CAUSE NO. 23-1030

THE STATE OF TEXAS, *ex rel.* **[UNDER SEAL]**	§	**IN THE DISTRICT COURT**
Plaintiffs,	§	
v.	§	**71st JUDICIAL DISTRICT**
[UNDER SEAL]	§	
Defendants.	§	**HARRISON COUNTY, TEXAS**

FILED UNDER SEAL

CAUSE NO. 23-1030

THE STATE OF TEXAS, *ex rel.* TARIK AHMED	§	**IN THE DISTRICT COURT**
Plaintiffs,	§	
v.	§	**71st JUDICIAL DISTRICT**
TRIS PHARMA, INC. and KETAN MEHTA	§	
Defendants.	§	**HARRISON COUNTY, TEXAS**

PLAINTIFFS' FIRST AMENDED PETITION

The State of Texas, by and through the Attorney General of Texas, Ken Paxton, (the State) and Private Person Plaintiff/Relator Tarik Ahmed (Relator) bring this law enforcement action pursuant to the Texas Medicaid Fraud Prevention Act (TMFPA), TEX. HUM. RES. CODE Chapter 36.[1] Plaintiffs, the State and Relator, file this First Amended 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 fraudulent conduct committed by Tris Pharma, Inc. (Tris) and Tris CEO Ketan Mehta (Mehta). Specifically, Defendants targeted Texas Medicaid with a fraudulent marketing

[1] On September 1, 2023, TEX. HUM. RES. CODE Ch. 36 was expanded to include state health care programs beyond the Medicaid program. In this action, however, most of the conduct at issue pre-dates September 1, 2023, and Plaintiffs seek only remedies with respect to the Medicaid program. Accordingly, Plaintiffs refer to the pre-September 2023 version of TEX. HUM. RES. CODE Ch. 36.

scheme for their powerful ADHD drug, Dyanavel XR (Dyanavel). Under this scheme, Tris, at the direction of CEO Mehta, disseminated false and/or misleading messages overstating the drug's efficacy during thousands of sales calls to doctors and other healthcare practitioners who were enrolled Texas Medicaid providers. Additionally, as part of this unlawful marking scheme, Tris misrepresented Dyanavel's efficacy directly to Texas Medicaid decision-makers during public testimony. This illegal conduct caused Dyanavel to be in violation of state and federal law, and rendered false Tris's sworn certification of compliance to Texas Medicaid, which is required for drugs to be listed on the Texas Medicaid formulary. As a result, Tris obtained the benefit of virtually unfettered Medicaid reimbursements for Dyanavel on the basis of fraudulent and unlawful misrepresentations, and in so doing, Tris and Mehta violated the TMFPA.

III. THE PARTIES

A. Plaintiffs

3. Plaintiffs are the State of Texas, by and through the Attorney General of Texas, Ken Paxton, and Relator Tarik Ahmed (collectively, Plaintiffs).

4. Relator Tarik Ahmed is a citizen of the United States and a resident of New Jersey. From 2013 until approximately June 2017, Relator was employed by Defendant Tris as Head of Technology. During his time at Tris, Relator also served as the Head of the IT Steering Committee, and was a member of the Executive Committee, Quality Committee, and Commercial Committee. Through his employment at Tris, Relator gained a wealth of direct and independent knowledge of Defendants' unlawful marketing practices.

B. Defendants

5. Defendant TRIS is a corporation organized under the laws of New Jersey and has its principal place of business in New Jersey, at 2031 U.S. Highway 130, Monmouth Junction,

New Jersey 08852. Tris marketed and distributed Dyanavel in Texas. Tris conducts business in Texas. At the time of filing, its registered agent for service of process is CT Corporation System, 1999 Bryan St., Ste. 900, Dallas, TX 75201.

6. Defendant MEHTA is the founder and Chief Executive Officer of Tris. CEO Mehta may be served with process at his home address: 42 Elm Road, Princeton, New Jersey 08540. CEO Mehta has direct knowledge of and directly participated in substantially all of the fraudulent conduct alleged herein.

IV. JURISDICTION AND VENUE

7. 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.

8. Since at least 2015, the State of Texas has licensed Defendant Tris to sell and distribute its drugs throughout Texas. This Court has jurisdiction over Defendant Tris because it purposefully availed itself of the benefits, privileges, and responsibilities of doing business in Texas; subjected itself to Texas law, including the TMFPA; and then committed unlawful acts, in whole or in part, in Texas.

