Robert G. Wing (4445) Kevin M. McLean (16101) Assistant Attorneys General SEAN D. REYES (7969) Utah Attorney General Utah Attorney General's Office 160 East 300 South, 5th Floor PO Box 140872 Salt Lake City, UT 84114-0872 Ph. (801) 366-0310 rwing@agutah.gov kmclean@agutah.gov Linda Singer Elizabeth Smith Lisa Saltzburg Motley Rice LLC 401 9th St. NW, Suite 1001 Washington, DC 20004 Ph. (202) 386-9627 Isinger@motleyrice.com esmith@motleyrice.com Isaltzburg@motleyrice.com Matt McCarley Misty Farris Majed Nachawati Fears Nachawati, PLLC 5473 Blair Road Dallas, Texas 75231 Ph. (214) 890-0711 mccarley@fnlawfirm.com mfarris@fnlawfirm.com mn@fnlawfirm.com

Attorneys for the Utah Division of Consumer Protection

BEFORE THE DIVISION OF CONSUMER PROTECTION OF THE UTAH DEPARTMENT OF COMMERCE

IN THE MATTER OF:

PURDUE PHARMA L.P., a Delaware limited partnership; PURDUE PHARMA INC., a New York Corporation; THE PURDUE FREDERICK COMPANY, a Delaware corporation; RICHARD SACKLER, M.D., individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities; and KATHE SACKLER, M.D., individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities;

Respondents.

DIVISION'S MEMORANDUM IN OPPOSITION TO THE PURDUE RESPONDENTS' MOTION TO DISMISS THE DIVISION'S CITATION AND NOTICE OF AGENCY ACTION

DCP Legal File No. CP-2019-005

DCP Case No. 107102

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The Utah Division of Consumer Protection ("Division") respectfully submits this Memorandum in Opposition to Respondents Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company (collectively "Purdue")'s Motion to Dismiss the Division's Citation and Notice of Agency Action ("Motion"). For the reasons set forth below, Purdue's Motion should be denied.

I. PRELIMINARY STATEMENT

As detailed in the Citation, Purdue for many years has maintained a sophisticated campaign to convince the medical community and the public that opioids were safe: essentially, that high doses of pharmaceutical-grade heroin could treat even run-of-the-mill, chronic pain, without significant risk of addiction. Purdue knowingly or intentionally engaged in and continues to engage in and/or has failed to correct an aggressive marketing campaign to overstate the benefits and misstate and conceal the risks of treating chronic pain with opioids to increase its profits. $\P 16.^1$ Purdue disseminated misstatements through multiple channels, representing opioids as beneficial in treating chronic pain long-term and as having a low risk of addiction. *Id*.

This campaign included, for example, websites, promotional materials distributed in Utah, conferences available to Utah prescribers, dinner programs held in Utah for Utah prescribers, guidelines for doctors, and thousands of personal visits between Purdue's sales representatives and Utah prescribers in their medical offices. ¶¶ 16, 26.

¹ All references to " \P _" are to paragraphs of the Citation. References to "Purdue Mot. _" are to Purdue's Motion to Dismiss the Division's Citation and Notice of Agency Action.



Purdue also helped cultivate a narrative – directly, through key opinion leaders, and through industry-sponsored publications – that pain was undertreated and pain treatment should be a higher priority for health care providers. *Id.*; *see also* ¶¶ 17, 32-105. The problems engendered by the deceptive and unfair marketing of opioids were specifically known by Purdue. ¶ 113. It also knew that its continuing efforts to employ deceptive and unfair marketing would contribute to the opioid epidemic in Utah and would create access to opioids by at-risk and unauthorized users, which, in turn, would perpetuate the cycle of abuse, addiction, demand, and illegal transactions. ¶ 117. Purdue's deceptive messages tainted virtually every source doctors and patients could rely on for information and prevented them from making informed treatment decisions. Purdue, through its multi-pronged campaign – which included sales representatives, as well as respected pain specialists and organizations that touted a false narrative – helped callously manipulate what doctors wanted to believe: that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

Seeking to evade responsibility for this conduct, Purdue includes a kitchen sink of arguments in its Motion, none of which have merit. First, Purdue is wrong to claim that it can obtain a free pass from the administrative process, or civil penalties, by engaging particularly egregious or pervasive misconduct. Second, courts across the country in opioids cases brought by other attorneys general have rejected many of the very same arguments raised by Purdue on the

merits here. See, e.g., South Carolina v. Purdue Pharma L.P., No. 2017-CP-40-04872 (S.C. Ct. Com. Pl. Apr. 12, 2018) (the "South Carolina Order") (Ex. 1); In re Opioid Litig., 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018) (Ex. 2); In re Opioid Litig., 2018 WL 3115100 (N.Y. Sup. Ct. June 18, 2018) (Ex. 3); Washington v. Purdue Pharma L.P., No. 17-2-25505-0 SEA (Wash. Super. Ct. May 14, 2018) (the "Washington Order") (Ex. 4); Ohio v. Purdue Pharma L.P., 2018 WL 4080052 (Ohio Ct. Com. Pl. Aug. 22, 2018) (Ex. 5); Missouri v. Purdue Pharma, L.P., No. 1722-CC10626 (Mo. Cir. Ct. Apr. 25, 2018) (the "Missouri Order") (Ex. 6); Kentucky v. Endo Health Sols. Inc., 2018 WL 3635765 (Ky. Cir. Ct. July 10, 2018) (Ex. 7); New Hampshire v. Purdue Pharma Inc., 2018 WL 4566129 (N.H. Super. Ct. Sept. 18, 2018) (Ex. 8); Alaska v. Purdue Pharma L.P., 2018 WL 4468439 (Alaska Super. Ct. July 12, 2018) (Ex. 9); Grewal v. Purdue Pharma L.P., 2018 WL 4829660 (N.J. Super. Ct. Oct. 2, 2018) (Ex. 10); Delaware, ex rel. Jennings v. Purdue Pharma L.P., 2019 WL 446382 (Del. Super. Ct. Feb. 4, 2019) (Ex. 11); Commonwealth of Kentucky, ex rel. Beshear v. Johnson & Johnson, No. 18-CI-00313 (Ky. Cir Ct. Nov. 20, 2018) (Ex. 12); Commonwealth of Kentucky, ex rel. Beshear v. Mallinckrodt plc, No. 18-CI-00381 (Ky. Cir. Ct. Jan. 22, 2019) (Ex. 13); State of Vermont v. Purdue Pharma L.P., No. 757-9-18 Cncv (Vt. Super. Ct. Mar. 19, 2019) (Ex. 14); State of Tennessee, ex rel. Slatery v. Purdue Pharma L.P., No. 1-173-18 (Tenn. Cir. Ct. Feb 22, 2019) (Ex. 15). This tribunal should join these other state courts that have addressed motions to dismiss in their state's opioid litigation and deny Purdue's motion to dismiss in its entirety.

II. LEGAL STANDARD

Pleadings in administrative proceedings must contain "(a) a clear and concise statement of the allegations or facts relied upon as the basis for the pleading; and (b) an appropriate request for relief when relief is sought." U.A.C. R151-4-202(2). The standard is simply notice pleading, the equivalent of Utah Rule of Civil Procedure 8(a)'s mandate of a short and plain statement. *Cf.*

Parker v. State of Indiana, 400 N.E.2d 796, 798 (Ind. Ct. App. 1980) ("[U]nder our system of 'notice' pleading, the plaintiff is merely required to make a clear and concise statement in order to put the defendant on notice that he has a justiciable claim and is entitled to relief under some legal theory.").

The Administrative Code does not have a corollary to Utah Rule of Civil Procedure 9(c), which requires that fraud be pleaded with particularity, and Rule 9(c) does not control here because "administrative proceedings are not subject to the Utah Rules of Civil Procedure unless the governing statute or regulations so provide." *Pilcher v. State Dep't of Soc. Servs.*, 663 P.2d 450, 453 (Utah 1983); *see also Entre Nous Club v. Toronto*, 287 P.2d 670, 672 (Utah 1955) ("The Utah Rules of Civil Procedure are the rules for the government of the courts adjudicating formal contest between adverse parties; clearly they are inapplicable to a proceeding before an administrative body seeking to regulate activities burdened with a public interest." (citations omitted)). The Utah Rules of Civil Procedure and related case law are persuasive, but not controlling, authority when evaluating a party's pleadings. *See* U.A.C. R151-4-106 ("The Utah Rules of Civil Procedure and related case law are persuasive, but not controlling, authority when evaluating a party's pleadings. *See* U.A.C. R151-4-106 ("The Utah Rules of Civil Procedure and related case law are persuasive, but not controlling, authority when evaluating a party's pleadings. *See* U.A.C. R151-4-106 ("The Utah Rules of Civil Procedure and related case law are persuasive, but not controlling, authority when evaluating a party's pleadings. *See* U.A.C. R151-4-106 ("The Utah Rules of Civil Procedure and related case law are persuasive authority in this rule (R151-4), but may not, except as otherwise provided by Title 63G, Chapter 4, Administrative Procedures Act or by this rule, be considered controlling authority."). However, even if the Tribunal applies Rule 9 to the Division's claims, the Division's claims are properly pleaded.

