BEFORE THE

DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION

STATE OF CALIFORNIA

In the Matter of the Penalty Issued to: **PARSOLEX GMP CENTER, INC.** Appellant.	HCAI No. 20-021-Q1

DECISION OF THE DIRECTOR

This appeal of a penalty assessment under Health and Safety Code section 127679 came before Elizabeth A. Landsberg, the Director of the California Department of Health Care Access and Information ("Director"), for decision following the Director's review and rejection of the proposed decision prepared by the Hearing Officer. The Director independently reviewed the hearing record, including the video recording of the hearing and the exhibits. For the reasons provided below, the Director concludes that the Appellant, Parsolex GMP Center, Inc., established good cause for reduction of the penalty assessment.

HEARING AND RECORD

This matter was originally heard before Michelle Church-Reeves, Hearing Officer, Health Care Access and Information ("HCAI"), successor to the Office of Statewide Health Planning and Development ("OSHPD"), State of California, heard this matter on Thursday, October 28, 2020, beginning at 11:03 a.m. PDT.

Ty Christensen, Health Program Audit Manager II, Accounting and Reporting Systems Section, over the Cost Transparency in Prescription Drug Pricing ("CTRx") program, represented HCAI.

Parsolex GMP Center, Inc., manufacturer and distributor of CycloSERINE, "Appellant," was represented by Alfonso Chang, President and CEO, and Michael Chao, Chairman of the Board of Parsolex GMP Center, Inc.

Both documentary and testamentary evidence were received. The matter was submitted for decision and the record was closed on Thursday, October 22, 2020, at 11:41 a.m. PDT.

PROCEDURAL HISTORY

The Director adopted the following findings of procedural facts made by the Hearing Officer.

1. On July 31, 2020, HCAI assessed a penalty against Appellant in the amount of $455,000 for its delinquent quarterly Wholesale Acquisition Cost ("WAC") Increase Report.

2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated August 19, 2020 and received by the HCAI Hearing Office on September 10, 2020.

3. Appellant submitted its appeals within the required thirty days from the date of the penalty notice.[1]

4. The hearing was held electronically at the election of the Hearing Office. No party requested an in-person hearing or objected to an electronic hearing.

5. HCAI representatives submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. The Hearing Officer found Exhibits 1 through 5 to be authentic and relevant, and admitted then into the record.

6. Appellant submitted written exhibits to the Hearing Office and HCAI representatives in advance of the hearing. The Hearing Officer found Exhibits A through C to be authentic and relevant, and admitted them into the record.

FACTUAL FINDINGS

[1] Health & Saf. Code, § 127681(f).

1. Until July 2015, Chao Center for Industrial Pharmacy and Contract Manufacturing held the rights to produce cycloserine (under license from Purdue Research Foundation). In or around September 2015, Purdue Research Foundation sold the rights to manufacture the drug to Rodelis Therapeutics. Purdue Research Foundation manufactured the drug through a subsidiary corporation, losing $10 million over eight years. In part due to financial losses, Purdue Research Foundation sold the rights to Rodelis Therapeutics, which immediately increased the drug price more than 20 times to $10,800 for 30 capsules. In September 2015, Purdue Research Foundation deemed this increase so excessive that it asked Rodelis Therapeutics to return the rights to manufacture the drug.

2. In September 2015, Purdue Research Foundation repurchased its rights and transferred the rights to manufacture back to its previous manufacturer, Chao Center for Industrial Pharmacy and Contract Manufacturing. Additionally, Purdue Research Foundation reduced the price from $10,800 to around $1,050 for 30 capsules, approximately double its previous price. Dan Hasler, of Purdue Research Foundation, stated that with the price increase to $1,050 the supply of the drug could be maintained without further losses.

3. Appellant testified that it was affiliated with Purdue Research Foundation (associated with Purdue University) until July 1, 2016. When the affiliation ended Parsolex had four staff members, and an increase of staffing was required to replace the back office and other operations previously performed by Purdue Research Foundation.

4. In March 2018, Appellant had general knowledge of legislation regarding pricing transparency. Appellant testified that it reached out to consultants regarding pricing transparency requirements but did not receive any assistance or advice.

5. On March 28, 2018, the package insert for cycloserine was revised and stated, "Manufactured by Purdue GMP Center LLC West Lafayette, IN, 47906, USA." The revised package insert notes that cycloserine treats multi-drug resistant tuberculosis and acute urinary tract infection. The ability to treat both complaints is highlighted by the Appellant as its exhibit containing the insert language adds a bold heading that reads "CycloSERINE is approved by the U.S. Food & Drugs Administration ("FDA") to treat multi-drug resistant ("MDR-TB") and acute urinary tract infection ("UTI").

