BEFORE THE

OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT

STATE OF CALIFORNIA

In the Matter of the Penalty Issued to: **SUPERNUS PHARMACEUTICALS** Appellant.	OSHPD No. 20-010-Q11

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 Office of Statewide Health Planning and Development ("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, Supernus Pharmaceuticals, failed to establish good cause for waiver or reduction of the penalty assessment.

HEARING AND RECORD

This matter was originally heard before Michelle Church-Reeves, Hearing Officer, Office of Statewide Health Planning and Development ("OSHPD"), State of California, on Tuesday, September 15, 2020 beginning at 10:30 a.m. PDT.

Ty Christensen, Health Program Audit Manager II, Accounting and Reporting Systems Section, and Chaz Chung, Staff Services Manager I, Cost Transparency in Prescription Drug Pricing, represented OSHPD.

Supernus Pharmaceuticals, Inc. ("Appellant" or "Supernus"), owner and distributor of Trokendi XR and Oxtellar XR, was represented by Kevin Anderson, In House Counsel, and Chris Kaganzev, Senior Director, Contracts and Pricing.

Both documentary and testamentary evidence was received. The matter was submitted for decision and the record was closed on Tuesday, September 15, 2020 at 11:11 a.m. PDT.

PROCEDURAL HISTORY

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

1. On February 21, 2020, OSHPD assessed a penalty against Appellant in the amount of $2,849,000 for its delinquent quarterly Wholesale Acquisition Cost ("WAC") Increase Reports.

2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated March 17, 2020 and received by the OSHPD Hearing Office on March 19, 2020.

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

4. Appellant requested a continuance on May 29, 2020 via email. OSHPD's representative concurred with the continuance request. The hearing was continued to July 2, 2020.

5. On June 24, 2020, the hearing was continued to July 28, 2020 at the election of the Hearing Office due to the Hearing Officer being on military leave. No party objected to the rescheduling of the hearing.

6. Appellant requested a continuance on July 20, 2020 due to a scheduling conflict. OSHPD's representative concurred with the continuance request. The continuance was granted.

7. The hearing was held electronically at the election of the Hearing Office. No party objected to an electronic hearing.

8. OSHPD representatives submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. Exhibits 1 through 10 were found to be authentic and relevant and admitted to the record.

[1] Cal. Health & Safety Code, § 127681(f).

9. Appellant submitted written exhibits to the Hearing Office and OSHPD representatives in advance of the hearing. Exhibit A was found to be authentic and relevant and admitted to the record.

FACTUAL FINDINGS

1. Appellant is the owner and distributor of the drugs Trokendi XR and Oxtellar XR. WAC increases for eight Trokendi XR drug products and three Oxtellar XR drug products, which were effective on January 1, 2019, resulted in a greater than 16% cumulative WAC increase for each drug product over the duration of the two prior calendar years and through to the January 1 increase. Prior to this period, the WAC of each drug product given at its recommended daily dosage during a normal course of therapy exceeded $40 within 30 days.

2. Appellant filed a WAC Increase Quarterly Report for each of the eleven drug products on January 14, 2020. OSHPD assessed penalties in the amount of $1,000 per day for the 259 days each report was filed after April 30, 2019, as required by Health and Safety Code section 127679.[2] This resulted in OSHPD issuing a notice of penalty to Appellant for an aggregated penalty assessment totaling $2,849,000. The notice of penalty was sent by mail and email to the addresses provided by the Appellant when it registered to file reports with OSHPD.

3. These facts, substantiated both by oral statements made by Mr. Christensen and written exhibits offered by OSHPD, were not contested by the Appellant.

4. Appellant submitted a written statement with its appeal, and made oral statements at hearing, offering facts intended to show good cause for why its reports were not submitted in a timely manner and that the penalty was excessive, seeking thereby a reduction or waiver of the penalty assessment.

5. Appellant acknowledged that it did not provide quarterly reporting to OSHPD when required for the January 1, 2019, WAC increases for Trokendi XR and Oxtellar XR, but asserted it did file the reports shortly after it became aware of the requirement. Appellant has sold drugs in California since 2013, registered with the Board of Pharmacy as a nonresident wholesaler, and

[2] *See also* Cal. Code Regs. tit. 22, § 96071.

believed itself to be in compliance with state regulations. Appellant disavowed receipt of any prior notices from OSHPD, or other knowledge of California's Prescription Drug Pricing Program[3] ("CTRx") at the time it increased the WAC for Trokendi XR and Oxtellar XR products at the beginning of 2019. After learning of the California law in the fourth quarter of 2019 through a third party, Supernus assessed whether any of its drugs required reporting and registered with OSHPD's CTRx Program on or about December 9, 2019. Appellant then began preparing the reports for filing, and, after corresponding with OSHPD staff several times to verify filing requirements, submitted reports regarding Trokendi XR and Oxtellar XR products to OSHPD on or about January 14, 2020.