A motion to dismiss may be premised "on a ground described in Rule 12(b)(1) through (7) of the Utah Rules of Civil Procedure." U.A.C. R151-4-302(1). The Administrative Code does not provide a standard for reviewing a motion to dismiss under Rule 12(b), but case law provides persuasive authority to guide this review. When ruling on a motion to dismiss under Utah Rule of Civil Procedure 12(b)(6), the presiding officer must "accept the factual allegations in the complaint

as true and consider them and all reasonable inferences to be drawn therefrom in a light most favorable to the plaintiff." *Lowe v. Sorenson Research Co.*, 779 P.2d 668, 669 (Utah 1989). Dismissal is appropriate only if the petitioner "could not in any event establish a right to recover." *Barrus v. Wilkinson*, 398 P.2d 207, 208 (Utah 1965).

Under Utah Rule of Civil Procedure 12(b), "on a motion asserting the defense numbered (6) to dismiss for failure of the pleading to state a claim upon which relief can be granted, matters outside the pleading" cannot be considered unless the motion is "treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56." Utah R. Civ. P. 12(b).

III. PURDUE'S EXHIBITS A THROUGH G MUST BE EXCLUDED, AND THE ARGUMENTS IN RELIANCE THEREUPON BE DISREGARDED

Purdue's motion is procedurally flawed. Instead of confining its arguments to the Division's pleadings, Purdue attaches to its motion a pleading and docket information in a prior dismissed case (Purdue Exhibits A and B), a press release and news articles (Purdue Exhibits C, D, and E), certain OxyContin labeling (Exhibit F), and correspondence from the FDA to a non-party (Exhibit G). As a matter of law, these exhibits cannot be the basis for granting Purdue's motion. Purdue's attempt to secure dismissal based on documents outside of the four corners of the pleadings should be rejected for two independent reasons. First, a motion to dismiss cannot be premised on documents outside of the pleadings. Second, even if it could, Purdue has not demonstrated that each of these documents is subject to judicial notice.

First, these exhibits must be excluded from consideration at the motion to dismiss stage. If these materials are "not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56." Utah R. Civ. P. 12(b). Purdue's motion cannot proceed under Rule 56, however, without granting the Division an opportunity for response and discovery. *See* Utah R. Civ. P. 56; *see also Carlton v. Brown*, 2014 UT 6, ¶ 14, 323 P.3d 571, 576 n.5 (noting it was error for district court to treat motion to dismiss as motion for summary judgment when parties were not given notice of conversion and an opportunity to supplement the record under Rule 56). Thus, Purdue's errant reliance on matters and facts extraneous to the Division's pleadings is a defect fatal to its motion to dismiss.

Indeed, Purdue does not attempt to articulate any basis for this Tribunal to consider its cherry-picked exhibits at this stage. Rather, Purdue summarily quotes one decision for the proposition that "public records" may be considered. Purdue Mot. 5 n.1. (citing *BMBT*, *LLC v*. *Miller*, 2014 UT App. 64, ¶ 6, 322 P.3d 1172, 1174). Purdue does not attempt to explain why each of these exhibits – including news articles – qualifies as a "public record." Even assuming for the sake of argument that they do, the exhibits must be excluded because these documents are not referred to in, nor made central to, the pleadings. *See BMBT*, ¶ 6, 322 P.3d at 1174.

Far from supporting Purdue's claimed entitlement to rely upon materials extraneous to the Division's pleadings, the *BMBT* case demonstrates the opposite. Specifically, there the Court of Appeals cited the general rule that, "**it is reversible error** for a trial court to consider and rely on matters outside the pleadings without converting the rule 12(b)(6) motion to a motion for summary judgment." *Id.* (citing *Oakwood Vill. LLC v. Albertsons, Inc.*, 2004 UT 101, ¶ 12, 104 P.3d 1226) (emphasis added). The exception to this rule is when the document at issue is "referred to in the complaint and [is] central to the plaintiff's claim." *Id.* (quoting *Oakwood Vill.*, ¶ 13, 104 P.3d at 1231. This exception is necessary because if the rule were

otherwise, a plaintiff with a deficient claim could survive a motion to dismiss simply by not attaching "a dispositive document upon which the plaintiff relied." *BMBT*, ¶ 6, 322 P.3d at 1174 (quoting *Oakwood Vill.*, ¶ 13, 104 P.3d at 1231). Purdue does not and cannot claim that Exhibits A through G are referred to in the State's Citation and Notice of Agency Action ("Notice"), nor does Purdue articulate any theory as to how these materials could possibly be deemed as "central" to or dispositive in the Division's claims. Therefore, under the sole authority cited by Purdue, the Exhibits must be excluded. *See id.* ("[T]he Deed was implicit in BMBT's claim of title *and* the Deed was central to that claim. (emphasis added)); *Oakwood Vill.*, ¶¶ 12-13, 104 P.3d at 1231.

Exhibits A and B should be excluded because documents related to the prior case are not referenced in nor made central to the Division's Citation and Notice here. When a defendant attaches a prior federal judgment in support of its motion to dismiss, the trial court errs in failing to convert the motion into one for summary judgment and in failing to give the parties reasonable notice or an opportunity to submit other Rule 56 materials. *Tuttle v. Olds*, 2007 UT App 10, ¶¶ 9-10, 155 P.3d 893, 896-97.

As further example, one trial court's reliance on, *inter alia*, a newspaper article and information regarding the negative side effects of Lexapro prompted the court to convert the motion to dismiss into a summary judgment proceeding. *See Rhinehart v. State*, 2012 UT App 322, ¶ 3, 290 P.3d 921, 924-25 (citing *Oakwood Vill.*, ¶¶ 12, 14, 104 P.3d at 1231-32). These materials could not be relied upon in a motion to dismiss because they substantiated, rather than merely reiterated, the party's claims. *See id.* Pursuant to this reasoning, Exhibits C through F, which constitute press materials and information Purdue deems relevant to OxyContin, should be excluded at the motion to dismiss stage.

Second and independently, Purdue has not attempted to lay a foundation for admission of these exhibits. Looking to the Rules of Evidence as persuasive, judicial notice is allowed in the following circumstances:

The court may judicially notice a fact that is not subject to reasonable dispute because it:

(1) is generally known within the trial court's territorial jurisdiction; or

(2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.

Utah R. Evid. 201(b). Purdue does not attempt to frame these exhibits as falling within this Tribunal's general knowledge. While Purdue states that Exhibit A at least is a "public record," which would satisfy Rule 201(b)(2), Purdue does not attempt to explain why news articles and third party correspondence could meet this standard. Even relaxing the Rules of Evidence in this administrative action, Purdue fails to articulate any basis for laying a foundation – even a relaxed one.

Finally, even assuming *arguendo* the Court could take judicial notice of the *existence* of these documents, it cannot take judicial notice of their *contents*. Purdue urges this Court to accept without proof that excerpts of selected documents from a much larger universe of documents concerning the regulatory treatment of opioids conclusively establish the truth about these drugs. These documents are offered to persuade this Court that their contents are accurate and complete. Where, as here, a party seeks "notice of its own interpretation of the contents of . . . documents' and not just notice of their existence," judicial notice must be denied. *Goldfarb v. Mayor & City Council of Baltimore*, 791 F.3d 500, 511 (4th Cir. 2015). Further, courts must remain vigilant that judicial notice not "be used as an expedient for courts to consider 'matters beyond the pleadings' and thereby upset the procedural rights of litigants to present evidence on disputed matters." *Id.*

(internal quotation marks omitted).² The Division has included certain arguments which reference and address these materials out of abundance of caution to correct Purdue's characterization, but in doing so does not in any way suggest that they should be considered or waive its objection to their consideration.

IV. THE FLEXIBLE AND FAIR RULES OF THIS TRIBUNAL SATISFY DUE PROCESS

A. A Respondent Does Not Obtain Special Solicitude by Violating the UCSPA More Often or More Egregiously than Other Respondents

Purdue conceded at the April 17, 2019 hearing that it does not question this tribunal's competence to adjudicate other respondents' cases. Such cases would involve the same time frames, evidentiary rules, discovery rules, absence of a jury trial, and limitations periods as in this action. They would also involve the same types of violations of the Utah Consumer Sales Practices Act ("UCSPA") as alleged here. Purdue contends that this action is different, however, because of the scope and duration of the misconduct at issue. That Purdue's deceptive and unconscionable practices targeted more people over a longer period of time than other respondents who have faced citations from the Division, however, does not exempt Purdue from an administrative proceeding. Tellingly, Purdue cites no authority for its position that it can seek dismissal on the grounds that it engaged in worse misconduct than other parties. Such a rule would create a perverse incentive for anyone violating the UCSPA to do so more egregiously.

