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

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.**	**REPLY IN SUPPORT OF RENEWED MOTION TO CONVERT INFORMAL HEARING** **DCP Legal File No. CP-2019-005** **DCP Case No. 107102**

The Utah Division of Consumer Protection ("Division") respectfully submits the following reply to Respondents Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company (collectively "Purdue"), Dr. Richard Sackler, and Dr. Kathe Sackler (collectively, "the Sacklers") Opposition to the Division's Motion to Convert Informal Hearing. Respondents offer no basis to

dispute that conversion would be both in the public interest and in no way prejudicial to their rights.[1] *See* Utah Code Ann. § 63G-4-202. Instead, they argue, contrary to binding precedent, that *any* administrative proceedings, whether formal or informal, would be unconstitutional. Respondents are wrong to claim that the number and duration of their Utah Consumer Sales Practices Act ("CSPA") violations somehow exempt them from procedures that are fair and constitutional for other respondents. Their effort to cast unfounded aspersions on the Division's motives for bringing this Administrative Citation is similarly unavailing. As explained below, a prompt and efficient administrative proceeding would in no way prejudice Respondents, and is in the best interest of the public, the Division, and Respondents alike.

A. The Efficient and Even-Handed Procedures of Formal Adjudications Satisfy All Requirements of Due Process.

Respondents' chief argument does not pertain to conversion at all. Instead, they contend that administrative procedures that do not exactly mirror the rules and procedures applied in court inherently deny due process rights. Utah courts, however, "have recognized the importance and necessity of preserving fundamental requirements of procedural fairness in administrative hearings," while at the same time making clear that do so, "administrative hearings need not possess the formality of judicial proceedings." *Nelson v. Dep't of Employment 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 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.*

[1] This reply references Purdue and the Sacklers together as "Respondents."

City of Columbus, Ohio, 841 F.2d 1272, 1280 (6th Cir. 1988) (explaining that the fact that the agency at issue was "a state agency does not change the analysis"). Respondents simply ignore this binding precedent.

Respondents also argue that they wish to go through the motions of an informal proceeding only to (wastefully, in this context), repeat all that was done in a trial *de novo*. Nothing in *Brinkerhoff v. Schwendiman*, 790 P.2d 587, 590 (Utah Ct. App. 1990), suggests that such inefficiency is necessary, much less preferable. There, the court found an absence of prejudice in an informal proceeding in which the respondent was not informed of the nature of the proceeding at hand (whether informal or formal procedures would apply). It in no way diverged from the uniform precedent holding that formal proceedings need not apply all the same rules as a judicial proceeding to protect due process rights. Here, conversion to a formal proceeding may prevent duplicative work by the Division, save unnecessary expenses ultimately borne by Utah's taxpayers, and result in a more timely final decision. Given that Purdue has publically disclosed that it is considering filing for bankruptcy, *see* Respondents' Exhibits 4 & 5, avoiding unnecessary litigation expenses would seem to be in Purdue's best interest as well.

Respondents are wrong to claim that judicial review is somehow unfairly or unconstitutionally limited in a formal proceeding. Judicial review occurs in the appellate court according to the appellate court rules of procedure, as prescribed by the legislature. *See* Utah Code Ann. § 63G-4-403(2). Moreover, it is for good reason that judicial review following a formal procedure occurs at the appellate court level rather than through a trial in the district court. As explained in the Division's Motion, the procedural safeguards available to Respondents in a formal adjudicative proceeding are similar to those available to a party in a trial, including the ability to conduct discovery, Utah Code § 63G-4-205, and "the opportunity to present evidence, argue,

respond, conduct cross-examination, and submit rebuttal evidence." Utah Code § 63G-4-206(1)(d).

Respondents argue that judicial review is "limited" because they would have to show some "substantial prejudice" to overcome the outcome of a formal proceeding on appeal. Opposition at 8. Their apparent belief that the proceedings will be conducted with propriety, and they will be able to mount their defense, such that they will be unable to show any prejudice later, however, is not a basis to presume some contra-factual harm now.[2] It only illustrates the groundless nature of their due process claim.

It bears noting that Respondents mischaracterize the few differences from judicial proceeding that they cite. The rules concerning the admission of hearsay evidence (available to both sides, not only the Division) apply equally in informal and formal proceedings, and, as explained above, pose no constitutional issue. This is particularly true given that findings of fact in an administrative proceeding cannot be based exclusively on hearsay evidence, but must also be supported by "a residuum" of remaining legally competent evidence competent in a court of

[2] Respondents also ignore that prejudicial error is required to support a reversal in other contexts as well. *See, e.g.*, *Littlejohn v. Royal*, 875 F.3d 548, 570 (10th Cir. 2017), *cert. denied*, 139 S. Ct. 102, 202 L. Ed. 2d 65 (2018) (stating, in the context of a capital murder case that although the court would "assume *arguendo* that [the defendant] suffered modest prejudice" from errors that occurred, these errors, even "when cumulated" still did not cause a "resentencing proceeding to be fundamentally unfair and cause [the court] to have grave doubts about whether the errors affected the jurors' verdict"); *Oldham v. O.K. Farms, Inc.*, 871 F.3d 1147, 1150 (10th Cir. 2017) (court will affirm a summary judgment grant absent prejudice from lack of notice); *State v. Edgar*, 397 P.3d 664, 667 (Utah Ct. App. 2017) (explaining that "showing that an objection would have resulted in the exclusion of inadmissible evidence falls short of demonstrating prejudice" necessary to support an ineffective assistance of counsel claim, which required more). Respondents also ignore the level of deference that would exist following a jury trial. *See Reynolds v. W.W. Clyde & Co.*, 5 Utah 2d 151, 152, 298 P.2d 530, 531 (1956) (stating, absent any error, that "in cases where there is substantial evidence which, if believed, will support the jury's verdict, the trial court may exercise its discretion in sustaining the verdict, and [the appellate court] having no discretion in such event, must sustain both").

law." *Tolman v. Salt Lake Cty. Attorney*, 818 P.2d 23, 32–33 (Utah Ct. App. 1991). In addition, the presiding officer "may exclude evidence that is irrelevant, immaterial, or unduly repetitious." Utah Code Ann. § 63G-4-206 (B)(i). Further, a jury trial is equally unavailable following an informal proceeding, even on trial *de novo* in the district court. *See* Utah Code Ann. § 63G-4-402(3)(a) ("The court, without a jury, shall determine all questions of fact and law . . . ."). There is no right to a jury trial on CSPA claims for civil penalties.

