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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 INC., 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.**	**RESPONDENTS PURDUE PHARMA L.P., PURDUE PHARMA INC., AND THE PURDUE FREDERICK COMPANY INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS THE DIVISION'S CITATION AND NOTICE OF AGENCY ACTION** **DCP Legal File No. CP-2019-005** **DCP Case No. 107102**

Pursuant to Utah Code Ann. § 63G-4-102(4)(b) and Department of Commerce Administrative Procedures Act Rule ("Utah Admin. Code") R151-4-302, Respondents Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc. (collectively,

"Purdue"), through counsel, hereby submit this *Reply in Support of Its Motion to Dismiss the Division's Administrative Citation and Notice of Agency Action.*

INTRODUCTION

This administrative proceeding must conclude in 189 days. In that time, the Parties must conduct discovery, including expert discovery, and present evidence—and the Administrative Law Judge ("ALJ") must make rulings—on each accusation in the Division's 174-paragraph Citation. The Division alleges that, during a period spanning two decades, Purdue made false representations on a wide array of highly technical and scientific subjects through "websites," "promotional materials," "conferences," "dinner programs," "guidelines," and "personal visits between Purdue's sales representatives and Utah prescribers." (Pl.'s Resp. at 1.) But the Division has not yet identified ***any*** representation made in connection with a consumer transaction in the State of Utah, as the UCSPA requires. It has not identified ***even one*** specific Utah doctor, patient, prescription, or allegedly improper sales visit. Although the Division does plead that sales representatives visited over 5,000 unidentified Utah doctors on unidentified dates, mere sales calls do not amount to a violation of the UCSPA—the Division will have to prove more.

But the Division's truncated procedures guarantee that Purdue will not be able to discover and defend against even a modicum of the facts purportedly underlying these unprecedented claims. The Division offers no suggestion whatsoever as to how, within the deadline, the Parties can complete discovery, prepare dispositive and other motions, and present evidence on these sprawling allegations—much less afford the ALJ sufficient time to consider and rule on the motions and conduct a full and fair hearing—without allowing the Division to cut corners and precluding Purdue from fully presenting its defenses. Instead, the Division tries to sidestep the

impossibility of resolving this proceeding by the deadline, and responds with simplistic mischaracterizations of Purdue's arguments; the Division fails even to acknowledge the volume and complexity of the evidence required to prove its claims.

189 days may be appropriate for many consumer matters under the UCSPA, but this action—involving claims that Purdue caused the opioid abuse crisis and allegedly-related harms in the State of Utah—is not such a matter. Because the Division will be unable to prove its claims in a manner that safeguards Purdue's due process rights, asserts claims that are not cognizable and conflict with the expert judgment of the FDA, and has not satisfied its pleading obligations, the ALJ should grant Purdue's Motion and dismiss the Division's Citation.

LEGAL STANDARDS

Rule 9(c) applies to the Division's claims. Utah's Civil Rules "and related case law" are not controlling "except as otherwise provided by" Title 63G or Rule 151. UTAH ADMIN. CODE R151-4-106. Both Title 63G and Rule 151 explicitly incorporate "the requirements of [Civil] Rule 12(b)" as the standard for motions to dismiss, UTAH CODE ANN. § 63G-4-102(4)(b); UTAH ADMIN. CODE R151-4-302(1), including for failure "to state a claim [for] relief." UTAH R. CIV. P. 12(b)(6). Because Rules 8 and 9 set out the requirements to state a claim for relief, they apply here. UTAH R. CIV. P. 8(a); UTAH R. CIV. P. 9(c).

Contrary to the Division's arguments, the ALJ may consider Purdue's exhibits. All Purdue's exhibits are public records, including court documents from the State's Civil Action, an official press release from the State's website, Purdue's FDA-approved labeling available on the FDA website, and the FDA public response to PROP's Citizen Petition. *See Stahl v. U.S. Dep't of Ag.*, 327 F.3d 697, 700 (8th Cir. 2003) (taking notice of an Administrative Notice issued by the

USDA). Moreover, in the Citation, the Division explicitly discusses and even ***quotes from*** Purdue's labeling and the FDA response to the Citizen Petition. (*See, e.g.*, Citation ¶¶ 66, 66 n.51, 73–82.) Documents which are referenced by a Citation are considered to be incorporated into the pleadings and therefore may be considered on a motion to dismiss. *Oakwood Village LLC v. Albertsons, Inc.*, 2004 UT 101, ¶ 15, 104 P.3d 1226, 1232 ("[W]e include in our analysis additional evidence referred to in the pleadings.").[1]

ARGUMENT

I. THE DIVISION'S PROCEDURES VIOLATE DUE PROCESS.

The Division does not dispute that this proceeding is *sui generis*: it is vastly different in size, complexity, and character from any action ever presented in this forum before. Yet, the Division wrongly believes that this proceeding can conclude on time. In reality, the Division has greatly underestimated the work that must be done to prepare the claims and defenses—including conducting discovery and presenting evidence about individual statements allegedly made in Utah, whether those statements were false, whether they had a connection to a consumer transaction, whether and to what degree they caused harm, as well as the State's own policies, procedures, and conduct related to opioids. The Division mischaracterizes almost all of Purdue's arguments, as well as the case law on which the Division relies. Because the Division's procedures will deprive Purdue of a meaningful hearing, and are not equipped to accommodate this action, they violate due process, and the Citation should be dismissed.

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[1] Exhibits D and E contain the undisputed public statements of Attorney General Reyes. *See* UTAH R. EVID. 201(b) (permitting judicial notice of facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned"). Even if Exhibits D and E are determined not to be public records, they were offered to provide the procedural background of this action and are not essential to the merits of Purdue's arguments.