Purdue mischaracterizes the case law it cites. The reference to "notice and opportunity for hearing appropriate to the nature of the case" in *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306 (1950), references the type of case at issue, not the individual facts of each

² Purdue cites only one case in support of its request for judicial notice, and it does not apply. In *Doe v. Bishop of Charleston*, 754 S.E.2d 494 (S.C. 2014), the court merely held that "reliance on transcripts and court orders in the underlying class action did not convert the motion to one for summary judgment." *Id.* at 497 n.2.

adjudication. See id. at 313. In fact, the Supreme Court has held that "procedural due process rules are shaped by the risk of error inherent in the truthfinding process as applied to the generality of cases, not the rare exceptions." Mathews v. Eldridge, 424 U.S. 319, 344 (1976) (emphasis added). The Court further cautioned that, in applying the same Mathews factors that Purdue purports to address in its Motion, one "must keep in mind" both "the deference owed to" the legislature and "the fact that the very nature of the due process inquiry indicates that the fundamental fairness of a particular procedure does not turn on the result obtained in any individual case." Walters v. Nat'l Ass'n of Radiation Survivors, 473 U.S. 305, 321 (1985) (reiterating that, "rather, 'procedural due process rules are shaped by the risk of error inherent in the truth-finding process as applied to the generality of cases, not the rare exceptions"). Accordingly, Walters rejected the notion that a subgroup of "undoubtedly 'complex cases'" pending before the VA required special treatment. Id. at 330 ("What evidence we have been pointed to in the record regarding complex cases falls far short of the kind which would warrant upsetting Congress' judgment that this is the manner in which it wishes claims for veterans' benefits adjudicated."). If this matter were proceeding in district court, there would be no different standards for discovery, experts, or motion practice because of the complexity of the case; the rules apply equally to all parties. Here, too, the legislature has determined to make respondents subject to the administrative process. There is no basis, and no authority, to upset this judgment.

Purdue argues that if the legislature had anticipated the scope of Purdue's alleged UCSPA violations, it would have created a different, complex case process here, or exempted Purdue from administrative proceedings altogether. Purdue's selective citation to legislative history, however, is a red herring. Purdue argues, relying on hearsay, that the sponsor of a 1992 bill relayed that the Department of Commerce had told him they did not anticipate, at that time, a case in which civil

penalties would exceed \$75,000, and therefore limited the amount required to be placed in the Consumer Protection Education and Training Fund (the "Fund") to that amount. *See* Purdue Mem. 11.³ In fact, the provision Purdue cites was not a cap on civil penalties, but simply relates to how much money the Fund could retain, rather than transferring the amount collected to the State's general fund. Purdue also neglects to mention that the legislature not only has increased that amount, but has made provision for larger fines. The statute, last amended in 2013, raised the threshold amount of funds in Fund, from \$100,000 to \$500,000. *See* 2013 Utah House Bill No. 245, Utah Sixtieth Legislature - 2013 General Session; *see also* Utah Code Ann. § 13-2-8. Further, now, as in 1992, the statute does not cap the amount of penalties that may be assessed in an administrative proceeding. To the contrary, it made provision for administrative fines or civil penalties exceeding the size of the Fund. *See id.* (providing for transfer of excess funds to the general fund).⁴

In sum, Purdue is wrong to claim that the duration and scope of its UCSPA violations grant it a free pass from administrative proceedings. Under the Utah Constitution, "[a]ll laws of a general nature shall have uniform operation." Utah Const. art. I, § 24. If anything would violate constitutional constraints, it is Purdue's position, not application of the same statutes and regulations consistently upheld as providing Due Process in binding precedents discussed below.

³ Purdue also improperly relies on its attorneys' unsworn description of the "average fine" it calculated and the size of penalties in certain actions that Purdue "could locate" online. *See id.* at 10-11.

⁴ Utah is not the only state to bring an administrative action against an opioid manufacturer. Administrative proceedings against Insys Therapeutics, Inc. ("Insys") were filed in Minnesota and Maryland. Moreover, unlike the Citation here, the Maryland Consumer Protection Division's Statement of Charges, a public record of which the Court may take judicial notice, seeks not only civil penalties, but economic damages, citing \$20 million in revenue Insys obtained from prescriptions in Maryland.

B. Purdue Offers No Support for Its Claim that the Same Procedures That Afford Due Process to Other Respondents Are Inadequate for Purdue

1. Purdue mischaracterizes the interests at stake

Purdue, without citing any Utah, Tenth Circuit, or U.S. Supreme Court authority, claims that it has a particularly weighty interest at stake because the monetary amount of civil penalties imposed could be large. The interest Purdue alleges, however, is no different in kind than that of any other respondent in a proceeding such as this. Further, Purdue, which made billions of dollars in profits, *see* ¶ 128, fails to place the monetary amount in context. Other administrative proceedings may concern licensing or disability benefits, with the potential to impact a person's livelihood or means of support, and may be equally important to the petitioner. And although this is of course a civil proceeding, by way of analogy, in the criminal context, "[a] monetary fine is the lightest . . . sanction the state can impose." *Zissi v. State Tax Comm'n of Utah*, 842 P.2d 848, 855-59 (Utah 1992).

Purdue has no legitimate interest in indefinite delay, while the State seeks to protect the strong public interest and stop conduct that has caused a public health epidemic. Notably, in the federal criminal context, where weighty liberty interests are at stake, the Speedy Trial Act, 18 U.S.C. § 3161, *et seq.*, "requires that a criminal defendant's trial commence within 70 days after he is charged or makes an initial appearance, whichever is later," with certain periods permitted to be excluded from the calculation. *Bloate v. United States*, 559 U.S. 196, 198-99 (2010). In that context, time limits cannot be unilaterally waived, because "the Act serves not only to protect defendants, but also to vindicate the public interest in the swift administration of justice." *Id.* at 211; *see also Zedner v. United States*, 547 U.S. 489, 501 (2006) ("[T]he Act was designed not just to benefit defendants but also to serve the public interest by, among other things, reducing

defendants' opportunity to commit crimes while on pretrial release and preventing extended pretrial delay from impairing the deterrent effect of punishment.").

Purdue's attempt to cast aspersions on the State's motives is nothing more than a distraction, and does not change this analysis. Briefly, however, to correct the record, the State notes, as previously explained in Response to the same arguments when raised by the Sackler Respondents: the same news articles and press statement Purdue cites refute its arguments that the Division is attempting to somehow pressure Purdue into a settlement. As an initial matter, the same news articles and press statement that Purdue cites in its Motion show that the State of Utah actively pursued its lawsuit, though it took some time to obtain outside counsel to assist it in pressing its case, such that the docket activity did not fully reflect this effort. These materials quote Attorney General Reyes explaining the aim of the administrative proceeding "is not just to get a 'payout.'" Purdue Ex. E. And, in fact, in the interest of promptly adjudicating this case under this Tribunal's supervision, the State has foregone the possibility of an even more expansive relief, with the potential settlement leverage that provides. The Attorney General has further explained that "we want to send a message and we want the practice and behaviors to stop," and that the "administrative process, with the Division of Consumer Protection regularly uses will provide 'prompt and full consideration of the state's claims." Id.

Purdue conveniently ignores important intervening circumstances disclosed in its own exhibits. "After seeing multiple media reports about Purdue retaining restructuring counsel – along with other indications the company could be considering bankruptcy – Utah Attorney General Sean Reyes said his team decided that filing an administrative action would be 'in the best interest of the people of Utah.'" *Id.*; *see also* Purdue Ex. D. In addition, all district court claims

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have been stayed due to a pending consolidation of lawsuits filed in Utah state courts. Purdue Ex. C.

2. Purdue fails to identify a risk of error

For a scattershot list of reasons, Purdue claims to lack confidence this proceeding will proceed appropriately, and baldly asserts a high risk of error. As explained below, each of Purdue's arguments misses the mark.

a. The time frame is sufficient

Purdue is wrong to claim that the governing rules do not provide adequate time for this straightforward proceeding. *First*, in seeking to move forward with an administrative citation, the Division did not merely change the venue. Utah's judicial action included not only causes of action for violation of the UCSPA, but also nuisance, negligence, unjust enrichment, and fraud counts, and sought, among other relief, compensatory damages, fines, abatement of the public nuisance, restitution, and disgorgement. In this proceeding, the Division asserts only UCSPA violations. As remedies, it also seeks only injunctive relief and civil penalties. As such, there will be no need for the Presiding Officer to consider, in this proceeding, questions of causation and damages. In this context, it is also well established that the division need not show proof of reliance. *See F.T.C. v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1203 (10th Cir. 2005) (explaining, in the context of the FTC Act, that "[n]either proof of consumer reliance nor consumer injury is necessary to establish a § 5 violation" and that "[o]therwise, the law would preclude the FTC from taking preemptive action against those responsible for deceptive acts or practices, contrary to § 5's prophylactic purpose").⁵ Unlike in a private action, where, for example, a

⁵ Although this case concerned the Federal Trade Commission, the UCSPA expressly seeks to "to make state regulation of consumer sales practices not inconsistent with the policies of the Federal Trade Commission Act relating to consumer protection." Utah Code Ann. § 13-11-2(4).

consumer seeks restitution for a purchase made *as a result of* the respondent's misleading advertising, the Division's responsibility is to police the marketplace and protect consumers and competitors from deceptive or unconscionable conduct.

