IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC, Plaintiffs, v. ERIC HARGAN, Acting Secretary of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SCOTT GOTTLIEB, Commissioner of Food and Drugs; and U.S. FOOD AND DRUG ADMINISTRATION, Defendants.	Civil Action No.: 1:17-CV-02221 (APM)

MEMORANDUM OF ATHENEX PHARMA SOLUTIONS, LLC AND ATHENEX PHARMACEUTICAL DIVISION, LLC IN SUPPORT OF THEIR MOTION TO INTERVENE

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I. INTRODUCTION

Pursuant to Rule 24 of the Federal Rules of Civil Procedure, Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC (collectively, "Athenex") move to intervene as defendants in the above-captioned matter on the grounds that they meet the requirements for both intervention as of right and permissive intervention. By their complaint, Plaintiffs Par Sterile Products, LLC and Endo Par Innovation Company, LLC. ("Par" or "Plaintiff") seek undeserving declaratory and injunctive relief that: (i) vasopressin be delisted from Category 1 of the U.S. Food and Drug Administration's ("FDA") list of bulk drug substances under evaluation pursuant to Section 503B of the Federal Food, Drug and Cosmetic Act ("FDCA") ("Category 1 List"); (ii) the FDA's January 2017 *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act* ("2017 Guidance"), which lawfully applies FDA's enforcement discretion to Category 1 substances, be enjoined; and (iii) that the FDA be enjoined from authorizing the compounding of vasopressin under Section 503B of the FDCA.

Vasopressin, a life-saving drug that increases blood pressure in adults with vasodilatory shock in emergency scenarios, is included on FDA's Category 1 List. Athenex has a substantial interest in this litigation because it produces and sells to health care providers a drug product produced by compounding[1] vasopressin in accordance with Section 503B of the FDCA. Athenex has conducted extensive research in developing its compounded vasopressin products and spent considerable efforts and financial resources to develop its 503B facilities and operation. Athenex started selling its vasopressin compounded products on August 13, 2018.

[1] Section 503B of the FDCA defines "compounding" to mean "combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug." 21 U.S.C. § 353b(d)(1).

The disposition of this case may impair Athenex's ability to protect its continued compounding of bulk vasopressin and its sale of vasopressin products because Athenex would be forced to cease compounding and selling them if Plaintiff succeeds in this litigation. Such a result would deprive Athenex of millions of dollars in lost profits and waste the research and development costs already sunk into its 503B operation. It would also cripple Athenex's existing Clarence, New York facility and its in-progress development of a new Dunkirk, New York facility. The Dunkirk facility will provide hundreds of jobs as part of the "Buffalo Billion," a New York state government project that aims to invest $1 billion in the Buffalo-area economy.

Furthermore, Athenex has standing as a defendant, none of the parties adequately represent Athenex's interests, and its motion is timely because no party has filed a dispositive motion on the merits. For these reasons and as more fully set forth below, Athenex's motion to intervene as of right as a defendant should be granted. In the alternative, Athenex also meets the test for permissive intervention under Rule 24(b).

II. SECTION 503B LEGAL FRAMEWORK

In 2013, Congress enacted the Drug Quality and Security Act ("DQSA"), amending the FDCA to add, *inter alia*, the Compounding Quality Act, which is commonly referred to as Section 503B. *See* Drug Quality and Security Act, Pub. L. 113-54, 127 Stat. 587 (2013). Section 503B describes the conditions that must be satisfied for human drugs compounded by an "outsourcing facility"[2] to be exempt from Section 505 and other sections of the FDCA that relate to the approval of new drug applications. 21 U.S.C. § 353b(a) (2012). Section 503B was designed to recognize two equally important objectives. First, Congress recognized the

[2] Section 503B defines "outsourcing facility" to mean a facility that is engaged in the compounding of sterile drugs, has registered with FDA as an "outsourcing facility," and complies with all of the requirements of Section 503B. 21 U.S.C. § 353b(d)(4)(A).

importance of drug compounders in our health care system. *See, e.g.*, 159 Cong. Rec. S8071-04 (daily ed. Nov. 18, 2013) (statement of Sen. Boozman) ("Without compounders, doctors would not perform surgeries. Without compounders, oncologists would be forced to administer alternative chemotherapy drugs. Without compounders, patients would suffer from limited access. These are real issues and real problems… ."). Second, Congress also recognized the need for and importance of stringent safety requirements that "outsourcing" facilities must follow. *Id*. (statement of Sen. Warner) ("The [Compounding Quality Act]… ensures that patients and providers have access to safe compounded drugs."). Accordingly, Section 503B creates comprehensive requirements for regulated "outsourcing facilities," including registration, labeling, rigorous controls and quality standards, adverse incident reporting, and FDA inspections. *See* 21 U.S.C. § 353b(b) (setting forth requirements for registration of outsourcing facilities and reporting of drugs).

Congress also provided that "outsourcing facilities" could compound using "bulk drug substances" only if those bulk drug substances "appear on a list established by the Secretary identifying bulk drug substances for which there is a clinical need through notice and comment procedures (the "Clinical Need List"). *Id*. § 353b(a)(2).[3] In the interim, while FDA works through the process of establishing the Clinical Need List, FDA published the 2017 Guidance to articulate its enforcement discretion in a way that "avoid[ed] unnecessary disruption to patient treatment." 2017 Guidance at 7. The 2017 Guidance states that "FDA does not intend to take action against an outsourcing facility for compounding a drug product using a bulk drug

[3] Section 503B(a)(2) requires that in setting the list of bulk drug substances, FDA (i) publis[h] a notice in the Federal Register proposing bulk drug substances… including a rationale for such proposal; (ii) provid[e] a period of not less than 60 calendar days for comment on the notice; and (iii) publis[h] a notice in the Federal Register designating bulk drug substances for inclusion on the list. 21 U.S.C. § 353b(a)(2).

substance that does not appear on the 503B bulks list [(*i.e.*, the Clinical Need List)]," providing that certain conditions are met. *Id*. at 8. Those conditions are: (i) the bulk substance appears on the 503B Category 1 List on FDA's website[4]; (ii) the manufacturer has registered with FDA as an outsourcing facility; (iii) the bulk substance is accompanied by a valid Certificate of Analysis; (iv) the bulk substance complies with any applicable USP or NF monograph; and (v) the drug product is compounded in compliance with all other provisions of section 503B, including FDA's Current Good Manufacturing Practices ("cGMP") under Section 501(a)(2)(B) of the FDCA. *Id*.

