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

LISA TORREY, et al.,	§
	§
Plaintiffs,	§
	§
V.	§ CIVIL ACTION NO. 5:17-cv-00190-RWS
	§
INFECTIOUS DISEASES SOCIETY OF	§
AMERICA, et al.,	§
	§ JURY TRIAL DEMANDED
Defendants.	§

PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' RICO AND ANTITRUST CLAIMS

TABLE OF CONTENTS

TABL	E OF C	ONTENTSii	
TABL	E OF A	UTHORITIESiii	
I.	INTRO	DDUCTION1	
II.	ANTI	TRUST EVIDENCE AND DESTRUCTION OF DOCUMENTS	
III.	SECTION 1 ANTITRUST CLAIM		
	A.	IDSA and Insurance Companies Engaged in a Conspiracy To Restrain Trade	
	B.	The IDSA and the Insurance Defendants Acted to Restrain Trade in an Antitrust Relevant Market	
	C.	IDSA Dominates and Controls a Monopoly Share of Lyme Disease Treatment Market	
	D.	Voluntary Guidelines Can Be Unreasonable Restraint on Competition	
IV.	SECTI	ON 2 ANTITRUST CLAIM	
V.	PLAINTIFFS' ANTITRUST DAMAGES ARE NOT DERIVATIVE OF PERSONAL INJURIES		
VI.	PLAIN	TIFFS' CLAIMS ARE NOT BARRED BY STATUTE OF LIMITATIONS25	
VII.	CONC	LUSION	
CERT	IFICAT	E OF SERVICE28	

TABLE OF AUTHORITIES

Abraham & Veneklasen Joint Venture v. Am. Quarter Horse Ass'n, 776 F.3d 321, 331–32 (5th Cir. 2015)	, 16
Accord Poster Exchange, Inc. v. Nat. Screen Serv., 517 F.2d 117, 126 (5th Cir. 1975)	25
Accord Todd v. Exxon Corp., 275 F.3d 191, 199-200 (2d Cir. 2001)	8
Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 501 (1988)	17
Am. Soc. of Mech. Engineers, Inc. v. Hydrolevel Corp., 456 U.S. 556, 558, 102 S. Ct. 1935, 1938, 72 L. Ed. 2d 330 (1982)	23
Bell Atl. Corp. v. AT & T Corp., 339 F.3d 294, 302 (5th Cir.2003)	24
Bio-Med. Applications Mgmt. Co., Inc v. Dallas Nephrology Associates, 4:94CV37, 1995 WL 215302, at *2 (E.D. Tex. Feb. 6, 1995)	19
Consol. Metal Products, Inc. v. Am. Petroleum Inst., 846 F.2d 284, 292 (5th Cir. 1988)23,	, 24
Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49 (1977)	17
Creative Copier Servs. v. Xerox Corp., 344 F. Supp. 858, 863 (D. Conn. 2004)	18
Domed Stadium Hotel, Inc. v. Holiday Inns, Inc., 732 F.2d 480, 486 (5th Cir. 1984)	2
Hughes v. Tobacco Inst., Inc., 278 F.3d 417 (5th Cir. 2001)	24
Jackson v. Sedgwick Claims Mgmt. Services, Inc., 731 F.3d 556 (6th Cir. 2013) 24	25
Kaiser Aluminum & Chemical Sales, Inc. v. Avondale Shipyards, Inc., 677 F.2d 1045, 1051 (5th Cir. 1982)	25
Leyba v. Renger, 874 F. Supp. 1229, 1238 (D.N.M. 1994)	19

Monsanto Co. v. Spray–Rite Serv. Corp., 465 U.S. 752, 761, 104 S.Ct. 1464, 79 L.Ed.2d 775 (1984)
O'Dell v. General Motors Corp., 122 F. Supp. 2d 721, 726 - 27 (E.D. Tex. 2000)
Oltz v. St. Peter's Cmty. Hosp., 861 F.2d 1440, 1447 (9th Cir. 1988)
Reiter v. Sonotone Corp., 442 U.S. 330, 337, 99 S. Ct. 2326, 2330, 60 L. Ed. 2d 931 (1979)25
Shah v. VHS San Antonio Partners, L.L.C., 985 F.3d 450, 454 (5th Cir. 2021)
Spectators' Commc'n Network Inc. v. Colonial Country Club, 253 F.3d 215, 220 (5th Cir.2001)
Sportservice, Inc. v. Charles O. Finley, 676 F.2d 1291, 1299 (9th Cir., 1982) State Oil Co. v. Khan, 522 U.S. 3, 10 (1997)
State Oil Co. v. Khan, 522 U.S. 3, 10 (1977)
T&T Geotechnical, Inc. v. Union Pacific Resources Co., 944 F. Supp. 1317, 1323 (N.D. Tex. 1996)
Taylor Pub. Co. v. Jostens, Inc., 216 F.3d 465, 474 (5th Cir.2000)24
Torrey v. Infectious Diseases Soc'y of Am., 5:17-CV-00190-RWS, 2018 WL 10124894, at *8 (E.D. Tex. Sept. 27, 2018)25
Transource International, Inc. v. Trinity Industries, Inc., 725 F.2d 274 (5th Cir.1984)
Vaughn Med. Equip. Repair Serv., L.L.C. v. Jordan Reses Supply Co., No. 10-00124, 2010 WL 3488244, at *19 (E.D. La. Aug. 26, 2010)
Viazis v. Am. Ass'n of Orthodontists, 314 F.3d 758, 763 (5th Cir.2002)
Weiss v. York Hosp., 745 F.2d 786, 827 (3d Cir. 1984)
Wilk v. Am. Med. Ass'n, 671 F. Supp. 1465, 1478 (N.D. III. 1987), aff'd, 895 F.2d 352 (7th Cir. 1990)

Statutes

15 U.S.C. § 1	12
15 U.S.C. § 2	24

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PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' RICO AND ANTITRUST CLAIMS¹

COMES NOW Plaintiffs and file this Response to the Motion for Summary Judgment filed by the IDSA and Doctor Defendants/IDSA Panelists and Plaintiffs show the Court as follows:

I. <u>INTRODUCTION</u>

As set forth in more detail below, the IDSA and IDSA Panelists destroyed or failed to produce relevant documents that were in their possession establishing the large consulting fees paid to the IDSA Panelists from health insurance companies. As a result of the Defendants destruction of the documents that were solely in Defendants' possession, Plaintiffs are unable to answer, with specificity, the newspaper questions required by RICO. Therefore, Plaintiffs are dismissing their RICO claim against Defendants. Plaintiffs are also dismissing the Doctor Defendants because Plaintiffs' jurisdiction over the Doctor Defendants stems from Plaintiffs' RICO claim. Plaintiffs will dismiss the RICO claim and the Doctor Defendants before the April 8, 2021 hearing on Defendants' Motion.

