CAUSE NO. 23-1031

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. 23-1031

THE STATE OF TEXAS, *ex rel.* **TARIK AHMED**	§	**IN THE DISTRICT COURT**
Plaintiffs,	§	
v.	§	**71st JUDICIAL DISTRICT**
PFIZER, INC., 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 Pfizer, Inc. (Pfizer), Tris Pharma, Inc. (Tris), and Tris CEO Ketan Mehta (Mehta). Specifically, these Defendants knowingly distributed a

[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.

powerful pediatric attention-deficit/hyperactivity disorder (ADHD) medication, Quillivant XR (Quillivant), to patients throughout Texas, despite knowing Quillivant was adulterated due to deficient manufacturing practices. This illegal conduct caused Quillivant to be in violation of federal and state law, and rendered false Pfizer's sworn certification of compliance to Texas Medicaid, which is required for drugs to be eligible for reimbursement under the Texas Medicaid program. Defendants additionally misrepresented and concealed Quillivant's status as an adulterated drug when providing public testimony before Texas Medicaid decision-makers. As a result, Pfizer and Tris obtained the benefit of virtually unfettered Medicaid reimbursements for Quillivant on the basis of fraudulent and unlawful misrepresentations and concealments, thereby violating 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 the substandard manufacturing practices implemented by the Defendants.

B. Defendants

5. Defendant PFIZER is a corporation organized under the laws of Delaware, with its principal office and place of business located at 1209 Orange Street, in the City of Wilmington,

Delaware. Pfizer marketed and distributed Quillivant in Texas. Pfizer 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, Texas 75201.

6. 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 manufactured Quillivant, which it marketed and distributed 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.

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

IV. JURISDICTION AND VENUE

8. 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.

9. Since at least 2011, the State of Texas has licensed Defendants Pfizer and Tris to sell and distribute their drugs throughout Texas. This Court has jurisdiction over these Defendants because they purposefully availed themselves of the benefits, privileges, and responsibilities of doing business in Texas; subjected themselves to Texas law, including the TMFPA; and then committed unlawful acts, in whole or in part, in Texas.

10. This Court has personal jurisdiction over Defendant Mehta, a non-resident of Texas, because from 2011 to the present, he has purposefully availed himself of the privileges and

benefits of conducting business in Texas. Defendant Mehta, either personally or by his direction of others: 1) caused Quillivant to be marketed, sold, and/or distributed to Texas customers, including Texas Medicaid providers; 2) caused Quillivant 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. Defendant 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.

11. 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.

12. More specifically, Defendant Pfizer knowingly promoted Quillivant to Medicaid providers in Harrison County, and knowingly distributed Quillivant to pharmacies participating in the Medicaid program in Harrison County, ultimately leading to its use by Harrison County Medicaid patients, during which time Quillivant was adulterated as a result of the conduct of Defendants Tris and Defendant Mehta.

V. BACKGROUND

A. ADHD and Quillivant XR

13. 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

[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).

school-aged children, it can cause struggles with low self-esteem, troubled relationships, and poor performance in school.[4]

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

15. Quillivant is an extended-release oral suspension methylphenidate indicated for the treatment of ADHD in children. 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 provided to pharmacies as a powder, and pharmacists reconstitute the drug by combining the powder with water and then shaking the medication by hand. Caregivers are then instructed to shake the reconstituted medicine prior to administering each dose.

16. Though Quillivant 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 insomnia, nausea, vomiting, anxiety, and tachycardia. There is also a chance for patients to experience severe side effects, including serious cardiovascular reactions (which can cause sudden death), psychiatric adverse reactions (including mania), and long-term suppression of growth. Additionally, when Quillivant is not taken at the

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[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).

[6] *Id.*

correct dose, patients could experience an overdose requiring emergency medical intervention.

17. Quillivant was developed and owned by Nextwave Pharmaceuticals, Inc. (Nextwave). Tris held a 5% ownership portion of Nextwave and owned intellectual property that was part of Quillivant's development. Nextwave submitted the New Drug Application (NDA) to the FDA for Quillivant. After Pfizer acquired Nextwave in May 2012, Pfizer contracted with Tris (through its wholly owned subsidiary, Nextwave) for Tris to manufacture Quillivant on Pfizer's behalf. Pfizer, through Nextwave, agreed to compensate Tris for meeting certain milestones, including product approval, as well as paying Tris a 25% royalty on net sales of Quillivant. The FDA approved Quillivant's New Drug Application (NDA) on September 27, 2012, allowing it to be prescribed within the United States.

B. The Federal Food, Drug, and Cosmetic Act and Current Good Manufacturing Practices

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

18. 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 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."[7] 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."[8] Approval of the drug by the FDA is the final step in a multi-year process consisting of clinical studies and testing.

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[7] 21 U.S.C. § 355(d)(5). "Substantial evidence" as used in this section is defined at 21 U.S.C. § 355(d)(7).

[8] 21 U.S.C. § 355(d)(1).

19. 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—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."[9]

2. FDA Regulations Prohibit the Adulteration of Prescription Drugs

20. Under the FDCA, it is illegal to adulterate a drug, or to introduce into interstate commerce any drug that is adulterated.[10] A drug becomes adulterated if "the methods used in, or the facilities or controls used for, its manufacture . . . do not conform to or are not operated or administered in conformity with current good manufacturing practice."[11] The purpose of conforming to Current Good Manufacturing Practice (CGMP) is to assure that a drug "meets the requirements ... as to safety and has the identity and strength, and meets the quality and purity characteristics" that it is claimed to have.[12] CGMP regulations act as a floor, establishing a minimum set of standards that must be observed by manufacturers to ensure that drug products are made according to their approved specifications.[13] Underscoring the importance of maintaining safety and uniformity in drug manufacturing, courts have broadly interpreted adulteration requirements, noting that "[d]rugs produced in violation of . . . CGMP regulations are deemed to be adulterated without the [FDA] having to show that they are actually contaminated." *John D. Copanos & Sons, Inc. v. Food & Drug Admin.*, 854 F.2d 510, 514 (D.C. Cir. 1988) (citing 21

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[9] 21 U.S.C. § 355(b)(1)(A).

[10] 21 U.S.C. §§ 331(a), (b).

[11] 21 U.S.C. § 351(a)(2)(B).

[12] *Id.*

[13] U.S. Food and Drug Administration, *Facts About the Current Good Manufacturing Practices (CGMP)*, available at https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmp (last visited Nov. 8, 2023).