Plaintiff brought this lawsuit against the FDA, Scott Gottlieb, U.S. Health and Human Services, and Eric Hargan (collectively, "Federal Defendants"), seeking: (1) a declaration that the 2017 Guidance is "contrary to law," (2) vacatur of the FDA's "listing of vasopressin in Category 1," and (3) an injunction prohibiting FDA from "authorizing bulk drug compounding using vasopressin" without first complying with the notice and comment procedures. *See* 10/26/17 Compl., ECF No. 1, at 34-35.

[4] The January 2017 Guidance sets forth three categories: 503B Category 1 – Substances Nominated for the Bulks List Currently Under Evaluation; 503B Category 2 – Substances Nominated for the Bulks List That Raise Significant Safety Risks; and 503B Category 3 – Substances Nominated for the Bulks List Without Adequate Support. *See* 2017 Guidance at 5-6.

Vasopressin is listed as a Category 1 Substance, even after the FDA removed certain other drugs from the Category 1 List on July 23, 2018. *See* FDA, *Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 503B Category 1 – Bulk Drug Substances Under Evaluation* (July 2017), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467374.pdf (last visited July 24, 2018).

III. STATEMENT OF FACTS

A. Athenex Manufactures to the Same Stringent FDA Safety Standards as Manufacturers of FDA Approved Branded Drug Products.

Athenex, Inc.[5] is a global pharmaceutical company headquartered in Buffalo, New York. *See* Declaration of Joseph Mase ("Mase Decl.") ¶ 2. Its mission is to improve the lives of patients by creating more effective, safer and tolerable treatments. *Id*. In 2014, Athenex (a subsidiary of Athenex, Inc.) was formed when Athenex, Inc. acquired QuaDPharma, Inc. ("QuaDPharma"), who operated a Clarence, New York laboratory and manufacturing facility that produced and tested small-batch, FDA-approved, pharmaceuticals for drug companies and researchers. *See* Declaration of Robert Keem ("Keem Decl.") at ¶ 2. Athenex, Inc. acquired QuaDPharma and changed its name to Athenex Pharma Solutions, LLC. *Id*.

Because of its roots in manufacturing FDA-branded drugs, Athenex's Clarence facility is perfectly suited for manufacturing compounded drug products from bulk drug substances. Mase Decl. ¶ 5. The facility operates in accordance with the FDA's stringent cGMP manufacturing regulations, Keem Decl. ¶ 3, which set a high bar to meet and require painstaking attention to detail. *See* 21 C.F.R. Parts 210 and 211 (setting out cGMP requirements). cGMP is the same standard by which FDA-branded drugs, like Plaintiff's Vasostrict®, are produced. *Id.* ¶ 3.

Given its cGMP-compliant facility, and extensive history manufacturing FDA-branded drugs, Athenex was a natural fit for 503B compounding. Mase Decl. ¶ 5. Unlike most other 503B compounders, Athenex already had more than seven years of experience producing FDA branded drugs under the FDA's stringent cGMP requirements. *See* Keem Decl. ¶ 4. On April

[5] Athenex, Inc. was formed under the name Kinex Pharmaceuticals LLC in November 2003. Mase Decl. ¶ 3. It was incorporated in the State of Delaware under the name Kinex Pharmaceuticals, Inc. on December 31, 2012 and changed its name to Athenex, Inc. on August 26, 2015. *Id*.

10, 2017, Athenex registered with the FDA as a 503B facility, *id*. ¶ 5, launching its bulk compounding operation with the same attention to detail and safety standards as a facility manufacturing FDA-branded drugs. Athenex meets all criteria for 503B compounding set forth in the Guidance. Mase Decl. ¶ 7. Athenex is one of only about 75 registered 503B facilities nationwide. Athenex's manufacturing process has been inspected and approved by the FDA, most recently on December 2017.[6] Keem Decl. ¶ 5.

B. In Reliance on FDA Guidance, Athenex Has Invested Considerable Resources Into Its 503B Compounding Business.

After FDA published its 2017 Guidance, Athenex fully committed to operating a 503B compounding business. Mase Decl. ¶¶ 7-8. Athenex made significant investments in—and built its long-term business plan around—large scale 503B manufacturing, in reliance on FDA's articulation of how it would exercise its enforcement discretion during the period leading up to its forthcoming bulk drug substance rulemakings. Mase Decl. ¶ 8-9.

Athenex has invested more than $2 million renovating the Clarence facility's aseptic operations space. Mase Decl. ¶ 8. Additional improvements are already underway, including work to expand the space by an additional 8,000 square feet. *Id*. The facility currently employs approximately fifty workers, including two registered pharmacists, a manufacturing engineering group of six, a quality control group of thirteen, a manufacturing group of ten, a quality assurance group of six, a supply chain group that includes five, a facility group of three, and a research and development group of three. Keem Decl. ¶ 5. The facility will accommodate more

[6] Athenex, Inc. is also cGMP-compliant. Keem Decl. ¶ 4. The Athenex family of companies for years has been manufacturing branded drug products and active pharmaceutical ingredients ("API") used by other pharmaceutical companies. Keem Decl. ¶ 4. All of the manufacturing completed by the Athenex, Inc. family of companies is cGMP-compliant and FDA-inspected, including its plant in Chongqing, China, where it manufactures active pharmaceutical ingredients. Keem Decl. ¶ 4.

staff as its operation grows. Keem Decl. ¶ 5. Athenex invested millions of dollars outfitting laboratory space in Buffalo to use for its 503B operations. Mase Decl. ¶ 8. And, Athenex's marketing and commercialization team invested significant time researching the viability of vasopressin as a compounded product, including the market need for a ready-to-use product, market research on product needs, and labeling and packaging development procedures. Mase Decl. ¶ 8. Approximately six key members of that team worked on the development and launch of vasopressin for the last year. *Id*.

Expanding on its current 503B Clarence operation, Athenex is building a second facility in Dunkirk, New York for large scale 503B compounding and other cGMP-compliant drug manufacturing. Mase Decl. ¶ 9. The $209 million Dunkirk facility will span approximately 320,000 square feet and will employ approximately 450 staff; the facility's concrete foundation has been laid and Athenex has begun ordering equipment for its 503B compounding operations. *Id.* The Dunkirk facility is funded by a $225 million grant from the State of New York, as part of Governor Cuomo's "Buffalo Billion" initiative to revitalize the Buffalo economy, and in line with New York State's initiatives for Western New York to become a leading hub for health and life sciences innovation and commercialization. *Id.* In return, Athenex committed to provide hundreds of jobs in Dunkirk and Buffalo over the next ten years. *Id.* Within five years of operations at the Dunkirk facility, Athenex intends to employ 450 employees at the Dunkirk facility, with approximately 80 percent of the Dunkirk workforce focusing on 503B compounding from bulk drug substances. *Id.*

C. Athenex Designed its Compounded Vasopressin in Ready-to-Use Form, which is a Faster and Safer Form than Vasostrict®.

Relying on FDA's inclusion of vasopressin as a 503B Category 1 substance, Athenex selected vasopressin as one of its first bulk compounded products. Mase Decl. ¶ 15. Intravenous

vasopressin is a polypeptide hormone that causes contraction of vascular and other smooth muscles; it is used to increase blood pressure in adults with vasodilatory shock (*e.g.*, post-cardiotomy or sepsis) who remain hypotensive, despite fluids and catecholamines. Mase Decl. ¶ 10. Vasopressin is used mostly in emergency scenarios, like when a patient goes into cardiac arrest during surgery. *Id.*

Medical professionals have used intravenous vasopressin for this purpose for almost 100 years. *See* Declaration of Bridget S. McCabe ("McCabe Decl."), Ex. 1, Aaron Hakim, Ravi Gupa & Joseph S. Ross, *High Costs of FDA Approval for Formerly Unapproved Marketed Drugs*, 318 Journal of American Medical Association 2181, at 2181 (2017) (hereinafter "JAMA"). In November of 2014, Par received FDA approval for its version of vasopressin (Vasostrict®),[7] Compl. ¶ 52, and on December 15, 2014, FDA instructed all other suppliers of unapproved intravenous vasopressin to stop manufacturing their products by January 30, 2015, leaving only Par with an FDA-approved product, JAMA at 2181. During this time, Par leveraged its exclusivity to maximize sales. The average wholesale price of intravenous vasopressin surged from $4.27 to $138.40 per vial in November 2016—an increase of 3141%. JAMA 2181. In 2013, when there were multiple competing suppliers, total sales from intravenous vasopressin approximated $4 million. *Id*. As of November 2016, annualized sales

[7] Prior to the 1938 FDCA, thousands of drug products were on the market without FDA approval. JAMA 2181. In 2006, as part of the FDA's Unapproved Drugs Initiative, the FDA permitted companies to obtain FDA approval to market a drug already on the market through an abbreviated process that would not cause undue burden on consumers already using the drug. *Id*. Although Plaintiff's complaint refers to "painstaking efforts" to obtain FDA approval, Compl ¶ 2, its application for Vasostrict® to the FDA relied only upon a review of then published literature to characterize the pharmacology, safety, and efficacy of its drug, JAMA 2181. No new nonclinical pharmacology, toxicology or human studies supported the regulatory approval. JAMA 2181.

of Vasostrict® totaled nearly $400 million.[8] *Id*.

Par's Vasostrict® Is Not Ready-to-Use. Vasostrict® is not produced in ready-to-use form and has a short shelf life. Mase Decl. ¶ 11. The health care provider must manipulate Vasostrict® into a saline or dextrose solution just before administering it to a patient;[9] once the product is readied, it must be discarded after 18 hours at room temperature (or 24 hours if the product was refrigerated), Compl. ¶ 53. The unavailability of a ready-to-use form of the drug has two primary shortcomings: (1) it takes precious time to prepare the drug for administration in emergency situations, *see* Mase Decl. ¶ 11; and (2) it presents a higher risk of human error or contamination when medical professionals admix vasopressin hurriedly and outside of an aseptic environment (*e.g*., without a laminar flow hood), *see id*.

For example, if the Vasostrict® is not in a cart in the medical unit it must be ordered from the pharmacy during the middle of a procedure, which can take 15 minutes or longer, if nothing goes wrong, where it will have to be mixed, and brought to the patient. Mase Decl. ¶ 12. Even if the Vasostrict® is stored in a cart in the medical unit, the multi-step process of mixing the right dosage is performed by the nurse or medical professional on the spot, outside of a sterile environment, and not under an aseptic hood. *Id*. To administer Vasostrict®, the following aseptic admixture steps are generally required:

1) Wash hands, remove any jewelry, put on gloves;

2) Gather all necessary materials for preparing the IV, making sure they are not expired, are free from particulate matter, and not leaking;

3) Select the correct number of Vasostrict® vials needed for the proper dosage (this frequently requires the nurse or medical professional to correctly measure part of a

[8] "As a result of the high cost, reports have surfaced of [Vasostrict®] being removed from code carts, making it unavailable in life-threatening situations." JAMA 2181.
[9] *See* McCabe Decl., Ex. 6, Vasostrict® Sell Sheet (product label), available at http://www.parsterileproducts.com/products/assets/pdf/PI/2017/Vasostrict-1mL-10mL-3003619D.pdf (last visited on August 12, 2018).

vial (*e.g.*, to measure out two and a half vials)—a step that adds time and potential for error);

4) Select the smallest gauge needle suited for the task and attach the needle to the syringe;

5) Clean the top of the vial with alcohol;

6) Inject an equal amount of air into the vial with the syringe and needle, before withdrawing the medication;

7) Draw into the syringe the proper amount of Vasostrict®, measuring and using partial doses if needed;

8) Remove the needle, activate the needle's safety device and dispose of needle;

9) Attach new needle;

10) Verify which IV bag diluent must be used and what volume should be added to make a sterile solution, then select the correct diluent;

11) Clean the insertion port of the IV bag with alcohol;

12) Input needle into IV bag insertion port and inject the Vasostrict® to mix with the diluent in the bag;

13) Inspect the product for particulate matter and discoloration prior to administration;

14) Create a label for the IV admixture, which includes the patient's name and identifying information, drug name and strength, infusion period, flow rate, expiration date and time (often in emergent situations, labeling is not available, which can lead to medication errors);

15) Insert IV tubing spike into bag; and

16) Hang the bag for intravenous delivery to the patient.