¹ As a result of the freeze, counsel for Plaintiffs' lost power for several days. Counsel for Defendants agreed to a one-week extension for Plaintiffs to file this Response – making this Response due on March 2, 2021.

Even though Plaintiffs are forced to dismiss their RICO claim, there is more than sufficient evidence creating fact questions and precluding summary judgment on Plaintiffs' antitrust claims. Contrary to the claims made in Defendants' Motion for Summary Judgment, there is ample evidence that the IDSA Panelists who created the Lyme disease guidelines received money from insurance companies and then created and enforced arbitrary guidelines. The evidence shows that insurance companies paid large sums of money to IDSA Panelists in return for the IDSA Panelists creating and enforcing arbitrary Lyme disease guidelines that were used by insurance companies to deny treatment to Plaintiffs.

When all the evidence is considered, there are numerous fact questions precluding summary judgment. This is especially true considering the Fifth Circuit's rule regarding summary judgments in antitrust cases: "district courts should grant summary judgments sparingly in antitrust cases." *Transource International, Inc. v. Trinity Industries, Inc.*, 725 F.2d 274 (5th Cir.1984); *Domed Stadium Hotel, Inc. v. Holiday Inns, Inc.*, 732 F.2d 480, 486 (5th Cir. 1984).

II. ANTITRUST EVIDENCE AND DESTRUCTION OF DOCUMENTS

Initially, health insurance companies 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. (Ex. A, Dr. Richard Sanchez deposition, page 90, line 8 – page 93, line 14). This policy 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.

Dr. Richard Sanchez began working as the Senior Vice President for Empire Blue Cross/Blue Shield in 1995. (Ex. A, Sanchez deposition, page 11, lines 2-12). Dr. Sanchez was deposed in 1999 about the changes that occurred at that time with insurance companies and the treatment of Lyme disease. According to Dr. Sanchez, in 1995, Empire Blue Cross/Blue Shield

brought in Deloitte, one of the largest accounting firms in the world, to create a plan to make Empire Blue Cross/Blue Shield more profitable. (Ex. A, Sanchez deposition, page 53, lines 11-18). The plan developed to create profits was to reduce the amount spent on health care by denying procedures, reducing care rendered, and "increase the number of denials". (Ex. A, Sanchez deposition, page 68, line 23 – page 70, line 10).

Empire Blue Cross/Blue Shield and other health insurance companies decided that treatment of Lyme disease was too expensive and red-flagged Lyme disease. (Ex. A, Sanchez deposition, pages 90 – 116). According to Dr. Sanchez, the health 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. *Id.* Dr. Sanchez testified that Empire Blue Cross/Blue Shield wanted to increase profits, so it 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.

(Ex. A, Sanchez deposition, page 116, lines 2-10).

When Sanchez was asked if Empire Blue Cross/Blue Shield had "any medical or scientific justification for that policy, to restrict approval of IV antibiotic treatment", Sanchez answered with "No". (Ex. A, Sanchez deposition, page 114, lines 3-9). Once these arbitrary guidelines were put into place by Empire Blue Cross/Blue Shield and other health insurance companies followed suit by denying coverage for Lyme treatment after the arbitrary timeframe.²

² See Pamela Weintraub, Cure Unknown, Inside the Lyme Epidemic, pages 306-31, St. Martin's Griffin, 2008.

From the mid-1990's up to the enactment of the 2000 IDSA Guidelines, health insurance companies began improperly denying insurance coverage for antibiotics after short term treatment – usually 28 days of treatment.³ The health insurance companies began referring to any treatment beyond shot-term antibiotics as "experimental".

At the same time that health insurance companies created arbitrary guidelines for Lyme disease, they began paying large consulting fees to some of the most influential Lyme disease "experts". For example, in the 1990's and early 2000's Dr. Leonard Sigal was an "active expert witness for insurance companies" and was hired on up to 5 Lyme disease cases a year for more than ten years. (Ex. B, Sigal deposition, page 44, lines 7-19). Sigal charged insurance companies \$560 an hour plus \$5,000 a day for deposition and trial testimony for each of these cases. (Ex. B, Sigal deposition, page 80, lines 7-12 and page 26, lines 14-23). Sigal testified that it is "doubtful", but possible, that he was paid over a million dollars by insurance companies. (Ex. B, Sigal deposition, page 25, lines 12-15).

Defendants downplay Sigal's role with the 2006 IDSA guidelines because of his extensive relationships with insurance companies. The IDSA cannot escape the fact that Sigal was hired by the IDSA to review the Lyme disease guidelines before they were published. (Ex. B, Sigal deposition, page 59, lines 9-24). Sigal's role was to provide approval of the IDSA guidelines after he reviewed them and determined whether there were any inaccuracies or errors. (Ex. B, Sigal deposition, page 58, lines 12-16). The 2006 IDSA guidelines thank Sigal for his "thoughtful review of an earlier draft of these guidelines" and rely on many of Sigal's studies to support the guidelines. (Ex. C, 2006 IDSA guidelines).

³ See Pamela Weintraub, Cure Unknown, Inside the Lyme Epidemic, pages 306-31, St. Martin's Griffin, 2008.

⁴ *Id*.

Sigal testified that the last time he worked as an expert witness for an insurance company was 2006. (Ex. B, Sigal deposition, page 14, line 25 – page 15, line 2). Coincidentally, 2006 is the last time Sigal had a role in preparing, reviewing, or correcting the IDSA guidelines. (Ex. ?, Sigal deposition, page 69, line 14-16).

Sigal worked on hundreds of files for insurance companies and earned hundreds of thousands of dollars, yet he does not have one email, one letter, or even one document setting forth the work he did for insurance companies. (Ex. B, Sigal deposition, page 20, lines 2-22). When asked about documents related to the work he did for insurance companies, Sigal testified "Those have been shredded." *Id*.

Eugene Shapiro testified that he provided expert testimony in around 75 to 80 cases, offered testimony in court more than a "dozen" times, and twice testified in front of medical boards. (Ex. D, Shapiro deposition, page 6, lines 3-24). In 2017, Shapiro published a paper related to Lyme disease. In the footnotes, he admitted he "has been an expert witness in malpractice cases involving Lyme disease". When Shapiro was appointed to the federal Tick-Borne Disease Working Group, close to 40,000 people petitioned to have Shapiro removed from the Group.

