

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

BARBARA VINCENT, et al.,
Plaintiffs,

v. Civil Action No. 2:13-cv-08669

BOSTON SCIENTIFIC CORPORATION,
Defendant.

MEMORANDUM OPINION AND ORDER

Pending before the court are several *Daubert* motions filed by both the defendant and the plaintiffs. Briefing is complete regarding these motions, and the motions are now ripe for consideration.

I. Background

This case resides in one of seven Multidistrict Litigations (“MDLs”) assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). This case resides in the Boston Scientific Corporation (“BSC”) MDL, MDL No. 2326. The parties have disclosed experts to render opinions regarding the elements of the case's various causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading;” the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by [v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); see also *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’” (alteration in original)); see also *Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (citations and internal quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the “the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.” *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matter

I begin by addressing a preliminary matter that affects many of the *Daubert* motions. Both parties consistently challenge experts’ opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury’s fact-finding function by allowing an expert to testify as to a party’s knowledge, state of mind, or whether a party acted reasonably. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant’s knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party’s then-existing state of mind “are the sort of questions that lay jurors have been answering without expert assistance from time immemorial,” and therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int’l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Likewise, “opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using “legal terms of art,” such as “defective,” “unreasonably dangerous,”

or “proximate cause.” *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to apply them in this case. This does not mean that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

IV. BSC’s Daubert Motions

a. Dr. Niall Galloway, M.D.

BSC raises a number of objections to the testimony of Dr. Niall Galloway. [ECF No. 30]. I have addressed all of these objections before in *Heatherly v. Boston Sci. Corp.*, No. 2:13-cv-00702, 2018 WL 3797507 (S.D. W. Va. Aug. 9, 2018). I adopt my reasoning and findings in *Heatherly* here. As such, BSC’s Motion with regard to Dr. Galloway’s opinions on alphabetizing risks in DFU trails and his opinions on trocars is **GRANTED**, and these opinions are **EXCLUDED**. The remaining objections in BSC’s Motion are **DENIED**. BSC’s Motion [ECF No. 30] is **GRANTED in part** and **DENIED in part**.

b. Michael Thomas Margolis, M.D.

BSC seeks to exclude the testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist who offers general causation

opinions in this case. I have addressed these objections in *Sanchez v. Boston Scientific Corp.*, No. 2:212-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014). I adopt my reasoning and findings from *Sanchez*. As such, BSC's Motion with regard to Dr. Margolis's failure to consider contrary studies and his opinion on a lack of long-term data on reliability ground is **DENIED**. BSC goes on to challenge opinions offered by Dr. Margolis that were not disclosed in his expert report and discussion of materials that were not cited to in his expert report. Any testimony on direct examination using undisclosed sources as support for opinions is **EXCLUDED** on Rule 26 grounds. BSC also seeks to exclude case-specific causation testimony of Dr. Margolis. I **RESERVE** ruling on case-specific causation testimony until trial. Per my reasoning in *Sanchez*, all other aspects of BSC's Motion to Exclude the testimony of Dr. Margolis are **GRANTED**. BSC's Motion to exclude certain testimony of Dr. Margolis [ECF No. 31] is **GRANTED in part, DENIED in part, and RESERVED in part**.

c. Dr. Thomas H. Barker, Ph.D.

The plaintiffs offer Dr. Barker as a biomaterials expert. He seeks to testify as to general opinions, such as those related to the biocompatibility of polypropylene mesh, mesh degradation, scar formation, mesh design, and mesh testing. I have consistently excluded the testimony of Dr. Barker, and do so here again. *In re Boston Sci. Corp. Pelvic Repair Litig.*, MDL No. 2326, 2018 WL 2426222 (S.D. W. Va. May 29, 2018); *Sanchez v. Boston Sci. Corp.*, 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014). I adopt my reasoning and findings from these orders here. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [ECF No. 33] is **GRANTED**.

d. Dr. Bobby Shull, M.D.

Dr. Shull is a urogynecologist offered by the plaintiffs to provide expert opinion testimony on the design and labeling of the Uphold device. I have previously addressed BSC's objections to Dr. Shull's testimony in *In re Boston Sci. Corp. Pelvic Repair System Prods. Liab. Litig.*, MDL No. 2326, 2018 WL 2440257 (S.D. W. Va. May 30, 2018). I adopt my reasoning and findings from that opinion here. Therefore, BSC's *Daubert* Motion concerning Dr. Shull [ECF No. 41] is **GRANTED**.

e. Dr. Jimmy Mays, Ph.D.

Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee. His particular field of expertise is polymer science. I have previously addressed BSC's objections to the testimony of Dr. Mays in *In Re Boston Sci. Corp. Pelvic Repair System Prods. Liab. Litig.*, MDL No. 2326, 2018 WL 2426132 (S.D. W. Va. May 29, 2018). I adopt my reasoning and findings from that opinion here. Therefore, BSC's *Daubert* Motion concerning Dr. Jimmy Mays [ECF No. 42] is **GRANTED**.

f. Dr. Bruce Rosenzweig, M.D.

Dr. Rosenzweig is a urogynecologist and a professor of obstetrics and gynecology in Chicago, Illinois. Plaintiffs offer Dr. Rosenzweig as a general causation expert and a case specific expert. I have addressed BSC's objections to Dr. Rosenzweig's testimony in *Carlson v. Boston Sci. Corp.*, No. 2:13-cv-05475, 2015 WL 1931311 (S.D. W. Va. April 28, 2015). I adopt my reasoning and findings from that opinion here. Therefore, BSC's Motion with regard to Dr. Rosenzweig's opinions based on his general causation report is **GRANTED**. BSC also objects to Dr. Rosenzweig's

case specific testimony. I **RESERVE** ruling on the case specific testimony until trial. BSC's Motion [ECF No. 43] is **GRANTED in part** and **RESERVED in part**.

g. Dr. Peggy Pence, Ph.D., RAC, FRAPS

Dr. Peggy Pence is a clinical and regulatory consultant who provides advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the FDA. I have addressed BSC's objections to Dr. Pence's testimony before in *Armstrong v. Boston Sci. Corp.*, No. 2:13-cv-24784, 2018 WL 3824375 (S.D. W. Va. Aug. 10, 2018). I adopt my reasoning and findings in that opinion here. Accordingly, BSC's Motion with regard to Dr. Pence's qualifications is **DENIED**. I also **DENY** BSC's Motion to exclude any opinion based on the HAS, NICE, or GHTF. BSC's Motion to exclude Dr. Pence's opinion on premarket clinical testing is also **DENIED**. All other aspects of BSC's Motion to Exclude Dr. Pence's testimony are **GRANTED**. In summary, BSC's Motion to Exclude [ECF No. 44] is **GRANTED in part** and **DENIED in part**.

h. Dr. Russell Dunn, Ph.D.

Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies LLC, a company that focuses on process and product design issues, process and product safety, and polymer product analysis. I have addressed BSC's objections to Dr. Dunn's testimony before in *Bethune v. Boston Scientific Corp.*, No. 2:13-cv-06199, 2016 WL 2983697 (S.D. W. Va. May 20, 2016). I adopt my reasoning and findings from that opinion here. Accordingly, BSC's Motion to Exclude [ECF No. 45] is **GRANTED**.

i. Dr. Scott Guelcher, Ph.D.

Dr. Guelcher is a chemical engineer offered by the plaintiff to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. I have addressed BSC's objections to Dr. Guelcher's testimony before in *Bethune v. Boston Sci. Corp.*, No. 2:13-cv-06199, 2016 WL 2983697 (S.D. W. Va. May 20, 2016). I adopt my reasoning and findings from that opinion here. Accordingly, BSC's Motion to Exclude [ECF No. 46] is **GRANTED**.

j. Dr. Richard Trepeta, M.D.

Dr. Trepeta is a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease. I have addressed BSC's objections to Dr. Trepeta's testimony before in *Bethune v. Boston Sci. Corp.*, No. 2:13-cv-06199, 2016 WL 2983697 (S.D. W. Va. May 20, 2016). I adopt my reasoning and findings from that opinion. As such, BSC's Motion with regard to any opinions based on the 24 pathology reports is **GRANTED**. I **RESERVE** ruling on Dr. Trepeta's case specific opinions until trial. The remaining objections in BSC's Motion to Exclude are **DENIED**. In summary, BSC's Motion to Exclude [ECF No. 48] are **GRANTED in part** and **DENIED in part**.

k. Dr. Vladamir Iakovlev, M.D.