U.S.C. § 351(a)(2)(B)). Accordingly, it is critical for manufacturers to conform to the safety practices established under CGMP.

21. The FDA's CGMP regulations are set forth in 21 CFR Part 211.[14] These legally binding regulations require various forms of testing and implementation of related procedures to ensure drugs meet the identity, strength, quality, and purity they purport to represent or possess—in other words, that the drugs being made are exactly the same as when FDA first approved them.[15] Under this regulatory system, a pharmaceutical company must have a "quality control unit" with the "responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products," as well as "the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated."[16] The responsibility for approving or rejecting drug products extends to products "manufactured, processed, packed, or held under contract by another company."[17] Additionally, all "production and control records" must "be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed."[18]

22. Furthermore, unexplained discrepancies or failures of a batch or its components to meet its specifications must "be thoroughly investigated."[19] The investigation must "extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy," and a "written record of the investigation" must be made

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[14] *See Nat'l Ass'n of Pharm. Mfrs. v. Food & Drug Admin.*, 637 F.2d 877, 889 (2d Cir. 1981).
[15] *See e.g.* 21 CFR § 211.100.
[16] 21 CFR § 211.22(a).
[17] *See id.*
[18] 21 CFR § 211.192.
[19] *See id.*

and must "include the conclusions and followup."[20]

23. A drug manufacturer must also establish and follow "[w]ritten procedures describing the handling of all written and oral complaints regarding a drug product."[21] These procedures must "include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for" a thorough investigation.[22] The procedures must also "include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the" FDA.[23]

24. Through these CGMP regulations, the FDA requires pharmaceutical manufacturers to institute standard processes for evaluating the quality of their products and to thoroughly investigate complaints about their products as well as unexplained discrepancies in product quality. This critical regulatory system protects patients and consumers by establishing minimum standards to ensure that the finished drug products taken by patients do not deviate over time, but rather, remain as safe, effective, and uniform as initially approved by the FDA.

C. Texas's Role in Regulating Prescription Drugs

25. In Texas, the sale, promotion, and distribution 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).[24]

26. The TFDCA largely mirrors the FDCA. For example, the TFDCA, like the FDCA,

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[20] *See id.*

[21] 21 CFR § 211.198.

[22] *See id.*

[23] *See id.*

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

prohibits the adulteration of drugs and the introduction of adulterated drugs into commerce.[25] Additionally, TFDCA § 431.112 defines drug adulteration to include the same relevant provisions as the FDCA: a drug is adulterated if "the methods used in, or the facilities or controls used for, its manufacture, . . . do not conform to . . . current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.[26]

27. Violations of the TFDCA, including violations of rules adopted under the TFDCA,[27] can result in a written warning, administrative penalties, civil penalties, or criminal penalties.[28]

D. Texas Medicaid

1. Overview

28. 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.[29] It is a lifeline ensuring that children, pregnant women, elderly adults, and disabled individuals receive the medical care they need.[30]

29. The Texas Health and Human Services Commission (HHSC) administers the Texas Medicaid program and has authority to promulgate rules and other methods of administration

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

[26] TEX. HEALTH & SAFETY CODE § 431.111(a)(2)(B).

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

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

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

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

governing the program.[31] 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.[32] To that end, Texas Medicaid uses various procedures to monitor prescription drug benefits.

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

30. The Vendor Drug Program (VDP) within HHSC oversees the outpatient prescription drug portion of the Texas Medicaid program.[33] VDP is also charged with safeguarding against fraud, waste, and abuse within the program.[34] VDP was in operation at all times relevant to this case.

31. 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.[35] To have its particular pharmaceutical products listed on the VDP formulary, a drug company or manufacturer must file an application with VDP.[36] 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.[37] VDP may return or reject an application on the discovery of "false, erroneous, or incomplete information."[38]

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[31] TEX. GOV'T CODE § 531.021.

[32] *See In re Xerox Corp.*, 555 S.W.3d 518, 524 (Tex. 2018).

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

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

[35] 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.

[36] 1 TEX. ADMIN. CODE § 354.1921(b).

[37] *Id. See also* 1 TEX. ADMIN. CODE § 354.1923(b).

[38] 1 TEX. ADMIN. CODE § 354.1923(b)(1).

32. 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.

33. 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 provided with their VDP application.[39] Moreover, a new VDP application must be submitted each time a drug first becomes available in a new formulation or in different dosages.

34. 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.[40] Pursuant to that obligation, Texas Medicaid created the DUR program to promote optimal and cost-effective pharmaceutical therapy in the Texas Medicaid VDP.[41]

35. Specifically, the DUR program exists to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes.[42] The program is

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[39] *See* 1 TEX. ADMIN. CODE § 354.1921(c)(1).

[40] 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.

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

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

designed to educate providers and to identify and reduce the frequency of patterns of fraud, abuse, overuse, or inappropriate or medically unnecessary care.[43]

36. 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.[44] 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.[45] As part of this program, the DUR Board monitors and analyzes provider-level activity.[46]

37. 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.[47] In making these recommendations, the DUR Board must consider the clinical efficacy, safety, and cost-effectiveness of each drug reviewed.[48] 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.[49] Drugs that are reviewed but not selected for the PDL require prior

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[43] *See id.*, § 531.0736(b).

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

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

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

[47] *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).

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

[49] 1 TEX. ADMIN. CODE § 354.1924(c).

authorization.[50]

38. In carrying out its functions, the DUR Board frequently receives information from drug manufacturers, including Defendants, concerning their drugs.[51] 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.

39. 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 enter into agreements with Texas Medicaid in order to be covered providers.[52] The TMFPA seeks to protect against fraud at all levels of the Texas Medicaid program.[53] 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

40. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 39 of this Petition.

41. A person commits an unlawful act as defined under the Texas Medicaid Fraud Prevention Act[54] 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

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

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

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

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

[54] 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.

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 or causing to be made 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 making or causing to be made a claim under the Medicaid program for . . . a product that has been adulterated, debased, mislabeled, or that is otherwise inappropriate. TEX. HUM. RES. CODE § 36.002(7)(C).

42. 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 41 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

A. Background

43. Hoping to carve out a share of the multibillion-dollar ADHD medication industry for themselves, Pfizer—a multinational pharmaceutical powerhouse—invested heavily in Quillivant. Pfizer had big ambitions for Quillivant and sought to differentiate it from the competition as the only extended-release oral suspension methylphenidate indicated for the treatment of ADHD in children. To manufacture Quillivant, Pfizer partnered with Tris, a relatively new and growing pharmaceutical company with fewer than 200 employees at the time of Quillivant's approval. For Tris, properly manufacturing Quillivant at the quantities requested by Pfizer would prove to be a significant challenge.

