicine in its purported "reasoned justification," *see id.* at 3154, and in that instance, the TMB grossly misrepresented the study's findings, as one of the study's authors has stated. *See* Decl. of Ateev Mehrotra in Support of Pls.'s Appl. for TRO & Prelim. Injunc. (Dist. Ct. ECF No. 35-2) ¶¶ 24-35.

only where such an examination is medically necessary.[58] As the AMA Council on Ethical and Judicial Affairs stated in the report underlying the guidelines:

> *[R]equiring a physical examination . . . as a condition for making a clinical diagnosis and prescribing, is out of step with the evolution of telehealth/telemedicine capabilities . . . .* Rather than a blanket prohibition against diagnosing and prescribing, a more nuanced and sustainable approach would permit physicians utilizing telehealth/telemedicine technology to exercise discretion in conducting a diagnostic evaluation and prescribing therapy, within certain safeguards.[59]

The AMA also recommends that physicians "advocate for policies and initiatives to promote access to telehealth/telemedicine services for all patients who could benefit from receiving care electronically."[60] The AMA amicus brief is "out of step" with the organization's own guidelines. The AMA's *guidelines* are about as far from the TMB's position as one can get.

The FSMB brief similarly ignores the FSMB's own "Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine." That policy reflects the understanding that remote diagnosis and treatment can be appropriate in certain circumstances, and that a blanket ban is unjustified and

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58 AMA, *AMA Adopts New Guidance for Ethical Practice in Telemedicine* (June 13, 2016), http://www.ama-assn.org/ama/pub/news/news/2016/2016-06-13-new-ethical-guidance-telemedicine.page [hereinafter "AMA Press Release"].

59 AMA Council on Ethical & Judicial Affairs, *Report on Ethical Practice in Telemedicine* 3 (2016) (emphasis added).

60 *Id.* at 10.

unreasonable. It states:

> Prescribing medications, in-person or via telemedicine, is at the professional discretion of the physician. The indication, appropriateness, and safety considerations for each telemedicine visit prescription must be evaluated by the physician in accordance with current standards of practice and consequently carry the same professional accountability as prescriptions delivered during an encounter in person. However, where such measures are upheld, and the appropriate clinical consideration is carried out and documented, physicians may exercise their judgment and prescribe medications as part of telemedicine encounters.[61]

Again, the FSMB's *guidelines*, which emphasize deference to the provider's clinical judgment, bear no resemblance to the TMB's position in New Rule 190.8.

Other respected medical organizations have taken positions similar to the AMA and FSMB guidelines, uniformly rejecting the concept of a complete prohibition on diagnosis and prescription through telemedicine like New Rule 190.8. For example, the American College of Physicians ("ACP") takes the position that an appropriate patient-physician relationship can be established through telemedicine so long as the provider "[t]ake[s] appropriate steps to establish a relationship based on the standard of care required for an in-person visit."[62] This is similar to Old Rule 190.8, not New Rule 190.8. The ACP does not

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[61] FSMB, *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine* 7 (adopted Apr. 2014), https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf.

[62] *See* Daniel & Sulmasy, *supra* note 15, at 788.

suggest the illogical requirement that a provider conduct an in-person physical examination even where one is not medically indicated. The American Academy of Dermatology has taken a similar position:

> For direct-to-patient teledermatology, the Academy believes that the consulting dermatologist must either: i. Have an existing physician-patient relationship (having previously seen the patient in-person), *or ii. Create a physician-patient relationship through the use of a live interactive face-to-face consultation before the use of store-and-forward technology*, or iii. Be a part of an integrated health delivery system where the patient already receives care . . . .[63]

Contrary to the suggestions in the AMA brief, *see* AMA Br. at 25-27, none of these guidelines provides any support to the TMB's position of requiring an in-person examination before any drug can be prescribed.[64]

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[63] Am. Acad. of Dermatology & AAD Ass'n, *Position Statement on Teledermatology* (amended Mar. 7, 2016), https://www.aad.org/Forms/Policies/Uploads/PS/PS-Teledermatology.pdf (emphasis added).

[64] The AMA brief erroneously implies that the American Academy of Neurology ("AAN") has taken a position that somehow supports New Rule 190.8. *See* AMA Br. at 26-27. It has not. The quoted language states only that a neurologic examination through telemedicine would be difficult to achieve for persons *untrained in neurology*. Far from concluding that telemedicine is inappropriate for neurology, the AAN "recommend[s] the availability of telemedicine services as an alternative for hospitals lacking critical elements for stroke care." Lawrence R. Wechsler et al., *Teleneurology Applications: Report of the Telemedicine Work Group of the American Academy of Neurology*, Neurology, Feb. 12, 2013, at 670, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3590056/.

CONCLUSION

This appeal is about immunity. However, to the extent the TMB, AMA, and FSMB briefs have managed to create the impression that New Rule 190.8 is a rational regulation based on credible evidence—that impression is false. In fact, New Rule 190.8 has all the hallmarks of a market-protective action, including a reliance on speculative and anecdotal "evidence," an overbroad response, and an illogical carve-out to protect traditional market participants.

Telemedicine is good for consumers. It can increase patient access to care without compromising the quality of care. New Rule 190.8's effective ban on direct care telemedicine protects traditional market participants at the expense of telemedicine providers, plan sponsors, and patients.

The district court correctly held that the TMB enacted New Rule 190.8 without the State's "active supervision" and that this is not the type of situation *Parker v. Brown* was intended to immunize. ERIC therefore respectfully urges this Court to affirm the district court's order denying the motion to dismiss.

Dated: September 9, 2016

Respectfully submitted,

/s/ J. Mark Gidley

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of September, 2016, a true and correct copy of the foregoing document was served via electronic transmission via portable document format (.pdf) to the CM/ECF internet web portal for this Court in this case on all counsel of record.

By:

/s/ J. Mark Gidley
J. Mark Gidley

Dated: September 9, 2016

Counsel for Amicus Curiae the ERISA Industry Committee

CERTIFICATE OF COMPLIANCE

Undersigned counsel certifies that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,949 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

Undersigned counsel further certifies that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced 14-point Times New Roman typeface using Microsoft Word 2010.

/s/ J. Mark Gidley
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