6. The Appellant offered that monitoring emerging regulations in many states presents a difficulty for manufacturers, especially smaller companies. As a specialty pharmaceutical company focusing on treatments for central nervous system diseases, Supernus does not have a large compliance department. Supernus maintains its own specialty sales force for marketing domestically but collaborates with other pharmaceutical manufacturers to market its drug products internationally. According to the Appellant's assessment of OSPHD records it obtained through a public records act request in 2020, 91 companies filed quarterly reports with OSHPD and 40 penalty letters were issued. Appellant argued that these numbers show even large companies were unable to maintain compliance, let alone a smaller manufacturer.

7. The Appellant also argued that there were relatively minor harms from its untimely reports. Supernus provides notice of price changes to its direct purchasers, including state purchasers, so purchasers would already have known about the price. The WAC pricing information was publicly available on database services and online at the time the quarterly reports were due to OSHPD. The period of noncompliance was less than a year. Trokendi XR and Oxtellar XR products are, according to Supernus, relatively low cost and generally lower volume. While recognizing that disclosure of a drug WAC increase serves a public benefit, Appellant claimed that a substantial penalty assessment could impair its production and distribution into California and reduce funding for research into new treatments.

[3] Cal. Health & Safety Code Div. 107, Pt. 2, Ch. 9

8. The Appellant also sought a reduced assessment because only two prescription drugs, Trokendi XR and Oxtellar XR, were the subject of the WAC increases, yet penalties were assessed on eleven late reports. The late quarterly reports covered the two drugs, but the different strength dosages offered for each drug have their own National Drug Code ("NDC") and WAC, resulting in a total of eleven filed reports. The percent increase on January 1, 2019, for each Trokendi XR product WAC was the same. This was also true for the January 1, 2019, WAC increases for the Oxtellar XR products.

9. Lastly, the Appellant asserted that the CTRx, as codified, is unconstitutional for the reasons set forth in *Pharmaceutical Research and Manufacturers of America v. Brown, et al.*, currently pending in the United States District Court for the Eastern District of California, case no. 2:17-cv-02573. The Appellant also alleged that the assessed penalty was in violation of the United States Constitution as an excessive fine under the Eighth Amendment, and as a grossly excessive and disproportionate penalty prohibited by due process.

10. The parties offered no rebuttals following the initial statements.

DISCUSSION AND LEGAL CONCLUSIONS

1. The issue here is whether Appellant had good cause, as required by Health and Safety Code section 127679, for failing to file Supernus' eleven quarterly WAC Increase Reports for Trokendi XR and Oxtellar XR by April 30, 2019, or other good cause for reduction of the penalty, such that the penalty should be waived in whole or in part.

2. 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."[4] Good cause must be directly related to the specific legal requirement

[4] *Waters v. Super. Ct. of Los Angeles County* (1962) 58 Cal2d 885, 893 (hereafter *Waters*).

which the party failed to perform and should be outside the reasonable control of the party.[5] Good cause is sometimes defined as circumstances beyond the party's control, and not related to the party's own negligent act or failure to act. On an individual basis, courts and administrative bodies have often found that hospitalization, incapacitation, accident involvement, or loss or unavailability of records may constitute good cause.[6] However, good cause is not limited to the listed reasons. The determination of good cause in a particular context should utilize common sense based upon the totality of the circumstances, including the purpose of the underlying statutory scheme.[7]

3. As its initial grounds for good cause for its late reports, the Appellant explained that it was unaware of the CTRx program at the time of the WAC increases on January 1, 2019, but took prompt action to provide compliant reporting once it became aware of the program nearly a year later. Mere ignorance is not a strong showing of good cause.[8] The Appellant's prompt response upon becoming aware of the CTRx program was prudent, but it does not show good cause for the extended failure to file timely reports. A party's diligence is a factor in determining good cause for an extension or a delay.[9] 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. The Appellant does not explain why its compliance department remained unaware of the CTRx program two years after the bill creating it was signed, or what actions its compliance department took during that time to stay apprised of regulatory developments beyond an initial registration with the Board of Pharmacy. Quickly updating its compliance processes upon becoming aware of the CTRx program was

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[5] *Waters, supra,* 58 Cal.2d 885,893 and Secretary of State, "Good Cause" Reasons for Waiving Late Campaign & Lobbying Filing Fees https://www.sos.ca.gov/campaign-lobbying/good-cause-reasons-waiving-late-campaign-lobbying-filing-fees/ [as of December 4, 2019].

