

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

PFIZER, INC

Plaintiff,

v.

**TEXAS HEALTH AND HUMAN
SERVICES COMMISSION and
CHARLES SMITH, Executive
Commissioner, in his official capacity**

Defendants.

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CIVIL ACTION NO. 1:16-cv-1228

**PLAINTIFF’S ORIGINAL COMPLAINT FOR
DECLARATORY AND INJUNCTIVE RELIEF**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW Plaintiff Pfizer, Inc., and files this Original Complaint for Declaratory and Injunctive Relief, and in support thereof would show as follows:

I. Parties

1. Plaintiff Pfizer, Inc. is a corporation, duly formed and existing under the laws of Delaware, with its principal place of business in New York, New York.

2. Defendant Texas Health and Human Services Commission (“HHSC”) is an executive branch agency of the State of Texas, and has been designated by Texas as the “single state agency designated to administer the medical assistance program... in accordance with 42 U.S.C. Section 1396a(a)(5).” TEX. HUMAN RES. CODE § 32.021(a). The Commission may be served with process through its Executive Commissioner Charles Smith at HHSC headquarters, 4900 N. Lamar, Austin, Texas 78751.

3. Defendant Charles Smith is the Executive Commissioner of the Texas Health and Human Services Commission, and is named solely in his official capacity for purposes of injunctive relief. Executive Commissioner Charles Smith may be served with process at HHSC headquarters, 4900 N. Lamar, Austin, Texas 78751.

II. Jurisdiction and Venue

4. This court has federal question jurisdiction over the subject matter of this case pursuant to Article 3, Section 2 of the United States Constitution and 28 U.S.C. § 1331. Plaintiff's cause of action is based upon, and seeks judicial interpretation of, 42 U.S.C. § 1396r-8(b)(3)(D).

5. This court has personal jurisdiction over the Defendants in this case because they are an executive branch agency of the State of Texas and its Executive Commissioner, both of which are headquartered in Austin, Travis County, Texas.

6. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims asserted herein occurred within this District. In addition, both Defendants named herein reside in this state and within this District. 28 U.S.C. § 1391(b)(1).

III. Background

A. The Law

7. Texas Medicaid is a federal program administered by the states. Plaintiff is required to report highly confidential detailed pricing and rebate information for its drugs included in the Texas Medicaid Vendor Drug Program pursuant to 42 U.S.C. § 1396r-8(b)(3). This information is provided by Plaintiffs in reliance on the confidentiality guaranteed by 42 U.S.C. § 1396r-8(b)(3)(D) which provides as follows:

(D) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section (other than the wholesale acquisition cost for purposes of carrying out section [1395w-3a](#) of this title) **is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency¹ (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler,** except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section [1395w-3a](#) of this title (including the determination and implementation of the payment amount), or to carry out section [1395w-3b](#) of this title,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this subchapter, and

(v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f).

The previous sentence shall also apply to information disclosed under section [1395w-102 \(d\)\(2\)](#) or [1395w-104 \(c\)\(2\)\(E\)](#) of this title and drug pricing data reported under the first sentence of section [1395w-141 \(i\)\(1\)](#) of this title.

¹ 42 U.S.C. § 1396r-8(k)(9) provides: “State agency The term ‘State agency’ means the agency designated under section 1396a (a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.”

42 U.S.C. § 1396a(a)(5) provides: “(a) Contents A State plan for medical assistance must—
(5) either provide for the establishment or designation **of a single State agency** to administer or to supervise the administration of the plan...or by the agency or agencies administering the supplemental security income program...” (emphasis added).

HHSC has been designated by Texas as the “single state agency designated to administer the medical assistance program... in accordance with 42 U.S.C. Section 1396a(a)(5).” Tex. Human Res. Code § 32.021(a).

8. HHSC receives Plaintiffs' confidential information only because it has been designated as the "single state agency designated to administer the medical assistance program... in accordance with 42 U.S.C. Section 1396a(a)(5)." Tex. Human Res. Code § 32.021(a).

9. Plaintiffs confidential information is also protected from disclosure by HHSC by Texas law:

Sec. 531.071. CONFIDENTIALITY OF INFORMATION REGARDING DRUG REBATES, PRICING, AND NEGOTIATIONS. (a) Notwithstanding any other state law, information obtained or maintained by the commission [HHSC] regarding prescription drug rebate negotiations or a supplemental Medicaid or other rebate agreement, including trade secrets, rebate amount, rebate percentage, and manufacturer or labeler pricing, is confidential and not subject to disclosure under Chapter 552.

Texas Gov't Code §531.071(a).

10. Nevertheless, Plaintiff has obtained documents from HHSC that establish that the confidentiality guaranteed by 42 U.S.C. § 1396r-8(b)(3)(D) and by Texas Gov't Code §531.071(a) has been and will continue to be violated by Defendants.²

B. Factual Background

11. HHSC has provided documentation indicating that in or about February or March 2016 HHSC received a request from the Chair of the Texas Senate Health and Human Services Committee ("Requestor #1"), under the Texas Public Information Act ("TPIA") apparently for, among other things, Plaintiff's confidential pricing and rebate information.³ HHSC initially complied with 42 U.S.C. § 1396r-8(b)(3)(D) and did not release the confidential information. However, contrary to the mandatory provisions of Tex. Gov't Code § 552.305(d), Defendant

² The documents and other information have been released by HHSC in response to Plaintiff Pfizer's counsel's Public Information Act requests and subsequent communications.

³ Despite repeated request for a copy of Sen. Schwertner's February or March 2016 request, HHSC has yet to provide same. Exhibit "B" August 17, 2016 –October 14, 2016 emails with HHSC.

HHSC did not notify Plaintiff of the TPIA request for its highly confidential rebate and pricing information. As set forth below, HHSC has recently provided documents which reflect that HHSC initially responded with de-identified examples because identified pricing and rebate information is confidential under 42 U.S.C. § 1396r-8(b)(3)(D). Importantly, in the documents HHSC expressly recognized the application of 42 U.S.C. 1396-r8 (b)(3)(D) and Texas Government Code §531.071 to the information it was providing to Requestor #1. Specifically, HHSC inserted the following warning in the footer of the document:

Confidential and Proprietary; unauthorized disclosure prohibited by federal law at 42 U.S.C. 1396-r8(b)(3)(D) and Texas Government Code §531.071.