9. This Court has personal jurisdiction over Defendant CEO Mehta, a non-resident of Texas, because from 2015 to the present, he has purposefully availed himself of the privileges and benefits of conducting business in Texas. CEO Mehta, either personally or by his direction of others: 1) caused Dyanavel to be marketed, sold, and/or distributed to Texas customers, including Texas Medicaid providers; 2) caused Dyanavel to be included in the Texas Medicaid formulary; and 3) applied for and obtained from the State of Texas a license for Tris to sell and distribute its drugs in Texas. CEO Mehta's purposeful availment of the privileges and benefits of conducting

business in Texas and committing unlawful acts in violation of the TMFPA create sufficient minimum contacts with Texas to give this Court personal jurisdiction over him.

10. Venue is proper in Harrison County, Texas and this judicial district pursuant to TEX. HUM. RES. CODE § 36.052(d), as Plaintiffs' causes of action are based upon alleged violations of the TMFPA which occurred, in part, in Harrison County.

11. More specifically, Tris sales representatives promoted Dyanavel to healthcare providers in Harrison County, including physicians participating in the Texas Medicaid program. During these sales calls, the Tris sales employees were instructed to promote, and did promote, Dyanavel using false and misleading messages of efficacy.

V. BACKGROUND

A. ADHD and Dyanavel XR

12. ADHD is a chronic and debilitating condition affecting millions of children in the United States.[2] As a neurodevelopmental disorder, ADHD can cause persistent problems such as difficulty sustaining attention, hyperactivity, and impulsive behavior.[3] Typically diagnosed in school-aged children, it can cause struggles with low self-esteem, troubled relationships, and poor performance in school.[4]

13. There is no cure for ADHD. Rather, the goal of pharmacological treatment is to manage the symptoms that would otherwise be present.[5] The most commonly prescribed medications used to help improve the signs and symptoms of ADHD are methylphenidates and

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[2] American Psychiatric Association, *What is ADHD*, available at https://www.psychiatry.org/patients-families/adhd/what-is-adhd (last visited Nov. 8, 2023).

[3] Mayo Clinic Patient Care & Health Information, *Attention-deficit/hyperactivity disorder (ADHD) in children*, available at https://www.mayoclinic.org/diseases-conditions/adhd/symptoms-causes/syc-20350889 (last visited Nov. 8, 2023).

[4] *Id.*

[5] American Psychiatric Association, *What is ADHD*, available at https://www.psychiatry.org/patients-families/adhd/what-is-adhd#section_5 (last visited Nov. 8, 2023).

amphetamines.[6] These medications form the foundation of the multibillion-dollar ADHD pharmaceutical industry.

14. Dyanavel is an extended-release oral suspension amphetamine indicated for the treatment of ADHD in patients six and older. It is a Schedule II Controlled Dangerous Substance and is required by the Federal Food and Drug Administration ("FDA") to display a "Black Box Warning"—FDA's strictest labeling requirement—for abuse and dependence. The drug is supplied as a liquid and includes an oral dosing dispenser.

15. Though Dyanavel is approved by the FDA as acceptably safe and effective for ADHD when taken as directed, it still has risks associated with normal use. According to the FDA, the most common adverse reactions include drug dependence, cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, and long-term suppression of growth, many of which can be develop into serious issues.[7] Additionally, when Dyanavel is not taken at the correct dose, patients could experience an overdose requiring medical intervention.[8] A severe overdose of Dyanavel can be fatal.[9]

B. The FDA Regulatory System

1. The FDA's Role in Regulating Prescription Drug Promotion

16. 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

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[6] *Id.*

[7] Tris Pharma, Inc. Dyanavel XR (amphetamine) [package insert], Section 5, Warnings and Precautions. U.S. Food and Drug Administration website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208147s016,210526s008lbl.pdf. Revised October 2023 (last visited Nov. 8, 2023).

[8] *Id*, at Section 10, Overdosage.

[9] *Id.*

marketed in the United States unless the sponsor of the drug demonstrates to the 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."[10] 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."[11] Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

17. To determine whether a drug is "safe and effective," the 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."[12]

18. The FDCA requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness.[13] The gold standard example of an "adequate and well-controlled investigation" is a study that is double-blinded and placebo-controlled.[14] 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."[15] 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.[16] Importantly, FDA's determination of a drug's "safety" consists of a risk-benefit analysis that includes consideration of the severity of conditions

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[10] 21 U.S.C. § 355(d)(5). "Substantial evidence," as used in this section, is defined at 21 U.S.C. § 355(d)(7).
[11] 21 U.S.C. § 355(d)(1).
[12] 21 U.S.C. § 355(b)(1)(A).
[13] *See* 21 U.S.C. § 355(d)(7).
[14] 21 CFR § 314.126(b).
[15] 21 CFR § 314.126(e).
[16] *See* 21 U.S.C. § 355(d)(5).

for which the drug's approval is sought, as well as the other available treatments for such conditions.[17]

