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ATTORNEYS FOR PLAINTIFFS

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF WYOMING

CODY LABORATORIES, INC., a Wyoming corporation, and LANNETT CO., INC., a Delaware corporation, Plaintiffs, v. THE HONORABLE KATHLEEN SEBELIUS, SECRETARY, U.S. Department of Health and Human Services, and DR. MARGARET A. HAMBURG, COMMISSIONER, U.S. Food and Drug Administration, Defendants.	)	Civil Action No. 10CV0147

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Plaintiffs Cody Laboratories, Inc. ("Cody"), a Wyoming corporation located at 601 Yellowstone Avenue, Cody, Wyoming 82414, and Lannett Co., Inc. ("Lannett"), a Delaware corporation located at 9000 State Road, Philadelphia, PA 19136 (collectively "Cody/Lannett") hereby submit this Memorandum of Law in Support of Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction against Defendants Kathleen Sebelius and Margaret Hamburg (collectively "Defendants"). Cody/Lannett manufacture, market, and sell a concentrated oral solution of the pain medication Morphine Sulfate, a drug that has been in use in the United States for more than 150 years. Cody/Lannett's product is primarily used to treat patients in hospitals, hospices, and palliative care communities. By their Motion, Cody/Lannett respectfully request that this Court issue temporary and preliminary injunctive relief preventing the U.S. Food and Drug Administration ("FDA") from requiring Cody/Lannett to remove its product from the market as of July 24, 2010. In support of this Motion, Cody/Lannett state as follows:

STATEMENT OF FACTS[1]

Morphine Sulfate is a pain medication that has been in use in the United States for more than 150 years. Cody/Lannett have been manufacturing, marketing, and selling the generic drug product, Morphine Sulfate Solution Immediate Release 20 mg/ml ("the Product") in the United States for more than five years. The Product is a concentrated liquid intended to be delivered orally to patients with chronic or acute pain. The concentrated nature of the Product makes it

[1] The facts of this case are more fully articulated in the Complaint and the exhibits attached thereto, which are incorporated herein by reference. This statement of facts is also supported and supplemented by the Affidavits of Richard Asherman and Arthur Bedrosian, which are attached hereto as Exhibits L and M respectively.

ideal for patients who cannot tolerate intravenous morphine and who are unable to swallow more heavily diluted forms of the drug. The most common use of the Product is in comforting terminally ill patients in hospitals, hospices, and palliative care communities. Cody/Lannett supplied a majority of this formulation in the U.S. marketplace.

Despite the lengthy history of common use of Morphine Sulfate in the United States to manage chronic and acute pain, the Product is, as a technical matter, an "unapproved" drug under the regulatory framework for the manufacture and sale of drugs in the United States. This is because the original Food and Drug Act of 1906 was amended by the Food Drug and Cosmetics Act of 1938, 23 U.S.C. § 301 et seq., ("FDCA") to require the FDA to determine, pursuant to an application by a product sponsor, whether a drug was "safe" and was again revised in 1962 to require the FDA to determine, pursuant to an application, whether a drug was also "effective."

The FDCA applies only to "new drugs" rather than the class of drugs that were already in use at the time the FDCA was enacted in 1938. Drugs that are grandfathered under the FDCA have become known as "unapproved drugs" simply because the drugs have been commonly used for so long that manufacturers and sellers of such "unapproved drugs" are not required to file a New Drug Application ("NDA") with the FDA in order to manufacture, market, and sell the drugs in the United States. Of the thousands of "unapproved drugs" that are manufactured, sold, and prescribed every day in the United States, hundreds are commonly known medications.[2]

[2] By way of example, the following commonly prescribed drugs are technically "unapproved drugs": Aspirin and Codeine Phosphate, Codeine Sulfate, Ephedrine Sulfate, Nitroglycerin, Phenobarbital, Potassium Bicarbonate, and Sodium Fluoride. See United States Pharmacopeia's Drug Information's "Listing of 'Pre-1938' Products" attached hereto as Exhibit A. Morphine Sulfate is included on this list, and, prior to the FDA actions giving rise to this case, was commonly understood to be among the class of drugs in common use at the time of the 1938 amendments to

Significantly, this wide class of "unapproved drugs" does not exist wholly outside of the significant regulatory apparatus of the FDA. Quite the contrary, "unapproved drugs," including the Product, are manufactured in drug establishments required to be registered with the FDA.[3] The products are required to be listed with the FDA[4] and manufactured according to strict current good manufacturing practices[5] subject to FDA inspection.[6] Manufacturers and others are required to report adverse events related to the drugs to the FDA.[7] The FDA can immediately pull such drugs from the market if they are shown to cause harm to the public.[8] Advertising and promotion must conform to labeling containing the same conditions of use as the pre-1938 formulations,[9] and such drugs are commonly recommended and frequently prescribed by the medical community as accepted standard treatments for certain types of patients and conditions. In addition, many "unapproved drugs" deemed to have addictive effects, including the Product, are also controlled, or scheduled, by the Drug Enforcement Agency ("DEA") which regulates the amount that can be manufactured and how they are prescribed and sold.[10]

In 2006, the FDA issued policy guidance related to "unapproved drugs" in which the FDA stated its view that the grandfathering provisions of the FDCA were no longer applicable to all or virtually all of the thousands of "unapproved drugs" then being sold in the United States.

FDCA. Significantly, the United States Pharmacopeia is identified as an "official compendium" under the FDCA, 21 U.S.C. § 321(j), and the FDCA defines the term "drug" to include any drug "recognized in the official United States Pharmacopoeia." 21 U.S.C. § 321(g)(1).

[3] 21 U.S.C. §§ 360(b), 510(b).

[4] 21 U.S.C. §§ 360(j)(1), 510(j)(1).

[5] 21 U.S.C. §§ 351(a)(2)(B), 510(a)(2)(B).

[6] 21 U.S.C. §§ 360(h), 510(h).

[7] 21 C.F.R. § 314.80.

[8] 21 U.S.C. §§ 334(a)(1), 304(a)(1).

[9] 21 U.S.C. §§ 352(n), 502(n).

[10] See Cooperate Drug Abuse Prevention and Control Act, 21 U.S.C. §§ 801-966 (1970).

FDA determined unilaterally in this non-binding guidance, that had little public input or administrative record, that any of these older drugs, if they were not approved by FDA in an New Drug Application ("NDA") or an Abbreviated New Drug Applications ("ANDA"), were subject to enforcement action as unapproved "new drugs."[11] See Exhibit B. In issuing this blanket guidance, FDA failed to make any individualized determinations or develop any administrative record as to any particular drug.

The FDA did not order the removal of all "unapproved drugs" from the market, however, because it recognized that many such drugs were medically necessary and the public interest demanded that such drugs remain available for medical use. Instead, the FDA set forth criteria under which it would exercise its discretion in initiating enforcement proceedings to remove particular "unapproved drugs" from the market. By that point, however, it was clear that the FDA believed that all "unapproved drugs" then on the market were required to submit NDAs, or ANDAs if an NDA-holder was already on the market, and were not grandfathered under the FDCA.