12. However, the documents reflect that Requestor #1 disagreed with HHSC and by April 26, 2016 letter Requestor #1 maintained that:

In conversations with you and your staff, I had previously requested information pertaining to rebates received by the state on medications included on the state's Medicaid Preferred Drug List (PDL). The response received from your agency on March 10 provided several de-identified examples stating that the Texas Health and Human Services Commission (HHSC) would be unable to share exact rebate amounts based an interpretation of state law that would classify such information as confidential.

However, the Texas Government Code provides legislators with the clear statutory authority to access any records, documents, and/or files of each state agency, department, or office as necessary to perform their official duties.

Therefore, under the Texas Public Information Act (see Texas Government Code, Sec. 552.008), I am formally requesting the following information to use for legislative purposes:

- The federal and state rebate amounts for all drugs listed on the Texas Medicaid Preferred Drug List.

13. HHSC has provided documentation indicating that, contrary to 42 U.S.C. § 1396r-8(b)(3)(D), on May 6, 2016 HHSC requested a letter ruling from the Texas Attorney General's Open Records Division ("ORD") as to whether the requested confidential information was exempt from disclosure under the TPIA. Further, contrary to the mandatory provisions of Tex. Gov't Code § 552.305(d), Defendant HHSC did not notify Plaintiff that its highly confidential rebate and pricing information had been requested, or that HHSC had requested an ORD letter ruling. As a result, Plaintiff was deprived of its right to submit briefing to ORD to protect its confidential pricing and rebate information from disclosure by HHSC.

14. HHSC has provided documentation indicating that on June 3, 2016 Requestor #1 provided legal briefing to ORD regarding the TPIA request. However, contrary to the mandatory provisions of Tex. Gov't Code § 552.305(d), no one provided Plaintiff with notice of Requestor #1's briefing. As a result, Plaintiff was deprived of its right to submit briefing to ORD to protect their confidential pricing and rebate information from disclosure by HHSC.

15. HHSC has provided documentation indicating that on July 27, 2016 ORD issued a *non-precedential* letter ruling⁴, OR2016-16919, which opines that Plaintiff's confidential

⁴The Texas Attorney General's office makes this lack of precedential effect quite clear:

Unlike Open Records Decisions, these informal letter rulings are applicable only to the specific documents and circumstances surrounding them; therefore, Open Records Letter Rulings should not be cited as precedent when briefing to the Office of the Attorney General.

Texas Attorney General's web site at: https://texasattorneygeneral.gov/open/index_orl.php (last viewed October 20, 2016); Also, as explained by the Texas Attorney General:

"Open Records Decisions are formal opinions relating to the Public Information Act (formerly the Open Records Act). These decisions usually address novel or problematic legal questions and are signed by the Attorney General. Open Records Decisions may be cited as precedent in briefing to the Open Records Division."

<https://texasattorneygeneral.gov/og/open-records-decisions-ords> (last viewed October 20, 2016).

pricing and rebate information should be released to Requestor #1. However, ORD did not send a copy of its letter ruling to Plaintiff. Further, the ORD letter ruling erroneously did not consider the federal confidentiality provisions in 42 U.S.C. § 1396r-8(b)(3)(D). The letter ruling also erroneously determined, in violation of Texas Government Code §531.071, that the Texas Public Information Act (“TPIA”) provides state legislators with special rights of access that are not subject to the confidentiality provision in the Texas Government Code related to Medicaid pricing and rebate information.

16. HHSC has provided documentation indicating that on July 28, 2016 it provided Requestor #1 with Plaintiff’s **identified** confidential pricing and rebate information. This was in violation of 42 U.S.C. § 1396r-8(b)(3)(D). Further, no one advised Plaintiff that its confidential pricing and rebate information was provided to Requestor #1. In addition, documents provided by HHSC reflect that Requestor #1 was not required to sign a non-disclosure agreement. Instead, HHSC sent a cover letter referencing Texas Government Code §552.008 with the confidential information to Requestor #1.

17. When Plaintiff learned of the *non-precedential* ORD letter ruling and release of information to Requestor #1, it filed suit in Texas State District Court on August 19, 2016, pursuant to the TPIA to appeal the letter ruling and HHSC’s failure to provide any notice or opportunity to submit briefing to ORD on Requestor #1’s request. By August 19, 2016 email to HHSC’s Chief Legal Counsel, Defendant HHSC was notified of the suit and was provided a courtesy copy of the Petition. Plaintiff Pfizer’s counsel’s August 19, 2016 email also requested certain related documents and information. HHSC treated the request as a TPIA request and subsequently produced the documents referenced herein.⁵

⁵ As of the date of the filing of this Complaint, HHSC has yet to provide all of the information that has been requested.

18. HHSC has provided documentation reflecting that it received a similar Texas Public Information Act request dated August 25, 2016 from the Chair of the Texas Senate Finance Committee (“Requestor #2”), for, among other things, Plaintiff’s **identified** confidential pricing and rebate information. The request reads as follows:

I am writing to request information received by your agency regarding rebates for drugs included on the Medicaid Preferred Drug List (PDL) under the Texas Public Information Act (Texas Government Code, Sec. 552.008) to be used for legislative purposes.

Specifically, I request all state and federal rebate amounts for drugs listed on the Texas Medicaid Preferred Drug List. Additionally, I request the information be organized to include the following: data from the last four quarters, grouped by PDL class, which rebates are state or federal, any federal rebate offsets, label name, general name, whether the drug is brand name or generic, and the net cost the state pays after rebates are applied.

As Chair of the Senate Finance Committee, I seek this information to assist in making critical budget decisions for the state and request your prompt attention to this matter.

