CAUSE NO. D-1-GN-19-005458

THE STATE OF TEXAS,	§	**IN THE DISTRICT COURT**
	§	
Plaintiff,	§	
	§	
v.	§	
	§	**126TH JUDICIAL DISTRICT**
JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, AND ALZA CORPORATION,	§	
	§	
	§	**TRAVIS COUNTY, TEXAS**
Defendants.	§	

PLAINTIFF'S ORIGINAL PETITION

The State of Texas, by and through the Attorney General of Texas, Ken Paxton, ("the State") brings this law enforcement action pursuant to the Texas Medicaid Fraud Prevention Act ("TMFPA"), TEX. HUM. RES. CODE Chapter 36. The State files this Original Petition ("Petition") and would respectfully show the Court as follows:

I. DISCOVERY CONTROL PLAN

1. Discovery is intended to be conducted under Level 3 of Rule 190, Texas Rules of Civil Procedure.

II. PRELIMINARY STATEMENT AND NATURE OF THIS ACTION

2. This is a law enforcement action under the TMFPA to recover taxpayer dollars spent as a result of Janssen's fraudulent conduct. Specifically, Janssen targeted Texas Medicaid with a fraudulent marketing scheme for its Duragesic pain patch, which contains the extremely dangerous opioid fentanyl. Under this scheme, Janssen disseminated false and/or misleading messages during thousands of sales calls to doctors and other healthcare practitioners who were enrolled Texas Medicaid providers, including: (1) false and/or misleading messaging concealing

the true nature of fentanyl's potential for abuse and addiction; (2) false and/or misleading messaging relating to the drug's efficacy; and (3) false and/or misleading messaging claiming that expensive branded Duragesic was safer and/or more efficacious than generic fentanyl pain patches, all while ignoring the U.S. Food and Drug Administration's ("FDA") repeated admonitions to stop such unlawful conduct. This illegal conduct caused Duragesic to be in violation of state and federal law, and rendered false Janssen's sworn certifications of compliance to Texas Medicaid, which are required for drugs to be listed on the Texas Medicaid formulary. As a result, Janssen obtained the benefit of virtually unfettered Medicaid reimbursements for Duragesic on the basis of fraudulent and unlawful misrepresentations, and in so doing, Janssen violated the TMFPA.

III. DEFENDANTS

3. Defendant JANSSEN PHARMACEUTICALS, INC. ("Janssen Pharmaceuticals") is a corporation organized under the laws of Pennsylvania and has its principal place of business in New Jersey, at 1125 Bear Tavern Rd., Titusville, NJ 08560. Janssen Pharmaceuticals marketed and distributed the drug Duragesic in Texas. Janssen Pharmaceuticals conducts business in Texas. At the time of filing, its registered agent for service of process is C T Corporation System, 1999 Bryan St., Ste. 900, Dallas, TX 78201.

4. Defendant JANSSEN PHARMACEUTICA, INC. ("Janssen Pharmaceutica"), n/k/a Janssen Pharmaceuticals, is a corporation organized under the laws of Pennsylvania and has its principal place of business in New Jersey, at 1125 Bear Tavern Rd., Titusville, NJ 08560. Janssen Pharmaceutica marketed and distributed the drug Duragesic in Texas. Janssen Pharmaceutica conducts business in Texas. At the time of filing, its registered agent for service of process is C T Corporation System, 1999 Bryan St., Ste. 900, Dallas, TX 78201.

5. Defendant ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("Ortho-

McNeil-Janssen"), n/k/a Janssen Pharmaceuticals, is a corporation organized under the laws of Pennsylvania and has its principal place of business in New Jersey, at 1125 Bear Tavern Rd., Titusville, NJ 08560. Ortho-McNeil-Janssen marketed and distributed the drug Duragesic in Texas. Ortho-McNeil-Janssen conducts business in Texas. At the time of filing, its registered agent for service of process is C T Corporation System, 1999 Bryan St., Ste. 900, Dallas, TX 78201.

6. Defendant ALZA CORPORATION ("Alza") is a corporation organized under the laws of Delaware and has its principal place of business in California, at 700 Eubanks Dr., Vacaville, CA 95688. Alza manufactured Duragesic and placed it in the stream of commerce. Alza marketed, distributed, and sold Duragesic in Texas, both through its own accord and/or through its affiliate Janssen Pharmaceutica f/k/a Ortho-McNeil-Janssen f/k/a Janssen Pharmaceuticals, with the expectation that it would be used by consumers in Texas. Although Alza conducts business in Texas, it does not maintain a regular place of business in Texas and has not designated an agent on whom service of citation may be made in this action. Service of citation on Alza may be accomplished by serving the Secretary of State of Texas, provided that the citation and petition are forwarded to Alza's address at 700 Eubanks Dr., Vacaville, CA 95688.

7. Defendant JOHNSON & JOHNSON is a corporation organized under the laws of New Jersey and has its principal place of business in New Jersey, at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Johnson & Johnson is the parent company of Janssen Pharmaceuticals, Janssen Pharmaceutica, Ortho-McNeil-Janssen, and Alza. Although Johnson & Johnson conducts business in Texas, it does not maintain a regular place of business in Texas and has not designated an agent on whom service of citation may be made in this action. Service of citation on Johnson & Johnson may be accomplished by serving the Secretary of State of Texas,

provided that the citation and petition are forwarded to Johnson & Johnson's address at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

8. At all relevant times, Johnson & Johnson, Janssen Pharmaceuticals, Janssen Pharmaceutica, Ortho-McNeil-Janssen, and Alza (collectively, "Defendants" or "Janssen") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

IV. JURISDICTION AND VENUE

9. This Court has jurisdiction of this action pursuant to TEX. HUM. RES. CODE § 36.101. Jurisdiction is further proper because the amounts sought from each Defendant exceed the minimum jurisdictional limits of this Court.

10. Venue is proper in Travis County and this judicial district pursuant to TEX. HUM. RES. CODE § 36.052(d), as Plaintiff's causes of action are based upon alleged violations of the TMFPA. Moreover, the unlawful acts and omissions described herein occurred, in substantial part, in Travis County. Consequently, venue is proper in Travis County pursuant to TEX. CIV. PRAC. & REM. CODE § 15.002(a)(1).

V. BACKGROUND

A. Opioids and Associated Safety Risks

11. Humans have long known that derivatives of the poppy plant—opioids—are highly addictive when ingested.[1] Throughout history, opioids have been rediscovered, only to unleash addiction, desperation, destruction, and ultimately, death on communities.[2] Despite having learned

[1] Patrick R. Keefe, *The Family that Built an Empire of Pain: The Sackler dynasty's ruthless marketing of painkillers has generated billions of dollars—and millions of addicts*, THE NEW YORKER (Oct. 30, 2017), at 7, www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

[2] *Id.*

this lesson before, this addictive nature has tempted profit-seekers to find ways to unleash yet another opioid boom—and to reap the rewards for themselves.

12. Opioid drugs are derivatives of the poppy plant that have been used to treat pain.[3] The association between this analgesic benefit and the risk of death has been known since the ancient world.[4] Indeed, six of the top ten drugs involved in overdose deaths between 2011 and 2016 were opioids, and during that time, the number of drug overdose deaths increased by 54%.[5] Opioids have other serious side effects as well, including fatigue, sedation, nausea, vomiting, dizziness, respiratory depression, bradycardia, and unconsciousness.[6] Higher doses exacerbate some of these side effects.[7]

13. Today, about 20% of patients with non-cancer pain symptoms are prescribed opioids, and in 2012, doctors wrote 259 million prescriptions, enough for every adult in America.[8] Over 200,000 Americans have died as a result of opioid overdoses in the last 20 years, and the CDC says that about 145 Americans per day die from such overdoses.[9]

14. Fentanyl is a synthetic opioid that was first developed by the founder of Janssen Pharmaceuticals, Dr. Paul Janssen, in 1960.[10] Until the development of a patch delivery system in the mid-1980s, fentanyl was delivered by IV in controlled medical settings.[11] Fentanyl is regulated

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3 *Id.*

4 *Id.*

5 Holly Hedegaard et al., *Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2011-2016*, 67 NAT'L VITAL STATS. REPORTS (Nat'l Ctr. for Health Stats, Hyattsville, Md.), no. 9, Dec. 12, 2018, at 3, 7.

6 Theodore H. Stanley, *The Fentanyl Story*, 15 J. PAIN 1215, 1217, no. 12 (Dec. 2014).

7 *Id.*

8 Deborah Dowell et al., CTRS. FOR DISEASE CONT. & PREV., *CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016*, at Background (2016).

9 Keefe, *supra* note 1, at 3.

10 Stanley, *supra* note 6, at 1215.

11 *Id.* at 1220.

as a Schedule II narcotic in the United States, due to its "high potential for abuse which may lead to severe psychological or physical dependence."[12] Dr. Janssen himself was hesitant to put fentanyl in a patch, but was convinced to do so after market analysis showed that the fentanyl patch could be highly profitable.[13] That analysis was correct. In the last year of Duragesic's patent life, it reached over $2 billion in sales worldwide.[14]

15. Yet, even among opioids, fentanyl is a particularly potent agent. It was the strongest in the world at its creation.[15] Even a very small amount of the drug may lead to overdose and death. In its patch form, fentanyl was not safe for acute pain, as it could cause severe suppression of breathing for patients who were not already on opioids.[16] Further, as a synthetic opioid, it is not detected in standard drug tests.[17]

16. Accordingly, during the lifetime of fentanyl products' availability, a relationship between administration and death has remained. A few years after it was first approved—and even in the controlled environment of a hospital—overdoses, including ones causing death, increased.[18] As more methods of administration were produced, more overdoses and death followed.[19] In 2016, fentanyl was involved in at least 28.8% of overall overdose deaths, or 18,335 deaths.[20] Between 2013 and 2016, the rate of fentanyl-involved deadly overdoses doubled each year.[21]

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12 DRUG ENF. ADMIN, DIVERSION CONTR. DIV., Controlled Substance Schedules, www.deadiversion.usdoj.gov/schedules/ (last visited Jul. 24, 2019).
13 Stanley, *supra* note 6, at 1220.
14 *Id.*
15 *Id.* at 1216.
16 *Id.* at 1220.
17 Michael C. Milone, *Laboratory Testing for Prescription Opioids*, 8 J. MED. TOXICOL. 408, 412 (Nov. 2012).
18 Stanley, *supra* note 6, at 1223.
19 *Id.*
20 Hedegaard et al., *supra* note 5, at 4, 5.
21 *Id.* at 8.

