

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

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|--|---|------------------------------------|
| LISA TORREY, <i>et al.</i> , | § | |
| | § | |
| Plaintiffs, | § | |
| | § | CIVIL ACTION NO. 5:17-cv-00190-RWS |
| v. | § | |
| | § | JURY DEMANDED |
| INFECTIOUS DISEASES SOCIETY OF AMERICA, <i>et al.</i> , | § | |
| | § | |
| Defendants. | § | |

PLAINTIFFS' SECOND AMENDED COMPLAINT¹

COME NOW Plaintiffs LISA TORREY, KATHRYN KOCUREK Individually and on behalf of the Estate of J. DAVID KOCUREK, PH.D., AMY HANNEKEN, JANE POWELL, CAROL FISCH, JOHN VALERIO, Individually and as Next Friend of Christopher Valerio, RANDY SYKES, BRIENNA REED, ROSETTA FULLER, ADRIANA MONTEIRO MOREIRA, JESSICA MCKINNIE, KRISTINE WOODARD, GAYLE CLARKE, ALLISON LYNN CARUANA, CHLOE LOHMEYER, TAWNYA DAWN SMITH, Individually and as Next Friend of MONET PITRE, MIKE PEACHER, Individually and as Next Friend of ASHLEIGH PEACHER, ALARIE BOWERMAN, Individually and as Next Friend of ELISA BOWERMAN, EMORY BOWERMAN, and ANAIS BOWERMAN, on behalf of themselves against the INFECTIOUS DISEASES SOCIETY OF AMERICA (“IDSA”), DR. GARY P. WORMSER, DR. RAYMOND J. DATTWYLER, DR. EUGENE SHAPIRO, DR. JOHN J. HALPERIN, DR. LEONARD SIGAL, and DR. ALLEN STEERE (collectively “IDSA Panelists”) herein, and in support thereof, show the Court the following:

¹ Pursuant to the current Amended Control Order (Dkt. #309) “It is not necessary to file a Motion for Leave to Amend before the deadline to amend pleadings” of April 16, 2021.

PARTIES AND SERVICE

1. Plaintiff Lisa Torrey is an individual and a citizen of the State of Texas.
2. Plaintiff Kathryn Kocurek is an individual and citizen of the State of Texas.
3. Amy Hanneken is an individual and a citizen of the State of Florida.
4. Jane Powell is an individual and a citizen of the State of Connecticut.
5. Carol Fisch is an individual and a citizen of the State of Florida.
6. Christopher Valerio is an individual and citizen of the State of Pennsylvania.
7. Randy Sykes is an individual and a citizen of the State of Connecticut.
8. Brienna Reed is an individual and a citizen of the State of Ohio.
9. Rosetta Fuller is an individual and a citizen of the State of Alabama.
10. Adriana Monteiro Moreira is an individual and citizen of State of Florida.
11. Jessica McKinnie is an individual and a citizen of the State of Michigan.
12. Kristine Woodard is an individual and a citizen of the State of Iowa.
13. Gayle Clarke is an individual and a citizen of the State of Iowa.
14. Allison Lynn Caruana is an individual and a citizen of the State of Florida.
15. Chloe Lohmeyer is an individual and a citizen of the State of Nevada.
16. Tawnya Dawn Smith is an individual and a citizen of the State of Nevada.
17. Mike Peacher is an individual and a citizen of the State of Florida.
18. Alarie Bowerman is an individual and a citizen of the State of Arkansas.
19. Defendant INFECTIOUS DISEASES SOCIETY OF AMERICA already made an appearance in this case.

“IDSA PANELISTS” DEFENDANTS

20. Defendant Dr. Gary P. Wormser already made an appearance in this case.
21. Dr. Raymond J. Dattwyler already made an appearance in this case.

22. Dr. Eugene Shapiro already made an appearance in this case.
23. Dr. John J. Halperin already made an appearance in this case.
24. Dr. Leonard Sigal already made an appearance in this case.
25. Dr. Allen Steere already made an appearance in this case.
26. Collectively these doctors are identified by name or as the “IDSA Panelists”.

SETTLING DEFENDANTS

27. Defendants BLUE CROSS AND BLUE SHIELD ASSOCIATION, ANTHEM, INC., BLUE CROSS AND BLUE SHIELD OF TEXAS. AETNA INC., CIGNA CORPORATION, KAISER PERMANENTE, INC., UNITED HEALTHCARE SERVICES, INC., and UNITEDHEALTH GROUP INCORPORATED (hereinafter referred to as “Settling Defendants” or “Settling Insurance Companies”) reached confidential settlement agreements with Plaintiffs. The Plaintiffs and Settling Defendants expect the settlements to be finalized shortly. Once the settlements are finalized, Plaintiffs will file a stipulation dismissing these Defendants. Because the settlements are not yet finalized, these Settling Defendants are still parties to the case.

JURISDICTION AND VENUE

287. The Racketeer Influenced and Corrupt Organizations Act (RICO) authorized nationwide service of process on nonresident defendants in civil RICO suits brought in Texas district court, where the court has personal jurisdiction over at least one participant in alleged conspiracy and there was no other district that had personal jurisdiction over all the alleged coconspirators. 18 U.S.C.A. § 1965(b). Venue is proper pursuant to 18 U.S.C.A. § 1965 because Defendants transact their affairs in this venue. 18 U.S.C.A. § 1965.

FACTS AND ALLEGATIONS

29. All of the facts and allegations in all of the subsequent paragraphs are made upon information and belief. Additionally, the facts and allegations are based upon information acquired

by Plaintiffs because Defendants have not produced documents that are solely in their control. Moreover, Defendants have indicated they may not actually have the documents sought during the relevant time period due to their document retention policies.

30. Lyme disease is the most common tick-borne infection in both North America and Europe and is the fastest-growing infectious disease in America. The CDC estimates that 300,000 Americans are infected with Lyme disease each year.² Once infected, patients typically experience a wide range of symptoms, including fever, headache, swollen joints, fatigue, and skin rash. If the infection goes untreated, the disease may spread to the joints, heart, and the nervous system and may result in debilitating symptoms, including severe fatigue, anxiety, migraines, light sensitivity, and severe joint pain. If Lyme disease continues untreated for a prolonged period, the infected suffer with crippling muscle and joint pain, disabling fatigue, arthritis, neurological disorders, cardiac disorders, and eventually invades the brain causing depression, thoughts of suicide, brain fog, severe weakness, memory or concentration difficulties, bladder or bowel dysfunction, and visual loss. Left untreated, Lyme disease can lead to a painful and agonizing death.

31. The doctors who actually treat Lyme disease have known for a long time that while many patients who contract Lyme disease can be cured with short-term antibiotic treatment, a large number of patients do not respond to short-term antibiotic treatment. Even using the most conservative numbers possible, at least 20% of Lyme disease patients each year do not respond to short-term antibiotic treatment (ILADS estimates 40% of Lyme disease patients do not respond to a short-course of antibiotics³). Therefore, at least 60,000 Lyme patients a year require long-term

² <http://www.ilads.org/lyme/lyme-quickfacts.php>

³ *Id.*

antibiotic treatment, including expensive intravenous antibiotics. The cost of long-term antibiotic treatment ranges from \$1,000 to \$50,000 per year.⁴

32. These patients with chronic Lyme disease require long-term antibiotic treatment for many months until the symptoms are resolved. Lyme doctors also know that chronic Lyme disease patients who do not respond to short-term antibiotic treatment, and do not receive long-term antibiotic treatment, will suffer debilitating symptoms, will be in constant pain, will be unable to function or live a normal life, and will eventually die from Lyme disease.

33. Similarly, Lyme doctors know that if Lyme patients are undiagnosed, or are misdiagnosed with another ailment, the Lyme disease can become so severe that without long-term antibiotic treatment the disease will spread to their joints, their heart, and their nervous system causing crippling muscle and joint pain, disabling fatigue, arthritis, neurological disorders, cardiac disorders, depression, memory loss, bladder loss, bowel dysfunction, visual loss, and death.

34. Initially, the Settling Insurance Companies⁵ provided coverage for Lyme disease patients, covered long-term antibiotic treatment, and even paid for extended hospital stays to treat patients with Lyme disease who did not respond to short-term antibiotic treatment. This allowed doctors to properly assesses and treat patients with chronic Lyme disease and prevented the suffering and death of many thousands of Lyme disease patients.

35. As set forth in the deposition of Dr. Richard Sanchez, the Senior Vice President for the Blue Cross Defendants, in the 1990's insurance companies decided that treatment of Lyme disease was too expensive and red-flagged Lyme disease.⁶ According to Sanchez, the health

⁴ https://static-content.springer.com/esm/art%3A10.1186%2Fs12911-016-0270-y/MediaObjects/12911_2016_270_MOESM1_ESM.pdf

⁵ These are Blue Cross and Blue Shield Association (“BCBSA”), Anthem, Inc., Blue Cross and Blue Shield of Texas, Aetna Inc., Cigna Corporation, Kaiser Permanente, Inc., United Healthcare Services, Inc., and Unitedhealth Group Incorporated and referred to collectively as “Settling Insurance Companies.”

⁶ See Exhibit “A”, Sanchez deposition, pages 90 – 116.

insurance industry made a concerted effort to deny coverage for treatment of Lyme disease because of the costs associated with the long-term treatment of some Lyme patients.⁷ Sanchez testified that in order to save money, the Blue Cross Defendants created an arbitrary policy of restricting antibiotic treatment for Lyme disease to 42-days:

Q. As far as you know, what was the rationale for selecting the 42-day period of time that I just read from the corporate Lyme disease policy from 1993?

A. It's an arbitrary number, six times seven is 42, it's six weeks, and that's just the way we tended to divide up courses of treatment, ten days, 14 days, four weeks, six weeks, nothing magical or scientific about it.⁸

36. When Sanchez was asked if Blue Cross had “any medical or scientific justification for that policy, to restrict approval of IV antibiotic treatment”, Sanchez answered with “No”.⁹ Once these arbitrary guidelines were put into place by Blue Cross, the other Settling Insurance Companies followed suit by denying coverage for Lyme treatment after the arbitrary timeframe.¹⁰

37. From the early 1990's up to the enactment of the 2000 IDSA Guidelines, the Settling Insurance Companies began improperly denying insurance coverage for antibiotics after 28 days of treatment.¹¹ The Settling Insurance Companies began referring to any treatment beyond short-term antibiotics as “experimental”¹².

⁷ *Id.*

⁸ *See* Exhibit “A”, Sanchez deposition, page 116, lines 2-10.

⁹ *See* Exhibit “A”, Sanchez deposition, page 114, lines 3-9.

¹⁰ *See* Pamela Weintraub, *Cure Unknown, Inside the Lyme Epidemic*, pages 306-31, St. Martin's Griffin, 2008.

¹¹ *See* Pamela Weintraub, *Cure Unknown, Inside the Lyme Epidemic*, pages 306-31, St. Martin's Griffin, 2008.

¹² *Id.*

A. Payment of Consulting Fees to IDSA Panelists

38. Plaintiffs hereby allege that the Settling Insurance Companies paid consulting fees to the IDSA panelists to influence the IDSA guidelines and the IDSA Panelists based on information and belief, which includes the following:

39. As set forth in more detail below, the Attorney General of the state of Connecticut, Richard "Dick" Blumenthal (now Senator Blumenthal) investigated the IDSA Guidelines and served Civil Investigative Demands (CID) on the IDSA Panelists and most of the Settling Insurance Companies, including UnitedHealth, Cigna, Aetna, Anthem, and Anthem Blue Cross¹³.