Second, Purdue is wrong to claim that identifying individualized misrepresentations or conducting discovery against the State will take too long. The claims in the Citation and Notice require the Division to prove that Purdue engaged in deceptive or unconscionable conduct in marketing its opioids in connection with consumer transactions in Utah, but not, as noted above and discussed further below, causation, reliance, or damages. See infra Part VI.B; see Freecom Commc'ns, Inc., 401 F.3d at 1203. If liability is established, the Division also will have to prove the amount of the fine that is appropriate and its entitlement to injunctive relief. See, e.g., R. & R., In re Nat'l Prescription Opiate Litig., 2018 WL 4895856, at *11 (N.D. Ohio, Oct 5, 2018) (Ruiz, Mag. J.) (Ex. 16); In re Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 32 (1st Cir. 2013); United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 563 (E.D. Tenn. 2014); United States v. Life Care Ctrs. of Am., Inc., 2015 WL 10987029, at *3 (E.D. Tenn. Feb. 18, 2015) (Ex. 17); Order Regarding Discovery Ruling #5, In re: Nat'l Prescription Opiate Litig., No. 17md-2804 (DAP) (N.D. Ohio Oct. 16, 2018), ECF No. 1047 (Ex. 18); accord Opinion & Order, In re: Nat'l Prescription Opiate Litig., No. 1:17-md-2804 (DAP) (N.D. Ohio Dec. 19, 2018), ECF No. 1203 (Ex. 19). Thus, Purdue's suggestion that it needs extensive discovery against the Division or individual doctors is misplaced. The relevant evidence, such as "call notes" from Purdue's sales representatives reflecting statements made and materials delivered, has long been available to Purdue in Purdue's own files. But the broad discovery related to claims for abatement or damages that Purdue has obtained in other cases regarding whether the government knew of or sufficiently mitigated its false marketing, or whether its marketing caused doctors to write

prescriptions or prescriptions to cause harm, are simply not relevant in this proceeding. *See* Order of Special Discovery Master at 2, *Oklahoma, ex rel., Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dist. Ct. Cleveland Cty. Okla. Oct. 10, 2018) (concluding "proportionality would prohibit individualized discovery" in connection with State of Oklahoma's claims under Oklahoma Medicaid False Claims Act) (Ex. 20).

Third, Defendants' argument concerning Motley Rice LLC's representation of plaintiffs in separate multidistrict litigation (the "MDL") is misplaced. The Division, not outside counsel, directs this litigation, which must conform to the law, policies, and practices of Utah.⁶ In any event, that much discovery has already been done in the MDL actually undermines Purdue's due process argument. Purdue has already engaged in extensive discovery in producing documents and taking and defending depositions in the MDL, which may be produced or relied on in this action; thus, the scope of, and time needed for, discovery is substantially reduced. Additionally, the defenses that Purdue has developed in responding to consumer protection claims in other jurisdictions will be available to it here. Indeed, much of its Motion mirrors the same arguments made – and rejected – elsewhere. It is also by no means unusual for the Division to have the benefit of pre-litigation discovery in an administrative proceeding. Administrative subpoenas aid the Division in evaluating claims to ensure that only those that are meritorious result in citations.

Fourth, Purdue's vague assertion that it will want to call a number of witnesses and experts is insufficient to carry its burden of demonstrating a due process violation. And, notably, this is not the only proceeding in which Purdue is claiming inadequate time to conduct discovery, especially expert discovery. Purdue recently sought to extend expert discovery in the MDL, a

⁶ The Division is not a party to the MDL. Purdue, by contrast, is a party to the MDL and all Respondents are named in actions by MDL plaintiffs. Accordingly, Purdue attempted to cross-notice MDL depositions in the State of Utah's case while it was pending.

proposal the Court found not only unnecessary, but counterproductive. *See Nunc Pro Tunc* Order Re Expert Deps., at 1-2, *In re: Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804 (DAP) (N.D. Ohio Apr. 11, 2019), ECF No. 1540 (noting if Defendants did, in fact, require the number of experts proposed, "the Court believes that any jury will reject their arguments" and "[o]n top of that, there is no way either side could call even a small fraction of these experts within the time the Court has allotted for this trial"). This was true even though the MDL trial, unlike this proceeding, will involve complex civil racketeering and other statutory and regulatory claims not at issue here.

Finally, although the Division does not believe any extension would be warranted here, if the parties were unable to adhere to a case-management order, the governing rules permit an extension or continuance if the presiding officer finds that injustice would otherwise result. U.A.C. R151-4-109(2)(b)(ii).

b. The evidentiary and expert discovery rules are consistent with due process

Purdue argues that its Due Process rights will be violated because the evidentiary and expert discovery rules are not exactly the same as they would be in court. It fails to offer any legal or factual support, however, for suggestion this would create a Due Process violation. Nor could it. Utah courts "have recognized the importance and necessity of preserving fundamental requirements of procedural fairness in administrative hearings," while at the same time making clear that to do so, "administrative hearings need not possess the formality of judicial proceedings." *Nelson v. Dep't of Emp't Sec.*, 801 P.2d 158, 163 (Utah Ct. App. 1990). Further, "it has long been settled that the technical rules for the exclusion of evidence applicable in jury trials do not apply to proceedings before federal administrative agencies in the absence of a statutory requirement that such rules are to be observed." *Opp Cotton Mills, Inc. v. Adm'r of Wage*

& Hour Div. of Dep't of Labor, 312 U.S. 126, 155 (1941); see also, e.g., Levers v. Berkshire, 151 F.2d 935, 939 (10th Cir. 1945) (same); *Gardner v. City of Columbus*, 841 F.2d 1272, 1280 (6th Cir. 1988) (explaining fact that the agency at issue was "a state agency does not change the analysis"). Purdue simply ignores this binding precedent.

Turning to the specific differences at issue, Purdue argues that the admission of hearsay evidence would violate its Due Process rights, but fails to offer any case law to support this proposition. Meanwhile, "it is generally accepted ... that nothing in the due process clause precludes the use of hearsay evidence in administrative proceedings." *Toribio-Chavez v. Holder*, 611 F.3d 57, 66 (1st Cir. 2010). Here, Purdue ignores that although evidence cannot be excluded solely on the ground that is it hearsay, "findings of fact [in an administrative proceeding] cannot be based exclusively on hearsay evidence. They must be supported by a residuum of legal evidence competent in a court of law." *Yacht Club v. Utah Liquor Control Comm'n*, 681 P.2d 1224, 1226 (Utah 1984) (emphasis omitted). In this respect, the governing rules are more protective than those at issue in *Toribio-Chavez*. In addition, the presiding officer "may exclude evidence that is irrelevant, immaterial, or unduly repetitious." Utah Code Ann. § 63G-4-206(1)(b)(i). As the Presiding Officer observed in the April 19, 2019 Order on Renewed Motion to Convert Informal Hearing ("April 19, 2019 Order"), this Rule resembles Rules 402 and 403 of the Utah Rules of Evidence.⁷

Purdue's arguments that it will not receive "meaningful" information about the Division's experts is similarly unavailing. As the Presiding Officer has already explained, the "assertion that

⁷ As explained above, the Presiding Officer also should take Purdue's arguments concerning hearsay with a grain of salt. Despite not being permitted to introduce materials outside the complaint on a motion to dismiss, Purdue already is relying on hearsay in support of its own position.

'there are no established procedures for vetting expert opinions' is categorically incorrect as to formal proceedings." *In the Matter of Purdue Pharma, L.P.*, No. CP-2019-005, slip op. at 11 (Apr. 19, 2019) (Ex. 21) (citation omitted). In fact, parties to formal proceedings such as this must disclose their opinions, and the basis and reasons for them. *See* U.A.C. R151-4-504(1)(a)(ii). As the Presiding Officer explained in the April 19, 2019 Order, "The clear direction in the rule that 'an expert may not testify in a party's case-in-chief concerning any matter not fairly disclosed in the report' is a significant incentive for the written report to be robust and informative." Moreover, in judicial proceedings, the Utah Rules of Civil Procedure applicable in judicial proceedings permit either a deposition or a written report of an expert, but not both. *See* Utah R. Civ. P. 26(a)(4)(B).

Purdue makes other passing criticisms of the relevant evidentiary rules but fails to explain how they would be at all prejudicial, much less rise to the level of a Due Process violation. It also ignores that as a rule, there is no "constitutional right to formal discovery in administrative proceedings." *Petro-Hunt, LLC v. Dep't of Workforce Servs., Div. of Adjudication*, 2008 UT App 391, ¶¶ 9-12, 197 P.3d 107, 110-11. The discovery available already more than meets Due Process requirements. Here all testimony in a hearing is given under oath, and the parties will have the opportunity to cross-examine the opposing party's experts. *See* Utah Code Ann. §§ 63G-4-206(1)(d) & (f). Overall, the presiding officer has the authority and obligation to "regulate the course of the hearing to obtain full disclosure of relevant facts and to afford all the parties reasonable opportunity to present their positions." Utah Code Ann. § 63G-4-206(1)(a). There is no reason to believe that the Presiding Officer here would disregard this statutory admonition.

3. The Legislature sets the limitations period

Purdue is wrong to claim that by filing the Citation and Notice, the Division somehow "revive[d]" or "extended" the limitations period for the UCSPA claims at issue. In fact, the Division has always had the statutory right to pursue administrative proceedings, regardless of whether it also has filed or would file a lawsuit in court. As Purdue concedes, the same statutory limitations period, set by the legislature, applies to all administrative actions of this nature. *See* Utah Code Ann. § 13-2-6(6)(a); *Phillips v. Dep't of Commerce*, 2017 UT App 84, ¶¶ 9, 15, 397 P.3d 863, 866-67 (explaining that "[u]nder the Utah Uniform Securities Act the Division has three avenues for enforcing the provisions of the Act: equitable actions, administrative proceedings, and criminal actions" and that the "civil statute of limitation did not apply to the Division's administrative enforcement efforts under the Act").