17. Janssen contributed centrally to this ongoing public health emergency. Based on the long history of opioids in medicine, doctors had long had deep reluctance to prescribe opioids because of their addictive and deadly attributes—recently termed narcotic conservatism.[22] Through a years-long, multi-channel effort, Janssen contributed to changing this reluctance.[23] They did so by propagating junk science questioning the abuse potential and addictive properties of opioids, and even downplaying the need for more reliable data identified in that science.

18. Throughout the relevant time period, Janssen exaggerated benefits and downplayed risks, preventing Texas Medicaid from making fully informed decisions necessary to safeguard patient health within its system.

B. Duragesic's FDA-Approved Label

19. Duragesic is an adhesive patch that delivers the potent synthetic opioid fentanyl by way of contact with, and absorption through, the skin.

20. Duragesic was originally approved in 1990 by the FDA for the management of chronic pain in patients requiring opioid analgesia, based on clinical trials evaluating patients experiencing chronic pain due to malignancy (cancer). Due to the risk of developing respiratory depression—a potentially deadly side effect—all but the lowest dose was limited for use in opioid tolerant patients.

21. Over time, FDA has gradually narrowed Duragesic's approved use and expanded warnings within the label, as more information has become known regarding the risks particular to long acting opioids. For instance, in June 1993, the Duragesic indication was changed to

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22 Keefe, *supra* note 1, at 2.

23 Celine Gounder, *Who Is Responsible for the Pain—Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), at 4, www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic.

explicitly note that it should not be used for treatment of acute pain due to the life-threatening risk of hypoventilation (*i.e.*, a condition of dangerously slowed breathing).

22. In January 1994, FDA changed the label to indicate that Duragesic should only be used "for chronic pain (such as that of malignancy) that: cannot be managed by lesser means such as acetaminophen-opioid combinations, non-steroidal analgesics, or PRN dosing with short-acting opioids," underscoring its placement as a pain treatment of last resort.[24] FDA also issued a "black box warning"—the strongest type of warning that can be placed on a medication—which contained contraindications (*i.e.*, specific situations where the risks of Duragesic outweigh the benefits) for post-operative pain, mild or intermittent pain, and doses over 25 mcg/hour for opioid-naïve patients.

23. In February 2005, FDA again narrowed Duragesic's indication by changing its approved usage to be "for the management of <u>persistent</u>, moderate to severe chronic pain that:

- requires continuous, around-the-clock opioid administration for an extended period of time, and
- cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids."

(Emphasis in original). FDA further expanded the list of contraindications to include "patients who are not opioid-tolerant," for all doses of Duragesic.

24. At all times, the FDA-approved label for Duragesic contained warnings related to its potential to be abused and to cause addiction (*i.e.*, psychological dependence) and withdrawal symptoms (*i.e.*, physical dependence). Additionally, at all times the FDA-approved label for Duragesic cautioned that fentanyl causes mental and physical impairment, and cautioned patients against performing potentially hazardous tasks, such as driving or operating heavy machinery,

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[24] "PRN dosing" refers to taking a drug "as needed" by a patient.

while taking Duragesic.

C. The FDA Regulatory System

1. The Role of FDA in Regulating Prescription Drug Promotion

25. In the United States, the sale and promotion of prescription drugs is regulated by the U.S. Food and Drug Administration, pursuant to the authority granted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Under the FDCA, new drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to FDA "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."[25,26] The drug's sponsor must also show by substantial evidence that the drug is safe for the conditions of use "prescribed, recommended, or suggested in the proposed labeling."[27] Approval of the drug by FDA is the final step in a multi-year process of study and testing.

26. To determine whether a drug is "safe and effective," FDA relies on information provided by a drug's manufacturer; it does not conduct any clinical investigations itself. Applications for FDA approval of pharmaceutical products (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use."[28]

27. The FDCA requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness.[29] The gold standard example of an "adequate and

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25 21 U.S.C. § 355(d)(5).
26 "Substantial evidence," as used in this section, is defined at 21 U.S.C. § 355(d)(7).
27 21 U.S.C. § 355(d)(1).
28 21 U.S.C. § 355(b)(1)(A).
29 *See* 21 U.S.C. § 355(d)(7).

well-controlled investigation" is a study which is double-blinded and placebo-controlled.[30] FDA regulations specifically note that "[u]ncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness."[31] FDA approves a drug if there are adequate and well-controlled clinical trials that demonstrate a drug's safety and effectiveness for its intended conditions of use.[32] Importantly, FDA's determination of a drug's "safety" consists of a risk-benefit analysis that includes consideration of the severity of conditions for which the drug's approval is sought, as well as the other available treatments for such conditions.[33]

28. Once FDA has approved a drug's NDA for a specific condition—an "indication for use" in FDA terminology—the drug's sponsor is legally only authorized to promote the drug for that particular indication.[34] In order to expand an approved drug's indications for use under the FDCA, the sponsor must submit—and FDA must approve—a supplemental New Drug Application ("sNDA") for each new intended use. In evaluating an sNDA, FDA applies the same statutory standards for safety and effectiveness as with the original NDA, including carefully balancing the drug's risks and benefits for the new potential indication for use.[35]

2. <u>FDA Regulations Prohibit the Misbranding of Prescription Drugs</u>

29. Under the FDCA, it is illegal to misbrand a drug, or to introduce into interstate commerce any drug that is misbranded.[36] A drug is misbranded if the labeling is false or misleading in any particular; the labeling does not contain adequate directions for use; or the

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30 21 C.F.R. § 314.126(b).
31 21 C.F.R. § 314.126(e).
32 *See* 21 U.S.C. § 355(d)(5).
33 *See* 21 U.S.C. § 355(d)(7).
34 *See* Section V.C.2, *infra*.
35 *See* 21 U.S.C. § 355(d)(7).
36 21 U.S.C. §§ 331(a), (b).

manufacturer utilizes false or misleading advertisements relating to the drug.[37]

30. "Labeling" is a core concept of pharmaceutical regulation within the FDCA, and is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[38] Courts have interpreted labeling broadly to encompass printed material even when not physically attached or connected to the related pharmaceutical product.[39]

31. Pursuant to the authority granted by the FDCA, FDA promulgated a series of regulations further expanding on the drug-related statutory requirements of the FDCA.[40] Under these regulations, 21 C.F.R. § 201.5 defines "adequate directions for use" to mean "directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines 'intended use.')." For prescription drug products that require the supervision of a medical professional to safely administer, 21 C.F.R. § 201.100 clarifies that product labeling must contain:

> Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration *and any relevant warnings, hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended*, including all conditions for which it is advertised or represented … and any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

(Emphasis added). One vital component of "adequate directions for use" required under 21 C.F.R. § 201.100 is a drug's established side effect profile, which allows a practitioner to weigh the known drug risks with potential patient benefit prior to initiating treatment using a particular drug.

32. "Intended use" is defined by 21 C.F.R. § 201.128 as referring "to the objective

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37 21 U.S.C. §§ 352(a), (f), (n).
38 21 U.S.C. § 321(m).
39 *See Kordel v. United States*, 335 U.S. 345 (1948).
40 *See* 21 C.F.R. §§ 200-369.

intent of the persons legally responsible for the labeling of drugs." Intended use "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." Furthermore, "this objective intent may … be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives."

33. FDA requires pre-approval of changes to prescription drug labels.[41] Thus, a manufacturer that creates a new "intended use" for its prescription drug product cannot unilaterally amend the label to include this new intended use;[42] rather, the drug will necessarily be misbranded at that point in time for failing to provide adequate directions for use, in violation of the FDCA.

34. In sum, the misbranding regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body—the FDA. Moreover, the prohibition on false or misleading labeling claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on deceptive marketing tactics.

3. <u>The Limited Role of FDA in Regulating Prescription Drug Promotion</u>

35. FDA's Office of Prescription Drug Promotion[43] ("OPDP") is charged with overseeing the marketing and promotion of approved drugs to ensure that drug promotion: (a) is not false or misleading; (b) provides a fair balance between the benefits and risks of the drug; and

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41 *See* 21 C.F.R. §§ 314.50, 314.70. This provision does not apply to a drug company unilaterally adding newly-discovered drug safety information to the label. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

42 As discussed in Section V.C.1, *supra*, FDA requires "substantial evidence" of efficacy and safety, in the form of well-controlled clinical trials, for a new intended use to be approved for a drug.

43 Formerly known as the Division of Drug Marketing, Advertising, and Communications ("DDMAC").

(c) does not misbrand the drug.[44]

36. OPDP's ability to regulate misbranding is limited. In 2003, its entire staff consisted of 40 members, with 25 reviewers responsible for reviewing all drug advertisements and promotional materials.

37. Moreover, materials promoting pharmaceutical products do not have to be pre-approved. FDA review of promotional materials occurs, if at all, after the materials have already appeared in public.[45] Upon finding a violation, OPDP generally requests the company to stop using the violative promotional materials.[46] OPDP occasionally requires sponsors to publicly correct product misimpressions created by materials that are false, misleading, and/or lacking in fair balance.[47]

D. <u>Texas's Role in Regulating Prescription Drugs</u>

38. In Texas, the sale and promotion of prescription drugs is further regulated by the Drugs and Medical Devices Group of the Texas Department of State Health Services, pursuant to the authority granted by the Texas Food, Drug, and Cosmetic Act ("TFDCA").[48]

39. The TFDCA largely mirrors the FDCA. For example, the TFDCA, like the FDCA, prohibits the misbranding of drugs and the introduction of misbranded drugs into commerce.[49] Similarly, TFDCA § 431.003 establishes that omissions should be taken into account for misbranding allegations relating to misleading labeling or advertising, mirroring 21 U.S.C. § 321(n) of the FDCA. Additionally, TFDCA § 431.112 defines drug misbranding to include the

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44 *See* Statement by Janet Woodcock, M.D., Director Center for Drug Evaluation and Research, FDA, Before the Senate Special Committee on Aging (July 22, 2003).
45 *See* Woodcock Statement, *supra*.
46 *Id*.
47 *Id*.
48 TEX. HEALTH & SAFETY CODE, Ch. 431, *et seq*.
49 *See* TEX. HEALTH & SAFETY CODE §§ 431.021(a), (b).

same relevant provisions as the FDCA: a drug is misbranded if the labeling is false or misleading in any particular; the labeling does not contain adequate directions for use; or the manufacturer utilizes false or misleading advertisements relating to the drug.[50]

40. Violations of the TFDCA, including violations of rules adopted under the TFDCA,[51] can result in a written warning; administrative penalties; civil penalties; or criminal penalties.[52]

E. Texas Medicaid

1. Overview

41. The state and federal governments fund health care for the poor and disabled through public health assistance programs. The Medical Assistance Program in Texas, commonly referred to as Texas Medicaid, was created to provide medical assistance for low-income individuals and families in Texas.