A. Purdue's property interest is significant.[2]

The Division has not pointed to a single case in its entire history in which it sought penalties of this magnitude. *See Van Harken v. City of Chicago*, 103 F.3d 1346, 1353 (7th Cir. 1997) ("The less that is at stake, other things being equal, the less process is due . . . ."); *Armout Transp. Co. v. Pennsylvania Pub. Util. Comm'n*, 10 A.2d 86, 90 (Pa. Super. 1939) (due process "depends necessarily upon [*inter alia*] the penalty or order sought to be imposed"). Such unprecedented penalties are extremely significant to Purdue's business.[3]

The Division argues that its requested penalties are not significant because "by way of analogy, in the criminal context, '[a] monetary fine is the lightest . . . sanction the state can impose.'" (Pl.'s Resp. at 12 (alteration in original) (quoting *Zissi v. State Tax Comm'n of Utah*, 842 P.2d 848 (Utah 1992)).) Because this is a civil action, however, the sanctions available in criminal proceedings are irrelevant to assess the significance of Purdue's property interest.[4]

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[2] Corporations are entitled to due process. *United States v. Rockwell Int'l Corp.*, 124 3d 1194, 1201 (10th Cir. 1997); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 585 (1996); *see also Metropolitan Life Ins. Co. v. Ward*, 470 U.S. 869, 881 n.9 (1985).

[3] *See, e.g., Sadwick v. Univ. of Utah*, No. 00-412, 2001 WL 741285, at *5 n.2 (D. Utah Apr. 16, 2001) (finding "interest in royalties from and ownership of [inventions]" amounting "to thousands of dollars or more" was not "a de minimus property interest"); *Barrientos v. City of Los Angeles*, 30 Cal. App. 4th 63, 70 (1994) (finding that $1,500 is "financially significant" sanction in determining adequacy of notice to attorney of sanctions); *cf. Fidelity & Guar. Life Ins. Co. v. Chiange*, No. 14-1837, 2014 WL 6090559, at *7 (E.D. Cal. Nov. 13, 2014) (finding substantive due process interest implicated because costs of audit were in the hundreds of thousands of dollars).

[4] Indeed, if this were a criminal proceeding, Purdue would have a litany of unbending rights, many of which would require extensions of the hearing deadline to protect. *See, e.g., Brady v. Maryland*, 373 U.S. 83 (1963) (discovery of all material exculpatory or impeachment evidence in the State's possession); *Washington v. Strickland*, 466 U.S. 668 (1984) (effective assistance of counsel); *Powell v. Alabama*, 287 U.S. 45, 59 (1932) ("[A] defendant, charged with a serious crime, must not be stripped of his right to have sufficient time to advise with counsel and prepare his defense."); *Crawford v. Washington*, 541 U.S. 36 (2004) (the confrontation of witnesses); *Duncan v. Louisiana*, 391 U.S. 145 (1968); *United States v. R.L. Polk & Co.*, 438 F.2d 377, 379 (6th Cir. 1971) (jury trial).

Moreover, contrary to the Division's claim that Purdue is asserting an "interest in indefinite delay," (Pl.'s Resp. at 12), Purdue is entitled to protect its fundamental property rights from an unconstitutionally high risk of erroneous deprivation without an adequate opportunity to be heard.[5] Under *Mathews*, the risks of error created by the Division's ordinary procedures must be judged in light of the unprecedented sums of money the Division seeks to confiscate and in which Purdue has a constitutionally protected interest. As explained below and in Purdue's Motion, those procedures are patently inadequate here.

B. The Division's procedures will deprive Purdue of a meaningful opportunity to be heard and substantially increase the risk of error.

In addition to seeking unprecedented penalties, the Division's claims also are more numerous and complex than any action that has ever been brought in this forum. The Division makes the *ipse dixit* assertion that its procedures are adequate for this task, without even mentioning the massive amount of complicated evidence that must be exchanged, presented, and adjudicated before the deadline. Instead, the Division argues it already has the discovery it needs—without regard for what ***Purdue*** needs to defend itself—and therefore its procedures are adequate because they work for "the generality of cases," such as run-of-the-mill telemarketing or car repair scams. That is not the law.

First, it is black letter law that Purdue is entitled to a meaningful opportunity to be heard. *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965). Based on the Division's sweeping allegations and Purdue's experience in other opioid actions, the Division's truncated procedures will make it

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[5] The Division once again analogizes to federal criminal law (this time, the Speedy Trial Act), and once again it misses the mark. To ensure adequate time for trial preparation, federal courts routinely grant (and the Justice Department routinely consents to) extensions of and exclusions from the speedy trial deadline. 18 U.S.C. § 3161(h)(2), (7).

impossible to complete discovery, dispositive motions, and a hearing by the deadline provided by the Regulations. The Division's argument to the contrary suggests it intends to cut corners and use the impossible schedule to deprive Purdue of full discovery and eviscerate Purdue's ability to assert defenses to which it is entitled.[6]

Purdue has not "vague[ly] assert[ed] that it will want to call a number of witnesses and experts." (Pl.'s Resp. at 16.) To the contrary, in its Motion, Purdue described with particularity the elements of the Division's claims and the discovery and evidence required to address them. (Def.'s Mot. at 11–14.) Specifically, the Division must identify, disclose, and prove, within the next 189 days, the contents and circumstances surrounding ***each*** of the potentially thousands of alleged representations—including those made by hundreds of sales representatives and dozens of third parties—so that Purdue and the ALJ can evaluate which (if any) of those representations, taken in context, violated the UCSPA. Indeed, the Division cannot show that a representation was false or deceptive unless it identifies what was said and the context in which it was said. The Division has not yet identified ***any*** prescribing physicians who allegedly received or were influenced by the alleged representations, let alone the contents of those representations. *Cf. Interstate Commerce Comm'n v. Louisville & N.R. Co.*, 227 U.S. 88, 93 (1913) ("All parties must be fully apprised of the evidence submitted or to be considered, and must be given opportunity to cross-examine witnesses, to inspect documents, and to offer evidence in explanation or rebuttal."). Moreover, the Division will also have to show that each representation was made in connection with a consumer transaction, as well as what harm (if any) is attributable to Purdue's alleged

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[6] Indeed, the Division is *already* seeking to curtail Purdue's access to public records via the Government Records Management Act via its recently filed Motion for a Restrictive Order.

conduct. (*See* Part III.B, *infra.*) Whether the Division must prove the alleged harm claim-by-claim (as Purdue argues) or in the aggregate (as the Division implies), the evidence required to link any alleged representation to a consumer transaction, or to trace the causes of the opioid epidemic, will be enormously complicated and voluminous. Purdue cannot possibly investigate the alleged representations and harms, as well as prepare a meaningful defense to both, by mid-October.