40. The CIDs to the Settling Insurance Companies asked for any compensation paid by the Settling Insurance Companies to the IDSA Panelists (including Defendants Wormser, Dattwyler, Halprin, Shapiro, and Steere) from August 1, 1998 to July 31, 2007.¹⁴

41. The Settling Insurance Companies and IDSA Panelists responded to these CIDs and AG Blumenthal concluded: "several of the most powerful IDSA panelists" had undisclosed financial interests in insurance companies including "consulting arrangements with insurance companies".¹⁵

42. On August 12, 1996 Dr. Leonard Sigal, one of the IDSA Panelist Defendants, testified during a deposition that he reviewed many Lyme disease files for insurance companies, almost always denied coverage, and charged \$560 an hour to perform his work. He testified that he reviewed files for most of the Settling Insurance Companies:

Q. What insurance companies have you reviewed for with regard to Lyme disease?

¹³ See Exhibit "B" CIDs.

¹⁴ *Id.*

¹⁵ <http://www.empirestatelymediseaseassociation.org/Archives/CTAGPressReleaseIDSAResponse.htm>

A. Prudential, Aetna, Blue Cross Blue Shield. Something called Anthem. Met Life, or Met Health¹⁶, I guess, Metro Health¹⁷. Whatever it's called. I believe that's it.

Q. And have payments from these insurance companies been made directly to you in your name?

A. Yes.¹⁸

43. Dr. Sigal testified that he was paid \$560 an hour, in 1996, by these insurance companies.¹⁹ Dr. Sigal quipped that the money he was paid by insurance companies "would pay for a lot of college tuition, actually".²⁰

44. Dr. Joseph Burrascano, Jr., an internationally known infectious disease specialist, made the following statements at a hearing before the Senate Committee on Labor & Human Resources:

There is in this country a core group of university-based Lyme disease researchers and physicians whose opinions carry a great deal of weight. Unfortunately, many of them act unscientifically and unethically. They adhere to outdated, self-serving views and attempt to personally discredit those whose opinions differ from their own. They exert strong, ethically questionable influence on medical journals, which enables them to publish and promote articles that are badly flawed. They work with Government agencies to bias the agenda of consensus meetings and have worked to exclude from these meetings and scientific seminars those with ultimate opinions.

¹⁶ In 1995, UnitedHealth acquired both MetraHealth Companies Inc. and Metropolitan Life Insurance Company.

¹⁷ *Id.*

¹⁸ <http://www2.lymenet.org/domino/law.nsf/34bb600f91c4b4a9852565070004d48a/9d925dad11e6c2c28525651d000abd32?OpenDocument> page 142, lines 5-14.

¹⁹ *Id.* at page 11, line 23 – page 12, line 8.

²⁰ See Pamela Weintraub, Cure Unknown, Inside the Lyme Epidemic, page 306, St. Martin's Griffin, 2008.

They behave this way for reasons of personal or professional gain and are involved in obvious conflicts of interest.

[T]hese individuals who promote this so-called “post Lyme syndrome” as a form of arthritis depend on funding from arthritis groups and agencies to earn their livelihood. Some of them are known to have received large consulting fees from insurance companies to advise the companies to curtail coverage for any additional therapy beyond the arbitrary 30-day course.²¹

45. It is clear from the evidence set forth above that consulting fees were paid by the insurance companies to the IDSA Panelists before the IDSA Panelists created the IDSA guidelines. Not surprisingly, when the 2000 IDSA Lyme guidelines were created, they contained the same arbitrary requirements limiting Lyme treatment to only short-term antibiotics treatment.²²

46. The IDSA Panelists who created these guidelines, and who were paid by the insurance companies, discounted chronic Lyme disease even though they admitted in the 2000 guidelines that they had no studies to support their conclusion that chronic Lyme disease does not exist:

Randomized controlled studies of treatment of patients who remain unwell after standard courses of antibiotic therapy for Lyme disease are in progress. To date, there are no convincing published data that repeated or prolonged courses of either oral or iv antimicrobial therapy are effective for such patients. **The consensus of the Infectious Diseases Society of America (IDSA) expert-panel members is that there is insufficient evidence to regard “chronic Lyme disease” as a separate diagnostic entity.**²³

47. Dr. Sam Donta, one of the most respected Lyme doctors in the world, questioned why the guidelines did not include treatment for patients with chronic Lyme

²¹ https://archive.org/stream/lymediseasediagn00unit/lymediseasediagn00unit_djvu.txt

²² https://academic.oup.com/cid/article/31/Supplement_1/S1/327386

²³ *Id* at S3. (emphasis added).

disease.²⁴ He was then removed from the panel by the IDSA. Dr. Benjamin Luft, originally the chairman of the IDSA panel, questioned why the panel was not considering Dr. Donta's request and recommended that the IDSA panel simply hear from the doctors who believed that short-term antibiotic treatment was not sufficient for all Lyme disease patients.²⁵ Dr. Luft was demoted by the IDSA for expressing these ideas and was not identified as an author of the 2000 guidelines.²⁶

48. In 2017, Eugene Shapiro, one of the IDSA Panelists, published a paper related to Lyme disease. In the footnotes, he admitted he "has been an expert witness in malpractice cases involving Lyme disease".²⁷

49. There is sufficient evidence to establish that the IDSA panelists were paid by, and influenced by, insurance companies, including those of the Settling Insurance Companies as specified above. As a result, the IDSA panelists created the guidelines created by the Settling Insurance Companies.

B. Relaxed Pleadings Necessary - All Evidence of Payments Solely in Defendants' Possession

50. All of the evidence of payments made from the Settling Insurance Companies to the IDSA Panelists are solely in the possession of the Defendants.

51. Plaintiffs sent subpoenas to the Office of the Attorney General for the State of Connecticut requesting the documents and information obtained during their investigation into the IDSA, the Settling Insurance Companies, and the IDSA Panelists. The Attorney General's office

²⁴ See Pamela Weintraub, *Cure Unknown, Inside the Lyme Epidemic*, page 270-271, St. Martin's Griffin, 2008.

²⁵ *Id.*

²⁶ *Id.*

²⁷ [https://www.amjmed.com/article/S0002-9343\(17\)30138-9/pdf](https://www.amjmed.com/article/S0002-9343(17)30138-9/pdf)

produced the CIDs send to the Defendants but not the responses because documents and information acquired were returned to the Defendants:

The documents were subpoenaed or furnished voluntarily to the Connecticut Office of the Attorney General ("CTOAG") in connection with an antitrust investigation. Pursuant to Conn. Gen. Stat. § 35-42(c)(1) & (2), such documents are held in the custody of the CT-OAG, shall not be available to the public, and shall be returned to the person who produced or furnished the documents upon the termination of the CT-OAG's investigation. The majority of the documents obtained in connection with the CT-OAG's antitrust investigation of the Infectious Diseases Society of America were returned at the termination of the investigation.²⁸

52. The heightened pleading standards of Rule 9(b) should be relaxed "upon a showing by the plaintiff that he or she is unable, without pretrial discovery, 'to obtain essential information' peculiarly in the possession of the defendant." *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 709 (S.D. Tex. 2014) (citing *Freitas v. Wells Fargo Home Mortg., Inc.*, 703 F.3d 436 (8th Cir.2013); *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir.2009); *U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F.Supp.2d 745, 768 (S.D.Tex.2010); *U.S. ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 (5th Cir. 2008).

53. Rule 9(b) is generally satisfied when the Complaint answers the "newspaper questions" about the alleged fraud ("who, what, when, where, and how"). *Melder v. Morris*, 27 F.3d 1097, 1100 n.5 (5th Cir. 1994). It is impossible for Plaintiffs to answer the newspaper questions regarding payments to the IDSA panelists until meaningful discovery to conducted.

54. Based on the evidence set forth above, Plaintiffs know that payments were made, were sent to the IDSA Panelists, and were received by the IDSA Panelists. Plaintiffs believe, based upon information and belief, that these payments were made through the mail or by wire.

²⁸ See Exhibit "C".

55. It is believed that Dr. Gary P. Wormser was paid via mail in New York from 1995 to 2017; Dr. Raymond J. Dattwyler was paid via mail in New York from 1995 to 2017; Dr. Eugene Shapiro was paid via mail in New Jersey from 1995 to 2006; Dr. John J. Halperin was paid via mail in New Jersey from 1995 to 2017; Dr. Robert B. Nadleman was paid via mail in New York from 1995 to 2017; and Dr. Leonard Sigal was paid via mail in New Jersey from 1995 to 2017. Based on the evidence set forth above, these payments, as well as communications related to the doctors' responsibilities and findings, were sent from insurance companies to the IDSA Panelists. These payments and communications harmed Plaintiffs because they deprived Plaintiffs, and all other people suffering with Lyme disease, insurance coverage and prevented them from being properly diagnosed and treated for Lyme disease. Additionally, Plaintiffs, and all others suffering with Lyme disease, were forced to pay out-of-pocket for their treatment, thus costing them vast sums of money.

C. Reporting Doctors to Medical Boards

56. Plaintiffs hereby allege that the Settling Insurance Companies set forth below, sent correspondence by mail to medical boards reporting doctors for treating Lyme disease based on information and belief, including the following:

57. Anonymously reporting Lyme doctors to medical boards is such an epidemic in the United States that many states have legislature protecting doctors who prescribe antibiotics beyond the 28-day cutoff. Many of the doctors reported to medical boards regarding Lyme disease are reported by insurance companies.

58. For example, in 2002 the New York Assembly unanimously passed Resolution 2155 protecting doctors who treat chronic Lyme disease.²⁹ According to the New York Assembly,

²⁹ https://www.empirestatelymediseaseassociation.org/Lyme_Activism/ny_lyme_activism_part_2.htm

the reason they were forced to protect Lyme doctors is because insurance companies report so many doctors for treating chronic Lyme disease:

WHEREAS, Considerable scientific controversy surrounds the diagnosis and treatment of Lyme disease and other tick-borne illnesses; and

WHEREAS, New York State has the highest number of reportable Lyme disease cases in the United States; and

WHEREAS, Insurance companies can and do file complaints with the New York State office of Professional medical Conduct against doctors who treat chronic Lyme disease, and have thus injected themselves into the debate; and

WHEREAS, Doctors whose practices are devoted to treating chronic Lyme disease patients, and who continue to provide treatment if they feel such treatment is medically necessary, have noted significant improvement in the condition of their patients; and

WHEREAS, a high percentage of doctors who treat chronic Lyme disease patients, and who continue to treat patients if they feel such treatment is medically necessary, have been investigated by the OPMC pertaining to their treatment of Lyme disease; and

WHEREAS, Tests for Lyme Disease are highly inaccurate and often are negative even when a person has Lyme disease; and

...

RESOLVED, That this Legislative Body pause in its deliberations to request that insurance companies and the Office of Professional Medical Conduct cease and desist from targeting physicians who fall on one side or the other of this controversy, until such time as medical research and the medical community have determined the appropriate parameters for the diagnosis and treatment of tick-borne illnesses; and be it further

RESOLVED, That a copy of the Resolution, suitably engrossed, be transmitted to the Office of Professional Medical Conduct.³⁰

59. New York is just one of many states forced to pass legislature to protect doctors reported to medical boards for the treatment of chronic Lyme disease. Other states including

³⁰ <http://www.lymeinfo.net/nyresolution.html> (emphasis added).

Connecticut³¹, Massachusetts³², New Hampshire³³, Rhode Island³⁴, Vermont³⁵, Virginia³⁶, Iowa³⁷, and many others.³⁸

60. Due to state privacy laws, public medical boards refuse to disclose the identities of the persons or entities who report doctors to medical boards. For example, Plaintiffs served a third-party subpoena on the Texas Medical Board and the subpoena was quashed³⁹ because of the following statute:

(c) Each complaint, adverse report, investigation file, other investigation report, and other investigative information in the possession of or received or gathered by the board or its employees or agents relating to a license holder, an application for license, or a criminal investigation or proceeding is privileged and confidential and is not subject to discovery, subpoena, or other means of legal compulsion for release to anyone other than the board or its employees or agents involved in discipline of a license holder. For purposes of this subsection, investigative information includes information relating to the identity of, and a report made by, a physician performing or supervising compliance monitoring for the board.