Dr. Vladamir Iakovlev is an anatomical pathologist and the Director of Cytopathology as the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. I have addressed BSC's objections to Dr. Iakovlev's testimony in *Armstrong v. Boston Sci. Corp.*, No. 2:13-cv-24784, 2018 WL 3824375 (S.D. W. Va. Aug. 10, 2018). I adopt my reasoning and findings from that opinion. Accordingly, BSC's Motion to Exclude Dr. Iakovlev's general causation testimony is **GRANTED**. I

RESERVE decision on Dr. Iakovlev's case specific testimony until trial. In summary, BSC's Motion to Exclude [ECF No. 56] is **GRANTED in part** and **RESERVED in part**.

V. Plaintiffs' Daubert Motions

a. Dr. Gary L. Winn, Ph.D.

Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University. Dr. Winn offers expert opinions with regard to the nature and purpose of an MSDS generally, and specifically as to the MSDS for the polypropylene used by BSC in the manufacture of its pelvic mesh products. The plaintiffs argue that Dr. Winn's opinions should be excluded entirely, consistent with this court's decisions in *Tyree* and *Eghnayem* because his expert report is identical to the reports filed and excluded in those two cases. BSC has not presented any new arguments to convince me that Dr. Winn is warranted as an independent expert. However, I acknowledge the potential need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Winn's expert opinions [ECF No. 34] for trial.

b. Dr. Patrick Culligan, M.D.

Plaintiff objects to the case specific testimony of Dr. Culligan. [ECF No. 39]. I **RESERVE** ruling on Dr. Culligan's case specific testimony until trial.

c. Dr. Christine Brauer, Ph.D.

Dr. Christine Brauer is the President of Brauer Device Consultants LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements. I have addressed objections to Dr. Brauer's testimony in *Armstrong v. Boston Sci. Corp.*, No. 2:13-cv-24784, 2018 WL 3824375 (S.D. W. Va.

Aug. 10, 2018). I adopt my reasoning and findings from that opinion. Accordingly, plaintiff's Motion to Exclude [ECF No. 40] is **GRANTED**.

d. Dr. Roger Goldberg, M.D.

Dr. Goldberg is the Director of the Division of Urogynecology at NorthShore University Health System and an Associate Professor of Obstetrics and Gynecology at the University of Chicago Pritzker School of Medicine. He is a member of the board of directors for the American Urogynecologic Society and is the co-inventor of the Uphold. I have addressed these same objections to Dr. Goldberg's testimony in *In Re Boston Sci. Corp. Pelvic Repair System Prods. Liab. Litig.*, MDL No. 2326, 2018 WL 2440268 (S.D. W. Va. May 30, 2018). I adopt my reasoning and findings from that opinion here. Plaintiffs' Motion to Exclude Dr. Goldberg's opinions because he has a conflict of interest is **DENIED**. Plaintiffs' Motion to Exclude Dr. Goldberg's opinions because they are based solely on his personal experience is **DENIED**. Plaintiffs' Motion to Exclude Dr. Goldberg's opinion about the complication rate for the Uphold is **DENIED**. Plaintiffs' objection that Dr. Goldberg is not qualified to opine on the physical properties of polypropylene is **DENIED**. I **RESERVE** ruling on the reliability of Dr. Goldberg's opinions on the physical properties of polypropylene until trial. I **RESERVE** ruling on Dr. Goldberg's opinions on vaginal mesh implantation until trial. I **RESERVE** ruling on Dr. Goldberg's MSDS opinions until trial. Dr. Goldberg's opinion on the adequacy of warnings and the DFU are **EXCLUDED**. To summarize, plaintiffs' *Daubert* Motion concerning Dr. Goldberg [ECF No. 38] is **GRANTED in part, DENIED in part, and RESERVED in part**.