19. 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.[18] 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.[19]

2. FDA Regulations Prohibit the Misbranding of Prescription Drugs in Labeling

20. Under the FDCA, it is illegal to misbrand a drug, or to introduce into interstate commerce any drug that is misbranded.[20] 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.[21]

21. "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."[22] Courts have interpreted labeling broadly to encompass printed material even when not physically attached or connected to the related pharmaceutical product.[23]

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[17] *See* 21 U.S.C. § 355(d)(7).
[18] *See* Section V.B.2, *infra*.
[19] *See* 21 U.S.C. § 355(d)(7).
[20] 21 U.S.C. §§ 331(a), (b).
[21] 21 U.S.C. §§ 352(a), (f), (n).
[22] 21 U.S.C. § 321(m).
[23] *See Kordel v. United States*, 335 U.S. 345 (1948).

22. 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.[24] Under these regulations, 21 CFR § 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." For prescription drug products that require the supervision of a medical professional to safely administer, 21 CFR § 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). Accordingly, where a prescription drug's labeling does not contain accurate statements on each of these points, then under 21 CFR § 201.100, the drug does not meet the requirements for adequate directions for use by a layperson and is misbranded.

23. FDA requires pre-approval of changes to prescription drug labels.[25] Thus, a manufacturer cannot unilaterally amend the label to include new statements of efficacy, duration, or dosing.[26] If a manufacturer acts in contravention of this requirement, the drug will necessarily be misbranded at that point in time for failing to provide adequate directions for use, in violation of the FDCA.

3. FDA Regulations Prohibit the Misbranding of Prescription Drugs in Advertisements

24. Prescription drug advertising, on the other hand, does not involve written, printed,

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[24] *See* 21 CFR §§ 200-369.

[25] *See* 21 CFR §§ 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).

[26] As discussed in Section V.B.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.

or graphic material, and is governed separately by the FDA CFRs. *See* 21 CFR § 202.1. An example of prescription drug advertising would be a drug company's sales representative delivering a sales message to a doctor regarding a prescription pharmaceutical product.

25. Among other restrictions, prescription drug advertisements must provide a "[t]rue statement of information in brief summary relating to side effects, contraindications, and effectiveness." 21 CFR § 202.1(e). In this context, a drug company fails to provide a "true statement of information" if the advertisement "is false or misleading with respect to side effects, contraindications, or effectiveness," or the advertisement fails to present fair balance between efficacy and side effects. 21 CFR § 202.1(e)(5).

26. Where a drug company fails to comply with FDA's established advertising regulations, the drug is deemed to be misbranded under the FDCA. *See* 21 U.S.C. § 352(n).

27. In sum, the misbranding regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs in a manner other than as approved by an independent, scientific government body—the FDA. Moreover, the prohibition on false or misleading claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on deceptive marketing tactics.

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

28. FDA's Office of Prescription Drug Promotion ("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 (c) does not misbrand the drug.[27]

29. OPDP's ability to regulate misbranding is limited. Moreover, materials promoting

[27] *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).

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.[28] Upon finding a violation, OPDP generally requests the company stop using the violative promotional materials.[29] OPDP occasionally requires sponsors to publicly correct product misimpressions created by materials that are false, misleading, and/or lacking in fair balance.[30]

C. Texas's Role in Regulating Prescription Drugs

30. 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).[31]

31. 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.[32] 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 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.[33]

32. Violations of the TFDCA, including violations of rules adopted under the TFDCA,[34] can result in a written warning; administrative penalties; civil penalties; or criminal

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[28] *See id.*

[29] *Id.*

[30] *Id.*

[31] TEX. HEALTH & SAFETY CODE, Ch. 431, *et seq.*

[32] *See* TEX. HEALTH & SAFETY CODE §§ 431.021(a), (b).

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

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

penalties.[35]

D. Texas Medicaid

1. Overview

33. The state and federal governments fund health care for the poor and disabled through public health assistance programs. Together, the State of Texas and the federal government fund the Medical Assistance Program in Texas, commonly referred to as Texas Medicaid. Texas Medicaid provides vital health care coverage to Texas's most vulnerable populations.[36] It is a lifeline ensuring that children, pregnant women, elderly adults, and disabled individuals receive the medical care they need.[37]

34. 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.[38] Texas Medicaid reimburses participating providers for the approved pharmaceuticals they provide to Medicaid recipients. The program strives to provide safe and effective health services to beneficiaries while maximizing the efficient use of taxpayer funds within the Texas Medicaid program.[39] To that end, Texas Medicaid uses various procedures to monitor and control prescription drug benefits.