Purdue also ignores that the doctrine of equitable tolling applies with respect to the limitations periods for both judicial and administrative actions. "Under the fraudulent concealment doctrine, Utah courts toll the running of the limitations period if 'a plaintiff does not become aware of the cause of action because of the defendant's concealment or misleading conduct." *Colosimo v. Roman Catholic Bishop of Salt Lake City*, 2007 UT 25, ¶ 38, 156 P.3d 806, 816 (quoting *Russell Packard Dev., Inc. v. Carson*, 2005 UT 14, ¶ 25, 108 P.3d 741, 747).⁸

4. There is no entitlement to a jury trial in this context

Purdue argues that it is entitled to a jury trial. In fact, however, as the legislature has recognized, there is no right to a jury trial on UCSPA claims for civil penalties. *Cf.* Utah Code Ann. § 63G-4-402(3)(a) ("The court, without a jury, shall determine all questions of fact and law"); *Rhodes Pharmacal Co. v. F.T.C.*, 208 F.2d 382, 387-88 (7th Cir. 1953) ("The meaning of advertisements to the public and their capacity to deceive are questions of fact for the Commission to determine 'The Commission had a right to look at the advertisements in question, consider

⁸ The statute of limitations also may be tolled "where the case presents exceptional circumstances and the application of the general rule would be irrational or unjust, regardless of any showing that the defendant has prevented the discovery of the cause of action." *Russell Packard Dev.*, 2005 UT 14, ¶ 25, 108 P.3d at 747.

the relevant evidence in the record that would aid it in interpreting the advertisements, and then decide for itself whether the practices engaged in by the petitioner were unfair or deceptive."" (citations omitted)), *modified*, 348 U.S. 940 (1955). Moreover, Purdue's claims that a jury trial of these issues would be superior contradicts its arguments, made throughout its Motion, that the subject matter at hand is highly technical and primarily a province of experts, again undermining its credibility.

C. The UCSPA's Potential Statutory Penalties Are Both Constitutional and Comparatively Modest

As an initial matter, Purdue, which bears the burden of demonstrating a constitutional violation, cites no authority to establish that corporations receive the protection of any constitutional prohibition on excessive fines. Assuming *arguendo* such protection were to apply here, civil penalties cannot possibly be judged excessive because none have yet been awarded. Under Utah Code Ann. § 13-11-17:

A fine imposed under Subsection (1)(d) or Subsection (2)(b)(i)(D) shall be determined after considering the following factors:

(a) the seriousness, nature, circumstances, extent, and persistence of the conduct constituting the violation;

(b) the harm to other persons resulting either directly or indirectly from the violation;

(c) cooperation by the supplier in an inquiry or investigation conducted by the enforcing authority concerning the violation;

(d) efforts by the supplier to prevent occurrences of the violation;

(e) efforts by the supplier to mitigate the harm caused by the violation, including a reimbursement made to a consumer injured by the act of the supplier;

(f) the history of previous violations by the supplier;

(g) the need to deter the supplier or other suppliers from committing the violation in the future; and

(h) other matters as justice may require.

Utah Code Ann. § 13-11-17(6). The Presiding Officer has not yet had occasion to weigh these factors. Purdue claims to make only an "as applied" challenge, which it cannot do at this stage. *See Bodell Constr. Co. v. Robbins*, 2009 UT 52, ¶ 29, 215 P.3d 933, 941-42 ("An issue is not ripe for appeal if there exists no more than a difference of opinion regarding the hypothetical application of a provision to a situation in which the parties might, at some future time, find themselves." (quotation marks and brackets in original omitted)).

Further, even if it were to contest the maximum statutory penalty as a matter of law, such an argument would fail, particularly given the egregious conduct at issue (which Purdue itself claims is both unprecedented and unanticipated) and the modest civil penalties under the UCSPA in comparison to a range available under consumer protection statutes in a number of other states. *See, e.g.*, 815 Ill. Comp. Stat. Ann. § 505/7(b) (civil penalty up to \$50,000 per violation when intent to defraud is shown); Alaska Stat. § 45.50.551 (civil penalties up to \$25,000 per violation with no willfulness or knowledge requirement); Minn. Stat. § 8.31(3) (civil penalties up to \$25,000); Or. Rev. Stat. § 646.642 (civil penalties up to \$25,000 per violation if willful).

Moreover, Purdue ignores the relevant inquiry. The question is not whether a civil penalty against Purdue would be high as compared to the amount imposed against a different respondent in the past. The inquiry does concern proportionality, but it is with respect to *Purdue's* conduct. Specifically, courts have applied a "gross disproportionality analysis by comparing the fine assessed to the maximum fine that could have been levied under the applicable administrative rule, and by taking into account the nature of the defendant's conduct." *Brent Brown Dealerships v. Tax Comm'n, Motor Vehicle Enf't Div.*, 2006 UT App 261, ¶¶ 12-29, 139 P.3d 296, 300-04. In *Brent Brown Dealerships*, the agency "had never assessed a fine as large as that levied against Brent Brown." *Id.* ¶ 6, 139 P.3d at 299. Agency officials testified, however, "that they had never

encountered such an egregious violation of the licensing laws." *Id.* The court rejected the argument that the fine was excessive, and stressed that the legislature, through the statutory language, had expressly sanctioned a maximum civil penalty.

V. THE DIVISION'S CLAIMS ARE COGNIZABLE

A. The Division's Claims Are Not Barred by the UCSPA's Safe Harbor Provision or Preempted by Federal Law

Purdue argues that "many of the statements that the Division claims were improper are permitted by, or consistent with, OxyContin's FDA-approved product labeling, and therefore fall within the express language of the UCSPA's safe-harbor provision." Purdue Mem. 22. The fact that the FDA-approved labels contain certain warnings does not mean that Purdue did not mislead the medical community and the public about the safety, efficacy, and risks associated with opioids when it saturated the market with misinformation that contradicted the findings and guidance of the FDA and CDC. See ¶ 64 ("The CDC has directly contradicted Purdue's representations that opioid addiction is rare when opioids are used properly. The CDC has stated that there is 'extensive evidence' of the possible harms of opioids, including opioid use disorder and overdose, and stated that '[o]pioid pain medication use presents serious risks' including addiction; and highlighted that using opioids to treat chronic pain 'substantially increases' the risk of addiction." (alteration in original)); see also, e.g., ¶¶ 87-88. FDA-approved warning labels do not absolve Purdue from telling the truth in marketing materials or immunize it from a violation of what the Supreme Court calls "the duty not to deceive." Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 529 (1992). Put another way, the FDA does not require labeling "so that manufacturers can mislead consumers and then rely on [labeling] to correct those misinterpretations and provide a shield for liability for the deception." Williams v. Gerber Prods. Co., 552 F.3d 934, 939 (9th Cir. 2008).

That the FDA regulates labeling and promotional activity is of no moment to the claims in this case.

Purdue's next argument, that "[t]he Division's claims must be dismissed because they impermissibly conflict with federal law," is equally devoid of merit. Purdue Mem. 25. In the seminal case of *Wyeth v. Levine*, 555 U.S. 555 (2009), the U.S. Supreme Court rejected the argument that FDA approval of pharmaceutical labeling preempts state law failure-to-warn claims. In so holding, the Supreme Court expressly declared that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. To the contrary, Congress "determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* at 574. The FDA, likewise, "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 579.

Here, there can be no preemptive conflict between the Division's state law claims and federal law, because federal law did not require Purdue to promote its products – let alone to promote them misleadingly, through falsehoods and omissions. Purdue was not required, by virtue of FDA approval of its products for long-term use, to send sales representatives into doctors' offices to urge them to prescribe more opioids, nor was Purdue required by FDA regulations to disseminate falsehoods about the likelihood, frequency, and seriousness of addiction. FDA approval is not a license, much less a mandate, to misrepresent the risks and benefits of any drug. *See, e.g., In re Opioid Litig.*, 2018 WL 3115102, at *7 (finding no preemption when "manufacturer defendants have failed to show that the FDA has approved their means, methods, and/or the content of their drug promotion").

Indeed, opioid manufacturers asserted a similar argument against the City of Chicago in opioid litigation in the Northern District of Illinois. The court explicitly rejected the argument, stating:

defendants argue that any claims based on misrepresentations about the risks of abuse and addiction are foreclosed by the FDA-approved labels for their products because the labels disclose those risks. But, as the cases cited by defendants illustrate, drug labels do not preclude fraud claims based on misrepresentations of the label information, which is what the City alleges. In short, the Court rejects defendants' argument that their alleged misrepresentations cannot be the basis for any fraud-based claim.

City of Chicago v. Purdue Pharma L.P., 2015 WL 2208423, at *10 (N.D. Ill. May 8, 2015) (Ex. 22)

(citations omitted).

