BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

| IN RE: SoClean, Inc. Litigation | MDL No |
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BRIEF IN SUPPORT OF MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. §1407

I. <u>INTRODUCTION</u>

Pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Movants-Plaintiffs Larry Hunter-Blank and William Wheeler ("Movants") respectfully submits this brief in support of his Motion for Transfer of Actions Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings. Movants' cases, filed under CAFA jurisdiction in the District of Kansas and the Western District of Texas, along with similar class actions filed in other federal courts, arises out of the use of ozone (O³) to clean, sanitize, or disinfect CPAP machines and accessories utilizing SoClean CPAP devices. The FDA has determined that the use of ozone (O³), sometimes called "activated oxygen," is a gas that can be used to kill harmful bacteria. However, for ozone (O³) to be effective in destroying harmful bacteria it must

¹ See Larry Hunter-Blank v. SoClean, Inc., Civil Action No. 21-cv-2425 (D. Kan.), filed September 28, 2021; William Wheeler vs. SoClean, Inc., Case No. 1:21-cv-00837-LY (W.D. Tex.), filed September 20, 2021.

² As of October 8, 2021, Movants identified eight additional related actions filed in federal court. *See* Exhibit A (Schedule of Actions).

be present at a concentration above levels considered safe for humans.³ Further, the FDA conducted preliminary laboratory research on a few products claiming to use ozone (O³) gas to clean, sanitize, or disinfect CPAP machines and accessories. For the ozone (O³) gas products that claimed to clean CPAP machines and accessories, tests performed in a minimally ventilated space with a volume representation of a small enclosed bathroom showed that several marketed ozone gas products generated ambient ozone levels above stated regulatory limits.⁴ Ozone (O³) levels were also elevated inside CPAP tubing even after recommended wait times in ozone cleaning gas products that do not perform an automatic clean air purge toward the end of the cleaning cycle.⁵

On February 27, 2020, federal health officials were warning against the use of ozone (O³) gas to clean continuous positive airway pressure (CPAP) devices or accessories, indicating this cleaning method has not been approved and could result in adverse health consequences. In a safety communication issued on February 27, 2020, the FDA indicates that patients and healthcare professionals should refrain from using illegally marketed ozone (O³) gas cleaning product to disinfect or sanitize CPAP devices.

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³ https://www.epa.gov/ozone-pollution-and-your-patients-health/course-outline-and-key-points-ozone

⁴ https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=801.415

See Press Release: FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized (/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or).; Consumer Update: Continuous Positive Airway Pressure (CPAP) Machine Cleaning (/consumers/consumer-updates/cpap-machine-cleaning-ozone-uv-light-products-are-not-fda-approved). Consumer Update Video: Watch This Before You Consider Using Ozone Gas or UV Light CPAP Cleaning Devices (https://youtu.be/K9Bb7MzvVuM). (http://fda.gov/about-fda/website-policies/website-disclaimer).; Ozone Generators that are Sold as Air Cleaners (https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#ozone-health). – United States Environmental Protection Agency (EPA); UVA Radiation (https://www.cdc.gov/nceh/features/uv-radiation-safety/). – The Centers for Disease Control and Prevention (CDC)

This warning comes after nearly a dozen reports involving patients suffering from respiratory complications after trying either ozone (O³) disinfecting or ultraviolet (UV) light disinfecting methods. The FDA has never approved the use of ozone (O³) gas-based products to clean CPAP machines and is instructing patients and healthcare professionals to stop using this cleaning method immediately. In fact, the FDA has received at least eleven reports of CPAP cleaning problems involving the use of ozone (O³) from 2017 through 2019 which involved individuals who experienced coughing, difficult breathing, nasal irritation, headaches, asthma attacks, and other breathing problems after using the unapproved product.