We protest Eugene Shapiro's appointment to the federal Tick-Borne Disease Working Group, because he works against the interests of patients.



He denies chronic Lyme disease, testifies against Lyme-treating doctors, helps insurance companies deny disability benefits to Lyme patients, and has financial conflicts of interest. (For starters....)

Tell HHS that Shapiro has no place in this group.

⁵ https://www.amjmed.com/article/S0002-9343(17)30138-9/

⁶ https://www.change.org/p/tick-borne-disease-working-group-keep-eugene-shapiro-off-the-federal-tbdwg?recruiter=73619306

Shapiro failed to produce any documents related to his testimony, failed to produce any documents related to the disability claims he worked on for insurance companies, and failed to produce any documents related to his work in which he "has been an expert witness in malpractice cases involving Lyme disease". In fact, Shapiro failed to produce a list of testimony that he currently has in his possession:

- Q. Do you have a list of your deposition and trial testimony somewhere?
- A. Yes.
- Q. Is it included in the CV?
- A. No, I never -- it's -- I never include it in the CV. If somebody asks -- asks -- if somebody asks me for it, I -- I can get it.
- Q. Do you currently have a copy of that list?
- A. Yes.
- Q. If I were to ask your attorney for that list, you could send it over to him?
- A. I could.

(Ex. D, Shapiro deposition, page 17, line 24 – page 18, line 12).

This Court's discovery rules require that all relevant documents be produced by Defendants. Clearly Shapiro's list of deposition testimony in his possession is relevant to this case.

To date, Defendants have not produced Shapiro's list of deposition testimony.

James Dattwyler was hired numerous times by insurance companies to testify as an expert witness in Lyme cases. (Ex. E, deposition, page 13, lines 1-4). Dattwyler was also hired by insurance companies as a consulting expert and to review medical records for Lyme patients. (Ex. E, deposition, page 13, lines 7-16). When working for insurance companies, Dattwyler charged between \$500 and \$600 an hour:

- Q. What is your rate as an expert witness?
- A. As much as I can get. You know, the lawyers taught me in general it's around \$500 an hour. Occasionally, I'll be offered \$600 an hour.
- Q. So generally speaking, it's either 5- or \$600 an hour?
- A. Yes.
- Q. Do you keep track of the amount of money that you receive in serving as an expert witness?
- A. No.

(Ex. E, Dattwyler deposition, page 189, line 19 – page 190, line 6).

Dattwyler cannot remember any of the cases he worked on, the number of cases, the names of cases, the names of who hired him, or how much he was paid over the years:

- Q. You've never been asked by a judge or by a lawyer to provide a list of the cases that you have worked on as an expert witness?
- A. I may have been asked, but I don't keep those records.
- Q. Do you have a list somewhere in your house or at work or anywhere in which you identify the cases that you've been hired as an expert witness?
- A. No.
- Q. If I wanted to look through your records to determine how many cases you've been hired as an expert witness, how would I find that information?
- A. I would guess you'd have to do it through legal resources that you have at your command. I certainly don't keep records like that.

(Ex. E, Dattwyler deposition, page 18, line 22 – page 19, line 15).

Likewise, Dattwyler failed to retain, or produce, any documents related to his extensive work for insurance companies:

Q. My question is: As it relates to communications with respect to cases and Lyme cases, we have received nothing as it relates to these cases or any other cases in which you have been an expert witness; did you have any of those documentation or documents?

A. I do not.

(Ex. E, Dattwyler deposition, page 189, line 19 – page 190, line 6).

In November of 2006, shortly after the 2006 IDSA Guidelines were released, the Attorney General of the state of Connecticut, Richard Blumenthal (now Senator Blumenthal) investigated the IDSA Guidelines and served Civil Investigative Demands (CID) on many of the guideline authors including Defendants Shapiro, Dattwyler, Wormser, Halprin, , and Steere. (Ex. F, CIDs from Connecticut AG's office). Blumenthal also issued CIDs to many health insurance companies, including UnitedHealth, Cigna, Aetna, Anthem, and Anthem Blue Cross. *Id*.

The CIDs to the health insurance companies asked for any compensation paid by the health insurance companies to the 2006 Guideline authors, including Wormser, Dattwyler, Halprin, Shapiro, and Steere, from August 1, 1998 to July 31, 2007. *Id.* The CIDs to the Guideline authors similarly asked for conflicts related to payments from insurance companies. *Id.*

The insurance companies and the IDSA guideline authors responded to these CIDs and after reviewing their responses, AG Blumenthal concluded: "several of the most powerful IDSA panelists had undisclosed financial interests in insurance companies including 'consulting arrangements with insurance companies'".⁷

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 insurance companies, and the IDSA Panelists. The Attorney General's office produced the CIDs

⁷ http://www.empirestatelymediseaseassociation.org/Archives/CTAGPressReleaseIDSAResponse.htm

sent to the Defendants but not the responses because documents and information acquired were returned to the Defendants pursuant to Connecticut statutory requirements:

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)(l) & (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.

(Ex. F, correspondence from Connecticut AG's office).

It is important to note that the same lawyer who represents the IDSA and Doctor Defendants in this case also represented the IDSA and Doctor Defendants in the Connecticut Attorney General's investigation. Despite this, none of the documents or answers produced in response to the CIDs were produced in this case. None of the Doctor Defendants kept any of the documents or answers sent to the IDSA's lawyers to respond to the CIDS:

- Q Do you have any of the answers that you gave?
- A. No.
- Q. Did you provide your answers to Mr. Dunn over the phone or via e-mail or in writing?
- A. I think it was mostly over the phone.
- Q The documentation that you may have sent Mr. Dunn to produce on your behalf, do you still have that documentation?
- A. No, I do not.
- Q. Do you recall what the answers that you gave to these questions were?
- A. No, I don't.

(Ex. E, Dattwyler, deposition, page 171, line 15 - page 172, line 4).

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.

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.8

After receiving the large consulting fees from insurance companies, the IDSA guideline authors put the same arbitrary guidelines into the IDSA Guidelines that the insurance companies created in the late 1990's. (Ex. G, 2000 IDSA Guidelines and Ex. C, 2006 IDSA Guidelines). For example, the 2006 guidelines call for only short-term antibiotics and claim there is no reason to ever administer long-term antibiotics because there is absolutely no treatment failure for Lyme disease:

"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."

⁸ https://archive.org/stream/lymediseasediagn00unit/lymediseasediagn00unit djvu.txt (emphasis added).