44. Even prior to FDA approval, Tris struggled to achieve consistency in

manufacturing Quillivant, as reflected in Quillivant's failure of mandatory quality control tests. Following one such early failure in August 2011, which resulted in FDA issuing a Form 483 citation,[55] Tris promised to correct the identified deficiencies, including conducting root cause investigations of its manufacturing processes as required by federal CGMP. In the months and years that followed, however, Tris concealed subsequent quality control test failures by manipulating the test process itself, in violation of federal and state laws and regulations.

45. At the same time, Tris and Pfizer both recognized that Texas Medicaid business would be crucial for Quillivant's success. To fully exploit the economic potential of Texas Medicaid, Defendants needed Medicaid decision-makers to add Quillivant to the VDP Formulary and the Preferred Drug List. These steps would effectively allow Medicaid providers to prescribe Quillivant to their Medicaid patients and would streamline the prescribing process by eliminating the need for the treating doctor to go through the burdensome process of obtaining prior authorization. Describing Texas as a "populous state with a disproportionately high percentage of children covered by Medicaid," Pfizer projected that Texas sales of Quillivant were expected to increase significantly if Quillivant was added to the PDL.

46. Pfizer successfully campaigned to have Quillivant added to the Texas Medicaid Formulary in June 2013, including by certifying on the VDP Application that Quillivant was not in violation of state or federal law, and agreeing to update VDP of any changes in "formulation, product status price, or availability." From that point forward, Quillivant was listed as being reimbursable under the Texas Medicaid program. Defendants also successfully obtained

[55] "An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts." U.S. Food & Drug Administration, *FDA Form 483 Frequently Asked Questions*, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last visited Nov. 8, 2023).

"preferred" placement on the PDL for Quillivant in 2014, following an initial failed attempt in 2013.

47. Quillivant's status with Texas Medicaid became a selling point, and the Pfizer salesforce actively promoted Quillivant to Texas Medicaid Providers, including pediatricians and pharmacists. Defendants knew that Quillivant's placement on the VDP formulary and the PDL would not only increase Quillivant's utilization amongst children enrolled in Texas Medicaid but would also increase their market share within the commercial insurance population in Texas by having the State's stamp of approval.

48. Defendants, however, would not fulfill their obligations to Texas Medicaid. Despite engaging in conduct that clearly violated FDCA CGMP regulations; regularly receiving failing test results on required quality control measures; and receiving notices of deficiencies and a warning letter from the FDA, at no point in time did Defendants provide Texas Medicaid or VDP with a relevant product update, as required by their VDP Application certification.

B. Defendants Modified the Dissolution Test Method to Conceal Manufacturing Defects, in Violation of FDA's CGMP

49. Almost immediately after it received FDA approval—and prior to Pfizer submitting the VDP application—Quillivant began failing routine quality tests. Under financial pressure to produce large quantities of Quillivant after a lengthy approval process, Tris tried to rapidly increase production without adequate protocols to maintain acceptable quality, leading to defects in the manufacturing process.

50. Beginning at least as early as October 2012, Tris quality control personnel observed that samples of Quillivant tested under FDA-required dissolution specifications were not generating passing results. Dissolution testing is an important quality control tool used to measure whether a drug was properly manufactured, by comparing a simulated release of the drug to a

standard set upon the drug's initial approval. This in turn helps to predict whether the drug (as manufactured) will be released as expected in a patient's body—which is critical for ensuring proper and consistent patient dosing.[56] Here, the Quillivant samples formed lumps during reconstitution.

51. As noted in the October 2012 Deviation Report, the "probable cause" of the out-of-specification result was "related to sample reconstitution/hydration," which refers to the process by which the drug—manufactured by Tris as a powder—is properly mixed with water prior either to being dispensed to a patient or tested in Tris's lab.

52. Rather than seeking to understand why the sample formed lumps during reconstitution, Tris "retrained" its analysts to shake the water/drug mixture longer, as well as to conduct the test only when "foaming is absent from the suspension." Put simply, Tris's meager "retraining" was insufficient to prevent further out-of-specification dissolution test results.

53. Just one month later in November 2012, Quillivant failed dissolution testing due to slower initial dissolution at the 0.5-hour time point. In other words, inadequate amounts of Quillivant were dissolved half an hour after testing began. Once again, Tris blamed the method of mixing the sample instead of conducting a proper manufacturing investigation.

54. In February 2013, Tris issued a Notice of Investigation for Quillivant related to out-of-specification dissolution test results that far exceeded the reference standard at every tested timepoint. Shortly thereafter, Tris Quality Control issued another Notice of Investigation in March 2013, where the analyst noted that the sample's dissolution test results were ***below*** the minimum standard. This stark contrast in out-of-specification test results should have resulted in Tris investigating and revamping its manufacturing process (and thereby incurring substantial costs) to

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[56] U.S. Pharmacopeia, *Dissolution and Drug Release Tests*, available at https://www.usp.org/small-molecules/dissolution (last visited Nov. 8, 2023).

rectify Quillivant's inconsistency as a finished product. However, that again did not occur.

55. Rather than thoroughly investigating the root cause of Quillivant's failures as required by federal CGMP regulations, Tris—under the direct orders of CEO Mehta—halted dissolution testing under the existing test method (Method 5) and focused on creating a new test under which its defective product could meet FDA criteria. Tris Quality Control staff implemented the problematic new test (Method 6) on or about July 26, 2013. Alarmingly, the new test method was not representative of real-world usage by patients, and worse, went against the pharmacy reconstitution instructions contained in the FDA-approved label for Quillivant.[57]

56. Method 5, the dissolution testing method approved by the FDA, required that dissolution testing samples be "well shaken." This aligned with the instructions on Quillivant's FDA-approved label, which instructed pharmacists and caregivers to shake Quillivant for at least 10 seconds during reconstitution and again prior to administration of a dose.

57. However, under Method 6, after shaking the sample to reconstitute it (all that was required under Method 5), Tris lab personnel were instructed to let the sample sit for 30 minutes; sonicate it for three minutes; and then mix it gently with a spatula or glass rod for an additional minute.[58] Each of these new steps differed from the steps contained in Quillivant's label, which meant that Tris's dissolution testing procedure was no longer measuring dissolution as it would be experienced by patients taking Quillivant.

58. A sonicator, or ultrasonic bath, works by using sound waves outside the range of

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[57] A drug's "label" or "package insert" is the detailed information sheet that is provided with every prescription drug product. It contains all information that FDA has approved as being necessary for a patient to safely take the drug for an indicated condition. This information includes proper dosing, warning and precautions, and usage instructions.

[58] For further description of accepted dissolution practices, *see* United States Pharmacopeia ("USP") Ch. 711, available at https://www.usp.org/sites/default/files/usp/document/harmonization/gen-method/stage_6_monograph_25_feb_2011.pdf (last visited Nov. 8, 2023). *See also* FDA Guidance for Industry, available at https://www.fda.gov/downloads/drugs/guidances/ucm070239.pdf (last visited Nov. 8, 2023).

human hearing to create millions of microscopic bubbles in a solution that then implode, releasing enormous amounts of energy.[59] That energy can then be used to dissolve and homogenize liquids.[60] Tris lab personnel were instructed to sonicate Quillivant using a particular ultrasonic bath model for three minutes "at maximum power." Per the specifications sheet for the specified model, it is one of "the most technologically advanced ultrasonic baths available," and maximum power equates to 40 kilohertz, or 40,000 pulses *per second.* The machine retails for well over $1,000. In sharp contrast, Quillivant's label instructed pharmacists to shake the medication bottle "with vigorous back and forth motion for at least 10 seconds to prepare suspension." Similarly, the label instructed caregivers to "vigorously shake bottle for at least 10 seconds" prior to administering a dose of the medication. Thus, sonication plays no part in normal patient or pharmacy usage of Quillivant.

59. Under FDA regulations, "a supplement must be submitted" to the FDA "for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, or potency of the drug" at least 30 days before distribution of drugs made using the changes.[61] This notice is referred to as "CBE-30." Changes requiring a 30-day prior notice include "Relaxation of an acceptance criterion or deletion of a test to comply with an official compendium (USP) that is consistent with FDA statutory or regulatory requirements."[62] In implementing Method 6, Defendants failed to notify FDA by submitting a CBE-30 prior to its use, in violation of FDA regulations.

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[59] *See* https://www.emerson.com/documents/automation/manual-bransonic-power-supply-en-5410610.pdf (last visited Nov. 8, 2023).

[60] *Id.*

[61] 21 CFR § 314.70(c).

[62] 21 CFR § 314.70(c)(2)(iii).

60. Even Tris Quality Control personnel realized the absurdity of substituting an expensive machine for 10 seconds of shaking by hand. In response to an internal report purporting to justify the new sonication step, Tris's Senior VP of Quality observed that based on the data he reviewed, there was "absolutely no reason to sonicate" Quillivant samples. Another Quality Control employee noted that "we might be pushing it" to add the sonication step, given that it demonstrably increased the dissolution rate during testing.

61. The Senior VP of Quality continued to voice his objections in a later email directly to CEO Mehta, where he plainly stated that sonication of samples was "not scientifically sound" due to the impact on the sample results, and that "we can't just keep ignoring these [quality] issues." Nevertheless, Tris, under orders from its CEO Mehta, moved forward using sonication as part of Method 6. This would not be the last method change, as Tris was unable to produce Quillivant that consistently met acceptance criteria even under revised Method 6.

62. Internally at Tris, employees of the Quality Assurance division understood the sonication step to be affecting Quillivant test results. While investigating a customer complaint in October 2013, one analyst questioned whether the currently employed Method 6 (including sonication) should be used, since "the initial results with [Method 5] are on the higher side of the specification," and noted that testing with sonication could result in a 5-8% increase in the dissolution rate, which would exceed the upper limit.

63. Through its Contract Operations Quality Assurance Department (COQA), Pfizer was responsible for oversight of Tris manufacturing, including CGMP compliance. Pfizer also had a multidisciplinary team, known as the Audit Quality Response Team (AQRT), tasked with investigating quality control failures.

64. As early as October 2012, Pfizer was aware that Quillivant was having difficulty

meeting its FDA-mandated testing specifications. Pfizer understood that Tris was seeking to change the test method to include sonication at least as early as June 19, 2013. Pfizer did not object to Tris's decision to change the test method, but rather, sought to understand what it would entail for Pfizer in terms of regulatory filings to FDA.

65. In an email in March 2014, after several lots of Quillivant failed dissolution testing under the new test Method 6 by exceeding the ***upper limit*** of the specification, one Pfizer External Supply employee noted to another Pfizer employee that sonication "did the trick to address low disso results and then some," showing that Pfizer understood the real reason for sonication was to influence dissolution test results.

66. Pfizer's Senior Director of COQA noted that test Method 6 did not align with the test method approved by FDA, stating "I read this as they are out of compliance with our [FDA] filing." Unfortunately, this realization did not prompt Pfizer COQA to demand that Tris perform a root cause investigation into Quillivant's dissolution testing failures, nor did it trigger Pfizer's own AQRT to investigate the problem.

67. Instead, Tris began working up a justification to update the test method once again. In response to seeing the preliminary dissolution report, Tris's Senior VP of Quality remarked, "right now it looks like when the product is slow we sonicate and when it's fast we don't sonicate … we need to take a serious scientific approach to solving this issue." Despite this criticism, Tris continued forward with once again altering the test method.

68. In a later email in April 2014, a Pfizer External Supply employee characterized the situation involving Quillivant's out-of-specification dissolution results as "pretty serious." The Pfizer employee further explained that Pfizer COQA had expected Tris to "present data to quantify the impact of [a] sonication step in the dissolution method," but that Tris untimely provided "a

statement but no data." He went on to conclude that, as a result, Pfizer could not continue to release Quillivant using the new test method until Tris could justify its use.

69. Roughly a month later, Pfizer's Senior Director of COQA admitted: "I agree [the method] doesn't represent patient usage and am surprised it was [internally] approved..." Despite Pfizer's obvious concerns and skepticism regarding the validity of sonication, Pfizer failed to ensure Tris thoroughly investigated the root cause of Quillivant's quality issues and failed to alert Texas Medicaid to those ongoing problems.