42. The Texas Medicaid program, which includes Texas Medicaid decision makers as well as Texas Medicaid providers, is a system that provides medical products and services to qualified recipients. Texas Medicaid reimburses participating providers for the approved pharmaceuticals they provide to Medicaid recipients. The program is funded jointly by the State of Texas and the federal government. The Texas Health and Human Services Commission ("HHSC") administers the Texas Medicaid program and has authority to promulgate rules and other methods of administration governing the program.

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50 *See* TEX. HEALTH & SAFETY CODE §§ 431.112(a), (e), (k); 21 U.S.C. § 352(a), (f), (n).

51 TEX. HEALTH & SAFETY CODE § 431.046. *See*, *e.g.*, 25 TEX. ADMIN. CODE Ch. 229.

52 *See* TEX. HEALTH & SAFETY CODE §§ 431.061, 431.054, 431.0585, 431.059.

2. Texas Medicaid Tools for Managing Appropriate and Cost-Effective Pharmaceutical Therapy

43. The Vendor Drug Program ("VDP") within HHSC was established to oversee the outpatient prescription drug portion of the Texas Medicaid program. VDP is also charged with safeguarding against fraud, waste, and abuse within the program. VDP was in operation at all times relevant to this case.

44. Providers can obtain Medicaid reimbursement through VDP for pharmaceutical products approved for use and reimbursement under this program, and which are listed on the VDP formulary.[53] To have its particular pharmaceutical products listed on the VDP formulary, a drug company or manufacturer must file an application with VDP.[54] Included in the application is a detailed 16-point questionnaire that, pursuant to state law, must be completed and filed. Texas Medicaid requires information provided to it by pharmaceutical manufacturers as part of the VDP application process to be complete, truthful, and up-to-date.[55]

45. VDP applications require drug manufacturers to report, for each drug submitted, the recommended daily dosages, formulation of the drug, FDA approval letters, and copies of the package inserts and materials for physicians. The VDP application also requires manufacturers to certify that all the information provided with their application is correct and that their drug is not in violation of either state or federal law. The application further requires manufacturers, on a going-forward basis, to submit notification of any changes pertaining to their product's status within fifteen (15) days of such changes occurring.

46. In approving VDP applications, HHSC expressly provides that manufacturers are

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53 1 TEX. ADMIN. CODE § 354.1831(a). The VDP formulary is also referred to as the Texas Drug Code Index or "TDCI."

54 1 TEX. ADMIN. CODE § 354.1921(b).

55 *Id. See also* 1 TEX. ADMIN. CODE § 354.1923(b).

responsible for submitting notification of changes pertaining to the 16 points specified in the application no later than the date such revisions are scheduled to occur. Accordingly, manufacturers owe a continuing duty to Texas Medicaid to supplement information provided with their VDP application after its initial submission to the VDP. Moreover, a new VDP application must be submitted each time a drug first becomes available in a new formulation or in different dosages.

47. Pharmaceutical manufacturers' interactions with Texas Medicaid, and Texas Medicaid's review of drugs placed on its formulary, do not stop with submission of the initial VDP application. Texas Medicaid has an ongoing obligation to manage its drug formulary through Drug Utilization Review ("DUR") in accordance with the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"). Pursuant to that obligation, Texas Medicaid created the DUR program to promote optimal and cost-effective pharmaceutical therapy in the Texas Medicaid VDP.[56]

48. Specifically, the DUR program exists to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. The program is designed to educate pharmacists and physicians to identify and reduce the frequency of patterns of fraud, abuse, overuse, or inappropriate or medically unnecessary care associated with specific drugs or groups of drugs.

49. The DUR Board has a number of tools available to it to achieve these goals, including prior authorization, educational letters expressing therapeutic concerns to Texas Medicaid providers, DUR alerts, and clinical edits. If necessary, the DUR Board initiates recommendations that certain drugs be made subject to prior authorization or to restrictions concerning the types of patients (*e.g.*, children, elderly persons, etc.) or the types of conditions for

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[56] 1 TEX. ADMIN. CODE § 351.3(3).

which Medicaid reimbursement is obtainable.

50. As part of this program, the DUR Board monitors and analyzes provider-level activity. Drug manufacturers, including Defendants, provide the DUR program with information concerning their drugs. The DUR program expects—and Texas law requires—all such provided information to be complete and accurate.

51. By way of example, due in part to the great expense and serious potential side effects associated with Duragesic, the DUR Board implemented a clinical edit on transdermal fentanyl starting in 2004.[57] This clinical edit sought "to promote prudent prescribing" by limiting claims for reimbursement of this powerful opioid where the patient was very young; was not tolerant to other opioid medications; or was prescribed a very high dose. However, the DUR Board's ability to take such restrictive action is limited by its knowledge of the unlawful conduct. Thus, the DUR Board cannot effectively address issues of improper utilization where the illicit promotional scheme is concealed by the drug company.

52. In February 2004, Texas Medicaid implemented another means through which Texas Medicaid could manage its expenditures for pharmaceuticals—the Texas Medicaid Preferred Drug List (the "PDL").[58] In making recommendations for the PDL, the Texas Medicaid Pharmaceutical and Therapeutics Committee (the "P&T Committee")[59] considers the clinical efficacy, safety, and cost-effectiveness of each drug reviewed.[60] As part of this PDL process, the P&T Committee receives information from drug manufacturers, including Defendants, concerning their drugs. The P&T Committee expects—and Texas law requires—all such information to be

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57 This clinical edit remains in-place today under the title "Fentanyl Agents."

58 1 TEX. ADMIN. CODE § 354.1924 (2010).

59 Since 2016, the P&T Committee and DUR Board were combined into a single, expanded, committee known as the DUR Board, which handles the functions of the two previous committees.

60 1 TEX. ADMIN. CODE § 354.1928 (2010).

complete and accurate. HHSC then decides which drugs are placed on the PDL based on P&T Committee recommendations, the cost of competing drugs to the state, clinical considerations, written information offered by manufacturers about their products, and the existence of a supplemental rebate agreement and/or other program benefits. Drugs that are reviewed but not selected for the PDL require prior authorization. Defendants sought and achieved the placement of Duragesic on the PDL without prior authorization, including by making presentations to the P&T Committee and submitting written information to the State and/or State contractors concerning Duragesic. As with the DUR Board, the P&T Committee cannot effectively make recommendations to manage the Preferred Drug List where material information has been misrepresented and/or concealed by a drug company.

3. The Texas Medicaid Program

53. As discussed above, Texas Medicaid includes not just the Medicaid decision makers such as the VDP, DUR Board, and P&T Committee members, but also Medicaid providers such as pharmacies and physicians, which enter into agreements with Texas Medicaid in order to be covered providers. Together, Texas Medicaid decision makers and providers constitute the Texas Medicaid program. The Texas Medicaid Fraud Prevention Act seeks to protect against fraud at all levels of the Texas Medicaid program.[61]

F. Defendants Specifically Targeted the Texas Medicaid Program

54. Patients suffering from cancer-related pain (also known as malignant pain), or severe chronic non-cancer pain, are often debilitated to the point of being unable to work. Accordingly, Defendants recognized early on that public-sector health plans, such as Texas Medicaid, would be significant payors of long-acting opioid ("LAO") medications like the fentanyl

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61 *See* TEX. HUM. RES. CODE § 36.001 *et seq.*

patch. At the same time, Defendants anticipated that "the chronic pain category is expected to draw significant state scrutiny" that could potentially limit reimbursement from these health plans, and Defendants' high-level planning documents listed the prospect of "government intervention / cost control" as a "threat[]." Understanding the need to obtain significant government buy-in to achieve their financial goals for the fentanyl patch, Defendants planned and executed the "Duragesic initiative: TX Medicaid" to target and influence Texas Medicaid decision makers and providers, which they sought to leverage into a "HUGE Opportunity!!" for the brand.

VI. APPLICABLE TEXAS STATUTORY LAW

55. Plaintiff re-alleges and reincorporates by reference as set forth herein the allegations contained in Paragraphs 1 through 54 of this Petition.

56. Prior to August 31, 2005, a person committed an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

A. Knowingly or intentionally making or causing to be made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program. TEX. HUM. RES. CODE § 36.002(1)(A), (B).

B. Knowingly or intentionally concealing or failing to disclose an event: (A) that the person knows affects the initial or continued right of the person to a benefit or payment under the Medicaid program; and (B) to permit a person to receive a benefit or payment that is not authorized, or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002(2).

C. Knowingly or intentionally making, or causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of a material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program. TEX. HUM. RES. CODE § 36.002(4)(B).

D. Except as authorized under the Medicaid program, knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued

service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program. TEX. HUM. RES. CODE § 36.002(5).

57. Since August 31, 2005, a person commits an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

A. Knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002(1).

B. Knowingly concealing or failing to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002(2).

C. Knowingly making, causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program. TEX. HUM. RES. CODE § 36.002(4)(B).

D. Knowingly paying, charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program. TEX. HUM. RES. CODE § 36.002(5).

Hereinafter, references to conduct as constituting "statutory fraud" mean that the conduct being described was done by Defendants at times when one or more of the statutory provisions set forth in Paragraph 56 or this Paragraph 57 applied, and was done in ways and through means that satisfy all the required elements of at least one applicable statutory provision.

VII. DEFENDANTS' UNLAWFUL ACTS

58. At an estimated 80-100 times stronger than morphine,[62] fentanyl can kill. Even

[62] *Fentanyl*, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION DRUG FACTS, www.dea.gov/factsheets/fentanyl (last visited August 30, 2019).

when used as indicated by the FDA label, fentanyl can cause significant impairment, constipation, lifelong addiction issues, and life-threatening hypoventilation (difficulty breathing). Defendants' fentanyl patch, Duragesic, contains a very high concentration of fentanyl, due to its delivery of the dangerous opioid over a three-day period.