On March 30, 2009, the FDA trained its sights on the manufacturers of concentrated oral solution Morphine Sulfate. The FDA sent warning letters to all manufacturers of unapproved Morphine Sulfate products, in all dosage forms, demanding removal of the products from the market in 60 days. See Exhibits C and D. The March 30, 2009 letter to Cody directed it to stop manufacturing within 60 days while the letter to Lannett directed it to stop shipping within 90

[11] Guidance for FDA Staff and Industry Marketed Unapproved Drugs — Compliance Policy Guide Sec. 440.100 Marketed New Drugs Without Approved NDAs or ANDAs (June 2006), available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/UCM070290.pdf (hereinafter "FDA 2006 Guidance").

days. Cody/Lannett informed the FDA immediately upon receipt of their letters that such an action would deny a medically necessary drug to the public and would create shortages because no manufacturer of the concentration of Morphine Sulfate solution including that manufactured by Cody had submitted an NDA. The FDA initially disagreed based on what it characterized as "extensive" research and analysis provided by its Drug Shortage Division, but the FDA publicly reversed course a few days later under pressure from the palliative care and hospice communities, which relied on the concentrated formulation of Morphine Sulfate. See Exhibit G.

The FDA then acknowledged that concentrated oral solution Morphine Sulfate was medically necessary, and it encouraged the manufacturers of the Morphine Sulfate products to submit NDAs. See Exhibit F. Thus, on April 9, 2009, the FDA sent Cody/Lannett and other manufacturers follow-up letters extending its deadline for removal of the products to 180 days from the date on which the FDA approved the first NDA for a Morphine Sulfate solution of a given concentration. See Exhibits D and E. In addition, because a shortage of the product occurred, the FDA requested that Cody/Lannett increase its production to meet the needs of the medical community, and Cody/Lannett did so after obtaining additional quota of the necessary base material from the DEA.[12]

In response to the FDA's actions, Cody/Lannett requested meetings with the FDA to discuss the grandfathered status of the Product, and determine the form and content of a market approval application if the FDA refused to allow continued marketing of the Product. The FDA

[12] Cody/Lannett did so despite its concern that the FDA would view this as a violation of the terms set forth in the FDA's March 30, 2009 warning letters, which specifically warned Cody/Lannett about increasing production.

reactions to Cody/Lannett's requests were less than responsive—for example, the FDA granted its first pre-Investigational New Drug ("IND") meeting with the review division, to discuss the clinical research protocols required to prepare the application, at least two months after Cody/Lannett had requested it. Moreover, a number of the studies that the FDA requested that Cody/Lannett submit in the form of an NDA, rather than the ANDA or suitability petition sought by Cody/Lannett, required a minimum of 180-days each to prepare. Finally, when Lannett submitted its complete NDA on February 26, 2010, the FDA reversed themselves and denied its request for expedited consideration of the NDA. This denial occurred despite a 5-month expedited review granted to another competitor, Roxane Laboratories ("Roxane"), and a demand by the FDA to withdraw the drug from the market no later than July 24, 2010. As of the date of this filing, the NDA has been in the hands of the FDA for more than five months without any final action. Cody/Lannett continues to respond to all additional requests for information from the FDA promptly.

While Cody/Lannett's attempt to obtain FDA approval for the Product was delayed, the FDA engaged in an interactive, cooperative, and speedy process with Roxane, a competitor of Cody/Lannett's that also sells concentrated oral solution Morphine Sulfate, to encourage Roxane to remain in the market for this concentrated formulation despite its expressed intent to exit the market for this dosage form. The FDA worked cooperatively with Roxane, and, when Roxane submitted its NDA on August 26, 2009, FDA granted Roxane's request for expedited consideration and approved Roxane's NDA on January 25, 2010—before Lannett's application could even be filed. See Exhibit H. Pursuant to the FDA's April 2009 letters, the FDA's

approval of Roxanne's NDA started the clock running such that the FDA will require Cody/Lannett to cease manufacturing, marketing, and selling the Product as of July 24, 2010. (180-days from approval of a first NDA). The FDA reiterated that deadline in March 1, 2010 letters to Cody/Lannett. See Exhibits I and J.

Based on the FDA's position, the DEA has refused to grant Cody/Lannett any additional quota of the raw materials necessary to manufacture the Product and all manufacturing of the Product has ceased. Layoffs at Cody's plant in Cody, Wyoming, are imminent. Moreover, because Roxane has been granted an effective monopoly on the relevant market until, and unless, the FDA approves Lannett's application, Cody/Lannett will likely be unable to successfully regain the market share that it will lose if it is forced to remove its product from the market. As such, if this Court does not grant Cody/Lannett's requested relief, Cody/Lannett will likely be forced to permanently cease manufacturing, marketing, and selling their product, which currently represents more than a third of its projected revenues for 2010.

SUMMARY OF THE ARGUMENT

This case presents the quintessential example of a situation in which temporary and preliminary injunctive relief are necessary and appropriate. The primary purpose of such relief has always been to maintain the status quo when the outcome of a case has the potential to have an irreparable impact on the moving party or a negative impact on the public at large. If the Court refuses to grant the relief requested, Cody/Lannett would be forced to stop manufacturing, marketing, and selling their product as of July 24, 2010, devastating Cody/Lannett's business and

forcing the health care community and sick and dying patients to rely on a limited, single source to obtain a medically necessary drug. If that were to happen, the status quo could never be restored, regardless of this Court's final decisions on the weighty and challenging questions of law presented in this case. In addition, the four factors that courts consider when determining whether to grant temporary and preliminary injunctive relief weigh strongly in Cody/Lannett's favor.

First, Cody/Lannett will suffer irreparable harm if they are required to stop manufacturing, marketing, and selling the Product on July 24, 2010. Cody/Lannett once held the largest market share for the sale of this concentration of Morphine Sulfate solution. As a result of the FDA's actions to date, Cody/Lannett have already begun losing significant market share. If this Court permits the FDA to require Cody/Lannett to remove their product from the market on July 24, 2010 entirely, the companies will suffer an irreparable loss of market share, manufacturing capacity, and business relationships, all of which will never be compensable in monetary damages. In addition, Cody/Lannett, the only pharmaceutical manufacturer in the state of Wyoming, will suffer a significant reduction in income that will force Cody to layoff numerous employees at its Cody, Wyoming factory. These layoffs will likely include many individuals with specialized skills and knowledge (e.g., pharmacologists, good manufacturing practices quality assurance specialists, skills not readily available in Wyoming), many of whom Cody will likely never be able to rehire and retain in Wyoming should it eventually receive approval to continue selling its product. Thus, Cody/Lannett satisfy the irreparable harm standard.

Second, while Cody/Lannett will suffer irreparable harm if temporary and preliminary injunctive relief is not granted, the FDA will suffer absolutely no harm. Morphine Sulfate has been used and prescribed safely and effectively in the United States for more than 150 years. The Product has been manufactured, marketed, and sold in the United States for more than five years. Indeed, the FDA itself recognized the medical necessity of the Product to the public, and the lack of safety/effectiveness concerns, when it rescinded its previous demand that Morphine Sulfate be removed from the market in May 2009. Thus, it is difficult to conceive of *any harm* that could result to the FDA, or to the public health, from issuance of the temporary and preliminary relief requested, much less a harm sufficient to outweigh the irreparable harm that Cody/Lannett face if such immediate relief is not granted. Indeed, the FDA has already obtained what it apparently sought to achieve with its April 2009 letters insofar as Cody/Lannett has submitted an NDA for the Product. Thus, the balance of harms weighs strongly in favor of Cody/Lannett.