Both the 2000 and 2006 Guidelines contain similar language claiming treatment failure does not exist. (Ex. G, 2000 IDSA Guidelines and Ex. C, 2006 IDSA Guidelines). The guideline authors, after receiving large consulting fees from insurance companies, promoted 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 short-term antibiotics. (Ex. C, 2006 IDSA Guidelines).

After paying the IDSA Guideline authors large sums of money, the insurance companies used the IDSA Guidelines to deny treatment for long-term antibiotics. (Ex. C, Lyme policies for various health insurers). As medical journals point out:

Moreover, insurance companies have used these guidelines to justify their restricted coverage of long-term antibiotic treatment of Lyme disease. And, in the past, these guidelines have been widely cited to justify conclusions that chronic Lyme disease does not exist.⁹

The problem is so bad that the states with the highest incidents of Lyme disease passed laws, or have pending legislation, requiring insurers pay for long term antibiotic treatment for Lyme disease patients who experience treatment failure including Massachusetts¹⁰, Rhode Island¹¹, Connecticut¹², Vermont¹³, New York¹⁴, Maine¹⁵, and Iowa¹⁶.

In response to states passing Lyme legislature requiring coverage for long-term antibiotic treatment, the IDSA issued a statement to state legislatures around the country called: "Lyme

⁹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2435453/

 $^{^{10}\} https://www.bostonglobe.com/metro/2016/08/01/legislature-orders-insurers-cover-long-term-lyme-treatment-overriding-baker-veto/YBZ3DGaUy8bHRWMYaOyQdM/story.html$

¹¹ https://www.lymedisease.org/wp-

content/uploads/2011/10/RI passes bill mandating insurance coverage 2003 978837748.pdf

¹² https://www.lymedisease.org/127/

¹³ http://www.providencejournal.com/breaking-news/content/20140712-new-vt.-law-aims-to-aid-in-treatment-of-lyme-disease-as-cases-soar.ece

¹⁴ https://www.poughkeepsiejournal.com/story/news/health/lyme-disease/2014/12/18/cuomo-signs-lyme-disease-bill/20576915/

¹⁵ https://www.pressherald.com/2015/06/29/maine-legislature-clears-way-for-long-term-lyme-disease-treatment

 $^{^{16}}$ http://www.tamatoledonews.com/page/content.detail/id/603916/Cornfileds--Common-Sense-and-Community.html?nav=5002

Disease and State Policy Primer for State Legislators". ¹⁷ In this publication, the IDSA criticized legislature "Requiring health insurers to cover Lyme disease treatments that are not supported by scientific evidence, including long-term antibiotic use". ¹⁸ A search of the IDSA's website shows enormous concern on behalf of the IDSA regarding health insurers being allowed to deny long term antibiotic treatment for Lyme patients with treatment failure. ¹⁹

III. SECTION 1 ANTITRUST CLAIM

To state a claim under Section 1 of the Sherman Act, Plaintiffs must show that the IDSA "(1) engaged in a conspiracy (2) that restrained trade (3) in a particular market." *Spectators' Commc'n Network Inc. v. Colonial Country Club*, 253 F.3d 215, 220 (5th Cir.2001). A necessary ingredient of any Section 1 conspiracy is a showing of concerted action on the part of the defendants. *See Monsanto Co. v. Spray–Rite Serv. Corp.*, 465 U.S. 752, 761, 104 S.Ct. 1464, 79 L.Ed.2d 775 (1984). To establish concerted action, the plaintiff must present "evidence that reasonably tends to prove that the [defendants] had a conscious commitment to a common scheme designed to achieve an unlawful objective." *Id.* at 768, 104 S.Ct. 1464.

Plaintiffs can rely on circumstantial evidence as long as they show that circumstantial evidence supports an inference of conspiracy and tends to exclude independent conduct. *Viazis v. Am. Ass'n of Orthodontists*, 314 F.3d 758, 763 (5th Cir.2002); *Abraham & Veneklasen Joint Venture v. Am. Quarter Horse Ass'n*, 776 F.3d 321, 331–32 (5th Cir. 2015).

A. IDSA and Insurance Companies Engaged in a Conspiracy to Restrain Trade

As a result of the Defendants destruction of evidence in this case, Plaintiffs are forced to rely on circumstantial evidence to support the conspiracy between the IDSA and health insurance companies.

¹⁷ https://www.idsociety.org/globalassets/idsa/topics-of-interest/lyme/lyme-state-policy-primer-update-2016-final.pdf

 $[\]overline{}^{18}$ *Id.* at page 2.

¹⁹ https://www.idsociety.org/search-results?query=lyme#/score/DESC/0/lyme-insurer

The evidence before this Court establishes that up until the mid-1990's, health insurance companies paid for long term antibiotics for Lyme disease until they determined it cut into profits. (Ex. A, Dr. Richard Sanchez deposition, page 90, line 8 – page 93, line 14). One of the areas flagged by insurance companies was Lyme disease. (Ex. A, Sanchez deposition, pages 90 – 116). Dr. Sanchez testified that Empire Blue Cross/Blue Shield created an arbitrary policy of only covering short-term antibiotic treatment that had no "medical or scientific justification". (Ex. A, Sanchez deposition, page 114, lines 3-9).

Once these arbitrary guidelines were put into place by Empire Blue Cross/Blue Shield, the other health insurance companies followed suit by denying coverage for Lyme treatment after the arbitrary timeframe.²⁰ From the mid-1990's up to the enactment of the 2000 IDSA Guidelines, health insurance companies began improperly denying insurance coverage for antibiotics after short term treatment – usually 28 days of treatment.²¹ The health insurance companies began referring to any treatment beyond shot-term antibiotics as "experimental"²².

At the same time that health insurance companies created arbitrary guidelines for Lyme disease, they began paying large consulting fees to some of the most influential Lyme disease "experts". For example, in the 1990's and early 2000's Sigal, was hired by the IDSA to review the Lyme disease guidelines before they were published, was an "active expert witness for insurance companies" and was hired on up to five Lyme disease cases a year for more than ten years. (Ex. B, Sigal deposition, page 44, lines 7-19 and page 59, lines 9-24).

Shapiro, one of the people hired by the IDSA to author the 2000 and 2006 IDSA Guidelines, testified that he provided expert testimony in around 75 to 80 cases, offered testimony

²⁰ See Pamela Weintraub, Cure Unknown, Inside the Lyme Epidemic, pages 306-31, St. Martin's Griffin, 2008.

²¹ See Pamela Weintraub, Cure Unknown, Inside the Lyme Epidemic, pages 306-31, St. Martin's Griffin, 2008.