Nor is it possible for Purdue to present its own expert and lay witnesses ***and*** meaningfully to cross examine each of the Division's witnesses in the three weeks allotted for trial—particularly in light of the prohibition against expert depositions, which would allow Purdue to explore the bases of the claims made by the Division's experts and to refine its questioning before the hearing. And while the Division consumes the limited hearing days with its case in chief, Purdue will be prejudiced knowing that each question it asks on cross examination will cut into the time left for its own defense presentation.

The Division does not even attempt to explain how the Parties and ALJ will accomplish these herculean feats before the deadline. Instead, it argues only that these procedural restrictions are reasonable because, unlike the State's Civil Action, the Division's claims are limited to the UCSPA, and therefore it no longer has to prove causation. The Division's procedures, however, are inadequate even to address the thousands of alleged representations, let alone causation. The fact that more claims could have been properly adjudicated by a court does not cure that inadequacy here. Moreover, the Division ***does*** have to prove causation, as explained below, (*see* Part III.C, *infra*), and does not point to any other difference between the scope of discovery or proof for its UCSPA claims as compared to the State's Civil Action. Finally, even if the scope of

proof is meaningfully different (it is not), the factual allegations in the Citation are virtually ***identical*** to the State's Civil Complaint. Accordingly, Purdue is still required to sift through, conduct discovery on, and defend against the exact same factual averments.

The unfairness is exacerbated—not cured, as the Division contends—by the Division's significant head start on discovery. The causes and characteristics of the opioid abuse crisis vary widely from state to state, and even county to county. Purdue has not had any opportunity to investigate the causes of the opioid abuse crisis in Utah, including the State's own role in that crisis. Although the Division might be prepared to present its case, Purdue will have to struggle to gather evidence to test that case and to present its own defenses in a very limited time frame.

In sum, Purdue has specified exactly why these procedures will deprive Purdue of its rights to a meaningful hearing.[7] Purdue has ***not***, however, even suggested that "the Presiding Officer here [will] disregard" his "obligation to . . . afford all the parties reasonable opportunity to present their positions." (Pl.'s Resp. at 19 (quoting UTAH CODE ANN. § 63G-4-206(1)(a)).) It is not the fault of the ALJ that the Division's Counsel changed course and filed this action with an arbitrary deadline that is impossible for the Parties or the ALJ to meet. The Division is not permitted simply to close its eyes to the mountain of discovery needed fairly to adjudicate these claims and vaguely assert that, ***somehow***, the Parties and the ALJ will be able to get this done within the deadline. Due process demands more.

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[7] *See, e.g.*, *Tolman v. Salt Lake Cty. Attorney*, 818 P.2d 23, 33 (Utah 1991) ("The admission of the hearsay evidence without an opportunity to cross-examine the acquaintance, and the failure of the CSC to address Tolman's legal claims, create an 'appearance of unfairness [that] is so plain that we are left with the abiding impression that a reasonable person would find the hearing unfair.'" (quoting *Bunnell v. Indust. Comm'n of Utah*, 740 P.2d 1331 (Utah 1987))); *D.B. v. Div. of Occupational & Prof. Licensing of the Dep't of Bus. Reg.*, 779 P.2d 1145, 1148 (Utah 1989); *see also United States v. Shaygan*, 652 F.3d 1297, 1318 (11th Cir. 2011).

Second, whatever evidence the Parties are able to present will be evaluated without the greater reliability afforded by the Rules of Evidence and Civil Procedure, a reasonable limitations period, or a jury. The Division argues that there is no standalone right to these procedures in an administrative proceeding. Again, Purdue never asserted otherwise. Rather, Purdue argues that ***because of the complexity and circumstances of this particular case***, these proceedings not only will deprive Purdue of a meaningful hearing, but will also dramatically increase the risk that Purdue will be erroneously deprived of its property to a degree that is ***not commensurate with the state and private interests involved here***—specifically, Purdue's property interest in the unprecedented penalties sought by the Division, and the Division's interest in adjudicating this action in this forum under these truncated procedures.

The Division's reliance on *Petro-Hunt, LLC v. Dep't of Workforce Servs.*, 2008 UT App 391, 197 P.3d 107, is thus misplaced. In that case, an employer challenged a decision of the Workforce Appeals Board, arguing that parties are entitled to discovery in ***all*** administrative proceedings if the agency had adopted formal discovery rules. *Petro-Hunt, LLC*, 2008 UT App 391, ¶¶ 10–12. The court held that due process's "fairness requirement [does not] ***necessarily*** include[] a constitutional right to formal discovery." *Id.* ¶ 11 (emphasis added). The court also found that the Board's rules provided for formal discovery whenever necessary for the parties to prepare for trial, and the petitioner did not explain why informal discovery was inadequate or allege that the Board had abused its discretion. *Id.* ¶ 14. By contrast, Purdue has explained exactly why, under the specific circumstances of this matter, the Division's procedures violate its due process rights.

