No. 16-50017

United States Court Of Appeals
For The Fifth Circuit

TELADOC, INC.; 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.

Appeal from the United States District Court
for the Western District of Texas, Case No. 1:15-cv-343
The Hon. Robert Pitman, Presiding

BRIEF OF MDLIVE AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES TELADOC, INC.

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

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INTEREST OF THE AMICUS CURIAE

This brief is submitted on behalf of MDLIVE, Inc. and MDLIVE Medical Group, P.A. (collectively, "MDLIVE"). MDLIVE is a large-scale provider of telehealth services and technologies throughout the United States, including Texas, and thus is subject to and impacted by the rules of the Texas Medical Board ("TMB"). The decision of this Court will determine whether the TMB can summarily ban an entire modality of health care, which will have a direct, and potentially deleterious, impact on MDLIVE's ability to provide telehealth services in Texas and beyond. For this reason MDLIVE has a direct stake in the outcome of this case and so submits this brief as *amicus curiae* in support of Plaintiff-Appellee Teladoc, Inc.'s ("Teladoc") submission to this Court asking it to affirm the district court's December 14, 2015 order denying the TMB's motion to dismiss.[1]

INTRODUCTION

Founded in 2009, MDLIVE is a leading telehealth provider with over ten million members nationwide, over 433,000 of whom reside in Texas. MDLIVE provides online and on-demand health care delivery services 24 hours a day, 365 days a year, for a fraction of the cost of a comparable visit to a physician's office,

[1] All parties have consented to the filing of this brief. 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.

urgent care center, or hospital emergency room. MDLIVE has one of the nation's largest networks of board-certified physicians and has designed proprietary technology and software that the MDLIVE Medical Group, health insurers, self-insured employers, hospitals, health systems, and others rely on for treating their patients. Like Teladoc, MDLIVE patients typically access MDLIVE's services through their employer or through their health insurer that has contracted with MDLIVE to make the service available to its members for a monthly per-member subscription fee. Additionally, MDLIVE provides health systems with telehealth technology, which enables the health systems to treat the health system's new and existing patients via telehealth—thereby providing patients with access to health care that they might not otherwise have. MDLIVE provides this technology to the largest not-for-profit health care system in Texas. The TMB's rules at issue will not only harm MDLIVE and other telehealth providers, but the damage will also be borne by each of the hospitals, health systems, and providers in Texas that are currently relying on MDLIVE's technology as part and parcel of their practice of medicine.

Telehealth is an important innovation in the health care industry and has gained considerable national attention and patronage because of its ability to improve quality and access to care at lower cost than traditional modes of service. Notwithstanding these factors of quality, efficiency, economy, and access to care,

the TMB has adopted and attempted to enforce rules that effectively would ban the telehealth modality throughout Texas.

The TMB rules at issue are 22 Tex. Admin. Code § 174 ("New Rule 174") and 22 Tex. Admin. Code § 190.8(1)(L) ("New Rule 190.8"), which would require, among other things, an in-person physical examination—regardless of medical necessity—before a telehealth provider could prescribe medication to a patient. Since MDLIVE's physicians' ability to prescribe medications is an essential function of the service and the treatment of patients, New Rule 174 and New Rule 190.8, as applied, are tantamount to an outright ban on telehealth in Texas.

Teladoc's Answering Brief accurately describes the reasons why, under the law enunciated by the Supreme Court of the United States and other courts, the TMB is not entitled to "state action" immunity from the antitrust laws, especially because of the lack of active state supervision as has been required by the Supreme Court. That argument, with which MDLIVE generally agrees, need not be repeated here. However, as noted below and by various other *amici* in this case, New Rule 174 and New Rule 190.8 are going to have damaging effects on Texas health care providers, Texas businesses, and Texas citizens and thus it is especially important that the TMB act consistent with the active supervision and clear articulation requirements of the state action doctrine in the promulgation of these

rigid rules. State action antitrust protection from what would otherwise clearly be an antitrust violation can only be afforded under rigorous conditions that are not present here.

ARGUMENT

I. Contemporary Telehealth is a Safe, Sophisticated, and Cost-Effective Modality of Health Care

Telehealth is revolutionizing the way health care is delivered in the United States and so is gaining broad formal acceptance by state legislatures around the country—illustrated below. Telehealth is not a one-player industry only affecting Teladoc; the Court's decision on the injunction of New Rule 174 and New Rule 190.8 would have impact on the entire Texas telehealth industry, including MDLIVE, Teladoc, and others, and could block Texans from choosing a health care modality that best suits their needs.