Finally, Respondents' argument, concerning expert witnesses if anything supports conversion to a formal proceeding. Expert discovery is not available at all in an informal proceeding. In a formal proceeding, it is both available and even-handed. Both sides will be required to exchange expert reports, and "an expert may not testify in a party's case-in-chief concerning any matter not fairly disclosed in the report." Utah Admin. Code R151-4-504. All testimony in a formal hearing is given under oath, and in a formal proceeding, the parties will have the opportunity to cross-examine the opposing party's experts under oath. *See* Utah Code § 63G-4-206(1)(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(a). There is no reason to believe that the presiding officer here would disregard this statutory admonition.

B. The Number of CSPA Violations at Issue Does Not Exempt Respondents from Regularly-Employed Procedures or Grant them Special Privileges.

Respondents argue that the number and duration of their alleged CSPA violations make this case too complex for the administrative procedures that would apply to other respondents who engaged in the same type of misconduct, but targeted fewer people, or for a shorter period of time. As the basis for this argument, they contend, in a single paragraph devoid of any citation, that the presiding officer will need to "wade through" "state and federal controlled substances regulations"

and matters such as "epidemiology," to decide whether Respondents violated the CSPA and to grant the civil penalties and relief sought. Opposition at 2. In fact, the citation is far more straightforward than Respondents claim. The Division seeks only injunctive relief and damages for deceptive and unconscionable trade practices violating the CSPA. The same types of violations are regularly addressed through Utah's administrative process, as the materials attached to Respondents' Opposition themselves make clear. *See* Respondents' Exhibits 3 & 5.

Respondents cite no authority for their position that this case is among a class of cases that are too complex for administrative hearing. And, in reality, "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, 347 (1976). Nor would this case qualify as a rare exception in any event. *Compare Rhodes Pharmacal Co. v. Fed. Trade Comm'n*, 208 F.2d 382, 387–88 (7th Cir. 1953), *modified sub nom. F T C v. Rhodes Pharmacal Co*, 348 U.S. 940, 75 S. Ct. 361, 99 L. Ed. 736 (1955) ("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 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[.]") (internal quotation marks omitted).[3] Indeed, the citation at issue here lays out a set of specific statements and omissions that the Division contend were misleading and unfounded, and that can be proved or challenged, as in any other cases, with the aid of fact and expert witnesses and documentary evidence.

[3] Although this case concerned the Federal Trade Commission, Utah's CSPA 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 (footnote omitted).

Unable to offer any legal support for their position, Respondents attempt to claim sympathy by arguing that the Division is bringing its "immense resources to bear against private litigants." This too is disingenuous at best. According to IMS Health, in just the years 2012-2013, Purdue had U.S. sales of OxyContin totaling $5.34 billion.[4] Further, internal documents made public through the Massachusetts Attorney General's action show that from the time of the Purdue Frederick Company's 2007 criminal convictions until 2018 alone, Purdue's Board voted to pay to out more than four billion dollars that would go to the Sackler family.[5] Purdue has engaged multiple well-resourced and well–qualified law firms to defend its conduct in litigation and other public fora across the country, asserting and defending discovery disputes and other legal challenges, as well as running regular full-page advertisements in major newspapers and appearing recently, through one of the Sackler family lawyers, for instance, on Good Morning America.

C. The background Respondents Selectively Cite if Anything Supports Conversion.

Respondents devote much of their Opposition to unsupported efforts to cast aspersions on the Division's motives. Although these contentions are irrelevant to the question at hand the Division briefly addresses each argument in turn. ***First,*** Respondents neglect to disclose that, 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 CSPA, 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 CSPA violations. As remedies, it also seeks only

[4] In the Matter of Purdue Pharma, L.P., Assurance No. 15-151 Attorney General of the State of New York, August 17, 2015 ¶ 3.3.

[5] *Commonwealth of Mass. v. Purdue Pharma L.P., et al.*, C.A. No. 1884-cv-01808 ¶ 238 & n. 154 (citing a collection of internal documents).

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. *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 otherwise, the law would preclude the FTC from taking preemptive action against those responsible for deceptive acts or practices, contrary to § 5's prophylactic purpose").

Second, Respondents are wrong to suggest that every state seeking to stop an opioid manufacturer from, and obtain accountability for, violations of its laws has eschewed administrative proceedings in favor of judicial proceedings. In fact, administrative proceedings against Insys Therapeutics, Inc. ("Insys") were filed in Minnesota and Maryland. Unlike the citation here, the Maryland Consumer Protection Division's Statement of Charges, attached as Exhibit A, seeks not only civil penalties, but economic damages, citing $20 million in revenue Insys obtain from prescriptions in Maryland.[6]

Although a number of state attorney generals are pursuing judicial actions against Respondents and/or other opioid manufacturers, wholesale distributors, or pharmacies, many of these cases are multi-party actions alleging misconduct by and/or a conspiracy among, multiple defendants not part of or directors of the same corporate family. Further, regardless of the defendants named, these actions often involve claims such as state (or in case of Alabama, which is unique in choosing the join the federal multi-district litigation, federal) racketeering statutes, as