Mase Decl. ¶ 12. This process might take approximately 5-7 minutes in a best-case scenario, if nothing goes wrong. *Id*. If multiple vials are needed to make the right dose for a patient, some of these steps must be repeated. *Id*.

There is potential for devastating human error at every step in this process. Mase Decl. ¶ 13. For example, if the patient is given the wrong dose of Vasostrict®, serious medical

complications could arise that may lead to death. *Id*. If the aseptic steps are not performed or are ineffective, the patient could have contaminated product injected into his or her bloodstream, which can lead to life-threatening infections. *Id*. As Plaintiff admits, "vasopressin products are associated with an array of potential adverse reactions including hemorrhagic shock, heart failure, and acute renal insufficiency." Compl. ¶ 53. "[T]he improper storage, preparation, or administration of vasopressin products may also have significant adverse consequences." *Id*. The availability of a clearly labeled, ready-to-use form of vasopressin addresses the risks that are otherwise presented by having someone who is not a pharmacist prepare the patient's Vasostrict® mixture in an unlabeled bag while the medical emergency is unfolding. Mase Decl. ¶ 12, 17.

Athenex's vasopressin products are faster and safer. Recognizing these shortcomings and after extensive market research, Athenex relied on the 2017 Guidance and worked to develop a ready-to-use form of vasopressin. Mase Decl. ¶¶ 14-15. Athenex's compounded vasopressin products are supplied in IV bags that do not require dilution or refrigeration and have a shelf life of 60 days. *Id*. ¶ 16. Athenex launched its vasopressin products on August 13, 2018, Mase Decl. ¶ 18; it currently supplies the products in 50 unit per 50 ML saline and 100 unit per 100 ML saline concentrations, *id*. ¶ 16.

Athenex's vasopressin products are faster to administer, not requiring any further dilution or mixing, because they are in ready-to-use form. Mase Decl. ¶ 17. Administering them to a patient also carries less risk of human error because, unlike the complex, multi-step process for Vasostrict®, Athenex's products can be administered to patients by simply selecting the proper dosage (by referencing the easy-to-read label that is applied on every bag during the manufacturing process) and connecting the bag to the patient's IV line. *Id.* Having a ready-to-

use product is especially important in emergency cardiac events, where minutes matter. *Id*. These clinically important benefits were unavailable to patients and health practitioners when Vasostrict® was the only vasopressin product available.

Such clinical benefits enjoy a strong consensus in the medical community and government agencies alike. A highly-regarded health care accreditation organization called the Joint Commission[10] maintains two hospital accreditation standards that emphasize the importance of ready-to-use for medication management in the hospital setting. The standard titled "The hospital safely manages emergency medications" (MM.03.01.03) requires that "[e]mergency medications and their associated supplies are readily accessible in patient care areas" and "[w]henever possible, emergency medications are available in unit-dose, age-specific, and ready-to-administer forms." *See* McCabe Decl., Ex. 2, Joint Commission Standard MM.03.01.03. Similarly, the standard titled "The hospital safely dispenses medications" (MM.05.01.11) requires that "[m]edications are dispensed in the most ready-to-administer forms commercially available and, if feasible, in unit doses that have been repackaged by the pharmacy or licensed repackager." *See* McCabe Decl., Ex. 3, Joint Commission Standard MM.05.01.11.

The Centers for Medicare & Medicaid Services ("CMS"), part of Defendant U.S. Health and Human Services, provides in its State Operations Manual that "[w]henever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy." McCabe Decl., Ex. 4,

[10]The Joint Commission is an independent, not-for-profit, health-care-accreditation organization, formerly known as the Joint Commission on Accreditation of Healthcare Organizations. *See* https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (last visited on Aug. 12, 2018). "Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards." *Id*.

Excerpt of CMS, State Operations Manual, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals ("CMS Manual") at 312. The CMS Manual interprets 42 C.F.R. § 482.25, which is the federal regulation requiring hospitals to "have pharmaceutical services that meet the needs of the patients." 42 C.F.R. § 482.25.

In addition to timeliness, ready-to-use drugs like Athenex's vasopressin products are also clinically important because they decrease the risk of human error in administration. Mase Decl. 17. With a ready-to-use drug, the health care provider knows it has already been mixed properly, so the indicated dose is accurate. The clear labeling on a pre-packaged, ready-to-use drug ensures the right drug is administered in the intended dose. Mase Decl. ¶ 17.

D. Athenex Applies its cGMP-Compliant Manufacturing Process to Every Batch of Compounded Drug Product.

The Athenex manufacturing process—applied to every batch of compounded drug product—comports with the same strict manufacturing process standards that govern FDA-approved, branded drug products. Keem Decl. ¶¶ 8-9.

Athenex's cGMP-compliant process of producing its compounded vasopressin products can be broadly described in five steps:

1) Athenex acquires all the materials needed to compound its vasopressin products from qualified sources, which it vets according to standard operating procedures, including ensuring that the supplier for the API (*i.e.*, bulk substance) is one approved by the FDA and recently audited to cGMP standards by the Athenex quality group. The materials needed to compound vasopressin include bulk drug substance (vasopressin), excipients, water for injection, formulation pH adjusters, and the intravenous ("IV") bags.
2) Although the bulk drug substance is one approved by the FDA, Athenex also

conducts its own testing of critical parameters (*e.g.*, potency) using industry-recognized standards, which are outlined in its standard operating procedures.

3) Athenex formulates the vasopressin from bulk and aseptically processes the material using validated methods, which includes a media fill validation using industry-recognized standards. The formulated product is then transferred to our aseptic suite (*i.e.*, a "clean room") for further manufacturing.

4) Athenex fills the IV bags with the vasopressin substance in a clean room under ISO5 hoods using a standardized, automated process to ensure all bags are filled with the correct quantities. Athenex weighs each bag before and after filling to verify the amount delivered matches the batch record.

5) Athenex then rigorously inspects, labels, and packages the bags for delivery, testing and issuing a Certificate of Analysis for every batch it produces, to demonstrate the products are uniformly within prescribed quality, testing, and safety parameters.

Keem Decl. ¶ 8. At each step along the way, trained professionals check and double-check the processes described above. *Id.* Athenex also conducts destructive testing to demonstrate the absence of contamination in a microbiology suite, where gowned personnel use specially-designed techniques to confirm sterility. *Id.* ¶ 9. These rigorous manufacturing standards, which meet cGMP requirements—the same standard applied to the manufacture of branded pharmaceuticals—are followed every time Athenex produces a batch of compounded vasopressin. Keem Decl. ¶ 9.

E. Athenex's Bulk-Compounded Vasopressin is Safer than Compounding Sterile-to-Sterile.

Compounding from bulk drug substances with a process like the one Athenex uses is safer than traditional sterile-to-sterile compounding starting from a finished drug product. The

Institute for Safe Medication Practice ("ISMP"), an independent, nonprofit organization focused on the safe use of medications and the prevention of medical errors with over 35 years of experience, recommends using a compounded, premixed product over a substance manually compounded.[11] It states that, "[t]o the maximum extent possible, COMMERCIALLY-PREPARED, premixed parenteral products and unit dose syringes are used versus manually compounded sterile products."[12] The term "commercially-prepared" means a "product available from either a commercial manufacturer or compounding facility."[13]

There are many ways in which compounding from bulk under Section 503B is safer than compounding from sterile-to-sterile.[14] For example, there is risk of contamination when bringing vials of an FDA-branded starting drug (like Vasostrict® for example) into an aseptic manufacturing suite for compounding because although the drug inside the vial is sterile, the outside is not and thus, each vial must be wiped down. Keem Decl. ¶¶ 11-12. These risks do not apply to bulk compounding, like with Athenex's process, because each bulk substance is processed into a sterile environment before coming into the clean room for processing. *Id*. ¶ 12. The chance for human error is also reduced when compounding from bulk drug substances because there are fewer manipulations in the manufacturing process. *Id*. By validating and automating the process, Athenex has reduced the risks of error. *Id*.

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[11] Plaintiff also relies on the ISMP as an authority on medical safety. *See* Compl. ¶ 53.
[12] *See* McCabe Decl., Ex. 5, ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations, Revised 2016, *available at* https://www.ismp.org/sites/default/files/attachments/2017-11/Guidelines%20for%20Safe%20Preparation%20of%20Compounded%20Sterile%20Preperations_%20revised%202016.pdf ("ISMP Report") (last visited August 12, 2018), at 8.
[13] *Id.* at 16.
[14] The FDCA also authorizes compounding drugs by starting with a sterile, FDA-branded drug to create the compounded substance. This method, sanctioned under Section 503A, is favored by large drug companies producing FDA-branded products, likely because doing so requires the compounder to purchase their branded product, boosting their sales, rather than decreasing them.

IV. ARGUMENT

A. Athenex is Entitled to Intervene as of Right.

Under Rule 24(a), a person is entitled to intervene "as of right" based on its showing of four factors: "(1) the timeliness of the motion; (2) whether the applicant 'claims an interest relating to the property or transaction which is the subject of the action'; (3) whether 'the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest'; and (4) whether 'the applicant's interest is adequately represented by existing parties.'" *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (quoting Fed. R. Civ. P. 24(a)) (citations omitted).[15] In this Circuit, a party seeking intervention as of right must also demonstrate Article III standing. *Fund For Animals, Inc. v. Norton*, 322 F.3d 728, 731-32 (D.C. Cir. 2003) ("[B]ecause a Rule 24 intervenor seeks to participate on an equal footing with the original parties to the suit, he must satisfy the standing requirements imposed on those parties.") (internal quotations omitted).

As demonstrated below, Athenex meets the requirements to intervene "as of right" because it (1) has standing as a defendant; (2) its motion is timely (the case has been stayed since January 2018 and no dispositive motions have been filed); (3) its manufacture and sale of compounded vasopressin is a significant protectable interest relating to the subject matter of this litigation; (4) disposition of this action will impair or impede Athenex's interest in the

[15] Rule 24(a)(2) states in relevant part:

> Upon timely application anyone shall be permitted to intervene in an action ... when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

Fed. R. Civ. P. 24(a)(2).

manufacture and sale of compounded vasopressin; and (5) Athenex's interests are inadequately represented by the parties (Athenex and Plaintiff are directly adverse on the matter and the FDA cannot raise all of the same arguments available to Athenex).

1. Athenex Has Article III Standing to Intervene as a Defendant.

Athenex has standing to intervene as a defendant seeking to uphold the 2017 Guidance on which it relies for its operations and sales of its compounded vasopressin products. When a party seeks to intervene as a defendant seeking to uphold government action, it needs to establish injury in fact caused by Plaintiff's requested relief, causation, and redressability. *Fund For Animals, Inc.*, 322 F.3d at 732-33 (intervening defendant showed injury-in-fact, causation, and redressability when the challenged government regulation threatened revenue and funding, that injury was "fairly traceable to the regulatory action," and a decision favorable to the government would prevent that loss from occurring); *Am. Horse Protection Assoc., Inc. v. Veneman*, 200 F.R.D. 153, 156-59 (D.D.C. 2001) (group of show horse trainers authorized to intervene as a right to defend the USDA's enforcement regime, when an animal protection group sued over the USDA's lax enforcement of a rule related to the method of training show horses).

Athenex meets the standing requirement for intervention as a defendant because Athenex would be injured in fact if the Court were to grant Plaintiff's requested relief, of either or both removing vasopressin from the 503B Category 1 List or vacating the 2017 Guidance. Mase Decl. ¶ 21. Denial of such relief would prevent harm to Athenex. *Fund For Animals*, 322 F.3d at 733; *Am. Horse Protection Assoc.*, 200 F.R.D. at 156-57. Plaintiff filed this lawsuit to vacate the FDA Guidance and remove vasopressin from the 503B Bulks List. As set forth above in Part III.B. *supra*, Athenex has expended considerable research effort and financial resources in reliance on the 2017 Guidance to develop its compounding business. Mase Decl. ¶¶ 8-9. If Plaintiff prevails, Athenex faces immediate concrete injury in the form of the loss of research

and financial resources invested into its 503B operation, the loss of jobs (current and planned) dedicated to 503B compounded, and lost profits from being forced to cease selling its vasopressin products. Mase Decl. ¶ 21. Each of these harms is sufficient to show injury-in-fact. *See Fund For Animals*, 322 F.3d at 732-33 (intervenor's threatened loss of tourist dollars and reduction in funding for a conservation program established injury-in-fact).