The Division also asserts that the lengthy limitations period here is irrelevant because the

statute of limitations may be tolled in judicial proceedings. (Pl.'s Resp. at 20.) The fact that the statute may be tolled in exceptional cases, however, does not make the evidence in those cases reliable, or change the Utah Supreme Court's pronouncement that limitation periods exist in part to exclude unreliable evidence. *Packard Dev., Inc. v. Carson*, 2005 UT 14, ¶ 28, 108 P.3d 741. Additionally, the Division's argument that UCSPA claims cannot be tried by a jury is disingenuous. The State itself demanded a jury trial in its Civil Action. In sum, not only will the Division's procedures deny Purdue a meaningful hearing, they unreasonably increase the risk of error.

Finally, the Division argues that because its procedures are adequate in the "generality of cases," it does not matter that, as applied here, they will deprive Purdue of a meaningful hearing and increase substantially the risk of error. Clearly, the "generality of cases," however, do not involve the high stakes at issue here. Furthermore, the Division's own authority establishes that a party may challenge a procedure's risk of error as applied to a complex case.[8] In *Walters v. National Association of Radiation Survivors*, 473 U.S. 305 (1985), the plaintiffs alleged that a $10 limit on attorney's fees for VA combat-related disability applications was a *de facto* denial of their ability to hire counsel of choice. *Walters*, 473 U.S. at 307. The district court ruled that the fee limitation violated due process ***in all cases*** based on an unidentified subset of complex cases in which an attorney allegedly would reduce the risk of forfeiture under the VA's appellate rules. *Id.* at 313. The Supreme Court held that the fee limitation was not unconstitutional ***per se*** because,

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[8] The Division also incorrectly asserts that, in a judicial proceeding, "there would be no different standards . . . because of the complexity of the case." (Pl.'s Resp. at 10.) A trial court may alter discovery deadlines and procedures to meet the needs of each case. (Mot. at 13.) But, again, the Division misses the point: Purdue is arguing about what is required by due process, not the Rules of Civil Procedure.

inter alia, there was no evidence in the record that such complex cases were common, that counsel was particularly helpful in ordinary cases, or that the appellate rules had "led to an unintended forfeiture on the part of a diligent claimant." *Id.* at 327–30. Emphasizing that the Court was only addressing the ***facial*** challenges to the fee limitation, the concurring Justices[9] stated that "[t]he determination of what process is due [may] var[y] with regard to a group whose situation differs in important respects from the typical . . . claimant," and "the Court . . . does not determine the merits of the appellee's individual 'as applied' claims." *Id.* at 337 (O'Connor, J., concurring) (alterations in original) (quotation marks and citations omitted); *accord Marozsan v. United States*, 849 F. Supp. 617, 645 (N.D. Ind. 1994).[10]

The Division argues that the ALJ cannot consider Senate discussions to determine whether the Legislature envisioned using administrative procedures for an action of this size and

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9 The two concurring Justices were essential to establishing the six-Justice majority.

10 *See also, e.g.*, *Hicks v. Comm'r of Soc. Sec.*, 909 F.3d 786, 801 (6th Cir. 2018) ("[E]ven if the risk of an erroneous deprivation were not intolerably high whenever claimants are precluded from rebutting material factual assertions about their case, the risk of an erroneous deprivation is nevertheless too high in these cases."); *Salas v. Wis. Dep't of Corr.*, 493 F.3d 913, 927 (7th Cir. 2007) (finding no due process violation because defendant's "alleged lack of access to [specific evidence] did not prevent him from explaining his side of the story"); *Smock v. Board of Regents of Univ. of Mich.*, 353 F. Supp. 3d 651, 657–58 (E.D. Mich. 2018) ("Plaintiff had many opportunities to be heard in this case, but none were meaningful."); *Silva v. Berryhill*, 263 F. Supp. 3d 342, 347–48 (D. Mass. 2017) ("An administrative order is void if a hearing was granted but 'was inadequate or manifestly unfair.'" (quoting *Interstate Commerce Comm'n v. Louisville & N.R. Co.*, 227 U.S. 88 (1913))); *Whiteside v. Smith*, 67 P.3d 1240, 1242 (Colo. 2003) (holding that workers' compensation fee requirements were facially valid but violated due process as applied to indigent litigants); *O'Brien's Case*, 673 N.E.2d 567, 572 (Mass. 1996) ("[T]here is some opportunity to submit evidence under this scheme and in any particular case the administrative judge may afford a quite sufficient opportunity. In any case where that opportunity is insufficient, the statutory scheme may work a deprivation of due process as applied, but that is not the challenge before us."); *Nelson v. Jacobsen*, 669 P.2d 1207, 1212–13 (Utah 1983) (holding that notice of hearing was insufficient to allow defendant to prepare his defense in light of specific circumstances of case and characteristics of the defendant).

complexity.[11] This argument is absurd, *see, e.g.*, *Roberts v. C.R. England, Inc.*, 321 F. Supp. 3d 1251, 1257 (D. Utah 2018); *Garfield Cty. v. United States*, 2017 UT 41, ¶ 69, 424 P.3d 46, 69–70 (considering statements of a bill's sponsor in Utah House and Senate debates), but ultimately it does not matter. Even if the Legislature did contemplate an action of this complexity somehow being litigated in this forum (which it did not), the Legislature cannot ignore due process, which guarantees Purdue a meaningful opportunity to be heard and a risk of error commensurate with the stakes involved. As explained above and in Purdue's Motion, the Division's procedures are wholly inadequate for those purposes.

C. The Division's interest in this Action is, at best, *de minimis*.

The Division does not mention a single state interest in its truncated administrative procedures. Instead, it identifies an interest in "stop[ping]" conduct that allegedly has "caused a public health epidemic." (Pl.'s Resp. at 12.). This is particularly curious in light of the exceedingly slow pace with which the State prosecuted the civil action and the State's decision to abandon its civil action, which included a public nuisance claim and a request to abate that nuisance.