19. Despite Plaintiff’s filing of suit regarding Requestor #1’s TPIA request, once again HHSC did not provide Plaintiff with notice of its receipt of Requestor #2 TPIA request prior to making its response to the request. Also, HHSC did not seek an open records letter ruling. As a result, Plaintiff once again was deprived of its right to submit briefing to ORD to protect its confidential pricing and rebate information from disclosure by HHSC.

20. HHSC has provided documentation reflecting that it actually released Plaintiff’s **identified** confidential pricing and rebate information to Requestor #2. This release was in violation of 42 U.S.C. § 1396r-8(b)(3)(D). Further, contrary to the mandatory provisions of Tex. Gov’t Code § 552.305(d), prior to the release Defendant HHSC did not notify Plaintiff that its highly confidential rebate and pricing information had been requested. As a result, Plaintiff

was once again deprived of its right to submit briefing to ORD to protect their confidential pricing and rebate information from disclosure by HHSC.

21. Further, HHSC has provided documentation reflecting that it had Requestor #2 and three other individuals sign “Legislative Nondisclosure Agreements” (“LNDA”) which cite to Texas Government Code §552.008. Even with the LNDAs, the release was in violation of 42 U.S.C. § 1396r-8(b)(3)(D). Further, the LNDAs may be problematic in that they provide, among other things, that the signatory can release confidential information merely if they are “advised by legal counsel that disclosure is required by law or legal process”. As a result, the LNDAs may provide only limited protection against further improper release of Plaintiffs’ confidential information.

22. Ironically, HHSC is invoking Texas Government Code §552.101 to prevent Plaintiff from seeing, among other things, its own confidential information which HHSC provided to Requestor #1. Specifically, HHSC has provided a copy of its September 2, 2016 letter to the Texas Attorney General’s Open Records Division in response to Plaintiff counsel’s August 19, 2016 TPIA request. HHSC’s letter asserts that “a portion of the requested information is excepted from public disclosure pursuant to section 552.101 of the Government Code.”

23. By November 9, 2016 letter ruling, OR2016-25018, ORD responded to HHSC’s September 2, 2016 letter and opined that Pfizer’s confidential pricing and rebate information “is confidential pursuant to section 531.071(a) of the Government Code, and the commission must withhold it under section 552.101 of the Government Code.” Therefore, although it is ironic that Plaintiff itself is being prevented from seeing, among other things, its own confidential information which HHSC provided to Requestor #1, there certainly is no dispute that section

531.071 applies to Pfizer's information that HHSC provided to Requestor #1. As set forth thoroughly below, disclosure of Plaintiff's confidential pricing and rebate information sought by the TPIA requests of Request #1, Requestor #2, and Plaintiff⁶ is expressly prohibited by 42 U.S.C. § 1396r-8(b)(3)(D) and by Texas Government Code §531.071. The application of the statutes and the facts establish that the TPIA requests seek the release of valuable and commercially-sensitive trade secrets that, if disclosed, would substantially harm Plaintiffs' ability to compete in the marketplace, including within the Texas Medicaid Preferred Drug List.

24. On August 31, 2016, HHSC's Chief Counsel advised Plaintiff through its counsel of the existence of Requestor #2's TPIA request, but also advised that the information had already been released pursuant to the TPIA.

25. By September 1, 2016 email to HHSC's Chief Counsel, Plaintiff's counsel raised the impropriety of the release to Requestor #2 without prior notice and opportunity to brief the issues to the Open Records Division. Plaintiff's counsel also requested the status of the documents that he had requested on August 19. In response, HHSC's Chief Counsel advised that HHSC was "gathering information in response to your request".

26. By Friday, September 2, 2016 email Plaintiff's counsel followed up on his September 1, 2016 email, again requesting the status of the documents that had been requested on August 19, and further requested:

Please also confirm as soon as possible whether or not HHSC:

- 1) will notify us if and when it receives further PIA requests from members of the legislature (or others) for our client's confidential information; and

⁶ For Plaintiff's TPIA request, only to the extent it seeks confidential pricing and rebate information for products other than Plaintiff's.

2) will refrain from providing the requestor with responsive information until we have an opportunity to brief the issues to the Texas Attorney General's Open Records Division.

Our client obviously wants to avoid a repeat of the current situation.

27. By September 2, 2016 email, HHSC's Chief Counsel confirmed that although HHSC would notify Plaintiff's counsel when it received further TPIA requests for its rebate information, HHSC would **not** refrain from providing the requestor with responsive information before Plaintiff would have an opportunity to brief the issues to the Open Records Division:

Good afternoon, Ed. I'm glad we were able to talk earlier today. HHSC is gathering information in response to your questions concerning requests made by [Requestor #1], chair of the Senate Health and Human Services Committee, and [Requestor #2], chair of the Senate Finance Committee, for rebate information relating to drugs on Texas Medicaid's preferred drug list. As we discussed, however, the sample of rebate information provided to the Office of the Attorney General (OAG) with the briefing on [Requestor #1's] request includes confidential information. HHSC is seeking a ruling from OAG on that portion of your request, which seeks a public disclosure of confidential information.

I'll continue to notify you of Public Information Act requests for your client's rebate information, **but I can't agree to withhold information from a legislative requestor who, under section 552.008 of the Public Information Act, is requesting the information for a legislative purpose.**

Thanks for your time today. I hope you enjoy the long weekend.

C. HHSC's Production of Documents

28. By Friday, September 9, 2016 emails HHSC made its first production of the documents requested by Plaintiff's counsel. The information provided by HHSC reflected that Requestor #1 had apparently originally requested Plaintiff's confidential information in or about February or March 2016. However, HHSC failed to produce Requestor #1's original TPIA request for Plaintiff's confidential information. Further, the information provided by HHSC

reflected that despite representations to the contrary, it did not have Requestor #1 sign a non-disclosure agreement. Ironically, HHSC refused to produce to Plaintiff its own information which HHSC provided to Requestor #1 citing “confidentiality”. Therefore, by Monday, September 12 email Plaintiff’s counsel requested clarification from HHSC. By September 13, 2016 email, HHSC provided Plaintiff with a copy of HHSC’s September 12, 2016 “Request for open records decision” regarding the August 19, 2016 request.