59. Notwithstanding the potential problems associated with widespread fentanyl distribution and use, including the increased possibility for criminal diversion, Defendants saw the fentanyl patch as an opportunity: an opportunity to rival the up-and-coming (and now infamous) opioid OxyContin, which was spreading through Texas and the country, leading to what has become an opioid epidemic; an opportunity to create a new billion-dollar blockbuster drug; and an opportunity to elevate Janssen's status as the premier pain management company.

60. To exploit this opportunity, starting in 1997 Defendants began promoting the fentanyl patch using a series of false and misleading sales messages. Even in the face of numerous FDA rebukes of these messages, Defendants continued to promote Duragesic in a manner that dangerously misrepresented the body of scientific evidence. These false and misleading messages were delivered not only on sales calls throughout Texas, but also to Texas Medicaid decision makers, in a targeted scheme to influence the Texas Medicaid program.

61. As part of its participation in the Texas Medicaid program, Defendants certified—on multiple occasions—that Duragesic was not in violation of state or federal law, and that Defendants would update Texas Medicaid if the product status changed. Despite numerous clear notices of violations from FDA, at no point in time did Defendants fulfil this duty to Texas Medicaid to update their Duragesic certification.

A. Background

62. Defendants initially launched the fentanyl pain patch in 1991 as a powerful

treatment for cancer pain. During this initial launch, Defendants' sales force primarily called on oncologists treating end-stage cancer patients, delivering the message that Duragesic was a novel pain patch option that supplied a 72-hour dose of fentanyl.

63. The only other long acting opioid in the early 1990s was Purdue Pharma L.P.'s ("Purdue") MS Contin, which Defendants recognized as their number one competitor and the "gold standard" of chronic pain management at the time. Defendants closely tracked the sales of MS Contin.

64. Defendants faced a number of early setbacks in the promotion of the fentanyl pain patch, including manufacturing issues; negative publicity as a result of patient deaths due to misuse; and an ensuing boxed warning added to its label. In spite of these setbacks, Defendants were able to expand fentanyl patch sales from $23 million in 1991 to $123 million in 1995 within the oncology market. By 1995—termed a landmark year by Defendants' leadership—sales of Duragesic surpassed that of MS Contin.

B. Defendants Expanded Duragesic's Promotion to Include Non-Cancer Pain

65. In 1995, Defendants formulated their grand ambitions for the fentanyl patch and the company, including plans to make Duragesic the drug of choice for treating chronic pain and for Duragesic to be the foundation of Janssen's pain franchise. Simply put, Defendants wanted the fentanyl patch to be their next blockbuster drug.

66. Yet, several roadblocks stood in the way. First, while the oncology market contained the vast majority of what was considered "chronic pain" at the time, the overall market size was limited. Defendants estimated, however, that they could more than double the market for their drug if all chronic pain were managed "adequately." In other words, they needed to expand their market beyond cancer pain, and then to expand what doctors considered to be chronic non-

cancer pain requiring opioid treatment. Defendants thus set out to "educate" the medical community on the so-called "undertreatment of pain," including by creating alliances with third-party pain organizations; offering Janssen-developed continuing medical education (CME) to physicians that furthered Defendants' marketing efforts; and implementing a public relations plan in various forms of media.

67. Under this new direction, Defendants' sales representatives began making sales calls on primary care physicians (PCPs) and pain specialists, directly promoting the fentanyl patch for use in non-cancer pain, such as lower back pain. One goal Defendants hoped to achieve by expanding the list of physician targets was to convince doctors to use the fentanyl patch earlier in the pain continuum, as opposed to being a treatment of last resort.

68. Additionally, Defendants prepared for the impending arrival of Purdue's latest pain medication, OxyContin, which Defendants viewed as a formidable competitor. Defendants sought to expand their Duragesic marketing to better compete against OxyContin's position as a broad-spectrum analgesic agent.

69. Finally, Defendants recognized that as of 1995, the fentanyl patch had performed well without much clinical data, but physicians were starting to request studies on Duragesic as its use became more widespread. Specifically, Defendants realized that quality of life data was needed to distinguish the fentanyl patch from its competition. Despite this lack of evidence, Defendants sought to position Duragesic based on its quality of life benefits.

70. Through 1996 and into 1997, Defendants began executing their multi-pronged approach to expand the use of the fentanyl patch and to change doctors' minds about the appropriate role of opioids in pain treatment.

C. Defendants Promoted Duragesic Using False and Misleading Tolerability and Quality of Life Messaging in 1997 and 1998, Thereby Misbranding the Product

71. As part of the strategy to gain widespread use in non-cancer pain, and to differentiate Duragesic from other pain treatment options, including OxyContin, in 1997 Defendants developed a nation-wide promotional campaign titled, "Stops the pain. Not the patient." Key components of the "Stops the pain. Not the patient." campaign included the false and misleading messages that Duragesic has fewer side effects than other opioids; that Duragesic provides a better quality of life than other opioids; and that Duragesic should be the preferred opioid of choice for chronic pain.

72. Defendants trained their sales force across the country to deliver these false and misleading messages to healthcare providers on every call, in order to differentiate Duragesic from the competition. Sales representatives were also provided with sales materials to show and/or leave behind with healthcare providers, which purported to provide support for the false and misleading messages being conveyed.

73. Defendants promoted the fentanyl patch under this campaign at least until March 5, 1998, on which date FDA's DDMAC issued an "untitled letter" to Defendants, stating that Defendants' marketing materials were in violation of the FDCA. Specifically, FDA noted:

- Defendants' "[s]tops the pain. Not the patient" message indicates "that fentanyl transdermal patch is not associated with impairment of mental or physical abilities. However, the approved product labeling contains a precaution that the use of strong opioid analgesics impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving … DDMAC considers the use of this statement to imply that the use of Duragesic is not associated with the impairment of mental or physical capabilities to be false or misleading."

- Defendants lacked substantial evidence to make various superiority claims related to safety, including that Duragesic caused significantly less constipation than morphine; that Duragesic provides less frequency and impact of side effects; and that Duragesic has a superior tolerability profile than sustained-release morphine. Specifically, Janssen failed to disclose that the Duragesic

group reported a greater number of sleep disturbances and shorter duration of sleep, as well as greater abdominal pain, difficulty breathing, and sweating.

- Defendants' statements highlighting "that the fentanyl transdermal system is recommended for use in chronic pain" is considered misleading, since the full indication also includes, "in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means…." This statement therefore promotes Duragesic for a much broader use than approved in the label.

In a letter dated April 18, 1998, FDA further noted:

- Defendants "submitted no data to substantiate such quality of life claims." Therefore, "Janssen should delete such claims or provide evidence that the use of Duragesic does significantly increase the patient's quality of life."

74. By misrepresenting Duragesic's safety, efficacy, and appropriate use through the use of promotional labeling and/or advertisements that were false and/or misleading, and inconsistent with the FDA-approved label, Defendants caused Duragesic to be misbranded in violation of state and federal law, including the TFDCA and FDCA.

D. Defendants Continued to Promote Duragesic Using False and Misleading Messages Following the 1998 FDA Letter, Thereby Misbranding the Product

75. Defendants' motivation to continue misrepresenting its drug is clear. Defendants saw that the market for long-acting opioids was experiencing tremendous growth with both Duragesic and OxyContin leading the way. Defendants also recognized that their sales representatives were a major reason for this growth, and that they were well on the way to making the billion dollar sales goal a reality. Yet, even with Defendants' campaign of misrepresentations, OxyContin surpassed Duragesic as the market leader in late 1998, and Defendants pushed to regain market leadership.

76. In response to FDA's 1998 letters, Defendants replaced sales resources that contained the phrase, "Stops the pain. Not the patient." However, beyond this superficial change, Defendants ignored the issues identified by FDA, and continued promoting Duragesic using false and misleading messages that implied the fentanyl patch was not associated with mental and

physical impairment, while improving patient quality of life, without having credible evidence to support either claim.

77. For instance, in 1999, Defendants' sales direction referenced the replacement of "Stops the pain" sales materials, yet continued to direct the sales force to deliver false and misleading messages relating to Duragesic (1) improving patients' overall quality of life; (2) having a better safety profile than other opioids; and (3) causing less constipation than other opioids. Sales representatives were again instructed to deliver these messages "on every call" to differentiate Duragesic from the competition.

78. Additionally, in order to fully convince physicians that the fentanyl patch should be used earlier in the pain continuum—and to compete with messaging being delivered by Purdue representatives—Defendants had to address some of the most troubling aspects of opioid treatment: the potential for abuse and addiction. In furtherance of this objective, Defendants provided their sales representatives with a "Pain Specialist Backgrounder" training document that, among other dubious statements, referred to the "lack of scientific evidence that opioid analgesic agents cause addiction."

79. Defendants also developed a series of presentations for "handling resistance" that were used to train sales representatives on how to respond to doctors' legitimate concerns regarding the use of strong opioids, including concerns that patients would abuse or become addicted to fentanyl. Among the false and misleading talking points contained in these presentations are the following: that "addiction in appropriate medical use is very rare"; a citation to the Porter and Jick letter[63] as purported support for a near-zero opioid addiction rate; a reference

[63] Porter and Jick is a single-paragraph letter to the editor of the New England Journal of Medicine, published in 1980 by Hershel Jick, a doctor at the University of Boston Medical Center, and Jane Porter, his graduate student, that briefly described an earlier study of hospitalized patients

to the concept of "pseudoaddiction"[64]; and redirecting physicians back to the "advantages" of the fentanyl patch when faced with concerns of abuse or addiction.

80. As before, Defendants' sales representatives were instructed to deliver, and did deliver, these false and/or misleading sales messages on thousands of calls on Texas healthcare providers, including Texas Medicaid providers and decision makers.

81. On March 30, 2000, FDA issued its second untitled letter related to the promotion of Duragesic. Among the items identified as false and/or misleading by DDMAC were as follows:

- The claim of "significantly less constipation" is false, misleading, and misrepresents the safety profile for Duragesic.
- The claim "low abuse potential" is false, misleading, and is contrary to the approved product labeling.
- Claims of increased quality of life from using Duragesic are misleading, as they have not been demonstrated with substantial supporting evidence designed specifically to assess these outcomes.

82. By misrepresenting Duragesic's safety and efficacy through the use of promotional labeling and/or advertisements that were false and/or misleading, and inconsistent with the FDA-approved label, Defendants again caused Duragesic to be misbranded in violation of state and federal law, including the TFDCA and FDCA.