70. Rather than conducting a proper manufacturing investigation, Pfizer and Tris concocted a convenient narrative to explain away the problem. In a May 2014 Field Action Report (FAR), Pfizer's Senior Director/Team Lead for COQA claimed the root cause of Quillivant's dissolution testing issues was "confirmed to be laboratory error associated with lack of clarity within the analytical method." More specifically, they claimed that an analyst erroneously sonicated Quillivant samples during a later stage of the testing process, "causing an increase in the rate of dissolution" observed at that time point in the testing process.

71. This response to FDA was misleading for two reasons. First, contrary to Defendants' assertion, Method 6 as implemented plainly instructed analysts to sonicate Quillivant samples prior to testing, so there was no method ambiguity. Second, by stating that the analyst sonicated "in error," Defendants concealed the fact that Quillivant samples were being sonicated in order to manipulate dissolution test results to falsely pass quality control.[63]

72. After submitting the FAR to FDA, Tris worked to revise its dissolution test method from Method 6 to Method 7. During the development of Method 7, Pfizer asked Tris about shipping Quillivant despite the failure to pass dissolution testing. Tris personnel responded that,

[63] Under the test method approved by FDA—Method 5—sonication is never appropriate.

although they preferred to not do so, they were "trying to keep up with Pfizer's demand" and the decision was up to Pfizer. However, Tris cautioned that the shipment in question would not have a Certificate of Analysis showing Quillivant met its FDA-required specifications.

73. At that point, Pfizer's Director and Team Lead for COQA replied that with no ability to test and no Certificate of Analysis, Pfizer did "not have any support for any [Quillivant] in distribution," and that the product would either need to be tested and re-released or recalled. Despite this grim assessment, the discussion did not prompt Pfizer to press Tris for a thorough investigation of the underlying cause of the dissolution testing failures that necessitated the creation of a new test method. It also did not trigger an investigation by Pfizer's AQRT.

74. The new method went into effect in June 2014. Under the Method 7 test, samples used for release testing were sonicated, while samples reconstituted and held for stability testing were not sonicated.

75. A month after Pfizer expressed alarm about whether there was any support for Quillivant's continued distribution, Pfizer simply accepted that Tris's implementation of the updated test method (Method 7) solved the problem. Minutes from a July 2014 Joint Steering Committee meeting between Tris and Pfizer noted that a "delay in updating the dissolution method . . . resulted in a supply risk," but conveniently explained that, with the new method's approval, the Quillivant supply situation was "[n]o longer an issue."

76. Importantly, neither Tris nor Pfizer had thoroughly investigated the actual root cause of the quality control failures that prompted the method change in the first place. Both companies knew the continued use of sonication in Method 7 was inconsistent with the test method on file with the FDA; was inconsistent with patient use; was not supported by the appropriate data; and had an impact on the dissolution test results. But Defendants chose to move forward with its

use to avoid a potential supply disruption.

77. At the same time Pfizer and Tris were working to bypass rather than solve known quality issues with Quillivant, Pfizer was petitioning the Texas Medicaid P&T Committee for Quillivant's addition to the Preferred Drug List. The P&T Committee relies on drug manufacturers to provide truthful and complete information about their drug products in order to carry out its duties of recommending preferred drugs based on their efficaciousness, clinical significance, cost effectiveness, and safety.[64] At no point did Pfizer or Tris inform P&T Committee decision-makers that there were ongoing and unresolved quality issues with Quillivant.

78. Having kept this crucial information from the P&T Committee, Pfizer and Tris succeeded in their efforts to have Quillivant added to the Texas Medicaid Preferred Drug List on July 17, 2014. This removed the need for prior authorizations for Quillivant prescriptions, broadening the drug's market appeal and increasing the likelihood that children on Texas Medicaid would be prescribed Quillivant. Unfortunately for those children, Quillivant also continued to generate out-of-specification dissolution test results due to the unresolved manufacturing issues during this time.

79. In October 2014, Tris again altered the test method, switching to Method 8. But just a few months later, Quillivant produced more out-of-specification results using the new method.

80. Even more out-of-specification dissolution testing results were observed in 2015 and 2016, despite testing occurring under revised Methods 8 and 9. In the Deviation Report for one of the 2016 failures, Tris's Senior Compliance Specialist concluded that "the root cause of the subject deviation was related to method," thus continuing Tris's trend of blaming the test method rather than finding the underlying cause for its product's variability.

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[64] Vendor Drug Program, *Preferred Drugs*, available at www.txvendordrug.com/formulary/preferred-drugs (last visited Nov. 8, 2023).

81. Following this Report, Tris changed the dissolution test method to Method 10. But rather than adjusting the test method to better resemble real-world usage, Tris continued to increase the extent to which Quillivant samples were manipulated prior to dissolution testing by adding a rest period of six hours after sonication. This extra step was not included in the only dissolution testing method properly reported to the FDA (Method 5) and was not reflective of the patient usage described in the drug's label. No matching six-hour waiting period was added to Quillivant's instructions for pharmacists and caregivers.

82. Tris observed additional out-of-specification dissolutions results for Quillivant in December 2016. However, this time the failure occurred eight hours after reconstitution—a first for Quillivant. In response, Pfizer notified the FDA through another Field Action Report. Following additional negotiations with FDA, Pfizer agreed to commit to internally narrowing Quillivant's dissolution test specifications, which upset Tris personnel and caused Tris CEO Mehta to personally complain to Pfizer.

83. Tris modified the dissolution test method to Method 11 in May 2017. Method 11 still included a sonication step. This test method remained in place until at least January 2018.

84. During this time, Defendants failed to properly conduct investigations into the root causes of the various dissolution failures, electing instead to continue modifying the dissolution test itself. Both Defendants' changes in the dissolution testing procedure—at the insistence of CEO Mehta—as well as Defendants' failure to investigate the out-of-specification test results constitute ongoing violations of FDA regulations, causing Quillivant to be adulterated in violation of state and federal law, including the TFDCA and FDCA.

C. Defendants Failed to Determine the Root Cause of Particle Size Testing Failures, in Violation of FDA CGMP

85. Not only was Quillivant routinely failing dissolution testing, but it was also

regularly failing particle size testing. By way of background, Quillivant's extended-release technology used a special coating to control the release of Quillivant's active pharmaceutical ingredient—methylphenidate.[65] To manage the release of the active ingredient, Tris applied various thicknesses of the time-release coating to Quillivant's active ingredient particles: the thicker the coating, the longer it takes for the methylphenidate to be released.