e. **Dr. Stephen Spiegelberg, Ph.D.**

Dr. Stephen Spiegelberg is the president and co-founder of Cambridge Polymer Group Inc., where he directs a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer industries. I have addressed these same objections to Dr. Spiegelberg's testimony in *Armstrong v. Boston Sci. Corp.*, No. 2:13-cv-24784, 2018 WL 3824375 (S.D. W. Va. Aug. 10, 2018). I adopt my reasoning and findings from that opinion here. Plaintiffs have stated that Dr. Spiegelberg will not testify about position statements of medical organizations or BSC's state of mind. Therefore, Plaintiffs' Motion to Exclude testimony on these two topics is **DENIED as moot**. To the extent that Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiffs' Motion with regard to Dr. Spiegelberg's qualifications is **DENIED**. The plaintiffs' Motion with regard to black specks or spots is **DENIED**. The plaintiffs' Motion with regard to Dr. Spiegelberg's FTIR and EDS testing is **DENIED**. I **RESERVE** ruling on Dr. Spiegelberg's opinions regarding individual plaintiff's meshes until trial.

In sum, plaintiffs' Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 53] is **DENIED in part, DENIED as moot in part, and RESERVED in part**.

f. **Dr. Stephen F. Badylak, D.V.M., Ph.D., M.D.**

Dr. Stephen Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a tenured professor with the Department of Surgery at the University of Pittsburgh. I have

addressed these same objections to Dr. Badylak's testimony in *Armstrong v. Boston Sci. Corp.*, No. 2:13-cv-24784, 2018 WL 3824375 (S.D. W. Va. Aug. 10, 2018). I adopt my reasoning and findings from that opinion here. Accordingly, plaintiffs' Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 54] is **DENIED**.

VI. Effect of Daubert Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VII. Conclusion

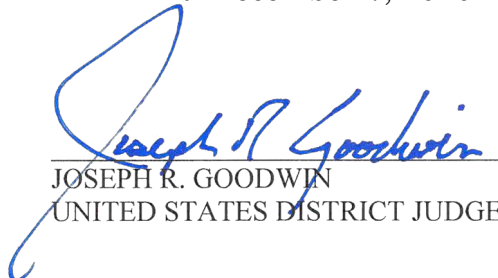
For the reasons discussed above, my rulings on BSC's Motions are as follows: Motion to Exclude the Testimony of Dr. Niall Galloway, M.D. [ECF No. 30] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Testimony of Dr. Michael Thomas Margolis, M.D. [ECF No. 31] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**; Motion to Exclude the Testimony of Dr. Thomas H. Barker, Ph.D. [ECF No. 33] is **GRANTED**; Motion to Exclude the Testimony of Dr. Bobby Shull, M.D. [ECF No. 41] is **GRANTED**; Motion to Exclude the Testimony of Dr. Jimmy Mays, Ph.D. [ECF No. 42] is **GRANTED**; Motion to Exclude the Testimony of Dr. Bruce Rosenzweig, M.D. [ECF No. 43] is **GRANTED in part** and **RESERVED in part**; Motion to Exclude the Testimony of Dr. Peggy Pence, Ph.D., RAC, FRAPS [ECF No. 44] is **GRANTED in part** and **DENIED in part**; Motion to

Exclude the Testimony of Dr. Russell Dunn, Ph.D. [ECF No. 45] is **GRANTED**;
Motion to Exclude the Testimony of Dr. Scott Guelcher, Ph.D. [ECF No. 46] is
GRANTED; Motion to Exclude the Testimony of Dr. Richard Trepeta, M.D. [ECF
No. 48] are **GRANTED in part** and **DENIED in part**; Motion to Exclude the
Testimony of Dr. Vladamir Iakovlev, M.D. [ECF No. 56] is **GRANTED in part** and
RESERVED in part.

My rulings on plaintiffs' motions are as follows: Motion to Exclude the
Testimony of Dr. Gary L. Winn, Ph.D. [ECF No. 34] is **RESERVED**; Motion to
Exclude the Testimony of Dr. Patrick Culligan, M.D. [ECF No. 39] is **RESERVED**;
Motion to Exclude the Testimony of Dr. Christine Brauer, Ph.D. [ECF No. 40] is
GRANTED; Motion to Exclude Dr. Roger Goldberg, M.D. [ECF No. 38] is
GRANTED in part, DENIED in part, and RESERVED in part; Motion to Exclude
the Testimony of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 53] is **DENIED in part,**
DENIED as moot in part, and RESERVED in part; Motion to Exclude the
Testimony of Dr. Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 54] is
DENIED.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of
record and any unrepresented party.

ENTER: December 7, 2020


JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE