IN THE UNITED STATES BANKRUPTCY COURT
EASTERN DISTRICT OF ARKANSAS
LITTLE ROCK DIVISION

IN RE: CANTRELL DRUG COMPANY, **Case No. 4:17-bk-16012**
(Chapter 11)

Debtor-in-Possession,

CANTRELL DRUG COMPANY **PLAINTIFF**

AP No. 4:18-ap-1024

UNITED STATES OF AMERICA

FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Springs, MD 20993

SCOTT GOTTLIEB, M.D., In His Official Capacity as Commissioner of Food and Drugs, Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993

THOMAS E. PRICE, M.D.,
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201 **DEFENDANTS**

ORDER GRANTING, IN PART, AND DENYING, IN PART, EMERGENCY MOTION TO EXTEND AUTOMATIC STAY AND FOR PRELIMINARY INJUNCTION

On March 1, 2018, the Cantrell Drug Company ("Cantrell Drug Company" or the "Debtor") commenced the above-referenced adversary proceeding against the United States of America, the Food and Drug Administration (the "FDA"), Scott Gottlieb, M.D., in his capacity as Commissioner of the FDA, and Thomas E. Price, M.D., Secretary of Health and Human Services (collectively the "Defendants" or "United States"). Also on March 1, 2018, the Debtor

filed an *Emergency Motion to Extend Automatic Stay and For Preliminary Injunction* [Doc. #4] (the "Emergency Motion"), followed by a *Supplement to Emergency Motion to Extend Automatic Stay and for Preliminary Injunction* [Doc. #11] filed on March 5, 2018 (the "First Supplement"), and a *Second Supplement to Emergency Motion to Extend Automatic Stay and for Preliminary Injunction* [Doc. #13] also filed on March 5, 2018 (the "Second Supplement").

The United States, on March 5, 2018, filed its *Opposition to Plaintiff's Emergency Motion to Extend Automatic Stay and for Preliminary Injunction* [Doc. #20] and the next day filed its *Response to Plaintiff's Supplement to Emergency Motion to Extend Automatic Stay and for Preliminary Injunction* [Doc. #21]. The Court set the Debtor's Emergency Motion, First Supplement, Second Supplement and the United States' Responses to the Emergency Motion and First Supplement for hearing on an emergency basis and received testimony and documentary evidence March 6 through March 9, 2018.

On March 9, 2018, the parties announced an agreement to stay the proceedings for a short time for reasons that will be discussed below and the hearing was continued to March 26, 2018. Prior to the March 26 setting, the United States, on March 16, 2018, filed its *Opposition to Plaintiff's Emergency Motion to Extend Automatic Stay and for Preliminary Injunction* [Doc. #32] and, on March 18, 2018, filed its *Response to Plaintiff's Second Supplement to Emergency Motion to Extend Automatic Stay and For Preliminary Injunction* [Doc. #33].

The day before the hearing was to resume the Debtor filed its *Second [sic] Supplement to Emergency Motion to Extend Automatic Stay and for Preliminary Injunction* [Doc. #44] (which was actually the third supplement to the Emergency Motion and will be referred to as the "Third Supplement"), and its *Reply to United States' Response to Plaintiff's Second Supplement to Emergency Motion to Extend Automatic Stay and for Preliminary Injunction* [Doc. #46]. The

hearing resumed on March 26, 2018, and continued to conclusion on March 28, 2018. On the morning of the last day of the hearing the United States filed its *Response to Plaintiff's Third Supplement to Emergency Motion to Extend Automatic Stay and for Preliminary Injunction* [Doc. #52].

Kevin P. Keech appeared at the hearing as counsel for the Debtor. The United States was represented by Stacey E. McCord, Shannon Short Smith, Raquel Toledo, Jeffrey Ira Steger, and Jonathan Edward Jacobson. At the close of the evidence the Court took the matter under advisement.

In summary, this case involves a dispute between Cantrell Drug Company and the FDA concerning the sterility of certain injectable drugs compounded by Cantrell Drug Company. As will be further explained below, the United States filed an action in federal district court alleging violations of 21 U.S.C. § 331(a) and (k) and seeking, among other things, an injunction to stop Cantrell Drug Company from "manufacturing" or "distributing" any drugs until its operations are in compliance with the Federal Food, Drug, and Cosmetic Act (the "FDCA") to the satisfaction of the FDA. Debtor's Ex. 2. The day after the lawsuit was filed the FDA issued a press release alerting health care professionals and patients not to use compounded drugs from Cantrell Drug Company and stating that deficiencies in the Debtor's operations could result in contaminated products adding that the use of contaminated products could cause serious injury or death to the patient. Debtor's Ex. 3.

Cantrell Drug Company adamantly disputes the United States' allegations. It also asserts that its drug orders have plummeted since the press release was disseminated and without relief from the bankruptcy court its business will have to shut down, its drug users will suffer due to the unavailability of drugs it produces that are on the FDA's drug shortage list, employees will

lose their jobs, the Debtor's reorganization proceeding will become a bankruptcy liquidation, and both creditors and equity security holders will suffer. Cantrell Drug Company also asserts that although the FDA filed an action seeking a preliminary injunction in District Court that the effect of FDA's press release was to *grant* FDA an injunction prior to a judicial determination on the merits of the action in violation of Cantrell Drug Company's due process rights.

Jurisdiction

The Court has jurisdiction pursuant to 28 U.S.C. § 1334 and 28 U.S.C. § 157. This is a core proceeding pursuant to 28 U.S.C. § 157(b)(2)(A), and (G). The following constitutes the Court's findings of fact and conclusions of law in accordance with Federal Rule of Bankruptcy Procedure 7052.

Relief Sought

As reflected in the first paragraph of this order the parties have filed a total of ten pleadings since March 1, 2018, the date the Debtor initially filed its Emergency Motion. Five of the pleadings were filed after the court proceedings began as events continued to unfold. After review of the Emergency Motion, its three supplements, and the Debtor's closing arguments, the Court understands the Debtor seeks the following relief:[1]

[1] In the Emergency Motion, the Debtor sought an order enjoining the FDA from taking "any adverse action" against the Debtor for at least forty-five days to allow the Debtor and FDA to continue to negotiate a resolution of the issues raised in a letter the Debtor had received from the Department of Justice (discussed in further detail in the background section) and also barring the FDA from taking the "threatened actions" stated in that letter. (Emergency Motion, ¶¶ 15, 26). At the time of the filing, however, the threatened actions had, in fact, already been taken and the injunction action was pending in the District Court. This request, therefore appears moot.

In addition, in its Third Supplement, the Debtor sought an order from this Court allowing the Debtor to continue to produce and distribute its products unless or until the FDA obtained a legally enforceable order or agency adjudication barring the Debtor from doing so. The evidence and testimony revealed, however, that while the FDA strongly urged the Debtor not to distribute its drugs and did disseminate the press release with the "do not use" alert to consumers, no evidence of an injunction or other legally enforceable order against the Debtor ordering the Debtor to stop producing or distributing products was introduced.

(1) For this Court, pursuant to Section 105(a) of the Bankruptcy Code, to extend the automatic stay to the injunction action filed by the United States in the District Court for a period of forty-five days; and

(2) For this Court to "un-ring the bell" of the press release disseminated by the FDA and restore the status quo of the parties to a time before the press release was issued.

Background Facts

Cantrell Drug Company was purchased by Dr. James Liddell McCarley, Jr. and his wife from her father in 1992. Dr. McCarley became interested in compounding drugs during the next several years and expanded the business into the compounding business.

In 2013 President Obama signed into law the Drug Quality and Security Act ("DQSA") that, among other things, created 503B outsourcing facilities. Cantrell Drug Company was one of the first facilities to register with the FDA as a 503B outsourcing facility registering in December 2013. Cantrell Drug Company supplies medications that are on the FDA's drug shortage list. Many of its customers, including hospitals, have been purchasing products from Cantrell Drug Company for many years.

Prior to registering as a 503B outsourcing facility, the FDA conducted an inspection of Cantrell Drug Company's facilities (the "2013 Inspection"). At the conclusion of the 2013 Inspection the FDA issued a Form 483 inspection report (the "2013 Form 483"). There were twelve observations regarding various aspects of Cantrell Drug Company's operations generally including deficiencies in procedures designed to prevent microbiological contamination, to handle complaints, and to monitor environmental conditions. Additional deficiencies were noted regarding clothing worn by personnel, processes for cleaning and disinfecting equipment, written testing programs, and training procedures.

The next month after the 2013 Inspection, Cantrell Drug Company sent its response to the 2013 Form 483 to the FDA discussing the FDA's inspection and proposing certain corrective actions to address the FDA's concerns (the "November 2013 Response"). After reviewing the November 2013 Response, the FDA sent Cantrell Drug Company a "Warning Letter" dated January 21, 2015. The Warning Letter acknowledged that since the 2013 Inspection Cantrell Drug Company had registered as a 503B outsourcing facility and stated because of that the FDA would focus on the current good manufacturing practices ("CGMP") violations noted in the 2013 Form 483. The violations stated in the Warning Letter included, in general: (1) the failure to establish and follow written procedures designed to prevent microbiological contamination of drug products; (2) the failure to insure that manufacturing personnel wear clothing appropriate to protect the drug product from contamination; (3) the failure to establish an adequate system for monitoring environmental conditions in the aseptic processing areas; and (4) the failure to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions. Gov't Ex. 1. The Warning Letter discussed the November 2013 Response received from Cantrell Drug Company. The FDA acknowledged that several of Cantrell Drug Company's proposed corrective actions appeared to be adequate but noted that other proposed corrective actions were deficient. Gov't Ex. 1.

The FDA conducted another inspection of Cantrell Drug Company's facilities from September 14 through October 14, 2016 (the "2016 Inspection"). At the conclusion of the 2016 Inspection the FDA issued a Form 483 inspection report (the "2016 Form 483"). There were twelve observations regarding various aspects of Cantrell Drug Company's operations, and four of the items were noted as repeat observations from the 2013 Inspection. In abbreviated terms here, the observation titles indicated deficiencies in the aseptic processing areas for cleaning and

disinfecting equipment, the need for written procedures designed to prevent microbiological contamination and laboratory testing, deficiencies in testing products for conformance to the identity and strength of each active ingredient prior to release, deficiencies in the monitoring of environmental conditions in the aseptic processing areas, and deficiencies in air supply filtered through high-efficiency particulate air filters under positive pressure in the aseptic processing areas. Gov't Ex. 3. Other deficiencies noted were a lack of adequate space for placement of equipment and materials to prevent mix-ups, a failure to review thoroughly any unexplained discrepancy whether or not a product batch has already been distributed, the failure to include, "This is a compounded drug" on product labels, and the failure to record and justify deviations from written production and process control procedures. Gov't Ex. 3.

On November 18, 2016, Cantrell Drug Company disseminated a company announcement stating that it was voluntarily recalling "select sterile drug products due to lack of sterility assurance."[2] Gov't Ex. 4. The recalled products were distributed nationwide to health care facilities from May 25 to October 31, 2016. Gov't Ex. 4.

The FDA conducted another inspection of Cantrell Drug Company's facilities in June 2017 (the "2017 Inspection"). At the conclusion of the 2017 Inspection the FDA issued a Form 483 inspection report (the "2017 Form 483"). Debtor's Ex. 8; Gov't Ex. 5. There were eight observations regarding various aspects of Cantrell Drug Company's operations, and five of the items were noted as repeat observations from the 2016 Inspection. Debtor's Ex. 8; Gov't Ex. 5. Again, in abbreviated terms for purposes of brevity, the observation titles included failure of the quality control unit to fully investigate errors that have occurred, failure to follow responsibilities

[2] Dr. McCarley testified that although Cantrell Drug Company's announcement stated it was "voluntary" it would be better characterized as a mandatory recall by the FDA. This sentiment was repeated in connection with a second recall that is discussed later in this order.

and procedures applicable to the quality control unit, deficiencies regarding air supply filtered through high-efficiency particulate air filters under positive pressure in the aseptic processing areas, failure to thoroughly review any unexplained discrepancy, failure to follow procedures to prevent microbiological contamination of drug products, and deficient cleaning and disinfecting procedures in the aseptic processing areas. Debtor's Ex. 8; Gov't Ex. 5.

On July 25, 2017, Cantrell Drug Company disseminated a company announcement stating that it was voluntarily recalling "all sterile drug products due to lack of sterility assurance." The products recalled were "all lots of unexpired sterile drug products to the hospital and user level." Gov't Ex. 7.

On July 27, 2017, counsel for Cantrell Drug Company emailed John Diehl, Acting Director, Compliance Branch, Office of Pharmaceutical Quality Operations, Division II for the FDA, stating the Cantrell Drug Company "will not resume operations and distribution of sterile product until after the company provides FDA with further documentation. Cantrell will notify the FDA tomorrow when it plans on producing the documentation to FDA." Gov't Ex. 8.

On July 28, 2017, Dr. McCarley emailed Mr. Diehl attaching Cantrell Drug Company's response and documentation to the 2017 Form 483 providing evidence of corrective action taken by Cantrell Drug Company to address the 2017 Form 483 concerns. The email stated, "Based on this, Cantrell believes that it has satisfied the observations listed in the Form 483 and will resume production late today." Gov't Ex. 9. The email then stated that "No product will be released into the market before 8-2-17." Gov't Ex. 9. The documentation was placed in a "share file" due to the voluminous nature of the documentation provided.

On August 1, 2017, Mr. Diehl responded to Dr. McCarley's email stating that the FDA was still reviewing the documentation and stated, "At this time, we recommend you do not

release product into the market. We anticipate completing our review by next week, and will reach out to you at that time." Gov't Ex. 9.

On August 2, 2017, counsel for Cantrell Drug Company emailed Mr. Diehl stating:

> Cantrell is a small business and each day of delay is a hardship on [its] budget and payroll. As noted in our discussion, Cantrell has a third party contractor (ProPharma) who has reviewed the response and is of the opinion that Cantrell is ready to resume production. The company believes it is ready to resume production. Therefore, I ask that we please discuss the email below today, if at all possible. I understand FDA's position based on the 483. But, Cantrell has addressed the 483 observations, as noted in the response and is ready to resume production.

Gov't Ex. 9. Mr. Diehl responded that same day, "As FDA continues to review the firm's 483 response and has committed to communicate to your client next week, we do not believe a call is warranted at this time." Gov't Ex. 9.

Later that same day, August 2, 2017, counsel for Cantrell Drug Company again urged the FDA to move quickly stating:

> On multiple occasions, you have asked Cantrell for a response within 24 hours. While those response timelines were harsh on Cantrell, Cantrell met those timelines. FDA then asked Cantrell to use a third party consultant. Again, Cantrell met FDA's request and is utilizing their services and this third party agrees that Cantrell is ready to produce product.
>
> In other words, FDA has made Cantrell jump through hoops on multiple occasions. And, Cantrell has done so on multiple occasions. Now, that Cantrell has provided the FDA with the documentation it has requested, it seems unduly harsh to take over a week to review (Cantrell had 24 hours to respond) the response. In comparison, the review of this document is nearly as long as the entire inspection of many other 503B whole facilities.
>
> Cantrell simply asks for an expedited review of the materials. Specifically, Cantrell asks because it is one of very few 503Bs in the country to compound Sodium Bicarbonate. As you know, that drug is on FDA's drug shortage list and is in dire need for life saving procedures across the country. Multiple facilities are pleading for this drug and Cantrell wants to ensure patient needs are meet [sic].

Gov't Ex. 9.

Nine days later counsel for Cantrell Drug Company sent another email to Mr. Diehl asking the status of the review of the information sent on July 28, 2017. Gov't Ex. 10. Mr. Diehl responded that the FDA was completing its review adding, "Until you hear back from the Agency, our recommendation remains that you do not release product into the market." Gov't Ex. 10.

Dr. McCarley emailed Mr. Diehl on August 14, 2017, stating that "Cantrell has not released any sterile product in the market. We respect the agency's authority and have tried in earnest to be responsive to the concerns it has noted." Gov't Ex. 10. Mr. Carley added:

> However, Cantrell cannot continue to hold on to employees without revenue. The assurance of a response last week was not realized. I implore you to respond soon. Cantrell is a provider of critical drug shortage sodium bicarbonate injection and Cantrell is a small business with limited resources. It is likely Cantrell will be forced to file for bankruptcy protection should this matter continue to be unresolved into mid-week.

Gov't Ex. 10.

On August 18, 2017, the FDA sent Cantrell Drug Company its response to the July 28, 2017, documentation. The letter stated the "FDA has determined that, in the interest of public health, it is *not* appropriate for you to resume product distribution." Gov't Ex. 11 (emphasis in original). The headings on the discussions in the letter included: Inadequate Environmental Monitoring Program, Inadequate Control of Air Pressure Differentials, and Inadequate Cleaning and Disinfection Practices. Gov't Ex. 11. In the conclusion the letter stated, "The drug products you seek to distribute were processed under a significant risk of contamination. Therefore, FDA denies your request to distribute them, as there can be no assurance of their sterility." Gov't Ex. 11. Cantrell Drug Company responded August 24, 2017. This response does not appear to be in the record.

On August 30, 2017, John Toth, the Director of Quality for Cantrell Drug Company emailed Mr. Diehl stating, "In an effort to demonstrate our commitment to working with the Food and Drug Administration and be transparent in our activities, we wanted to make you aware that we will begin shipping the on-hold products from production dates July 28th through August 18th to our customers by close of business today August 30, 2017." Gov't Ex. 12. Mr. Diehl responded, "We emphasize in the strongest possible terms that, although we are currently reviewing your most recent submission, we have no assurance at this time that your products that are intended to be sterile are in compliance with the law and we urge you to continue to refrain from distributing them to the public." Gov't Ex. 12. Dr. McCarley responded to Mr. Diehl's email stating that Cantrell Drug Company "has not shipped any products intended to be sterile" and "does not intend to ship against the agency's recommendations." Gov't Ex. 12.

Mr. Toth sent an additional email to the FDA on August 31, 2017, urging the FDA to let him know what further information the FDA needs for Cantrell Drug Company to be able to ship the July 28th production. Gov't Ex. 12.

On October 6, 2017, the FDA overnighted a letter to Dr. McCarley responding to correspondence sent by Cantrell Drug Company to the FDA on August 24 and 30, 2017, and on September 6 and 18, 2017 regarding additional corrective actions taken since the August 18, 2017, FDA letter. The letter stated that the FDA had "carefully reviewed" the responses and "remains concerned that the drug products you seek to distribute appear to have been produced under insanitary conditions and in violation of the current good manufacturing practice (CGMP) requirements for drugs." Gov't Ex. 13. In conclusion the letter states:

> FDA remains concerned with your distributing finished drug products you have held at your facility since July 19, 2017, because these products were processed before you completed all corrective actions and therefore, they were made under conditions that present a significant risk of contamination. We advise that you not

> distribute these drug products because there is no assurance of their sterility and we strongly recommend that Cantrell complete all corrective actions before further producing drug products intended to be sterile.

Gov't Ex. 13.

Cantrell Drug Company sent a letter to the FDA dated October 12, 2017, in response to the FDA's October 6, 2017, letter. The letter enumerated sixteen remedial actions Cantrell Drug Company had taken since the June 2017 Inspection summarized as follows:

- initiating a voluntary cessation of production July 21, 2017
- initiating a voluntary product recall in July 2017
- implementing new procedures, policies and forms for quality management systems
- upgrading existing equipment and acquiring additional equipment
- retaining a third party compliance firm, ProPharma Group, for ongoing quality assurance support
- firing employees involved with unacceptable observations
- hiring a new, experienced Director of Quality in July 2017
- hiring a new lead microbiologist
- contracting an independent third party, Air Safe, to access and execute a controlled environment performance test in August 2017
- contracting with Integrated Project Services, LLC to perform an assessment of the classified areas in September 2017
- contracting with an independent third party, Escalate Sciences, to prepare a quality risk assessment and determine the suitability of product to resume shipment
- dispositioning all product produced between July 19 and August 21, 2017 to be rejected

- contracting with Kymanox for it to assess progress on remediation activities identified by Cantrell Drug Company's responses to the 2017 Form 483
- resuming shipment of product on September 22, 2017 with manufacturing dates beginning on August 22, 2017, after implementing all identified remediation activities
- contracting with Kynamox to provide final review for all lots produced going forward with total authority on lot disposition decisions effective October 13, 2017
- exploring acquisition of the company by BelHealth, which if consummated will allow Dr. McCarley to exit the business and allow BelHealth with others to continue the business to achieve the highest level of quality and CGMP compliance.

Debtor's Ex. 9; Gov't Ex. 14.

The sale to BelHealth did not take place. Due to the financial difficulties from the two recalls and production shutdowns, Cantrell Drug Company sought relief from its financial pressures by filing a Chapter 11 reorganization proceeding on November 7, 2017. During the early stages of the bankruptcy proceeding Cantrell Drug Company entered into a cash collateral order with one of its lenders. That cash collateral order anticipates the continuing operation of the business. At the time it filed bankruptcy Cantrell Drug Company was licensed to do business in over forty-five states.

On November 20, 2017, Mr. Toth sent Mr. Diehl a "promised strategic improvement plan" for Cantrell Drug Company. Debtor's Ex. 10; Gov't Ex. 16. It stated that the following additional items have been completed since the last communication:

- update to Form No. 100.4 – Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

- Creation of Form No. 416.0 – Monthly Controlled Area Audit Checklist
- Update to P&P No. 2.120 (R2) – Good Documentation Practices
- Update to P&P No. 2.150 (R3) – Controlled Area Management
- Creation of P&P No. 3.012 (R0) – Temperature, Humidity and Pressure Calibrations Procedure
- Update to P&P No. 4.263 (R3) – Aseptic Process Simulation Protocol
- Update to P&P No. 7.233 (R2) – Batch Record Review and Release
- REES (Building Automation System) Performance Quality Protocol Approved

Debtor's Ex. 10; Gov't Ex. 16. The letter discussed other specific items and their status as part of the Strategic Quality Plan and added a number of commitments to FDA. Debtor's Ex. 10; Gov't Ex. 16.

At the end of 2017, Cantrell Drug Company received a letter from the Department of Justice dated December 27, 2017 ("DOJ Letter"). Debtor's Ex. 12. The DOJ Letter stated that the Department of Justice had been advised by the FDA that Cantrell Drug Company is in violation of the FDCA "by, among other things, introducing or delivering for introduction into interstate commerce drugs that are adulterated." Debtor's Ex. 12. The DOJ Letter stated that the Department of Justice is prepared to seek preliminary and permanent injunctions against Cantrell Drug Company and Dr. McCarley to prevent further violations. Debtor's Ex. 12.

The specific statutes referenced in the letter are 21 U.S.C § 331(a) and (k). Section 331(a) prohibits the introduction or delivery for introduction into interstate commerce any drug that is adulterated. Section 331(k) prohibits causing articles of drugs to become adulterated while held for sale after shipment of one or more of their components in interstate commerce.

The DOJ Letter stated that an attached proposed consent decree included "the terms upon which the government would be willing to settle the suit." Debtor's Ex. 12. It further stated that if the Department of Justice had not heard from Cantrell Drug Company by January 4, 2018, it would assume that Cantrell Drug Company is not interested in settling the case and an action would be commenced in federal court against Cantrell Drug Company for injunctive relief.

The DOJ Letter also stated, "Given Cantrell's representation in a letter to FDA dated October 12, 2017 that Cantrell resumed shipment of product on September 22, with manufacturing dates beginning on August 22, it is the United States' position that there is an imminent threat to the public health. Therefore, this deadline cannot be extended." Debtor's Ex. 12.

Dr. McCarley testified that the Debtor and the Department of Justice entered into negotiations in an attempt to enter into a consent decree but could not agree to terms. One of the primary obstacles to the settlement was the Department of Justice's requirement that Cantrell Drug Company shut down its operations until the FDA inspectors were satisfied that Cantrell Drug Company was in compliance with CGMP. Although the December 27, 2017 DOJ Letter indicated its "position that there is an imminent threat to the public health" the injunction action was not filed until February 28, 2018.[3] Debtor's Ex. 2. The action seeks a preliminary injunction rather than a temporary restraining order and was filed in the United States District Court for the Eastern District of Arkansas, Case No. 4:18-cv-159 (the "District Court Action"). Debtor's Ex. 2. The complaint alleges violations of 21 U.S.C. § 331(a) and (k) and seeks, among other things, an injunction to stop the Debtor from manufacturing and distributing drugs until its

[3] The complaint has an electronic filing date at the top of February 28, 2018, but March 1, 2018, is stamped in the upper right hand corner as well. The Court will use the earlier date as the filing date but does not believe the difference is material to this ruling.

operations are in compliance with FDCA regulations to the satisfaction of the FDA. Debtor's Ex. 2.

Dr. McCarley testified it was his understanding that the parties would take their dispute to the District Court to decide and it would be heard several weeks from the date it was filed.

The day after the District Court Action was filed, on March 1, 2018, the FDA issued an "FDA News Release" with the title, "FDA alerts health care professionals and patients not to use compounded drugs from Cantrell Drug Company; agency seeks action to stop production and distribution" (the "Press Release"). [4] Debtor's Ex. 3. The Press Release stated it was "alerting health care professionals and patients not to use drug products produced by Cantrell Drug Company" because the FDA "is concerned about serious deficiencies in Cantrell's compounding operations, including its processes to ensure quality and sterility assurance that put patient safety at risk." Debtor's Ex. 3. A quote from the FDA Commissioner contained in the Press Release stated, "Despite the FDA's concerns about egregious conditions observed at Cantrell's facility, during several inspections, with the most recent in 2017, the company continued to compound and distribute drugs without adequately addressing their potentially dangerous conditions. This reckless activity threatens patient safety and will not be tolerated." Debtor's Ex. 3. The Press Release stated that the FDA has sought legal action asking "the court to order Cantrell to stop manufacturing, processing, packing, labeling, holding, and/or distributing any drugs until the company complies" with the FDCA. Debtor's Ex. 3.

The Press Release further stated, in part: "Products from the company can be identified by looking at the drug labels – which should include the company name, 'Cantrell Drug Co.'

[4] The Department of Justice also issued a press release with information concerning the filing of the lawsuit and the relief sought by the United States generally. This press release is not at issue in this proceeding.

Health care professionals should immediately check their medical supplies, quarantine any drug products from Cantrell Drug Company and not administer them to patients." Debtor's Ex. 3.

It further stated:

> The FDA urges health care professionals who obtained products from Cantrell to make alternative arrangements to obtain medications they administer or dispense to patients from sources that adhere to proper quality standards. . . .
>
> FDA investigators most recently inspected . . . Cantrell's facility in June 2017, and observed poor compounding drug operations. . . . In response to the FDA's recommendation, in July 2017, Cantrell recalled . . . all drug products marketed as sterile and ceased sterile compounding. However, against FDA advice, the company resumed production and distribution without demonstrating that it had adequately addressed the problems identified.

Debtor's Ex. 3.

Dr. McCarley testified that this Press Release "blind-sided" him and the language in the Press Release was "shocking" to read. Tr., Vol. I, at 65. After the Press Release was disseminated numerous product orders were cancelled and new product orders plummeted.

Dr. Julie Dohm, a Senior Science Advisor for Compounding for the FDA, testified that she was one of several people with the FDA who "cleared" the Press Release prior to its release. She testified that this type of alert is referred to as a "do not use" alert. As to the timing of the Press Release, it was Dr. Dohm's testimony that while in a meeting she learned that someone had filed a complaint with the FDA about an announcement that Cantrell Drug Company had record sales in December 2017 and the complainant inquired about why the FDA was not doing anything about the sales given the June 2017 inspection. Dr. Dohm said she then asked about why Cantrell Drug Company was still shipping and learned that the Dallas office was aware that Cantrell Drug Company was still distributing product. She said the FDA's focus at that time was to complete the injunction complaint for filing and added that in "hindsight" she believes the

FDA would have issued a "do not use" alert earlier if it had not been focusing on the injunction paperwork.

These latter two actions by the FDA – the filing of the District Court Action and the dissemination of the Press Release – are the two actions that are the focus of the issues before the Court. Additional relevant facts from the evidence will be included with the discussion and analysis of the various issues raised by the parties below in order to expedite the drafting of this decision.[5]

Discussion and Analysis

Due to the emergency nature of the relief sought and the voluminous record of the proceedings, the Court will make additional findings of fact below. Both these additional findings of fact and the Court's conclusions of law are stated with as much brevity as possible.

I. Did the FDA Violate the Automatic Stay by Filing the District Court Action and Disseminating the Press Release?

A. District Court Action

The first issue to be decided is whether the filing of the District Court Action violated the automatic stay provisions of 11 U.S.C. § 362(a), which generally operates as a stay as to the commencement or continuation of several types of judicial and administrative actions. 11 U.S.C. § 362(a) (2012). The United States responded to the Debtor's Emergency Motion arguing that its filing of the District Court Action did not violate the automatic stay because the action is excepted from the automatic stay provisions by Section 362(b)(4).

[5] On the third day the proceedings were to continue, the parties announced to the Court that they had entered into an agreement to stay the proceedings for a period of ten business days during which time the FDA could inspect Cantrell Drug Company's facilities. This inspection took place and at the conclusion of the inspection the FDA issued a Form 483. Additional facts concerning the inspection and the Form 483 are contained later in this order.

While most judicial and administrative actions are automatically stayed by Section 362(a), an exception to the stay is found in Section 362(b)(4) for police and regulatory actions. More specifically, Section 362(b)(4) provides that the filing of a bankruptcy petition does not operate as a stay "of the commencement or continuation of an action or proceeding by a governmental unit . . . to enforce such governmental unit's . . . police and regulatory power, including the enforcement of a judgment other than a money judgment." 11 U.S.C. § 362(b)(4) (2012).

The legislative history explains that "where a governmental unit is suing a debtor to prevent or stop violation of fraud, environmental protection, consumer protection, safety, or similar police or regulatory laws, or attempting to fix damage for violation of such laws, the action or proceeding is not stayed under the automatic stay." *EEOC v. Rath Packing Co.*, 787 F.2d 318, 324 (8th Cir. 1986) (quoting S. REP. NO. 95-989, at 52 (1978), *reprinted in* 1978 U.S.C.C.A.N. 5787, 5838; H. REP. NO. 95-595, at 343 (1978), *reprinted in* 1978 U.S.C.C.A.N. 5787, 6299).

"In light of the legislative history and court decisions under the earlier bankruptcy act," the Eighth Circuit has stated that it believes "that the term 'police or regulatory power' refers to the enforcement of state laws affecting health, welfare, morals, and safety, but not regulatory laws that directly conflict with the control or the res or property by the bankruptcy court." *Missouri v. U.S. Bankr. Court for the E. Dist. of Ark.*, 647 F.2d 768, 776 (8th Cir. 1981).

In determining whether an action falls within the exception provided by Section 362(b)(4), the initial inquiry is the underlying purpose of the law the government is seeking to enforce. *Rath Packing Co.*, 787 F.2d at 324; *Missouri*, 647 F.2d at 776. Courts have used both

the pecuniary purpose test (*Missouri*, 647 F.2d at 776) and the public policy test (*Rath Packing Co.*, 787 F.2d at 324) in analyzing the purpose of the underlying law.

The "relevant inquiry under [the pecuniary purpose] test is whether the 'specific acts the government wishes to carry out . . . would result in an economic advantage to the government or its citizens over third parties in relation to the debtor's estate.'" *United States v. Commonwealth Cos., Inc. (In re Commonwealth Cos., Inc.)*, 913 F.2d 518, 523 (8th Cir. 1990) (quoting *In re Charter First Mortg., Inc.*, 42 B.R. 380, 382 (Bankr. D. Or. 1984)).

In contrast, the public policy test '"distinguishes between proceedings that effectuate public policy and those that adjudicate private rights: only the former are excepted from the automatic stay.'" *Commonwealth*, 913 F.2d at 527 n.6 (quoting *NLRB v. Edward Cooper Painting, Inc.*, 804 F.2d 934, 942 (6th Cir. 1986)).

'"[O]ne of the purposes of [the police or regulatory power] exception is to protect public health and safety."' *Commonwealth*, 913 F.2d at 521 (quoting *Midatlantic Nat'l Bank v. N.J. Dep't of Envtl. Prot.*, 474 U.S. 494, 503 (1986)). The language of Section 362(b)(4) '"does not limit the exercise of police or regulatory powers to instances where there can be shown imminent and identifiable harm or urgent public necessity."' *Commonwealth*, 913 F.2d at 522 (quoting *Commonwealth Oil Refining Co., Inc. v. EPA (In re Commonwealth Oil Refining Co., Inc.)*, 805 F.2d 1175, 1184 (5th Cir. 1986)).

The complaint filed in the District Court Action alleges violations of 21 U.S.C. § 331(a) and (k). These two subsections are part of the FDCA, Subchapter III, Prohibited Acts and Penalties. Section 331 begins, "The following acts and the causing thereof are prohibited." Subsection (a) provides, "The introduction or delivery for introduction into interstate commerce

of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C § 331(a) (2012). Subsection (k) provides:

> The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

21 U.S.C. § 331(k) (2012). Under Section 351 of Title 21, a drug is deemed "adulterated" if it has been prepared, packed, or held under insanitary conditions" or the "methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to . . . current good manufacturing practice." 21 U.S.C. § 351(a)(2)(A)-(B) (2012). Current good manufacturing practices for the manufacture, processing, packing, or holding of drugs are found in the Code of Federal Regulations, including in 21 C.F.R. parts 210 and 211. *See* 21 C.F.R. § 210.1(a) (2011) ("The regulations set forth in this part and in parts 211, 225, and 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug . . . .").

"The FDCA statutory regime is designed primarily to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca–Cola Co.*, 134 S. Ct. 2228, 2234 (2014). "The FDCA's primary focus is ensuring that drugs are 'safe, effective and not misbranded.'" *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010) (quoting *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (2d Cir. 1990)). This task is '"vested in the FDA to implement and enforce."' *In re Bayer Corp.*, 701 F. Supp. 2d at 371 (quoting *Mut. Pharm. Co.*, 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006)).

In the District Court Action, the government asks the Court: (1) to order the Debtor to cease manufacturing and distributing drugs until their operations are in compliance with the FDCA; (2) to enjoin the Debtor from delivering any adulterated drugs into interstate commerce in violation of 21 U.S.C. § 331; and (3) to allow the FDA to inspect the Debtor's business and records to ensure compliance with the injunction, with the costs of inspection to be borne by the Debtor. Debtor's Ex. 2.

Brook Higgins, a senior policy advisor and compliance officer with the FDA responsible for reviewing inspection reports, Form 483s, and responses, testified that the relief sought is intended to set out a process for the Debtor to be compliant, not put them out of business. Dr. Dohm testified that filing an action for injunctive relief is one of the remedies of the FDA to enforce its regulatory power when the agency is concerned about the safety of a firm's drugs.

It is undisputed that the commencement of the District Court Action will have (and from the evidence already has had) a financial effect on the Debtor and, if the injunction is issued, the Debtor's ability to reorganize may be strongly jeopardized. In addition, the government seeks for the costs of inspection to be borne by the Debtor. Nevertheless, the Court finds that lawsuit will not result in an economic advantage to the government in relation to the Debtor's bankruptcy estate. The government primarily seeks injunctive, not monetary, relief against the Debtor, and even if the government is successful, it will not enjoy an economic advantage over the Debtor's creditors. Of course, if any monetary judgment is awarded to the FDA, the enforcement or collection of that monetary judgment would not be excepted from automatic stay provisions of 362(a) by the language of Section 362(b)(4), itself. 11 U.S.C. § 362(b)(4) (2012) (excepting enforcement of a judgment "other than a money judgment"). The pecuniary interest test, therefore supports the government's position that its commencement of the District Court

Action did not violate the automatic stay, but was excepted under Section 362(b)(4) of the Bankruptcy Code.

Similarly, the public interest test supports the government's position that it has not violated the automatic stay by initiating the District Court Action. The District Court Action is not an attempt to adjudicate private rights; rather, the evidence revealed it was taken to promote the FDCA's policy of protecting the public health and safety of the public. The action clearly seeks to enjoin alleged violations of the FDCA and is an action that falls within the FDA's police and regulatory powers.

For these reasons, the Court finds the government's commencement of the District Court Action was excepted from the automatic stay by Section 362(b)(4) of the Bankruptcy Code.

B. Press Release

As to the FDA's Press Release, Section 362(a)(1) of the Bankruptcy Code stays the commencement or continuation of a "judicial, administrative, or other action or proceeding against the debtor." 11 U.S.C. § 362(a)(1) (2012). Colliers on Bankruptcy explains that this subsection gives a broad stay of "*legal* proceedings" against the debtor. 3 COLLIER ON BANKRUPTCY ¶ 362.03[3] (Alan N. Resnick & Henry J. Sommer eds., 16th ed.) (emphasis added). The Press Release is not a legal proceeding. Nor does it appear to be (nor was it argued to be) any other type of act covered under another subsection of Section 362(a). Accordingly, the Court finds that the Press Release did not violate the automatic stay because it was not covered by the automatic stay in the first instance.

Even if the Press Release were covered by the automatic stay of Section 362(a), it would be excepted from the automatic stay by Section 362(b)(4) as an exercise of a governmental unit's police or regulatory power.

Dr. Dohm testified that such news releases were another tool at the FDA's disposal, which it could use to serve its mission of protecting the public health. Moreover, 21 U.S.C. § 375 provides that the Secretary may "cause to be disseminated information regarding . . . drugs . . . in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer." 21 U.S.C. § 375(b) (2012).

The Press Release would pass the pecuniary interest test because while it may have been devastating on the Debtor's business, it did not give FDA a pecuniary advantage over the Debtor's creditors.

The Press Release would also pass the public policy test because the FDA has been given regulatory authority to disseminate warnings that exist "in the opinion of the Secretary" as a method to fulfill its purpose of protecting the public health and cannot be construed as an attempt to adjudicate a private right.

For these reasons the Court finds that the FDA did not violate the automatic stay by disseminating the Press Release.

II. Does the FDA Have Legal Authority to Bring the District Court Action?

Before analyzing the Debtor's request that the Court use its equitable powers under Section 105(a) to enjoin the District Court Action, the Court will address the Debtor's argument that the FDA did not have legal authority to bring the District Court Action. Indeed, much of the evidence and testimony at trial involved whether the Debtor, as a 503B outsourcing facility, was subject to CGMP requirements found at 21 C.F.R. parts 210 and 211, which form much of the basis of the District Court Action.[6]

[6] In the District Court Action, the FDA seeks an order enjoining the Debtor from violating 21 U.S.C. § 331(a) and (k), which prohibit the introduction of adulterated drugs into interstate commerce or causing drugs to become adulterated while held for sale in interstate commerce. What makes a drug "adulterated" is described in 21 U.S.C. § 351. A drug is deemed adulterated if, among other things the methods used in the manufacture, processing,

The Debtor argued at the hearing that many of the provisions forming the basis for the FDA's conclusion that the Debtor's drug products are "adulterated" apply to *manufacturers*, but not *compounders*. This argument is based on provisions of the DQSA, which created a new category of compounding pharmacies called 503B outsourcing facilities. The DQSA was enacted in 2013. Many of the rules and regulations predate the DQSA, which the Debtor argues makes them applicable to manufacturers, which have existed for years, but not outsourcing facilities such as the Debtor, which have only recently come into existence.

In support of its argument that the FDA exceeded its authority in filing the District Court Action, the Debtor introduced a draft guidance promulgated by the FDA dated July 2014. Debtor's Ex. 17. The guidance, when finalized, was to represent the FDA's "current thinking" on the topic of CGMP requirements for 503B outsourcing facilities. Debtor's Ex. 17. The guidance explained that outsourcing facilities will be inspected by the FDA and must comply with other provisions of the FDCA, including CGMP requirements under Section 501(a)(2)(B). It further explained, however, that it was not binding, that the FDA intended to promulgate more specific CGMP regulations for outsourcing facilities, and "[t]he use of the word *should* in Agency guidances means that something is suggested or recommended, but not required." Debtor's Ex. 17.

The Debtor also introduced the FDA's "2018 Compounding Policy Priorities Plan," which explained the agency is still revising the 2014 draft guidance. Debtor's Ex. 26. FDA's goal, as stated in the 2018 Compounding Policy Priorities Plan, is "for more compounders to register as outsourcing facilities with the understanding that they can still meet the FDA's core requirements for drug quality, based on the size and scope of their compounding operations."

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packing, or holding of the drug do not conform to CGMP standards, which are found, in part, at 21 C.F.R. parts 210 and 211.

Debtor's Ex. 26. Similar to the draft guidance, the 2018 plan stated drugs produced by outsourcing facilities must be compounded in compliance with CGMP requirements; however, the FDA also explained that it is revising the guidance to develop a "flexible, risk-based approach to CGMP requirements for outsourcing facilities." Debtor's Ex. 26.

The Debtor also introduced a draft guidance document promulgated by the FDA dated August 2016 that concerned "insanitary conditions" at outsourcing facilities. Debtor's Ex. 27. Similar to the 2014 draft guidance and 2018 plan concerning CGMPs, the 2016 draft guidance on insanitary conditions states the guidance, when finalized, will represent the "current thinking" of the FDA, but is not binding. Debtor's Ex. 27.

A memorandum from the Office of the Attorney General dated November 16, 2017, addressed to all its "components" directed that guidance documents should not "create binding standards by which the Department [of Justice] will determine compliance with existing regulatory or statutory requirements." Debtor's Ex. 18. An updated memorandum from the Office of the Associate Attorney General dated January 25, 2018, addressed to "Heads of Civil Litigating Components United States Attorneys" further directed that the Department of Justice is prohibited "from using its guidance documents to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation." Debtor's Ex. 19.

Ms. Higgins testified that she believes 503B outsourcing facilities are required to follow CGMP standards as stated in 21 C.F.R. parts 210 and 211. These are the standards she used in formulating her opinion that the Debtor is not in compliance with CGMP standards even after the 2018 Inspection, and therefore that the Debtor's drug products are "adulterated." According to Ms. Higgins, if a drug is not produced in compliance with CGMP standards it is deemed

"adulterated" under the law. Similarly, Ms. Higgins testified that when a drug is produced under "insanitary conditions," it is deemed "adulterated."

The Debtor's frustration with the FDA's finding of noncompliance arises from its perception that it has no way to determine what standard a particular inspector may use for a 503B facility inspection.

During the ten days that the proceedings were stayed, the FDA inspected Cantrell Drug Company's facilities pursuant to the agreement between the parties. This inspection resulted in a Form 483 being issued (the "2018 Form 483"). Ms. Higgins testified that from looking at the 2018 Form 483 comparing it to the 2017 Form 483, the Debtor's practices are probably better but still not up to standards. She admitted that even though Cantrell Drug Company received a "Warning Letter" in 2015 that the FDA did not take actions to enjoin production and distribution of product. Camerson Moore, an employee of the FDA who was one of the inspectors for the 2018 Inspection, testified on behalf of the FDA. When asked what the Debtor could do to resolve the issues listed on the most recent 2018 Form 483, Mr. Moore stated he could not give any specific corrective action; rather, the Debtor should review its current procedures and processes and use its quality department to make that assessment.

Dr. Dohm also testified on behalf of the FDA. She acknowledged that the FDA's approach, pursuant to the 2018 Compounding Policy Priorities Plan, is to make compliance with certain CGMP standards easier on outsourcing facilities. She also testified, however, that until such regulations are actually promulgated, her opinion is that the provisions of 21 C.F.R. parts 210 and 211 apply to outsourcing facilities, and that future flexibility with CGMP standards on outsourcing facilities will be in areas other than environmental monitoring. Dr. Dohm acknowledged that many outsourcing facilities hire third party consultants to assist in compliance

with CGMP standards, and in fact, that the agency routinely recommends this to outsourcing facilities that have trouble complying with CGMP standards. Dr. Dohm further testified she was aware the Debtor had hired such a third party consultant, Kymanox.

It is clear to the Court that 503B outsourcing facilities are relatively new entities and that rules and regulations specific to such entities are still being promulgated and developed. It is also clear to the Court that the FDA believes 503B outsourcing facilities are subject to all the CGMP standards, and that the Debtor disputes this contention. The Court understands the Debtor's frustration in not only its uncertainty of which regulations are binding on it, but even more, the subjective nature of individuals' standards used in issuing Form 483s.

That being said, in determining whether Section 362(b)(4) excepts an action from the automatic stay this Court is bound by the United States Supreme Court's decision in *Board of Governors of the Federal Reserve System v. MCorp Financial, Inc.*, 502 U.S. 32 (1991). There, the debtor argued that in order for the government to proceed under its regulatory authority against the debtor as allowed by Section 362(b)(4), the court "must first determine whether the proposed exercise of police or regulatory power is legitimate." *Bd. of Governors*, 502 U.S. at 40.[7] The Supreme Court disagreed. It held the Debtor's "broad reading of the stay provisions would require bankruptcy courts to scrutinize the validity of every administrative or enforcement action brought against a bankrupt entity." *Id*. The Court found the Debtor's interpretation "problematic, both because it conflicts with the broad discretion Congress has expressly granted many administrative entities and because it is inconsistent with the limited authority Congress has vested in bankruptcy courts." *Id.*

[7] The Debtor points out that in the *Board of Governors* case there was a factual difference in that a statute precluded judicial review of many of the Board's actions; however, the proposition that the case is cited for here does not rest on this distinguishing fact.

Furthermore, 21 U.S.C. § 332 expressly gives the District Court jurisdiction over alleged violations of the statutes at issue. 21 U.S.C. § 332(a) (2012) ("The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j)."). This same statute buttresses the idea that bankruptcy courts have limited authority in this sphere; jurisdiction is accorded the district courts, not the bankruptcy courts, in matters of enforcement of the FDCA. The Debtor's argument concerning the FDA's authority to bring the action is more appropriately brought before the District Court.

Therefore, for the reasons stated, the Court declines to scrutinize the FDA's exercise of regulatory authority on the basis that there may not be regulations promulgated to specifically apply to 503B outsourcing facilities.

III. Should the Court Use its Powers Under Section 105(a) of the Bankruptcy Code to Require the FDA to Retract or Modify the Press Release or Enjoin the District Court Action?

The Debtor requests this Court to use its powers under Section 105(a) to issue a discretionary stay: (1) to restore the status quo and "do something" to "un-ring the bell" of the Press Release; and (2) to stay the District Court Action for a period of forty-five days to allow the Debtor time to "get back on its feet" before having to litigate before the District Court.

Eighth Circuit precedent provides that "debtors are not left without an avenue for relief if they or the estate would be harmed by a governmental action excepted from the automatic stay under § 362(b)(4)." *Commonwealth*, 913 F.2d at 527. One of the avenues is the bankruptcy court's authority to use "the discretionary power under 11 U.S.C. § 105(a) to 'issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title."' *Id.* (quoting 11 U.S.C. § 105(a) (2012)).

In appropriate circumstances, bankruptcy courts may use Section 105(a) to enjoin parties from taking action outside of the bankruptcy case. As explained by Colliers on Bankruptcy:

> Debtors and estates often believe that activities outside of the bankruptcy need to be stopped in order for the bankruptcy to achieve its goal. To stop such activity, application is made to the bankruptcy court for an injunction to cease the outside activity. While the automatic stay stops most offending action, there are some cases in which courts have recognized that discretionary stays are appropriate.

2 COLLIER ON BANKRUPTCY ¶ 105.03 (Alan N. Resnick & Henry J. Sommer eds., 16th ed.).

Discretionary stays may be issued against actions that are otherwise not covered by the automatic stay, including regulatory actions and proceedings excepted under Section 362(b)(4). *E.g.*, *NLRB v. Superior Forwarding, Inc.*, 762 F.2d 695 (8th Cir. 1985) (holding that "the bankruptcy court has the discretion and authority to enjoin federal regulatory proceedings under § 105 when those proceedings would threaten the debtor's estate").

Imposition of a discretionary stay is not automatic, but is appropriate when a party "shows a necessity for a stay" under "the usual rules governing the issuance of injunctions." *Commonwealth*, 913 F.2d at 527 (citing *Rath Packing Co.*, 787 F.2d at 325). In the Eighth Circuit, courts must consider the following factors in determining whether to issue an injunction: "(1) the threat of irreparable harm to the movant; (2) the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981); *see also Superior Forwarding, Inc.*, 762 F.2d at 699 n.3.

"No single factor in itself is dispositive; rather, each factor must be considered to determine whether the balance of equities weighs toward granting the injunction." *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1179 (8th Cir. 1998). "Although the overall analysis of the four relevant factors is generally a flexible one, a likelihood of actual irreparable harm remains

essential, and the movant's burden on that factor may not be diminished on a strong showing of the other three factors." *In re Medtronic, Inc. Derivative Litig.*, 68 F. Supp. 3d 1054, 1060 (D. Minn. 2014).

The Court will address the Press Release first.

A. Press Release

The Debtor argues that company management was "blind-sided" by this unexpected communication and its immediate financial consequences to the Cantrell Drug Company. Dr. McCarley testified that within days of the dissemination of the Press Release, company sales were "nonexistent" and "decimated."

Vann Wayne Vaupel, the Debtor's business development officer, testified that to reestablish the company's customer base, it would be necessary for the FDA to issue a retraction or amendment to the Press Release stating that the Debtor is within a "state of control." Moreover, the Debtor argues that sufficient revenue is necessary to continued operations and without the ability to produce and distribute products the Debtor's Chapter 11 reorganization will fail.

From the testimony presented the Court believes that Dr. McCarley was of the understanding that, once the parties knew they could not agree to the terms of a consent decree, the FDA would file the District Court Action so the District Court could resolve their dispute. He did not anticipate the FDA sending a "do not use" alert to its customers. In addition, at the time the Press Release was issued, Cantrell Drug Company believed the violations in the 2017 Form 483 had been remediated and it was in a state of control. This belief was confirmed by Kynamox, a third party consultant Cantrell Drug Company hired to review batch lots before shipping. The FDA was aware of the remedial actions and Cantrell Drug Company's opinion of

the readiness of the Debtor to distribute products. The language in the Press Release, however, not only failed to acknowledge that the Debtor had been taking remedial measures but made disparaging remarks suggesting otherwise.

The Debtor particularly complains of language in the Press Release describing conditions at the facility as "egregious" and the Debtor's continued distribution of drugs as "reckless." Dr. Dohm was one of the agency officials who reviewed and cleared the Press Release for distribution. Dr. Dohm explained that when an outsourcing company is seriously out of compliance, the FDA requests the company to voluntarily recall product and cease production until the FDA determines the risk to patients is no longer present. She stated that most companies acquiesce to such a request, but if a company does not comply with recall and cessation, a "do not use" alert is one of the ways to warn users of the drugs that there are risks.

Ms. Higgins testified that based on her reviews of the Form 483s issued to Cantrell Drug Company, including the most recent Form 483 issued during the stay in the proceedings, Cantrell Drug Company was not in compliance with the FDCA and CGMP regulations. She further testified that the lack of sterility assurance posed a risk to public health. Dr. Dohm testified that the Press Release was necessary because users might not otherwise be aware of the potential for risk. Further, if a patient displayed certain symptoms, health care professionals could more easily make the connection between the symptom and the warning about the possibility of a contaminated drug.

In the wake of the Press Release, the Debtor asks the Court to "restore order" and provide "some assurances to the Debtor's customers." The Debtor urges the Court to use its Section 105(a) powers to order the FDA to either retract or amend the Press Release. It further argues that the Press Release violated the Debtor's due process rights under the Fifth Amendment by

impairing the Debtor's revenue stream to the extent that it has been or shortly will be forced out of business without judicial involvement.

This Court has already found that the Press Release is not an action either stayed by the automatic stay or excepted from it under Section 362(b). Therefore, some form of injunction pursuant to Section 105(a) concerning FDA publicity would not circumvent or run afoul of the automatic stay provisions.

The Court will look at the statutory authority and the facts stated in the Press Release to determine whether to order a retraction or amendment of the Press Release. First, the communication at issue is expressly authorized by Congress in a specific provision of the Food, Drug and Cosmetic Act:

> (b) Information regarding certain goods
>
> The Secretary may also cause to be disseminated information regarding . . . drugs . . . in situations involving, *in the opinion of the Secretary*, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

21 U.S.C. § 375(b) (2012) (emphasis added).

With this provision Congress has authorized the Secretary to disseminate information regarding imminent danger to the consumer and to report the results of the FDA's investigations. The Press Release is properly within the scope of the provision and the stated mission of the FDA.

As stated above, the Debtor takes issue with some of the language in the Press Release, including the Secretary's quoted opinion regarding "egregious conditions" and "reckless activity," words of disparagement that the Debtor argues are particularly damaging. The use of this language appears to the Court to contradict the aim of FDA publicity "to provide media . . .

with factual, accurate information, which is correct in description without disparagement of the person or firm subject to the publicity." 2 James T. O'Reilly & Katherine A. Van Tassel, Food & Drug Admin. § 22:61 4th ed., Westlaw (database updated Nov. 2017) (citing 42 Fed. Reg. 12440 (Mar. 4, 1977), proposed 21 C.F.R. § 2.741(b)).

A "do not use" alert could have been issued and would have been equally effective to meet the purposes of the FDA to protect public health and safety without this added language. However, despite that the disparaging language may be contrary to the FDA's policy, the facts remain that the statements are Dr. Gottlieb's opinions, the Press Release states that it is based on the June 2017 inspection, and the Secretary has been given statutory authority to disseminate his opinion. Aside from the discussion of the dangers to patient safety, the Press Release informs the public that the FDA is seeking a preliminary injunction against the Debtor, advises health care professionals to quarantine the drugs already distributed, states that the poor compounding operations were caused by the Debtor's operation in June 2017, mentions that the Debtor recalled its products in response to the FDA's recommendation, and asserts that there have been no reported illnesses associated with the Debtor's products. Although the Debtor disputes some of the facts contained in the Press Release and although the Press Release was based on an inspection made eight months prior to the Press Release and makes no mention of the Debtor's remediation efforts, retraction is not warranted under the circumstances of the case.

The FDA is acting within the authority allocated to it under the United States Code, and the Court has no independent basis, such as inaccurate reporting, for ordering a retraction or correction. Even if, on the basis of improvement exhibited by the 2018 Form 483, the Court ordered the FDA to re-issue the Press Release without the disparaging remarks, the Court could not order the FDA to retract the language in the Press Release as to the Secretary's opinion that

he is not assured of the sterility of the sterile drugs and, in his opinion, the drugs should not be used by the hospitals and patients. Indeed it is the "do not use" language in the Press Release rather than the disparaging remarks that caused the Debtor's drug orders to suffer.

However, the fact remains that the Debtor is in bankruptcy, and the consequence of the Press Release has been to diminish the Debtor's revenue, which is an asset of the Debtor's estate. 11 U.S.C. § 541 (2012). Such adverse publicity could ultimately cause the cessation of the Debtor's operations and the failure of the reorganization proposed by the Debtor.

On the other hand, the FDA zealously guards the safety of the users and patients, and financial consequences to producers are, understandably, not a priority. When a debtor in bankruptcy is also subject to federal regulatory powers, conflict between the bankruptcy statutes and the agency's regulatory authority may arise, as it has here.

To ensure that the provisions of the Bankruptcy Code are carried out, a court may employ its Section 105(a) powers to stay activities that are not otherwise subject to the automatic stay. 2 COLLIER ON BANKRUPTCY ¶ 105.03 (Alan N. Resnick & Henry J. Sommer eds., 16th ed.). While the FDA's publicity authority is granted by federal statute, this Court has Section 105(a) power to impose a discretionary stay of future adverse publicity if the Debtor "shows a necessity for a stay" under the four-part analysis applicable to the issuance of injunctions. *Commonwealth*, 913 F.2d at 527.

The Court proposes to impose a stay enjoining the FDA from issuing any more press releases regarding the Debtor until the case in District Court is concluded, a consent decree is signed, or some other event brings the issues between the FDA and the Debtor to a conclusion or resolution. Such an injunction would be similar to the automatic stay of Section 362 in that the FDA would be allowed to file an emergency motion for relief from the stay with the bankruptcy

court in the event of some new risk of imminent harm to consumers that has not already been reported by the March 1, 2018 Press Release.

(1) Threat of irreparable harm to the movant.

The first of the four factors to consider in determining whether to issue an injunction is whether the threat of irreparable harm to the Debtor exists. In the instant case, the Debtor has shown that the Press Release has already resulted in dire financial consequences. While the Debtor has not closed its doors yet, more adverse publicity concerning its operations would be the Debtor's death knell. It would drive away more customers, resulting in further decrease in income which would eventually lead to cessation of operations, loss of financing, and a failure of the business and the bankruptcy reorganization. The Court is convinced that more adverse publicity would cause irreparable harm to the Debtor.

(2) Balance between harm and the injury granting the injunction will inflict on other parties litigant.

The second factor is the balance between the harm to the Debtor and the injury to the FDA. Under the conditions the Court proposes, there is little likelihood of harm to the FDA or to its policy of protecting public health and safety. The discretionary stay affords the FDA the opportunity for immediate relief from the stay upon a showing of new risk of imminent danger to users and is proposed as a temporary measure to be lifted as soon as possible to cause the least amount of restriction on the FDA. This slight delay to seek relief from stay is not likely a harm to the FDA's ability to fulfill its mission to protect public health and safety. Therefore, the FDA's role of protecting the public will not be diminished, and the Court sees little if any potential for injury to the FDA.

At the same time, this condition of the stay will afford the Debtor some advance notice of any proposed adverse publicity, enabling the Debtor to take counter measures it deems advisable, including filing a response to the motion. The Court will make the final determination about whether the publicity is warranted by considering not only the degree of risk asserted but also how lifting the stay will affect the Debtor's bankruptcy reorganization.

(3) Probability that movant will succeed on the merits.

The third factor, the probability of the Debtor's success on the merits, is not readily applicable to an injunction staying an activity rather than a court action. The Court will focus on the probability of the Debtor's success in continuing to meet its obligations under the Chapter 11 case during the temporary stay.

The Court finds that the purpose of the stay will be achieved because the evidence demonstrated no extra-judicial remedy available to the FDA, other than more adverse publicity, that could further affect the Debtor's revenue prior to trial. Another circumstance is that the Debtor has recently undergone another inspection, and Ms. Higgins of the FDA admitted the Debtor's practices have improved since the 2017 Inspection. Dr. Dohm acknowledged that the Debtor's employment of a third party to assist in compliance with standards is a practice the FDA often recommends to producers who receive Form 483s. While there remain observations to address from the 2018 Form 483, to the layman's eye the observations were much less serious than those identified in the June 2017 inspection. In addition, there is a bona fide dispute between the parties regarding the observations and the standards that apply to 503B facilities. These facts support the Court's conclusion that the Debtor has made great strides since the 2017 inspection and that there will, in fact, be no need for further adverse publicity prior to trial. For

these reasons, the Debtor will be able to continue in Chapter 11 during the imposition of the temporary stay.

(4) Public interest.

The last factor is a consideration of the public interest. The principle concern is the protection of the public from the risk of adulterated drugs. The stay proposed would allow the FDA to warn the public of any such new risk by receiving relief from stay from the Bankruptcy Court so the public interest remains protected. Furthermore, the bankruptcy policy of providing relief to the honest but unfortunate debtor is furthered because the Debtor would be able to continue in bankruptcy without fear of another press release being disseminated without Court approval.

Therefore, the four-part analysis regarding the issuance of an injunction weighs in favor of the Debtor for all the reasons stated above. The Court imposes a stay enjoining the FDA from issuing any more press releases regarding the Debtor until the case in District Court is concluded, a consent decree is signed, or some other event brings the issues between the FDA and the Debtor to a conclusion or resolution. This injunction will be like the automatic stay of Section 362(a) in that the FDA is allowed to file an emergency motion for relief from the stay with the bankruptcy court in the event of some new risk of imminent harm to consumers that has not already been reported by the March 1, 2018 Press Release. Similarly, if the parties were to agree to a news release being issued the parties may submit an agreed order to the Court to relax the imposed stay to allow the dissemination of such a news release.

The Debtor also raised the issue of whether the dissemination of the Press Release, having the effect of granting the FDA an injunction against the Debtor without judicial involvement, violated its due process rights. District courts have specifically addressed

constitutional challenges to the FDA's statutory authority to issue press releases and other types of publicity. *See Ajay Nutrition Foods, Inc. v. FDA*, 378 F. Supp. 210, 217-18 (D.N.J. 1974) (ruling that a due process claim against FDA statements would require an allegation that the statements, even if true, would violate the FDA's executive authority); *Hoxsey Cancer Clinic v. Folsom*, 155 F. Supp. 376 (D.D.C 1957) (finding no due process violation; publicity provision authorizes the Secretary to disseminate information, not adjudicate rights and issue orders); *accord Dimare Fresh, Inc. v. United States*, 808 F.3d 1301 (Fed. Cir. 2015) (asserting that FDA press releases warning of possible link between salmonella and tomatoes were not regulatory takings under Fifth Amendment on the basis of the publicity's impact on the tomato market).

This argument would be more properly asserted before the District Court in the course of the FDA's Motion for Preliminary Injunction. In light of the "broad discretion Congress has expressly granted" administrative entities and the "limited authority Congress has vested in the bankruptcy courts," this Court declines to decide this issue. *Bd. of Governors*, 502 U.S. at 40.

The Court will now address the Debtor's request that this Court enjoin the District Court Action for a period of forty-five days.[8]

B. District Court Action

Both parties argued the four factors from the *Dataphase* case in support of their respective positions. Below are the parties' arguments and the Court's analysis of the four factors:

[8] The parties did not address whether the bankruptcy court as an Article I court has the ability to enjoin an Article III district court. The Court has found at least one case where a bankruptcy court has enjoined a federal district court action, *Securities Investor Protection Corp. v. Bernard L. Madoff Investment Securities LLC (In re Madoff)*, 429 B.R. 423 (Bankr. S.D.N.Y 2012), *aff'd, Fox v. Picard (In re Madoff)*, 848 F. Supp. 2d 469 (S.D.N.Y. 2012), *aff'd, Marshall v. Picard (In re Madoff)*, 740 F.3d 81 (2d Cir. 2014), but that case involved facts very different from the case at hand because in *Madoff* the district court action was void *ab initio* because it was filed in violation of the automatic stay, and even more, the action itself was property of the bankruptcy estate to be brought by the bankruptcy trustee. Because this Court denies the Debtor's request to enjoin the District Court Action and because this issue was not raised by either party, the Court will not further address this issue.

(1) Threat of irreparable harm to the movant.

The Debtor argues if the Court does not stay the District Court Action, it will be forced to liquidate because it does not have sufficient cash reserves to allow it to continue for more than a week following the hearing. The Debtor argues this will cause harm to the Debtor's reorganization efforts, result in employees losing jobs, patients not being supplied with needed drugs, and harm to the Debtor's stakeholders.

The FDA argues there is no irreparable harm because any harm the Debtor may suffer is self-inflicted harm. It argues that compliance with the FDA rules and regulations may be costly, but the action taken by the FDA in District Court was a last resort. The FDA argues that the District Court Action was filed after years of noncompliance by the Debtor, after the Debtor began distributing sterile products against the FDA's recommendation, and negotiations failed as to a proposed consent decree.

The Court has clear and convincing evidence that the Debtor has already suffered financial harm in its struggles to produce its sterile drug products to the satisfaction of the FDA. The most recent obstacle for the Debtor's production and distribution efforts came as a result of the FDA's dissemination of the Press Release and the downturn of sales thereafter.

The Court has already ruled that it is without authority to require the FDA to retract the Press Release. In so ruling, short of compliance with applicable regulations to the satisfaction to the FDA, its approval for Cantrell Drug Company to resume distribution, and possibly the issuance of some type of follow-up news release announcing that the FDA now has assurance that Cantrell Drug Company's products are sterile, it is doubtful to the Court that product orders will resume to a level attained prior to the Press Release.

There was substantial evidence of the Debtor's efforts to meet the FDA's requirements. After the 2017 Form 483 was issued, the Debtor ceased its operations and recalled all sterile drug products. The Debtor spent the next several months working to improve its operations to address the issues noted by the FDA on the 2017 Form 483. Although the Debtor and FDA exchanged numerous communications about Cantrell Drug Company's remedial actions, the FDA continually responded that it was reviewing the Debtor's submissions and that until the Debtor heard otherwise, FDA continued to recommend the Debtor not release product into the market. After petitioning for Chapter 11 relief, the Debtor entered into a cash collateral order with one of its lenders. The Debtor also, at the recommendation of the FDA, contracted with a third party to assist with the quality control aspects of the Debtor's operations. The Debtor resumed production and shipment of sterile drugs with the assistance of the third party consultant's review of the batches before shipping. The Debtor communicated its actions to the FDA.

The Debtor's business came to a halt again, however, when the FDA issued the Press Release on March 1, 2018, alerting hospitals and patients not to use drugs compounded by Cantrell Drug Company and quarantine any drugs in their inventory. Dr. McCarley testified that following the Press Release, numerous product orders were cancelled and incoming orders plummeted.

The FDA cites the case of *Swift Power Services, LLC v. North Country Construction & Rentals, Inc.*, 4:12-cv-108, 2013 WL 12085489 (D.N.D. Jan. 7, 2013) in support of its proposition that the Debtor's harm is self-inflicted and thus cannot be irreparable harm for purposes of an injunction. That case is distinguishable, however. There, the movant breached an agreement with the defendants and sought an injunction prohibiting the defendants from foreclosing on certain collateral. *Id.* at *3. The court found the harm of foreclosure was self-

inflicted, because the movant could have placed the payments in escrow until the dispute was litigated, rather than disregarding the payments altogether. *Id*. at *4.

Here, the Court does not believe the Debtor's harm is self-inflicted. The Debtor has made great efforts to comply with FDA regulations. It ceased operations and issued voluntary recalls at the recommendation of the FDA, it hired independent third party consultants, and it took significant actions to address the issues listed on the 2017 Form 483.

Richard Motruk, the Senior Director of Technical Operations for Kymanox, a third party consultant hired by Cantrell Drug Company to assist in FDA compliance, testified about the operations. His company was hired to review each lot disposition since November 21, 2017. The evidence revealed that many of the observations listed on the 2017 Form 483 have been addressed, and it was even admitted by Ms. Higgins that the Debtor's compliance has improved since the 2017 inspection.

The evidence further revealed the Debtor believes it is in compliance with applicable FDA regulations, and it has assurances of the same from its third party consultant, Kymanox. Kymanox has opined that the Debtor is in a "state of control," and has been each time it has distributed sterile drug product since Kymanox was hired.

Even though there has been a great deal of improvement in the Debtor's operations, the FDA still believes the Debtor is not in compliance. The Debtor and FDA have a bona fide dispute regarding which regulations apply and the extent to which the applicable regulations are not met, due in large part to the subjective nature of the application of the regulations to individual facilities' operations. The parties attempted to resolve their differences by engaging in several weeks of negotiations before the District Court Action was filed. While the negotiations were ultimately unsuccessful, the Court cannot find that the Debtor's harm is self-

inflicted. The facts in this case are not analogous to the facts in the *Swift Power* case where the movant consciously chose to breach an agreement and not make payments resulting in the foreclosure action; the Debtor here has made significant attempts to comply with FDA regulations and resolve the issues between the parties and, indeed believes it is in compliance.

The Court finds that the Debtor has suffered financial harm and will continue to suffer financial harm as long as the dispute between the FDA and Debtor continues. However, it is unclear to the Court what irreparable harm will be avoided if this Court grants the Debtor's request to stay the District Court Action for forty-five days. The evidence revealed that the Debtor's business has significantly decreased since the issuance of the Press Release. The Debtor argues it needs to operate again, but this Court does not believe a stay of the District Court Action for forty-five days, in and of itself, will allow the Debtor's operations to return to levels needed for an effective reorganization. While there is no court order enjoining the Debtor from producing and shipping product, the effect of the Press Release has been to cause sales to decrease. A resolution of the issues between the parties is what is needed to avoid irreparable harm to the Debtor. This Court does not believe staying the District Court Action will avoid such harm. Therefore, the Court finds this factor weighs against the Debtor.

(2) *Balance between harm and the injury granting the injunction will inflict on other parties litigant*.

The Debtor argues its harm outweighs any injury the FDA would suffer or any potential harm to patients. The Debtor truly believes its products are sterile and do not pose a threat to the public health or safety. This is based not only on the Debtor's improved procedures and operations, but also its policy of destroying any product if it suspects any risk is associated with the product. In fact, the Debtor argued there is a greater risk to the public if it is not allowed to

distribute drugs that are on the FDA's drug shortage list because of the dire public need for the products.

The FDA argues that most of the drugs Cantrell Drug Company is producing are for seriously ill patients. The FDA further argues that one microbe in an injectable product makes that product have the potential of causing serious injury or death to a patient. The FDA argues that to have a sterile product it is important that all CGMP standards are followed. It argues the Debtor's procedures fall short of CGMP standards, which pose a threat to patient safety.

The evidence at the hearing revealed that the most recent 2018 Form 483 listed deficiencies in the Debtor's investigatory procedures as the most significant observation (listed at Observation 1). In other words, the FDA believes the most significant deviation from CGMP standards is that the Debtor has not sufficiently investigated the root cause or trends associated with certain excursions. There was no evidence that excursion rates occurred at unacceptable levels. However, the FDA argues that it cannot be assured of product sterility if the Debtor's investigatory processes are inadequate, according to its interpretation of CGMP standards to the Debtor's operations. As discussed in detail earlier in Part II, the parties strongly disagree as to the standards to be applied to a 503B outsourcing facility.

Federal law allows the FDA to seek injunctive relief for a violation of 21 U.S.C. § 331. 21 U.S.C. § 332(a) (2012). Section 331 prohibits the distribution of "adulterated" drug products into interstate commerce. 21 U.S.C. § 331(a) (2012). A drug is deemed "adulterated" if prepared under insanitary conditions or manufactured, processed, packed, or held in conditions that are not in conformity with CGMP. 21 U.S.C. § 351(a)(2)(A)-(B) (2012). While the Debtor argues not all CGMP standards are applicable to it because it is a 503B outsourcing facility, and further argues it and its third party consultant believe the Debtor is in compliance with all

applicable CGMPs, this Court believes those are arguments the Debtor should make to the District Court. By staying the District Court Action for forty-five days, this Court will infringe on a right given the FDA under law to seek injunctive relief to protect the public health and safety. When this injury is balanced with the harm to the Debtor the second factor weighs against the Debtor.

(3) Probability that movant will succeed on the merits.

In the bankruptcy context, there is a split of authority regarding what action the court should consider in determining probability of success on the merits. Some courts have held that the movant must show a likelihood of success in the bankruptcy reorganization, others have held that the movant must show a likelihood of success in the non-bankruptcy action, and at least one court has determined that it should simultaneously consider the movant's likelihood of success in both actions. *See In re First Alliance Mortg. Co.*, 264 B.R. 634, 653 (D.C.D. Cal. 2001) (discussing split).

It does not appear the Eighth Circuit has ruled on this issue, but at least three courts within the Eighth Circuit have analyzed the likelihood of a successful reorganization when analyzing this factor. *See In re Catalano*, 155 B.R. 219, 224 (Bankr. D. Neb. 1993) ("The probability of success in this case means successful confirmation of a Chapter 13 plan."); *In re ML Barge Pool VII Partners-Series A*, 98 B.R. 957, 959–60 (E.D. Mo. 1989) ("Under this circumstance, the Court cannot find that the bankruptcy court abused its discretion by considering the likelihood of confirmation of the plan as the 'merits' upon which ML Barge may succeed in making its decision as to reimposition of the stay."); *Lahman Mfg. Co.. v. First Nat'l Bank of Aberdeen (In re Lahman Mfg. Co.)*, 33 B.R. 681, 684-85 (Bankr. D.S.D. 1983) ("In the bankruptcy context, the probability of success on the merits has been defined as the probability

of a successful plan of reorganization."). *But see EEOC v. Consol. Freightways Corp. of Delaware*, 312 B.R. 657, 660 (W.D. Mo. 2004) ("Though the Eighth Circuit has not spoken on the issue, the parties' briefs only address CF's likelihood of achieving success on the merits of [the non-bankruptcy] case. Finding no binding authority to suggest this is the wrong approach, the Court follows the parties' lead.").

In making their arguments before this Court, the parties addressed both the bankruptcy action and the District Court Action. The Debtor argued in its pleadings that a shut-down of operations will interfere with the Debtor's ability to rehabilitate and therefore it expected to be successful in its request for this Court to issue a stay. At the hearing, the Debtor argued it will be successful in the District Court Action because the FDA did not have authority to file the action in the first instance, and the Debtor has remediated the issues raised in the 2017 Form 483, and believes it is in compliance with applicable FDA regulations. The Debtor argued the issues raised in the 2018 Form 483 were so miniscule that the FDA standards regarding compliance with CGMP are either arbitrary and capricious or directed and targeted at the Debtor.

The FDA argued there is not a likelihood of success in the bankruptcy because the regulatory action is excepted from the automatic stay under Section 362(b)(4). It further argued it will likely succeed in the District Court Action because the government will only have to show the Debtor has violated the statute and a cognizable risk of harm exists in order to be successful.

To the extent this Court should look at the underlying bankruptcy case, the Court believes the Debtor may be able to reorganize, but only if the dispute between it and the FDA is quickly resolved. The evidence presented to the Court indicated that the Debtor has historically been a profitable company, but the regulatory compliance issues with the FDA have caused it to file for bankruptcy protection, and those continuing compliance issues, although disputed by the parties,

threaten the Debtor's ability to reorganize. There is a demand for the drug products produced by the Debtor and the Debtor has enjoyed long term relationships with a number of its customers. It seems evident to this Court that in order for the Debtor to successfully reorganize under Chapter 11, the issues between it and the FDA must be resolved. This Court does not believe, however, that staying the District Court Action for forty-five days will aid in the expeditious resolution of issues between the parties. The parties have had ample time to negotiate a resolution, to no avail. Based on the testimony the Court does not believe the parties will be able to resolve their dispute without court intervention. Therefore, a forty-five day stay of the District Court Action will not aid in the Debtor's reorganization under Chapter 11.

To the extent this Court should look at the District Court Action, this Court has already stated that there are significant issues which this Court will not decide; namely, whether the FDA has the authority to bring the District Court Action against a 503B outsourcing facility like the Debtor, and which, if any, CGMP regulations are applicable to 503B outsourcing facilities. It is clear this is a developing area of the law, and the Debtor raises new arguments regarding the scope and applicability of FDA regulations to 503B outsourcing facilities. Under the *Board of Governors* precedent, however, this Court was not to determine those issues as to the Section 362(b)(4) issue and will likewise refrain from making a determination of the issue in analyzing this factor in its preliminary injunction analysis.

For these reasons, this Court finds that the likelihood of success on the merits, whether it is the merits of the underlying bankruptcy case or the District Court Action, does not weigh in favor of either party.

(4) Public interest.

The Debtor argues it is in the public interest to stay the District Court Action for forty-five days because the Debtor's drugs are sterile, there are adequate safeguards in place to ensure sterility, and the public is harmed by the Debtor not being able to distribute drugs that are on the drug shortage list.

The FDA responds that its mission is to protect the public health and safety, it is not assured that the Debtor's drugs are sterile, and lack of assurance poses a risk to patient safety. It also argues that morphine sulfate, one of the drugs currently on the drug shortage list that the Debtor produces, is available from other sources.

The Court recognizes two public policy interests are at stake in this matter. On the one hand the Court is concerned with the Debtor's rehabilitation efforts to keep its company operating, pay employees, provide drugs on the FDA's drug shortage list, and pay its creditors. On the other, the Court must recognize the public interest in assuring that sterile drug products are in fact sterile and do not pose a risk to patient safety.

While the Court recognizes the significant steps the Debtor has taken to remediate the issues of the 2017 Form 483, it also recognizes that the FDA continues to believe it lacks necessary assurances of sterility. The Court understands the Debtor's frustration with the subjective nature of the perceived continued violations, but in weighing the public policy of reorganization with the public policy of patient health and safety, the Court must find that the equities favor the latter. For these reasons, the Court finds that this factor weighs in against the Debtor.

For the foregoing reasons, the Court finds that the Debtor's request to impose the automatic stay or enjoin the District Court Action for a period of forty-five days is denied.

Conclusion

To summarize, the Court finds that the FDA did not violate the automatic stay by filing the District Court Action or disseminating the Press Release. Pursuant to United States Supreme Court precedent and federal statute, the Court declines to scrutinize the FDA's legal authority to bring the District Court Action based on the Debtor's argument that the FDA has erroneously determined the Debtor's product was adulterated by applying inapplicable standards.

Further, the Court denies the Debtor's request for an order requiring the FDA to retract or modify the Press Release. However, pursuant to Section 105(a) and under the four factors necessary to demonstrate an injunction is necessary, the Court hereby imposes a temporary stay on the issuance of any future news releases or alerts by the FDA as stated in more detail above. This stay is subject to numerous conditions as discussed in this Order. Finally, the Court, after again applying the four injunction factors, denies the Debtor's request to impose the automatic stay on the District Court Action or to enjoin the District Court Action for a period of forty-five days.

IT IS SO ORDERED.

Phyllis M. Jones
United States Bankruptcy Judge
Dated: 04/04/2018

CC: Attorney for Plaintiff(s)
Plaintiff(s)
Attorney for Defendant(s)
Defendant(s)
Trustee
US Trustee