E. Despite FDA Warnings, Defendants Expanded Their False and Misleading Messaging in a New Promotional Campaign for Duragesic, Thereby Misbranding the Product

83. In an effort to compete more effectively against OxyContin, Defendants in 2000 "conducted extensive market research" to better understand how the fentanyl patch was being

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treated with opioids in a regimented setting. Despite lacking scientific relevance to outpatients using opioids in a home setting, this letter has been heavily and uncritically cited for the idea that opioids very rarely cause addiction. Dr. Jick has since expressed regret in writing the letter.

[64] "Pseudoaddiction" is a questionable concept that suggests drug-seeking behavior is not necessarily a red flag signaling opioid addiction, but rather, should be addressed with an *increased* opioid dose.

perceived in the market, and how to position Duragesic going forward. Defendants outlined the results in their 2001 Business Plan: PCPs and pain specialists were interested in improving patient quality of life and restoring functionality; Duragesic was promotionally responsive (meaning, Defendants' promotion to doctors was paying off); and non-cancer pain was the growth opportunity, though "**DURAGESIC data is non-existent**" in this market. (Emphasis added). Another note underscored that Defendants "[n]eed non-malignant pain data (lower back, OA/RA)."

84. Utilizing this information, Defendants began a new promotional campaign for Duragesic, titled "Life, Uninterrupted." Under this campaign—which focused on the benefits of the fentanyl patch in non-cancer pain[65]—sales representatives were instructed to highlight how Duragesic can help patients return to a normal, pain-free life.[66] Additional benefits of the patch touted by Defendants include: achieving better quality of sleep and having fewer nighttime awakenings; improving activities of daily living; and improving functionality, such as allowing patients to "spend more time with [their] family." The stated goal of this new campaign was to "cause [physicians] to prescribe DURAGESIC as a 1st choice for chronic pain." Each of these claims had previously been identified as false or misleading by FDA's 1998 and/or 2000 untitled letters.

85. Defendants also instituted various logistical changes in selling Duragesic, including

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[65] In the 2001 Cycle Write-Up, Defendants specifically noted, "Chronic, non-malignant pain states, **such as lower back pain**, represent considerable growth opportunities for the brand; it is imperative that we accelerate our growth in these areas." (Emphasis added).

[66] The CDC recently conducted a thorough review of the scientific literature and determined that, for chronic non-cancer pain, no long-term outcomes data exists proving opioids effective at pain reduction, improving function, or improving quality of life. Dowell, *supra* note 3, at 7. Despite these unproven benefits, the evidence is very strong regarding the risks of "long-term opioid use for chronic pain," including "opioid use disorder, overdose, myocardial infarction, and motor vehicle injury." *Id*. at 12.

expanding the size of their pain sales team[67] and by increasingly focusing their promotional efforts on high opioid prescribers, which were viewed as a "significant opportunity" and the "most important customers" to the company. Both of these changes were enacted to better compete with Purdue's "share of voice" in promoting OxyContin.

86. Defendants' efforts were successful. By the end of 2001—termed a "record-breaking year for DURAGESIC"—total sales were over $540 million. At the same time, OxyContin's market share declined, due in part to media reports concerning OxyContin abuse issues. In an attempt to distinguish the fentanyl patch on the issue of abuse, Defendants disseminated to their sales force instructions to deliver the statement that "DURAGESIC is less likely to be abused than other opioids" due to its patch technology—knowing that FDA had previously found this message to be false and misleading in 2000. This was reinforced to the sales force through a number of internal communications, including in a "Cycle Write Up" and "Product News Update."

87. From 2002 onward, Defendants fine-tuned the false and misleading "Life, Uninterrupted" messages delivered by sales representatives, as well as the manner in which these messages were conveyed to healthcare providers, both nationwide and in Texas.

1. Defendants Focused the "Life, Uninterrupted" Campaign on Duragesic's Ability to Improve Patient Functionality, Which Was False and Misleading

88. Following another round of "extensive market research," Defendants in 2002 "identified the opportunity to place even greater emphasis on patient functionality." Specifically, Defendants' research showed that functionality drove brand selection; functionality was the end-benefit treatment goal; and importantly, no brand "owned" functionality. Since Defendants'

[67] Defendants' pain specialty sales force was known by various names, including 275, 340, and the Green Team.

internal business plan in 2002 continued to acknowledge the lack of non-cancer pain data, Defendants' promotional focus was not guided by science, but rather, by the desire to profit from increased fentanyl usage.

89. Defendants updated the false and misleading "Life, Uninterrupted" sales materials to reflect these market findings, and trained their sales representatives to tout the alleged physical and social functionality benefits of taking Duragesic, including better quality of sleep. Training on the new functionality message included step-by-step walkthroughs for the updated sales aid (which sales representatives were instructed to use on every call), a functionality workshop, and role playing. Defendants held various sales contests to further incentivize delivery of these functionality messages. Depending on the particular contest, top performing sales representatives could select an item from a rewards catalogue, receive an all-expense-paid vacation, or receive a monetary reward (in addition to a quarterly sales-based bonus).

90. Sales representatives in Texas delivered the updated false and misleading functionality messages to healthcare providers starting in mid-2002. Examples of the messages delivered on sales calls to Texas healthcare providers, as recorded in Defendants' call notes, include:

- "explained [Duragesic] perfect fit for these pt types due to steadier serum levels which means pain is controlled giving pts opportunity to work, walk, garden etc."
- "discussed how functionality helps improve mental health so pts want to interact with people and how 72hrs doesn't just mean pain control but more importanly improved daily activities."
- "[Discussed] increased in functioning specifically quality of sleep and increased physical functioning when on Dur."
- "painted picture of pts during holiday. focused on pts being depressed b/c they can't holiday shop, travel to see relatives. discussed using duragesic for these pts to improve functionality especially reduce depression."

- "Dur - clbp pat on loratab round the clock. conv to Dur. pat will see benifts 1) 72 hr pain relief and 2) imp in mental, social and physical functioning. Dr agreed to use dur instead of oxy."

91. Defendants disseminated false and/or misleading claims in their labeling and/or advertisements for Duragesic by stating it could restore patient functionality, improve quality of life, improve sleep quality, and provide a "Life, Uninterrupted," causing Duragesic to be misbranded in violation of state and federal law, including the TFDCA and FDCA.

2. Defendants Further Developed the False and Misleading Message that the Fentanyl Patch Has Less Abuse Potential Compared to Other Opioids

92. Publicity related to the abuse of OxyContin continued to surface in 2002. Rather than taking the responsible road of coming clean with the fact that all opioids carry a significant risk of addiction and associated abuse, Defendants instead planned to "leverage any opportunity to benefit from abuse issues."[68] In a 2002 Tactics Plan, Defendants' "Critical Success Factor Review" listed "prevent abuse issues from impacting DURAGESIC's performance." To enact this critical success factor, Defendants planned to refine their promotional messaging, and planned to implement a direct mail campaign targeted at "providers, policymakers and payors" to highlight the safety of the fentanyl patch on the measure of abuse.

93. Additionally, Defendants disseminated another abuse-related "Product News Update" to their sales teams in May 2002. In this memo, which contained the subject "Responding to DURAGESIC Abuse Potential Questions- Revised DAWN statistics," Defendants informed sales representatives that "[r]eports of DURAGESIC abuse and misuse have been low and stable since the product's introduction in the United States more than 10 years ago"; that mentions of fentanyl in the Drug Abuse Warning Network (DAWN) database support the low abuse potential of Duragesic; and that a "study" authored by David Joranson (a Janssen-funded "thought leader"),

[68] 340 Cycle 1 Sales Presentation, January 2002.

which primarily reviewed the DAWN database, found that increasing medical opioid use from 1990-1996 "does not appear to be contributing to increases in the health consequences of opioid analgesics." Information related to DAWN was further emphasized on Defendants' updated sales aid in 2002, which sales reps were instructed to use on every call.

94. Moreover, Defendants developed peer-to-peer resources for physicians containing its false and misleading message of low addiction and abuse rates. An example of this included a speaker slide deck for Duragesic, which was presented to groups of healthcare providers by physicians under contract with, and paid by, Defendants.[69] In this speaker slide deck—drafted by Defendants—one slide notes, "[t]he potential for addiction is in the patient, not the opioid," while citing to the aforementioned Porter and Jick letter on a chart showing <1% addiction rate for non-addicts. Another slide in this presentation suggested physicians should "[s]elect opioids with lower abuse potential," mirroring Defendants' Duragesic message. An additional peer-to-peer example was Defendants' Substance Abuse TeleTopic video. The slides for this presentation contained a nearly-identical chart as the speaker program slide discussed above, again citing Porter and Jick for very low addiction rates in "non-addicts." The Substance Abuse TeleTopic video also touted the advantages that long-acting opioids (such as Duragesic) provide when used by former substance abusers, including that long-acting opioids cause less drug craving, and that transdermal fentanyl has a low street value. These presentations were dangerously misleading, yet due to being delivered by doctors seemingly unaffiliated with Defendants, maintained an aura of credibility and persuasiveness.

95. Another tactic Defendants utilized to downplay issues of abuse and addiction was

[69] Such speaker programs typically took place in a lunch or dinner setting at a restaurant, where attendees' meals were also paid for by Defendants.

to enlist Janssen's Regional Medical Services to present to groups of physicians and/or pharmacists. Regional Medical Services was ostensibly intended to be a non-promotional, educational role for the purpose of disseminating unbiased medical information to interested healthcare providers. In practice, Defendants used Regional Medical Services as another promotional tool, providing marketing messages disguised as neutral and scientific medical information. For instance, in 2003 a sales representative in Texas circulated the Regional Medical Services presentation to the rest of his sales team, remarking that it "is a great resource at our disposal and there is no reason why market share should not grow if we use all our resources." Within the attached presentation was a discussion related to pseudoaddiction; a citation to Porter and Jick as support for opioids causing <1% addiction in non-addicts; and a lengthy discussion of the DAWN data. In February 2003, a Texas sales representative sent a report of her use of Regional Medical Services with pharmacists in Austin. The stated goal of this program was to target pharmacists that were frustrating Austin-area physicians "by questioning their prescribing habits" of opioids. Following this program, the Austin sales representative noted, "the Pharmacists that attended are much more secured in their outlook on pain management."