Under *Mathews*, the question is not whether the Division has an interest in particular ***claims***, but whether it has an interest in using these unreliable ***procedures***. Because these proceedings involve issues that are paramount to public health, the Division's professed goal would be better served by ***more*** robust and accurate fact-finding procedures, not the truncated

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[11] Contrary to the Division's arguments, (Pl.'s Resp. at 11), Purdue explicitly stated that § 13-2-8 "required the transfer of any balance exceeding $100,000 into the general fund at the end of the fiscal year," that this amount was lowered to $75,000 in 1992, and that "[u]nder the current statute, the maximum permitted balance for the fund is . . . $500,000." (Def.'s Mot. at 11 (emphasis omitted).)

procedures employed here. *Cf. Nordgren v. Mitchell*, 716 F.2d 1335, 1338 (10th Cir. 1983) ("[t]he state shares with the mother, the child, and the defendant the interest in resolving paternity accurately. The presence of a lawyer can enhance the efficiency of a paternity proceeding and, as we have noted, the accuracy of the result."). Moreover, the Division fails to explain why it cannot address this alleged conduct just as well in ordinary judicial proceedings—which is exactly how many other states across the country have brought similar claims and what the State purported to be doing when it filed its Civil Action. It also does not explain how bringing an action for civil penalties against a single entity with only a 2% share of the national prescription opioid market will accomplish that task. That is particularly true because Purdue discontinued detailing physicians nationwide in February 2018." (*See* Part II.B.1, *infra.*)

Because the Division's procedures, in these circumstances, violate due process, its Citation must be dismissed.

D. The Division seeks excessive fines.

Initially, the Division questions whether corporations are entitled to protection from excessive fines. The U.S. Supreme Court has held that the Due Process Clause protects business entities from excessive punitive damage awards. *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 426 (2003). Other courts expressly have held that the Eighth Amendment does apply to business entities. *See, e.g., Tyson v. Amerigroup*, No. 02-6074, 2007 WL 7034899, at *1 (N.D. Ill. Jan. 30, 2007); *United States v. Advance Tool Co.*, 902 F. Supp. 1011, 1018–19 (W.D. Mo. 1995); *United States ex rel. Smith v. Gilbert Rlty. Co., Inc.*, 840 F. Supp. 71, 74 (E.D. Mich. 1993). The Division points to no cases to the contrary.

Next, the Division argues that "Purdue ignores the relevant inquiry" because "[t]he

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." (Pl.'s Resp. at 22.) Again, the Division misrepresents Purdue's argument. The fact that the Division seeks unprecedented penalties here is relevant to Purdue's interest under *Mathews*, not to Purdue's excessive fines argument. Purdue argues that any penalties will be unconstitutionally excessive because they ***cannot logically be proportional to Purdue's own conduct*** if the Division asserts that it: (1) does not have to show harm attributable to Purdue; and (2) can base its claims on third-party conduct over which Purdue had no control. And because any penalties will *necessarily* not be proportional, this challenge is ripe.

II. THE DIVISION'S CLAIMS ARE NOT COGNIZABLE.

A. The Division's claims are barred by the UCSPA's safe harbor provision and preempted by federal law.

The Division argues that FDA approval of Purdue's opioid labeling does not automatically foreclose a claim that Purdue's promotions misled doctors. (Pl.'s Resp. at 23.) This misses the point. Rather, Purdue argues that because the FDA "specifically permitted" Purdue to make the statements on which all or most of the Division's claims are based—in particular, that OxyContin is safe and effective for long-term treatment of chronic pain—the UCSPA's safe harbor provision precludes liability for statements made in Purdue's labeling or in its FDA-approved marketing materials. *See* UTAH CODE ANN. § 13-11-22(1). The Division does not even mention the UCSPA.

Moreover, Purdue's marketing and promotional materials ***are*** "labeling." *Strayhorn v. Wyeth Pharma., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013). The term "labeling" includes not only the warning on the product's packaging, but all brochures, booklets, mailings, catalogues, films, sound recordings, and literature advertising it. 21 C.F.R. § 202.1(l)(2); *see also Del Valle v.*

PLIVA, Inc., 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011). It is illogical to assert that Purdue is prohibited from making the same statements in its marketing materials that it is ***required*** to make in its package inserts.[12]

Next, the Division argues that its claims are not preempted because "federal law did not require Purdue to promote its products." (Pl.'s Resp. at 24.) The United States Supreme Court has expressly considered and rejected the argument that a pharmaceutical manufacturer should have stopped selling its products to avoid liability under state law where federal law would not permit the manufacturer to change its labeling to add the warnings or safety information that a plaintiff's claims would require. *Mutual Pharma. Co., Inc., v. Bartlett*, 570 U.S. 472, 488–89 (2013). Here, although Purdue was not permitted to change its FDA-approved labeling, the Division nonetheless seeks to impose state-law liability for promoting opioid medications for their FDA-approved uses. These claims, too, are preempted.

Finally, the Division ignores that Purdue was required to, and did, submit its branded promotional material for FDA review. At a minimum, that material cannot be the basis of a UCSPA claim.

B. The Division may not pursue claims based on omissions, unconscionability, or purely past conduct.

Despite chiding Purdue for not "citing any case law whatsoever for its argument[s]," (Pl.'s

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12 *Cf. Newman v. McNeil Consumer Healthcare*, No. 10-1541, 2013 WL 7217197, at *5 (N.D. Ill. Mar. 29, 2013) (statements in press release were "specifically authorized" by federal law because they were consistent with FDA-approved labeling); *DePriest v. AstraZeneca Pharm., L.P.*, 351 S.W.3d 168, 177–78 (Ark. 2009) (statements not actionable where "FDA labeling supports statements made in advertising for an FDA-approved drug"); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234–35 (S.D. Fla. 2007) (advertisements for medication's indicated uses are not misleading as a matter of law).