Tex. Occ. Code Ann. § 164.007.

61. Plaintiffs have evidence, as cited, of insurance companies anonymously reporting doctors to the medical review boards. Reporting of Lyme doctors to medical boards are done anonymously or the medical boards refuse to disclose the entity that reported the doctors. Either

³¹ <https://www.cga.ct.gov/2009/act/Pa/pdf/2009PA-00128-R00HB-06200-PA.PDF>

³² https://budget.digital.mass.gov/bb/gaa/fy2011/os_11/h67.htm

³³ <https://www.lymedisease.org/740/>

³⁴ <http://webserver.rilin.state.ri.us/PublicLaws/law02/law02159.htm>

³⁵ <http://www.leg.state.vt.us/docs/2014/Acts/ACT134.pdf>

³⁶ <https://www.lymedisease.org/members/lyme-times/2016-summer-advocacy/virginia-senate-passes-doctor-protection-bill/>

³⁷ <https://www.lymedisease.org/iowas-lyme-doc-protection-bill-signed-governor/>

³⁸ <https://www.lymedisease.org/wp-content/uploads/2014/04/Legislation-PDF-12.5.14-2.pdf>

³⁹ See Exhibit “D”.

way, it is impossible for Plaintiffs to determine the who, what, when, where, and how of reports to medical boards unless that information is obtained from the entity who actually filed the complaint.

62. For example, the Maryland State Board of Physicians investigated Dr. Hope McIntyre for treating chronic Lyme disease.⁴⁰ According to the Consent Order:

4. On March 24, 2014, **the Board received a complaint from a health insurance company** stating that Respondent may be inappropriately prescribing medication to a patient, Patient 4, 1 for the treatment of Lyme disease.

5. On or about June 5, 2014, **the Board received an amended complaint from the insurance company including Patient 4's name and medical records.** The insurance company reported the following:

a. **The insurance company's Medical Director reviewed available records** and engaged in peer to peer review with Respondent regarding diagnosis and treatment of Patient

b. **The Medical Director concluded that based on national guidelines on the treatment of Lyme disease, the medications prescribed by Respondent for this diagnosis do not fit evidence-based recommendations for the treatment of Lyme disease.**⁴¹

63. Lyme doctors who treat chronic Lyme disease and try to help their patients face complaints to their medical boards and are forced to spend their time and money trying to keep their medical licenses. Some examples include Dr. Joseph G. Jemsek, one of the pioneers in HIV/AIDS research and treatment. Dr. Jemsek established twenty-two protocols for the treatment of HIV/AIDS and published more than forty peer-reviewed articles. When Dr. Jemsek learned about the growing number of Lyme disease patients who were not being properly treated, he turned

⁴⁰ <https://lymescience.org/rogues/Hope-McIntyre/Hope-McIntyre-consent-order-2016.pdf>

⁴¹ *Id.* (emphasis added).

his attention to Lyme disease. After treating patients with chronic Lyme disease, Dr. Jemsek spent many years in litigation fighting to keep his medical license.⁴²

64. Another example is Dr. Kenneth B. Liegner, Dr. Liegner is a board-certified internist with training in pathology and critical care medicine. He has been forced to defend himself in front of the New York State Department of Health for treating patients with chronic Lyme disease.⁴³

65. Dr. Charles Ray Jones is the world's leading pediatric specialist on Lyme Disease. Yet, Dr. Jones has been hounded by the Connecticut State Medical Board for years and his patients and colleagues have had to help to defray the costs of his legal defense. Dr. Jones' legal defense costs have exceeded one million dollars.⁴⁴

66. As a result of the actions of the above actions and others like it, doctors around the country are afraid of diagnosing and treating Lyme disease.⁴⁵

67. The above is sufficient evidence to establish that the Settling Insurance Companies have the information of when and how they improperly reported doctors to medical boards for the treatment of Lyme disease. These actions had a chilling effect on the medical community and caused doctors who would normally treat Lyme patients to refuse to treat patients with Lyme disease.

⁴² *In re Jemsek Clinic, P.A.*, 850 F.3d 150 (4th Cir. 2017), reh'g denied (Mar. 31, 2017), cert. dismissed sub nom. Blue Cross Blue Shield of N. Carolina v. Jemsek Clinic, P.A., 138 S. Ct. 1611, 200 L. Ed. 2d 791 (2018).

⁴³ See Pamela Weintraub, *Cure Unknown, Inside the Lyme Epidemic*, page 306-313, St. Martin's Griffin, 2008.

⁴⁴ See Pamela Weintraub, *Cure Unknown, Inside the Lyme Epidemic*, page 330-336, St. Martin's Griffin, 2008.

⁴⁵ *Id.*

D. Relaxed Pleadings Necessary - All Evidence of Communications to Medical Boards

68. All of the evidence of reports to medical boards made from any of the Settling Insurance Companies to the medical boards are solely in the possession of the Defendants.

69. The heightened pleading standards of Rule 9(b) should be relaxed “upon a showing by the plaintiff that he or she is unable, without pretrial discovery, ‘to obtain essential information’ peculiarly in the possession of the defendant.” *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 709 (S.D. Tex. 2014) (citing *Freitas v. Wells Fargo Home Mortg., Inc.*, 703 F.3d 436 (8th Cir.2013); *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir.2009); *U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F.Supp.2d 745, 768 (S.D.Tex.2010); *U.S. ex rel. Rafizadeh v. Cont’l Common, Inc.*, 553 F.3d 869, 873 (5th Cir. 2008).

70. Rule 9(b) is generally satisfied when the Complaint answers the “newspaper questions” about the alleged fraud (“who, what, when, where, and how”). *Melder v. Morris*, 27 F.3d 1097, 1100 n.5 (5th Cir. 1994). It is impossible for Plaintiffs to answer the newspaper questions regarding reports to medical boards made from the Settling Insurance Companies to the medical boards until meaningful discovery to conducted.

71. Plaintiffs have detailed the communications and who sent the communications above and based upon information and belief that these payments were made through the mail.

E. Chronic Lyme Disease

72. Although the IDSA claims its guidelines are not “mandatory,” they have been regarded as mandatory within the medical community. The Settling Insurance Companies treat the guidelines as mandatory and use the IDSA Panelists to enforce them as mandatory regulations in the treatment of Lyme disease. The Settling Insurance Companies, the IDSA, and the IDSA Panelists have spent the last few decades aggressively preventing the treatment of chronic Lyme

disease even though they know there is overwhelming evidence to prove the existence of chronic Lyme disease:

- There are over seven hundred (700) peer reviewed scholarly articles proving the existence of chronic Lyme disease.⁴⁶
- The states with the highest incidents of Lyme disease passed laws requiring the treatment of chronic Lyme disease and requiring insurers to pay for long term antibiotic treatment for chronic Lyme disease including Massachusetts⁴⁷, Rhode Island⁴⁸, Connecticut⁴⁹, Vermont⁵⁰, New York⁵¹, Maine⁵², and Iowa⁵³.
- Texas Senator Chris Harris introduced a Lyme disease bill, SB 1360, because he contracted Lyme disease and was not cured by short-term antibiotic treatment.⁵⁴ Senator Harris' doctor, afraid of being reported to the medical disciplinary board, refused to prescribe more than one month of antibiotics. Instead, his doctor arranged for 17 different physicians to take turns writing prescriptions for Senator Harris's treatment.⁵⁵ If Chris Harris was not a

⁴⁶ See Exhibit "E".

⁴⁷<https://www.bostonglobe.com/metro/2016/08/01/legislature-orders-insurers-cover-long-term-lyme-treatment-overriding-baker-veto/YBZ3DGaUy8bHRWMYyOyQdM/story.html>

⁴⁸https://www.lymedisease.org/wp-content/uploads/2011/10/RI_passes_bill_mandating_insurance_coverage_2003_978837748.pdf

⁴⁹<https://www.lymedisease.org/127/>

⁵⁰<http://www.providencejournal.com/breaking-news/content/20140712-new-vt.-law-aims-to-aid-in-treatment-of-lyme-disease-as-cases-soar.ece>

⁵¹<https://www.poughkeepsiejournal.com/story/news/health/lyme-disease/2014/12/18/cuomo-signs-lyme-disease-bill/20576915/>

⁵²<https://www.pressherald.com/2015/06/29/maine-legislature-clears-way-for-long-term-lyme-disease-treatment/>

⁵³<http://www.tamatoledonews.com/page/content.detail/id/603916/Cornfileds--Common-Sense-and-Community.html?nav=5002>

⁵⁴<https://www.prohealth.com/library/texas-legislature-passes-lyme-bill-recognizing-long-term-antibiotic-treatment-as-option-for-persistent-disease-28562>

⁵⁵ *Id.*

Senator, he would still be struggling to cure his chronic Lyme disease, like the Plaintiffs in this case.

- In 2016, Congress, as part of the 21st Century Cures Act, created the Tick-Borne Disease Working Group because “Lyme disease is the most common tick-borne disease” and Congress wanted the Working Group to make recommendations to fix the gaps in the “prevention, treatment and research” of Lyme disease.⁵⁶
- Dr. Allan Steere, the researcher who discovered Lyme disease and is one of the authors of the IDSA guidelines, acknowledged the existence of chronic Lyme disease in 1994, before the Settling Insurance Companies decided they no longer wanted to pay for long-term antibiotic treatment:

“It has become increasingly apparent that the Lyme disease spirochete, *Borrelia burgorferi*, may persist in some patients for years. Of particular concern, recent studies have shown that the spirochete may persist in the nervous system in a small percentage of patients and may cause chronic neurological involvement. The purpose of our long-term follow-up studies is to determine whether past patients may still have evidence of Lyme disease and, if so, to offer appropriate treatment.”⁵⁷

- Dr. Burton A. Waisbren, one of the founding members of the IDSA, discredited the current IDSA guidelines for failing to acknowledge the existence of chronic Lyme disease:

“Chronic Lyme disease is a syndrome that results when individuals who have been inoculated with multiple microorganisms by infected ticks and who have not responded to an initial course of doxycycline develop extreme fatigue, intermittent fever, joint pain, muscle pain, “brain fog,” concentration difficulties, skin rashes, and in many instances symptoms of autoimmune disease to the extent that they impinge upon their quality of life.

When one comes face-to-face with patients of this type in whom other diseases are ruled out, it is obvious that something serious is amiss.

⁵⁶ <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html>

⁵⁷ See Exhibit “F”.

It is a conundrum why a group of respected physicians who are members of the Infectious Disease Society of America have not recognized this and have, instead, written a guideline that essentially denies that the syndrome exists.”⁵⁸

- Attorney General (now Senator) Richard Blumenthal of Connecticut conducted an antitrust investigation into the lack of treatment of chronic Lyme disease and found:
 - The IDSA’s guideline panel improperly ignored or minimized medical opinion regarding chronic Lyme disease. As a consequence, serious questions have arisen as to whether the panel’s recommendations reflected all of the relevant science available.
 - The IDSA failed to conduct a conflict-of-interest review for any of the participants before their appointment to the 2006 Lyme disease guideline panel. Several of the panelists, however, subsequently disclosed financial interests in drug companies, Lyme disease diagnostic tests, patents, and consulting arrangements with insurance companies.
 - The IDSA allowed the panel chairman, who held a bias against the existence of chronic Lyme disease, to hand-pick a like-minded panel without scrutiny by, or formal approval from, the IDSA’s oversight committee.
 - The IDSA also blocked appointment to the panel of scientists and physicians who supported the concept of chronic Lyme disease. A panelist who dissented from the group’s position was actually removed in order to achieve “consensus”.⁵⁹
- A recent study found that Lyme disease survives a 28-day course of antibiotic if the Lyme disease is not treated within 4 months after the date of infection.⁶⁰
- The Association of American Physicians and Surgeons recently opposed the IDSA guidelines as “mandates and prohibitions” because they do not allow the treating doctors discretion to treat their patients for chronic Lyme disease:

“These Guidelines should be revised to recognize that the physician must retain full flexibility in the diagnosis and treatment of Lyme disease. Medical societies do not practice medicine; physicians do.