SoClean, Inc. manufactures a CPAP cleaning device that utilizes ozone (O³) to clean, sanitize and disinfect the CPAP machine and its accessories. SoClean controls about 90% of the mechanical cleaning device market in the United States. SoClean marketing materials fail to disclose that its devices emit ozone (O³), which is a requirement of federal law. Instead, SoClean falsely represents that its devices use "activated oxygen" to clean a CPAP machine and accessories. While advertising the mechanical cleaning device as "safe" and "healthy," these representations are false because the cleaning devices generate toxic ozone (O³) gas at levels that substantially exceed federal regulations. SoClean falsely represents that its devices use "no water chemicals" or "no harsh chemicals" to clean CPAP machines, despite using ozone (O³) gas – a harsh and toxic chemical that causes respiratory problems in humans. The issue of the use of ozone to clean CPAP machines is so dangerous and destructive that several of the largest manufacturers of CPAP machines in the United States require purchasers

to acknowledge that they have been informed that if the purchaser uses a SoClean device to clean their CPAP machine, the warranty of their CPAP machine will be voided.

Testing of a SoClean 2 model SC1200 Serial/No. SC120018100700580 by Research Triangle Laboratories in March of 2019 with a Resmed CPAP machine revealed that the production of ozone (O³) exceeded federal ozone (O³) limits. This test ran for one minute. Subsequently, using the same equipment, a twelve-minute cycle test was performed, which likewise resulted in an ozone (O³) level which significantly exceeded federal ozone (O³) limits.

On information and belief, Movants aver that there are several million SoClean devices in use in the United States. This Action seeks recovery of damages for personal injury, refund of medical expenses, refund of cost of seller device, medical monitoring, together with pre and post judgment interest, as well as attorney fees as prescribed by law.

The underlying facts concerning the manufacture, advertising, and sale of the SoClean ozone cleaning device are uniform throughout the proposed class of Plaintiffs in the Actions filed in various federal courts across the country. Indeed, the issue of whether the several million SoClean CPAP cleaning devices have been rendered worthless as a result of the creation of ozone (O³) in the devices, entitles all purchasers and users to economic damages, is present in all of the Actions. In addition, all users of the SoClean CPAP cleaning devices are facing risk of serious injury as a result of exposure to ozone (O³). Addressing these issues in a consistent manner through coordinated and consolidation factual discovery from the SoClean entity, as opposed to potentially

disparate treatment by different courts helps to serve one of the main purposes of Section 1407. And, utilizing such transfer and consolidation or coordination on issues that have nationwide significance and broad application among all plaintiffs is prudent under the circumstances.

Further, Plaintiffs Larry Hunter-Blank and William Wheeler have served SoClean, Inc.

Therefore, Movants seek the transfer and assignment of the Actions, which all seek a finding that purchasers and users of SoClean, Inc.'s CPAP cleaning devices are entitled to damages, to the District of Kansas, as well as any Actions subsequently filed involving similar facts or claims. Movants also seek that, once transferred the Actions, and any future tag-along Actions, be assigned to the Honorable Holly Teeter, United States District Court Judge for the District of Kansas, who is currently presiding over two SoClean cases.

II. BACKGROUND

SoClean, Inc.'s CPAP cleaning devices are used by patients throughout the United States to clean, sanitize and disinfect their CPAP breathing machines and accessories. A CPAP machine is used by patients to treat a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and chronic obstructive pulmonary disease (COPD), and the mechanical ventilators that are used to assist those individuals that require invasive and non-invasive ventilation for acute and sub-acute hospital environments. The SoClean CPAP cleaning device utilizes ozone (O³) to clean, sanitize, and disinfect CPAP machines and accessories.

In February 2020, the FDA determined that the use of ozone (O³) in a CPAP cleaning device was not authorized, and the use of ozone (O³) was illegal in the United States. Ozone (O³) is a toxic gas and is inimical to human life and may cause coughing, difficult breathing, nasal irritation, headaches, asthma attacks and other breathing problems when ozone is used to clean the CPAP machine and its accessories. Further, the FDA has specifically instructed patients and healthcare professionals to stop using ozone (O³) as a cleaning method for a CPAP machine. Therefore, SoClean devices are rendered worthless, and patients are now burdened with having to expend sums of money to replace their CPAP cleaning machine as quickly as possible. Possibly even their CPAP machine.