86. Particle size testing was an important tool to measure the ratio of how big the particles of coated methylphenidate present in a sample were, which would directly impact how rapidly the drug would be absorbed within the body. Critically, the FDA required Quillivant to pass particle size testing in addition to dissolution testing.

87. At least as early as June 2014, Quillivant started generating out-of-specification particle size testing results. Quillivant continued to fail particle size tests throughout 2014 and 2015. In an email dated November 12, 2014, Tris's Senior VP of Quality bluntly stated: "for those that were unaware, this is now the 8th [methylphenidate] particle size failure in 5 months. I am absolutely 'pointing the finger' at all of us for doing a less than acceptable job investigating this issue and finding a true root cause."

88. Quillivant's particle size is a direct function of the manufacturing process, and repeatedly failing to meet particle size specifications was another symptom of Tris's flawed manufacturing process for Quillivant.

89. But in a familiar move, Tris continued "doing a less than acceptable job" by failing to investigate the root cause of the manufacturing problem. Instead, Tris had the creative idea to remove particle size testing altogether.

90. In communications with Pfizer, Tris alleged that batches were failing in-process

[65] Tris Pharma, *LiquiXR Technology*, available at https://www.trisadhdhcp.com/liquixr-technology/ (last visited Nov. 8, 2023).

particle size testing but meeting their final dissolution specifications, and that the "inappropriate test" could "potentially impact [Tris's] ability to supply" Quillivant to Pfizer. During this discussion, Tris did not inform Pfizer that Tris continued to use the unapproved dissolution test that improperly manipulated the test samples, thereby making it easier for Quillivant to pass.

91. Tris needed Pfizer's support to seek FDA approval for the removal of particle size testing, and they complained that Pfizer's regulatory group was moving slowly. Pfizer's Commercial Lead for Quillivant replied that, while they were "also extremely concerned about the upcoming out of stock situation" for Quillivant, there were concerns that particle size "was still out of specification and no root cause [had] been found." They further cautioned that there were "significant implications to . . . Quillivant if this is not fully vetted."

92. On the same day Pfizer shared their concerns with Tris, they also circulated internal emails outlining their apprehension about removing particle size testing. Pfizer's Director of Business Development for the QXR Franchise noted that Pfizer's internal analysis contradicted Tris's position, explaining that Pfizer personnel were "concerned that sufficient data currently [did] not exist to eliminate or widen the in-process specification" for particle size testing.

93. A Pfizer memo attached to an email chain by their Senior Director of Chemistry, Manufacturing, and Controls acknowledged that "[i]ntrinsically, particle size influences [bioavailability] due to differences in surface area," and that, because dissolution testing was "not able to adequately demonstrate clinical performance. . . dissolution testing alone" could not be relied on to justify removal of particle size testing. He further cautioned, "we are not being transparent with the [FDA] as . . . we are deleting this specification for cause. This is an issue from a [C]GMP perspective." He concluded that sufficient data did not exist to eliminate or widen the specifications for particle size testing, and that additional testing would be needed to support Tris's

proposed course of action.

94. A month later, after Tris's continued insistence on removing particle size testing based solely on the alleged sufficiency of dissolution testing, Pfizer capitulated. They agreed to support the change request to the FDA, in large part due to Tris's agreement to submit the change as a prior approval supplement (PAS) to Quillivant's NDA that would include information about Quillivant's out-of-specification particle size testing results.

95. But tension still existed regarding how to handle the request. Pfizer personnel wanted to bring in an external consultant to facilitate the process, but Tris CEO Mehta was anxious to move forward and thought the consultant added "unnecessary time and convolution."

96. In response to pushback from Tris, Pfizer's General Manager for US Brands discussed the problem internally with her colleagues. In an email dated December 2, 2015, she provided the following summary of the situation:

> Regulatory believes that they need to be certain that [Tris'] manufacturing process is fully in control before requesting this of the FDA. We have gotten several lack of effect comments from patients that have been reported to the FDA, as well as we have had a consistency issue with the particle size which has caused a high percentage of batches to be discarded as they didn't meet spec. [T]his is why Tris wants to eliminate the additional standards testing. While these events are not necessarily connected, regulatory must have confidence that they are not. **Tris was not able to establish a root cause for the manufacturing issues** and as a hard-to-make product, the departure of their key manufacturing person seems to have coincided with these issues. Since Tris has not been amenable to a Pfizer review of the data the compromise was to bring in an external/neutral party to enable this confidence level to be reached before requesting something of the FDA.[66]

97. Despite Pfizer's misgivings, Tris and Pfizer ultimately moved forward with submission of the PAS to FDA, requesting removal of particle size testing on February 17, 2016. Unsurprisingly, the FDA rejected the request. The agency's Complete Response Letter

[66] Emphasis added.

summarized Pfizer's argument as follows: "You claim that dissolution is a precise quality control tool and a more relevant and appropriate test for the assessment of the product performance and evaluation of batch to batch reproducibility compared to the particles size testing." The FDA critiqued this claim, noting that Quillivant's dissolution testing and acceptance criteria—as understood by FDA—were insufficient to replace particle size testing. Importantly, while Quillivant was still regularly failing the dissolution tests even under Tris's increasingly modified and unapproved dissolution methods, Pfizer was making grandiose claims about the alleged reliability and sufficiency of dissolution testing.[67]

98. As approved by the FDA, Quillivant had to meet certain particle size standards. Tris recorded numerous out-of-specification results for the mandated particle size test from 2014 to at least 2016, while failing to properly conduct investigations into the root causes of the particle size failures. Defendants' failure to investigate the out-of-specification test results constitutes an ongoing violation of FDA regulations, causing Quillivant to be adulterated in violation of state and federal law, including the TFDCA and FDCA.

D. Defendants Failed to Properly Investigate Numerous Complaints Regarding Quillivant and Lack of Effect, in Violation of FDA's CGMP

99. Given the numerous quality control issues plaguing Quillivant between 2013 and 2018, it is unsurprising that a significant number of consumers took the extraordinary step of officially complaining that Quillivant was failing to work as expected. As early as September 2013, Defendants began receiving consumer complaints that Quillivant had a "lack of effect."

100. In December 2014, the FDA issued a Postmarket Drug and Biologic Safety Evaluations report identifying lack of effect for Quillivant as a "new potential issue" the agency

[67] As of 2016, Tris had not identified the root cause of particle size failures, though they had taken steps that they claimed reduced the frequency of such failures.

was monitoring. The FDA sent another notice regarding lack of effect complaints to Pfizer in April 2015, identifying it as a "potential safety issue." Pfizer forwarded the notice to Tris, along with questions about Tris's procedures for monitoring and investigating product complaints.