⁵⁸ See Exhibit “G”.

⁵⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2435453/>

⁶⁰ <https://www.bayarealyme.org/blog/new-study-finds-lyme-bacteria-survive-28-day-course-antibiotics-treated-four-months-infection-tick-bite/>

The mandate for specific laboratory confirmation is particularly objectionable, as testing for Lyme disease is notoriously insensitive and unreliable. Patients who do not meet this criterion would often be denied treatment that could mitigate severe chronic disability. In some cases, long-term treatment is required. Physicians must be able to exercise their professional judgment concerning the best treatment for each individual patient, without restraint by one size-fits-all Guidelines, which amount to mandates and prohibitions.”⁶¹

73. Even with all of this overwhelming evidence of chronic Lyme disease, the 2006 IDSA Guidelines claim:

There is no convincing biologic evidence for the existence of symptomatic chronic *B. burgdorferi* infection among patients after receipt of recommended treatment regimens for Lyme disease.⁶²

74. The Settling Insurance Companies, the IDSA, and the IDSA Panelists do everything in their power to fraudulently conceal the fact that chronic Lyme disease exists, and short-term antibiotic treatment is not effective for all Lyme patients. Instead of acknowledging that treatment failure exists, the 2006 IDSA Guidelines actually promote the idea that Lyme is a simple, rare illness that is easy to avoid, difficult to acquire, simple to diagnose, and easily treated and cured with 28 days of antibiotics.⁶³

75. Even though the IDSA guidelines are not supposed to be rules or requirements, the Settling Insurance Companies treat them as "de facto" law that must be followed by doctors and refuse to cover treatment beyond the IDSA guidelines. The IDSA, the IDSA Panelists, and the Settling Insurance Companies ignore the organizations, information, and scientific data reporting that chronic Lyme disease is a legitimate medical condition, that chronic Lyme disease requires long-term antibiotic treatment, and that the current testing criteria fails to diagnose a majority of people with Lyme disease.

⁶¹ <https://www.ncims.com/wp-content/uploads/2016/01/HwObjectionToLymeDiseaseGuidelines.pdf>

⁶² <https://academic.oup.com/cid/article/43/9/1089/422463>

⁶³ <https://academic.oup.com/cid/article/43/9/1089/422463>

76. The reason hundreds of thousands of people suffer with chronic Lyme disease is because they are refused long-term antibiotic treatment beyond the 28 days. The Settling Insurance Companies ignore their patients, ignore the results (people who get better with long term antibiotic treatment), ignore the many studies showing that many patients need antibiotic treatment beyond the 28 days, and ignore the doctors who keep saying that some patients need long term antibiotic treatment. The Settling Insurance Companies refuse to provide insurance coverage for long term antibiotics which could cure the chronic Lyme disease simply because the Settling Insurance Companies do not want to pay for the treatment.

77. As set forth above, the Settling Insurance Companies identified work with, and compensate, the IDSA Panelists to keep the 28-day standard in place. The IDSA Panelists benefit financially from their arrangements with the Settling Insurance Companies by receiving consulting fees.

F. Testing

78. In addition to improper treatment, the 2006 IDSA Guidelines cause many people suffering with Lyme disease to go undiagnosed for years, or even their entire lives. According to the guidelines, a physician diagnoses Lyme disease in two ways: (1) the patient must exhibit an EM rash or (2) the patient must test positive with a two-tier serology test. The IDSA and the Settling Insurance Companies know that many patients never develop the EM rash and the Guidelines' requirement of a positive lab test is problematic because the two-tier serology test fails to detect up to 50% of Lyme cases. As a result, many Lyme sufferers are left undiagnosed and untreated.

79. Lyme disease that goes undiagnosed for even a short period of time can render the patient chronically ill and even totally disabled. In addition, because these people fail the Lyme disease test, Lyme patients are often misdiagnosed with other numerous conditions, including

chronic fatigue syndrome, fibromyalgia, amyotrophic lateral sclerosis, multiple sclerosis, heart disease, and numerous neurological and psychological conditions, such as autism, strokes, and bipolar disorder.

80. The Settling Insurance Companies support, and strongly enforce, the IDSA testing guidelines because it allows them to avoid covering expensive antibiotic treatment. When doctors diagnose patients with Lyme disease that do not meet the IDSA testing requirements, the Settling Insurance Companies and the IDSA work together in an attempt to make sure the patient's treatment is not covered and the doctor loses her medical license.

G. Fraudulent Concealment

81. Plaintiffs are entitled to the estoppel effect of fraudulent concealment because: (1) the Defendants had actual knowledge of the wrong, and (2) the Defendants had a fixed purpose to conceal the wrong. As a result, fraudulent concealment operates to toll limitations in this case.

82. As set forth above, the Defendants know there is overwhelming evidence to support the existence of chronic Lyme disease. In fact, Dr. Allen Steere, one of the IDSA Panelists acknowledged in 1994 that chronic Lyme disease existed: "It has become increasingly apparent that the Lyme disease spirochete, *Borrelia burgorferi*, may persist in some patients for years."⁶⁴

83. Despite this evidence, the Defendants have spent the last few decades, since the early 1990's, fraudulently and improperly denying the existence of chronic Lyme disease. The Defendants report doctors to medical boards who treat chronic Lyme disease, deny insurance coverage for any treatment beyond short-term antibiotic treatment, and claim that chronic Lyme disease does not exist.

⁶⁴ See Exhibit "F".

84. The current IDSA guidelines, claim that chronic Lyme disease does not exist and there is no treatment failure for any Lyme patient who receives short-term antibiotics.⁶⁵ The Defendants claim all Lyme disease patients are cured by a short course (14 to 28 days) of antibiotic treatment. According to the Defendants, the treatment of Lyme disease, unlike every other disease on the planet, involves no treatment failure and there are no Lyme disease patients who suffer from chronic Lyme disease after the short course of antibiotic treatment.

85. Treatment failure exists for every medical condition, especially those requiring treatment with antibiotics.⁶⁶ For example, the guidelines for treating pneumonia is a short course of antibiotic treatment.⁶⁷ However, twenty-one percent (21%) of all pneumonia patients treated with a short course of antibiotic treatment experience treatment failure and require a longer course of antibiotic treatment.⁶⁸ Syphilis, which like Lyme disease is also a bacterial spirochetal infection, is treated with a short course of antibiotics. However, Syphilis has a treatment failure rate of between fifteen and twenty-one percent (15% - 21%).⁶⁹ When there is treatment failure, Syphilis requires a longer course of antibiotic treatment.⁷⁰

86. When treating every other medical condition, the treating doctor has discretion to determine whether the treatment is working and if the patient needs more, or different, treatment. When doctors treating Lyme disease determine a short course of antibiotics is not working, they know that prescribing additional antibiotics will cause problems for themselves and the patients. If the treating doctor prescribes a longer course of antibiotic treatment, the Settling Insurance

⁶⁵ <https://academic.oup.com/cid/article/43/9/1089/422463>

⁶⁶ <https://www.ncbi.nlm.nih.gov/pubmed/19596109>

⁶⁷ <https://www.medscape.org/viewarticle/536011>

⁶⁸ https://www.medscape.com/viewarticle/880408#vp_1

⁶⁹ <https://www.medscape.com/viewarticle/473422>

⁷⁰ <https://www.cdc.gov/std/tg2015/syphilis.htm>

Companies not only deny coverage for the treatment, they report the doctors to their medical boards for treating chronic Lyme disease and try to take their medical licenses.

87. The Defendants have perpetrated a fraud on the American people. The Settling Insurance Companies claim there is no chronic Lyme disease, there is no treatment failure for Lyme disease after short-term antibiotics and claim that any doctor treating chronic Lyme disease should lose her license. The Defendants knew these claims were false. They did so for the purpose of saving and making more money.

H. RICO Allegations Against All Defendants

88. The IDSA and the Settling Insurance Companies are corporations, either for profit or non-profit, and are thus persons pursuant to Section 1961(3). The IDSA Panelists are persons pursuant to Section 1961(3). Together, the IDSA, Settling Insurance Companies, and the IDSA Panelists constitute an enterprise engaged in activities affecting interstate commerce. The IDSA, Settling Insurance Companies, and the IDSA Panelists engage in a pattern of racketeering, their acts are related and continuous, and their acts form a “pattern of racketeering.”

89. The IDSA, Settling Insurance Companies, and the IDSA Panelists, acting through their officers, agents, employees and affiliates, committed numerous predicate acts of “racketeering activity,” as defined in 18 U.S.C. §1961(5), prior to and during the period made the basis of this suit, and continues to commit such predicate acts, in furtherance of their scheme to prevent treatment of chronic Lyme disease and to prevent the proper testing of potential Lyme disease patients, including (a) mail fraud, in violation of 18 U.S.C. §1341, and (b) wire fraud, in violation of 18 U.S.C. §1343. Such predicate acts include the following:

- a. mailing, causing to be mailed, knowingly agreeing to the mailing of various materials and information, and/or wiring information including, but not limited to, correspondence regarding the following: fraudulently and wrongfully claiming lack

of insurance coverage for chronic Lyme disease; fraudulently and wrongfully denying insurance coverage to people with chronic Lyme disease; issuing false and misleading EOB's to patients with Lyme disease; fraudulently and wrongfully claiming all Lyme disease patients can be easily treated and cured with short-term antibiotics; fraudulently and wrongfully claiming Lyme disease patients only have Lyme disease if they exhibit an EM rash or test positive with a two-tier serology test; wrongfully and illegally reporting doctors to their medical boards for treating chronic Lyme disease; fraudulently and wrongfully misleading people with Lyme disease, and their doctors, by classifying their chronic Lyme disease as a mental disorder; fraudulently and wrongfully misleading people with Lyme disease, and their doctors, by classifying their chronic Lyme disease as a different physical condition such as chronic fatigue syndrome or fibromyalgia; and fraudulently and wrongfully enforcing the IDSA guidelines even when doctors determine a patient requires long-term antibiotic treatment.

b. mailing, wiring, causing to be mailed or wired, and/or knowingly agreeing to the mailing or wiring of various materials and information including, but not limited to, correspondence between the IDSA and the Settling Insurance Companies regarding the following: payments from the Settling Insurance Companies to IDSA Panelists to promote the false narrative "that Lyme is a simple, rare illness that is easy to avoid, difficult to acquire, simple to diagnose, and easily treated and cured with 28 days of antibiotics"; payments from the Settling Insurance Companies to the IDSA and the IDSA Panelists to promote the false claim that chronic Lyme disease is not real; payments from the Settling Insurance Companies to the IDSA and the IDSA Panelists to promote the false claim that long-term

antibiotic treatment is improper and unnecessary; payments from the Settling Insurance Companies to the IDSA Panelists so the IDSA panelists will serve as expert witnesses for the Settling Insurance Companies and testify that patients' requests for repeat or prolonged courses (e.g., greater than 4 weeks) of IV antibiotic therapy are considered not medically necessary; payments from the Settling Insurance Companies to the IDSA Panelists so that IDSA Panelists will serve as expert witnesses for the Settling Insurance Companies and testify that denial of long-term antibiotic treatment was proper; payments from the Settling Insurance Companies to the IDSA Panelists so the IDSA Panelists will serve as expert witnesses for the Settling Insurance Companies and testify that patients' chronic Lyme disease is actually a mental disorder or a different physical ailment not requiring long-term antibiotics; payments from the Settling Insurance Companies to the IDSA Panelists so the IDSA Panelists will serve as expert witnesses for the Settling Insurance Companies and testify against doctors who provide long-term antibiotic treatment to patients; and payments from the Settling Insurance Companies to the IDSA Panelists so the IDSA Panelists will serve as expert witnesses for the Settling Insurance Companies and testify that patients do not have Lyme disease because they do not exhibit an EM rash or test positive with a two-tier serology test.