In short, Purdue can point to nothing in the Division's claims that directly conflicts with, or undermines, any FDA determination about the safety or effectiveness of its opioid drugs. Instead, Purdue mischaracterizes the Division's claims in an attempt to create a conflict where none exists. Both the safe harbor and preemption claims have repeatedly been raised – and rejected – in other opioid litigation. *See, e.g., Ohio,* 2018 WL 4080052, at *3; *New Hampshire,* 2018 WL 4566129, at *2-4; *Alaska,* 2018 WL 4468439, at *6 n.65.

B. Purdue's Argument that More Specific Regulatory Schemes Bar the Division's Claims Is Without Merit

The UCSPA does not apply to "an act or practice required or specifically permitted by or under federal law, or by or under state law." Utah Code Ann. § 13-11-22(1)(a). Purdue takes this to mean that "[t]he Division's claims also cannot be brought under the UCSPA because more specific laws govern the alleged conduct." Purdue Mem. 26. This argument is flawed. Contrary to Purdue's argument, the Division has made claims under the UCSPA that are distinct from claims available to it under federal or state law. Indeed, similar arguments to those advanced here by Purdue were recently rejected in *Naranjo v. Cherrington Firm, LLC*, 285 F. Supp. 3d 1242 (D. Utah 2018). There, the defendant "moved to dismiss Naranjo's UCSPA claim on the grounds that debt collection is governed by a more specific statute, the FDCPA." *Id.* at 1243. While "finding this argument meritless" and denying the defendant's motion to dismiss, the court also noted that "Cherrington misunderstands Utah law," which provides that "courts must construe legislative enactments to 'give effect to the legislature's underlying intent." *Id.* at 1243-44.

Purdue's case law does not change this analysis. The *Naranjo* court expressly distinguished one case relied on by Purdue, *see* Purdue Mem. 26 (citing *Carlie v. Morgan*, 922 P.2d 1 (Utah 1996)), noting that the UCSPA did not provide a remedy for violations of basic health and safety standards and did not speak "directly to the alleged violations," unlike another statute (the Utah Fit Premises Act). 285 F. Supp. 3d at 1244. Purdue's citation to *Thomas v. Wells Fargo Bank, N.A.*, 2014 WL 657394 (D. Utah Feb. 20, 2014) (Ex. 23), is equally unpersuasive. *See* Purdue Mem. 27. First, the UCSPA expressly exempts credit reporting from its purview. *See* Utah Code Ann. § 13-11-22(1)(d). Second, the Fair Credit Reporting Act contained language explicitly preempting state law on the claims at issue. Indeed, the *Naranjo* court held:

The holding in *Thomas* is wrong for two reasons. *First*, neither *Berneike*[*v*. *CitiMortgage*, *Inc.*, 708 F.3d 1141, 1150 (10th Cir. 2013)] nor *Carlie* stands for the proposition that UCSPA does not provide a remedy when the alleged acts are governed by more specific *federal* law. Both cases looked to more specific *state* law to conclude that the UCSPA did not provide a remedy. In fact, in *Berneike*, the court ignored the fact that there was more specific federal law, RESPA, which regulated the alleged wrongful conduct. *Second*, § 13-11-22(1)(a) speaks only to situations where state or federal law "require[s] or specifically permit[s]" the alleged wrongful conduct. It does not speak to a situation where both federal and state laws *prohibit* certain conduct.

285 F. Supp. 3d at 1245 (second and third alterations in original).

Put simply, the fact that federal and state laws impose various restrictions on labeling, that manufacturers and distributors must register with the DEA, and that the Controlled Substances Act and Utah law govern the legal distribution of Purdue's opioids does nothing to displace the Division's UCSPA claims. *See id.* ("[T]he Court is unaware of any Utah Supreme Court case in which a party has been denied a remedy under Utah law because of a more specific, but not conflicting, federal law."); *id.* at 1246 (upholding claims when plaintiff alleged defendant "*violated* both federal and state law," and holding the "UCSPA claim would be barred . . . only if there were a more specific state law that regulated the subject matter of this suit").

C. The Division May Pursue Statutory Remedies for Purdue's Past Conduct

Purdue argues that "[p]rior to May 18, 2018, the Division could issue administrative citations only to those persons presently 'engaged in violating' the UCSPA" and that it was not until May 2018 that the Division could "issue a citation against a supplier who '*has violated* or is violating' the UCSPA." Purdue Mem. 29 (citations omitted). This is precisely the case here. The Division filed its Citation on January 30, 2019, placing it within the May 2018 amendments. Purdue acknowledges as much. *See id.* at 2 ("[I]n January 2019 ... the Division issued its Administrative Citation ... and initiated the present administrative proceeding").

Despite this, Purdue contends that "[b]ecause Purdue stopped marketing its opioid medications by February 2018 . . . Purdue's right not to be subjected to an administrative citation for past violations of the UCSPA vested before the amendment took effect in May 2018." *Id.* Purdue's argument as to when it stopped marketing its opioids is entirely improper on a motion to dismiss. The Citation does not allege that Purdue stopped marketing its opioids in February 2018, and such self-serving factual averments must be disregarded. *See St. Benedict's Dev. Co. v. St. Benedict's Hosp.*, 811 P.2d 194, 196 (Utah 1991) ("When determining whether a trial court properly granted a rule 12(b)(6) motion to dismiss, we accept the factual allegations in the complaint as true and consider them and all reasonable inferences to be drawn from them in a light most favorable to the plaintiff."). In fact, Purdue has failed to correct its deceptive marketing and

its misleading materials are still available online. *See ¶* 95. Moreover, by statute, the Division has always had the right to pursue, and collect civil penalties for past violations. *See* Utah Code Ann. § 13-2-6(4)(a) ("A person who *has violated*, is violating, or has attempted to violate a chapter identified in Section 13-2-1 is subject to the division's jurisdiction." (emphasis added)). The 2018 amendment Purdue cites, *see* Purdue Mem. 29-30, concerns only a procedural rule, not the substantive statutory provision governing Purdue's liability. Before that amendment, the Division could and did obtain civil penalties for past violations. It simply used a different procedure, relying on a Notice of Agency Action in lieu of the format in which this action was initiated.

D. The Division May Bring Claims for Unconscionability

Purdue also argues that claims for unconscionable practices may not be brought in an administrative proceeding. *See* Purdue Mem. 30-31. Failing to cite any case law for its argument, Purdue instead places weight on the reference to "the court" in Section 13-11-5 of the Utah Code. Contrary to Purdue's argument, whether an act is unconscionable under the UCSPA is a question for the fact-finder, whether or not the fact-finder is an agency. *See Sexton v. Poulsen & Skousen P.C.*, 2019 WL 1258737, at *10 (D. Utah Mar. 19, 2019) (Ex. 24) ("Questions of whether a particular act is oppressive, abusive, unfair, deceptive, or *unconscionable* under the FDCPA or *UCSPA* are mixed questions requiring the *fact-finder* to apply the facts to a legal standard." (emphases added)). Here, the Division of Consumer Protection is the fact-finder. *See Garrard v. Gateway Fin. Servs., Inc.*, 2009 UT 22, ¶ 6, 207 P.3d 1227, 1229 ("[T]he [Utah Unfair Practices] Act gives the Division of Consumer Protection authority to prevent the use of unfair methods of competition and to enforce the prohibitions of the chapter through agency adjudications."). Accordingly, the Division may bring its unconscionability claims in this forum.

Indeed, Purdue's argument is flatly contrary to the statutory framework. Utah Code Annotated § 13-2-6 expressly provides that the Division may convene administrative hearings to pursue penalties for "*all* the chapters identified in Section 13-2-1," including the full UCSPA, and that the presiding officer is to determine whether "there is substantial evidence that the recipient [of the citation] violated a chapter listed in Section 13-2-1." Utah Code Ann. §§ 13-2-6(1) & 6(3)(d) (emphasis added); *see also* Utah Code Ann. § 13-2-1(2)(c). This authority admits of no exception.

E. The Division's Omissions Claims Are Viable

Again without citing any case law whatsoever for its argument, Purdue contends that "the Division's claims should be dismissed insofar as they assert that fines should be imposed based on alleged 'omissions.'" Purdue Mem. 31. This is not the law. *See Callegari v. Blendtec, Inc.*, 2018 WL 5808805, at *2 (D. Utah Nov. 6, 2018) (Ex. 25) (discussing pleading of "a UCSPA claim [that] 'arises out of allegations of deception, false misrepresentations *and omissions*'" (emphasis added)); *Miller v. Basic Research, LLC*, 285 F.R.D. 647, 656 (D. Utah 2010) (finding commonality on Rule 23 motion when plaintiffs alleged "Defendants' acts *and omissions* related to the uniform misrepresentation of Akävar violated RICO, the UPUAA and the UCSPA." (emphasis added)). Accordingly, to the extent the Division alleges violations of the UCSPA based on omissions, those allegations are properly pleaded.