101. On May 21, 2015, Tris's Senior Manager of Compliance sent Pfizer a memo addressing the steps Tris had taken to investigate lack of effect complaints concerning Quillivant. Among other things, the memo assured Pfizer that Tris had tested relevant samples for dissolution and the samples had met release specifications. The memo concluded there "were no discrepancies noted in the manufacturing or packaging processes that would have resulted in the report of a lack of effect."

102. But what the memo failed to acknowledge is that in May 2015, Tris was using dissolution test Method 8, which included sonication and was not approved by the FDA. By using this unapproved test method, Tris was unable to properly investigate whether the previously released product actually met the FDA's finished product specifications.

103. Even when faced with an influx of actual patient complaints about the drug lacking effect, Tris could not say whether the drug as manufactured was consistent with the drug as approved, because Tris had changed one of the primary methods to verify that fact. Tris continued to use unapproved quality control testing methods despite FDA's warnings regarding patients' lack of effect complaints.

104. Pfizer was far from blameless in its handling of Quillivant product complaints. In July 2015, the FDA asked Pfizer for specific information related to Quillivant's lack of effect complaints. The FDA's Information Request was eventually shared with Tris's Chief Medical Officer, who emailed Tris CEO Mehta to express her concerns about Pfizer's handling of the situation. Pfizer wanted to argue that the lack of effect complaints largely occurred during the

titration phase and were caused by doctors failing to adjust the medication to a fully optimized dose. But according to Tris, the majority of complaints contained no dosage information, with only 21% of the complaints arising during the initial titration period. Tris's Chief Medical Officer worried that "a solution [was] being proposed [by Pfizer] before the problem [was] well understood."

105. Even Pfizer personnel recognized weaknesses in the position that dose titration was to blame for the uptick in product complaints, as the VP of Safety Surveillance and Risk Management acknowledged, "in the absence of conclusive data it seems we are left with some 'hypothesizing.'" Nevertheless, when Pfizer submitted its response to the FDA's Information Request, its report concluded that "the root cause [was] most likely associated with the titration phase of the dosing regimen." Pfizer additionally placed some blame on the patients and their caregivers, suggesting that they were not properly shaking the product prior to use.[68]

106. While Pfizer's response to the Information Request was sufficient to close that particular inquiry, FDA continued to have concerns regarding Quillivant's efficacy. For instance, in an October 2016 email detailing Tris's discussion with FDA on Quillivant's particle size testing requirement, Tris noted that FDA appeared to have the lack of effect topic on their mind, and that FDA linked it to potential safety issues.

107. Internally, Tris and Pfizer continued to conceal the true scope of lack of effect complaints, and continued to improperly investigate the complaints by using their unapproved dissolution test methods. In early 2017, after Tris obtained out-of-specification dissolution test results for Quillivant, Pfizer compiled a graph summarizing all reported lack of effect complaints for Quillivant. According to this graph, complaints in 2017 had again spiked to some of the highest

[68] This claim was particularly disingenuous given that Pfizer knew Tris was sonicating Quillivant samples prior to dissolution testing. Sonication mixes the drug far more effectively than shaking per the label instructions.

reported levels.

108. Defendants understood the link between the Quillivant's quality control failures and the lack of effect complaints. Yet at no point did Defendants warn Texas Medicaid providers or decision-makers that Quillivant had known manufacturing issues affecting its efficacy. Defendants thereby deprived the Medicaid program of the crucial information it relies on to ensure the safety and quality of care provided to Medicaid beneficiaries. As a result, thousands of Texas children received an adulterated Schedule II Controlled Dangerous Substance.

109. Defendants' inability to properly compare the consistency of the Quillivant batches referenced in the lack of effect claims meant that Defendants were unable to properly investigate the complaints as required by FDA CGMP regulations. Accordingly, Defendants' actions caused Quillivant to be adulterated in violation of state and federal law, including the TFDCA and FDCA.

C. FDA Issues Notices of Violations to Tris and Pfizer

110. By 2017, Quillivant's persistent quality issues triggered an FDA inspection of Tris's manufacturing facilities, beginning in February and extending into March 2017. During that time, Pfizer recalled multiple lots of Quillivant due to dissolution testing failures.

111. After the inspection, the FDA issued a Form 483 Inspectional Observations finding, in relevant part, that: 1) the "quality control unit lack[ed] the responsibility and authority to reject all components and drug products"; 2) "Out-of-Specification (OOS) results were obtained for dissolution testing for" multiple lots of Quillivant; 3) the "responsibilities and procedures applicable to the quality control unit [were] not in writing and fully followed"; 4) the "accuracy, sensitivity, specificity[,] and reproducibility of test methods [had] not been established and documented"; and 5) "[e]stablished test procedures and laboratory control mechanisms [were] not followed and documented at the time of performance."

112. Pfizer's Director of Business Development for the QXR Franchise circulated the FDA 483 Inspectional Observations to others in Pfizer senior leadership positions, noting that the report revealed "several systemic issues at Tris." After describing the FDA's findings, he summarized: "In essence, I believe FDA is saying that Tris Quality System [i]s broken." Despite this dire assessment, when Tris recommended that Pfizer place all lots of Quillivant on hold until the issues raised by the FDA could be fully investigated, Pfizer pushed Tris to continue supplying the marketplace with Quillivant.

113. The events of early 2017 finally prompted Pfizer to internally examine the workings of its COQA team. In a July 2017 email, Pfizer's Senior Director of Regulatory Affairs admitted that Pfizer had not followed "the normal change control process" for making changes to Quillivant's dissolution testing method. He blamed this failing on the progression of Pfizer's working relationship with Tris, as well as Tris's position regarding the proprietary nature of information concerning Quillivant. He further admitted Pfizer's COQA team had "dropped the ball" when, after requesting that additional testing be performed regarding the introduction of sonication, "nothing materialized."

114. In October 2017, the FDA sent Tris a Drug Master File (DMF) Deficiency Letter critiquing Tris's repeated revisions to Quillivant's dissolution testing method. The agency explained that the introduction of sonication in Method 6 and its continued use in subsequent test methods was unacceptable. The agency likewise found unacceptable the six-hour sample rest period introduced in Method 10. As a result, the FDA concluded that the only appropriate dissolution testing method for Quillivant was Method 5. The FDA instructed Tris to update Quillivant's DMF accordingly.