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

35. The Vendor Drug Program (VDP) within HHSC oversees the outpatient prescription drug portion of the Texas Medicaid program.[40] VDP is also charged with safeguarding

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[35] *See* TEX. HEALTH & SAFETY CODE §§ 431.061, 431.054, 431.0585, 431.059.

[36] *See* TEX. HUM. RES. CODE § 32.001.

[37] *See* 1 TEX. ADMIN. CODE § 358.107; 1 TEX. ADMIN. CODE § 366.307; 1 TEX. ADMIN. CODE § 366.507.

[38] TEX. GOV'T CODE § 531.021.

[39] *See In re Xerox Corp.*, 555 S.W.3d at 524.

[40] *See* 1 TEX. ADMIN. CODE § 354.1809, § 354.1891; TEX. GOV'T CODE § 531.069.

against fraud, waste, and abuse within the program.[41] VDP was in operation at all times relevant to this case.

36. 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.[42] To have its particular pharmaceutical products listed on the VDP formulary, a drug company or manufacturer must file an application with VDP.[43] 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.[44] VDP may return or reject an application on the discovery of "false, erroneous, or incomplete information."[45]

37. 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.

38. By signing the application, manufacturers accept an ongoing duty to submit notifications of changes pertaining to the information in their application no later than the date such revisions are scheduled to occur, and to submit notifications of any changes pertaining to their product's status, formulation, or availability within fifteen days of such changes occurring. Accordingly, manufacturers owe a continuing duty to Texas Medicaid to supplement information

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[41] *See* 1 TEX. ADMIN. CODE § 354.1891.

[42] 1 TEX. ADMIN. CODE § 354.1831(a). The VDP formulary is also referred to as the Texas Drug Code Index or TDCI. *See* 1 TEX. ADMIN. CODE § 354.1921.

[43] 1 TEX. ADMIN. CODE § 354.1921(b).

[44] *Id. See also* 1 Tex. Admin Code § 354.1923(b).

[45] 1 Tex. Admin Code § 354.1923(b)(1).

provided with their VDP application.[46] Moreover, a new VDP application must be submitted each time a drug first becomes available in a new formulation or in different dosages.

39. 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.[47] Pursuant to that obligation, Texas Medicaid created the DUR program to promote optimal and cost-effective pharmaceutical therapy in the Texas Medicaid VDP.[48]

40. Specifically, the DUR program exists to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes.[49] The program is designed to educate providers and to identify and reduce the frequency of patterns of fraud, abuse, overuse, or inappropriate or medically unnecessary care.[50]

41. 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.[51] 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 which Medicaid reimbursement is obtainable.[52] As part of this program, the DUR Board monitors

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[46] *See* 1 Tex. Admin Code § 354.1921(c)(1).

[47] H.R.5835 - 101st Congress (1989-1990): Omnibus Budget Reconciliation Act of 1990, H.R.5835, 101st Cong. (1990), https://www.congress.gov/bill/101st-congress/house-bill/5835; *see also* 1 TEX. ADMIN. CODE § 354.1941.

[48] *See* TEX. GOV'T CODE § 531.0736; *see also* 1 TEX. ADMIN. CODE § 354.1941.

[49] *See* TEX. GOV'T CODE § 531.0736(k).

[50] *See id.*, § 531.0736(b).

[51] *See* TEX. GOV'T CODE § 531.0736(k); *see also* 1 TEX. ADMIN. CODE § 354.1831(b), § 354.1941(a).

[52] *See* 1 TEX. ADMIN. CODE § 354.1831(b), § 354.1941(a).

and analyzes provider-level activity.[53]

42. The DUR Board is also tasked with developing recommendations for the Texas Medicaid Preferred Drug List (PDL), providing another mechanism for managing Texas Medicaid's expenditures for pharmaceuticals.[54] In making these recommendations, the DUR Board must consider the clinical efficacy, safety, and cost-effectiveness of each drug reviewed.[55] HHSC then decides which drugs are placed on the PDL based on DUR Board 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 or other program benefits.[56] Drugs that are reviewed but not selected for the PDL require prior authorization.[57]

43. In carrying out its functions, the DUR Board frequently receives information from drug manufacturers, including Defendants, concerning their drugs.[58] The DUR Board expects—and Texas law requires—all such information to be complete and accurate. The DUR Board cannot effectively make recommendations to manage drug utilization through clinical edits, the PDL, or other interventions where material information has been misrepresented or concealed by a drug company.

44. The Texas Medicaid program includes not just Medicaid decision-makers such as the VDP and DUR Board, but also Medicaid providers such as pharmacies and physicians that

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[53] *See* TEX. GOV'T CODE § 531.0736(g); *see also* 1 TEX. ADMIN. CODE § 354.1941(a).