²² *Id*.

in court more than a "dozen" times, and twice testified in front of medical boards. (Ex. D, Shapiro deposition, page 6, lines 3-24). In 2017, Shapiro admitted in a publication he "has been an expert witness in malpractice cases involving Lyme disease".²³

Dattwyler, another one of the guideline authors retained by the IDSA, testified he was hired numerous times by insurance companies to testify as an expert witness in Lyme cases. (Ex. E, deposition, page 13, lines 1-4). Dattwyler was also hired by insurance companies as a consulting expert and to review medical records for Lyme patients and charged between \$500 and \$600 an hour. (Ex. E, deposition, page 13, lines 7-16 and page 189, line 19 – page 190, line 6).

In November of 2006, the Attorney General of the state of Connecticut, Richard Blumenthal investigated the IDSA Guidelines and served CIDs on many of the guideline authors and health insurance companies. (Ex. F, CIDs from Connecticut AG's office). After reviewing their responses, Blumenthal concluded: "several of the most powerful IDSA panelists" had undisclosed financial interests in insurance companies including 'consulting arrangements with insurance companies".²⁴

After receiving the large consulting fees from insurance companies, the IDSA guideline authors put the same arbitrary guidelines into the IDSA Guidelines that the insurance companies created in the late 1990's. (Ex. G, 2000 IDSA Guidelines and Ex. C, 2006 IDSA Guidelines). For example, the 2006 guidelines call for only short-term antibiotics and claim there is no reason to ever administer long-term antibiotics because there is absolutely no treatment failure for Lyme disease. (Ex. C, 2006 IDSA Guidelines). Both the 2000 and 2006 Guidelines contain similar language claiming treatment failure does not exist. (Ex. G, 2000 IDSA Guidelines and Ex. C, 2006

²³ https://www.amjmed.com/article/S0002-9343(17)30138-9/pdf

²⁴ http://www.empirestatelymediseaseassociation.org/Archives/CTAGPressReleaseIDSAResponse.htm

IDSA Guidelines). As medical journals point out: "insurance companies have used these guidelines to justify their restricted coverage of long-term antibiotic treatment of Lyme disease." ²⁵

The problem is so bad that the states with the highest incidents of Lyme disease passed laws, or proposed legislation, requiring insurers pay for long term antibiotic treatment for Lyme disease patients who experience treatment failure including Massachusetts²⁶, Rhode Island²⁷, Connecticut²⁸, Vermont²⁹, New York³⁰, Maine³¹, and Iowa³².

In response to states passing Lyme legislature requiring coverage for long-term antibiotic treatment, the IDSA published a statement to state legislatures called: "Lyme Disease and State Policy Primer for State Legislators".³³ In this publication, the IDSA criticized legislature "Requiring health insurers to cover Lyme disease treatments that are not supported by scientific evidence, including long-term antibiotic use".³⁴

In its Motion, the IDSA claimed, numerous times, that it is an independent organization with no connection to insurance companies. If this is true, then why does the IDSA feel it is necessary to publish a statement to state legislatures around the country helping health insurance companies?

²⁵ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2435453/

²⁶ https://www.bostonglobe.com/metro/2016/08/01/legislature-orders-insurers-cover-long-term-lyme-treatment-overriding-baker-veto/YBZ3DGaUy8bHRWMYaOyQdM/story.html

²⁷ https://www.lymedisease.org/wp-

content/uploads/2011/10/RI passes bill mandating insurance coverage 2003 978837748.pdf

²⁸ https://www.lymedisease.org/127/

²⁹ http://www.providencejournal.com/breaking-news/content/20140712-new-vt.-law-aims-to-aid-in-treatment-of-lyme-disease-as-cases-soar.ece

³⁰ https://www.poughkeepsiejournal.com/story/news/health/lyme-disease/2014/12/18/cuomo-signs-lyme-disease-bill/20576915/

 $^{^{31}}$ https://www.pressherald.com/2015/06/29/maine-legislature-clears-way-for-long-term-lyme-disease-treatment/

³² http://www.tamatoledonews.com/page/content.detail/id/603916/Cornfileds--Common-Sense-and-Community.html?nav=5002

³³ https://www.idsociety.org/globalassets/idsa/topics-of-interest/lyme/lyme-state-policy-primer-update-2016-final.pdf

³⁴ *Id.* at page 2.

The circumstantial evidence supports an inference of conspiracy between the IDSA and health insurance companies and establishes the only reason the IDSA guideline authors created guidelines claiming there is 0% treatment failure is because they engaged in a conspiracy with health insurance companies. *Viazis v. Am. Ass'n of Orthodontists*, 314 F.3d 758, 763 (5th Cir. 2002); *Abraham & Veneklasen Joint Venture v. Am. Quarter Horse Ass'n*, 776 F.3d 321, 331–32 (5th Cir. 2015).

The evidence before this Court also tends to exclude independent conduct. For example, the IDSA panelists agree that there is treatment failure in the treatment of Lyme disease, just like there is treatment failure for every single disease. (Ex. H, Wormser deposition, page 36, lines 11-13m and Ex. B, Sigal deposition, page 42, lines 4-19). According to IDSA Guideline authors, treatment failure can be as high as 10%, which means that one in ten people need long-term antibiotic treatment. *Id*.

Sigal was hired by the IDSA to review the Lyme disease guidelines for accuracy before they were published and who was thanked by the IDSA for "thoughtful review of an earlier draft of these guidelines". (Ex. B, Sigal deposition, page 58, line 12 – page 59, line 24 and Ex. ?, 2006 IDSA guidelines). Sigal knew when he reviewed the guidelines that treatment failure existed for treatment of Lyme disease using short-term antibiotics. *Id.* Yet, he allowed the IDSA Guidelines to be published stating that there is no treatment failure:

"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."

The only reason why Sigal and the other guideline authors would allow false statements regarding treatment failure into the IDSA Guidelines is because of the large payments made by the health insurance companies. There is no other possible reason why these Lyme disease "experts" would get treatment failure so wrong.

The only possible explanation for the IDSA's claim that everyone with Lyme disease is cured with short-term antibiotics and treatment failure does not exist is that the IDSA and health insurance companies engaged in a conspiracy to restrain competition.

When analyzing whether the conduct imposes an unreasonable restraint on competition, "the finder of fact 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." *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *see also Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977). A standard-setting organization can obtain monopoly power by allowing members with an economic interest in restraining competition to bias its standard-setting process. *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 501 (1988).

The IDSA takes the position that it is the "leading medical authorities on the diagnosis and treatment of Lyme disease" and doctors all over the country rely solely on these guidelines:

- Q. When the IDSA puts these guidelines out, they anticipate that doctors all around the country are going to rely on the guidelines in the treatment and diagnosis of Lyme disease, correct?
- A. That is correct.