29. By September 14, 2016 email HHSC provided a clarification of the information provided to Plaintiff. HHSC explained that its position that it was not required to have Requestor #1 execute a non-disclosure agreement. HHSC further explained why it was refusing to provide Plaintiff with its own confidential information which HHSC had released to Requestor #1. In short, HHSC ironically took the position that Plaintiff was not entitled to see its own confidential information (as well as other company’s confidential information) which HHSC had released to Requestor #1 because it is “made confidential under section 531.071 of the Texas Government Code”:

You also asked why HHSC did not release Pfizer's confidential information to you. The information we provided to the Attorney General consisted of drug rebate information made confidential under section 531.071 of the Texas Government Code. **While some of the information at issue is initially from Pfizer, that section of the Government Code makes all information obtained or maintained by the Commission regarding prescription drug rebate negotiations or a supplemental Medicaid or other rebate agreement, including trade secrets, rebate amounts, rebate percentage, and manufacturer or labeler pricing, confidential and not subject to disclosure under the Public Information Act.** There does not appear to be a right of access granted to drug manufacturers. Accordingly, we have sent the information at issue to the Attorney General so we can obtain a ruling on the confidentiality of the information.

30. By September 14, 2016 return email Plaintiff's counsel requested that HHSC reconsider its position regarding Plaintiff's own information which HHSC had released to Requestor #1:

With regard to the information provided by Pfizer, we request that HHSC reconsider its position and produce same to us as counsel for Pfizer. If PIA Section 552.008 required the release of the information (with which we disagree), then we do not understand why Section 552.023 (copied below for your convenience) would not require release of Pfizer's information.

31. In a September 14, 2016 email Plaintiff further reiterated its request for Requestor #1's original TPIA request for Plaintiffs' confidential information.

32. By September 29, 2016 email HHSC provided Plaintiff with the document it sent to Requestor #1 on March 10, 2016 in response to Requestor #1's original February or March 2016 TPIA request. Interestingly, the document establishes that HHSC initially responded to Requestor #1's original TPIA request with largely de-identified pricing and rebate information. Importantly, HHSC expressly recognized the application of 42 U.S.C. 1396-r8 (b)(3)(D) and Texas Government Code §531.071 to the information it was providing to Requestor #1. Specifically, HHSC inserted the following warning in the footer of the document:

Confidential and Proprietary; unauthorized disclosure prohibited by federal law at 42 U.S.C. 1396-r8(b)(3)(D) and Texas Government Code §531.071.

33. However, HHSC's September 29, 2016 email still failed to provide Plaintiff with a copy of Requestor #1's original TPIA request which resulted in HHSC's March 10, 2016 response to Requestor #1. Therefore, by September 29, 2016 return email Plaintiff again requested that it be provided with same.

34. As of the date of the filing of this Complaint, HHSC has yet to produce Requestor #1's original TPIA request for Plaintiff's confidential information. HHSC has further refused to

produce to Plaintiff's counsel Plaintiff's own confidential information it actually released in response to Requestor #1's and Requestor #2's TPIA requests.

D. Harm to Plaintiff: Capable of Repetition But Evading Review

35. Due to Defendant HHSC's failure to provide any notice prior to releasing the confidential information and its stated intention to continue to release Plaintiff's confidential information without prior notice to Plaintiff, Plaintiff has a reasonable expectation that the situation will reoccur. In addition, Plaintiff has not and will not ever have an opportunity to assert the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) for consideration by the Open Records Division of the Texas Attorney General's Office before its confidential information is released by HHSC. Therefore, this is a situation that is capable of repetition, but evading review. *Murphy v. Hunt*, 455 U.S. 478, 482 (1982); *Honig v. Doe*, 484 U.S. 305 (1988). Injunctive relief is thus appropriate herein.

36. 42 U.S.C. § 1396r-8(b)(3)(D) provides five specific exceptions that would permit limited release of confidential Medicaid drug pricing and rebate information. None of the five exceptions would permit release of the information to individual state legislators, or release pursuant to any state's open records statute.

37. Plaintiff thus reasonably understands that when it submits the confidential pricing and rebate information it will be disclosed only to those within HHSC to carry out the Texas Medicaid program and not to members of the state legislature.

38. Plaintiff is a leading provider of pharmaceuticals in the United States. Plaintiff's products are on the Texas Medicaid Preferred Drug list. The pharmaceutical industry is fiercely competitive requiring significant investments in research, development, time and resources. In order to be successful a pharmaceutical company must be innovative in finding efficiencies and

cost savings. Small differences in pricing and rebates can make the difference between success and failure. Plaintiff's pricing and rebate information is therefore kept highly confidential.

39. Plaintiff takes careful measures to protect the confidentiality of its pricing and rebate information. Not only is the information kept confidential with respect to the public at large, but it is not even openly disseminated within Plaintiff's own company. Access to the relevant documents is provided to a limited number of employees only on a "need to know basis." In total, all the employees who have access to the pricing and rebate information make up a very tiny percentage of Plaintiff's workforce. Plaintiff maintains its own secure networks. All computers, PCs and laptops, are password protected and accessible only by the authorized employee or necessary supervisor. Access to pricing and rebate information is limited to the "need to know" employees described above. Any hard copies of the pricing and rebate information are appropriately protected against disclosure.

40. Plaintiff's employees with access to the confidential pricing and rebate information are required to sign confidentiality and non-disclosure agreements that expressly protect trade secrets like the confidential pricing and rebate information. Plaintiff vigorously enforces such confidentiality and non-disclosure agreements by all legal means at its disposal.

41. Plaintiff is vigilant in protecting its confidential pricing and rebate information from public disclosure. Plaintiff does not publish their confidential pricing and rebate information in any publically-accessible form, and will not provide it to any person or entity that requests. Indeed, when Plaintiff receives notice that its confidential pricing and rebate information is the subject of a records request, it diligently seeks to enforce its legal rights to protect such information. These efforts would include, if necessary, filing lawsuits to protect trade secrets exempt from disclosure under public records laws.