Resp. at 29), the Division ignores that such cases do not exist because no one has ever attempted such an outlandish extension of the Division's jurisdiction. The Division also ignores that it—not Purdue—has the burden of proof, and must establish that Purdue's alleged conduct falls within the scope of the UCSPA's enforcement reach. *Bateman v. JAB Wireless*, No. 14-147, 2015 WL 4077923, at *4 (D. Utah July 6, 2015). In fact, it is the Division that has not cited any authority for this unprecedented proceeding, and the Division that disregards the plain language of the UCSPA.

1. The Division cannot bring claims in this Action solely for past conduct.

Purdue does not dispute that the Division "has always had the right to pursue, and collect civil penalties for, past violations." (Pl.'s Resp. at 28.) Rather, Purdue argues that it could not ***initiate administrative proceedings*** based ***solely*** on past conduct—it only had jurisdiction if the respondent was presently violating the statute at the time it initiated the action (although it could retain jurisdiction even if the defendant stopped thereafter). *See* UTAH CODE ANN. § 13-2-6(4)(a) (2017) ("A person ***violating*** a chapter identified in Section 13-2-1 is subject to the division's jurisdiction . . . ."); *accord id.* § 13-2-6(3) (2017). Accordingly, Purdue's right to be free from such actions vested in February 2018. The Division cites no examples of NOAAs based solely on past conduct under the pre-May 2018 statute. Instead, it relies on the May 2018 version of § 13-2-6(4)(a) and its own *ipse dixit* that the amendment was "procedural."

The Division also fails to address the cases cited in Purdue's Motion establishing that the Legislature has not retroactively deprived Purdue of this entitlement. For example, Utah courts have "consistently maintained that the defense of an expired statute of limitations is a vested right" because "one who has become released from a demand by the operation of the statute of limitations

is protected against its revival by a change in the limitation law." *Roark v. Crabtree*, 893 P.2d 1058, 1062 (Utah 1995); *accord Garfield City v. United States*, 2017 UT 41, ¶ 72, 424 P.3d 46, 70. Under the former version of the Act, a respondent that ceased its conduct was released from a demand to answer or be held liable in proceedings. If this action had been initiated before May 2018, Purdue would have been entitled to assert that it was not presently "engaged in violating" the UCSPA. The Legislature cannot (and did not) retroactively deprive Purdue of that entitlement.

The Division further argues that the ALJ cannot consider this issue because the Division "does not allege that Purdue stopped marketing its opioids in February 2018." (Pl.'s Resp. at 27.) But the Division also does not allege that Purdue ***did*** make any of the alleged representations after February 2018. The Division relies on a single paragraph of its Citation, alleging that, "[u]pon information and belief," one CME allegedly taught by Dr. Lynn Webster is "still available online." (Citation ¶ 95.) But that is not a violation of "a chapter identified in Section 13-2-1." UTAH CODE ANN. § 13-2-6(4)(a) (2017). The Division does not allege that anyone in Utah has accessed the CME in years or that Purdue has the ability to remove the CME from the third party's website. Purdue is not subject to indefinite liability because someone else has kept materials online that may or may not contain misrepresentations and may or may not have been viewed by anyone in Utah in the last several years.

2. The Division cannot bring unconscionability claims.

The Division also cites no administrative actions where it has successfully brought an unconscionability claim. The Division should not be permitted to rely on the broad language in its enabling statute to displace the specific and unique language of § 13-11-5(3) requiring a determination by a "court." *See Muddy Boys, Inc. v. Dep't of Commerce*, 2019 UT App 33, ¶¶

22–27, 2019 WL 1066214, at *6–7 (Utah Ct. App. Mar. 7, 2019). Although it argues it may bring unconscionability claims here because "court" apparently means "fact finder," it relies on a case that did not mention § 13-11-5(3) and in which the court ***was the factfinder***.

3. The Division cannot bring omission claims.

Finally, the UCSPA says nothing about "omissions." The Division cites only two cases in support of its omission claims, neither of which supports its argument. In *Callegari v. Blendtec, Inc.*, No. 18-308, 2018 WL 5808850 (D. Utah Nov. 6, 2018), the court quoted a non-UCSPA case that mentioned "omissions" while describing the pleading standard under Rule 9(c). The plaintiffs' claims, however, all were based on affirmative representations. *See* Compl. ¶ 45, *Callegari v. Blendtec, Inc.*, No. 18-308 (D. Utah Apr. 13, 2018), attached as **Exhibit H**. In *Miller v. Basic Research, LLC*, 285 F.R.D. 647 (D. Utah 2010), the plaintiffs brought claims under several statutes, some of which undoubtedly allow liability for omissions. The court held that plaintiffs presented common factual questions for class certification purposes because they relied on the affirmative representation, "Eat all you want and still lose weight." *Miller*, 285 F.R.D. at 656.

In sum, the Division ignores the text of the statute and has not carried its burden of showing that its claims are cognizable. Accordingly, its claims should be dismissed.

C. <u>The Division's claims are barred by more specific federal and state laws.</u>

The Division argues that its claims are not barred by the more specific expert state and federal regulatory schemes governing the marketing, distribution, and prescribing of opioid medications because they do not provide the exact same remedy provided by the UCSPA. The Division relies entirely on *Naranjo v. Cherrington Firm, LLC*, 285 F. Supp. 3d 1242 (D. Utah 2018), a federal district court opinion that has not been cited by another court. Purdue is not aware

of any other cases that have required such precise overlap between the alleged conduct and the more specific law at issue; but at least one court has explicitly held they do not. *See Thomas v. Wells Fargo Bank, N.A.*, No. 13-686, 2014 WL 657394, at *3 (D. Utah Feb. 20, 2014). Purdue's medications are heavily regulated by both state and federal law, and Utah law provides specific remedies for the harms alleged, including license revocation and criminal proceedings against doctors who violate pharmaceutical regulations. There is no reason to think that the Legislature intended to use a blunt instrument such as the UCSPA in place of these detailed regulatory schemes. Accordingly, the Division's claims are barred.