As a result, an artificial monopoly will exist. Hospitals, hospices, palliative care communities, and innumerable seriously or terminally ill patients, all of whom have come to rely on the Cody/Lannett Product (with superior dosator and anti-diversion packaging to be made available shortly) will be unable to obtaining the Product. They will face the risk of supply shortages (which occurred merely when warning letters were issued by the FDA in March 2009 notwithstanding the FDA's "studied" public assurance that the product could be removed from the market without shortages). Patients and providers will also likely pay substantially increased prices to obtain medically necessary pain medication as a result of Roxane's market dominance.

Furthermore, fundamental limitations exist on the role of government. Free market principles at the core of the United States economy demand that government agencies not be permitted to unilaterally and arbitrarily select winners and losers among competitors in the marketplace. The public interest weighs in favor of this Court granting temporary and preliminary injunctive relief.

Fourth, Cody/Lannett has a substantial likelihood of success on the merits. The legal questions are serious, substantial, difficult, and relatively untested. The issues are ripe for litigation and deserve deliberate investigation and thought. The FDA improperly determined that one of the oldest and most recognized drugs on the planet has now become a "new drug," not entitled to grandfathering under the FDCA. The FDA made this determination unilaterally, without developing any meaningful administrative record to support its determination. The Tenth Circuit has already held, under analogous circumstances, that unilateral action by the FDA is impermissible as a matter of law. See Rutherford v. United States, 542 F.2d 1137 (10th Cir. 1976). Furthermore, the FDA's determination in this regard is contrary to the express language of the statute. In addition, even assuming *arguendo* that the FDA properly determined that the Product was not entitled to pre-1938 grandfathering under the FDCA, the FDA was arbitrary, capricious, abused its discretion, and acted contrary to law by favoring Roxane over Cody/Lannett in the NDA process for this high concentration formulation given that the entities were arguably similarly situated competitors. The FDA's actions are particularly egregious given that completion of FDA's review of Lannett's NDA, submitted nearly five months ago, is likely the only thing preventing Cody/Lannett from offering the provider/patient community an accepted, available, and competitive Morphine Sulfate concentrated solution. Small businesses,

like Cody Labs and Lannett, also deserve fair and equitable treatment by government regulators for the good of the State/communities in which they operate.

For the forgoing reasons, and as more fully discussed below, Cody/Lannett respectfully submits that temporary and preliminary injunctive relief to maintain the status quo is necessary and appropriate in this case.

SUMMARY OF THE ARGUMENT

The courts recognize that "the primary goal of a preliminary injunction is to preserve the pre-trial status quo." RoDa Drilling Co. v. Siegal, 552 F.3d 1203, 1208 (10th Cir. 2009). The status quo is the "last uncontested status between the parties which preceded the controversy until the outcome of the final hearing." Dominion Video Satellite, Inc. v. Echostar Satellite Corp., 269 F.3d 1149, 1155 (10th Cir. 2001) (internal quotation omitted). Cody/Lannett have manufactured and sold concentrated Morphine Sulfate solution for more than five years, and the drug has been made and sold for over 150 years, with the knowledge and review of the FDA. The agency's sudden decision in 2009 to require removal of the Product from the market and its later decision to maintain the arbitrary date of July 24, 2010, despite an application being under active agency review, is a key part of the challenge that Cody/Lannett is pursuing in this case. In order to maintain the status quo in this case, Cody/Lannett respectfully submit that the Court should grant Cody/Lannett temporary and preliminary injunctive relief to permit Cody/Lannett to continue manufacturing, marketing, and selling the Product until the issues described herein can be reviewed and resolved.

It is well established that, in order to obtain temporary and preliminary injunctive relief, the moving party must establish four factors: (1) it will suffer irreparable harm if the injunction is not granted, (2) its threatened injury outweighs the harm caused to the opposing party as a result of the injunction, (3) the injunction is not adverse to the public interest, and (4) it has a substantial likelihood of success on merits of the case.[13] Dominion Video Satellite, Inc., 356 F.3d at 1260. If a movant can show that the first three requirements tip strongly in its favor, it can satisfy the fourth factor by establishing that the legal issues underlying the merits are "so serious, substantial, difficult, and doubtful as to make the issue ripe for litigation and deserving of more deliberate investigation." Davis v. Mineta, 302 F.3d 1104, 1111 (10th Cir. 2002) (internal quotations omitted); see also RoDa Drilling Co., 552 F.3d at 1209; San Luis Valley Ecosystem Council v. U.S. Fish and Wildlife Service, 657 F.Supp.2d 1233, 1239 (D. Colo. 2009) ("[T]he Tenth Circuit appears to recognize the continuing validity of the modified success-on-the-merits formula."). But see Munaf v. Geren, 128 S.Ct. 2207, 2219 (U.S. 2008) (citing with disapproval the application of the modified test to the question of whether a plaintiff demonstrated a substantial likelihood that the court had jurisdiction of a case).

For the reasons set forth below, each of the balance of hardships factors weigh in favor of the issuance of the temporary and preliminary injunctive relief that Cody/Lannett request.

I. CODY/LANNETT WILL SUFFER IRREPARABLE HARM IF THEIR MOTION IS DENIED.

[13] Because Cody/Lannett seeks to maintain the status quo in this case, they bear a lesser burden of proof than they would if they were seeking to alter the status quo. See O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft, 389 F.3d 973, 975 (10th Cir. 2004).

Cody/Lannett will suffer irreparable harm if the FDA is permitted to force the companies to remove the Product from the market on July 24, 2010. A showing of probable irreparable harm is typically considered "the single most important prerequisite for the issuance of a preliminary injunction." Dominion Video Satellite, Inc. v. Echostar Satellite Corp., 356 F.3d 1256, 1260 (10th Cir. 2004). A plaintiff satisfies the irreparable harm requirement by demonstrating "a significant risk that he or she will experience harm that cannot be compensated after the fact by monetary damages." Greater Yellowstone Coal. v. Flowers, 321 F.3d 1250, 1258 (10th Cir. 2003) (internal quotations omitted). Thus, "[a] plaintiff who can show a significant risk of irreparable harm has demonstrated that the harm is not speculative" and will be held to have satisfied its burden. Id; see also Schrier v. University of Colo., 427 F.3d 1253, 1267 (10th Cir. 2005).

Cody/Lannett face a substantial risk of suffering irreparable harm if they are forced to remove their product from the market because: (1) Cody/Lannett will suffer the total, irreparable loss of the Product business; and (2) even if that loss was quantifiable monetarily, monetary damage are not available to Cody/Lannett due to the Defendant government agency's sovereign immunity.

A. CODY/LANNETT WILL SUFFER A TOTAL, IRREPARABLE LOSS OF THEIR MORPHINE SULFATE SOLUTION BUSINESS IF THEY ARE REQUIRED TO REMOVE THEIR PRODUCT FROM THE MARKET.

If Cody/Lannett are required to remove the Product from the market, there is a substantial risk that the companies will suffer irreparable harm in the form of an irretrievable loss of market share, harm to business reputation, and risk of loss of the viability of Cody's business as a whole.