90. In furtherance of its scheme to prevent patients with chronic Lyme disease from receiving proper treatment, preventing a positive diagnosis of Lyme disease for people with Lyme, and for trying to eliminate all doctors who properly treat chronic Lyme disease, the IDSA, Settling Insurance Companies, and the IDSA Panelists are in violation of 18 U.S.C. §§ 1341, 1343, 1961 and 1962, because they repeatedly and regularly used the U.S. mail and interstate wire facilities to

further all aspects of their fraudulent and illegal scheme and by delivering and/or receiving materials necessary to carry out the scheme to defraud Plaintiffs.

91. The foregoing communications, sent via U.S. mail and interstate wire facilities, contained false and fraudulent misrepresentations and/or omissions of material facts, had the design and effect of preventing a meaningful evaluation of Lyme patients and preventing the proper treatment of patients with chronic Lyme disease and/or otherwise were incident to an essential part of the IDSA and the Settling Insurance Companies' scheme to defraud Plaintiffs as described in this Complaint.

92. Each such use of the U.S. mail and interstate wire facilities alleged in this Complaint constitutes a separate and distinct predicate act of "racketeering activity" and, collectively, constituted a "pattern of racketeering activity. The direct and intended victims of the pattern of racketeering activity described previously herein are Plaintiffs whom were not properly, or timely, diagnosed with Lyme disease, were not properly, or timely, treated for their chronic Lyme disease, were forced to pay for treatment out-of-pocket, were forced to travel long distances to receive treatment, were forced to miss work and school because they were not properly treated or diagnosed with Lyme disease, and were forced to pay all costs and fees associated with their care and treatment.

93. Plaintiffs were injured by the IDSA, Settling Insurance Companies, and the IDSA Panelists because they were forced to pay for their treatments, were forced to pay all expenses associated with treating their Lyme disease, were forced to travel long distances for treatment, were forced to try to find doctors who would treat them, and were unable to work or earn money because of their debilitating illness. Further, because Plaintiffs were not timely diagnosed or treated, they now suffer long-term complications and are forced to continue to pay future medical costs for treatment and out-of-pocket expenses to receive this treatment. Plaintiffs are entitled to

recover threefold their damages, costs and attorneys' fees from the IDSA, Settling Insurance Companies, and the IDSA Panelists and other appropriate relief they are entitled.

94. As a result of the fraudulent concealment of the conspiracy set forth in this Complaint by the IDSA, Settling Insurance Companies, and the IDSA Panelists the running of any applicable statute of limitations has been tolled with respect to any claims made in this case. Also, as a result of the fraudulent concealment of the conspiracy by the IDSA and the Settling Insurance Companies, Defendants are equitably estopped from asserting statutes of limitations defenses.

95. Further, this is a multi-year conspiracy constituting a continuing tort. Therefore, the statute of limitations cannot accrue until the last act of the unlawful conduct. The unlawful conduct is still occurring.

I. Anti-Trust Allegations Against Defendants

96. Antitrust laws “are designed to preserve competition by prohibiting monopolistic practices and agreements that unreasonably restrict competition.” Associations that set commercial standards are known as standard-setting organizations (SSO) or standard-development organizations (SDO). *Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500, 108 S. Ct. 1931, 1937, 100 L. Ed. 2d 497 (1988); *Golden Bridge Tech., Inc. v. Motorola, Inc.*, 547 F.3d 266, 273 (5th Cir. 2008).

97. Standard-setting is important because of its pro-competitive benefits, such as quality and safety standards and the ability of products to interface with other products. But “a standard-setting organization . . . can be rife with opportunities for anticompetitive activity” because the standard-setting process can exclude products or businesses that fail to meet the standard. *Am. Soc’y of Mech. Eng’rs, Inc. v. Hydrolevel Corp.*, 456 U.S. 556, 571 (1982). When analyzing an SSO’s standards, fact finders must evaluate whether the standard causes a severe economic detriment to excluded or nonqualifying firms or whether competitors of the injured firm

participated in the standards development process, and whether the standards are voluntary. Standard-setting faces intense antitrust scrutiny when the standards are not voluntary.

98. Section 1 of the Sherman Act applies to concerted conduct by two or more entities and prohibits “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade of commerce among the several States” Section 2 of the Sherman Act supplements Section 1 and specifically prohibits monopolizing, or attempting to monopolize, any part of interstate or foreign commerce. A legal entity can monopolize interstate or foreign commerce by excluding competitors from a market.

99. Professional associations like the IDSA are subject to antitrust laws because their conduct is sufficiently commercial. Because the development of the IDSA guidelines involves commercial conduct with a “public service aspect,” the IDSA, the IDSA Panelists, and the Settling Insurance Companies are not immune from antitrust regulations.

100. The treatment of Lyme disease affects interstate commerce in that a large portion of money spent in treating chronic Lyme patients comes from all over the United States because many patients travel great distances to locate a doctor who is willing to treat the disease. Additionally, as Attorney General Blumenthal found in his antitrust investigation into the IDSA guidelines: “several of the most powerful IDSA panelists”, including the IDSA Panelists in this case, had “undisclosed financial interests” “in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies.” In addition to being paid by the Insurance Defendant, the IDSA Panelists have economic interests in Lyme diagnostic tests and vaccinations. The IDSA, the Settling Insurance Companies, and the IDSA Panelists are directly benefited by the 2006 IDSA Guidelines’ requirement of a positive lab test to diagnose Lyme disease. As stated above, many patients never test positive for Lyme disease because the two-tier serology test fails to detect up to 90% of Lyme cases. As a result, most Lyme disease sufferers are

left undiagnosed and untreated. This means the Settling Insurance Companies benefit because they do not have to treat these Lyme disease patients. Additionally, the IDSA Panelists with economic interests in Lyme diagnostic tests are left richer.

101. Although the 2006 IDSA claims its guidelines are not “mandatory,” they have been regarded as “mandatory” within the medical community. The Settling Insurance Companies treat the guidelines as mandatory and use the IDSA Panelists to enforce them as mandatory regulations in the treatment of Lyme disease.

102. The IDSA holds itself out as the pre-eminent authority on the treatment of infectious diseases in the United States. The IDSA, the IDSA Panelists, and the Settling Insurance Companies represent to state medical boards that the IDSA guidelines are the appropriate standard of care when investigating and sanctioning doctors who treat Lyme patients. The Settling Insurance Companies report Lyme doctors to medical boards who do not conform to the IDSA guidelines and testing protocols. As a result, many doctors are reluctant to diagnose or treat chronic Lyme patients because they do not want to become the subject of an investigation by their state board of medical examiners. In fact, the restraint on the Lyme treatment market is so great that members of Congress believe that the 2006 IDSA Guidelines “have ‘the potential to effectively shut down’ all treatment of chronic Lyme disease.”

103. The IDSA guidelines are treated as mandatory requirements by the IDSA, the IDSA Panelists, and the Settling Insurance Companies by: (1) denying the existence of chronic Lyme disease, (2) condemning the use of long-term antibiotics, (3) allowing doctors who treat chronic Lyme patients to be sanctioned by medical boards, and (4) using the guidelines as a basis to deny insurance coverage of chronic Lyme treatments. The power of the IDSA, the IDSA Panelists, and the Settling Insurance Companies restrains trade, therefore, the IDSA guidelines have significantly reduced the Lyme treatment market. Similarly, the IDSA, the IDSA Panelists, and the Settling

Insurance Companies' conduct in developing the IDSA guidelines and the treatment of Lyme disease is sufficiently commercial for Sherman Act purposes.

104. The IDSA, the IDSA Panelists, and the Settling Insurance Companies engaged in a conspiracy that restrained trade in the relevant market. The IDSA, the IDSA Panelists, and the Settling Insurance Companies uses the IDSA guideline development process to consciously agree to exclude actual Lyme doctors, exclude competing doctors who disagree with the IDSA guidelines, exclude doctors who use their own clinical discretion to diagnose Lyme disease, and exclude doctors who do not follow the IDSA's 28-day recommended treatment program. This exclusion has antitrust implications because the IDSA Panelists and the Settling Insurance Companies had an economic interest in the outcome of the development process.

105. As set forth above, the IDSA, the IDSA Panelists, and the Settling Insurance Companies "consciously committed to a common agreement of an unreasonable restraint on trade" in the relevant market. Courts allow plaintiffs to demonstrate an agreement by showing that the defendants had a tacit understanding, courts also "allow 'inferences [to be] fairly drawn from the behavior of the alleged conspirators' to prove conspiracy." It is clear from the behavior of the IDSA, the IDSA Panelists, and the Settling Insurance Companies that there is an ongoing conspiracy to prevent patients with chronic Lyme disease, including Plaintiffs, from receiving treatment that could cure them.

106. When analyzing whether the conduct of the IDSA, the IDSA Panelists, and the Settling Insurance Companies imposes an unreasonable restraint on competition, This Court and the jury must "tak[e] into account a variety of facts, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." As part of this analysis, the fact finder balances the SSO's "anticompetitive effect against the procompetitive justifications for the conduct." As set forth

above, there is a reduction of competition in the market as a result of the conduct of the IDSA, the IDSA Panelists, and the Settling Insurance Companies.

107. According to former Connecticut Attorney General Blumenthal's investigation, "[s]kewing medical guidelines to benefit health insurers and HMOs, drug makers and self-interested panelists is a serious and growing problem." For example, "[p]ress reports abound of medical companies using financial incentives--speaking and consulting fees, research support, potentially lucrative patents--to improperly influence medical professionals." Antitrust law requires that economically interested parties not be allowed to improperly influence or bias the standard-setting process, "especially when the standard-setting is done by an association or other entity that is highly influential or dominant in the relevant market."

108. In Blumenthal's antitrust investigation into the IDSA's guideline development process, he found that the IDSA and the IDSA Panelists, with the influence of the Settling Insurance Companies, consciously agreed to reduce competition in the Lyme treatment market in numerous way, including:

- The IDSA failed to conduct a conflicts of interest review for any of the IDSA Panelists prior to their appointment to the 2006 Lyme disease guideline panel even though it was well known that the IDSA Panelists had conflicts of interests;
- The IDSA failed to follow its own procedures for appointing the 2006 panel chairman, Dr. Gary P. Wormser, enabling Dr. Wormser, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by a formal approval of the IDSA's oversight committee;
- The IDSA's 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a

panelist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve "consensus";

- The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel by informing them that the panel was fully staffed, even though it was later expanded; and
- The IDSA portrayed the American Academy of Neurology's Lyme disease guidelines as corroborating its own when it knew that the two panels shared several authors, including the chairmen of both groups - Dr. Gary P. Wormser and also included Dr. Eugene Shapiro and Dr. John J. Halperin. In allowing its panelists to serve on both groups at the same time, IDSA violated its own conflicts of interest policy.