[54] *See* TEX. GOV'T CODE § 531.0736(b)(1). Previously, the Pharmaceutical and Therapeutics Committee (P&T Committee) made recommendations regarding the PDL. In 2016, however, the P&T Committee and DUR Board combined into a single, expanded, committee known as the DUR Board, which now handles the functions of the two previous committees. S.B. 200, 84th Leg. (Tex. 2015) (enacted).

[55] *See* TEX. GOV'T CODE § 531.0736(h).

[56] 1 TEX. ADMIN. CODE § 354.1924(c).

[57] *See* 1 TEX. ADMIN. CODE § 354.1832(a).

[58] *See* TEX. GOV'T CODE § 531.0736(g).

enter into agreements with Texas Medicaid in order to be covered providers.[59] The TMFPA seeks to protect against fraud at all levels of the Texas Medicaid program.[60] Providers cannot fully exercise their professional judgment regarding appropriate patient care for Medicaid beneficiaries when drug companies misrepresent or conceal material information about a drug's status.

VI. APPLICABLE TEXAS STATUTORY LAW

45. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 44 of this Petition.

46. A person commits an unlawful act as defined under the Texas Medicaid Fraud Prevention Act[61] 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).

47. 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 46 applied and was done in ways and through means that satisfy

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[59] *See* 1 TEX. ADMIN. CODE § 352.5(a), § 354.1801(g).

[60] *See* TEX. HUM. RES. CODE § 36.001 *et seq.*

[61] As amended on September 1, 2023, the Texas Medicaid Fraud Prevention Act is now the "Texas Health Care Program Fraud Prevention Act" and includes state health care programs beyond the Medicaid program. The substance of the unlawful acts remains unchanged.

all the required elements of at least one applicable statutory provision.

VII. DEFENDANTS' UNLAWFUL ACTS

48. Shortly after Dyanavel received FDA approval, Tris, at the direction of CEO Mehta, submitted a VDP application for inclusion on the Texas Medicaid formulary, which required Tris to certify that its product was not in violation of state or federal law, and that Tris would update Texas Medicaid if the product status changed. At no point in time did Defendants fulfill the duty to Texas Medicaid to update their Dyanavel certification.

A. Background

49. When Dyanavel joined the ADHD market in 2015, it was late to the party. The market was already crowded with multiple, well-established competitors, including fellow amphetamine Adderall XR; popular drug Vyvanse; Tris's other ADHD medication, Quillivant XR; and a number of cheap, generic drugs.

50. To gain a foothold in this lucrative—but competitive—market, Tris needed to convince doctors that they should prescribe Dyanavel to their patients instead of the existing ADHD treatments. To do that, Tris needed to find a way to differentiate Dyanavel from these established treatments.

51. Tris's early pre-launch market research, however, found that Dyanavel was perceived by doctors as lacking innovation and failing to satisfy an unmet medical need in the ADHD drug category. In other words, Dyanavel was seen as being more of the same. Predictably, uptake of Dyanavel was very low in 2016.

52. Dyanavel's perception as a "me too" product was a problem for Tris, particularly in the Medicaid space where utilization controls such as clinical edits and preferred drug lists could further inhibit the drug's adoption. Specifically, in a late-2016 internal email, Tris's Chief Medical

Officer worried that Texas Medicaid would restrict Dyanavel for use in patients that have difficulty swallowing pills, absent some other differentiating factor. The imposition of a clinical edit as such would have greatly reduced Tris's access to the Texas Medicaid population, and consequently the money Tris could make off the vulnerable Medicaid population.

B. Defendants Promoted Dyanavel XR as Having Onset as Early as 30 Minutes, Which Was False and Misleading

53. Through additional market research, Tris identified one possible way to differentiate Dyanavel from the competition: early onset.[62] Unfortunately for Tris, they had no data to support an early onset claim, as Dyanavel's FDA-approved label listed onset at one hour—a full 15 minutes slower than Tris's other ADHD medication, Quillivant XR. To overcome this problem, Defendants needed a way to create the data it wanted.

54. At the insistence of Tris CEO Mehta, Tris quickly designed a small study with the purpose of showing onset as early as 30 minutes. Tris submitted the study protocol to FDA in February 2017 for a special protocol assessment, wherein FDA would review the proposed study and provide feedback on whether the study design is sufficient to support changing the product's label.

55. But Tris CEO Mehta had a "dream"—to obtain 30-minute onset data and to start promoting it in the first quarter of 2017. Accordingly, he instructed Tris personnel to go ahead with the study as designed, prior to receiving FDA's feedback. The study commissioned by CEO Mehta was completed shortly thereafter, and sought to measure the effect on patients using both a subjective and objective assessment. The study included only eighteen participants.