The courts have recognized that the loss of market share and harm to business reputation and credibility may be sufficient to constitute irreparable harm. See Dominion Video Satellite, Inc., 269 F.3d at 1156-57; see also Bushnell, Inc. v. Brunton Co., 673 F.Supp.2d 1241, 1262 (D. Kan. 2009); Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008); Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1368 (Fed. Cir. 2001). Thus, for example, in Dominion, the Tenth Circuit held that a preliminary injunction was appropriate in a breach of contract case because the defendant's breach threatened plaintiff with the loss of its pre-existing business as well as harm to plaintiff's reputation and credibility among its customers. Id. Similarly, if Cody/Lannett are forced to remove the Product from the market, the companies will suffer a loss of their entire pre-existing Morphine Sulfate solution market share to the only remaining market participant, the much larger and more aggressive competitor Roxane (the generic subsidiary of German parent Boehringer Ingleheim). Cody/Lannett's customers will suddenly be unable to rely on Cody/Lannett for supply of their product, and previous contracts will not be honored. Such business disruption will harm the companies' respective reputations and credibility in the medical community.

In addition, Cody/Lannett's loss of customers, and resulting market share, would create a substantial risk to the viability of Cody's business as a whole. The Tenth Circuit recognized that "[a] threat to trade or business viability may constitute irreparable harm." Tri-State Generation and Transmission Ass'n, Inc. v. Shoshone River Power, Inc., 805 F.2d 351, 356 (10th Cir. 1986). In Tri-State, the court considered a motion for a preliminary injunction in a breach of contract case. The court held that Tri-State made a sufficient showing of irreparable harm based upon its

showing that, "[i]f the preliminary injunction does not issue, Tri-State has no protection against the loss of its business while the litigation progresses . . . . [the Defendant] may be found to have breached its contract with Tri-State, but in the meantime Tri-State would have ceased to exist." Id.

If Cody is forced to stop selling the Product, Cody will be required to layoff approximately one-third of its manufacturing employees, many of whom have unique skill sets, and reduce its production capabilities to eliminate excess overhead. Given that the Product accounts for approximately 33% of Cody's net profits, and the precedent set in FDA's actions against previously grandfathered products may jeopardize other products, there is a substantial risk that Cody may become unviable as a business entity located in Wyoming. As such, even if the FDA were to eventually approve Lannett's NDA and permit Cody/Lannett to reenter the Morphine Sulfate Solution market, Cody would no longer maintain the manufacturing capabilities, skilled employees, or customer base sufficient to justify manufacture of the Product, or manufacture at existing levels. These losses to Cody/Lannett's customer base, market share, business reputation, and credibility cannot be readily quantified or adequately remedied, and, therefore, constitute irreparable harm.

B. CODY/LANNETT WILL NOT BE ABLE TO OBTAIN MONETARY COMPENSATION FOR THE HARM THEY WILL SUFFER.

Even assuming *arguendo* that the harm to Cody/Lannett discussed above could be monetarily quantified and compensated, such harms would still be irreparable in this case. The Defendant government department/agency are immune from monetary damages. Absent a

waiver, sovereign immunity shields the federal government, its agents, and its agencies from suit. See generally F.D.I.C. v. Meyer, 510 U.S. 471, 475 (1994). While the Administrative Procedure Act ("APA") constitutes a waiver of the sovereign immunity that would otherwise protect the Defendants from suit, the APA only permits actions "seeking relief other than money damages." 5 U.S.C. § 702. Sovereign immunity, therefore, prevents this Court from entering a monetary judgment against the Defendants.

The courts recognized that any harm suffered by a plaintiff at the hands of a defendant which is immune from monetary damages is virtually *per se* irreparable. Kansas Health Care Ass'n, Inc. v. Kansas Dept. of Social and Rehab. Servs., 31 F.3d 1536, 1543 (10th Cir. 1994) ("Because the Eleventh Amendment bars a legal remedy in damages, and the court concluded no adequate state administrative remedy existed, the court held that plaintiffs' injury was irreparable. We agree."); see also Crowe & Dunlevy, P.C. v. Stidham, 609 F.Supp.2d 1211 (N.D. Okla. 2009) (finding irreparable harm when sovereign immunity of Indian tribe would bar plaintiff from recovering a monetary judgment); Temple Univ. v. White, 941 F.2d 201, 215 (3d Cir. 1991) (holding that the existence of sovereign immunity from monetary damages "clearly establishes that any legal remedy is unavailable and the only relief available is equitable in nature"); Feinerman v. Bernardi, 558 F.Supp.2d 36, 51 (D.D.C. 2008) (stating that when "the plaintiff in question cannot recover damages from the defendant due to the defendant's sovereign immunity," any loss of income suffered by a plaintiff is irreparable *per se*).

Thus, even if the harm that Cody/Lannett will suffer if forced to remove the Product from the market were quantifiable monetarily, Cody/Lannett's harm would still be irreparable. Temporary or preliminary injunctive relief is, therefore, appropriate.

II. WHILE CODY/LANNETT WILL SUFFER IRREPARABLE HARM ABSENT TEMPORARY AND PRELIMINARY INJUNCTIVE RELIEF, THE FDA WILL NOT SUFFER ANY HARM IF SUCH RELIEF IS GRANTED.

The balance of hardships as between Cody/Lannett and the Defendants weighs heavily in Cody's favor. While Cody/Lannett will suffer the irreparable harm detailed above if forced to remove the Product from the market on July 24, 2010, the Defendants will not suffer any harm from the granting of temporary and preliminary injunctive relief to maintain the status quo.

The FDA has permitted the sale of the Product for five years. Morphine Sulfate, in general, has been used for the treatment of pain in the United States for more than 150 years. The FDA itself recognized the safety and effectiveness of concentrated Morphine Sulfate oral solution by approving Roxane's NDA, reviewing Cody/Lannett's NDA, and by prolonging the sale of the Cody/Lannett Product in the face of shortages. Moreover, if the FDA believed that Cody/Lannett's Product posed a risk of harm to the public, it could deem the Product adulterated and use its authority to remove it from the market. The fact that the FDA has not done so suggests an absence of concern that Cody/Lannett's Product poses a risk of harm to the public.

While Cody/Lannett faces irreparable harm if this Court fails to grant temporary and preliminary injunctive relief, the FDA faces no appreciable risk of harm. The balance of hardships, therefore, weighs strongly in favor of granting Cody/Lannett temporary and preliminary injunctive relief.

III. THE PUBLIC INTEREST WOULD BE SERVED BY THE ISSUANCE OF TEMPORARY AND PRELIMINARY INJUNCTIVE RELIEF PERMITTING CODY/LANNETT'S PRODUCT TO REMAIN ON THE MARKET.

The public interest also weighs strongly in favor of granting Cody/Lannett temporary and preliminary injunctive relief. In balancing the four factors used to determine whether to grant such relief, courts have recognized that when a case arises under a public health related statute, "the Court will weigh heavily the general public's interest in the issuance of the injunction." Wilson v. Amoco Corp., 989 F.Supp. 1159, 1171 (D. Wyo. 1998); see also United States v. Power Eng'g Co. 10 F.Supp.2d 1145, 1149 (D. Colo. 1998); see generally Weinberger v. Romero-Barcelo, 456 U.S. 305, 313 (1982).