109. Because courts allow inferences to be drawn from the behavior of the alleged conspirators, this Court should find that the IDSA, the IDSA Panelists, and the Settling Insurance Companies conspired to unreasonably restrain trade in the relevant market--the treatment of Lyme disease. When the IDSA, the IDSA Panelists, and the Settling Insurance Companies worked together to block the appointments of physicians with divergent views and refused to accept or meaningfully consider the existence of chronic Lyme disease, they conspired to unreasonably restrain trade. Additionally, by excluding physicians with differing opinions from participating in its panel and suppressing scientific evidence, the 2006 IDSA Guidelines not only adversely affected IDSA competitors--physicians who treat chronic Lyme disease with long-term antibiotics --but also unreasonably restrained the Lyme treatment market. The 2006 IDSA Guidelines have significantly reduced the Lyme treatment market by denying the existence of chronic Lyme disease and condemning the use of long-term antibiotics. The Settling Insurance Companies have further reduced the Lyme treatment market by citing the 2006 IDSA Guidelines in their coverage plans to deny or limit treatment costs associated with chronic Lyme disease, claiming that the costly long-

term treatments are “experimental” or “not evidence-based.” Physicians who treat chronic Lyme sufferers know they should be allowed to use long-term antibiotics as treatment because “[e]vidence-based medicine requires only that medicine be practiced in accordance with the evidence that currently exists, not that treatment be withheld pending research.” Moreover, in a free marketplace, both viewpoints should be available to patients.

110. The 2006 Guidelines do not have a legitimate purpose. “In evaluating standards developed by private associations under the rule of reason, courts have [also] considered whether the standard is intended to accomplish a legitimate purpose and, if so, whether it is reasonably related to that purpose and is objective.”

111. The IDSA, the IDSA Panelists, and the Settling Insurance Companies claim that its 2006 Guidelines are intended to protect the public from the dangers of long-term antibiotic use. This is not true. The reasons the IDSA, the IDSA Panelists, and the Settling Insurance Companies rely solely on the IDSA Guidelines is to use the IDSA Guidelines as a predatory device to injure competitors--physicians who treat chronic Lyme patients. Further, the IDSA Guidelines’ denial of chronic Lyme disease and condemnation of long-term antibiotics are not the least restrictive methods available to the IDSA to protect the public.

112. The evidence set forth above establishes that the IDSA, the IDSA Panelists, and the Settling Insurance Companies use the Guidelines as a predatory device to injure doctors who do not follow the Guidelines. For example, the 2006 IDSA Guidelines say the EM rash “is the only manifestation of Lyme disease in the United States that is sufficiently distinctive to allow clinical diagnosis in the absence of laboratory confirmation.” Therefore, doctors are precluded from using their own clinical judgment in diagnosing Lyme disease and cannot provide treatment to Lyme disease patients who do not exhibit an EM rash. As many as fifty percent of all Lyme patients

never develop the EM rash, therefore, up to 50% of all Lyme disease patients are not treated for this debilitating disease.

113. The 2006 IDSA Guidelines also prevent doctors from providing patients with proven treatment options because the IDSA Guidelines are extremely restrictive. The IDSA Guidelines have an extensive list of prohibitive practices, including long-term antibiotic use and intravenous antibiotics. Doctors who treat chronic Lyme disease have successfully used long-term antibiotic treatment and intravenous antibiotics on chronic Lyme patients. These treatment options can even cure chronic Lyme disease. The IDSA Guidelines' restrictions are directly targeted at the treatment practices of doctors following other guidelines, including the ILADS treatment Guidelines. Unlike the IDSA Guidelines, the ILADS guidelines are flexible and recommend that physicians should decide how to treat their patients based "on the severity of each case, the patient's response to therapy and the physician's own clinical judgment."

114. The IDSA Guidelines also limit patients' ability to obtain health care and eliminate patients' choice of medical treatment in the Lyme treatment market. Most doctors refuse to treat Lyme patients because they fear the Settling Insurance Companies will report them to their medical boards and they will spend vast sums of money defending themselves. These doctors are also subject to sanctions or loss of their medical license because The IDSA, the IDSA Panelists, and the Settling Insurance Companies tell the medical boards that the IDSA Guidelines are standards that must be followed, instead of guidelines.

115. Additionally, the Settling Insurance Companies deny payment for treatments that do not conform to the IDSA Guidelines which means that many Lyme sufferers go undiagnosed and untreated. Lyme disease patients who can find a doctor willing to treat their disease suffer severe economic harm because they have to travel great distances and pay for the costly treatments themselves.

116. The IDSA Guidelines' denial of chronic Lyme disease and condemnation of long-term antibiotics is clearly not the least restrictive method available to protect the public. Instead of condemning the use of long-term antibiotics, the IDSA, the IDSA Panelists, or the Settling Insurance Companies could tell Lyme disease patients that a disagreement exists between actual Lyme disease doctors and research doctors as to whether chronic Lyme exists. The IDSA, the IDSA Panelists, or the Settling Insurance Companies could explain the nature of the controversy to patients and provide Lyme patients with a warning to address their concerns surrounding the use of long-term antibiotics. This information would allow patients to make an informed decision when deciding treatment options. Instead, Patients are told by the IDSA, the IDSA Panelists, or the Settling Insurance Companies that there are no treatment options, chronic Lyme disease does not exist, and they are not permitted to get better through the use of long-term antibiotic treatment.

117. The IDSA Guideline development process did not have procedural safeguards. Blumenthal's findings clearly demonstrate that "[t]he IDSA's Lyme guideline process lacked important procedural safeguards." The facts above demonstrate that the IDSA's guideline development process was not fair, open, or unbiased. The IDSA Panelists and the IDSA, with guidance from the Settling Insurance Companies, improperly influenced the guideline process by:

- refusing to meaningfully consider information regarding the existence of Lyme disease;
- excluding scientists and physicians with divergent viewpoints;
- failing to conduct a conflicts of interest review on the panelists; and
- failing to follow its own procedures for appointing panel members.

118. The IDSA Panelists were biased during the Guideline development process due to their financial interests in Lyme diagnostic tests and their consulting arrangements with the Settling Insurance Companies.

119. Because of this abuse in the Guideline development process, the Guidelines deny the existence of chronic Lyme disease and condemn the use of long-term antibiotics. This limits consumers' diagnosis and treatment options and causes economic harm to doctors who treat chronic Lyme disease. The Guidelines also cause further economic harm to competing doctors because the Guidelines prevent them from exercising their clinical discretion in diagnosing and treating Lyme disease. The Guidelines have also caused economic harm to chronic Lyme patients because they have to pay for their own treatment because the Insurance Defendant use the Guidelines to deny treatment. Consequently, the IDSA development process should constitute exclusionary conduct under the Sherman Act.

120. The IDSA, the IDSA Panelists, and the Settling Insurance Companies monopolize or attempt to monopolize the Lyme treatment market. Section 2 of the Sherman Act specifically prohibits monopolizing or attempting to monopolize, any part of interstate or foreign commerce. The IDSA, the IDSA Panelists, and the Settling Insurance Companies have possession of monopoly power in the relevant Lyme disease treatment and diagnosis market and they willfully acquired and maintain that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. The IDSA, the IDSA Panelists, and the Settling Insurance Companies also monopolize interstate commerce by excluding competitors from a market and their actions have an anticompetitive effect which harms consumers.

121. The IDSA, the IDSA Panelists, and the Settling Insurance Companies biased the Lyme treatment Guideline development process. They unlawfully monopolize the treatment of Lyme disease by excluding valid medical treatments, such as long-term antibiotic treatment. Finally, they deny the existence of chronic Lyme disease for their own economic benefits. This bias has allowed the IDSA, the IDSA Panelists, and the Settling Insurance Companies to eliminate consumer choice in the Lyme treatment market and exclude competing doctors, the same doctors

who actually treat chronic Lyme disease, clinically diagnose chronic Lyme disease, and are trying to help their patients. The IDSA, the IDSA Panelists, and the Settling Insurance Companies have also unlawfully monopolized the treatment of Lyme disease by forcing medical boards to investigate and sanction doctors who do not follow the IDSA Guidelines.

J. Some of the Harm Caused by Defendants

122. All of the Plaintiffs in this case, as well as hundreds of thousands of other people in the United States, suffer debilitating injuries as a result of the wrongful, illegal, and fraudulent actions of the IDSA, Settling Insurance Companies, and the IDSA Panelists. It is impossible to state everything Plaintiffs have gone through as a result of the Defendants, however, a brief summary is as follows:⁷¹

123. Lisa Torrey visited more than 36 doctors before she was properly diagnosed with Lyme disease. As a result, she suffers with neurological disorders affecting her balance, neurological disorders affecting her bladder, migraine headaches, heart arrhythmia, severe nerve pain, hearing problems, frequent fevers, muscle pain, fatigue, as well as many other symptoms. She was improperly diagnosed with Fibromyalgia, Multiple Sclerosis, and told her symptoms “were all in her head”. Since her diagnosis with Lyme disease, she was forced to spend hundreds of thousands of dollars of her own money to treat her Lyme disease because her insurers would not cover the necessary treatment. She still suffers every day.

124. David Kocurek earned his Ph.D. in Aerospace Engineering from Texas A&M. He worked as a researcher in the fields of aerodynamics and performance of rotary-wing aircraft. He published his research internationally and served on the NASA aerodynamics oversight

⁷¹ Many of the Plaintiffs still suffer neurological issues including memory loss and it is difficult for them to remember all of the details of their medical history. Further, there may be slight inaccuracies that are the fault of the lawyers preparing this Complaint, and not the fault of Plaintiffs. Any inaccuracies will be corrected as information and medical records are obtained by Plaintiffs and their lawyers.

committee. For years he suffered with all of the symptoms of Lyme disease (headaches, nerve pain, muscle pain, fatigue, fever, etc.) but also suffered more severe symptoms including Parkinson's like jerks and tremors as well as palsy. He visited more than 25 doctors and was told he did not have Lyme disease. He even tested negative for Lyme disease based on the IDSA testing guidelines. He was only diagnosed with Lyme disease after he researched the issue himself and convinced his doctor to test him again. He was finally diagnosed as "very positive" for Lyme and began treatment. His doctor agreed to treat him for chronic Lyme disease until she was told she could lose her medical degree if she continued to treat chronic Lyme patients. He went from doctor to doctor and was forced to pay out-of-pocket because his insurer refused to cover his treatment. David Kocurek died from Lyme disease on April 13, 2016.

125. Amy Hanneken had a successful career in real estate construction and land development. She became sick in 2009 with severe fatigue, muscle weakness, neurological and cognitive deficits, memory loss, and many other symptoms. Even though she had Lyme disease, she tested negative for Lyme disease because of the IDSA testing guidelines. Finally, in 2014 she tested positive for Lyme disease. She received the standard short term antibiotic treatment. The treatment did not cure her Lyme disease but her insurer refused to provide coverage for long-term antibiotic treatment. She was forced to pay out of pocket for this expensive treatment and is still trying to pay for treatment today. When she cannot afford the treatment, she is bedridden until she is able to pay for more care. As a result of the IDSA and the Settling Insurance Companies, Amy Hanneken lost her career, her family (her husband divorced her), and her home to foreclosure. Amy Hanneken once had a successful career, a family, and a house. Now she is sleeping on a friend's couch and trying to save money to pay for the treatment her insurer should be paying.

126. Jane Powell tested positive for Lyme disease and was given four weeks of antibiotic treatment. She partially recovered but still suffered with joint disease and severe fatigue. Her

doctors told her she could not have Lyme disease because she had already received the necessary amount of treatment. She was told she had either Lupus or another autoimmune disease. She suffered with pain and fatigue that eventually became so severe she was forced to go on disability. Five years later, after not getting better, she was finally given another Lyme disease test and tested positive. She was given antibiotics for 4 weeks and then another 4 weeks when she was still not better. She was told she could not have Lyme disease anymore because she received more than enough treatment. She again suffered with debilitating symptoms until she given another Lyme disease test more than fourteen years later. Not surprisingly, she tested positive for Lyme disease. She has been refused long-term antibiotic treatment and is currently paying large sums of money out-of-pocket to receive treatment even though she had insurance.