VI. THE DIVISION STATES A CLAIM FOR RELIEF

A. Purdue's Opioids Are "the Subject of a Consumer Transaction"

Purdue argues that its opioids are not the subject of a "consumer transaction" and are thus exempt from the reach of the UCSPA. *See* Purdue Mem. 31-32. Not so. First, Purdue ignores that the UCSPA is to be liberally construed. *See Reid v. LVNV Funding, LLC*, 2016 WL 247571, at *6 (D. Utah Jan. 20, 2016) (Ex. 26) ("The UCSPA 'shall be construed liberally' to 'protect consumers from suppliers who commit deceptive and unconscionable sales practices.'" (quoting Utah Code Ann. § 13-11-2)). Second, courts to have considered similar allegations in the state

opioid litigation have upheld such claims. For example, the Ohio Attorney General brought claims similar to those here. In upholding the Ohio Consumer Sales Practices Act claim, the court held:

The complaint sets forth a "consumer transaction" as defined by the statute. The complaint need not, at this stage, identify an Ohio citizen as a consumer. A consumer action is alleged by the complaint regardless of whether the plaintiff is an actual consumer. The complaint, as previously stated, sets forth in detail over 40 pages of allegations which are prohibited by Sections 1345.02 and 1345.03 and the administrative regulations promulgated thereunder. Plaintiff's prayer for civil penalties should not be stricken, at this stage, because they are statutorily authorized.

Ohio, 2018 WL 4080052, at *4; see also Alaska, 2018 WL 4468439, at *2-3 (upholding State of

Alaska's claims under Alaska Unfair Trade Practices and Consumer Protection Act).⁹ The

Division is aware of no court that has adopted Purdue's argument.¹⁰

In yet another attempt to displace the Citation's well-pleaded allegations with its own facts,

Purdue argues that it "never used branded prescription opioid marketing to patients; the claimed

marketing misrepresentations went to doctors, who are not the consumers the UCSPA was

designed to protect." Purdue Mem. 32. This is incorrect. The Citation specifically alleges that

⁹ The holding in *Ohio*, 2018 WL 4080052, is particularly instructive here because "Utah, Ohio, and Kansas have consumer protection laws derived from the same Uniform Consumer Sales Practices Act." *Brown v. Constantino*, 2009 WL 3617692, at *2 (D. Utah Oct. 27, 2009) (Ex. 27). Moreover, the safe harbor in the Ohio statute is the same as that here. *Compare* Ohio Rev. Code § 4165.04(A)(1) (excluding "[c]onduct that is in compliance with the orders or rules of, or a statute administered by, a federal, state, or local governmental agency") *with* Utah Code Ann. § 13-11-22(1)(a) (excluding "an act or practice required or specifically permitted by or under federal law, or by or under state law").

¹⁰ The Division is aware of only one readily distinguishable case that has found against consumer protection claims in state opioid cases. *See Oklahoma v. Purdue Pharma L.P.*, 2017 WL 10152334 (Okla. Dist. Ct. Dec. 6, 2017) (Ex. 28). That decision is an outlier in a sea of decisions to the contrary in the governmental entity opioid litigation, and is inapplicable to the law and the facts as alleged in the Division's Citation. *See, e.g., City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062 (W.D. Wash. Sept. 25, 2017) (Ex. 29); *California v. Purdue Pharma, L.P.*, No. 30-2014-00725287-CU-BT-CXC (Cal. Super. Ct. Feb. 13, 2018) (Ex. 30); *In re Opioid Litig.*, 2018 WL 3115102. The *Oklahoma* court based its decision concerning the consumer protection claim on language in a materially different statute. Other claims were allowed to proceed, and the language at issue in Oklahoma is not present here.

"Purdue hired other health care professionals that Purdue identified as 'key opinion leaders' and, through an extensive marketing scheme, set about convincing the rest of the medical establishment, *patients*, and policy makers to participate willingly in the experiment." ¶ 38 (emphasis added); *see also* ¶ 61 ("Purdue produced and *provided directly to* doctors *and patients* marketing materials that intentionally and fraudulently made similar misstatements" (emphases added)); ¶ 68

B. The Division Is Not Required to, but Nonetheless Alleges Causation

To establish that Purdue violated the UCSPA, the Division need not prove that individual prescribers relied on Purdue's misrepresentations, nor that the misrepresentations caused doctors to prescribe Purdue's opioids. The USCPA is to be "[c]onstru[ed] . . . so as to be 'not inconsistent' with the policies of the FTCA." Iadanza v. Mather, 820 F. Supp. 1371, 1379 (D. Utah 1993). It is well-settled law that the FTC need not prove losses on a claim-by-claim basis. For example, the Ninth Circuit has explained "proof of individual reliance by each purchasing customer is not needed" given that the FTC Act "serves a public purpose by authorizing the Commission to seek redress on behalf of injured consumers." F.T.C. v. Figgie Int'l, Inc., 994 F.2d 595, 605 (9th Cir. 1993). To the contrary, "[r]equiring proof of subjective reliance by each individual consumer would thwart effective prosecutions of large consumer redress actions and frustrate the statutory goals of the section." Id. "A presumption of actual reliance arises once the Commission has proved that the defendant made material misrepresentations, that they were widely disseminated, and that consumers purchased the defendant's product." Id. at 605-06; see also Freecom *Comm'cns*, 401 F.3d at 1205-06 (noting FTC "is not required . . . to show any particular purchaser actually relied on or was injured by the unlawful misrepresentations," but need only establish "a presumption of reliance"). Accordingly, contrary to Purdue's assertion, the Division does "allege a causal link between the alleged misrepresentations and the harm alleged." Purdue Mem. 32.

Notwithstanding, the Citation alleges that Purdue spent millions of dollars on promotional activities and materials that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. See ¶¶ 61-105. Through these efforts, Purdue was able to persuade prescribers that opioids were safer than was really the case. Prescribers then prescribed Purdue's opioids, causing the harms from Purdue's deceptive promotion and marketing scheme alleged by the Division: the opioid epidemic in the State and the societal and economic injuries associated therewith. See, e.g., New Hampshire, 2018 WL 4566129, at *4 ("Contrary to Purdue's position, the State has in fact articulated a causal connection linking Purdue's purported misconduct to the State's alleged harms."); In re Nat'l Prescription Opiate Litig., 2018 WL 4895856, at *12 n.20 ("To the extent Defendants maintain that Plaintiffs were required to name specific prescribers, this court disagrees. Where the alleged scheme is so broad in scope, no meaningful purpose would be served by merely naming a doctor or several doctors to serve as examples of physicians who were misled Defendants' marketing scheme."), adopted in part, rejected in part by 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018) (Ex. 31); In re Opioid Litig., 2018 WL 3115100, at *5 ("The complaint describes in detail how Insys engaged in acts and practices which were either directed at the consuming public or had a broad impact on consumers at large, and how such practices were harmful to the overall public interest.").¹¹

¹¹ Purdue's arguments regarding "an aggregate increase in prescription rates for opioid medications" is equally unavailing. Purdue Mem. 34. When, as here, a plaintiff alleges harm as a proximate result of actual and widespread deception, nothing suggests that a plaintiff may not allege increases in prescription rates without identifying the individual physicians who were deceived, much less individual prescriptions that were written as a result of a defendant's deception. *See In re Nat'l Prescription Opiate Litig.*, 2018 WL 4895856, at *14 (upholding

With respect to the Division's proximate cause allegations, Purdue contends that its conduct is "too remote from both the transactions and the alleged harms to be actionable." Purdue Mem. 34-35. As a preliminary matter, proximate cause is a question for the fact-finder and not proper for resolution on a motion to dismiss. *See Harris v. ShopKo Stores, Inc.*, 2013 UT 34, ¶ 27, 308 P.3d 449, 457 ("Indeed, proximate cause – although often a thorny issue – is generally a question of fact for the jury to decide.").

In support of its arguments, Purdue invokes the learned intermediary doctrine, Purdue Mem. 35-36, and then seeks to blame "the intervening criminal acts of third parties," *id.* at 36. These arguments are not well-taken. The learned intermediary doctrine is principally a defense in personal injury failure-to-warn cases against drug manufacturers. *See Downing v. Hyland Pharmacy*, 2008 UT 65, ¶ 7, 194 P.3d 944, 946 ("Many courts examining the learned intermediary rule have applied it to negligence as well as products liability claims."). Here, the Division has not brought a personal injury or failure to warn case against Purdue. Therefore, the doctrine has no bearing on this case.