Conversely, should Plaintiff's requested relief be denied,[16] Athenex would continue to produce and sell compounded vasopressin products and continue its 503B operation. This is precisely the injury-in-fact, causation, and redressability required to show Article III standing under D.C. Circuit precedent. *Id*.

Athenex's "standing to intervene is not diminished" simply "because it seeks to defend, rather than challenge, the [FDA] rule." *See, e.g.*, *Assoc. Dog Clubs of N.Y. State v. Vilsack*, 44 F. Supp. 3d 1, 5 (D.D.C. 2014) (rejecting plaintiff's argument to the contrary) (quoting D.C. Circuit cases). Indeed, "a number of decisions in this Circuit have permitted intervention by parties seeking to defend government action." *Id*. (intervening-defendant had standing to defend USDA

[16] Par's Complaint is meritless and should be dismissed on at least two grounds as set forth in Athenex's proposed Answer, attached hereto, as Exhibit A. First, the 2017 Guidance is not "final agency action" and thus, not reviewable under the Administrative Procedure Act ("APA") 5 U.S.C. § 704. The 2017 Guidance does "not establish legally enforceable standards." It is only the FDA's "current thinking," is "interim," and constitutes only "recommendations." 2017 Guidance at 1. The 2017 Guidance fails the two part test of "final agency action" set forth by the U.S. Supreme Court in *Bennet v. Spear,* 520 U.S. 154, 177-78 (1987) ("consummation of the agency's decision-making process" and a decision by which "rights or obligations have been determined" or from which "legal consequences have been determined"). Second, the 2017 Guidance is also unreviewable under the APA because it is agency action "committed to agency discretion by law." 5 U.S.C. § 701 (a)(2). The 2017 Guidance is an exercise of the FDA's enforcement discretion and accordingly, is presumed immune from judicial review. *Heckler v. Cheney*, 470 U.S. 821,832 (1985) (ruling that FDA decision not to bring proceedings and not enforce FDCA against the state conducting lethal injections with FDA unapproved drugs for that purpose in death penalty cases was "committed to agency discretion" because the FDCA "gives [] no indication" of when the FDA should bring an enforcement action; therefore, FDA's decision to not enforce was not reviewable under the APA).

rule that would impose injury if invalidated). *See, e.g.*, *Fund for Animals*, 322 F.3d at 733-34 (D.C. Cir. 2003) (intervening-defendant had standing to defend U.S. Department of Interior rule that would impose injury if invalidated); *Military Toxics Project v. EPA*, 146 F.3d 948, 954 (D.C. Cir. 1998) (same, regarding defense of U.S. Environmental Protection Agency rule); *Wildearth Guardians v. Salazar*, 272 F.R.D. 4, 13-18 (D.D.C. 2010) (same, regarding defense of action by the U.S. Department of Interior and U.S. Fish and Wildlife Service).

Moreover, Plaintiff itself recognizes that Athenex has a stake in this proceeding by impliedly referencing Athenex in its Complaint. Compl. ¶ 67. After alleging that the 2017 Guidance it challenges illegally permits another compounder, QuVa Pharma, Inc., to launch a compounded version of vasopressin, Compl. ¶¶ 57-66, Plaintiff further alleges that "at least one other compounder, is also working to prepare a bulk compounded vasopressin drug for launch" and cited the July 28, 2017 vasopressin nomination letter from Baker Hostetler. Compl. ¶ 67. This "other compounder" is Athenex and the relief Plaintiff seeks will injure Athenex, barring it from compounding its vasopressin products. Mase Decl. ¶¶ 14, 21. Under these circumstances, Athenex meets the requisite standing requirement to intervene as a defendant in this action.

2. Athenex Has a Significant Protectable Interest in Upholding the FDA Guidance and Vasopressin's Inclusion on the Category 1 List.

The first factor of Rule 24 (a)'s four-part test is that the putative intervenor have "an interest relating to the property or transaction which is the subject of the action." *See, e.g.*, *Fund For Animals, Inc.*, 322 F.3d at 735 (citing Fed. R. Civ. P. 24(a)). "The test operates in large part as a 'practical guide,' with the aim of disposing of disputes with as many concerned parties as may be compatible with efficiency and due process." *Wildearth Guardians v. Salazar*, 272 F.R.D. 4, 12–13 (D.D.C. 2010) (citing *U.S. v. Morten,* No. 09-1018, 2010 WL 3069060, at *5 (D.D.C. Aug. 4, 2010)).

Just as Athenex has Article III standing to defend the FDA Guidance and the Category 1 listing of vasopressin, *see supra*, Part IV.A.1, it also has an important interest in the "transactions," which here, are the FDA interim actions that are the subject of this litigation, because if Plaintiff obtains its requested relief, Athenex will be forced to cease its marketing and sale of its vasopressin products, Mase Decl. ¶ 21. *See Fund For Animals*, 322 F.3d at 735 ("The second factor is also readily dispatched. Our conclusion that the [intervenor] has constitutional standing is alone sufficient to establish that [it] has 'an interest relating to the property or transaction which is the subject of the action'"); *Assoc. Dog Clubs*, 44 F. Supp. 3d at 6 (litigant who had standing to intervene also had a protectable interest in the suit, under FRCP 24(a) because "in this Circuit, satisfying constitutional standing requirements demonstrates the existence of a legally protected interest") (internal quotations omitted); *Wildearth Guardians*, 272 F.R.D. at 13 ("In most instances, the standing inquiry will fold into the underlying inquiry under Rule 24(a): generally speaking, when a putative intervenor has a 'legally protected' interest under Rule 24(a), it will also meet constitutional standing requirements, and *vice versa.*") (citing *Roeder v. Islamic Republic of Iran,* 333 F.3d 228, 233 (D.C. Cir. 2003)).

Furthermore, it was Athenex, through its counsel Baker & Hostetler LLP, who nominated vasopressin for inclusion on the list of bulk drug substances that can be used for compounding under section 503B of the FDCA. Mase Decl. ¶ 14. As a result of its nomination, FDA listed vasopressin as a "503B Category 1" substance for purposes of the "Guidance." *Id.*; *see also* Compl. ¶ 67. Athenex has begun producing and selling its compounded vasopressin products in reliance on vasopressin's status as a Category 1 compounding substance under the Guidance. Mase Decl. ¶ 18, 20. Athenex has spent considerable time and resources developing ready-to-

use vasopressin products. *See* Part III.B., *supra*. Additionally, vasopressin is one of Athenex's inaugural bulk compounded products made under Section 503B, Mase Decl. ¶ 20, and part of Athenex's efforts to build its reputation for high quality and safe compounded products, which is a top priority for Athenex, Keem Decl. ¶ 4; Mase Decl. ¶ 21. It is crucial that Athenex continue the production and sale of vasopressin, so that Athenex may avoid the possibility of losing the goodwill and positive brand-reputation that it is continuing to build with its growing customer base. Mase Decl. ¶ 21. The alternative would be devastating to Athenex's 503B operation. *Id*.