96. In Texas, sales managers ensured their representatives delivered the company messages, including false and misleading messages related to abuse and addiction. Additional guidance was provided by a Regional Training Manager, who, in 2003, sent out an e-mail to the central region (including all of Texas), to help representatives "get past" the issue of "increased 'noise' by [the] Purdue/Abbot representatives on the abuse of Duragesic." Information provided by the Regional Training Manager in this e-mail included: "Duragesic has an extremely low potential for abuse" (including a reference to DAWN); "statistics show Duragesic to be less abusable than other opioids"; and asking the physician if he/she has personally seen abuse of

Duragesic, and if not, dismissing the concern as "hearsay" and focusing back on the benefits of Duragesic.

97. Sales representatives in Texas delivered the false and misleading abuse and addiction messages on calls to healthcare providers. Examples of the messages delivered, as recorded in Defendants' call notes, include:

- "Duragesic vs Oxy - inc pain control w/ consistent serum leves/low abuse potential discussed."
- "intro call; said he is very skeptical about the amount of pain a person says they are in; concerned with abuse/addiction; [discussed] difference between addiction and tolerance vs. abuse; stressed the benefit of Dur if abuse is primary concern but also consistent relief and improvements in function; cont. to stress ease for pt's and lower abuse potential with Dur."
- "dicussed using duragesic as a foundation for first line use instead of orals. went into DAWN data to assure him fentanyl safe, not abused like oxycodone and hydrocodone. dr indicated has one pt he will start next week."
- "discussed DAWN data-less mentions for fentanly meaning he can be assured pts not going to abuse duragesic like some of his pts have abused oxy and ms. dr. said he would switch some of his oxy patients over to duragesic."
- "Said no problem with Dur. Said not many pts for Dur at this time. Said with abuse in the news, not using many pain meds. Focus on low abuse vs Oxy. True effcy which allows pts to function."

98. Accordingly, Defendants disseminated false and/or misleading claims in their labeling and/or advertisements for Duragesic by stating it rarely caused addiction, had a low abuse potential, and was less abusable than other opioids, causing Duragesic to be misbranded in violation of state and federal law, including the TFDCA and FDCA.

3. Defendants Targeted the Texas Medicaid Program with False Statements and Misrepresentations to Achieve Favorable Preferred Drug List Placement

99. As mentioned in Section V.E.2, *supra*, Texas Medicaid in February 2004 implemented the Preferred Drug List ("PDL"). Yet, for nearly a year before the PDL was legislatively created, Defendants began plotting to actively influence the process, in what was

termed the "Texas Medicaid Influencer / Key Opinion Leader Initiative."

100. Under this early Medicaid initiative, Defendants' Medicaid Business Manager asked the Texas sales teams to identify Medicaid physicians that were high prescribers of opioids, key opinion leaders ("KOLs"), and other Janssen supporters, so that Defendants could lobby them to support Duragesic's inclusion on the PDL. In relaying this initiative to his sales team, one Texas district manager noted, "[t]his is an opportunity that does not come around often."

101. Once the initial P&T Committee meeting was scheduled, Defendants took action by targeting two important segments: Janssen/Duragesic supporters (KOLs), and Texas Medicaid's newly-appointed P&T Committee members. For each, Defendants directed their sales representative to deliver their false and misleading functionality and abuse/addiction messaging, and to ask for support in getting Duragesic added to the PDL with preferred status. Defendants' sales representatives also asked KOL supporters to contact specific P&T Committee members, and provided the KOLs with the Committee members' contact information to do such.

102. Following the inaugural P&T Committee vote, Duragesic was added as a preferred drug to the PDL, while OxyContin was not recommended for preferred status. Defendants' Medicaid Business Manager acknowledged the efforts of Defendants' various sales and governmental affairs teams and noted, "[t]his win presents yet another opportunity to continue to grow Duragesic share in the Medicaid marketplace, and I'm confident we'll take full advantage of the opportunity."

103. Almost immediately thereafter, Defendants' sales teams began promoting Duragesic's preferred PDL status on calls to Texas Medicaid providers and decision makers. One Texas district manager wrote to her team, "[w]e have a great opportunity to convert OxyContin patients … the PDL looks to take effect around the first/early Feb. Why wait?" Attached to this

e-mail was a list of Medicaid physicians throughout Texas for the sales team to target.

104. Similar instructions came from another Texas district manager, who forwarded a "Texas Medicaid Duragesic Pull-through" presentation to his sales team. In this presentation—which was intended to focus his sales reps on exploiting the Medicaid "opportunity"—Defendants set market share goals specific to Texas Medicaid, *i.e.*, goals for getting more Texas Medicaid patients on the fentanyl patch. To effect this, Defendants developed a three-step Medicaid sales message: (1) "SELL DURAGESIC: Differentiate vs. oral opioids **by embellishing functionality message**; Sell directly against the leading competitor [OxyContin]" (emphasis added); (2) "SELL THE MEDICAID DECISION"; and (3) "CLOSE FOR 1st LINE USE OF DURAGESIC WITH MEDICAID PATIENTS."[70] Sales representatives were also instructed to "Brand the offices" with Duragesic giveaway items. Following up on this presentation, the district manager encouraged his sales team to make "excess calls" on Texas Medicaid physicians, and to additionally call on four pharmacies per day to "maximize pull-through efforts with Texas Medicaid."

105. Understanding Defendants' clear direction to promote directly to the Texas Medicaid program, sales representatives in Texas delivered false and misleading messages while selling Duragesic's preferred PDL placement. Examples of messages delivered, as recorded in Defendants' call notes, include:

- "Discussed Medicaid update & is pleases - says sees great results w/ pts that don't have to be "convinced" - reminded less abuse potential based on DAWN presentation, etc."
- "Lunch - Dur - medicaid changes, convert direclty to duragesic instead of orals in order to give pat's 3 nights quality sleep."
- "reinforced starting clbp pt's on Dur after [short acting opioid]'s to improve quality of sleep; [discussed] Medicaid win with Dur; gave more sample vouchers"

[70] At no point was Duragesic indicated as a first-line agent.

- "d-tx medicaid message again...tied into using it for medicaid pts on [around the clock] short or a long acting that isn't giving adequate pain relief...functionality regain in terms of not thinking of pain, xtra pill popping, safer for elderly pts (no Tylenol)...convert these pts to duragesic instead of keeping them on shorts or when currently long acting isn't giving better pain relief to impact functionality."

- "Dur - Medicaid change in Texas, Dr stated that he has problem with abuse and is looking for info on proper documentation and how to make sure he stays out of trouble. Went over functionality tear sheet and by converting these pat's to dur pat will see imp in functionality and low abuse."

F. FDA's DDMAC Issued Defendants a Warning Letter Regarding the Promotion of Duragesic in 2004

106. On September 2, 2004, FDA issued its third notice of violation to Defendants for Duragesic, this time in the form of a Warning Letter. Within this Warning Letter, FDA identified Defendants' primary sales aid for Duragesic as containing a number of false or misleading statements, which resulted in Duragesic being misbranded. Specifically, FDA identified the following claims as false or misleading:

- Any suggestion that Duragesic is less abused than other opioid drugs, including "Low reported rate of mentions in DAWN data." Specific to DAWN, FDA noted, "The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database"; and "the relatively lower number of mentions [in DAWN] could be attributed to the lower frequency of use [of Duragesic], and not to lower incidence of abuse."

- The claims, "86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep," "Significantly reduced nighttime awakenings," and "Significant improvement in disability scores" as measured by particular index scales. These claims cite the open-label, single-arm, no control group Simpson study, which is inadequate to support such claims.

- "Significant improvement in physical functioning summary score," and "Significant improvement in social functioning." These claims cite the open-label, uncontrolled Milligan study, which is inadequate in design to show an analgesic effect, and inadequate to support these outcomes claims.

- "Improved patient outcomes: open-label, crossover comparison study," "Significant improvement in physical functioning summary score," and "Significant improvement in social functioning." These claims cite the open-

label Allan study, which is inadequate to support the cited claims.

- "Work, uninterrupted," "Life, uninterrupted," "Game, uninterrupted," "Chronic pain relief that supports functionality," "Helps patients think less about their pain," and "Improvements in physical and social functioning." These claims are misleading as they "imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic," when such has not been proven by substantial evidence.

107. FDA noted, in particular, that the claims of lower abuse potential were particularly dangerous, as it "could encourage unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation." FDA concluded by requesting that Defendants send out a truthful, non-misleading "Dear Doctor Letter," due to the seriousness of the violations described above.

108. FDA's Warning Letter should not have come as a surprise to Defendants. Defendants knew at least as far back as the 2000 FDA letter that it would be false and misleading to state that the fentanyl patch was less abusable than other opioids. Furthermore, in May 2001, Defendants' Director of Medical Development admitted internally that the DAWN data was flawed because, among other reasons, "**fentanyl was not routinely screened for in 'routine' toxicology screens for patients presenting to an emergency room during this period"**. (Emphasis added). In November 2001, Defendants' own KOLs in an advisory board soundly rejected the DAWN database as a legitimate source of information on fentanyl patch abuse rates. And internally, in December 2001, Defendants' medical writing contractors expressed "grave concerns about the acceptability of the DAWN data," citing many of the same reasons FDA would later express in the 2004 Warning Letter.

109. With respect to functionality, quality of life, and sleep-related claims, Defendants knew at least as early as the 1998 FDA letter, with further instruction from the 2000 FDA letter, that these claims were unsupportable in the absence of high-quality studies meant to examine each of these particular endpoints. Further communication between Defendants and FDA in December

2000 solidified FDA's position, as memorialized in Defendants' "Record of FDA Contact" form: "Although FDA expressed willingness to work with us on study design, they were very rigid in their opinion that an open label study would not support a promotional claim" due to potential bias with the design.

G. Defendants Testified to the Texas Medicaid P&T Committee Using the False and Misleading Claims Identified by FDA in the Warning Letter

110. In November 2004, Texas Medicaid's P&T Committee was set to re-review opioids to determine drug placement on the PDL. During the P&T meeting, Defendants targeted the Committee, in the form of public testimony, with the same false and misleading messages of functionality and low abuse potential that had been identified previously in FDA's 2004 Warning Letter, including:

- **"[A]s it relates to patient functionality**, in 2003, there were two studies or two results published, one addressing work productivity and one addressing patient quality of life and functionality from a cross-over study comparing Duragesic to OxyContin and acetamin – oxycodone and acetaminophen. This was a three-month crossover study and it did show, in fact, that in months four through six that **Duragesic consistently showed improvements in the work productivity, as well as the quality of life functionalities** measured by the SF-36 and the TOPS questionnaire, specific to the pain area."