42. Absent improper disclosure, Plaintiff's confidential pricing and rebate information could not be ascertained or duplicated, and could not be properly acquired by competitors or others who could obtain economic value from its use or disclosure. Although Plaintiff is a publicly-traded company, the confidential pricing and rebate information is not available from any public filings or disclosures.

43. Plaintiff's confidential pricing and rebate information is not known or used by its competitors, nor do its competitors share such information with each other. Given the highly competitive nature of the pharmaceutical industry, disclosure of the confidential pricing and rebate information would destroy the value of this confidential trade secret information. If competitors learned Plaintiff's respective pricing detail, those competitors would have an unfair advantage in a highly competitive marketplace and in competitive bidding situations.

44. Additionally, if Plaintiff's valuable trade secret pricing and rebate information were subject to disclosure by public records requests such as the requests at issue here, Texas Medicaid and other large purchasers of pharmaceuticals would also be ultimately harmed because Plaintiff, and others like Plaintiff, would have difficulty providing competitive rates to large purchasers. If every contracting entity were aware of such pricing detail and demanded the same pricing and rebate information, companies like Plaintiff would not be able to provide such pricing and rebates to every entity due to their unique differences in size, market and particular needs. If public disclosure were to lead to uniform pricing, the low rates that Texas Medicaid enjoys would disappear. Similarly, the purpose of competitive bidding would be defeated. The custom in the pharmaceutical industry is that large customers typically do not share pricing detail information with each other for this very reason.

IV. Application of 42 U.S.C. § 1396r-8(b)(3)(D)

45. 42 U.S.C. § 1396r-8(b)(3)(D) by its terms binds Defendant HHSC as the “State agency” designated by Texas to administer the Texas Medicaid program. As such, Defendant HHSC was provided Plaintiff’s confidential drug pricing and rebate information solely to administer the Texas Medicaid Program. At all times the information remained subject to 42 U.S.C. § 1396r-8(b)(3)(D), and could only be released in the five specific circumstances enumerated in the statute. Those exceptions permit release of the information (i) “as the Secretary determines...”, (ii) “to... the Comptroller General”, (iii) “to... the Director of the Congressional Budget Office...”, (iv) “to States to carry out this subchapter, and” (v) “to the Secretary....”.

46. Defendant HHSC was provided with Plaintiff’s confidential information solely in its role as the administrator of the Texas Medicaid program. As such, it was able to receive the data pursuant to exception 42 U.S.C. § 1396r-8(b)(3)(D)(iv), which allows access “to States to carry out this subchapter.”

47. 42 U.S.C. § 1396r-8(b)(3)(D) begins with the phrase “Notwithstanding any other provision of law”; thus communicating the intent of the Congress to maintain the confidentiality of the Medicaid “best price” rebate and discount data despite any other state or federal law to the contrary. Medicaid regulations originally adopted in the 1990 Omnibus Reconciliation Act (“OBRA”) require that pharmaceutical companies such as Plaintiff charge Medicaid their lowest or “best price” for their drugs. *See* 42 CFR §447.505. Such requirement was put in place to minimize prices paid by the program. It is thus vital to the continuation of the Medicaid program to obtain a truly “best price” for all drugs covered by the program. Congress requires the manufacturers to report such data, and in exchange for receiving the “best price”, enacted 42 U.S.C. § 1396r-8(b)(3)(D), to provide strict confidentiality. The reason for

this is simple. Should the confidential pricing and rebate information be released, other purchasers of drugs will request rebates and discounts to match or approach the Medicaid “best price.” If pharmaceutical manufacturers, including Plaintiff, are also required to give deeper discounts and rebates and thus the “best price” to other drug purchasers, they will not be able to offer the same type of deep preferential rebates and discounts to Medicaid programs and “covered entities” that provide health care services to indigent populations. Without such deep preferential discounts and rebates for Medicaid and covered entities alone, what once was the “best price” available only to Medicaid and “covered entities” will be driven up. Although Medicaid programs will still receive the then “best price”, the “best price” will actually be higher than before. As a result, the costs of the Medicaid program and for indigent care will increase at both the federal and state level.

48. Defendant HHSC has made clear that it will continue to release the highly confidential information protected by 42 U.S.C. § 1396r-8(b)(3)(D) to individual state legislators absent judicial intervention. The pending TPIA lawsuit in state court did not prevent the release of the same confidential information to a second requestor, without any notice to Plaintiff. This conduct prevents Plaintiff from obtaining any judicial review prior to release of the information. In short, HHSC has created a situation that is capable of repetition, but evading review.

V. Application of Texas Gov’t Code §531.071

49. Similarly, HHSC’s release of the pricing and rebate information violated Texas law which provides as follows:

Sec. 531.071. CONFIDENTIALITY OF INFORMATION REGARDING DRUG REBATES, PRICING, AND NEGOTIATIONS.
(a) Notwithstanding any other state law, information obtained or maintained by the commission regarding prescription drug rebate negotiations or a supplemental Medicaid or other rebate agreement,

including trade secrets, rebate amount, rebate percentage, and manufacturer or labeler pricing, **is confidential and not subject to disclosure under Chapter 552.**

(b) Information that is confidential under Subsection (a) includes information described by Subsection (a) that is obtained or maintained by the commission in connection with the Medicaid vendor drug program, the child health plan program, the kidney health care program, the children with special health care needs program, or another state program administered by the commission or a health and human services agency.

(c) General information about the aggregate costs of different classes of drugs is not confidential under Subsection (a), except that a drug name or information that could reveal a drug name is confidential.

(d) Information about whether the commission and a manufacturer or labeler reached or did not reach a supplemental rebate agreement under Section 531.070 for a particular drug is not confidential under Subsection (a).

Texas Gov't Code §531.071 (emphasis added). Texas Gov't Code Chapter 552 is the TPIA. Because Chapter 552 (the TPIA) is not applicable to Plaintiff's pricing and rebate information, the portion of the TPIA relied upon by HHSC in making the releases, Texas Gov't Code §552.008, is also simply not applicable.