III. THE DIVISION HAS FAILED TO STATE A CLAIM FOR RELIEF.

A. Purdue's medications are not the subject of a consumer transaction.

The Division does not bother to address the dozens of cases holding that prescription medications are not the subject of a consumer transaction because they may be obtained only through a licensed healthcare professional. (*See, e.g.*, Def.'s Mot. at 31–32.) Instead, it argues that "[t]he Citation specifically alleges that" Purdue engaged in direct-to-consumer marketing. (Pl.'s Resp. at 30–31.) First, the Division's conclusory allegations relating to consumer marketing are devoid of any factual support, and it never explains how Purdue's alleged prescription loyalty program violated the UCSPA. Indeed, the Division does not allege that any misrepresentations were made in connection with this program. If discounts and coupons were to violate the UCSPA solely by virtue of "encourage[ing]" purchases, supermarkets across the state would be violating the UCSPA every day.

Second, by its express language, the UCSPA makes unlawful only certain conduct made "in connection with a consumer transaction." UTAH CODE ANN. § 13-11-4. As the cases cited in

Purdue's Motion show, opioid medications are not the subject of a consumer transaction. The Division relies on two trial court opinions in cases pending in other jurisdictions, neither of which offered any explanation of its holding. *See State ex rel. Dewine v. Purdue Pharma, L.P.*, No. 17 CI 261, 2018 WL 4080052, at *4 (Ohio Ct. Comm. Pl. Aug. 22, 2018) (stating only that "[a] consumer action is alleged by the complaint regardless of whether the plaintiff is an actual consumer"). Indeed, in *State v. Purdue Pharma L.P.*, No. 3AN-17-09966CI, 2018 WL 4468439 (Alaska July 12, 2018), the court does not even mention "consumer transactions."

B. <u>The Division must, but does not, allege causation.</u>

The Division is required to show causation. In its Citation, the Division explicitly alleges a laundry list of harms "so that they may be weighed in determining the civil penalties appropriate for Purdue's conduct." (Citation ¶ 29.) In its Response brief, it again states that the penalty amount must be based in part on "the harm to other persons resulting either directly or indirectly from the violation." (Pl.'s Resp. at 21 (quoting UTAH CODE ANN. § 13-11-17(b)).) The Division thus concedes that, to obtain anything more than nominal penalties, it must show what harm (if any) was caused by Purdue. (*See* Part. I.D, *supra*.)

In addition to penalties, causation is an element of the Division's claims. As explained in Purdue's Motion, the Division must plead and prove that each alleged representation was made "in connection with a consumer transaction." UTAH CODE ANN. § 13-11-4. Because the Division does not allege that these representations were specifically directed toward particular transactions, the only thing "connecting" Purdue's alleged representations to (what the Division calls) "a consumer transaction" is the Division's assertion that the representations "deceiv[ed] prescribers"

into writing opioid prescriptions. (*E.g.*, Citation ¶¶ 12, 32.) Accordingly, in these specific circumstances, showing that prescribers actually relied on, or at least were influenced by, Purdue's alleged representations would be the only way that those representations could have been made "in connection with a consumer transaction."

The Division's reliance on the Federal Trade Commission Act ("FTCA") is misplaced. Unlike the UCSPA, the FTCA is not limited to statements made "in connection with a consumer transaction." Even if it were, the FTC proceedings cited by the Division, unlike the claims here, did not involve third parties standing between the defendant's representations and the consumers. In *F.T.C. v. Freecom Comm., Inc.*, 401 F.3d 1192 (10th Cir. 2005), the defendants misrepresented the projected earnings of vending machines *directly* to consumers to mislead them into purchasing the machines. *Freecom*, 401 F.3d at 1197. Similarly, in *F.T.C. v, Figgie Int'l, Inc.*, 994 F.3d 595 (9th Cir. 1993), a smoke-detector manufacturer micromanaged its distributors' sales presentations, which were made *directly* to the purchasers involved in the relevant transactions. *Figgie*, 994 F.2d at 600 n.1.

Additionally, both of those cases required at least aggregate-level reliance. *See Freecom*, 401 F.3d at 1206. The *Figgie* court stated that a presumption of reliance arises if it proves "that the defendant made material misrepresentations[] that . . . were widely disseminated." *Figgie*, 994 F.2d at 605. Apparently, the Division is asserting (incorrectly) that there is a presumption of reliance if it establishes wide dissemination of material misrepresentations and a corresponding increase in prescriptions. In the prescription medication context, however, whether a statement is "material" will vary drastically depending on the particular patient and doctor, and is thus tantamount to an individualized causation requirement.

Finally, the Division has failed to allege proximate cause. Utah courts can decide proximate cause at the motion to dismiss stage. *See Larsen v. Davis Cty. Sch. Dist.*, 409 P.3d 114, 124–25 (Utah Ct. App. 2017) (dismissing claim where complaint showed that teacher's immune conduct proximately caused injury and therefore school district was immune); *see also Miller v. Gastronomy, Inc.*, 2005 UT App 80, ¶ 12, 110 P.3d 144, 147 ("The proximate cause of the intoxicated person's injuries is the drinking of the alcohol, not the furnishing of it. . . . Thus, Plaintiffs' claim would fail under common law for want of proximate causation." (citation omitted)).