Telehealth is a safe and sophisticated source of health care and the physician ratings, quality scores, and patient satisfaction metrics are exceptional. For example, every MDLIVE physician is state licensed, board certified, and credentialed. They average 15 years of practice experience, and each receives specialized training in communicating with and diagnosing patients over the phone and through online video. The patient satisfaction and quality statistics are equally remarkable. For example, MDLIVE has 99% client retention, an average callback

time of 9 minutes, 97% customer satisfaction, and perhaps most notably, ***zero*** malpractice claims to date—either in Texas or anywhere in the United States.

MDLIVE's enrollment numbers—10 million nationwide and over 433,000 in Texas—demonstrate how attractive and desired these telehealth services are for Texans.

Telehealth, practiced appropriately, is in many ways superior to the traditional "on-call" coverage model, which the TMB expressly permits. With telehealth as practiced by MDLIVE, when a patient requests a consult, there is a highly trained physician with a computer or tablet (or similar device) and the patient's medical profile at hand. Moreover, subject to applicable law, MDLIVE's technology allows patients to choose from either an interactive audio consultation or an interactive audio-video consultation. Prior to an MDLIVE telehealth consultation, the patient is required to complete a thorough medical history, including an overview of his or her care, previous diagnoses, allergies, medications, lab tests, family history, and the name of the patient's primary care physician if he or she has one. This medical history intake does not simply rely on patient self-reporting; in some cases, the MDLIVE technology is able to pull information into the patient's chart from insurance records, health information exchanges, and medication databases depending on whether and to the extent such resources are available for a particular patient. An MDLIVE physician licensed in

the state where the patient is located is required to review and assess the patient's medical history and electronic health records prior to initiating the telehealth consultation with the patient.[2]

During an MDLIVE consultation, the telehealth physician keeps contemporaneous medical records while interacting in real-time with a patient. MDLIVE's interactive audio consultations include store-and-forward technology where patients can upload photographs or other records in real-time with the physician via a secure message and MDLIVE can forward a patient's consultation medical records to the patient's primary care physician to promote continuity of care.

Conversely, with the "on-call" coverage model, a patient typically speaks with a physician who is covering for the patient's regular physician. This interaction is generally conducted via telephone only where the patient and the physician are both only on their telephones instead of, with MDLIVE's model, via interactive audio with store-and-forward technology where the physician has access to technology allowing review of a patient's medical history and

[2] MDLIVE's technology platform geo-targets all patients coming through the MDLIVE CS line using a patient's Internet Protocol ("IP") address, not simply an area code like a telephone. The IP address is the unique numerical label assigned to each device (*i.e.*, computer, smart phone, etc.). MDLIVE does a reverse look-up of the IP address that allows it to see what state the patient is located in (with the ability to isolate the county in which the patient is located). The IP address location triggers the list of providers who are licensed in the state where the patient is located and it is from this list that a provider is selected for the patient. As an added safeguard, all MDLIVE providers are trained to confirm the physical location of the patient at the beginning of the telehealth consultation.

information, as well as the ability to take and forward records in real-time to the covered physician. The "on-call" coverage model is significantly less sophisticated than MDLIVE's model and those of contemporary telehealth providers, yet the covering physician is still legally permitted in Texas to treat a patient and prescribe medication over the telephone—including various "dangerous drugs" and those with the potential for abuse and dependence (*e.g.*, non-narcotic sleep aids).[3]

The rigorous quality control and safety precautions of contemporary telehealth providers do not end with the patient's consult. For example, among other things, MDLIVE's clinical team reviews the first five consultations completed by a telehealth provider as well as a random sample of 5% of consults completed by each physician annually. This is more that can be said of the traditional "on-call" coverage that is expressly permitted by the TMB.

MDLIVE providers only treat minor acute care conditions appropriate for telehealth—often conditions treatable with antibiotics, antifungals, skin creams, etc. If a patient's condition cannot be treated appropriately through telehealth, then the patient is referred to his or her in-person primary care physician or other appropriate in-person provider. MDLIVE physicians write prescriptions only

[3] The TMB touts the importance of a pre-existing relationship between the "on-call" physician and the covered physician. This seems clinically irrelevant if the "on-call" physician was not previously acquainted with the patient's information and clinical profile, which is often the case. *See* Tex. Health & Safety Code § 483.001(2) (definition of "dangerous drugs").

when medically indicated, within the standard of care in the community, and only within strict guidelines. MDLIVE physicians do not issue prescriptions for substances controlled by the DEA, for non-therapeutic use, and/or those which have the potential for abuse or addiction. In the event that a MDLIVE physician does prescribe medication, it is through e-prescribing software embedded in the MDLIVE technology. The use of the e-prescribing system enables MDLIVE's clinical team to track, review, and benchmark individual prescribing patterns for appropriateness of use.