As an initial matter, for the reasons fully articulated in the balancing of harm analysis above, it is apparent that there is no legitimate risk to public health or safety by allowing Cody/Lannett to continue selling its Product pending resolution of this case. The Product has been on the market for 5 years with the FDA's full knowledge and comprehensive oversight (through registrations, listings, filings, inspections, etc.). Furthermore, the Product's only active ingredient is Morphine Sulfate which has been used for pain relief in the United States for more than 150 years. Had the FDA determined that the Product presented any risk of harm to the public, it could have pulled it from the market immediately as adulterated. Based on its 2006 guidance, and its actions in this case, it is apparent that the FDA believes that it would be in the public interest to require NDAs, or ANDAs for all "unapproved" prescription drugs, thereby eliminating the grandfather provisions of the FDCA. This would, of course, grant the FDA the power to review and pre-approve all prescription drugs, regardless of their age, history of use, or

metamorphosis of the FDCA. Unfortunately, the FDA, as an incremental regulator, lacks the authority to supersede Congress's determination that grandfathering of "unapproved drugs" is appropriate under the FDCA, and that the retroactive application of the statute is inappropriate.

Far from presenting a risk to the public interest, issuance of temporary and preliminary injunctive relief in this case would actually protect the public interest. Morphine Sulfate solutions are liquid medications administered orally to patients to treat severe chronic and acute pain. The Product is a particularly strong concentration that is suited ideally for use by individuals who cannot receive intravenous Morphine and who are incapable of swallowing a larger volume of a more diluted form of the medication. Given these characteristics, the Product is most commonly used to treat patients in hospices and palliative care communities, many of whom are in such poor health that they can be offered little more than pain management in their final days. Indeed, as of the end of 2009, more than 90% of the end-users of the Product were patients in such communities.

Prior to the FDA's order requiring Cody/Lannett to remove the Product from the market on July 24, 2010, Cody/Lannett had more than a 50% market share of the Morphine Sulfate concentrated solution.[14] If the FDA is permitted to require Cody/Lannett to remove their Product from the market on July 24, 2010, Roxane will become the sole source for Morphine Sulfate in the United States. The creation of this artificial monopoly would likely have the undesirable consequences that the Congress and the courts tried to avoid through enactment of the Sherman

[14] Since the FDA's approval of Roxane's NDA, and in apparent response to actions by the FDA detailed more fully below, Cody/Lannett's customers have begun purchasing their concentrated Morphine Sulfate solution from Roxane in anticipation of the Product being removed from the market. Thus, Cody/Lannett has already lost a portion of their market share.

and Robinson Patman Acts: decreased availability, inferior products, reduced customer service, less customer choice and higher prices.

The public interest requires that Cody/Lannett be permitted to continue to manufacture, market, and sell the Product to avoid the inherent risk of market shortages when a pharmaceutical market is served by a single source. Such shortages could occur for any number of reasons including: manufacturing shortages at Roxane; adulteration of Roxane's product; failure to comply with Good Manufacturing Practices ("GMPs") recalls; supply chain issues such as shipping problems; or the prevalent delay in required up-front quota review and permission by the DEA.[15] As a result of any one of these issues, hospitals, hospices, clinics and other palliative care providers could suddenly be unable to supply this strong and effective pain medication to their end-of-life patients.[16]

Issuance of the relief requested would also protect the public interest by ensuring that the medical community has access to high quality, reasonably priced Morphine Sulfate concentrated

[15] When a substance is classified by the DEA, it is placed into one of five (5) schedules of regulation that grade drugs according to their potential for abuse, inherent danger and usefulness. It then becomes a controlled substance pursuant to the authority of the Comprehensive Drug Abuse Prevention and Control Act, and related regulations under 21 C.F.R. Part 1303. Morphine Sulfate is classified as Schedule II, as are most opium and opiate drugs, meaning that the drug has a high potential for abuse, a currently accepted medical use, and abuse may lead to severe psychological or physical dependence. 21 U.S.C. §§ 812(b)(2), 202(b)(2). Production of controlled substances is regulated upfront by the establishment of annual production quotas for each substance with the DEA to protect against illicit use or diversion.

[16] Indeed, the FDA is apparently aware of the risk of harm that a shortage in the market may cause. On March 30, 2009, the FDA issued a notice that it required all manufacturers to cease production of "unapproved" Morphine Sulfate within 60 days and cease shipping of the product within 90 days. This announcement created an immediate market shortage as customers stockpiled existing products, manufacturers stopped producing Morphine Sulfate and distributors stopped filling orders. The FDA was inundated with complaints from the provider community, especially from palliative care facilities, about the creation of a shortage of the drug. As a result of this shortage, the FDA was forced to seek assistance from Cody/Lannett to fill the gap in supply. At the FDA's request, Cody/Lannett increased manufacturing and was able to fill the supply gap created by the shortage. Apparently recognizing the impact on the medical community that a shortage in the market could create, the FDA thereafter extended the deadline for removal of concentrated oral Morphine Sulfate solutions from the market.

oral solution. One of the major benefits to our free market economy is that competition helps to ensure product quality and competitive pricing. If the FDA is allowed to create a monopoly for this product, there is a substantial risk that Roxane will significantly raise its prices to take advantage of the fact that it will be the sole source for a medically necessary drug.

Finally, the public interest would be served best by issuance of the relief requested because the government cannot be permitted to arbitrarily favor one competitor in the marketplace by unilaterally granting that competitor an artificial monopoly. The United States economy is built upon the theory that a free market encourages vigorous competition among competitors in the marketplace. If the FDA were permitted to arbitrarily favor one competitor to the exclusion of all others, the medical community at large would be denied the benefits of such competition. Furthermore, arbitrary favoritism by the government decreases public confidence in the government's ability and willingness to execute the laws fairly and even-handedly. FDA's likely explanation that it favored Roxane because of the company's size and existing NDAs for other dosage forms of Morphine Sulfate does not eliminate this issue. Lannett was the largest supplier of the concentrated solution, had increased production to mitigate the impact of the FDA warning letters, and was capable of producing sufficient amounts to supply the marketplace (assuming sufficient DEA quota was allocated to either or both Roxane and Lannett). The issue is that FDA does not have express authority to choose which company to favor, but must maintain a level playing field in which every qualified company can compete.

Thus, the public interest supports issuance of temporary and preliminary injunctive relief in this case.

IV. CODY/LANNETT HAS A SUBSTANTIAL LIKELIHOOD OF SUCCESS ON THE MERITS AND THE QUESTIONS ON THE MERITS ARE SUFFICIENTLY SERIOUS, SUBSTANTIAL, DIFFICULT, AND DOUBTFUL AS TO MAKE THE CASE RIPE FOR LITIGATION AND DESERVING OF MORE DELIBERATE INVESTIGATION.

The final factor also weighs in favor of granting Cody/Lannett temporary and preliminary injunctive relief. Under the ordinary application of the balancing test governing temporary and preliminary injunctive relief, a party must establish a "substantial likelihood of success on the merits." Dominion Video Satellite, Inc., 356 F.3d at 1260. A strong legal case exists on the merits of this case. In the alternative, even when the case may be debatable, when a party has shown that the first three factors of the balancing test tip strongly in its favor, the party "may meet the requirement for showing success on the merits by showing that questions going to the merits are so serious, substantial, difficult, and doubtful as to make the issue ripe for litigation and deserving of more deliberate investigation." See Davis, 302 F.3d at 1111; see also RoDa Drilling Co., 552 F.3d at 1209.