VI. Causes of Action

A. Count One: Declaratory Judgment

50. Plaintiff hereby incorporates the allegations set forth above, all of which are fully re-alleged here.

51. Pursuant to the Declaratory Judgments Act, 28 U.S.C. §§ 2201(a) and 2202, Plaintiff requests that the Court enter a judgment construing the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and Texas Gov't Code §531.071, and declaring and clarifying the rights and obligations of the parties under those statutes.

52. There is a live case or controversy between the parties. Defendant HHSC has on at least two occasions released Plaintiff's confidential information in violation of 42 U.S.C. § 1396r-8(b)(3)(D) and Texas Gov't Code §531.071 without providing any prior notice to Plaintiff, and thus preventing Plaintiff from seeking any judicial review prior to release. This is a situation that is capable of repetition, but evading review.

53. Plaintiff and Defendants have fundamental disagreements regarding the interpretation and application of 42 U.S.C. § 1396r-8(b)(3)(D) and Texas Gov't Code §531.071. A declaration from this court would resolve this controversy and provide the parties with certainty regarding their legal rights and obligations related to the confidential Medicaid pricing and rebate information.

54. Plaintiff thus asks that the Court declare the following:

- a. That the Medicaid pricing and rebate information released by Defendant HHSC is subject to 42 U.S.C. § 1396r-8(b)(3)(D),
- b. That Defendants may only release Medicaid pricing and rebate information, including, but not limited to, the "best price" discount and rebate information, if the release is of unidentified information and/or meets one of the five specific exceptions listed in 42 U.S.C. § 1396r-8(b)(3)(D),
- c. That requests pursuant to the Texas Public Information Act do not constitute a listed exception under 42 U.S.C. § 1396r-8(b)(3)(D), and thus cannot authorize a release of confidential Medicaid pricing information,
- d. That requests by individual state legislators for general legislative or budgeting purposes do not qualify as a provision of the information "to States to carry out

this subchapter” under 42 U.S.C. § 1396r-8(b)(3)(D)(iv), and thus cannot authorize a release of confidential Medicaid pricing information,

- e. That Texas Gov’t Code §531.071 provides that Texas Gov’t Code §552.008 is not applicable to Medicaid pricing and rebate information, and
- f. If Defendant HHSC receives a request to release confidential Medicaid pricing information covered by 42 U.S.C. § 1396r-8(b)(3)(D) and/or Texas Gov’t Code §531.071, Defendants must not release same and, instead, must timely notify the Centers for Medicare and Medicaid Services and any person or entity who provided the requested information, so that those parties may seek judicial review and relief prior to any release.

B. Count Two: Injunctive Relief

55. Plaintiff hereby incorporates the allegations set forth above, all of which are fully re-alleged here.

56. Injunctive relief is appropriate if Plaintiff shows:

- (1) a substantial likelihood of success on the merits;
- (2) a substantial threat of irreparable injury;
- (3) outweighing any damage caused to the defendant; and
- (4) no harm to the public interest.

Janvey v. Aguirre, 647 F.3d 585, 595 (5th Cir. 2011). The same four elements must be shown before a temporary restraining order can be granted. *See Clark v. Prichard*, 812 F.2d 991, 993 (5th Cir. 1987). However, if such an order is issued without notice to the adverse party or its attorney, the applicant must also “clearly show that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition.” FED. R. CIV. P. 65(b)(1). The analysis involves a “sliding scale ...which takes into account the intensity

of each [factor] in a given calculus.” *Texas v. Seatrain Int'l. S.A.*, 518 F.2d 175, 180 (5th Cir. 1975). “[T]he purpose of a preliminary injunction is always to prevent irreparable injury so as to preserve the court's ability to render a meaningful decision on the merits.” *Meis v. Sanitas Serv. Corp.*, 511 F.2d 655, 656 (5th Cir. 1975).

1. Plaintiff Is Likely To Succeed On The Merits

57. As set forth above, Plaintiff is likely to succeed on the merits, because the plain text of 42 U.S.C. § 1396r-8(b)(3)(D) reflects Congress’ intent that Medicaid pricing information remain confidential regardless of any other provision of federal or state law, and that Defendant HHSC’s release of such confidential information pursuant to the TPIA was not one of the five specific exceptions authorizing limited release.

58. Plaintiff is also likely to succeed on the merits, because the plain text of Texas Gov’t Code §531.071 provides that Medicaid pricing and rebate information remain confidential regardless of any other provision of law, and that Defendant HHSC’s release of such confidential information pursuant to the TPIA was not proper.

59. Although HHSC obtained a non-precedential informal letter ruling (“ORLR”) from a staff member of the Texas Attorney General’s Open Records Division that disclosure of Plaintiffs’ Medicaid rebate data in response to Requestor #1’s one specific Public Information Act request is required under the Texas Public Information Act, that one letter ruling has absolutely no precedential value. The Texas Attorney General’s office makes this lack of precedential effect quite clear:

Unlike Open Records Decisions, these informal letter rulings are applicable only to the specific documents and circumstances surrounding

them; therefore, Open Records Letter Rulings should not be cited as precedent when briefing to the Office of the Attorney General.⁷

60. Also, the ORLR was erroneously obtained without Plaintiff having an opportunity to brief the issues before the letter ruling as issued. Further, HHSC failed to apprise the Texas Attorney General's Open Records Division, and therefore that office did not consider, the confidentiality restrictions contained in 42 U.S.C. § 1396r-8(b)(3)(D) that expressly prohibit HHSC from disclosing this information. Similarly, the ORLR did not properly consider Texas Gov't Code §531.071.