Plaintiffs Larry Hunter-Blank and William Wheeler are two such users of the SoClean CPAP cleaning device. Their claims are typical of all other users. To date, nine additional Actions seeking similar relief in federal court have been filed:

- 1. Anthony Sakalarios vs. SoClean, Inc., Case No. 2:21-cv-00114-HSO-JCG (S.D. Miss.), filed September 3, 2021;
- 2. Thomas N. Hebert vs. SoClean, Inc., Case No. 6:21-cv-03225-RRS-CBW (W.D. La.), filed September 3, 2021;
- 3. Michael L. Stahl vs. SoClean, Inc., Case No. 2:21-CV-02424-HLT-GEB (D. Kan.), filed September 27, 2021;
- 4. John Cupp, Vunor Wood, and Mark Wright v. SoClean, Inc., Case No. 1:21-cv-01309-SGC (N.D. Ala.), filed September 30, 2021;

- 5. Paul Brackins, Rosetta Dejarnett, Shelly Key, Jonathan Griffin v. SoClean, Inc., Case No. 2:21-cv-00651-ECM-SRW (M.D. Ala.), filed September 30, 2021;
- 6. Jackie Turner v. SoClean, Inc., Case No. 4:21-cv-00722-FJG (W.D. Mo.), filed October 4, 2021;
- 7. Robert Jenkins v. SoClean, Inc., Case No. 4:21-cv-00723-BCW (W.D. Mo.), filed October 4, 2021;
- 8. Jessie Judson Brooks, Sr. v. SoClean, Inc., Case No. 5:21-cv-00357-MTT (M.D. Ga.), filed October 6, 2021;
- 9. Steve Landers, Sr. v. SoClean, Inc., Case No. 4:21-cv-00919-BSM (E.D. Ark.), filed September 7, 2021 in Circuit Court of Pulaski County, Arkansas, removed October 12, 2021.

Because of the number of users of the SoClean CPAP cleaning device are spread throughout the United States, Movants respectfully suggests that it is likely that numerous additional cases may be subsequently filed against SoClean, Inc.

While the various actions may contain different state law claims or seek damages for personal injuries, they all share key core factual questions: (1) whether the SoClean CPAP devices are worthless as a result of the use of ozone (O³) to clean, sanitize, or disinfect the CPAP machine thereby entitling all purchasers and users to economic damages, and (2) whether users have been exposed to risks of serious injury as a result of breathing a toxic gas generated by the cleaning device. These central questions are too important for the millions of purchasers and users of SoClean CPAP cleaning devices to leave their determinations to numerous courts across the country that could reach diverse

and conflicting results. Moreover, simply because plaintiffs may have different damages does not weigh in favor of denying centralization. *See In re Valsartan N-Nitrosodimenthlyamine (NDMA) Contamination Prod. Liab. Litigation.*, 363 F. Supp. 3d 1378, 1381-82 (J.P.M.L. 2019) (centralizing consumer claims for economic damages with personal injury claims).

Legally, the purpose of centralizing these claims is to promote the just and efficient litigation of these actions, to avoid inconsistent rulings on key and fundamental issues, and to prevent duplicative discovery and other inefficiencies that would threaten to drain judicial resources. It is not necessary that the cases are identical or that common issues predominate; all that is required are enough common questions to warrant coordination or consolidation. Federal judges are well equipped to manage centralization in cases where there are substantial differences and complexities. Often, the more complicated and voluminous situation confirm the strength of centralization, where skilled judges can work with experienced counsel to create plans for moving otherwise seemingly complex and overwhelming cases to an efficient and successful resolution.

While the sales and use of SoClean CPAP cleaning devices has unquestionably impacted users in many states, the District of Kansas would be an excellent and appropriate forum for this litigation. The District of Kansas has vast experience successfully managing multidistrict litigation.