[6] Maryland also has pending a judicial action to enforce a subpoena against Insys. With respect to Minnesota, there is both a judicial action and an administrative action pending by the Minnesota Board of Pharmacy (which also joined the lawsuit).

well as causes of action such as an public nuisance, Medicaid fraud, fraud, negligence, unjust enrichment, and civil conspiracy.[7]

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.[8] In any event, that much discovery has already been done in the MDL, if anything undermines Respondents' due process argument. To the extent Respondents may deem MDL documents and depositions produced or admitted in this action, the scope of, and time needed for, discovery is substantially reduced. Additionally, the defenses that Respondents have developed in responding to consumer protection claims in other jurisdictions will be available to them here. (Indeed, Respondents characterize themselves as having already been actively engaged in and working on their defense.) 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, the same news articles and press statement Respondents cite refute their arguments that the Division is attempting to somehow pressure them into a settlement. As an initial matter, Exhibits 1 and 2 to their Opposition show that the State of Utah actively pursued its lawsuit, though

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[7] The Division has not attached the complaints, given both the volume and, ultimately, the lack of relevance. The Division notes, however, that despite their purported concern with evidentiary formalities, Respondents neglect to provide evidence or even citations concerning the bulk of their argument concerning proceedings in other states and *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP) (N.D. Ohio) (the "MDL") ("the MDL").

[8] The Division is not a party to the MDL. Purdue, by contrast, is a party to the MDL bellwether cases and all Respondents are named in actions by MDL plaintiffs. Accordingly, the Respondents' attempted to cross-notice MDL depositions in the State of Utah's case while it was pending. *See* Respondents' Exhibit 1.

it took some time to obtain outside counsel, such that the docket activity did not fully reflect this effort. Moreover, Respondents' Exhibit 5 quotes Attorney General Reyes explaining the aim of the administrative proceeding "is not just to get a 'payout.'" Respondents' Exhibit 5 at 2. He 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,' Reyes said." *Id.*[9]

Respondents conveniently ignore important intervening circumstances disclosed in their 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.'" Respondents Exhibit 5 at 1; *see also* Respondents' Exhibit 4 (article stating that "[t]he attorney general cited reports that Purdue was seeking to restructure itself" in explaining the decision to institute an administrative proceeding). In addition, all district court claims have been stayed due to a pending consolidation of lawsuits filed in Utah state courts. *See* Respondents' Exhibit 3 at 3.

In sum, conversion is in the public interest and would in no way prejudice Respondents. The Division therefore respectfully requests that its motion be granted. If the presiding officer decides to hear argument, the Division requests that any argument take place the same day as, or before, the planned status conference.

DATED this 9th day of April, 2019.

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[9] There, the Attorney General stressed that "[o]ur families, health care professionals, first responders, and law enforcement officers know the urgency of the opioid epidemic" and "[a]s we recognized when we filed suit, and in the several months since then, we don't have more time to lose." *Id.*

By: */s/ Lisa Saltzburg*
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I certify that I have served or will serve the foregoing document on the parties of record in this proceeding set forth below:

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Dated this 9th day of April, 2019.

_____

Exhibit

A

CONSUMER PROTECTION DIVISION, OFFICE OF THE ATTORNEY GENERAL 200 St. Paul Place, 16th Floor Baltimore, Maryland 21202, Proponent, v. INSYS THERAPEUTICS, INC. 1333 South Spectrum Drive, No. 100 Chandler, Arizona, 85286 Respondent	*	IN THE CONSUMER PROTECTION DIVISION OF THE OFFICE OF THE ATTORNEY GENERAL CPD Case No.: 18-028-300480 OAH Case No.: _____

* * * * * * * * * * * * *

STATEMENT OF CHARGES

The Consumer Protection Division of the Office of the Attorney General of Maryland ("Division") hereby institutes this proceeding on behalf of the State of Maryland to enjoin Insys Therapeutics, Inc. ("Insys") from engaging in unfair and deceptive trade practices and to obtain relief for consumers victimized by Insys's unfair and deceptive trade practices.

Insys has engaged in a nationwide unfair and deceptive scheme characterized by extraordinary misconduct. Insys manufactures an extremely potent opioid medication – its fentanyl sublingual spray, Subsys – and markets and sells Subsys to inappropriate patients other than those in the narrow class of cancer patients for whose episodes of "breakthrough pain" Subsys is approved by the U.S. Food & Drug Administration ("FDA"). Instead of marketing Subsys lawfully to these cancer patients whose generally terminal prognoses make concerns about addiction and risk less prominent, Insys and local health care providers who became Insys's "business associates" have overwhelmingly targeted so-called "off-label" patients who do not have cancer – including, for example, patients with knee pain, back pain, migraine

headaches, or whose pain cannot be attributed to any clear etiology – and for whom Subsys is inappropriate, unsafe, and ineffective.

Insys's nationwide scheme – fully implemented in Maryland – involved providing inducements of tens of thousands of dollars, sexual or other inappropriate intimate social relationships with sales representatives (who gained improper influence and access to physicians and their patients' medical records and who profited in the form of higher bonuses from the doctors' prescribing), and Subsys itself for at least one Maryland doctor's own illegal use, to local "pill mills" willing to dole out Subsys because of these inducements. These prescribers also profited from payments from or on behalf of these patients, who returned for Subsys, an opioid that can deliver a strong and particularly rapid euphoria followed by severe and debilitating withdrawal.

Insys facilitated these inappropriate prescriptions by repeatedly lying to patients' insurers and their pharmacy benefit managers in order to ensure that plans covered inappropriate prescriptions. Because it is expensive and unsafe, Subsys usually must be pre-authorized by patients' health insurance plans. To overcome plan limitations that restricted coverage to "on-label" cancer patients with extraordinary episodes of pain, Insys created a "reimbursement unit" through which it unfairly and deceptively circumvented the safety and cost-management functions that insurers' prior authorization requirements provide to consumers. Insys instructed the prior authorization specialists it employed in its reimbursement unit to falsely represent to insurers, among other things, that Subsys patients had cancer, in order to obtain prior authorization for prescriptions that were inappropriate for the patients.