While Cody/Lannett contend that the first three factors tip sufficiently in their favor to warrant the application of this modified standard, the likelihood of success of their case on the merits would satisfy even the more stringent, traditional standard. This is so because: (1) the FDA acted arbitrarily, capriciously, contrary to law, and abused its discretion[17] in determining that Cody/Lannett's product was a "new drug" not entitled to grandfathered treatment under the FDCA; and (2) the FDA acted arbitrarily, capriciously, contrary to law, and abused its discretion

[17] The APA permits courts to set aside an FDA action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

in treating Cody/Lannett differently during the NDA process than their similarly situated competitor, Roxane.

A. CODY/LANNETT HAVE A SUBSTANTIAL LIKELIHOOD OF ESTABLISHING THAT THE FDA IMPROPERLY DETERMINED THAT CODY/LANNETT'S PRODUCT WAS A "NEW DRUG" NOT ENTITLED TO GRANDFATHERED TREATMENT UNDER THE FDCA.

Cody/Lannett have a substantial likelihood of success on the merits with regard to the question of whether the Product is a "new drug" for purposes of the FDCA because: (1) the FDA's decision to make the determination without developing a proper agency record was arbitrary, capricious, an abuse of discretion, and contrary to law and (2) the FDA's determination that the Product was a "new drug" was arbitrary, capricious, an abuse of discretion, and contrary to law.

1. THE FDA FAILED TO DEVELOP A PROPER AGENCY RECORD TO DETERMINE THAT MORPHINE SULFATE SOLUTIONS ARE "NEW DRUGS."

The FDA's unilateral determination that oral Morphine Sulfate solutions of the concentration manufactured and sold by Cody/Lannett were "new drugs," without the development of any agency record in support of that determination, was arbitrary, capricious, an abuse of discretion, and contrary to law. In Weinberger v. Hynson, Wescott & Dunning, Inc., the Supreme Court held that the FDA has the power to issue a declaratory order that a drug is a "new drug" to which the FDCA's grandfathering provision is inapplicable. 412 U.S. 609, 625-27 (1973).[18] As the Supreme Court noted, however, "FDA does not have unbridled discretion to

[18] A declaratory order is a "self-operative industry-wide regulation." Abbott Lab. v. Gardner, 387 U.S. 136, 147 (1967).

do what it pleases. Its procedures must satisfy the rudiments of fair play." Id. at 627. In this case, the FDA issued a *de facto* declaratory order that all oral Morphine Sulfate solutions of the concentration manufactured and sold by Cody/Lannett are "new drugs," without developing any agency record in support of that determination in violation of the rudiments of fair play.

For decades following the 1938 amendments to the FDCA, it was generally accepted that many "unapproved drugs," including oral solution Morphine Sulfate, were not "new drugs" and were therefore entitled to grandfathering under the FDCA.[19] In its 2006 Guidance regarding "unapproved drugs," however, the FDA suddenly and inexplicably took the position that it is "not likely that *any* currently marketed prescription drug is grandfathered or is otherwise not a new drug." FDA 2006 Guidance at 11. The FDA thus sought to eliminate by unilateral declaration the grandfathering provisions of the FDCA. The FDA did so without holding hearings and without developing an administrative record to support this determination as to any of the "unapproved drugs" then on the market.

Having already made the unilateral determination that all drugs are "new drugs" for purposes of the FDCA, the FDA issued a *de facto* declaratory order that oral solutions of Morphine Sulfate of the same concentration as Cody/Lannett's product are "new drugs" by issuing warning letters to that effect to all manufacturers of the products, including Cody/Lannett, in March 2009 and April 2009. Indeed, in those warning letters, the FDA specifically stated its conclusion that oral Morphine Sulfate solutions of the concentration sold by Cody/Lannett were "new drugs" not entitled to grandfathering. The FDA made this industry-

[19] Section IV(A)(2) below provides a full discussion of this issue

wide determination without a hearing and without developing any agency record in support thereof.

The Tenth Circuit has expressly rejected this sort of baseless, unilateral decision-making by the FDA on the question of whether a drug is a "new drug" for purposes of the grandfathering exception to the FDCA. In Rutherford v. United States, the court considered an appeal from a district court order granting a preliminary injunction in a case in which the FDA determined that the cancer drug Laetrile was a "new drug" that was not entitled to grandfathering under the FDCA. See generally 542 F.2d 1137 (10th Cir. 1976). The FDA did so "without citing any facts whatsoever." Id. at 1143. Specifically noting the "dearth of evidence in support of the FDA's determination," the court stated that it was "unable . . . to see how the FDA can escape the obligation of producing an administrative record to support its determination . . . that Laetrile is a new drug, for it is not a new drug merely because [the FDA says] it is." Id. Moreover, the court noted that "[s]uch a conclusory ruling [by the FDA] precludes effective review under 5 U.S.C. Section 706(2)," id., which requires a district court that is reviewing an agency determination to review the "whole record." 5 U.S.C. § 706(2). As the Supreme Court stated in Weinberger, while "[the] FDA may make a declaratory order that a drug is a 'new drug,'" such an order "is reviewable by the district court under the Administrative Procedure Act." 412 U.S. at 627. Thus, the Rutherford court upheld the preliminary injunction and referred the matter back to the FDA for further development of an adequate record.[20]

[20] The development of an administrative record in support of a determination that a drug is a "new drug" determination is particularly important when the only opportunity for an appeal of that determination is an APA claim. Compare Rutherford, 542 F.2d at 1143-44 (requiring the FDA to develop a record when the underlying basis

Just as it did in Rutherford, in this case the FDA made an industry-wide, unilateral determination that oral Morphine Sulfate solutions of the concentration manufactured and sold by Cody/Lannett are "new drugs" for purposes of the FDCA without developing any administrative record in support of that conclusion. Pursuant to Weinberger, Rutherford, and the APA, there is a substantial likelihood that the FDA will be found to have acted arbitrarily, capriciously, and contrary to law and to have abused its discretion in determining that Morphine Sulfate solutions are "new drugs" for purposes of the FDCA given the absence of a sufficient agency record in this case. Thus, in accordance with Rutherford, the issuance of temporary and preliminary injunctive relief is appropriate.

2. THE FDA'S DETERMINATION THAT MORPHINE SULFATE SOLUTIONS ARE "NEW DRUGS" WAS ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, AND CONTRARY TO LAW.

Even if this Court were to determine that the FDA had developed a minimally adequate administrative record in reaching its determination that Morphine Sulfate solutions constitute "new drugs" for purposes of the FDCA, Cody/Lannett would still have a substantial likelihood of success on the merits of their claim that the FDA's determination itself was arbitrary, capricious, an abuse of discretion, and contrary to existing law.