III. ARGUMENT

A. TRANSFER OF THE ACTIONS TO ONE COURT FOR COORDINATION OR CONSOLIDATION IS APPROPRIATE UNDER 28 U.S.C. § 1407.

Transfer is appropriate when motions pending in different judicial district involve similar questions of fact such that coordinating or consolidating pretrial proceedings would "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407. In relevant part, Section 1407 provides as follows:

When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.

Id.; see also In re Nifedipine, 266 F. Supp. 2d 1382, 1382 (J.P.M.L. 2003). The purpose of multidistrict litigation is to "eliminate the potential for conflicting contemporaneous pretrial rulings by coordinate district and appellate courts in multidistrict related civil actions." In re Plumbing Fixture Cases, 298 F. Supp. 484, 491-92 (J.P.M.L. 2017) (same); In re Capital One Customer Data Sec Breach Litig., 396 F. Supp. 3d 1364, 1365 (J.P.M.L. 2019) (same).

Pursuant to 28 U.S.C. § 1407, transfer of actions to one district for coordinated or consolidated pretrial proceedings is appropriate where: (1) actions pending in different districts involve one or more common question of fact, and (2) the transfer of such actions will be for the convenience of the parties and witnesses and will promote the just and

efficient conduct of such actions. 28 U.S.C. §1407(a); *Ethicon Physiomesh*, 254 F. Supp. 3d at 1382 (transfer of related actions to a single district for pretrial proceedings "conserve[s] the resources of the parties, their counsel, and the judiciary"); *Capital One Customer Data Sec. Breach*, 396 F. Supp. 3d at 1365 (same). Consolidation is especially important in multidistrict litigations where "the potential for conflicting, disorderly, chaotic" action is greatest. *Plumbing Fixture Cases*, 298 F. Supp. at 493.

Consolidation of actions involving common factual questions makes sense when numerous judges will be asked to address similar pretrial matters and resolve similar pretrial motions involving similar fact patterns. *See In re Fosamax Prods. Liab. Litig.*, 444 F. Supp. 2d 1347, 1349 (J.P.M.L. 2006). Notably, "[t]ransfer under Section 1407 does not require a complete identity or even a majority of common factual or legal issues as a prerequisite to transfer. Centralization will permit all actions to proceed before a single transferee judge who can structure pretrial proceedings to consider all parties' legitimate discovery needs, while ensuring that common parties and witnesses are not subjected to duplicative discovery demands." *In re Katz Interactive Call Processing Patent Litig.*, 481 F. Supp. 2d 1353, 1355 (J.P.M.L. 2007).

In the matter sub judice, there are already eleven pending federal actions in nine districts proceeding and, likely, many more to come. Inconsistent judicial rulings in litigation affecting potentially millions of purchasers and users of the SoClean CPAP cleaning device is precisely the type of disorderly and chaotic action that consolidation and coordination under Section 1407 was intended to prevent. The transfer of the Actions to the same court for consolidated or coordinated proceedings is appropriate because

common questions of fact exist, and consolidation or coordination before one court will ensure efficient management of the litigation and avoid inconsistent ruling on these issues impacting so many Plaintiffs across the United States.

1. The Actions Involve Common Factual Questions.

Here, all the Actions, and any tag-along actions, will require a determination of whether the use of SoClean CPAP cleaning devices containing ozone (O³) rendered the device as worthless, entitling several million purchasers and users to economic damages for the losses sustained. Further, all the Actions will require an assessment of the risks of serious injury that users are facing as a result of the ingestion of ozone (O³) into their lungs. Section 1407 does not require majority of common factual issues as a condition for transfer, only that there are common questions presented which justify consolidation and coordination. *See e.g., In re Ins. Brokerage Antitrust Litig.,* 360 F. Supp. 2d 1371, 1372 (J.P.M.L. 2005). In this case, the facts surrounding SoClean's conduct in the manufacture, sale, and testing of the SoClean CPAP cleaning device applies equally to all Plaintiffs and users.

The fact that the Actions are based on various state law claims for damages does not preclude consolidated or coordinated discovery because the central issues – whether the SoClean CPAP cleaning devices are worthless and whether they pose risk of injury to users – will be the same across all cases.