Telehealth, as practiced by MDLIVE and other contemporary providers, offers a panoply of rigorous quality control and safety precautions well beyond those permitted under the current "on-call" coverage model permitted by the TMB, illustrating how the purported "dangers" and "risks" theorized by the TMB are misplaced.[4]

[4] The TMB's inconsistency with respect to mental health services is also worth highlighting. The TMB has carved out mental health services from the in-person evaluation requirement of New Rule 190.8 (providing that "[t]he requirement for a face-to-face or in-person evaluation does not apply to mental health services . . . ."). Since a justification and concern of the TMB in imposing a mandatory in-person examination is ensuring patient safety, it is unclear why mental health services and the prescription of addictive and dangerous drugs (many with contraindications, such as anti-depressants) would not warrant equivalent "protections" to those governing telehealth physicians prescribing items such as acne medication and anti-fungal creams.

II. Contrariwise to the Tack of the TMB, States Increasingly are Passing Express Legislation to Embrace Telehealth Providers like MDLIVE and Teladoc

The American Medical Association and the Texas Medical Association as *amicus curiae* ("AMA/TMA") to the TMB seek to defend the TMB's prohibition on telehealth by contending that New Rule 174 and New Rule 190.8 are not outliers among other states.[5] While Arkansas still requires an in-person examination before medicine may be prescribed, this is certainly not the norm among other states that either permit "on-call" coverage (of which MDLIVE's services are an extension) or expressly permit provision of telehealth services.

While speaking in generalities about other states and overlooking "on-call" coverage exceptions in various states, the AMA/TMA highlights two particular states with rules that purportedly lend credibility to the TMB's New Rule 174 and New Rule 190.8.[6] Those states are Delaware and Missouri and, contrary to the AMA/TMA brief, both have long permitted telehealth. Indeed, both of these states have also recently enacted legislation to make it even more explicit that an in-person physical examination is not mandatory before medicine may be prescribed.

(A) ***Delaware*****.** According to the AMA/TMA's brief, "Delaware requires that a physician have 'conducted at least 1 in-person medical history and physical

[5] *Brief of American Medical Ass'n and Texas Medical Ass'n as Amicus Curiae in Support of Defendants/Appellants, Seeking Reversal*, at 22 (June 24, 2016).

[6] *Id.*

examination sufficient to establish a diagnosis…'."[7] This is incorrect. While Delaware previously permitted telehealth,[8] it enacted legislation on July 7, 2015 which expressly states that an in-person examination is not mandatory before a patient can be prescribed medication—providing in relevant part that:

> Physicians using telemedicine technologies to provide medical care to patients located in Delaware must, prior to a diagnosis and treatment, and only if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine, either provide: (1) an appropriate examination in-person, (2) have another Delaware-licensed practitioner at the originating site with the patient at the time of the diagnosis, ***(3) the diagnosis must be based using both audio and visual communication, or (4) the service meets standards of establishing a patient-physician relationship included as part of evidenced-based clinical practice guidelines in telemedicine*** developed by major medical specialty societies, such as those of radiology or pathology.[9]

Thus, in Delaware, there is no mandatory in-person examination requirement before a patient can be examined and prescribed medication.

(B) ***Missouri.*** According to the AMA/TMA's brief, "Missouri likewise requires that the prescribing physician have 'performed a sufficient physical examination and clinical assessment of the patient' before treatment and specifies

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[7] *Id.* at 24.

[8] *See* 16 Del. Code § 4701(31)(d) (exception for physicians providing on-call care); 24 Del. Code § 1769D(b) (providing that a "proper physician-patient relationship" may be "established either in-person or through telehealth").

[9] 24 Del. Code § 1769D(b) (effective Jan. 1, 2016) (emphasis added).

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.'"[10] Like Delaware, Missouri also previously permitted telehealth and the establishment of a physician-patient relationship without a physical examination,[11] but enacted legislation on June 8, 2016, that expressly allows providers to prescribe medication without the mandatory in-person examination requirement—providing in relevant part that:

> In order to establish a physician-patient relationship through telemedicine:
>
> (1) The technology utilized shall be sufficient to establish an informed diagnosis as though the medical interview and physical examination has been performed in person; and
>
> (2) Prior to providing treatment, including issuing prescriptions, a physician ***who uses telemedicine shall interview the patient, collect or review relevant medical history, and perform an examination sufficient for the diagnosis and treatment of the patient.*** 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.[12]

(C) ***Various Other States Embracing Telehealth.*** Aside from the two states highlighted in the AMA/TMA's brief, there are numerous others that have

[10] *Brief of American Medical Ass'n and Texas Medical Ass'n, supra note 5,* at 24 (June 24, 2016).