Through its misconduct, Insys has profited off of thousands of Americans, including hundreds of Marylanders (and their insurers), many of whom have either died or have been left

with debilitating addictions that place them at the very real risk of becoming the next casualties of the opioid crisis. Beyond any question, Insys has contributed and continues to contribute to the opioid crisis.

As set forth below, Insys has committed thousands of violations of the Maryland Consumer Protection Act:

The Parties

1. The Proponent in this proceeding is the Consumer Protection Division of the Office of the Attorney General of Maryland. This proceeding is brought by the Proponent to redress violations and to prevent future violations of Maryland's Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 *et seq*.

2. The Respondent in this proceeding is Insys Therapeutics, Inc., a Delaware corporation with its principal place of business located at 1333 South Spectrum Boulevard, Number One Hundred, Chandler, Arizona 85286.

3. From 2012 to 2017, Insys manufactured only one product, Subsys, which it marketed and sold and now continues to market and sell throughout the United States, including Maryland. In 2017, it added another drug, a synthetic cannabinoid, and is in the process of developing additional opioids and cannabinoids.

Statement of Facts

I. The Opioid Crisis

4. Maryland is in the midst of an opioid crisis that has resulted in large part from the over-prescription of prescription opioids in the State and from the subsequent use of illicit opioids by people who initially became addicted to prescription opioids. The opioid crisis has

killed thousands of Marylanders and has left far more with debilitating addictions that place them at risk of overdose death.

5. Opioids are highly addictive narcotic medicines that can relieve pain, but that at the same time carry substantial risks of addiction and death, usually from opioid-induced respiratory depression. Opioid use produces opioid dependence, altering the functioning of the brain and central nervous system so that when opioid users stop taking opioids they experience severe withdrawal symptoms like anxiety, nausea, vomiting, and abdominal pain. Dependence leads to addiction. It is possible to become addicted to opioids after taking them for only a relatively short duration, even for a legitimate medical condition. It becomes very difficult to stop taking opioids, especially when one has taken more potent opioids at higher doses for a longer term.

II. Fentanyl & The Development & Approval Of Subsys

6. Fentanyl is one of the most potent opioids lawfully available for human use. Fentanyl is approximately 50 times more potent than heroin, and approximately 100 times more potent than morphine.

7. Fentanyl is also extremely addictive.

8. Fentanyl has been approved for use in the United States as a Schedule II controlled dangerous substance, indicating its high potential for abuse. Because of its potency and associated risks, fentanyl is approved for only limited purposes. While fentanyl may relieve some types of pain, fentanyl is ineffective for others and can induce hyperalgesia, a condition where the patient's experience of pain worsens because of the drug and may increase as the patient receives higher doses of the drug.

9. Fentanyl has been available intravenously or through injections in the United States since 1968. In 2005, FDA approved a fentanyl patch for severe pain, a formulation that releases fentanyl to the patient over time.

10. In 1998, FDA approved the first transmucosal immediate release fentanyl ("TIRF") product, Actiq, "for the management of breakthrough pain in adult cancer patients," an approval that paved the way for the approval of subsequent TIRF products with the same indication. TIRF drugs – including Actiq, a fentanyl lollipop, Fentora, a fentanyl lozenge, Lazanda, a fentanyl nasal spray, Abstral, a fentanyl sublingual tablet, Onsolis, a fentanyl film not yet commercialized, and Subsys – are rapidly absorbed across the mucous membranes of the mouth or nose and are marketed as acting more quickly (*i.e.*, entering the bloodstream and producing a more rapid effect on the nervous system) than other opioids. Insys advertises, for example, that the onset of pain relief from taking Subsys occurs "in as little as five minutes." This rapid onset, however, increases the potential for addiction and abuse.

11. Breakthrough pain consists of episodic spikes of pain that are said to "break through" the pain relief provided by a cancer patient's already existing around-the-clock opioid treatment regimen and require additional relief. FDA limited Subsys and other TIRF products to cancer patients because it believed that the risks of these drugs made them appropriate only for usually end-of-life cancer patients in whom long-term concerns about addiction, abuse, and increased risk of death are not as significant as they are for other patients. FDA has repeatedly refused to broaden its approval of TIRF drugs beyond the limited indication for breakthrough cancer pain.

12. Because of their risks, FDA requires all TIRF products to be prescribed through a risk evaluation and mitigation strategy program ("REMS"), known as the TIRF REMS Access

program. The TIRF REMS Access program is required pursuant to 21 U.S.C. § 355-1, and one of its purposes is to protect against off-label use. Prescribers, pharmacies, and patients register with the TIRF REMS Access program, which tracks prescription data.

13. Beginning in approximately 2005, Insys began developing Subsys, a sublingual fentanyl spray, and acquired the sublingual spray technology from a developer in 2011.

14. Each unit of Subsys consists of a spray device and a solution containing fentanyl that is sprayed under the tongue for absorption across the sublingual mucosa.

15. On March 4, 2011, Insys filed a new drug application, asking FDA to approve its new fentanyl product Subsys "for the management of breakthrough cancer pain in opioid tolerant patients with malignancies." As a TIRF product, Insys acknowledged that Subsys would be subject to the TIRF REMS Access program. In reviewing Insys's new drug application for Subsys, FDA raised several concerns with the scientific research that Insys had submitted to support the application. Nevertheless, on January 4, 2012, consistent with its approval of other TIRF products, FDA approved Subsys only "for the management of breakthrough pain in adult cancer patients who are already receiving and are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

16. FDA's narrow approval of Subsys for "breakthrough pain in adult cancer patients" means that Subsys cannot lawfully be marketed for other conditions. Prescribers who write Subsys prescriptions for unapproved conditions are said to prescribe Subsys "off-label," and do so in the absence of a determination that the drug is safe and effective for that use or contrary to a determination that it is not safe and effective for that use.