115. Merely a month after receiving such harsh feedback from the FDA on Quillivant,

Pfizer had the audacity to provide a presentation to the Texas Medicaid DUR Board in an effort to maintain Quillivant's preferred status on the PDL. Pfizer did so before related safety and efficacy issues were fully understood or investigated, and with full awareness that a Quillivant shortage was imminent.

116. In fact, Pfizer did not notify Texas Medicaid of Quillivant supply issues until February 2018, when the shortage was already ongoing. Even that communication was exceedingly brief, providing zero explanation or discussion of the ongoing manufacturing and quality control issues causing the shortage. At no point did either Pfizer or Tris disclose to Texas Medicaid the quality or regulatory issues related to Quillivant, or that an alarming number of patients were submitting complaints that the drug was not working as intended.

117. Meanwhile, Pfizer's internal communications were far more candid. In a March 2018 email exchange discussing Quillivant's dissolution testing issues, Pfizer's COQA Director and Team Lead admitted: "I am getting less and less convinced we actually know how to make this product."

118. Pfizer's concerns were warranted. On March 26, 2018, the FDA issued a Warning Letter to Tris finding that it failed to conform to CGMP and declaring Quillivant to be adulterated, in violation of the Federal Food Drug and Cosmetic Act. The Warning Letter did not mince words, describing the issues within Tris manufacturing as "significant" violations of CGMP and stating in no uncertain terms that because Tris's "methods, facilities, or controls for manufacturing, processing, packing, or holding [did] not conform to CGMP," Tris's drug products were "adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."

119. The Warning Letter went on to explain the specific violations the FDA investigator

observed, including that Tris "failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications" as required under 21 CFR § 211.192. Furthermore, the Warning Letter noted that Tris had failed to "adequately investigate product failures and significant defect complaints"; lacked "thorough investigations into root causes"; and "failed to implement prompt and effective corrective actions and preventive actions (CAPA)."

120. FDA's Warning Letter put Pfizer on notice that it violated federal law requiring compliance with CGMP, and officially put Pfizer and Tris on notice of what was patently obvious from the start: Quillivant was adulterated starting in 2012 and continuing into 2018. Even after receiving this clear and unequivocal assessment, neither Tris nor Pfizer alerted Texas Medicaid decision-makers to the FDA's serious findings on adulteration. In failing to do so, Defendants' ongoing violations of the TMFPA became that much more flagrant.

121. Following the Warning Letter, Defendants made one final attempt at concealing the manufacturing issues with Quillivant by again altering the dissolution test method, this time to include a prolonged period of hydration.[69] However, since FDA had just rebuked Defendants for unilaterally changing the test method, Pfizer decided to submit the proposed change for FDA's approval. Not surprisingly, FDA rejected Pfizer's proposal, noting that it had concerns with Quillivant's reduced dissolution rate, including that Quillivant's performance in patients may be different from the batches used in approval.

122. In the wake of the FDA's Warning Letter and additional criticism from the agency in the ensuing months, Pfizer ultimately chose to divest itself of Quillivant by selling the subsidiary company that owned the drug to Tris. The transfer became effective on September 24, 2018. On

[69] Hydration, in this context, refers to allowing a recently reconstituted sample to sit for a specified period of time prior to testing—in other words, a rest period. The proposed hydration period in this instance was 24 hours.

November 16, 2018, Tris would finally inform the FDA that it had identified the true root cause of Quillivant's out-of-specification dissolution testing results. After over six years and a multitude of evasions, Tris finally acknowledged the utterly unsurprising fact that its flawed manufacturing process caused Quillivant's quality issues.

VIII. CAUSES OF ACTION

123. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 122 of this Petition.

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

124. Defendant Pfizer knowingly made or caused to be made false statements and/or misrepresentations of material facts to Texas Medicaid in applying for Quillivant's inclusion on the VDP formulary. Specifically, Pfizer falsely certified on the VDP application that Quillivant was not in violation of federal and state law, and that it would update Texas Medicaid as to any change in Quillivant's product status. Pfizer's false statements and/or misrepresentations permitted Pfizer 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, in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002(1).

125. Defendant Pfizer knowingly concealed information from, and/or failed to disclose information to, Texas Medicaid in conjunction with the VDP, DUR, and PDL processes. Specifically, Pfizer failed to disclose Quillivant's known quality issues to VDP, the DUR Board, and the former P&T Committee, including that Quillivant was adulterated. This conduct permitted Pfizer 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 Quillivant, in violation of the TMFPA. TEX.

HUM. RES. CODE § 36.002(2).

126. Defendant Pfizer 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, Defendant Pfizer falsely certified that Quillivant was not in violation of federal and state law, and that Pfizer would update Texas Medicaid as to any change in Quillivant's product status, which was a legal requirement for Quillivant to be added to the Texas Medicaid formulary. Despite making this certification, at no point thereafter did Pfizer inform Texas Medicaid about Quillivant becoming adulterated. Pfizer's false certification, which allowed Pfizer to receive the benefit of inclusion on the Medicaid formulary, therefore violated the TMFPA. TEX. HUM. RES. CODE § 36.002(4)(B).

127. Defendants Tris, Pfizer, and Mehta knowingly made or caused to be made claims under the Medicaid program for a product, Quillivant, that was adulterated. Specifically, Tris, under the direction of CEO Mehta, knowingly adulterated Quillivant and released it to Pfizer with the understanding that Pfizer would promote Quillivant to Texas physicians, including Texas Medicaid physicians, and would distribute Quillivant in Texas, ultimately leading to its use by Texas Medicaid patients. Pfizer, for their part, knew Tris was adulterating Quillivant, yet continued to distribute and to promote it throughout Texas, including promoting Quillivant to Texas Medicaid physicians and decisionmakers. Pfizer also continually undertook efforts to ensure Quillivant was available on the Texas Medicaid formulary and listed as preferred on the Medicaid PDL, despite being adulterated. These efforts by Defendants violated the TMFPA. TEX. HUM. RES. CODE § 36.002(7)(C).

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

129. 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).

130. 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.

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

132. 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.[70]

IX. STATUTORY INJUNCTION UNDER § 36.051 OF THE ACT

133. 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

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

XI. PRAYER

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

136. Plaintiffs ask for injunctive relief pursuant to § 36.051 of the TMFPA.

137. 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.

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

138. Plaintiffs seek monetary relief in excess of $1,000,000.

Respectfully submitted,

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