The pre-1938 grandfather clause of the FDCA provides that a drug "shall not be deemed a 'new drug'" that requires approval "if at any time prior to the enactment of this chapter [enacted June 25, 1938] it was subject to the Food and Drugs Act of June 30, 1906, as amended,

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for the action was an APA claim) with United States v. Tutag Pharmaceuticals, Inc., 602 F.2d 1387 (10th Cir. 1979) (determining that an agency record was not required in a case in which the FDA was the plaintiff and bore the burden of proving at the district court level that a drug was a "new drug.")

and if at such time its labeling contained the same representations concerning the conditions of its use." 21 U.S.C. § 321 (p)(1); see United States v. Allan Drug Corp., 357 F.2d 713, 717 (10th Cir. 1966). As an initial matter, the Tenth Circuit has recognized that the question of whether a drug is a "new drug" for purposes of the FDCA grandfathering provisions is a question that is sufficiently "substantial, difficult and doubtful so as to support the granting of a preliminary injunction." Rutherford, 542 F.2d at 1142-43. Thus, existing precedent suggests that this question alone is sufficient to warrant issuance of a preliminary injunction in this case. In addition, however, Cody/Lannett have a significant likelihood of prevailing on the merits of their claim that the FDA wrongly concluded that oral solutions of Morphine Sulfate are "new drugs" under the two prongs of the FDCA pre-1938 grandfathering test (and instead applied the more stringent pre-1962 grandfathering test and case law which is arguably inapplicable to a drug, like Morphine Sulfate, with irrefutable evidence that it was marketed before 1938). See Exhibit K.

As to the first prong of the pre-1938 test, whether the drug was subject to the 1906 Act at any time prior to June 25, 1938, there is ample evidence that oral solutions of Morphine Sulfate, in this concentration, were on the market between 1906 and 1938 and, thus, were subject to the 1906 Act. Oral solutions of Morphine Sulfate have been listed in, among other compendia, the Epitome of the Pharmacopeia of the U.S. and National Formulary, the Dispensatory of the United States of America, U.S. Pharmacopeia, the U.S. Dispensatory of the United States, the Materia Medica and Pharmacology/Materia Medicia Pharmacology and Therapeutics, and Merck's Manual of the Materia Medica between 1906 and 1938. See id. Additionally, there are numerous references to Morphine Sulfate in various strengths, for oral and hypodermic use

during this same time period (the National Dispensatory, the United States Dispensatory, and the Merck Manual discuss dosages of morphine sulfate in the range of that currently used) as well as numerous entries in various price lists from the relevant period. See id. Patent and trademark records also show that a number of companies submitted trademark applications showing first use of oral solutions of Morphine Sulfate from 1861 to 1927. See id.

Notably, Morphine Sulfate, oral solution, was listed on the United States Pharmacopeia's Drug Information's "Listing of 'Pre-1938' Products." See Exhibit A. According to the United States Pharmacopeia, the list was developed by comparing an earlier general listing of frequently prescribed 'pre-1938' drug entities compiled by the FDA against current dosage form listing in the Orange Book, which lists all drugs approved by the FDA. See id. Indeed, Compounding Today continues to list Morphine Sulfate (oral solution and tablets) as a grandfathered, pre-1938 drug, based on United States Pharmacopeia's Drug Information's "Listing of 'Pre-1938' Products," see Exhibit K; a source deemed authoritative by the United States Department of Health and Human Services Medicare Appeals Council. See In the Case of V.B.M., (Dep't of Health and Human Services Oct. 8, 2009), http://www.hhs.gov/dab/divisions/medicareoperations/macdecisions/vbm.pdf.

The FDA may try to argue that a couple minor excipient (inactive) ingredients contained in the Cody/Lannett Morphine Sulfate formulation as preservatives exclude the drug from pre-1938 grandfathered treatment. There is, however, evidence that these specific ingredients are also pre-1938, have no effect on the safety/efficacy of the active ingredient, and that there exists

no authority applicable to the grandfather provision that such technicalities override the intent of the pre-1938 provision. See id.

With regard to the second prong, whether during the period between 1906 and 1938, the drug label contained the same representations concerning "the conditions of its use," there is ample evidence that Morphine Sulfate labeling between 1906 and 1938 contained the same representations concerning the conditions of its use today. See id. Today, Morphine Sulfate is indicated "for the relief of moderate to severe acute and chronic pain" or "for the relief of severe acute and severe chronic pain." There are a number of dosage strengths and forms (solid, oral, injected), and dosing varies based on condition and patient. However, most pre-1938 drugs were not marketed or dispensed with modern product labels, but were compounded by pharmacists to order at various strengths based on patient need. See id. Thus, in order to avoid rendering the 1938 grandfather provision inoperative or superfluous—which is contrary to fundamental principles of statutory construction[21]—"labeling" as used in the grandfather provision ("at such time as its labeling") cannot be limited only to the product label itself, but must be understood more broadly,[22] similar to FDA's own interpretation of labeling as material accompanying the product.[23]

The FDCA sets forth the standard for when a drug product is not subject to the "new drug" requirements. The FDA cannot override or add to the unambiguous requirements of the

[21] See generally TRW, Inc. v. Andrews, 534 U.S. 19, 31 (2001).
[22] This is consistent with the fact that the 1938 Act defined "labeling" to include all labels and other written, printed, or graphic matter "(1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 453(s).
[23] See Kordel v. United States, 335 U.S. 345 (1948).

statute. See Pharmanex v. Shalala, 221 F.3d 1151, 1154 (10th Cir. 2000) (noting that the Court will not give effect to an agency's statutory interpretation if it is arbitrary, capricious, or manifestly contrary to the statue); see also Granutec, Inc. v. Shalala, No. 97-1873, 1998 U.S. App. LEXIS 6685 (4th Cir. Apr. 3, 1998) (noting that "regulations . . . that add to rather than elucidate a statutory requirement go beyond an agency's authority to interpret legislative grants of authority") (unpublished opinion). An FDA interpretation of the "labeling" language applicable to the pre-1938 version of grandfathered drugs that insists on the specificity of modern labeling (including specific indications, usage, formulations, strength, dosage form, modes of administration, intended patient population, etc.) would render the pre-1938 grandfather clause, 21 U.S.C. § 321 (p)(1), inoperative and/or superfluous because no pre-1938 drug could qualify. Such an application is contrary to the principles of statutory construction and unsupportable. See, e.g., TRW, Inc., 534 U.S. at 31 (emphasizing that "it is 'a cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'") (internal citations omitted).

At a minimum, such labeling should be considered to include manuals or other written material produced by companies that supplied Morphine Sulfate including, but not limited to, Merck's Manual of Materia Medica (1899, 1923), John Wyeth & Brothers Dose Book of Pharm. Preparations (1882), McNeil Laboratories Pharmedica (1920) and Physicians' Reference Book of Squibb Biological Products and Pharmaceutical Specialties (1936). See id. Because doctors, pharmacists, and others who prescribed or compounded Morphine Sulfate would have relied

upon treatises and compendia in prescribing or compounding such drugs, it is appropriate to look to those sources concerning "the conditions of its use." Indeed, Merck's Manual of the Materia Medica, subtitled "A Ready-Reference Pocket Book for the Physician and Surgeon" (1923), contains entries for Morphine (Alkaloid) Merck, Morphine Hydrochloride Merck, and Morphine Sulphate Merck. See id. Under "USES" it lists "[t]o relieve pain, nervous excitement, etc." Merck's Manual of Materia Medica also includes dosages within and over the ranges of the 20 mg/mL of the Product. See id.