127. Carol Fisch was bitten by a tick and exhibited the bullseye rash. She also tested positive for Lyme on the Elisa test, however, she did not test positive enough on the Western blot, as required by the IDSA, to be diagnosed with Lyme disease. She exhibited all of the normal symptoms of Lyme disease including severe fatigue, inability to think clearly, heart palpitations, and severe joint and nerve pain. The pain was so bad that she could not even walk up a flight of stairs. She was told that because she did not have Lyme disease she probably had Fibromyalgia or Chronic Fatigue. Eventually she also suffered short-term memory loss so severe that she was forced to stop working. She was eventually diagnosed with Lyme disease and given four weeks of antibiotic treatment. By this time, the treatment was ineffective. Carol Fisch's insurer will not pay for treatment so she tries to pay for long-term treatment out-of-pocket. The treatment helps with her symptoms but because she cannot afford long-term treatment. She is currently disabled.

128. Christopher Valerio began suffering from an uncontrollable twitch in his left hand. He visited more than fifteen doctors who performed multiple tests including blood tests, MRI's, and neurological tests. He was told he had everything from anxiety to Parkinson's disease. After a

couple of years, the tremors became so bad that Christopher Valerio was wheelchair bound. A friend of Christopher Valerio's saw a special on television about Lyme disease and told him he should get tested. He finally tested positive (after having to undergo multiple tests because he kept testing negative using the IDSA testing protocols). He was finally given antibiotics and was able to walk and talk normally. After he stopped receiving treatment, he went back to his prior condition. Christopher Valerio's family is currently trying to get him treatment and are forced to drive more than four hours each way. They also have to pay large amounts of money, out-of-pocket, to treat him.

129. Ashleigh Peacher suffered with a rash, fevers, aches, headaches, light sensitivity, shortness of breath, and other Lyme symptoms. She was diagnosed with everything but Lyme, including Fibromyalgia, Hypoglycemia, food sensitivity, Postural Orthostatic Tachycardia Syndrome, and others. Finally, she was tested for Lyme disease and tested positive. She underwent antibiotic treatment until her insurers refused treatment. Her family is currently trying to figure out how to pay for her treatment because her treatment is not covered by the Settling Insurance Companies.

130. The rest of the Plaintiffs have not fared much better:

- Randy Sykes suffers from severe Lyme disease symptoms because he was undiagnosed for years. Once diagnosed, he was refused long-term antibiotic treatment and was forced to find a doctor who would treat him. His insurance company refused to pay for long-term treatment and he is currently trying to pay for treatment himself.
- Brienna Reed Sykes suffers from severe Lyme disease symptoms because she was undiagnosed for years. After being forced to research her condition on her own, she was finally diagnosed with Lyme disease. She was forced to find a doctor who

would treat him because her insurer would not provide long-term antibiotic treatment. She is currently bedridden and suffers seizures as a result of her chronic Lyme disease.

- Rosetta Fuller suffers from severe Lyme disease symptoms because she was undiagnosed with Lyme Disease until 2016. Luckily, she found a doctor who would properly treat her and she is currently undergoing treatment but being forced to pay out-of-pocket.
- Adriana Moreira suffers from severe Lyme disease symptoms but was misdiagnosed with Dermatomyositis. Her condition got so bad that she ended up in intensive care. Her condition did not improve much and she was finally diagnosed with Lyme disease in 2016. She was placed on an IV of antibiotics for 28-days and saw a vast improvement, but she was not completely healed. After the 28-days of treatment, her doctor hugged her and wished her luck because the 28-days of antibiotics was all she could receive. Now her symptoms are returning and she has nowhere to turn for treatment.
- Jessica McKinne suffers from severe Lyme disease symptoms but was misdiagnosed with Multiple Sclerosis. When an MS specialist told her she did not have MS, she went from doctor to doctor looking for help. She was finally diagnosed with Lyme disease but cannot afford the long-term antibiotic treatment her insurer refuses to cover.
- Kristine Woodard was diagnosed with Lyme disease but refused long-term antibiotic treatment. Her condition became so bad that she was sent to a psychiatric ward due to her neurological issues caused by Lyme disease. When she can afford

antibiotics she feels better, but she struggles to pay for the treatment her insurers should be paying.

- Gayle Clarke suffered classic Lyme disease symptoms but was misdiagnosed for three years while she suffered. She received long-term antibiotic treatment from a doctor who understands Lyme disease but cannot afford any more treatment. She is currently disabled due to Lyme disease.
- Allison Caruana had classic Lyme disease symptoms and had the bullseye rash associated with Lyme disease. She tested positive for Lyme disease and received the normal treatment, which did not cure her. She then suffered for years with debilitating symptoms of Lyme disease but was diagnosed with Fibromyalgia, Chronic Fatigue Syndrome, Parkinson's, and at one point was given 9 months to live. Eventually she was diagnosed with Lyme again and is currently seeking long-term antibiotic treatment.
- Elise Bowerman, Emory Bowerman, and Anais Bowerman are siblings who all tested positive for Lyme Disease. All three were denied long-term antibiotic treatment by their insurer and were forced to pay out-of-pocket for treatment.
- Tawnya Smith, Chloe Lohmeyer, and Monet Pitre are a family and have been devastated by chronic Lyme disease. They have all of the severe symptoms of chronic Lyme disease and have spent years looking for a doctor to treat them. When they found a doctor, that doctor had to quit treating them because she was brought in front of the medical board for treating chronic Lyme disease beyond the 28-days. They have traveled to different states including California, New Mexico, and Nevada to receive the treatment they need. They are forced to pay cash to receive treatment and cannot afford the care their insurers will not pay for.

COUNT 1: RICO § 1962(c)

131. The allegations of the paragraphs above are incorporated herein by reference.

132. The IDSA, Settling Insurance Companies, and the IDSA Panelists operate an enterprise engaged in and whose activities affect interstate commerce. The IDSA and the Settling Insurance Companies are employed by or associated with the enterprise.

133. The IDSA, Settling Insurance Companies, and the IDSA Panelists agreed to and did conduct and participate in the conduct of the enterprise's affairs through a pattern of racketeering activity and for the unlawful purpose of intentionally defrauding Plaintiffs. Specifically: the IDSA and the Settling Insurance Companies acted to fraudulently and illegally prevent long-term treatment of chronic Lyme disease and to prevent the proper testing of potential Lyme disease patients.

134. Pursuant to and in furtherance of their fraudulent scheme, the IDSA, Settling Insurance Companies, and the IDSA Panelists committed multiple related acts of racketeering activity including, but not limited to, (a) mail fraud, in violation of 18 U.S.C. § 1341, and (b) wire fraud, in violation of 18 U.S.C. § 1343.

135. The acts identified above constitute a pattern of racketeering activity pursuant to 18 U.S.C.A. § 1961(5).

136. The IDSA, Settling Insurance Companies, and the IDSA Panelists have directly and indirectly conducted and participated in the conduct of the enterprise's affairs through the pattern of racketeering and activity described above, in violation of 18 U.S.C.A. § 1962(c).

137. As a direct and proximate result of the IDSA, Settling Insurance Companies, and the IDSA Panelists' racketeering activities and violations of 18 U.S.C.A. § 1962(c), Plaintiffs have been injured in their business and property in that: they were forced to pay for their treatments, were forced to pay all expenses associated with treating their Lyme disease, were forced to travel

long distances for treatment, were forced to try to find doctors who would treat them, and were unable to work or earn money because of their debilitating illness. Further, because Plaintiffs were not timely diagnosed or treated, they now suffer long-term complications and are forced to continue to pay future medical costs for treatment and out-of-pocket expenses to receive this treatment.

138. WHEREFORE, Plaintiffs requests this Court enter judgment against the IDSA, Settling Insurance Companies, and the IDSA Panelists for actual damages, treble damages and attorney's fees.

COUNT 2: RICO § 1962(a)

139. The allegations of paragraphs 131 through 184 are incorporated herein by reference.

140. The IDSA, Settling Insurance Companies, and the IDSA Panelists are an enterprise engaged in and whose activities affect interstate commerce. The IDSA, Settling Insurance Companies, and the IDSA Panelists used and invested income that was derived from a pattern of racketeering activity in an interstate enterprise. Specifically: the Settling Insurance Companies used the money it gained from not treating chronic Lyme patients, not treating misdiagnosed Lyme patients, and misclassifying Lyme disease as other disorders to compensate the IDSA Panelists to keep the 28-day standard in place, keep the improper testing protocols in place, to testify against Lyme patients, to testify against doctors who treat chronic Lyme disease patients, and maintain the scheme which forces people, like Plaintiffs, to not be properly diagnosed or treated for their Lyme disease.

150. The racketeering activity listed above constitutes a pattern of racketeering activity pursuant to 18 U.S.C.A. § 1961(5).

151. As direct and proximate result of the IDSA, Settling Insurance Companies, and the IDSA Panelists' racketeering activities and violations of 18 U.S.C.A. § 1962(a), Plaintiffs have been injured in their business and property in that: Plaintiffs have been injured in their business and property in that: they were forced to pay for their treatments, were forced to pay all expenses associated with treating their Lyme disease, were forced to travel long distances for treatment, were forced to try to find doctors who would treat them, and were unable to work or earn money because of their debilitating illness. Further, because Plaintiffs were not timely diagnosed or treated, they now suffer long-term complications and are forced to continue to pay future medical costs for treatment and out-of-pocket expenses to receive this treatment.

152. WHEREFORE, Plaintiffs requests this Court enter judgment against the IDSA and the IDSA Panelists for actual damages, treble damages and attorney's fees.

COUNT 3: RICO § 1962(b)

153. The allegations of paragraphs 131 through 184 are incorporated herein by reference.

154. The IDSA, Settling Insurance Companies, and the IDSA Panelists acquired and maintained interests in and control of the enterprise through a pattern of racketeering activity. Specifically: the IDSA and the Settling Insurance Companies refused to accept, acknowledge, or rely on the studies, organizations, information, and scientific data reporting that chronic Lyme disease is a legitimate medical condition, that chronic Lyme disease requires long-term antibiotic treatment, and that the current testing criteria fails to diagnose a majority of people with Lyme disease. Further, the IDSA, Settling Insurance Companies, and the IDSA Panelists work together to remove doctors who treat chronic Lyme disease and diagnose Lyme disease using different standards. These actions, among others, allow the IDSA, Settling Insurance Companies, and the IDSA Panelists to maintain control of the testing and treatment of Lyme disease.

155. The racketeering activity listed above constitutes a pattern of racketeering activity pursuant to 18 U.S.C.A. § 1961(5).

156. The IDSA and the Settling Insurance Companies have directly and indirectly acquired and maintained interests in and control of the enterprise through the pattern of racketeering activity described above, in violation of 18 U.S.C.A. § 1962(b).

157. As direct and proximate result of the IDSA, Settling Insurance Companies, and the IDSA Panelists' racketeering activities and violations of 18 U.S.C.A. § 1962(b), Plaintiffs have been injured in their business and property in that: Plaintiffs have been injured in their business and property in that: they were forced to pay for their treatments, were forced to pay all expenses associated with treating their Lyme disease, were forced to travel long distances for treatment, were forced to try to find doctors who would treat them, and were unable to work or earn money because of their debilitating illness. Further, because Plaintiffs were not timely diagnosed or treated, they now suffer long-term complications and are forced to continue to pay future medical costs for treatment and out-of-pocket expenses to receive this treatment.

158. WHEREFORE, Plaintiffs requests this Court enter judgment against the IDSA and the IDSA Panelists for actual damages, treble damages and attorney's fees.