[11] *See* Mo. Stat. § 191.1146(1)(3) ("The physician-patient relationship may be established by . . . A telemedicine encounter, if the standard of care does not require an in-person encounter . . . .").

[12] *See* Mo. Stat. § 191.1146(2)(2) (effective Aug. 28, 2016) (emphasis added).

also long permitted telehealth and recently enacted legislation expressly embracing it and permitting a patient-physician relationship to be established without a physical examination. To take a few recent examples:

(1) **Alaska.** Expressly authorizes prescriptions to be written without an in-person examination. Alaska Stat. § 08.64.364 ("The board may not impose disciplinary sanctions on a physician for prescribing, dispensing, or administering a prescription drug to a person without conducting a physical examination . . . ."). On July 11, 2016 S.B. 74 was enacted which eliminated the requirement that only an in-state Alaska provider may write a prescription for an Alaskan patient if the service occurred via telehealth.[13]

(2) **Florida.** On July 1, 2016 Florida enacted H.B. 7087 which provides that if the provider "conducts a patient evaluation sufficient to diagnose and treat the patient" then the provider is "not required to . . . conduct a physical examination of the patient before using telehealth to provide services to the patient."[14]

(3) **North Carolina.** On July 1, 2015 the North Carolina Medical Board issued a "Telemedicine Position Statement" where is stated that a patient-physician relationship can be established using telehealth, also noting that "[a] diagnosis should be established through the use of accepted medical practices, i.e., a patient history, mental status evaluation, physical examination and appropriate diagnostic and laboratory testing."[15]

(4) **South Carolina.** On June 3, 2016 South Carolina enacted S.B. 1035 which provides that a patient-physician relationship can be established using telehealth and that the patient evaluation prior to treatment "need not be done in-person if the licensee employs technology

[13] S. 74, 29th Leg., Second Reg. Sess. (Alaska 2016).

[14] H.R. 7087, 2016 Leg., Reg. Sess. (Fla. 2016).

[15] North Carolina Medical Board, *Telemedicine Position Statement* (July 1, 2016), *available at* http://www.ncmedboard.org/resources-information/professional-resources/publications/forum-newsletter/article/telemedicine-position-statement.

> sufficient to accurately diagnose and treat the patient in conformity with the applicable standard of care . . . ."[16]

As illustrated by these other states, their boards of medicine (each of which having patient safety responsibilities akin to that of the TMB), and recent legislation, New Rules 170 and 190.8 are outliers and inconsistent with the modern recognition of the value telehealth.

III. The TMB Rules will Exacerbate Texas' Physician Shortage, Undermine Benefits of Current Insureds, and Harm Access for the Uninsured and Underinsured

If not enjoined, New Rule 174 and New Rule 190.8 would end both MDLIVE's and Teladoc's provision of telehealth services in Texas. Such an outcome would be detrimental to Texas, its businesses large and small, and its citizens.

Texas has one of the most severe physician shortages in the United States, and struggles with high uninsured and underinsured populations. Texas ranks 47th in the United States in active primary care physicians per 100,000 population.[17] Indeed, 80 Texas counties have five or fewer physicians, and 35 Texas counties

[16] S. 1035, 121 Gen. Assemb., Second Reg. Sess. (S.C. 2016).

[17] Merritt Hawkins, *The Physician Workforce in Texas* 3 (Apr. 2015), *available at* www.merritthawkins.com/UploadedFiles/MerrittHawkings/Surveys/Merritt_Hawkins_NTREC_Physician_Workforce_Survey.pdf.

have no physicians of any kind.[18] According to the Texas Medical Association, Texas "does not have enough physicians to keep up with growing demand."[19]

Telehealth providers like MDLIVE are essential for increasing the supply of physicians in Texas and attempting to help Texas keep up with growing demand. MDLIVE's operations increase the overall supply of physicians in the market by enabling them to provide their services to patients on a flexible basis and operate across state lines. Physicians that might otherwise exit the market for various reasons (*e.g.*, relocation, early retirement, raising family, etc.) can extend their practice on a flexible basis and do so from multiple locations. For example, the district court noted the value of this in its order granting Teladoc's motion for a temporary restraining order and preliminary injunction:

> Plaintiffs have also cited evidence that Teladoc increases opportunities for physicians to provide health care. One physician testified telehealth allowed him to continue to practice medicine on a flexible schedule in his semiretirement. Another testified, without telehealth, he would treat fewer patients. This evidence is significant in light of the evidence presented by Plaintiffs that Texas suffers from a shortage of doctors, particularly in rural areas, and that approximately 50% of Teladoc's client patients do not have a regular physician. Elimination of physicians providing healthcare would thus negatively

[18] *Id.*

[19] Tex. Med. Ass'n, *Why Texas Needs More Physicians* (2006), *available at* https://www.texmed.org/template.aspx?id=5427.