6. On February 7, 2019, Appellant increased the WAC for cycloserine by $274 (for a total WAC of $2,090). On or about March 10, 2020, Appellant registered with the CTRx program. On or about March 23, 2020, Indiana implemented Covid-19 restrictions. On or about July 28, 2020, Appellant submitted its WAC Increase Report.

7. Section 127679 of the Health and Safety Code required Appellant to file its WAC Increase Quarterly Report for the drug CycloSERINE by April 30, 2019.[2]

8. Penalties accrued from May 1, 2019, until July 28, 2020 when the report was filed.[3] In accordance with Health and Safety Code section 127679, subsection (e), HCAI assessed penalties in the amount of $1,000 per day for 455 days, resulting in a total penalty amount of $455,000. On July 31, 2020, HCAI sent Appellant an e-mail informing it of the assessed penalty.[4] HCAI attached to the e-mail the Notice of Penalty – Late WAC Increase Report, which was dated July 31, 2020, and addressed to Edward Lee.

9. HCAI's representative testified that Appellant had no previous report filings.

10. The package insert for cycloserine states that the standard dose consists of one 250mg capsule taken twice daily. Another exhibit for the Appellant indicates that the dosage can vary from 250mg to 750mg daily, depending on plasma levels. The exhibit notes that a course of treatment can range from six months to more than 18 months. A treatment regimen for MDR-TB can include multiple drugs, and cycloserine is one of three drugs listed in its grouping for inclusion. Of the three drugs, only two are approved for use in the United States. In 2017, Appellant's exhibit notes, the World Health Organization's Model List of Essential Medicines included cycloserine.

DISCUSSION AND LEGAL CONCLUSIONS

The issue here is whether Appellant had good cause, as required by Health and Safety Code section 127679, for failing to file Parsolex GMP Center, Inc's quarterly WAC Increase Report

[2] See Cal. Code Regs., tit. 22, § 96071.
[3] Health & Saf. Code, § 127679(e). See also Cal. Code Regs., tit. 22, § 96080.
[4] See Cal. Code Regs., tit. 22, § 96081(a).

for the drug cycloserine by April 30, 2019, or other good cause, such that the penalties should be waived in whole or in part. The burden rests on Appellant to submit evidence demonstrating good cause for a reduction of the penalty.

1. In *Waters v. Superior Court*, the California Supreme Court stated that, "good cause may be equated to a good reason for a party's failure to perform that specific requirement from which he seeks to be excused."[5] Good cause must be directly related to the specific legal requirement which the party failed to perform and should be outside the reasonable control of the party.[6] Good cause is sometimes defined as circumstances beyond control such as "death, illness, or other excusable circumstances."[7] Good cause is not limited to the listed reasons, however, but is based on common sense in the totality of the circumstance, and "the purpose of the underlying statutory scheme."[8]

2. Appellant stated that it was unaware of the CTRx program when it increased the WAC for cycloserine on February 7, 2019. Mere ignorance is not a strong showing of good cause.[9] The diligence of the party is a factor in determining good cause.[10] California Senate Bill 17, creating the CTRx program, was signed by the Governor and filed with the Secretary of State on October 9, 2017, well over a year and a half before the WAC increase reports would be due. In March 2018, Appellant had general knowledge of legislation regarding pricing transparency. Appellant reached out to consultants regarding pricing transparency legislation and did not receive any assistance or advice. The California Supreme Court noted that a party seeking to extend a statutory time period should "develop and pursue *productive* investigative leads" and cannot "do just enough to appear diligent."[11] The Appellant had notice of pending legislation in March 2018, 11 months before it implemented its WAC increase. The failure by the Appellant to obtain specific information as to price transparency reporting requirements indicates a lack of due diligence that undermines a claim of good cause.

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[5] *Waters v. Super. Ct. of Los Angeles County* (1962) 58 Cal.2d 885, 893.
[6] *Ibid*.
[7] Cal. Rules of Court, rule 3.1332
[8] *Laraway v. Sutro & Co*. (2002) 96 Cal.App.4th 266, 274.
[9] *Tsingaris v. State of California* (1979) 91 Cal.App.3d 312, 314.
[10] *People v. Financial Casualty & Surety, Inc*. (2016) 2 Cal.5th 35, 47.
[11] *Ibid*.