17. FDA's approval also limits Insys's marketing to certain approved doses under specified conditions.

18. Insys has subsequently asked FDA to approve Subsys for other indications, but FDA has refused to do so.

19. As approved, Subsys is available in 100, 200, 400, 600, 800, 1,200 and 1,600 microgram doses. At the minimum frequency at which Insys encouraged prescribers to prescribe Subsys to their patients, the price of a monthly Subsys prescription could range from approximately $6,150 for 120 units at 100 microgram doses to $40,875 for 120 units at 1,600 microgram doses.

20. Insys derives a higher profit from higher dose prescriptions, and high-volume, high-dose prescriptions that exceed 120 units or 1,600 micrograms may cost over $60,000 for a one month's supply.

III. Insys Uses Inducements of Money, Intimacy & Subsys To Drive Prescriptions Of Subsys For Inappropriate Patients

21. The narrow market for the treatment of breakthrough pain in cancer patients was inconsistent with Insys's desire for "infinitely higher" profits.

22. With Subsys's approval, Insys therefore set in motion a strategy to profit from marketing Subsys for use in off-label patients for whom Subsys is inappropriate, addictive, and unsafe – including patients for whom it is contraindicated.

23. Prescription drugs are consumer goods. Typically, consumers rely on direct information provided to them and the information transmitted to their pharmacists, health care providers, and insurers.

24. Insys's strategy involved marketing Subsys – not to oncologists and their cancer patients – but to "pill mill" pain management providers already known to prescribe high volumes of certain opioids that are particularly subject to abuse. One former sales manager at Insys

testified under oath to the Division that: "You know, a lot of the targets were due to they were [*sic*] high prescribers of opioids. And just because they prescribed opioids, doesn't mean, you know, they're treating cancer patients either."

25. Such pain management providers typically do not treat patients with breakthrough pain from active malignancies. Instead, they tend to treat recurring chronic pain patients. Cancer patients generally receive treatment for cancer pain from the oncologists they see or from nurse practitioners and physician assistants within the oncology practice.

26. Despite knowing this and the restrictions that federal law placed on its marketing of Subsys, Insys provided its sales representatives with target lists that overwhelmingly included pain management providers, not oncologists. As one former sales representative has indicated in testimony under oath to the Division:

> Well, let me just cut to the chase here. This is a drug that was for breakthrough cancer pain.... For adults that are on an around-the-clock opioid that have typically failed other drugs. So you think I'd be calling on oncologists. I didn't have a single oncologist on my list. That was a red flag.

27. But even Insys's already-inappropriate target lists were not ordinarily used for the dissemination of marketing materials to garner any cancer patients that the targets might have been treating. Instead, Insys instructed its sales representatives to determine which of these targets would be readily susceptible to Insys's financial or other inducements, regardless of the target's patient population.

28. Insys repeatedly instructed its sales representatives to follow what its sales executives and managers dubbed "the formula." The Insys formula was to find the "one key player" who could be induced to write Subsys in high volumes. Sales representatives were instructed to "move in with" or "live with" this prescriber, to discover what made the prescriber

"tick" and to provide it "over and over again." Insys sales representatives were expected to "own" these customers.

29. Insys incentivized sales representatives to implement its strategies and ensure that targeted prescribers wrote frequently and in high amounts. Sales managers and representatives earned tens – and even hundreds – of thousands of dollars in bonuses directly tied to their assigned prescribers' writing and Insys's own resulting profits.

30. Consistent with "the formula," Insys provided a variety of inducements to prescribers to drive them to prescribe Subsys to inappropriate patients with increasing frequency at increasing doses, which were far more profitable to Insys than lower dose prescriptions. For example, Insys created an "effective dose" message that instructed prescribers to start patients at higher doses that were directly contrary to the FDA-approved prescribing information, and to quickly raise or titrate patients to medically inappropriate higher doses.

31. These inducements were often administered through the Insys Speaker Program, which Insys launched by approximately March 2012.

32. Speaker programs or bureaus are used by pharmaceutical manufacturers to conduct peer-to-peer education campaigns to inform audiences about the availability and characteristics of a manufacturer's product. Such programs have been controversial even when conducted with considerable discretion.

33. The Insys Speaker Program, however, outdid the usual controversy; it was a total sham. Insys designed the program, not for the purpose of educating audiences, but in order to mask the thousands of dollars in payments it made to prescribers in exchange for medically inappropriate and excessive prescriptions of Subsys in increasing quantities and strengths to increasing numbers of inappropriate off-label patients.

34. On many occasions, speaker dinners were attended only by the speaker's own staff or by family members and non-prescribers, and, in some cases, by no one at all.

35. To ensure that these doctors prescribed Subsys, Insys representatives were instructed to have "difficult conversations," to "ask for the business," to do something that might be "uncomfortable," and, above all else, to "close." These were code words used to instruct representatives to ask the prescribers to write Subsys in exchange for speaker program fees and other inducements.

36. Maryland speakers were paid anywhere from $1,000 to $3,700 for speaker lunches and dinners, speaker trainings, and other functions, with one speaker receiving as much as $5,400 for a single event. Insys tracked the "return on investment" it received from its payments to each speaker, calculated based on the number of prescriptions that the speaker – not the audience – wrote. The audience, if there was an audience, simply was not the target.