(Ex. I, IDSA corporate representative Busky's deposition, page 61, line 16 – page 62, line 6).

The very first paragraph of the 2006 guidelines state, in bold print, that the guidelines are to be used by healthcare providers in the diagnosis and treatment of Lyme disease:

The guidelines are intended for use by health care providers who care for patients who either have these infections or may be at risk for them. For each of these Ixodes tickborne infections, information is provided about prevention, epidemiology, clinical manifestations, diagnosis, and treatment.

(Ex. C, 2006 IDSA Guidelines).

The IDSA and the Guideline authors tell the entire Lyme disease market that it is the leading authority in the treatment of Lyme disease and that the only guidelines that should be followed are theirs. (Ex. I, Busky deposition, page 61, line 16 – page 62, line 6 and Ex. B, Sigal deposition, page 39, lines 14-18 and Ex. D, Shapiro deposition, page 58, line 20 – page 59, line 7). The IDSA represents that the only thing doctors treating Lyme disease need to rely on are their Guidelines. *Id*.

The circumstantial evidence in this case is sufficient to allow this case to proceed to a jury to allow them the opportunity to decide this case.

B. The IDSA and the Insurance Defendants Acted to Restrain Trade in an Antitrust Relevant Market

Courts in the Fifth Circuit recognize that "market definition is a deeply fact-intensive inquiry." *Vaughn Med. Equip. Repair Serv., L.L.C. v. Jordan Reses Supply Co., No.* 10-00124, 2010 WL 3488244, at *19 (E.D. La. Aug. 26, 2010). *Accord Todd v. Exxon Corp.*, 275 F.3d 191, 199-200 (2d Cir. 2001) ("market definition is a deeply fact-intensive inquiry"); *T&T Geotechnical, Inc. v. Union Pacific Resources Co.*, 944 F. Supp. 1317, 1323 (N.D. Tex. 1996) ("[P]roper market definition requires a factual inquiry into the commercial realities faced by consumers"); *Creative Copier Servs. v. Xerox Corp.*, 344 F. Supp. 858, 863 (D. Conn. 2004) (market definitions are "deeply fact-intensive inquiry").

The market Plaintiffs are asserting is the Lyme disease treatment market in the United States. This market is relevant and proper in an antitrust case. For example, in *Wilk v. Am. Med. Ass'n*, the court held that a nationwide market for "the treatment of musculoskeletal problems" was a relevant and proper antitrust market. *See Wilk v. Am. Med. Ass'n*, 671 F. Supp. 1465, 1478 (N.D. Ill. 1987), aff'd, 895 F.2d 352 (7th Cir. 1990) (holding "The relevant market was the provision of health care services to the American public on a nationwide basis, particularly for the treatment of musculoskeletal problems.").

Many other courts have determined that markets similar to the market asserted by Plaintiffs in this case are relevant and acceptable in an antitrust case. *Weiss v. York Hosp.*, 745 F.2d 786, 827 (3d Cir. 1984) (holding that nationwide "inpatient hospital health care" was a relevant market in an antitrust case); *Oltz v. St. Peter's Cmty. Hosp.*, 861 F.2d 1440, 1447 (9th Cir. 1988) (holding "anesthesia services" is a relevant market in antitrust case); *Leyba v. Renger*, 874 F. Supp. 1229, 1238 (D.N.M. 1994) (holding nationwide "hospital-based osteopathic anesthesiology" is a relevant market in antitrust case).

In *Bio-Med. Applications Mgmt. Co., Inc v. Dallas Nephrology Associates*, the district court dismissed the case because of lack of evidence but recognized that a relevant antitrust market is the "dialysis treatment market". *See Bio-Med. Applications Mgmt. Co., Inc v. Dallas Nephrology Associates*, 4:94CV37, 1995 WL 215302, at *2 (E.D. Tex. Feb. 6, 1995).

According to the CDC, Lyme disease exists in all fifty states.³⁵ The IDSA admits that the IDSA Guidelines are disseminated to doctors treating Lyme disease in the United States:

The objectives of these practice guidelines are to provide clinicians and other health care practitioners with recommendations for treatment of patients in the United States with suspected or established Lyme disease.

(Ex. C, 2006 IDSA Guidelines).

Defining the relevant market is a question of fact for the jury, unless a party's proposed markets are so unsupported by the evidence or proper antitrust economics that no reasonable jury could properly find in favor of the party on the issue. *Shah v. VHS San Antonio Partners, L.L.C.*, 985 F.3d 450, 454 (5th Cir. 2021); *Sportservice, Inc. v. Charles O. Finley*, 676 F.2d 1291, 1299 (9th Cir., 1982).

³⁵ https://www.cdc.gov/lyme/datasurveillance/maps-recent.html

The evidence before this Court establishes that there is a Lyme disease treatment market and, as set forth below, the IDSA restrains trade in that market by dominating it and controlling a monopoly share of the market.

C. IDSA Dominates and Controls a Monopoly Share of Lyme Disease Treatment Market

The IDSA represents to the country that it is the leading authority in the treatment of Lyme disease and continually pushes for its guidelines to be the only thing doctors need to follow in treating Lyme disease. (Ex. J, June 18, 2014 letter to congress and Ex. K, May 22, 2015 letter to congress). To protect their monopoly on the Lyme treatment market, the IDSA tries to influence state legislators and congress. *Id*.

When states were trying to pass legislature to protect Lyme patients with treatment failure, the IDSA published "Lyme Disease and State Policy Primer for State Legislators". ³⁶ In this publication, the IDSA pointed out its Lyme disease credentials: "The Infectious Diseases Society of America (IDSA) is the largest infectious diseases medical society in the United States, representing more than 10,000 physicians and scientists." The IDSA claims that long-term antibiotics are not necessary and the reason for that is their Guidelines which are recognized as the source doctors look to in treating Lyme disease: "IDSA's 2006 practice guidelines for the clinical assessment, treatment, and prevention of Lyme disease are widely recognized and referenced by physicians across the country." ³⁷

In 2014, United States Congress was trying to pass H.R. 4701 the Vector-Borne Disease Research Accountability and Transparency Act.³⁸ This act was written to "develop a scientific framework for the conduct or support of research on such vector-borne disease" including "the prevention, diagnosis, and treatment of acute and chronic vector-borne disease" like Lyme

³⁶ https://www.idsociety.org/globalassets/idsa/topics-of-interest/lyme/lyme-state-policy-primer-update-2016-final.pdf

 $^{^{37}}$ *Id*.