56. Tris received the topline results of the small study on March 21, 2017. According to this data, while Dyanavel showed statistical significance at 30-minutes based on the subjective

[62] In this context, "early onset" refers to a medication working quickly when ingested.

SKAMP[63] assessment, it did ***not*** show statistical significance on the objective PERMP[64] measurement. Thus, even before concocting a marketing scheme based on 30-minute onset, CEO Mehta and other high-level Tris officers knew that the pilot study, at best, provided mixed results, and at worst, was a failure.

57. Just over a week later, FDA provided its feedback on the special protocol assessment for the already-completed study. Among other comments, FDA noted that "the design and planned analysis of your study do not adequately address the objectives necessary to support a regulatory submission." In particular, FDA noted that it did not consider a single, "well-controlled" trial design—which FDA made clear this was not—sufficient to support "any broad promotional statement, such as 'Dyanavel XR provides therapeutic effect in 30 minutes.'" FDA further explained that such broad claims would be "deemed objectionable" due to a lack of evidence for adolescents and the lack of a second well-controlled trial."

58. Receipt of FDA's serious concerns did not deter CEO Mehta from pushing forward with the promotion of 30-minute onset. Under his direction, Tris submitted the new 30-minute onset claims to its internal Promotional Review Committee (PRC) to review for inclusion in Dyanavel's Core Visual Aid (CVA). The CVA is the primary promotional tool used by sales representatives during sales calls with doctors and must adhere to FDA's strict labeling guidelines.

59. On reviewing the 30-minute onset data, Tris's Regulatory Affairs group suggested deleting the proposed chart of the study's results—the central graphic on the page—"given [the] nature of study and study limitations." But Tris Commercial and Tris Leadership chose to include the misleading graph against the advice of Regulatory Affairs.

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[63] SKAMP stands for "Swanson, Kotkin, Agler, M-Flynn, and Pelham," and is a subjective, 13-item rating of subject impairment of classroom observed behaviors made by an independent observer.

[64] PERMP stands for "Permanent Product Measure of Performance," and is essentially a math test used to assess ADHD patients.

60. CEO Mehta maintained direct involvement in pushing the new CVA through Tris's internal approval process. A week after submitting the new promotional claims for consideration, CEO Mehta questioned why it was taking so long for PRC to approve the CVA with the new 30-minute data.

61. Around the same time, Tris's Chief Medical Officer reached out to the principal investigator of the 30-minute study to determine if she would be willing brief Tris's speakers on the study and its findings.[65] The principal investigator replied that while she was fine being credited with conducting the study, she did not want to brief anyone as she wanted to avoid "encouraging off label talk."[66] Tris's Chief Medical Officer also commented that the study data "will not be included in the speaker [PowerPoint] deck." These statements were forwarded to CEO Mehta.

62. Contrary to Tris's Chief Medical Officer's assertions, the 30-minute onset data was submitted to PRC to review for inclusion on the Core Slide Deck used by Tris's promotional speaker program. PRC would ultimately approve a slide containing this data, which was used during promotional speaker events throughout Texas.

63. In May 2017, Tris rolled out the new Dyanavel CVA to its sales force that included multiple false and misleading claims. The CVA included the graph displaying results from the 30-minute onset study that Regulatory Affairs had warned against using; failed to disclose that the PERMP results in the study failed to reach statistical significance; and omitted mentioning the study's many shortcomings and limitations as identified by FDA.

64. Not only were these unsubstantiated claims included in the CVA, but they were

[65] In this context, "speakers" refers to physicians that are paid by Tris to give presentations—provided by Tris—about Dyanavel to groups of other physicians. These promotional speaker events are often held in lavish restaurants, and the pharmaceutical company pays for the physicians' meals.

[66] "Off-label" generally refers to the idea of discussing information not contained in the FDA-approved product label.

also emphasized in sales training materials. Tris provided their sales representatives with a "Selling Message Flow to be used in conjunction with the current DYANAVEL XR Core Vis Aid." The document showed pictures of the CVA pages alongside a written script for sales reps to use when discussing the page on a sales call with a physician. Sales representatives were instructed to memorize these selling messages, and were warned they would be "required to deliver the entire script verbatim" as part of their training.

65. Critically, at no point during this training did Tris sales leadership make sales representatives aware of the fact that the study failed to show statistical significance in the objective PERMP assessment; that FDA took issue with numerous aspects of the study's design; or that FDA found it objectionable to broadly promote a claim of 30-minute efficacy based on the singly, small study.

66. Following the clear directive from leadership, Tris sales representatives delivered the false and misleading 30-minute onset messaging to physicians throughout Texas, including physicians participating in the Texas Medicaid program.