Because Morphine Sulfate is a pre-1938 drug subject to the 1906 Act prior to June 25, 1938, and because, during this same period, the drug labeling for morphine sulfate contained the same representations concerning "the conditions of its use" as it does now, the drug falls squarely within the grandfather exception to the FDCA. As such, Cody/Lannett are likely to prevail on the merits.

B. CODY/LANNETT HAVE A SUBSTANTIAL LIKELIHOOD OF ESTABLISHING THAT THE FDA ACTED ARBITRARILY, CAPRICIOUSLY, CONTRARY TO LAW, AND ABUSED ITS DISCRETION IN TREATING CODY/LANNETT DIFFERENTLY THAN THEIR SIMILARLY SITUATED COMPETITOR ROXANE.

There is also a substantial likelihood that Cody/Lannett will establish that the FDA improperly treated Cody/Lannett and their competitor, Roxane, differently despite the fact that they were similarly situated entities that were simultaneously marketing an "unapproved drug," i.e., concentrated Morphine Sulfate solutions. Specifically, the FDA aided Roxane in its NDA process and granted its supplemental NDA expedited treatment while the FDA did little to assist Cody/Lannett with its NDA and denied Cody/Lannett's NDA such expedited treatment.

In order to withstand an APA challenge, agency action must be "the product of reasoned decisionmaking." Olenhouse v. Commodity Credit Corp., 42 F.3d 1560, 1578 (10th Cir. 1994); see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co. 463 U.S. 29, 52 (1983). While the FDA has discretion in the exercise of its enforcement authority, see, e.g., Heckler v. Cheney, 470 U.S. 821 (1985), the FDA acts arbitrarily and capriciously when it fails to treat similarly situated parties in the same manner. Thus, the courts have held that "once FDA has initiated an enforcement action against certain manufacturers [of an "unapproved" drug], unless unusual circumstances are present, it must proceed in an equal manner against all such entities." Allergan Inc. v. Shalala, 1994 U.S. Dist. LEXIS 21716 (D.D.C. Nov. 10, 1994); see also Bracco Diagnostics, Inc. v. Shalala, 963 F.Supp. 20, 27-28 (D.D.C. 1997) ("Government is at its most arbitrary when it treats similarly situated parties differently."). Moreover, "disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious," id., and "[d]eference to administrative discretion or expertise is not a license to a regulatory agency to treat like cases differently." United States v. Diapulse Corp. of Am., 748 F.2d 56, 62 (2d Cir. 1984) (citations omitted).

Prior to the FDA's issuance of the March 2009 warning letters, Cody/Lannett and Roxane were similarly situated competitors in the concentrated Morphine Sulfate solutions market. Indeed, prior to that time, Cody/Lannett serviced over 50% of the market while Roxane serviced less than 5%. Both companies were marketing concentrated oral Morphine Sulfate solutions that were the same in all material respects. Since the issuance of the April 2009 follow-up letters, the FDA has given favorable treatment to Roxane at every turn. Initially, when the FDA learned that

Roxane intended to get out of the market, Cody/Lannett understands that the FDA actively persuaded Roxane to remain in the market. During the course of Roxane's subsequent NDA submission, the FDA apparently worked closely with Roxane to facilitate the NDA process. Indeed, the FDA granted expedited review and approval of Roxane's supplemental NDA.

In contrast, the FDA's treatment of Cody/Lannett was far less favorable than its treatment of the much larger Roxane. After the FDA's issuance of its initial warning letter in 2009, Cody/Lannett had an initial meeting with the FDA. To follow up on that meeting, Cody/Lannett requested a second meeting with the FDA. Due to a delay by the FDA, it was roughly two months before that meeting actually occurred. Thereafter, Cody/Lannett diligently pursued an NDA, but the FDA provided little assistance in that process. Indeed, after Cody/Lannett had already filed their NDA, the FDA changed its "recommended approach" to an ANDA, thus requiring Cody/Lannett to provide different and additional information which resulted in further delay. Most significantly, however, when Cody/Lannett requested the same expedited treatment of its NDA that Roxane had received, the FDA flatly denied the request. As such, while Roxane's NDA was quickly approved by the FDA, Cody/Lannett's NDA is still pending with the FDA, and, the lack of action by the FDA stands as the obstacle to Cody/Lannett's continued sale of its product.

Should there be any lingering doubt that the FDA treated Roxane and Cody/Lannett completely differently throughout this process, one need only consider the FDA's actions after its approval of Roxane's NDA. On January 26, 2010, the FDA announced that it had worked with Roxane to ensure that adequate supplies of the product would be available and noted that it

would "also be working with patient organizations and prescribers so that they are aware than an approved drug is available." Indeed, the FDA reportedly stated that it expected all demand to shift Roxane's way. All other company drugs were described as unapproved with a citation to the original March 30, 2009 warning letter requiring cessation of manufacturing within 60 days and cessation of shipping within 90 days, without reference to the April 9, 2010 extension. Finally, on January 27, 2010, the FDA updated its drug shortage supply website, identifying Roxane as the "only FDA approved morphine sulfate oral solution available at this concentration" and asserting that Roxane had sufficient supply to meet market demand. These statements failed to note that FDA's April 2009 letter permitted manufacturers of "unapproved" concentrated oral Morphine Sulfate solution on the market for 180 days, thereby giving the impression that Roxane was the only available source of the drug. To date, despite Cody/Lannett's authorization, the FDA has yet to even publicly acknowledge that Cody/Lannett have filed an NDA. Indeed, FDA's March 1, 2010 letter to Lannett (reiterating that the Product had to come off the market by July 24, 2010), which is posted on the FDA's website, contained language encouraging the submission of an NDA for the Product—without acknowledging that Lannett had already done so, on February 26, 2010. Based on the FDA's actions, it comes as no surprise that Cody/Lannett have seen a precipitous drop in monthly sales since December 2009.

Based on the foregoing, Cody/Lannett respectfully submit that Cody/Lannett has demonstrated a substantial likelihood of success on the merits.

CONCLUSION

For the reasons set forth herein, Cody/Lannett respectfully requests that this Court issue a temporary restraining order and preliminary injunction:

(1) Enjoining the FDA from any enforcement action or attempt to prevent Cody/Lannett from manufacturing, marketing, or selling the Product if such enforcement is based on the FDA's contention that the Product is an unapproved "new drug" for purposes of the FDCA;

(2) Enjoining the FDA from threatening or taking any enforcement action against Cody/Lannett's customers[24] if such threat of enforcement or actual enforcement is based on the FDA's contention that the Product is an unapproved "new drug" for purposes of the FDCA;

(3) Enjoining the FDA from any enforcement action or attempt to prevent Cody/Lannett from manufacturing, marketing, or selling the Product if such enforcement is based on the absence of an approved NDA or ANDA for the Product; and

(4) Enjoining the FDA from threatening or taking any enforcement action against Cody/Lannett's customers if such threat of enforcement or actual enforcement is based on the absence of an approved NDA or ANDA for the Product. See Exhibit N.

[24] "Customers" as used in this Prayer for Relief includes all direct customers of Cody/Lannett including wholesalers, distributors, and pharmacies, as well as all legal downstream purchasers and patients using the product.

Cody/Lannett further respectfully requests that such temporary and preliminary relief be effective until a final and conclusion resolution of the matters at issue in this case or until such time as the FDA approves Lannett's NDA, whichever may occur first.

Respectfully submitted this 21st day of July, 2010.

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