37. If speakers failed to write enough Subsys prescriptions or to write them in high enough doses or quantities, Insys would remove them from the speaker bureau or threaten to reduce the frequency of speaking engagements they received or postpone engagements (thereby reducing or delaying the honorarium payments the speaker received from Insys). As one witness testified under oath to the Division, former Vice President of Sales Alec Burlakoff "wanted to get [speakers] writing and that [Insys] would pay them a certain amount of money to do so, and if they didn't write, he wasn't going to give them programs. It wasn't even really [a veiled] conversation in most cases."

38. Insys also checked commercially available data regarding its speakers' prescribing of competitor TIRF products – like Fentora, Abstral, and Lazanda. When a speaker prescribed a competitor TIRF product, Insys would confront the speaker over the failure to

perform, indicating that Insys had "earned" the right to insist that the speaker prescribe Subsys. Insys sometimes obtained agreements from its speakers to grant Insys specific "market shares" of speakers' TIRF product prescribing (for example, 33 percent of the speaker's TIRF product prescriptions), including in Maryland. Additionally, speakers who wrote sufficient prescriptions were made "regional" or "national" speakers and received higher payouts, regardless of whether they traveled to speak for Insys regionally or nationally.

39. The speaker program also provided a platform through which Insys could encourage inappropriate social relationships between its sales force, its Subsys prescribers, and local pharmacists. "Speaker programs" were frequently social events for Insys employees, speakers, pharmacists, and their colleagues, friends, families, and others often held at inappropriate venues unconducive to any legitimate educational purpose, such as strip clubs, restaurants with scantily-clad waitresses, and private hotel rooms. Insys would provide large quantities of alcohol and sales managers and representatives would also pay for lavish perks, such as expensive bottles of wine, on their personal cards in order to avoid that expense being reported to Insys, and ultimately to the federal government through the Centers for Medicare & Medicaid Services reporting requirements. In numerous cases across the country, including in Maryland, Insys representatives had inappropriate sexual or other intimate relationships with prescribers while encouraging them to write Subsys.

40. Insys also regularly invited certain local pharmacists to its speaker events, pharmacists who in turn captured the bulk of the local Subsys market. Notably, Insys had an interest in obtaining cooperation from pharmacies, which have duties to report suspicious activities and can decline to fill problematic prescriptions (as occurred when CVS began refusing

to fill prescriptions written by one of Insys's speaker-prescribers who was Maryland's heaviest Subsys prescriber).

41. The Insys Speaker Program and Insys's other marketing devices were simply a way to funnel money or in kind benefits to these prescribers whom Insys had coopted in exchange for Subsys prescriptions that were inappropriate, dangerous, and would otherwise not have been written.

42. Insys also hired Business Relationship Managers (BRMs), earlier known as Area Business Liaisons and Assistant Specialty Sales Professionals, to assist prescribers with getting the Subsys patients' prescriptions approved by insurance companies. These BRMs operated as a further inducement to high-volume Subsys prescribers because they constituted additional staffing paid for by Insys.

43. Contrary to applicable law, sales representatives and BRMs in Maryland reviewed patient files, filled out paperwork, and had direct patient contact related to Subsys. BRMs, who were constantly present in Insys's prescribers' offices, also constantly assisted with marketing Subsys to prescribers. A Maryland BRM testified under oath to the Division, "I maintained the existing customers. [The sales representative] went out and looked for prospects."

44. Many of Insys's speakers and other top prescribers – including several in Maryland – have now had disciplinary action taken against them by professional disciplinary boards or have otherwise been forced out of the practice of medicine for inappropriate prescribing. Some are in prison, and others have been criminally charged. Many Insys employees who participated in its practices have pleaded guilty to federal or state criminal charges as a result of their participation.

45. In Maryland, where the vast majority of Subsys prescriptions were written for inappropriate patients, numerous prescribers received tens of thousands of dollars in Insys payments in exchange for writing these prescriptions. At least one high volume off-label Subsys prescriber, Roger Theodore of Towson, had an ongoing sexual relationship with the Insys sales representative assigned to him, placing numerous inappropriate off-label patients on Subsys while dating and then living with her. Another prescriber, Eva Dickinson (who maintained her office in Delaware but saw Maryland patients there or at her home in Maryland and was licensed in Maryland) with Insys's knowledge and while Insys continued to market Subsys through her, received Subsys for her own personal consumption from the patients to whom Insys encouraged her to provide Subsys. Although this prescriber's use of Subsys had been reported by both the sales representative and the sales manager to Insys's compliance director, Danielle Davis, Insys continued to work with Dickinson as a "house account" – managed from Insys's Arizona headquarters – until Dickinson's arrest.

46. In the end, more than 90 percent of the Subsys prescriptions written or filled in Maryland were written for patients who never should have received Subsys because their conditions did not warrant the use of rapid onset fentanyl. Many of these patients became addicted to Subsys and suffered as a result of their addictions.

IV. To Ensure Coverage For Inappropriate Prescriptions, Insys Misled Patients' Insurance Companies

47. Most consumers ultimately utilize health or prescription drug insurance, including commercial insurance plans sponsored by employers or others and government assistance programs like Medicare and Medicaid, to pay all or part of the costs of prescription drugs.

48. Insurance enables consumers to pool resources, and insurance plans generally maintain funds collected from patient premiums that are then available for consumers covered by the plans when they need medical treatment, including prescription drugs.

49. Insurance plans provide a variety of services to consumers that include managing consumer costs, providing consumer education, and ensuring the safety, appropriateness, and necessity of medical care, including prescription drugs, among other things.

50. An increasing number of health insurance plans have contracted with pharmacy benefit managers ("PBMs") to manage their members' prescription drug benefits.

51. To control costs and to ensure patient safety, many insurance plans have imposed prior authorization requirements on certain prescription drugs. Prior authorization is a process by which an insurer approves payment for treatment with a prescription drug before the prescription is filled by the pharmacy.