COUNT 4: RICO § 1962(d)

159. The allegations of paragraphs 131 through 184 are incorporated herein by reference.

160. As set forth above, the IDSA, Settling Insurance Companies, and the IDSA Panelists agreed and conspired to violate 18 U.S.C.A. § 1962(a) (b) and (c). The IDSA, Settling Insurance Companies, and the IDSA Panelists have intentionally conspired and agreed to directly and indirectly use or invest income that is derived from a pattern of racketeering activity in an interstate enterprise, acquire or maintain interests in the enterprise through a pattern of racketeering

activity, and conduct and participate in the conduct of the affairs of the enterprise through a pattern of racketeering activity. The IDSA and the Settling Insurance Companies knew that their predicate acts were part of a pattern of racketeering activity and agreed to the commission of those acts to further the schemes described above. That conduct constitutes a conspiracy to violate 18 U.S.C.A. § 1962(a), (b) and (c), in violation of 18 U.S.C.A. § 1962(d).

161. As direct and proximate result of the Count IV Defendant(s)' conspiracy, the overt acts taken in furtherance of that conspiracy, and violations of 18 U.S.C.A. § 1962(d), Plaintiffs have been injured in their business and property in that: Plaintiffs have been injured in their business and property in that: they were forced to pay for their treatments, were forced to pay all expenses associated with treating their Lyme disease, were forced to travel long distances for treatment, were forced to try to find doctors who would treat them, and were unable to work or earn money because of their debilitating illness. Further, because Plaintiffs were not timely diagnosed or treated, they now suffer long-term complications and are forced to continue to pay future medical costs for treatment and out-of-pocket expenses to receive this treatment.

162. WHEREFORE, Plaintiffs requests this Court enter judgment against the IDSA and the IDSA Panelists for actual damages, treble damages and attorney's fees.

COUNT 5: ANTITRUST VIOLATIONS OF THE SHERMAN ACT

163. Plaintiffs bring this civil action to obtain equitable and other relief against Defendants as a result of restrain Defendants' violation of Section 1 and Section 2 of the Sherman Act, 15 U.S.C.A. § 1.

164. Section 1 of the Sherman Act applies to concerted conduct by two or more entities and prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade of commerce among the several States"

165. As set forth above, Defendants violated Section 1 of the Sherman Act. Specifically, the IDSA, the IDSA Panelists, and the Settling Insurance Companies engaged in a conspiracy that restrained trade in the relevant market. The IDSA, the IDSA Panelists, and the Settling Insurance Companies uses the IDSA guideline development process to consciously agree to exclude actual Lyme doctors, exclude competing doctors who disagree with the IDSA guidelines, exclude doctors who use their own clinical discretion to diagnose Lyme disease, and exclude doctors who do not follow the IDSA's 28-day recommended treatment program. This exclusion has antitrust implications because the IDSA Panelists and the Settling Insurance Companies had an economic interest in the outcome of the development process.

166. The IDSA, the IDSA Panelists, and the Settling Insurance Companies "consciously committed to a common agreement of an unreasonable restraint on trade" in the relevant market. There is a reduction of competition in the market as a result of the conduct of the IDSA, the IDSA Panelists, and the Settling Insurance Companies.

167. Because courts allow inferences to be drawn from the behavior of the alleged conspirators, this Court should find that the IDSA, the IDSA Panelists, and the Settling Insurance Companies conspired to unreasonably restrain trade in the relevant market--the treatment of Lyme disease.

168. The 2006 Guidelines do not have a legitimate purpose. The IDSA, the IDSA Panelists, and the Settling Insurance Companies use the Guidelines as a predatory device to injure doctors who do not follow the Guidelines. The 2006 IDSA Guidelines also prevent doctors from providing patients with proven treatment options because the IDSA Guidelines are extremely restrictive. The IDSA Guidelines also limit patients' ability to obtain health care and eliminate patients' choice of medical treatment in the Lyme treatment market.

169. The IDSA Guidelines' denial of chronic Lyme disease and condemnation of long-term antibiotics is clearly not the least restrictive method available to protect the public.

170. The IDSA Guideline development process did not have procedural safeguards. The IDSA Panelists were biased during the Guideline development process due to their financial interests in Lyme diagnostic tests and their consulting arrangements with the Settling Insurance Companies.

171. Because of this abuse in the Guideline development process, the Guidelines deny the existence of chronic Lyme disease and condemn the use of long-term antibiotics. This limits consumers' diagnosis and treatment options and causes economic harm to doctors who treat chronic Lyme disease. The Guidelines also cause further economic harm to competing doctors because the Guidelines prevent them from exercising their clinical discretion in diagnosing and treating Lyme disease. The Guidelines have also caused economic harm to chronic Lyme patients because they have to pay for their own treatment because the Insurance Defendant use the Guidelines to deny treatment. Consequently, the IDSA development process should constitute exclusionary conduct under the Sherman Act.

172. As set forth above, Defendants violated Section 2 of the Sherman Act. The IDSA, the IDSA Panelists, and the Settling Insurance Companies monopolize or attempt to monopolize the Lyme treatment market. Section 2 of the Sherman Act specifically prohibits monopolizing or attempting to monopolize, any part of interstate or foreign commerce. The IDSA, the IDSA Panelists, and the Settling Insurance Companies have possession of monopoly power in the relevant Lyme disease treatment and diagnosis market and they willfully acquired and maintain that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. The IDSA, the IDSA Panelists, and the Settling Insurance

Companies also monopolize interstate commerce by excluding competitors from a market and their actions have an anticompetitive effect which harms consumers.

173. The IDSA, the IDSA Panelists, and the Settling Insurance Companies biased the Lyme treatment Guideline development process. They unlawfully monopolize the treatment of Lyme disease by excluding valid medical treatments, such as long-term antibiotic treatment. Finally, they deny the existence of chronic Lyme disease for their own economic benefits. This bias has allowed the IDSA, the IDSA Panelists, and the Settling Insurance Companies to eliminate consumer choice in the Lyme treatment market and exclude competing doctors, the same doctors who actually treat chronic Lyme disease, clinically diagnose chronic Lyme disease, and are trying to help their patients. The IDSA, the IDSA Panelists, and the Settling Insurance Companies have also unlawfully monopolized the treatment of Lyme disease by forcing medical boards to investigate and sanction doctors who do not follow the IDSA Guidelines.

**COUNT 6: FRAUDULENT MISREPRESENTATION INVOLVING RISK OF
PHYSICAL HARM (AGAINST THE IDSA ONLY)**

174. The IDSA made and continues to make fraudulent misrepresentations. This includes as specifically identified above:

- That chronic Lyme does not exist;⁷²
- That it is a simple, rare illness that is easy to avoid, difficult to acquire, simple to diagnose, and easily treated and cured with 28 days of antibiotics;⁷³
- That there is no treatment failure for any Lyme patient who receives short-term antibiotics;⁷⁴

⁷² See ¶ 46 of the Second Amended Complaint along with the footnotes which identify when this statement was made by the IDSA. Additionally, the IDSA has continued to republish and promulgate this statement to the medical community, the Lyme community and the public at large and has refused to withdraw the false statements.

⁷³ Id. at ¶ 74.

⁷⁴ Id. at ¶ 84.

- All Lyme patients are cured by a short course (14 to 28 days) of antibiotic treatment;⁷⁵
- The two-tier test can properly diagnose patients with Lyme disease when in fact it does not show an active infection and is highly inaccurate⁷⁶; and
- The two-tier test is accurate, reliable, and can determine whether an active infection exists when in fact it is described by the IDSA panelists as “inaccurate” “not very precise”, “unreliable” and fails to “determine whether the (Lyme) spirochete exists in the body”.⁷⁷

176. The IDSA knew the statements were false or made the statements recklessly and did not have the knowledge to which the IDSA professed in making the statements.

177. As a result, Plaintiffs have suffered physical injuries and emotional distress due to the IDSA’s fraudulent misrepresentation for which the Plaintiffs seek damages.

178. Plaintiffs have also suffered economic damages for which Plaintiffs seek damages.

**COUNT 7: NEGLIGENT MISREPRESENTATION INVOLVING RISK OF
PHYSICAL HARM (AGAINST THE IDSA ONLY)**

179. The IDSA made and continues to make negligent misrepresentations in the course of its business. This includes:

- That chronic Lyme does not exist;⁷⁸
- That it is a simple, rare illness that is easy to avoid, difficult to acquire, simple to diagnose, and easily treated and cured with 28 days of antibiotics;⁷⁹

⁷⁵ Id. at ¶ 84.

⁷⁶ Id. at ¶¶ 78-80.

⁷⁷ Id. at ¶¶ 78-80.

⁷⁸ See ¶ 46 of the Second Amended Complaint along with the footnotes which identify when this statement was made by the IDSA. Additionally, the IDSA has continued to republish and promulgate this statement to the medical community, the Lyme community and the public at large and has refused to withdraw the false statements.

⁷⁹ Id. at ¶ 74.

- That there is no treatment failure for any Lyme patient who receives short-term antibiotics;⁸⁰
- All Lyme patients are cured by a short course (14 to 28 days) of antibiotic treatment;⁸¹
- The two-tier test can properly diagnose patients with Lyme disease when in fact it does not show an active infection and is highly inaccurate⁸²; and
- The two-tier test is accurate, reliable, and can determine whether an active infection exists when in fact it is described by the IDSA panelists as “inaccurate” “not very precise”, “unreliable” and fails to “determine whether the (Lyme) spirochete exists in the body”.⁸³

180. This information is false. The IDSA did not exercise reasonable care or competence in obtaining or communicating the information.

181. These misrepresentations harmed the Plaintiffs.

182. The IDSA should expect this would occur as a result of the false information supplied by the IDSA.

183. As a result, Plaintiff has suffered physical injuries and emotional distress due to the IDSA’s negligent misrepresentation for which the Plaintiff seeks damages.

184. Plaintiff has also suffered economic damages for which Plaintiff seeks damages.

DAMAGES

185. The IDSA and the IDSA Panelists are liable to Plaintiffs and Plaintiffs are entitled to recover the following damages:

- a. Actual damages;

⁸⁰ Id. at ¶ 84.

⁸¹ Id. at ¶ 84.

⁸² Id. at ¶¶ 78-80.

⁸³ Id. at ¶¶ 78-80.

- b. Treble damages;
- c. Exemplary damages;
- d. Special damages;
- e. General damages;
- f. Reasonable attorney's fees; and
- g. Court costs.

186. Therefore, in accordance with the Racketeer Influenced and Corrupt Organizations Act, Plaintiffs seek all actual damages, treble damages, attorney fees, and any other relief allowed under Texas law and deemed appropriate by this Court, which is believed to exceed the jurisdictional requirement of this court.

187. Further, Plaintiff seeks all actual, general, exemplary, and special damages and other relief allowed under Texas law and deemed appropriate by this Court for the fraudulent and negligent misrepresentations by the IDSA.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand trial by jury on all claims for which the law provides a right to jury trial.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiffs LISA TORREY, KATHRYN KOCUREK Individually and on behalf of the Estate of J. DAVID KOCUREK, PH.D., AMY HANNEKEN, JANE POWELL, CAROL FISCH, JOHN VALERIO, RANDY SYKES, BRIENNA REED, ROSETTA FULLER, ADRIANA MONTEIRO MOREIRA, JESSICA MCKINNIE, KRISTINE WOODARD, GAYLE CLARKE, ALLISON LYNN CARUANA, CHLOE LOHMEYER, TAWNIA DAWN SMITH, Individually and as Next Friend of MONET PITRE, MIKE PEACHER, Individually and as Next Friend of ASHLEIGH PEACHER, ALARIE

BOWERMAN, Individually and as Next Friend of ELISA BOWERMAN, EMORY BOWERMAN, and ANAIS BOWERMAN, respectfully pray for actual damages in an amount to be determined by a jury, for treble damages according to proof, for costs of suit incurred herein, including reasonable attorneys' fees, and for such other and further relief, in law or in equity, to which they may be justly entitled and this Court deems just and proper.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on the 7th day of January, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all registered parties.

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/s/ Daniel R. Dutko

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