- "**Moving on from patient functionality to abuse**, I just wanted to cite one observation here, **that evidence so far presented in the Drug Awareness Network, or the DAWN data**, indicates that non-medical use or abuse or dependence of prescription of opioids has increased over the last several years. But to really put this into context, it would be useful to know the rate of change in abuse as it compares to the rate of illegitimate use – of legitimate use. The Zacny study, which was published in 2003, served to do just this. It really looked at emergency room mentions relative to prescriptions per thousand, and there were five different opioids that were referenced there. **Fentanyl, as on overall, had the lowest at .2 mentions**, followed by hydrocodone of .26, oxycodone of .69, morphine of 1.04, and hydromorphone of 2.49. **So again, really kind of putting into context that DAWN information, which is so frequently referenced, but really showing its proportion of – of the actual legitimate use in those mentions for abuse.**"

(Emphasis added).

111. Thus, despite knowing that FDA took issue with claims that were "the same as or similar to those described" within the 2004 FDA Warning Letter, including claims of functionality and low abuse potential, Defendants lied directly to the P&T Committee to maintain an advantage over their main competition, OxyContin.

112. Once again, Defendants' deception was successful. Following a vote, the P&T Committee maintained Duragesic as a preferred drug on the Texas Medicaid PDL. In response to the vote, Defendants' National Sales Director congratulated the government affairs and sales teams, saying: "Great Job! This is significant, and will certainly help in our efforts to continue growing our DURAGESIC business … now let's execute our pull through plan!"

113. The following year, in January 2005, Defendants' Medicaid Business Director sent an updated Duragesic Medicaid pull-through presentation to the Texas sales managers. Within this presentation, which lauded the continued placement of Duragesic on the Medicaid PDL, Defendants encouraged the sales force to get even more Medicaid patients on the fentanyl patch, asking the sales reps, "How High Can YOU Go??" Included in this presentation once again was the false and misleading Texas Medicaid sales message to "Differentiate vs. oral opioids by **embellishing functionality message** for the Specific Patient Type who is on Medicaid." (Emphasis added).

114. As a result, Defendants disseminated false and/or misleading claims directly to the Texas Medicaid program, related to functionality and the abuse potential of the fentanyl patch, causing Duragesic to be misbranded in violation of state and federal law, including the TFDCA and FDCA.

H. Defendants Implemented the "Grow and Defend" Strategy Using False and Misleading Messaging to Maintain Market Share Against the Generic Fentanyl Patch, Thereby Misbranding the Product

115. By 2004, sales of Duragesic nationally had soared past $1 billion, exceeding

Defendants' initial goals to make Duragesic a blockbuster drug. However, Defendants faced a looming problem for their fentanyl patch: the expiration of Duragesic's patent exclusivity and the entry into the US market of generic fentanyl patches. Typically, generic entrants[71] into a drug market spell the end for a branded drug's promotional efforts, as generic drugs are usually sold at a significant discount.

116. In an attempt to maintain their position in the market, Defendants developed the "grow and defend" plan. As described during a district manager meeting in 2004, this plan consisted of two components: "Must continue to GROW Duragesic to meet and exceed the 1.25 billion dollar forecast (Failure is not an option)" and "Must be prepared to DEFEND our billion dollar asset upon generic entry and fight to maintain our leadership position."

117. In terms of the "grow" portion of the plan, Defendants' message was similar to their prior false and misleading messaging: that Duragesic improved functionality and had less abuse potential than other opioids. On the other hand, the "defend" aspect presented a new set of false and misleading statements, including that branded Duragesic was safer, more effective, and harder to abuse than the generic fentanyl patch. Defendants summarized these points as "technology differences" between Duragesic's reservoir system and the generic fentanyl matrix patch, painting a misleading picture of the matrix patch as a simplistic, unreliable device that could easily be abused by addicts.

118. In reality, the matrix patch was an upgrade over the decade-old reservoir system used in branded Duragesic. At least as early as November 2000, Defendants' internal

[71] This assumes the generic entrant to be the therapeutic equivalent of the branded drug, as was the case with Duragesic and generic fentanyl patches. Therapeutic equivalence is an FDA designation indicating that a generic drug can be substituted with the full expectation that it will produce the same clinical effect and safety profile as the prescribed (branded) product.

"DUROGESIC Global Life Cycle Plan"[72] described the "second-generation" matrix patch as "an improved version of the reservoir patch, offering smaller sizes, greater cosmetic appeal, & reduced abuse potential." Furthermore, when developing their strategy to combat the generic matrix patch in 2004, Defendants admitted internally that it would be beneficial to conduct studies to "[u]nderstand potential safety differences between reservoir and matrix technologies." In other words, that data did not yet exist. One noted risk of this tactic was that the "[s]tudies may not provide desired results." As such, it is clear that Defendants understood that their claims of the reservoir patch being superior to the matrix version were, at best, wholly unsubstantiated.

119. Nevertheless, in mid-2004, Defendants provided an updated visual aid to their sales force, which contained the false and misleading message of Duragesic's technological superiority over the generic matrix patch. Defendants also trained their sales representatives, both nationwide and in Texas, to articulate these false and misleading technological differences during sales calls. Examples of Defendants' technology talking points can be seen on a 2004 objection handling recap document e-mailed from the Regional Training Manager to sales personnel in Texas, and included:

- "**Rate Controlling Membrane**: 80-120% Bioavailability range [with matrix] = variance for patients" … "Elderly patients may receive too much pain medicine; Unknown efficacy leads to patient non-compliance" … "Duragesic does not rely on skin to control absorption – reduces variability"
- "**Gel within Reservoir**: Makes it harder to misuse or abuse; Lowers the 'street value' of drug; DAWN Data reinforces low abuse potential"
- "**Cutting Patch**: Renders Duragesic useless – matrix reintroduces abuse potential; Doctor maintains control with Duragesic; Lowers opportunity for diversion"

(Emphasis in original).

120. Due to state pharmacy regulations in Texas,[73] a prescription for a branded drug

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72 "Durogesic" was the name given to transdermal fentanyl in non-US markets.

73 22 TEX. ADMIN. CODE § 309.3.

cannot be substituted for an equivalent generic drug if the physician hand-writes "brand medically necessary" on the prescription form. Defendants understood this regulation and began a Texas-specific campaign to mislead doctors—including Texas Medicaid physicians—by conveying that branded Duragesic was "medically necessary" due to the technological differences between the reservoir patch and generic matrix patch. In actuality, branded reservoir Duragesic is **more dangerous** than the generic matrix patch, due to the potential for the concentrated fentanyl to leak out of the reservoir. Because of this danger, in addition to the fact that FDA found the drugs to be therapeutic equivalents, stating that branded reservoir Duragesic is "medically necessary" is itself a misrepresentation. Nevertheless, Defendants' sales representatives in Texas were instructed to deliver the false and misleading "brand medically necessary" or "BMN" message on every call.

121. Pursuant to this plan, sales representatives in Texas delivered false and misleading messages to Texas healthcare providers indicating that branded Duragesic was medically necessary. Examples of messages delivered, as recorded in Defendants' call notes, include:

- "diff vs. generic using vis aid on rate controlling membrance, potential abuse, clinical data. closed her to write BMN for pts but use dur now for new starts."
- "Dur: Discussed tech piece & why import now to start writing BMN - discussed his new pt starts & comittend to all every new pt sees to writing Duragesic before Avinza."
- "Dur: Closed w/ comitment for new pt starts w/ vouchers. Work on dinner w/ Lewis & Joshi - said may invite some ortho's too. Committed to importance of BMN. Medicaid pts."
- "MEDICAID PREFERRED / TECHNOLOGY - reservoir vs. matrix - will let him know when to write BMN on triplicates - DISCUSSED HOW A VARIANCE WITH MATRIX COULD BE POTENTIALLY DANGEROUS FOR THEIR NURSING HOME PATIENTS"
- "Got into a lot of detail on technology and low abuse potential of Duragesic. Signed Dr. [] up for Rx pad program to serve as a reminder. Talked to Hank about technology also and got his buy in. F/U: Technology reminder, patient benefit message. Cover entire office."

122. Under this campaign to promote against the generic matrix patch, Defendants disseminated false and/or misleading claims in their labeling and/or advertisements for Duragesic by claiming it had superior safety and efficacy than the matrix patch, and by claiming that the reservoir version of the patch was "medically necessary," causing Duragesic to be misbranded in violation of state and federal law, including the TFDCA and FDCA.

I. In January 2005, FDA Notified Defendants that the Reservoir Patch Is Neither Safer nor More Effective than the Matrix Patch

123. Defendants' campaign against the generic matrix fentanyl patch was multi-faceted, including both litigation and regulatory actions. In terms of the regulatory action, Defendants (via Alza) submitted a "Citizen's Petition"[74] to FDA in October 2004, asserting that FDA should not approve generic matrix patch applications due to the increased potential for abuse and variability in delivery of the drug's fentanyl. In arguing this petition, Defendants cited the DAWN data (previously debunked by FDA in the 2004 Warning Letter), an "attractiveness" study showing that drug users in the US prefer to abuse the matrix patch over the reservoir version, and the idea that the matrix patch could be cut into smaller pieces.

124. FDA responded to Defendants' Citizen's Petition in January 2005, denying the request to block the matrix applications. Specifically, in terms of efficacy, FDA noted that the matrix patch was the same "dosage form" as the reservoir patch, and was successfully tested with the same bioequivalence standards as other fentanyl products, including Duragesic. FDA further noted that petitioners failed to provide any data to show the standard bioequivalence criteria were insufficient in this case. In terms of safety, FDA found that the "attractiveness" study was unreliable, as "nearly a quarter of [persons sampled] claimed experience with the fentanyl matrix

[74] A Citizen's Petition is a means through which an individual can request FDA to amend a drug's labeling or take a particular administrative action with respect to a drug.

patch, which was not available" in the markets studied; that Defendants have replaced reservoir patches with matrix patches in some European markets; and that while both the reservoir and matrix fentanyl patches may be subject to abuse, fentanyl can be extracted more rapidly from the reservoir patch.

125. Accordingly, Defendants were on notice at least as early as January 2005 that FDA considered their specific claims of superior safety and efficacy for the reservoir patch to be false, misleading, and unsupported by the evidence.