67. Tris sales representatives were periodically assessed by their managers during field rides to confirm they were delivering the core messaging for Dyanavel as instructed, including the message of 30-minute onset.

68. Further, Tris sales leadership regularly reinforced the Dyanavel messaging to be used during team meetings. For example, in 2018, the Houston Regional Manager wrote a list of "Critical Success Factors" to his sales team, including the directive to "Crystalize the DYANAVEL XR patient type to all customers 6-17 (30 min. onset, 13 hour duration…)." Included in this email was a reminder also to sell Dyanavel's preferred Medicaid status to doctors.

69. Tris continued promoting Dyanavel using this false and misleading 30-minute onset

messaging through at least 2020.

70. By overstating Dyanavel's onset time through the use of promotional labeling and/or advertisements that were false and/or misleading, and inconsistent with the FDA-approved label, Defendants caused Dyanavel to be misbranded in violation of state and federal law, including the TFDCA and FDCA.

C. Defendants Promoted Dyanavel XR Using Broad Claims of Efficacy, Which Were False and Misleading

71. In addition to the 30-minute onset messaging, Defendants promoted Dyanavel using various other efficacy messages that were false and/or misleading, including:

- Dyanavel helps patients reach their full potential;
- Dyanavel improves patient functionality; and
- Dyanavel allows patients to make the most of their chances for success.

72. As indicated by FDA advisory letters in 2012 and 2013, each of these claims is false and/or misleading, and had not been proven by substantial evidence.[67] Specifically, FDA noted that promotional claims related to having a "broad, positive impact on a patient's day" would be misleading "because they overstate the clinical benefit" of the medication since the product label describes improvements in SKAMP "but did not measure [the drug's] effect on other aspects of a patient's daily routine." FDA also noted that it would be misleading to describe improvements in specific symptoms (such as focus) since the approved product label only notes patient improvement through the SKAMP combined score.

73. Tris was aware of these FDA guidance documents prior to Dyanavel's approval. Yet, Tris sales representatives, under the direction of CEO Mehta, disseminated these false and/or

[67] While these advisory letters related to Tris's other ADHD medication, they are applicable to Dyanavel for analogous reasons, namely, that both Dyanavel and the other ADHD medication relied on the SKAMP combined score for their clinical trials.

misleading messages to physicians throughout Texas, including physicians participating in the Texas Medicaid program.

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

D. Defendants Specifically Targeted the Texas Medicaid Program

75. A critical component of Tris's Dyanavel marketing plan was to target government payers, including Texas Medicaid. Tris's Medicaid efforts served two main purposes: 1) to ensure Dyanavel was available for reimbursement without restrictions or prior authorizations; and 2) to increase prescriptions among Medicaid providers.

76. Tris developed a training presentation called "Medicaid Access for Dyanavel XR," which it used to train its sales representatives. At the outset, the presentation noted that "Medicaid and Medicaid Managed Care will be significant payers for Dyanavel XR." Under this program, Tris taught its sales representatives how Medicaid works; how to make effective sales calls on Medicaid providers; and why Medicaid was important to their territory business. One slide in the presentation listed Texas among the top largest Medicaid programs.

77. At the local level, Tris identified Texas Medicaid physicians and DUR Board members; disseminated lists of these individuals and their practices to the Texas sales teams; and instructed their Texas sales teams to makes sales calls on these providers. Internal emails discussing the Texas Medicaid effort clearly describe Tris's purpose for calling on decision-makers: "the goal isn't just to sell these DUR Board members on Dyanavel XR but rather to coach [the] DUR Board members on making the right motions at the actual Board meeting."

78. Tris also organized a letter-writing campaign, wherein the sales force encouraged Texas providers to write to the Texas Medicaid DUR Board expressing support for adding Dyanavel to the PDL. Tris sales leadership provided a template that providers could use to express support. Such requests for support were made by the sales force during sales calls on the providers.

79. Importantly, when Tris's sales representatives called on their targeted Texas Medicaid physicians, they delivered the promotional messaging as directed by the company, including the false and misleading messages of 30-minute onset and that Dyanavel improves functionality and helps patients reach their full potential.

80. Tris also leveraged two of its highly paid Texas speakers to attend Medicaid DUR Board meetings in-person to support Dyanavel's inclusion on the PDL. Despite Tris arranging for these speakers to provide testimony in support of Dyanavel, the speakers failed to disclose to the Board that they were speaking at Tris's behest, and only sometimes disclosed that they were paid by Tris as promotional speakers.

81. Tris additionally made key misrepresentations directly to Medicaid decision-makers. In January 2019, Tris's Senior Medical Science Liaison testified in-person to the Texas Medicaid DUR Board. In her remarks, she referred to the small early onset study, noting that, "the results demonstrate that there can be an onset of action in 30 minutes with Dyanavel." She did not provide any of the important caveats of the study, including that it was a partial failure, or that FDA took issue with various aspects of the study design. She also did not note that FDA objected to broad claims of 30-minute onset. Following these comments, the Texas Medicaid DUR Board voted to keep Dyanavel listed as preferred on the PDL.

82. Through this targeted Medicaid effort, which resulted in the dissemination of false and misleading claims to Texas Medicaid physicians and decision-makers, Tris was successful in

minimizing reimbursement restrictions for Dyanavel in the Texas Medicaid program.

VIII. CAUSES OF ACTION

83. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 82 of this Petition.

A. Defendants' Violations of the TMFPA for Which Plaintiffs Seek Civil Remedies and Penalties

84. Defendants Tris and CEO Mehta knowingly made or caused to be made false statements and/or misrepresentations of material facts to Texas Medicaid in applying for Dyanavel's inclusion on the VDP formulary, and during the Texas Medicaid DUR and PDL processes. Specifically, Defendants falsely certified on the VDP application that Dyanavel was not in violation of federal and state law, and that it would update Texas Medicaid as to any change in Dyanavel's product status. Defendants also made false statements to the DUR Board during public testimony, as described above. Defendants' false statements and/or misrepresentations permitted Tris 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 of Dyanavel, in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002(1).

85. Defendant Tris knowingly concealed information from, and/or failed to disclose information to, Texas Medicaid in conjunction with the VDP, DUR, and PDL processes. Specifically, Tris failed to disclose that they were promoting Dyanavel in a manner which overstated its efficacy, in violation of federal and state law. This conduct permitted Tris to receive benefits under the Medicaid program that were not authorized or that were greater than the benefits authorized, including, but not limited to, continued inclusion on the formulary and PDL, and virtually unfettered reimbursement of Dyanavel, in violation of the TMFPA. TEX. HUM. RES. CODE

§ 36.002(2).

86. Defendants Tris and CEO Mehta knowingly made, 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. Specifically, during the VDP application process, Defendants falsely certified that Dyanavel was not in violation of federal and state law, and that Tris would update Texas Medicaid as to any change in Dyanavel's product status, which was a legal requirement for Dyanavel to be added to the Texas Medicaid formulary. Defendants' false certification, which allowed Tris to receive the benefit of inclusion on the Medicaid formulary, therefore violated the TMFPA. TEX. HUM. RES. CODE § 36.002(4)(B).

87. 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 Dyanavel prescriptions. Defendants' illegal conduct, therefore, resulted in millions of dollars of unauthorized or greater-than-authorized reimbursements for Dyanavel by the State of Texas. Defendants' conduct additionally resulted in Defendants receiving the benefit of having Dyanavel listed and maintained on the Texas Medicaid formulary during times when the drug was in violation of federal and state law.

88. 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).

89. Plaintiffs invoke 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.

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

91. 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.[68]

B. Defendants' Violations of the TMFPA for Which Plaintiffs Only Seek Civil Penalties

92. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 91 of this Petition.

93. 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 Medicaid program. TEX. HUM. RES. CODE § 36.052(a)(3).

94. Texas law requires the VDP application to be complete and accurate for a drug to be added to the formulary. 1 TEX. ADMIN. CODE §§ 1921(b), 1923(b). As part of the VDP application process, the drug company must submit the product's FDA-approved label.

95. Defendants' false and misleading messages overstating the efficacy of Dyanavel

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

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 statements and/or misrepresentations of material fact to a 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).

96. Defendants' widespread use of false and misleading core visual aids (and associated false and misleading messaging), from 2017 to at least 2020, provides an example of this type of unlawful act. Defendants' CVAs, which contained information characterized by FDA as false and misleading, was utilized by Defendants' sales force during thousands of sales calls to Texas Medicaid providers and decision makers. The false and misleading messaging in the sales aid concerns—and directly conflicts with—information contained in the FDA-approved product label.

97. Plaintiffs, therefore, seek 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

98. 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

99. Plaintiffs respectfully request a trial by jury on all claims pursuant to Texas Rules of Civil Procedure 216.

XI. PRAYER

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

101. Plaintiffs asks for injunctive relief pursuant to § 36.051 of the TMFPA.

102. 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 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 $5,500 or more than $11,000 for each unlawful act committed by Defendants, as adjusted by 31 U.S.C. 3729(a);

D. prejudgment interest;

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

F. post-judgment interest at the legal rate.

103. Plaintiffs seeks monetary relief in excess of $1,000,000.

Respectfully submitted,

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