52. In the prior authorization process, insurers or their PBMs obtain additional information from the prescribing health care provider about the patient's diagnosis, medical history, and proposed treatment to determine whether the prescription drug is appropriate and necessary for the patient. Prior authorizations for Subsys were usually obtained by phone.

53. When Insys began marketing Subsys in 2012, many insurance companies imposed prior authorization requirements for Subsys prescriptions that resulted in denial of coverage for the product. Over time, the number of insurers requiring prior authorization for Subsys has increased.

54. Prior authorization requirements for Subsys include, among other things, (1) that the prescription be on-label, *i.e.* for the treatment of breakthrough pain in cancer patients; (2) that the patient have no contraindicated conditions, such as migraine headaches; (3) that the patient

be opioid-tolerant; and (4) that the patient have tried and have failed to obtain relief from less potent, less costly, or otherwise preferred opioid medicines for the treatment of the patient's breakthrough cancer pain.

55. These requirements presented a problem for Insys. The overwhelming majority of prescriptions resulting from Insys's marketing were off-label, written for patients who did not have breakthrough cancer pain or any cancer diagnosis at all. Moreover, many patients who received Subsys were being treated for contraindicated conditions like migraine headaches, and insurers refused to approve payments for such prescriptions. Additionally, especially if the patient was prescribed Subsys by an Insys speaker who had agreed to write Subsys instead of other required medications, the patient often had not tried and failed other required medications before being prescribed Subsys.

56. Accordingly, even though Insys was able to induce prescribers to write inappropriate Subsys prescriptions, most of the prescriptions that Insys's prescribers initially wrote were rejected at the pharmacy by the patient's insurance, which posed a significant obstacle to Insys obtaining profits.

57. In approximately November 2012, Insys solved this problem by creating the Insys Reimbursement Center (later the Patient Services Center or the Patient Services Hub) ("IRC"). Insys designed the IRC to ensure that inappropriate Subsys prescriptions were "pulled through" at pharmacies. The IRC operated by simply lying to insurers and PBMs to circumvent their requirements.

58. For example, at Insys's direction, IRC employees falsely claimed that they were calling "with," "for," "from," or "on behalf of" "the doctor's office." As a former reimbursement manger testified under oath: "We can't get [prior authorizations] done if they

didn't think we were from the [doctor's] office." Another IRC employee testified under oath: "[A] lot of insurance companies won't speak to a third party, so we just tell them that we're calling from the physician's office."

59. IRC employees were also trained to provide insurers with false diagnoses of dysphagia, a medical term for patients with difficulty swallowing, in order to convince insurers that the patient needed a spray instead of a lozenge or lollipop. The "lollipop" – Actiq – has been available generically, and is therefore less expensive and preferred by many insurers.

60. Insurers also were provided a fake list of tried and failed mediations that matched the payer's requirements, read from lists created by Insys and posted in the IRC.
As one IRC employee testified under oath to the Division: Insys had "a list of everything that could be tried-and-failed, and we were supposed to give them to every insurance company should they ask because according to [Insys], tried-and-failed was hearsay and it didn't matter." This was done "regardless of whether the patient they were calling about actually had those [tried and failed medications] on the opt-in form."

61. Notably, IRC employees were instructed to misrepresent patient diagnoses by responding affirmatively to routine insurer questions about whether the Subsys prescription was being used to treat breakthrough cancer pain. Insys's prior authorization specialists were instructed to answer: "Yes, for breakthrough pain." Sometimes they simply responded "yes" or "for cancer."

62. When Insys later came under investigation, Insys's compliance and legal departments developed or approved what became known in various versions as "the Spiel," "Statement 13," and "Agent 14." The original version of the Spiel required Insys prior authorization specialists, faced with insurers questioning whether the patient had cancer, to

respond: "The doctor is aware that the medication is intended for the treatment of breakthrough pain in cancer patients. The doctor is treating the patient's breakthrough pain." Slightly modified versions of this language became known as "Statement 13" and "Agent 14," but the basic idea – to give the false impression that the patient had breakthrough cancer pain without using the word "cancer" – remained the same throughout the IRC's history.

63. Insys's prior authorization specialists used the Spiel and other deceptive statements on every prior authorization call – including calls made regarding Maryland consumers – they made seeking prior authorization and reimbursement for an off-label Subsys prescription. One confidential witness testified under oath to the Division:

> Q. On every call where an insurance company asked that question, did you give "the spiel"?
>
> A. Yes.

Another witness similarly testified:

> Q Were you instructed to use the spiel on every call?
>
> A. Yes, we were advised – it was part of our script, you know, from introducing ourselves and how to say certain things, and that was how we were trained, yes.

Insys thereby circumvented the important safety and cost protections that insurance plans provide to consumers.

64. Another aspect of this scheme involved Insys's sales representatives and BRMs in the field, working from the offices of Insys's prescribers. Sales representatives and BRMs were charged with "educating" Insys's prescribers on the requirements of prior authorization and the IRC program and in assisting the prescribers in completing forms transmitted to the IRC for purposes of processing prior authorizations. These forms for Maryland patients often contain

diagnoses and other information that is false or misleading (including false or misleading cancer diagnoses). Insys took advantage of multiple opportunities to provide false and misleading information to patients' insurers.

65. In the event that, notwithstanding these practices, insurers failed to authorize prescriptions for Subsys, Insys also took control of the appeals process, providing free Subsys to patients throughout the pendency of the appeal to ensure that they became dependent on Subsys. The so-called "supervouchers" Insys provided these patients also ensured that prescribers could continue to profit by prescribing Subsys to patients for whom it was inappropriate.

66. To facilitate insurance appeals, Insys also prepared a template letter of medical necessity containing false statements – including statements that patients had difficulty swallowing or limited mobility – that it disseminated to its prescribers. Subsys prescribers from around the country used the same template letter of medical necessity (including statements that were, in context, false) over and over again to mislead reviewers involved in appeals from payer denials of coverage for Subsys.