J. In 2005 and Beyond, Defendants Continued to Deliver False and Misleading Messages Related to Functionality, Abuse, and Superiority Over the Matrix Patch, Thereby Misbranding the Product

126. Despite receiving multiple regulatory notices of violations from FDA related the promotion of Duragesic, in addition to FDA's response to the Citizens' Petitions, Defendants continued training their sales representatives to deliver false and misleading Duragesic messages. These sales representatives, in turn, promoted Duragesic to Texas healthcare providers, including providers enrolled in the Texas Medicaid program, using the company-directed false and misleading messaging.

127. Examples of continued training on false and misleading messages include:

- An October 2004 e-mail from a Texas district manager to her team, asking the team to continue "differentiating Duragesic based on improved functionality";
- A March 2005 e-mail from a Texas district manager to a list of "selling skills coordinators," suggesting the use of various "dual product positioning statements," including that Duragesic "can help manage the abuse of pain meds," can "reduce your patients' side effects," and can "get your pain patients'[sic] back to work."
- A May 2005 Duragesic "functionality workshop" held by a sales district that contained portions of both Oklahoma and Texas, with instructions from the district manager to use the information during sales calls;
- An e-mail in May 2005 from a district manager to her team, reminding the sales team that "With Duragesic, the steady state provides consistent pain relief AND

a full night sleep. Remember to relate the improvement in quality of life for each patient and a return to a high function level"; and

- An August 2005 training document sent to the Southwest Region Management Team (which covers Texas), that suggested sales representatives deliver a message including, "Branded Duragesic will provide 3 days of pain free living, 3 nights of painless sleep. They can return to their life of activity…"

These were not isolated incidents. Rather, these examples represent communications to and from the major sales districts in Texas, and at times involved the Regional Business Director over the region covering Texas.

128. Defendants' sales representatives were required to promote Duragesic according to Defendants' sales direction. From 2005 to 2006, Defendants' sales representatives delivered the false and misleading "brand medically necessary" and "technology" messages on thousands upon thousands of sales calls in Texas, including calls on Texas Medicaid healthcare providers and decision makers.

K. Defendants Internally Admit the Truth Regarding Duragesic

129. In early 2006, Defendants' Therapeutic Area Head for Analgesia and GI sent an internal memo summarizing the basis for Defendants' arguments against the matrix patch, which included two main (albeit flimsy) justifications—which FDA had previously rejected in 2005: the debunked "attractiveness" study, and unsupported predictions from one of Defendants' paid contractors that suggested it would be easier to abuse the matrix patch. The memo then concluded that Defendants should not conduct another "attractiveness" study for a number of reasons, notably including that the contractor's predictions of widespread abuse of the matrix patch simply had not borne out.

130. Later, in February 2008, Defendants' Product Director for Duragesic circulated an internal e-mail stating, among other things, that "Active surveillance initiated by our company that monitors abuse & diversion has not found definitive evidence of increased risk or misuse of the

matrix systems," which, he concludes, tended to refute the company position that the matrix system had higher abuse potential.

131. Finally, in March 2008, Defendants' Product Director relayed to others within the company that FDA had "strongly encourage[d] our organization to move to a matrix system," specifically referencing a recent safety issue with the reservoir patch. Defendants initiated this change and replaced the Duragesic reservoir system with a matrix system in 2009. However, by the time this change occurred, Defendants had ceased actively promoting Duragesic in the United States.

132. All in all, Defendants made billions pushing their addictive and dangerous fentanyl patch while using various false, misleading, and unsupported claims.

VIII. CAUSES OF ACTION

133. Plaintiff re-alleges and reincorporates by reference as set forth herein the allegations contained in Paragraphs 1 through 132 of this Petition.

A. Defendants' Violations of the TMFPA[75] for Which Plaintiff Seeks Civil Remedies and Penalties

134. Defendants knowingly made or caused to be made false statements and/or misrepresentations of material facts to Texas Medicaid in applying for Duragesic's inclusion on the VDP formulary, and during the Texas Medicaid PDL process. Furthermore, Defendants' false statements and/or misrepresentations permitted Defendants to receive benefits under the Medicaid program that were not authorized or that were greater than the benefits authorized, including, but not limited to, inclusion on the VDP formulary and PDL, and virtually-unfettered reimbursement

[75] In August of 2005, applicable provisions of the TMFPA were amended as set forth in Paragraphs 56 through 57, *supra*. Plaintiff is seeking the appropriate remedies for Defendants' unlawful acts (which include Defendants' conduct both prior to and after August 2005 for purposes of this lawsuit), as defined in the TMFPA at the time such unlawful acts were committed.

of Duragesic, in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002(1)(A), (B).

135. Defendants knowingly concealed or failed to disclose events or information from Texas Medicaid in conjunction with the VDP, DUR, and PDL processes. This conduct permitted Defendants to receive benefits under the Medicaid program, including, but not limited to, virtually unfettered reimbursement of Duragesic that was not authorized or that was greater than the benefits authorized, in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002(2).

136. Defendants knowingly or intentionally made, or caused to be made, induced, or sought to induce the making of false statements and/or misrepresentations of material facts concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002(4)(B).

137. As a result of Defendants' conduct, the Texas Medicaid program was prevented from making fully informed and appropriate policy decisions, and from fully utilizing the tools and safeguards available to the program, including the VDP, DUR, and PDL processes, to manage appropriately the reimbursement of Duragesic prescriptions. Defendants' illegal conduct, therefore, resulted in millions of dollars of unauthorized, or greater-than-authorized, reimbursements for Duragesic by the State of Texas. Defendants' conduct additionally resulted in Defendants receiving the benefit of having Duragesic listed and maintained on the Texas Medicaid formulary during times when the drug was in violation of federal and state law.

138. Under the TMFPA, each Defendant is liable to the State of Texas for the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of its unlawful acts; two times the amount of those payments or the value of the benefit; pre-judgment interest on the amount of those payments or

the value of the benefit; and a civil penalty for each unlawful act committed, in addition to reasonable fees, expenses, and costs of the State of Texas in investigating and obtaining civil remedies in this matter. TEX. HUM. RES. CODE §§ 36.052, 36.007, 36.110(c); TEX. GOV'T CODE § 402.006(c).

139. Plaintiff invokes in the broadest sense all relief possible at law or in equity under TEX. HUM. RES. CODE § 36.052, whether specified in this pleading or not.

140. The amounts sought from each Defendant are in excess of the minimum jurisdictional limits of this Court.

141. The TMFPA is a statute of absolute liability. There are no statutory, equitable, or common law defenses for any violation of its provisions. Further, Texas jurisprudence provides that the defenses of estoppel, laches, and limitations are not available against the State of Texas as a Sovereign.[76]

B. <u>Defendants' Violations of the TMFPA for Which Plaintiff Only Seeks Civil Penalties</u>

142. Plaintiff re-alleges and reincorporates by reference as set forth herein the allegations contained in Paragraphs 1 through 141 of this Petition.

143. Under the TMFPA, Defendants are liable to the State of Texas for a civil penalty for each unlawful act committed by Defendants without regard to whether that violation resulted in a payment by the Texas Medicaid program. TEX. HUM. RES. CODE § 36.052(a)(3).

144. Defendants' false and/or misleading messages regarding the safety, efficacy, and appropriate use of Duragesic were disseminated repeatedly on thousands of sales calls on Texas Medicaid providers and decision makers. Each time that Defendants knowingly made, caused to be made, induced, or sought to induce the making of such false and/or misleading statements to a

[76] *State v. Durham*, 860 S.W.2d 63, 67 (Tex. 1993).

Texas Medicaid provider or decision maker concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, Defendants committed an unlawful act under the TMFPA. *See* TEX. HUM. RES. CODE § 36.002(4)(B).

145. Defendants' widespread use of a false and/or misleading sales aid (and associated messaging) from 2002-2004, described in detail in Paragraphs 83 – 109, *supra*, provides just one of numerous examples of this type of unlawful act. Defendants' sales aid, which was characterized by FDA as false and misleading based on its presentation of Duragesic data, was utilized by Defendants' sales force during thousands of sales calls to Texas Medicaid providers and decision makers.

146. Defendants also knowingly made, caused to be made, induced, or sought to induce the making of false and/or misleading statements in violation of the TMFPA to Texas Medicaid providers and decision makers through journal publications, promotional materials (including the dissemination of false and misleading materials developed by third parties), advisory boards, continuing medical education ("CME"), company-sponsored speeches, sales calls, and other means.

147. Additionally, Defendants knowingly engaged in conduct that constituted a violation under TEX. HUM. RES. CODE § 36.002(5) by knowingly paying money, a gift, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product, where the cost of the service or product is paid for, in whole or in part, by the Medicaid program. By way of example, Defendants utilized peer-to-peer speaker program nominations as an incentive to increase prescribing from nominated physicians, including for prescriptions that were reimbursed by the Texas Medicaid program.

148. Plaintiff, therefore, seeks civil penalties under the TMFPA for each of Defendants' unlawful acts under the TMFPA. Plaintiff will seek an amount of civil penalties that will be justified and appropriate under the facts and the law.

IX. STATUTORY INJUNCTION UNDER § 36.051 OF THE ACT

149. The Attorney General has good reason to believe the Defendants are committing, have committed, or are about to commit unlawful acts as defined by the TMFPA. These illegal acts may be enjoined under § 36.051 of the TMFPA.

X. JURY DEMAND

150. Plaintiff respectfully requests a trial by jury on all claims pursuant to Texas Rules of Civil Procedure 216.

XI. PRAYER

151. Plaintiff asks that judgment be entered upon trial of this case in favor of the State against Defendants to the maximum extent allowed by law.

152. Plaintiff asks for injunctive relief pursuant to § 36.051 of the TMFPA.

153. The State of Texas asks that it recover from Defendants under the TMFPA:

A. the amount of any payments or the value of any monetary or in-kind benefits provided under the Texas Medicaid program, directly or indirectly, as a result of Defendants' unlawful acts;

B. two times the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of Defendants' unlawful acts;

C. civil penalties in an amount not less than $1,000 or more than $10,000 for each unlawful act committed by Defendants before May 4, 2007; in an amount not less than $5,000 or more than $10,000 for each unlawful act committed by Defendants on or after May 4, 2007 and prior to September 1, 2011; and in an amount not less than $5,500 or more than $11,000 for each unlawful act committed by Defendants on or after September 1, 2011;

D. prejudgment interest;

E. expenses, costs, and reasonable attorneys' fees; and

F. post-judgment interest at the legal rate.

154. Plaintiff seeks monetary relief in excess of $1,000,000.

Respectfully submitted,

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