3. The Appellant stated that it did not have a large compliance department, which caused difficulty in meeting the reporting requirements of the CTRx program. The Appellant stated that it had relied on Purdue University for back office and other operational work. The Appellant stated that it had four staff in 2016 and increased its workforce to backfill the operations previously performed by Purdue University. The Appellant, however, did not indicate what size its staff had reached in 2019 after a busy 2018. The Appellant's status as a smaller specialty pharmaceutical company operating across the United States without a large compliance department, and the challenges that encompasses, also fails to establish good cause for the late report. The California legislature provided that the quarterly reports to OSHPD would not commence until at least a year after the January 1, 2018 effective date of the statute requiring them.[12] This allowed time for manufacturers selling drug products in California to become aware of, and prepare for, the new statutory and regulatory requirements. The CTRx program does not apply differently to manufacturers based on the volume or market share of their products, but only on the cost of a course of therapy.[13] This statutory scheme does not provide for a reduction or waiver penalties for late reporting due to the size of the manufacturer or its compliance department. The Appellant chose to avail itself of domestic markets, including California. It cannot then look to the diminutive stature of its compliance department as good cause to gain exception in the California regulatory environment relative to its larger peers.

4. The Appellant stated that it produces only one drug, which has a limited distribution, and therefore should be relieved either in part, or whole of the assessed penalties. The Appellant is the only holder of an approved marketing application from the U.S. Food and Drug Administration (FDA) for cyclosyrine. The Appellant stated that cycloserine is approved to treat multi-drug resistant tuberculosis (MDR-TB), of which there are 100 cases per year in the United States. Additionally, the Appellant provided exhibits that report the losses that occurred in the distribution of the drug by a prior manufacturer. While exhibits were provided to show that the United States reports approximately 100 cases of MDR-TB per year, the Appellant holds a license for the United States and Canada. The same exhibits show that there are approximately 250 cases per year in the United States and Canada. Additionally, cycloserine is used to treat

[12] Health & Saf. Code, §127679(a).
[13] Health & Saf. Code, §127677(a).

recurrent urinary tract infections (UTI) for which the Appellant provided no data on sales. Similarly, the Appellant's exhibits on the losses by a prior manufacturer include a statement from Purdue that at a WAC of $1,050 that drug could be manufactured without additional losses in 2015. The current WAC is $2,090, almost twice the amount that addressed losses in 2015. Without the Appellant providing information on all sales (for both MDR-TB and UTI) and the sales specifically in California, and the profit or loss, it is difficult to determine the actual frequency of use, the size of distribution, and the financial impact of penalties.

5. The Appellant stated that it could not report the WAC increase due to limited staff and the impact of COVID-19 restrictions implemented by the State of Indiana. As noted above, the Appellant did not provide the number of staff that it had either at the time it received notice that states began passing price transparency legislation in March 2018, or at the time it increased the WAC for cycloserine in February 2019. On March 10, 2020, the Appellant registered an account with HCAI to report under the CTRx program. On or about March 23, 2020, the State of Indiana implemented COVID-19 restrictions that reduced the number of personnel at the Appellant's place of business. The Appellant testified that due to supply chain issues obtaining laptops for remote employees took longer than anticipated. The Appellant had almost two weeks to complete its report before COVID-19 restriction went into place. The Appellant noted supply chain issues, but it did not state that employees did not have alternative methods to work remotely. The Appellant reported minimal information, as it claimed that manufacturing rights were not acquired within five years[14], and the information it did report was mainly in the public domain.[15]

6. Lastly, the Appellant contends that the penalties are too high given the limited use of cycloserine in California, and would negatively impact the availability of the cycloserine if

[14] Section 127679(a)(3) requires that a manufacturer, which acquired the rights to a drug within the five years, to report WAC at acquisition, name of company from which rights acquired, date of acquisition, purchase price, the year of introduction to market, and WAC at time of introduction. If Appellant acquired rights in 2016 (as testimony indicated), or after the 2018 package insert was printed, then it should have either reported information, or provided rationale why not. The Appellant neither reported the information, nor provided a rationale for why not.

[15] The Appellant stated in its report that it had "left columns 14 through 22 intentionally blank for this submission, as the drug product was not acquired from another manufacturer in the last 5 years." The revised package insert for cycloserine dated March 28, 2018, however, stated it is "Manufactured by Purdue GMP Center LLC." The Appellant testified that there was a change of ownership on or about July 1, 2016. But these dates indicate that the Appellant acquired the rights to manufacture within five years.

upheld. Generally, a penalty must have some reasonable relation to the harm, and a penalty well in excess of the harm could be considered prohibitively high.[16] The purpose of the penalty is to incentivize compliance with the reporting requirements of the statute. The potential benefit that a company derives by skirting the reporting requirement is reflected in the company's increase in net sales as a result of nonreporting. That exact number is difficult to quantify but, by definition, the company's increase in net sales is strictly less than the company's gross sales of the product. In many cases that difference is significant. Barring abnormal circumstances, a penalty in the amount of the offender's gross sales would likely incentivize compliance with the statute.