> impact not just the competitor physicians, but consumers, a classic antitrust injury."[20]

MDLIVE also serves substantial Texas government employee populations, whose access to care would be harmed if the TMB can enforce New Rule 174 and New Rule 190.8. This includes approximately 394 school districts including, but not limited to the Arlington, Birdville, Humble, Mansfield, and Frisco independent school districts. Approximately 123,900 Texas school district employees are eligible to receive the MDLIVE telehealth benefit and 36,639 employees have received consultations. These numbers do not include the dependents of the Texas school district employees who also have access to and are currently participating in the MDLIVE telehealth benefit. A large portion of these school district employees represent rural Texans with little or no access to local doctors. MDLIVE's services provide this population with valuable access to care that they may not otherwise receive, and provide significant cost savings for school districts.

MDLIVE's convenient and affordable services also reduce the number of patients regularly seeking care in hospital emergency rooms for minor, non-emergent conditions, many of whom would undoubtedly be eager to avoid long emergency room wait times and seek telehealth services if offered an alternative like MDLIVE. Given these statistics and circumstances, the need for telehealth in

[20] Order Granting Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, ECF 44, at 8–9 (internal citations omitted).

Texas is manifest; if not enjoined, New Rule 174 and New Rule 190.8 will exacerbate the effects of the already dire Texas physician shortage and continue to harm access to care for Texans.

The harm caused by New Rule 174 and New Rule 190.8 would also be borne by current Texas insureds. The MDLIVE telehealth benefit has already been included in the benefits packages for many commercial health insurers and self-insured employers operating in Texas. It is already in ERISA plan documents, and has been submitted by MDLIVE's commercial insurer clients to state insurance regulators. Since patient premiums are often calculated based on the benefits included, removal of the MDLIVE benefit would mean that insured patients do not get access to a benefit they may have already paid for through premiums. Removal of the MDLIVE benefit may also impact the actuarial tables for MDLIVE's employer and health insurance clients.

IV. The TMB Rules Are Anticompetitive and Will Harm MDLIVE and the Telehealth Industry as a Whole

New Rule 174 and New Rule 190.8 are plainly anticompetitive as they will result in higher prices for consumers buying physician's services (*e.g.*, out of pocket costs and premiums), reduced choice and access (*e.g.*, no longer being able to choose telehealth or obtain medical care), and stifle telehealth providers from competing in the market.

The Federal Trade Commission ("FTC") views telehealth as "an area of particular interest" because of the "potential to increase practitioner supply, encourage competition, and improve access to affordable, quality health care."[21] The TMB's restriction on output and ban of an entire modality of care is the antithesis to each of these procompetitive features identified by the FTC and will only serve to insulate incumbent office-based physicians from competition.

New Rule 174 and New Rule 190.8 also appear calculated to prevent patients from electing to seek treatment outside of a traditional patient-physician relationship—threatening to keep them captive to established office-based physicians, like various members of the TMB. In doing so, the TMB is not only overlooking the access and other issues noted above, but is also failing to account for patients that have no current relationship with a physician but need treatment.

CONCLUSION

For the foregoing reasons, MDLIVE respectfully requests the Court to affirm the district court's December 14, 2015 order denying the TMB's motion to dismiss.

[21] Fed. Trade Comm'n, *FTC Staff Comment: Delaware Occupational Therapy Board Proposal to Expand Access to Telehealth Services Could Benefit Consumers* (Aug. 3, 2016), *available at* https://www.ftc.gov/news-events/press-releases/2016/08/ftc-staff-comment-delaware-occupational-therapy-board-proposal.

Respectfully submitted,

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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 4,255 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 has been prepared in a proportionally spaced typeface (14-point Times New Roman) using Microsoft Word.

/s/ *Stuart M. Gerson*
Stuart M. Gerson

September 9, 2016

Counsel for Amicus Curiae

CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2016, I electronically filed a copy of the foregoing with the Clerk of the United States Court of Appeals for the Fifth Circuit using the Court's appellate Case Management/Electronic Case Files (CM/ECF) system. Participants in the case who are registered CM/ECF users were served by the CM/ECF system at that time.

/s/ *Stuart M. Gerson*
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