67. Insys incentivized IRC employees to engage in deception by providing them biweekly bonuses of sometimes thousands of dollars – a substantial portion of their income. The size of those bonuses depended directly on the number of approvals obtained from payers.

68. When prior authorization specialists questioned whether these statements were deceptive, numerous witnesses have confirmed that Insys's compliance and legal departments and executives reassured them that these statements were legal and that it was not their place to question prescriptions.

69. To cover Insys's tracks, Insys's compliance personnel subsequently created sets of dummy instructions that the prior authorization specialists were not actually given or were

verbally instructed not to follow. Several prior authorization specialists have testified before the Division that they never saw or were told to ignore these instructions.

70. Additionally, several confidential witnesses have independently confirmed that Insys removed hard drives from the IRC and shredded paper documents once it came under investigation. Insys continued a practice of shredding IRC employees' documents and notes upon their separation from the company even after it came under subpoena.

71. Insys has told investors, regulators, and consumers that it has replaced its leadership, sales force, and practices. Yet throughout the course of the Division's investigation, Insys has been unwilling to produce certain documents that the Division has yet to receive, or has produced documents only at the last possible minute, when the threat of some consequence loomed heavily. Insys's current general counsel, Franc Del Fosse, and its Current Vice President of Compliance, Sanga Emmanuel, even participated in a presentation in which they provided information to the Division about the then-current status of the reimbursement unit – information that the Division later learned to have been materially misleading. Moreover, Insys continues to employ individuals who implemented its practices, or appear to be connected to those who did, in executive and management positions, in both its reimbursement and sales units. Insys's current chairman and its "chief of staff," for example, are longtime associates of its founder and former chairman and chief executive officer, John Kapoor, who stepped down from the board only when he was arrested in late 2017. Insys's sales manager for certain areas in Maryland has covered those areas since 2012, and was directly trained by the sales vice president who oversaw Insys's deceptive marketing scheme.

V. Results

72. Insys's unfair and deceptive schemes have been remarkably successful. Insys has derived more than $20 million in revenue from more than 3,000 prescriptions it has had written in Maryland. Most of these prescriptions were for off-label conditions.

73. Insys's Maryland patients have suffered from Insys's marketing of Subsys. In addition to the substantial financial toll from Insys's practices, there is ample evidence in Insys's files on Maryland Subsys patients of extraordinary addictions to Subsys that place Maryland consumers at substantial risk of serious health issues and death, and that cause them to experience more pain or painful withdrawal while or when they stop taking Subsys.

VI. Violations of the Consumer Protection Act

74. Insys's practices, as set forth above, constitute unfair or deceptive trade practices in the sale and offer for sale of consumer goods and services in violation of § 13-303 of the Consumer Protection Act.

75. Subsys is a consumer good pursuant to § 13-101(d) of the Consumer Protection Act because consumers use it for personal, family, or household purposes.

76. Insys's false and misleading statements and representations, including those regarding the appropriateness of Subsys for particular conditions, in certain amounts and doses, and/or for specific patients, or as to Subsys's benefits and risks, have had the capacity, tendency, and/or effect of deceiving and misleading consumers and constitute unfair or deceptive trade practices as defined in § 13-301(1) of the Consumer Protection Act.

77. Insys's false or misleading statements and representations, including those regarding the characteristics, uses, benefits or approval of Subsys, *e.g.*, that it was safe, effective, and appropriate for particular conditions and/or specific patients, and that it was selected by

prescribers as medically appropriate or necessary for their conditions, or as the result the prescriber's independent medical judgment, when, in fact, prescribers chose Subsys as a result of the inducements Insys provided, are unfair or deceptive trade practices as defined in § 13-301(2)(i) of the Consumer Protection Act.

78. Insys's failure to disclose material facts, the omission of which deceived or tended to deceive consumers, including its failure to disclose their marketing practices, the purpose of which was to induce prescribers to prescribe Subsys regardless of its safety, efficacy, and/or appropriateness, purpose, or associated risks, and failure to disclose that Subsys was not safe, effective, appropriate, and/or medically necessary in the amounts or for the conditions or patients for which it had been prescribed, constitute unfair or deceptive trade practices as defined in § 13-301(3) of the Consumer Protection Act.

79. Insys's scheme of marketing and selling Subsys for purposes for which it was never approved, while causing a significant risk of addiction and death for Maryland consumers, is an unfair trade practice as defined by the § 13-303 of the Consumer Protection Act. The practice of incentivizing prescribers to write addictive and dangerous drugs that are inappropriate injures consumers in a way that they cannot avoid, and impairs the marketplace. Likewise, the practice of deceiving insurers and circumventing valid plan limitations and safety initiatives injures consumers in a way that they are unable to avoid, and produces no benefit to the marketplace.

WHEREFORE, pursuant to Consumer Protection Act § 13-403(b)(1), Proponent respectfully requests that the Consumer Protection Division issue an Order:

A. requiring Insys to cease and desist from engaging in unfair or deceptive trade practices in violation of the Maryland Consumer Protection Act;

B. requiring Insys to take affirmative action, including, but not limited to, the restitution and disgorgement of all moneys that it received in connection with its unfair or deceptive trade practices and the creation of an adequate addiction treatment program available to all individuals in Maryland who received Subsys;

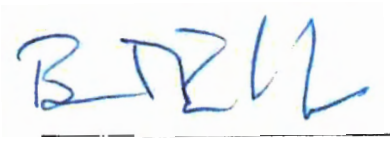
C. awarding economic damages;

D. requiring Insys to pay the costs of this proceeding, including all costs of investigation;

E. requiring Insys to pay civil penalties pursuant to § 13-410 for each violation of the Consumer Protection Act; and

F. granting such other and further relief as is appropriate and necessary.

Respectfully submitted,



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