7. Here, the Appellant provides no information to determine costs and profits, and the sales of the drugs either within the United States, or California. Assuming that the Appellant's testimony is correct that there are only 100 MDR-TB patients per year for cycloserine in the United States, and that California comprises 11.9%[17] of the population and the patients, then 12 MDR-TB patients reside within California. In the absence of other information from the Appellant, it is assumed that all MDR-TB patients are on a treatment regimen that includes cycloserine, and that regimen lasts 12 months[18] with a dosage of two capsules for a total of 500mg daily.[19] Based on these assumptions, the Appellant has total sales of 24 capsules daily,[20] which creates a daily revenue of $1,672.08.[21]

8. The Appellant submitted the mandated report on its WAC increase 455 days late. Based on the statutory requirement, HCAI determined that the Appellant incurred a penalty of $455,000. However, the gross sales of the Appellant are often used as an alternative to the statutory penalty, which can provide the Appellant with some reduction. Here, the Appellant's gross sales for the period of non-compliance are calculated at $760,796.40.[22] Therefore, there is

[16] *Simon v. San Paolo U.S. Holding Co., Inc.* (2005) 35 Cal.4th 1159, 1179-1180.
[17] U.S. Census data for populations: U.S. 331,449,281; California 39,538,223 (https://www.census.gov/quickfacts/fact/table/CA,US/PST045219, last accessed December 8, 2021.)
[18] The middle length of treatment, six months to more than 18 months, referred in the Appellant's exhibit.
[19] The dosage listed in the package insert introduced as an exhibit by the Appellant and accepted by the Hearing Office.
[20] 12 patients receiving two capsules daily
[21] The WAC for 30 capsules is $2,090, which equals $69.67 per capsule. The per patient daily cost being $139.34. Therefore, the daily cost for 12 patients equals $1,672.08.
[22] The Appellant daily gross sales were calculated at $1,672.08 and the Appellant was non-compliant for 455 days.

evidence that the mandated penalty of $455,000 may be less than the gross revenue for sales within California.

9. If the above sales assumptions are correct, the civil penalties assessed against the Appellant are consistent with the requirements of the CTRx statute.[23] But good cause may exist to reduce penalties considering common sense and the underlying statutory scheme,[24] even if penalties are not disproportionate. Here, the penalties cannot be conclusively found to exceed the Appellant's sales in California. The Appellant failed to provide the Hearing Office with information to mitigate the penalty. The report submitted by the Appellant provided no information on either unit sales, or cost increase factors. The Appellant failed to provide any evidence at the hearing on its unit sales in California, factors relating to WAC increase, loss or profit on the drug, discounts provided, the average actual cost to patients, or explain any substantive due diligence investigation that it undertook to comply with CTRx. Based on the underlying statutory scheme, the Appellant has not provided any information regarding its actions (including pricing) to merit a reduction in the statutory penalty.

10. In a unique case such as this however, common sense requires that one looks at other good cause to reduce the required penalty. Appellant is the only manufacturer of cycloserine in the United States, and cycloserine plays an important public health role in combatting MDR-TB. The American Thoracic Society Document, entered as an exhibit for the Appellant, recommends that a five-drug combination, from three classes, be used treat MDR-TB, and cycloserine is in a class of three drugs of which two should be chosen.[25] In that class, only cycloserine and one other drug are approved for use in the United States. The World Health Organization considers cycloserine an essential medicine. California's interest in controlling TB is such that the law allows confinement of an individual with TB in specific circumstances.[26] Public health factors and the potential to deter availability of cycloserine in California must be considered. However, the Appellant failed to demonstrate other good cause, which proves little guidance in determining an appropriate penalty.

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[23] *City and County of San Francisco v. Sainez* (2000) 77 Cal.App.4th 1302, 1322.
[24] *Laraway v. Sutro & Co., supra,* 96 Cal.App.4th at p. 274.
[25] Exhibit A, Appendix B: Nahid, P., *et al*. (2019). Treatment of Drug-Resistant Tuberculosis. An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. *American journal of respiratory and critical care medicine*, *200*(10), e93–e142, Table 10.
[26] Health & Saf. Code, § 121365; Levin v. Adalberto M. (2007) 156 Cal.App.4th 288.

11. Relieving the Appellant of all sanction would not compel it to submit timely reports and there is not good cause to do so. The public health importance of cycloserine and its very limited use create an unusual circumstance. Accordingly, the Director finds good cause to reduce the penalty to $99,736[27] - the sum of the WAC increase reported late.

CONCLUSION

For the reasons set forth above, the penalty assessed against the Appellant for failure to report the WAC increase on cycloserine is reduced to $99,736.

ORDER

The assessed penalties are reduced to $99,736 for good cause.

Dated: January 14, 2022

//original signed//
ELIZABETH A. LANDSBERG
Director
Department of Health Care Access and Information

[27] The WAC increase for 30 capsules was $274, so each capsule was increased by $9.13. Each patient takes two capsules daily and there are 12 patients for a daily total of $219.20. The Appellant was non-compliant for 455 days.