What is important and relevant to the Panel's decision is that transfer and consolidation or coordination will provide a consistent and uniform resolution to the common factual issues, which will facilitate the efficient administration of all the Action

even considering any differences that may exist. "[T]ransfer under Section 1407 has the salutary effect of placing all actions in th[e] docket before a single judge who can formulate a pretrial program that: 1) allows discovery with respect to any non-common issues to proceed concurrently with discovery on common issues, *In re Joseph F. Smith Patent Litigation*, 407 F. Supp. 1403, 1404 (J.P.M.L. 1976); and 2) ensures that pretrial proceedings will be conducted in a manner leading to a just and expeditious resolution of the actions to the benefit of not just some but all of the litigation's parties." *Ins. Brokerage Antitrust*, 360 F. Supp. 2d at 1372; *see also Checking Account Overdraft*, 626 F. Supp. 2d at 1335. The common questions of fact that are implicated here weigh heavily in favor of consolidation and coordination.

2. Transfer Will Serve the Convenience of the Parties and Witnesses and Will Promote the Just and Efficient Conduct of Actions.

According to the Manual for Complex Litigation, the following four factors govern whether transfer will facilitate the convenience of the parties and promote the just and efficient conduct of the transferred cases:

- 1. The elimination of duplicative discovery;
- 2. The avoidance of conflicting rules and schedules;
- 3. The reduction of litigation cost; and
- 4. The conservation of the time and effort of the parties, attorneys, witnesses, and courts.

Manual for Complex Litigation (Fourth), § 20.131, at 219.

In this litigation, there are currently eleven pending Actions in nine different districts, but these numbers are sure to rise rapidly.⁶ Each Action involves virtually identical factual questions regarding defendant's conduct, and overlapping issues exist concerning plaintiffs' damages. Consolidation or coordination will eliminate the likelihood of duplicative discovery and proceedings that might result in inconsistent rulings and will prevent judicial resources from being needlessly wasted. See In re Vioxx Prod. Liab. Litig., 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005); see also In re Amino Acid Lysine Antitrust Litig., 910 F. Supp. 696, 698 (J.P.M.L. 1995) (concluding that consolidation was necessary to eliminate inconsistent pretrial rulings); In re A.H. Robins Co. "Dalkon Shield" IUD Prod. Liab. Litig., 406 F. Supp. 540, 542 (J.P.M.L. 1975) (concluding that transfer was necessary to prevent duplication of discovery and to eliminate the possibility of conflicting pretrial rulings). Without transfer, coordination, and/or consolidation of the Actions and tag-along cases, litigation will needlessly entail judicial inefficiency and unnecessary expense. Further, different federal courts, in duplicating ruling on the same issues, could make contradictory findings. Litigation of this scope and importance should not be beset with such inconsistencies and inefficiencies. Additionally, for the defendants,

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⁶ Five actions are more than enough to warrant transfer and coordination or consolidation in light of the questions at issue here. *See, e.g.* Manual for Complex Litigation Fourth § 20.131, at * 1 ("As few as two cases may warrant multidistrict treatment...."); *In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 228 F. Supp. 2d 1379, 1380 (J.P.M.L. 2002) (transferring and consolidating two cases); *In re Philadelphia Life Ins. Co. Sales Practices Litig.*, 149 F. Supp. 2d 937, 938 (J.P.M.L. 2001) (granting transfer and consolidation of two cases); *In re Amoxicillin Patent & Antitrust Litig.*, 449 F. Supp. 601, 603 (J.P.M.L. 1978) (granting transfer and consolidation of three cases involving complex patent and antitrust issues); *In re: Park West Galleries, Inc., Mktg. & Sales Practices Litig.*, 645 F. Supp. 2d 1358, 1360 (J.P.M.L. 2009) (transfer ordered where three actions were pending in three districts); *In re FieldTurf Artificial Turf Mktg. & Sales Practices Litig.*, 2017 WL 2391963, at *2 (J.P.M.L. June 1, 2017) (transfer ordered where twelve to fourteen actions (including tag-alongs) were pending in nine districts).

having to defend multiple Actions in multiple districts will result in expenditures of money and resources that may be obviated by consolidation and coordination.