There is a need for Athenex's vasopressin products because the ready-to-use form is safer and has a longer shelf life than the branded vasopressin products Plaintiff sells. *See* Part III.C., *supra*. It is also less expensive than Plaintiff's drug, which has dramatically increased in price, by 3141% (from $4.27 to $138.40 per vial), in the roughly two years that Plaintiff has enjoyed exclusivity. *See* JAMA at 2181. Many healthcare providers recognize the clinical importance of Ahenex's ready-to-use form, *see* Part III.C., s*upra*, and the Institute for Safe Medical Practices agrees that to "the maximum extent possible," a commercially prepared (or compounded) "premixed" product should be used, "versus manually compounded sterile products," *see* McCabe Decl, Ex. 5, ISMP Report at 8, 16. Athenex worked to develop a product that would satisfy this market need, Mase Decl. ¶¶ 14, 19, and thus, it holds a significant interest in keeping its product on the market. Because the relevant "property" under Rule 24 intervention is Athenex's compounded vasopressin products, which it produces and sells in reliance on the 2017 Guidance, Mase Decl. ¶¶ 18-20, and the relevant Rule 24 "transaction" is the 2017 Guidance and FDA's corresponding list naming vasopressin as Category 1—which Plaintiff seeks to invalidate—"there can be no question that [Athenex] has the requisite interest." *See Fund For Animals*, 322 F.3d at 735; *Mova Pharm. Corp.*, 140 F.3d at 1074.

3. The Disposition of this Action May Impair or Impede Athenex's Ability to Protect its Interest.

Athenex easily meets the second factor of Rule 24(a): Plaintiff's lawsuit threatens to impair Athenex's interest in the action. Under this prong, "[t]he inquiry is not a rigid one: consistent with the Rule's reference to dispositions that may "as a practical matter" impair the putative intervenor's interest, Fed. R. Civ. P. 24(a)(2), courts look to the "practical consequences" of denying intervention." *Wildearth Guardians v. Salazar*, 272 F.R.D. 4, 13 (D.D.C. 2010) (citing *Fund for Animals, Inc. v. Norton,* 322 F.3d 728, 735 (D.C. Cir. 2003)). Simply put, if granted, Plaintiff's relief sought would force Athenex to stop selling its compounded vasopressin products. Mase Decl. ¶ 21. Thus, Athenex "is so situated that the disposition of the action may as a practical matter impair or impede" Athenex's "ability to protect its interest." *Mova Pharm. Corp.*, 140 F.3d at 1074.

The second factor is satisfied because the 2017 Guidance at issue benefits Athenex and vacating it and striking vasopressin from the Category 1 List—as Plaintiff asks the Court to do—would remove that benefit. *See, e.g*., *Assoc. Dog Clubs of New York State v. Vilsack*, 44 F. Supp. 3d 1, 6 (D.D.C. 2014) (concluding this factor was met because the intervenor would be harmed if Plaintiff prevailed and further observing that "[t]his potential harm is not obviated by the [intervenor's] ability to 'reverse an unfavorable ruling by bringing a separate lawsuit,' given the cost and delay of doing so") (citing *Fund for Animals,* 322 F.3d at 735); *accord Am. Horse Prot. Ass'n,* 200 F.R.D. at 158–59.

Furthermore, if Plaintiff were granted the relief it seeks, to remove vasopressin from inclusion as a Category 1 compound for purposes of the 2017 Guidance, that precedent may make it more difficult for Athenex to succeed in a future suit against FDA if the agency does not ultimately include vasopressin in its published list of bulk drug substances. Intervention is

warranted where the litigation "could establish unfavorable precedent that would make it more difficult for [the intervenor] to succeed" in any future suit to enforce his rights. *Roane v. Leonhart*, 741 F.3d 147, 151 (D.C. Cir. 2014).

4. Athenex's Interests Are Not Adequately Represented by the Existing Parties.

Athenex also satisfies Rule 24(a) because no existing party represents its interests. *Fund for Animals*, 322 F.3d at 735. "This requirement is 'not onerous'" and the "movant need only show that the current representation *may be* inadequate." *Assoc. Dog Clubs*, 44 F. Supp. 3d at 6–7 (quoting *Fund for Animals,* 322 F.3d at 735) (emphasis added). The "putative intervenor's burden here is *de minimis*." *Wildearth Guardians*, 272 F.R.D. 4, 13 (D.D.C. 2010) (citing *Fund for Animals,* 322 F.3d at 735). Courts in the D.C. Circuit often conclude that "governmental entities do not adequately represent the interests of aspiring intervenors," *Fund for Animals*, 322 F.3d at 736, and "that private companies can intervene on the side of the government, even if some of their interests converge," *Hardin v. Jackson*, 600 F. Supp. 2d 13, 16 (D.D.C. 2009).

Neither of the existing parties represent Athenex's interests. Plaintiff's interests are directly opposed to those of Athenex because Plaintiff seeks to invalidate the 2017 Guidance on which Athenex relies to sell its compounded vasopressin products and seeks to strike vasopressin from the 503B Category 1 list. The Federal Defendants do not adequately represent the interests of Athenex in this litigation because those Defendants are regulators, not private parties engaged in the regulated conduct at issue in this lawsuit and they are not charged with protecting Athenex's private interests. *See Fund for Animals*, 322 F.3d at 736 ("[W]e have often concluded that governmental entities do not adequately represent the interests of aspiring intervenors."); *accord Wildearth Guardians*, 272 F.R.D. at 13. The Federal Defendants do not have any commercial stake at issue, like Athenex has in the inclusion of vasopressin as a Category 1

compounding substance for purposes of the Guidance, *see* Part III.B, *supra* (demonstrating that Athenex has invested considerable resources). *See, e.g.*, *Hardin*, 600 F. Supp. 2d at 16 ("The D.C. Circuit has frequently found 'inadequacy of governmental representation' when the government has no financial stake in the outcome of the suit."). And, just because the FDA may argue broadly that the FDA Guidance is lawful and should be upheld, this does not mean the FDA has the same narrow and private interests as Athenex. *See Am. Horse Prot. Ass'n*, 200 F.R.D. at 159 (concluding that government's representation was not adequate, reasoning that "merely because parties share a general interest in the legality of a program or regulation does not mean their particular interests coincide so that representation by the agency alone is justified").