61. Even if the TPIA would apply, which is denied, because 42 U.S.C. § 1396r-8(b)(3)(D) prohibits the disclosure of the Medicaid rebate data at issue to members of the State legislature, any provision of the TPIA that would allow such disclosure is preempted under the Supremacy Clause of the United States Constitution. *See Gibbons v. Ogden*, 22 U.S. 1 (1824) (holding that state laws in conflict with federal laws are preempted pursuant to the Supremacy Clause). Specifically, absent express preemption language in a statute, the Supreme Court has recognized implied conflict pre-emption "where 'compliance with both federal and state regulations is a physical impossibility,' . . . or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Gade v. Nat'l Solid Wastes Management Assn.*, 505 U.S. 88, 98 (citing *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U. S. 132, 142-143 (1963); *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941); *Felder v. Casey*, 487 U. S. 131, 138 (1988); *Perez v. Campbell*, 402 U. S. 637, 649 (1971)).

⁷ See the Texas Attorney General's web site at: https://texasattorneygeneral.gov/open/index_orl.php (last viewed October 20, 2016); Also, as explained by the Texas Attorney General: "Open Records Decisions are formal opinions relating to the Public Information Act (formerly the Open Records Act). These decisions usually address novel or problematic legal questions and are signed by the Attorney General. Open Records Decisions may be cited as precedent in briefing to the Open Records Division." <https://texasattorneygeneral.gov/og/open-records-decisions-ords> (last viewed October 20, 2016).

62. Here, preemption of conflicting state law is clear. 42 U.S.C. § 1396r-8(b)(3)(D) forbids a State agency (here HHSC) releasing Medicaid rebate data except in five limited exceptions, none of which allow for disclosure to an individual state legislator for the purpose of fulfilling his or her legislative duties. 42 U.S.C. §1396r-8(b)(3)(D). Accordingly, any provision of the TPIA which would require the production of confidential Medicaid pricing and rebate data by a State agency to members of the legislature is preempted. As such, federal law prohibits HHSC from releasing Plaintiff's confidential Medicaid pricing and rebate data to members of the Texas Legislature, even in response to a request under the TPIA.

2. Plaintiff Will Suffer Irreparable Harm That Is Imminent

63. In general, a harm is irreparable where there is no adequate remedy at law, such as monetary damages.” *Janvey v. Alguire*, 647 F.3d 585, 600 (5th Cir. 2011). However, the availability of some economic damages does not always mean that a remedy at law is adequate. For example, courts have found irreparable harm when redress may be obtained only by pursuing multiple actions, or when a meaningful decision on the merits would be impossible without an injunction. *Id.* “The absence of an available remedy by which the movant can later recover monetary damages . . . may also be sufficient to show irreparable injury.” *Enterprise Intern. Inc. v. Corporation Estatal Petrolera Ecuatoriana*, 762 F. 2d 464, 473 (5th Cir. 1985); *see also California Pharmacists Ass’n v. Maxwell-Jolly*, 563 F.3d 847 (9th Cir. 2009) (holding that plaintiffs established irreparable harm because they could obtain no remedy against the state because of sovereign immunity). Additionally, “although monetary damages normally are insufficient to establish irreparable injury, they may be sufficient [to establish irreparable injury] if the economic damages are especially difficult to ascertain.” *AT&T Communications of the Southwest, Inc. v. City of Austin*, 975 F. Supp. 928, 942 (W.D. Tex. 1997) (Sparks, J.)

vacated as moot 235 F.3d 241 (5th Cir. 2000); *see also Heil Trailer Int'l Co. v. Kula*, 542 F. App'x 329, 335 (5th Cir. 2103) (unpub.) (“An irreparable injury is one that cannot be undone by monetary damages or one for which monetary damages would be ‘especially difficult to calculate.’”).

64. There is a substantial likelihood of irreparable harm to Plaintiff because Defendant HHSC has already released confidential information on two separate occasions without providing any notice or opportunity to seek judicial or other review. The pending TPIA lawsuit in state court did not prevent the release of the same confidential information to a second requestor, without any notice to Plaintiff. **HHSC has made clear that it will continue to release Plaintiff’s highly confidential information to individual state legislators absent judicial intervention.** This conduct prevents Plaintiff from obtaining any judicial review prior to release of the information. The TPIA process is effectively rendered a nullity. In short, HHSC has created a situation that is capable of repetition, but evading review. *Murphy v. Hunt*, 455 U.S. 478, 482 (1982); *Honig v. Doe*, 484 U.S. 305 (1988). Therefore, injunctive relief is appropriate herein. *Id.*

65. Plaintiff will be irreparably harmed by release of its pricing and rebate information, because such information is vigorously-protected trade secret information. Strict confidentiality like that required by 42 U.S.C. § 1396r-8(b)(3)(D) and Texas Gov’t Code §531.071 can never be restored once the information has been released. Plaintiff has made significant investments to price and market its products and has taken substantial measures to maintain the secrecy of its pricing and preferential Medicaid pricing and rebate information. This information is provided to HHSC solely for the purpose of administering the Medicaid rebate program pursuant to the Social Security Act. If an injunctive relief is not entered,

Plaintiff risks the loss of its confidential information, resulting in loss of competitive advantage for the foreseeable future. Only the prohibition of further releases can prevent further erosion of confidentiality and risk of further spread of the information. Moreover, even if monetary damages could compensate for the loss of Plaintiff's confidential information, which it could not, Defendant is an agency of the State of Texas releasing such information under color of law. Therefore, due to sovereign immunity, no monetary remedy would be available to compensate Plaintiff. *See Enterprise Intern. Inc.*, 762 F.2d at 473; *California Pharmacists Ass'n*, 563 F.3d at 851-52. Finally, the serial release of Plaintiff's confidential information to members of the Texas Legislature would require a multiplicity of actions to further protect such information and ensure no further disclosure. The more legislators and staffers gain access to such information, the more difficult it is to secure the information, identify the source of leaks, and sue the correct source. *See Janvey*, 647 F.3d at 600 (noting that harm which requires a multiplicity of actions to correct can constitute irreparable injury).