B. THE DISTRICT OF KANSAS IS THE APPROPRIATE FORUM FOR TRANSFER AND COORDINATION OR CONSOLIDATION

In this case, which has nationwide implications, potentially affecting millions of purchasers and users of SoClean CPAP cleaning devices, District of Kansas is an appropriate and ideal transferee district for the litigation. The District of Kansas is a geographically central and accessible forum for the plaintiffs who have been affected by the use of the SoClean CPAP cleaning devices. Kansas City, Kansas is easily accessible from all locations throughout the United States and is served by United Airlines, Delta Airlines, Southwest Airlines, American Airlines, Alaska Airlines and Spirit Airline. Kansas City, Missouri, which is directly across the Missouri River has ample accommodation for business travelers. Kansas City, Missouri contains over a half a million residents. Mover posits that the infrastructure is certainly in place to host this MDL in Kansas City, Kansas. In considering the transfer of cases involving a medical device affecting millions of purchasers around the nation (EpiPens), this Panel chose the District of Kansas because it "present[ed] a geographically central forum for this nationwide litigation" that is "relatively convenient and accessible to the parties." In re Epipen Mktg., Sales Pracs. & Antitrust Litig., 268 F. Supp. 3d 1356, 1360 (J.P.M.L. 2017); accord In re Power Morcellator Prod. Liab. Litig., 140 F. Supp. 3d 1351, 1354 (J.P.M.L. 2015) (another medical device MDL; concluding that "the District of Kansas is an appropriate

transferee district for this nationwide litigation" and noting that Judge Vratil is "a skilled and efficient jurist with a wealth of MDL experience").

Further, the District of Kansas has a capable staff with a long history of successfully managing high profile multidistrict litigation. Notably, the judges and staff in the District of Kansas have handled certified classes in multi-district litigation all the way through trial. See, e.g., In re: Motor Fuel Temperature Sales Practices Litigation, MDL No. 1840 (Vratil, J.); In re Syngenta AG MIR162 Corn Litigation, MDL No. 2591 (Lungstrum, J.); In re Universal Service Fund Telephone Billing Practices Litigation, MDL No. 1468 (Lungstrum, J.); In re Urethane Antitrust Litigation, MDL No. 1616 (Lungstrum, J.). The docket of the District of Kansas demonstrates that the court has the capacity to handle this litigation. As of March 31, 2021, the District of Kansas had 2,047 pending cases with a median time from filing to disposition of 7.8 months.⁷

In the District of Kansas, United States District Judge Holly Teeter is an excellent jurist who can shepherd this litigation. Judge Teeter is currently presiding over Movant Larry Hunter-Blank's case. Judge Teeter was appointed to the federal bench by President Donald J. Trump in 2018. She is a fair, demanding but reasonable, extremely organized, and efficient judge accustomed for providing over complex litigation. Judge Teeter is not currently managing any MDLs on her docket; however, she has the experience and demeanor necessary to guide this litigation. She also could rely on the mentorship of the

⁷ There are currently three MDLs in the District of Kansas. Two are in the final stages (*In re Hill's Pet Nutrition, Inc., Dog Food Products Liability Litigation, MDL No. 2887*, and *In re Syngenta AG MIR162 Corn Litigation, MDL No. 2591*) and the third is scheduled for a class-wide trial in January 2022 (*In re EpiPen, MDL No. 2785*).

experienced district court judges within the District and benefit from court staff who have routinely and recently handled MDLs.

IV. CONCLUSION

For these reasons, Movants respectfully request that the Panel grant their motion for transfer and coordination or consolidation under 28 U.S.C. § 1407 and transfer the Actions to the District of Kansas before the Honorable Holly Teeter, District Judge.

Dated: October 13 2021 Respectfully submitted,

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