³⁸ https://www.govinfo.gov/content/pkg/BILLS-113hr4701ih/pdf/BILLS-113hr4701ih.pdf

disease.³⁹ Not wanting anyone to interfere with its monopoly on the treatment of Lyme disease, the IDSA wrote to the committee chairperson and ranking member of the committee in charge of H.R. 4701. (Ex. J, June 18, 2014 letter to congress). The IDSA opposed H.R. 4701 and urged the committee to vote against it because the IDSA already published its findings on how to treat Lyme disease and "Approximately 20 clinical and scientific organizations in North America and Europe, and numerous scientific and public health bodies agree with the IDSA's perspective." *Id*.

In 2015, the IDSA again wrote to Congress to tout its guidelines and in the first sentence represented itself as the "leading medical authority on the diagnosis and treatment of Lyme disease." (Ex. K, May 22, 2015 letter to congress).

If the IDSA is an independent group simply publishing guidelines, then why does it go out of its way to protect its guidelines and tout them as the only real guidelines for the treatment of Lyme disease?

In December of 2016, Congress enacted the 21st Century Cures Act which authorized the U.S. Department of Health and Human Services to establish a Tick-Borne Disease Working Group to serve as a Federal Advisory Committee.⁴⁰ The Working Group is comprised federal and public members and charges the Working Group to provide a report to Congress and the HHS Secretary on its findings and any recommendations every two years.⁴¹

In the HHS 2020 Subcommittee Report to the Tick-Borne Disease Working Group, the Training, Education, Access to Care, and Reimbursement Subcommittee determined:

The IDSA is the largest infectious disease specialty society in the world, publishes the two largest medical journals in the field, dominates related peer review, and often functions as a gatekeeper for hospital staff privileges. Its restrictive Lyme disease guidelines—which make it difficult for patients to achieve diagnosis and receive care—have been adopted by many insurers and are often referred to as an authoritative source by many physicians who do

³⁹ *Id*.

 $^{{}^{40}\ \}underline{https://www.hhs.gov/ash/advisory-committees/tickbornedisease/about/21-century-cures-act/index.html}$

⁴¹ *Id*.

not specialize in the disease. In addition, members of the IDSA provide expert testimony to enforce its views through medical board disciplinary actions against practitioners who do not comply with its guidelines. 42

In its Motion, the IDSA claims that doctors can simply rely on other guidelines and ignore the IDSA Guidelines. This is impossible because of the IDSA's dominance in the Lyme disease treatment market. As the 2020 Tick-Borne Disease Working Group's final 2020 report to Congress shows, there are only two different guidelines for the treatment of Lyme disease – the IDSA Guidelines and the ILADS Guidelines.⁴³ Since the ILADS guidelines were not published until 2014, the IDSA clearly had a monopoly from 2000 until 2014.⁴⁴

Even after 2014, the IDSA maintained its monopoly on Lyme treatment guidelines. As the 2020 Tick-Borne Disease Working Group's final 2020 report to Congress points out, most doctors do not know about the ILADS Guidelines because the IDSA works hard to keep them secret: "Although IDSA is aware that there are two standards of diagnosis and care for patients with Lyme disease, their treatment guidelines do not disclose this fact, and many patients and clinicians may not be aware that another diagnostic and treatment approach exists." 45

As the IDSA's corporate representative testified, the IDSA touts itself as the leading medical authority on the treatment of Lyme disease so that doctors rely only on the IDSA Guidelines:

Q. If you were a small-town doctor in the city of Texarkana, Texas, and you are going to treat Lyme disease, you would rely, likely rely on the guidelines of the leading medical authorities on the diagnosis and treatment of Lyme disease, correct?

⁴² https://www.hhs.gov/ash/advisory-committees/tickbornedisease/reports/training-education-access-to-care-and-reimbursement-subcomm-2020/index.html

⁴³ https://www.hhs.gov/sites/default/files/tbdwg-2020-report to-ongress-final.pdf

⁴⁴ *Id*.

⁴⁵ *Id*.

- A. That would be my understanding.
- Q. When the IDSA puts these guidelines out, they anticipate that doctors all around the country are going to rely on the guidelines in the treatment and diagnosis of Lyme disease, correct?

A. That is correct.

(Ex. I, Busky's deposition, page 61, line 16 – page 62, line 6).

The evidence clearly establishes that the IDSA controls a monopoly share of the Lyme disease treatment market.

D. Voluntary Guidelines Can be Unreasonable Restraint on Competition

Defendants argue that the IDSA cannot be held liable for unreasonable restraint on competition because the IDSA Guidelines are voluntary. As set forth above, the Guidelines are no voluntary because the IDSA represents that they are the only guidelines that should be followed. Even if they are voluntary, the IDSA can still be held liable for unreasonable restraint on competition. *Am. Soc. of Mech. Engineers, Inc. v. Hydrolevel Corp.*, 456 U.S. 556, 558, 102 S. Ct. 1935, 1938, 72 L. Ed. 2d 330 (1982).

In American Society of Mechanical Engineers, Inc. v. Hydrolevel Corp., the Supreme Court held that the American Society of Mechanical Engineers, Inc. ("ASME"), a nonprofit standard-setting organization, could be held civilly liable under the antitrust laws for acts of its agents in creating voluntary guidelines. 456 U.S. at 559, 102 S.Ct. 1935. The Court held: "ASME promulgates and publishes over 400 separate codes and standards for areas of engineering and industry. These codes, while only advisory, have a powerful influence." 456 U.S. at 559, 102 S.Ct. 1935.

Defendants cite no law holding that so-called voluntary guidelines cannot unreasonably restrain trade. In fact, the primary case relied upon by Defendants is *Consol. Metal* and it has

nothing to do with guidelines. *Consol. Metal Products, Inc. v. Am. Petroleum Inst.*, 846 F.2d 284, 292 (5th Cir. 1988). Consol. Metal deals with "a trade association that evaluates products and issues opinions". *Id*.

IV. <u>SECTION 2 – ANTITRUST CLAIM</u>

Section 2 of the Sherman Act makes it unlawful for any person or firm to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2. Plaintiffs allege that Defendants attempted to monopolize or conspired to monopolize the Dallas–Fort Worth area taxicab market. Attempted monopolization has three elements: that (1) the defendant engaged in predatory or exclusionary conduct, (2) the defendant possessed the specific intent to monopolize, and (3) there was a dangerous probability that the defendant would succeed in his attempt. *Bell Atl. Corp. v. AT & T Corp.*, 339 F.3d 294, 302 (5th Cir.2003) (citing *Taylor Pub. Co. v. Jostens*, Inc., 216 F.3d 465, 474 (5th Cir.2000)).