66. Courts in Texas, including federal courts, have repeatedly held that damage from misappropriation of competitive information is difficult to calculate and constitutes irreparable harm. *See, e.g., Heil Trailer Int'l Co.*, 542 F. App'x at 335; *FMC Corp. v. Varco Intern., Inc.*, 677 F.2d 500, 504-05 (5th Cir. 1982); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Stidham*, 658 F.2d 1098, 1102 n. 8 (5th Cir. 1981); *Daily Instruments Corp. v. Heidt*, 998 F. Supp. 2d 553, 569-70 (S.D. Tex. 2014) (“[T]he disclosure of confidential information satisfies the irreparable injury prong for purposes of a preliminary injunction.”); *Propath Servs., L.L.P. v. Ameripath, Inc.*, No. Civ.A.3:04-CV-1912-P, 2004 WL 2389214, at *7 (N.D. Tex. Oct. 21, 2004); *American Express Fin. Advisors, Inc. v. Scott*, 955 F. Supp. 688, 693 (N.D. Tex. 1996) (“In a situation where trade secrets and goodwill are involved, the threat is significant that the

harm experienced by the misappropriation or misuse of trade secrets will be irreparable . . . and damages are impossible to calculate.”); *Graham v. Mary Kay, Inc.*, 25 S.W.3d 749, 753 (Tex. App.-Houston [14th Dist.] 2000, pet. denied). Moreover, the Texas Supreme Court has recognized that the public release of pricing information and internal financial data, especially in a highly-competitive industry (such as the pharmaceutical industry), “would give advantage to a competitor or bidder.” See *Boeing v. Paxton*, 466 S.W.3d 831, 839-41 (Tex. 2015) (holding that, in light of the highly competitive aerospace industry, Boeing’s bidding and pricing information constitute information that “if released would give advantage to a competitor or bidder” and therefore, Boeing had standing to protect such information under the Texas Public Information Act).

3. The Balance of Harm Favors Injunctive Relief

67. There is no harm to Defendants in preventing their improper release of the information, nor will it in any way impair the administration of the Texas Medicaid program. The balance of harms weighs in favor of injunctive relief.

4. Public Policy Favors Injunctive Relief

68. Injunctive relief preventing any further release of the Medicaid pricing and rebate information supports sound public policy recognized by both the federal government and by the Texas government. By enacting 42 U.S.C. § 1396r-8(b)(3)(D), Congress codified its public policy judgment that maintenance of strict confidentiality over Medicaid pricing and rebate information was vital to the continuation and success of the Medicaid program. By enacting Texas Gov’t Code §531.071, the Texas legislature codified its public policy judgment that maintenance of strict confidentiality over Medicaid pricing and rebate information was vital to the continuation and success of the Medicaid program. Without such confidentiality, Medicaid

would be unable to obtain such preferential discounts and rebates, which would dramatically increase the costs of the Medicaid program to both the states and the federal government. A temporary restraining order and preliminary injunction would benefit and not harm the public interest, as public policy favors the protection of trade secrets. *K&G Oil Tool & Serv. Co. v. G. & G Fishing Tool Serv.*, 314 S.W.2d 782, 790 (Tex. 1958). There is no public policy that would outweigh the financial integrity of the Medicaid program and the medical benefits it provides to those in need.

69. Plaintiff thus requests, by separate application, a temporary restraining order and preliminary injunction prohibiting Defendants from directly or indirectly releasing Medicaid pricing information, including rebate and discount data, until further Order of this Court.

70. Plaintiff further request a temporary and permanent injunction to support the declarations requested above providing that:

- a. Defendants Texas Health and Human Services Commission and its Executive Director Charles Smith and any person in active concert or participation with them are enjoined from directly or indirectly releasing Medicaid pricing or rebate information, including rebate and discount data, including all such data belonging to Plaintiffs, until further Order of this Court and,
- b. If any Defendant receives a request to release Medicaid pricing or rebate information then Defendants must not release same and, instead, must timely notify the Centers for Medicare and Medicaid Services and any person or entity who provided the requested information, so that those parties may seek judicial review and relief prior to any release.

71. Plaintiff further requests that the Court enter the following terms in the relief granted:

- a. That the Medicaid pricing and rebate information released by Defendant HHSC is subject to 42 U.S.C. § 1396r-8(b)(3)(D) and that, therefore, Defendants shall work with Plaintiff to ensure that there is no further dissemination of that information,
- b. That Defendants may only release Medicaid pricing and rebate information, including, but not limited to, the “best price” discount and rebate information, if the release is of unidentified information and/or meets one of the five specific exceptions listed in 42 U.S.C. § 1396r-8(b)(3)(D),
- c. That Defendants shall recognize that requests pursuant to the Texas Public Information Act do not constitute a listed exception under 42 U.S.C. § 1396r-8(b)(3)(D), and thus cannot authorize a release of confidential Medicaid pricing information,
- d. That Defendants shall recognize that requests by individual state legislators for general legislative or budgeting purposes do not qualify as a provision of the information “to States to carry out this subchapter” under 42 U.S.C. § 1396r-8(b)(3)(D)(iv), and thus cannot authorize a release of confidential Medicaid pricing information,
- e. That Defendants shall recognize that Texas Gov’t Code §531.071 provides that Texas Gov’t Code §552.008 is not applicable to Medicaid pricing and rebate information, and
- f. If any Defendant receives a request to release confidential Medicaid pricing information covered by 42 U.S.C. § 1396r-8(b)(3)(D) and/or Texas Gov’t Code

§531.071, then Defendants must not release same and, instead, must timely notify the Centers for Medicare and Medicaid Services and any person or entity who provided the requested information, so that those parties may seek judicial review and relief prior to any release.

72. Plaintiff only seeks prospective injunctive relief that does not implicate the expenditure or encumbrance of state budgetary resources.

VII. Conditions Precedent

73. All conditions precedent for Plaintiff to recover in this action have been performed or have occurred.

VIII. Prayer

WHEREFORE, Plaintiff prays that Defendants be cited to appear and answer herein, that a temporary restraining order and preliminary injunctive relief issue, and that upon final hearing this Court enter declaratory judgment and issue permanent injunctive relief as described above to preserve the confidentiality required by 42 U.S.C. § 1396r-8(b)(3)(D) and Texas Gov't Code §531.071, and for such other and further relief to which Plaintiff may show itself justly entitled.

Respectfully submitted,

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