Purdue also has not "invoke[d] the learned intermediary doctrine." (Pl.'s Resp. at 33.) Rather, Purdue has pointed out that there are many other actors, unrelated to Purdue, in the Division's attenuated causal chain, and that the harm is too remote as a matter of law. Finally, the Division's injury absolutely "depend[s] on . . . criminal conduct." (Pl.'s Reps. at 35 n.13.) The Division specifically alleges that it was harmed by opioid diversion and abuse. (*See, e.g.*, Citation ¶¶ 20, 28.) Such third-party criminal acts necessarily break the causal chain.

Because the Division has not pleaded causation, its Citation should be dismissed.

C. The Division has not alleged facts establishing agency.

Because the Division specifically alleges that Purdue's purported use of third parties was integral to the alleged fraud, (*see, e.g., id.* ¶ 41; *id.* ¶ 49 ("Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy"); *id.* ¶¶ 93–101 (alleging that Purdue used "a wide array of sources, each designed to maximize impact and each targeted to a specific receptive audience.")), agency must be pleaded with particularity. *In re Enron Corp. Secs., Derivative & "ERISA" Litig.*, 540 F. Supp. 2d 800, 805 (S.D. Tex. 2007); *Dover Ltd. v. A.B.*

Watley, Inc., 423 F. Supp. 2d 303, 319–20 (S.D.N.Y. 2006).

The Division does not even attempt to defend most of the third-party-statement allegations challenged in Purdue's Motion, such as those made at CMEs or by "Key Opinion Leaders." (*See, e.g.*, Citation ¶¶ 33–48, 94–101.) Any claims based on these statements therefore must be dismissed. Instead, the Division addresses only its allegations relating to certain third-party publications, baldly asserting that, somewhere between paragraphs forty nine and sixty of its Citation, it has alleged that Purdue "fund[ed] third-party projects," "collaborat[ed] with those organizations," had "editorial input and review" over their statements, and "adopted them as [its] own" by disseminating them. (Pl.'s Resp. at 36.) In reality, the Division alleges only that Purdue made financial contributions relating to three of these third-party publications, (*id.* ¶¶ 54, 59, 60), and that Purdue allegedly "distributed" one of these (the 2009 AAPM/APS Guidelines) and had "editorial input" into another (2007 book *Responsible Opioid Prescribing*). (*Id.* ¶¶ 56, 59.) These allegations do not satisfy Rule 8 or Rule 9's pleading standards. As explained in Purdue's Motion, financial contributions are insufficient as a matter of law to establish agency. (Def.'s Mot. at 37.) Moreover, the Division does not allege what "input" Purdue had into *Responsible Opioid Prescribing*, or that it is responsible for any of the allegedly untrue statements made therein. *Cf. In re GlenFed, Inc. Secs. Litig.*, 60 F.3d 591, 593 (9th Cir. 1995) (plaintiffs not entitled to presumption as to outside directors' participation in corporate financial statements where plaintiffs failed to plead with particularity that each "outside director either participated in the day-to-day corporate activities" or "participat[ed] in preparing or communicating group information at particular times").[13]

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[13] At most, the Division has alleged that Purdue itself made representations by "distributing"

As a fallback, the Division asserts that the ALJ should not address agency at the pleading stage. But the Division's allegations are insufficient as a matter of law. At least one other court has dismissed substantially similar claims against Purdue for failing to allege actual control over third-party publications. *See City of Chicago v. Purdue Pharma L.P.*, No. 14-4361, 2015 WL 2208423, at *11–12 (N.D. Ill. May 8, 2015). Moreover, the cases cited by the Division are inapposite. In *Telegraph Tower LLC v. Century Mortg. LLC*, 2016 UT App 102, 376 P.3d 333, the court reversed the trial court's grant of summary judgment because a jury could have drawn conflicting inferences from specific evidence of agency. *Telegraph Tower*, 2016 UT App 102, ¶¶ 32–36. *Telegraph Tower* did not involve pleading requirements, let alone allegations of fraud. Although *Ohio Pub. Employees Retirement Sys. v. Fed. Home Loan Mortg. Corp.*, 830 F.3d 376 (6th Cir. 2016), did involve fraud claims, it did not involve agency allegations.

Because the Division has failed to plead agency, its third-party conduct claims should be dismissed.

D. <u>The Division has not pleaded fraud with specificity.</u>

The Division points to six paragraphs in its Citation that, it believes, adequately plead fraud under Rule 9. Four of those paragraphs allege representations that occurred well outside the limitations period. (*See* Citation ¶ 43 (2003); *id.* ¶ 46 (1999); *id.* ¶ 48 (1999); *id.* ¶ 63 ("the late 1990s and early 2000s").) More importantly, these paragraphs merely assert the gist of the alleged

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the 2009 Guidelines through its own sales representatives. But even if these are Purdue's own statements, the Division does not allege the circumstances of these "distributions" with particularity, and cites no authority suggesting that "distributing" a third-party publication over which Purdue exercised no editorial input, without more, is sufficient to allege knowledge of the statement's falsehood.

representation's content. But Rule 9 requires more—the Division must plead "the identity of the person who made the alleged misrepresentation[] and the time and location at which it was uttered." *Webster v. JP Morgan Chase Bank, NA*, 2012 UT App. 321, ¶ 19, 290 P.3d 930 (internal quotation marks omitted) (alteration in original). The Division does not cite a single allegation that meets these requirements. *See Burnett v. Mortg. Elec. Registration Sys., Inc.*, 706 F.3d 1231, 1242 (10th Cir. 2013). Accordingly, its claims must be dismissed.

CONCLUSION

For the forgoing reasons, the Citation should be dismissed in its entirety.

Dated this 3rd day of May, 2019.

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CERTIFICATE OF SERVICE

I hereby certify that on this the 3rd day of May, 2019, I served the foregoing on the parties of record in this proceeding set forth below by delivering a copy thereof by electronic means and U.S. Mail and/or as more specifically designated below, to:

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