Furthermore, Athenex will bring to the matter a detailed understanding of compounding vasopressin from bulk in a commercial facility, which the other parties lack. As a bulk compounder with a cGMP-compliant manufacturing process, state-of-the-art facilities, and extensive experience manufacturing drugs from bulk substances, *see* Mase Decl. ¶¶ 8-9; Keem Decl. ¶¶ 3-5, 8, Athenex is uniquely positioned to rebut Plaintiff's inaccurate allegations regarding two important issues.

Plaintiff alleges that: (1) all bulk compounding is dangerously unsafe (*see, e.g.*, Compl. ¶¶ 1, 9, 51); and (2) there is no clinical need for a bulk compounded form of vasopressin (*id*. ¶10). Neither is true. And although the Court can grant this motion without deciding the merits of these issues, they are central to Plaintiff's lawsuit. The issues bear on the public's interest in leaving undisturbed the 2017 Guidance and on the hardship to Athenex and other bulk compounders if Plaintiff's requested relief were granted—two factors for the Court to consider in Plaintiff's request for injunctive relief. Athenex should be permitted to intervene to present

counter-arguments to Plaintiff's position, which the Federal Defendants are not equipped to do. Athenex epitomizes safe bulk compounding and is well-poised to rebut Plaintiff's allegations to the contrary by showing the cGMP manufacturing standard required of bulk compounders is the same standard applied to FDA-branded drugs; in other words, there is no meaningful difference between the manufacturing process used by Plaintiff and that used by Athenex. *See* Parts III.A, D, E, *supra*. Athenex is also uniquely positioned to establish a clinical need for vasopressin, contrary to Plaintiff's assertion that none exists. The ready-to-use vasopressin products that Athenex manufactures are faster and safer because they do not need to be further diluted like Vasostrict® or mixed on the spot, outside of a sterile environment, like Vasostrict® sometimes is. *See* Mase Decl. ¶ 12-13, 16. Athenex's products provide important clinical benefits and fill an unmet need—points that neither existing party is able to argue.

5. Athenex's Motion is Timely.

Finally, Athenex's motion is timely because no party would be disadvantaged by its intervention. This case has been stayed since January 25, 2018, *see* ECF Nos. 16-18, and no party has filed a merits brief. Because participation will not slow the resolution of this matter or otherwise prejudice the existing parties, Athenex's application meets this Circuit's requirements for timeliness. *See, e.g.*, *Roane v. Leonhart*, 741 F.3d 147, 151 (D.C. Cir. 2014) ("[T]he requirement of timeliness is aimed primarily at preventing potential intervenors from unduly disrupting litigation, to the unfair detriment of the existing parties."). This action was filed on October 26, 2017. ECF No. 1. But, in assessing timeliness, "the time elapsed since the inception of the suit" is "not in itself the determinative test." *Roane*, 741 F.3d at 151-152 (concluding a district court abused its discretion when it found an intervention motion untimely because the litigant "*could* have intervened earlier" the litigant "*should* have intervened earlier"; "relevant

caselaw says [that] the most important consideration [is]: the fact that granting [litigant] intervention was highly unlikely to disadvantage the existing parties") (emphasis in original).

Athenex's intervention at this early stage would not delay justice for the parties because the parties have voluntarily stayed the case (*see* ECF Nos. 13, 17 (joint motions to stay the case)) and nothing substantive has happened since the Federal Defendants filed their answer on January 5, 2018, *see* ECF No. 11. No discovery has occurred (and it may not, if this case is based entirely on the administrative record), no dispositive motions have been filed, and the case has not advanced whatsoever, since January 2018, when the parties agreed to stay the case. Under these circumstances, intervention is timely. *See, e.g.*, *Roane*, 741 F.3d at 151; *Hardin v. Jackson*, 600 F. Supp. 2d 13, 16 (D.D.C. 2009) (intervention motion was timely when case had been stayed for two years, even though plaintiff's motion for summary judgment had been filed, when the court had not issued any decisions on the merits of plaintiff's claim and "no discovery has or will occur in this case" because it was based on the administrative record).

B. Athenex May Intervene Permissively.

In the alternative, if the Court should conclude that Athenex may not intervene as of right, the Court should nevertheless permit Athenex to intervene permissively, under Rule 24(b) of the Federal Rules of Civil Procedure. A party may intervene permissively if has a claim or defense predicated on a question of law or fact common to the main action. *See* Fed. R. Civ. P. 24(b). Here, Athenex has invested significant time and resources into its 503B compounding operations—and its manufacture and sale of compounded vasopressin—in reliance on the 2017 Guidance. *See* Mase Decl. ¶¶ 8-9, 18-20. Because Plaintiff's lawsuit would invalidate the 2017 Guidance, and jeopardize Athenex's sale of vasopressin, *see* Mase Decl. ¶ 21, Athenex may permissively intervene to present defenses to Plaintiff's action. These defenses are set forth in the accompanying Proposed Answer, Exhibit A, and will be based on Athenex's status as a

registered 503B facility and its unique perspective on the 2017 Guidance and why it must be upheld. These are facts and questions of law common to Plaintiff's action and thus, Athenex meets the standard for permissive intervention. *See, e.g.*, Fed. R. Civ. P. 24(b).

V. CONCLUSION

For the foregoing reasons, Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC respectfully request that the Court grant their motion to intervene as defendants in the above-captioned case.

Dated: August 13, 2018

Respectfully submitted,

/s/ Gilbert S. Keteltas

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CERTIFICATE OF SERVICE

I HERBY CERTIFY that on this 13th day of August, 2018, a true and exact copy of the Memorandum of Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC in Support of Their Motion to Intervene was served via operation of the ECF system on all counsel of record pursuant to Local Civil Rule 5.4(d).

/s/ Gilbert S. Keteltas
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