On page 25 of its Motion, the IDSA begins section 4 with some of the elements of Plaintiffs' Section 2 claim. But the next sentence goes back into Section 1 and the rest of the paragraphs in section 4 seem to address Plaintiffs' Section 1 claim.

There is nothing in Defendants' Motion claiming Plaintiffs lack evidence to support their Section 2 antitrust claim and there are no Section 2 arguments for Plaintiffs to respond to in Defendants' Motion.

V. <u>PLAINTIFFS' ANTITRUST DAMAGES ARE NOT DERIVATIVE OF PERSONAL INJURIES</u>

Defendants argue that Plaintiffs' damages are derivative of their personal injury damages and are not recoverable. Most of the cases cited by Defendants relate to RICO claims and hold that derivative personal injury claims are not recoverable under RICO. See e.g. Hughes v. Tobacco Inst., Inc., 278 F.3d 417 (5th Cir. 2001); Jackson v. Sedgwick Claims Mgmt. Services, Inc., 731

F.3d 556 (6th Cir. 2013). The one case addressing antitrust claim is distinguishable because it does not relate to a standard setting case. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 337, 99 S. Ct. 2326, 2330, 60 L. Ed. 2d 931 (1979).

This Court already ruled that Plaintiffs' properly pled an antitrust injury in a standard setting antitrust lawsuit:

Plaintiffs have adequately claimed an antitrust injury, namely that Defendants have restrained trade by "treating the IDSA guidelines as mandatory" and setting a restrictive and false standard of care for the testing, diagnosing and treating of Lyme disease.

Torrey v. Infectious Diseases Soc'y of Am., 5:17-CV-00190-RWS, 2018 WL 10124894, at *8 (E.D. Tex. Sept. 27, 2018).

The antitrust injuries alleged in the Third Amended Complaint are the same as the antitrust injuries this Court held are antitrust injuries. (Docket #361 ¶¶ 119- 121). Since Plaintiffs' current antitrust injuries are the same injuries alleged in the Original Complaint "Plaintiffs have sufficiently alleged a reduction in competition as a result of Defendants' standard-setting behavior." Id. at *9.

VI. PLAINTIFFS' CLAIMS NOT BARRED BY STATUTE OF LIMITATIONS

The statute of limitations is tolled because this is a continuing conspiracy. The four-year statute of limitations for an antitrust action begins to run when a defendant commits an act that injures a plaintiff's business. *Kaiser Aluminum & Chemical Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1051 (5th Cir. 1982). An antitrust cause of action can "accrue whenever the defendant commits an overt act in furtherance of an antitrust conspiracy or, in the absence of an antitrust conspiracy, commits an act that by its very nature is a continuing antitrust violation." *Kaiser Aluminum*, 677 F.2d at 1051. *Accord Poster Exchange, Inc. v. Nat. Screen Serv.*, 517 F.2d 117, 126 (5th Cir. 1975); *O'Dell v. General Motors Corp.*, 122 F. Supp. 2d 721, 726 - 27 (E.D. Tex. 2000).

The evidence in this case establishes that the IDSA continues to commit overt acts that continue the antitrust violations. For example, in June of 2014, less than three years before this lawsuit was filed, the IDSA wrote to congress opposed H.R. 4701 denying the existence of treatment failure. (Ex. J, June 18, 2014 letter to congress, paragraph 3). This letter and attempt to prevent congress from enacting legislature helping Lyme patients with treatment failure was an overt in furtherance of the conspiracy to deny treatment for these Lyme patients.

In May of 2015, less than two years before this lawsuit was filed, the IDSA again wrote to Congress to tout its guidelines which deny the existence of treatment failure. (Ex. K, May 22, 2015 letter to congress).

In 2016, a year before this lawsuit was filed, the IDSA published "Lyme Disease and State Policy Primer for State Legislators" in an attempt to issues legislatures from all fifty states. ⁴⁶ In this publication, the IDSA claims that long-term antibiotics are not necessary and continues its conspiracy with the insurance companies by claiming that "Requiring health insurers to cover Lyme disease treatments that are not supported by scientific evidence, including long-term antibiotic use and experimental drugs."

As if that were not enough, the IDSA recently released the 2020 Guidelines for Lyme disease and again deny the existence of chronic Lyme disease.⁴⁸

VII. CONCLUSION

For these reasons, Plaintiffs respectfully ask this Court to deny Defendants Motion for Summary Judgment on Plaintiffs' antitrust claims and pray for any other relief to which they are entitled.

⁴⁶ https://www.idsociety.org/globalassets/idsa/topics-of-interest/lyme/lyme-state-policy-primer-update-2016-final.pdf

⁴⁷ *Id*.

⁴⁸ https://www.idsociety.org/practice-guideline/lyme-disease

Respectfully submitted,

SHRADER & ASSOCIATES, LLP

BY: /s/Eugene Egdorf
EUGENE EGDORF
State Bar No. 06479570
3900 Essex Lane, Suite 390,
Houston, TX 77027
(713) 782-0000 phone
(713) 571-9605 fax

E-mail: gene@shraderlaw.com

BY: /s/ Lance Lee

LANCE LEE
State Bar No. 24004762
5511 Plaza Drive
Texarkana, Texas 75503
(903) 223-0276 phone
(903) 223-0210 fax

Email: wlancelee@gmail.com

RUSTY HARDIN & ASSOCIATES, LLP

BY: /s/ Daniel R. Dutko
DANIEL R. DUTKO
State Bar No. 24054206
RYAN HIGGINS
State Bar No. 24007362
1401 McKinney St., Suite 2250
Houston, Texas 77010
(713) 652-9000 phone
(713) 652-9800 fax

Email: ddukto@rustyhardin.com
Email: rhiggins@rustyhardin.com

ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on March 2, 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.

Alvin Dunn Michael A. Warley PILLSBURY WINTHROP SHAW PITTMAN, LLP – WASHINGTON 1200 Seventeenth Street, NW Washington, D.C. 20036

-and-

Ronald C. Low PILLSBURY WINTHROP SHAW PITTMAN, LLP - AUSTIN 401 Congress Ave., Suite 1700 Austin, TX 78701

Attorneys for Defendants Infectious Diseases Society of America, Dr. Gary P. Wormser, Dr. Raymond J. Dattwyler, Dr. Eugene Shapiro, Dr. John J. Halperin, Dr. Leonard Sigal, and Dr. Allen Steere

/s/ Daniel Dutko
Daniel R. Dutko