Notwithstanding its irrelevance to this case, such a defense would fail nonetheless. Under the learned intermediary doctrine, a pharmaceutical manufacturer satisfies its duty to warn a user of its product by providing an *adequate* warning to the prescribing physician, who can then make an informed judgment about use of the drug and inform the patient of the risks. For the learned intermediary doctrine to apply, however, the intermediary must be learned, which means fully and adequately informed of the risks associated with a product. *See Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 2003 UT 43, ¶ 20, 79 P.3d 922, 928 (*"The physician, after having received*

plaintiffs' claims in opioid MDL action and noting "the injury asserted herein is rather aggregative").

complete and appropriate warnings from the drug manufacturer, *acts as a learned intermediary between the drug manufacturer and the patient* when preparing the drug prescription." (underlined emphasis added)). When drug manufacturers misrepresent the risks associated with the product – as is the allegation here – physicians cannot "be deemed 'learned intermediaries' who were aware of [the] dangers" associated with the drug. *Proctor v. Davis*, 682 N.E.2d 1203, 1212 (III. App. Ct. 1997); *see also Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) ("[A]n adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given."). Thus, courts routinely have allowed fraud and deceptive marketing claims to proceed when the plaintiffs allege that a doctor's judgment was compromised by the defendants' misrepresentations. *See, e.g., Colas v. Abbvie, Inc.*, 2014 WL 2699756, at *3 (N.D. III. June 13, 2014) (Ex. 32); *accord Sellers v. Boehringer Ingelheim Pharm., Inc.*, 881 F. Supp. 2d 992, 1008-09 (S.D. III. 2012).¹²

With respect to the criminal acts of third parties, numerous courts have considered identical arguments and rejected them. For instance, in *City of Everett*, the court found it "facially plausible that the involvement of third parties, even criminals, was reasonably foreseeable given the

¹² Indeed, as the First Circuit has explained, if marketing "could not be expected to affect a single doctor's decisionmaking, the . . . choice to undertake [a] marketing campaign" directed at doctors "would be inexplicable." *In re Neurontin Mktg. & Sales Practices*, 712 F.3d at 46. Accordingly, the First Circuit rejected nearly identical arguments in *In re Neurontin*, finding that fraudulent marketing to physicians "worked as intended, inducing a huge increase" in prescribing, thereby proximately causing harm to third-party payors. *Id.* at 39. Similarly, the Division alleges that Purdue engaged in deceptive and misleading marketing in order to increase the market for opioids – and succeeded. As in *In re Neurontin*, Purdue's "scheme relied on the expectation that physicians would base their prescribing decisions in part on [Purdue]'s fraudulent marketing." *Id.*

extensive facts of Purdue's knowledge in the pleadings" and therefore denied Purdue's motion to dismiss. 2017 WL 4236062, at *6.¹³

C. The Division Has Alleged Purdue's Control of Third Parties

Faced with the Division's allegations that Purdue is liable for the wrongdoing of third parties, Purdue argues that "the Division does not allege that Purdue controlled the contents or dissemination of these materials." Purdue Mem. 37. Purdue ignores that an agency relationship is a question of fact that is inappropriate for resolution on a motion to dismiss. *See Tel. Tower LLC v. Century Mortg. LLC*, 2016 UT App 102, ¶ 32, 376 P.3d 333, 341 ("[A]gency presents a question of fact that 'depends upon all the facts and circumstances of the case." (quoting *Gildea v. Guardian Title Co. of Utah*, 970 P.2d 1265, 1269 (Utah 1998))). An inability to describe the exact inner workings of these associations is not dispositive at this stage. *See Ohio Pub. Emps. Ret. Sys. v. Fed. Home Loan Mortg. Corp.*, 830 F.3d 376, 383 (6th Cir. 2016) (explaining pleading standards only require facts sufficient to "raise a reasonable expectation that discovery will reveal evidence" to support allegations).

Notwithstanding, the Citation alleges that Purdue paid front groups to produce patient education materials and treatment guidelines that, among other things, supported the use of opioids

¹³ Purdue's reliance on *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004), does not help it. *See* Purdue Mem. 36. *Beretta* stands for the proposition that there is no general duty to guard against the criminal misuse of one's product; the negligence claim in *Beretta* was completely reliant on the criminal conduct of third parties. 821 N.E.2d at 1148. In the absence of the use of firearms in criminal activity, the *Beretta* plaintiffs could not show any injury to the City. *Id.* This case is the opposite; the Division does not allege that Purdue had any general duty to guard against criminal conduct. Instead, the heart of the Division's claims center on Purdue's conduct in deceptively marketing its prescription opioids and in unreasonably providing an excessive supply of highly addictive prescription opioids. *See, e.g.*, ¶¶ 106-12. The injury is not dependent on any criminal conduct; instead it arises largely from the costs borne by the State of Utah because residents used addictive opioids legally. Thus, *Beretta* does not shield Purdue from liability.

for chronic pain, overstated their benefits, and understated their risks. *See, e.g.*, ¶¶ 49-60. Accordingly, Purdue's contention that "the Division does not allege that Purdue controlled the contents or dissemination" of third party publications, Purdue Mem. 37, is rebutted by any fair reading of the Citation. The combination of the Purdue's recurrent funding of third-party projects, its close collaboration with those organizations, *and* editorial input and review gives rise to the inference that Purdue could and did dictate the terms of the relationships. *See, e.g.*, ¶¶ 49-60. Further, by disseminating the false and misleading messages, Purdue adopted them as their own.

Accordingly, it is no surprise that courts that have considered the issue of whether manufacturer defendants such as Purdue controlled third-parties have upheld such allegations. *See, e.g., New Hampshire*, 2018 WL 4566129, at *5 n.3 ("Purdue argues that the State has failed, as a matter of law, to allege that Purdue 'controlled' these third-parties. Taking all reasonable inferences in the State's favor, the Court disagrees." (citation omitted)); *Ohio*, 2018 WL 4080052, at *4 ("The complaint adequately sets forth that ... third parties under defendant's control knowingly made or caused to be made false or misleading statements.").

D. The Division Has Pleaded Fraud with Particularity

As if an afterthought, Purdue's final argument is that the Division fails to plead with particularity. *See* Purdue Mem. 38-39. As described above, heightened pleading rules do not apply to the Division's allegations. *See supra* Part II. Even if the Division's allegations are subject to Rule 9, the Citation and Notice plead numerous false and misleading statements, alleges when they were made, and explains why they were false and misleading. By way of example only, the Citation alleges:

• "Purdue-sponsored studies, and the Purdue marketing materials that cited them, regularly made claims that the risk of psychological dependence or addiction is low absent a history of substance abuse. One such study, published in the journal *Pain* in 2003 and widely referenced since (with nearly 600 citations in Google Scholar), ignored previous Purdue-

commissioned research showing addiction rates between 8% and 13% – far higher than Purdue acknowledged was possible in its mainstream marketing." ¶ 43.

- "One such Purdue-sponsored study, which featured two Purdue-employed authors and appeared in the Journal of Rheumatology in 1999, misleadingly suggested that OxyContin was safe and effective as a long-term treatment for osteoarthritis." ¶ 46.
- "Another Purdue-authored study, published in the *Clinical Journal of Pain* in 1999, misleadingly implied that OxyContin was safe and effective as a long-term treatment of back pain." ¶ 48.
- "Notes taken by Purdue's sales representatives in Utah show that the sales representatives discussed the false concept of pseudoaddiction with Utah doctors." ¶ 52.
- "Purdue sales representatives were instructed to tell doctors that opioids' addiction risk was 'less than 1 percent."" ¶ 62.
- "Purdue sponsored training sessions in the late 1990s and early 2000s where opioid addiction was described as 'exquisitely rare."" ¶ 63.

Indeed, courts that have considered similar allegations against Purdue have upheld them under heightened pleading standards. *See, e.g., Alaska*, 2018 WL 4468439, at *7 ("The State's complaint meets the requirement of CR 9(b). It alleges Purdue knowingly misrepresented the efficacy, safety, and risk of its products, through marketing and direct promotion to doctors, for the purpose of increasing sales. The State alleges Purdue intended doctors to rely on their misrepresentations, knew doctors did rely on the misrepresentations, causing prescriptions for medically unnecessary opioids to be paid for by the State. The State has alleged all the elements of fraud with sufficient specificity."). The same result is warranted here.

VII. CONCLUSION

For the reasons stated above, Purdue's motion to dismiss should be denied. Purdue's scattershot arguments do not defeat the extensive allegations in the Citation and Notice, and Purdue cannot justify its attack on this administrative proceeding.

DATED this 23rd day of April, 2019.

SEAN D. REYES UTAH ATTORNEY GENERAL

By: <u>/s/ Robert G. Wing</u> Robert G. Wing (4445) Kevin M. McLean (16101) Assistant Attorneys General

Linda Singer Elizabeth Smith Lisa Saltzburg Motley Rice LLC 401 9th St. NW, Suite 1001 Washington, DC 20004 Ph. (202) 386-9627 Isinger@motleyrice.com esmith@motleyrice.com Isaltzburg@motleyrice.com

Matt McCarley Misty Farris Majed Nachawati Fears Nachawati, PLLC 5473 Blair Road Dallas, Texas 75231 Ph. (214) 890-0711 mn@fnlawfirm.com mccarley@fnlawfirm.com mfarris@fnlawfirm.com

Counsel for the Division

CERTIFICATE OF SERVICE

I certify that I have served or will serve the foregoing document on the parties of record in this proceeding set forth below:

By first class mail, postage prepaid:

Purdue Pharma L.P. One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901

Purdue Pharma Inc. One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901

The Purdue Frederick Company One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901

Snell & Wilmer L.L.P. Attn: Elizabeth McOmber 15 West South Temple, Suite 1200 Salt Lake City, UT 84101

By electronic mail:

Elizabeth McOmber, Esq. emcomber@swlaw.com

Mark Cheffo, Esq. Mark.Cheffo@dechert.com

Will Sachse, Esq. Will.Sachse@dechert.com

Sara Roitman, Esq. Sara.Roitman@dechert.com

Dated this 23rd day of April, 2019.

Dr. Richard Sackler 9901 E. Powder Run Road Alta, UT 84092

Dr. Kathe Sackler 136 Wells Hill Road Easton, CT 06612-1556

Cohne Kinghorn Attn: Patrick Johnson and Paul Moxley 111 East Broadway, 11th Floor Salt Lake City, UT 84111

Paul LaFata, Esq. Paul.LaFata@dechert.com

Patrick Johnson pjohnson@ck.law

Paul Moxley pmoxley@ck.law