[6] Fair Political Practices Commission, Guidelines for Waiving Late Fines (Nov. 2017) http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/TAD/FilingOfficer/700FO-Folder/Late%20Fine%20Guidelines.pdf [as of December 4, 2019]. See also *Waters*, *supra*, 58 Cal.2d 885, 893.

[7] *Laraway v. Sutro & Co.* (2002) 96 Cal.App.4th 266, 274.

[8] *Tsingaris v. State of California* (1979) 91 Cal.App.3d 312, 314.

[9] *People v. Financial Casualty & Surety, Inc.* (2016) 2 Cal.5th 35, 47. See also *Wang v. Unemployment Ins. Appeals Bd.* (1990) 225 Cal.App.3d 412, 420.

laudable, but with no evidence of the Appellant's diligence up to that time, it cannot support a finding of good cause for the late reports.

4. 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 filed reports. 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.[10] 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.[11] Given this statutory scheme, it would be nonsensical to reduce or waive penalties for late reporting based on the relative size of the manufacturer or its compliance department. Unlike the international arena, the Appellant chose to avail itself of domestic markets, including California, with its own sales force. 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.

5. The next basis argued by the Appellant for good cause for waiver or reduction of the penalty was the comparatively minimal harm of the late reporting on the public. This argument does not attempt to show good cause for the late filing of the reports. The CTRx statutes provide only one metric for calculating penalties, and it is $1,000 per day for every day that the required information is not reported.[12] Other factors such as the price of the drug, the volume of sales, total assets of the manufacturer, or prior publication, are not factors in the penalty calculation. The statutes actually contemplate that the information to be provided in the quarterly reports would be limited "to that which is otherwise in the public domain or publicly available."[13] Under this design, attempting to minimize the impact of the late reporting, because the

[10] Cal. Health & Safety Code § 127679(a).
[11] Cal. Health & Safety Code § 127677(a).
[12] Cal. Health & Safety Code § 127679(e), and § 127681(f).
[13] Cal. Health & Safety Code § 127679(b).

information might otherwise be available, relative to the penalty cannot serve as good cause for the penalty's reduction or waiver.

6. The Appellant's final reasoning for good cause to reduce or waive the penalty rests on the fact that only two drugs, Trokendi XR and Oxtellar XR, were the subject of the eleven late reports upon which the assessed penalties were calculated. Appellant argues that the statute[14] only requires reporting for each drug, hence penalties should have been assessed only for two late reports. This argument is inconsistent with the language and intent of the CTRx statutes. Reporting under the CTRx statutes is triggered based on the cost of a course of therapy.[15] Manufacturers determine how to market and price each drug, and may offer a drug at various dosages, dosage forms, and prices, and for different courses of therapy. As a result, the "cost of a course of therapy" for a drug may have multiple values, and more than one may trigger reporting. To provide for the notice and public reporting of these multiple costs and related information, the regulations require the WAC costs and information to be reported as they are listed, by "National Drug Code" (NDC) for each drug product.[16] To provide for reporting and penalties only by drug would miss the fact that there may be multiple courses of therapy where the information is not being reported. This is contrary to the intent of the CTRx statutes, which provide a penalty of $1,000 per day that the "required information is not reported" rather than $1,000 per day for each unreported drug.[17] The penalty was properly calculated based on the eleven drug products, each with separate NDCs and each with a WAC of over $40 for a course of therapy.

7. The other basis offered by appellant to support its appeal was challenging the constitutionality of the CTRx statutes themselves and the penalty they require. There exists no pending injunction on the enforcement of the CTRx statutes in the case cited by the Appellant, or any similar order outstanding in other known cases challenging enforcement of the CTRx statutes. The Appellant offered no analysis on the constitutionality of the CTRx statutes, other

[14] Cal. Health & Safety Code § 127679.
[15] Cal. Health & Safety Code § 127677(a).
[16] 22 CCR 96060, and 22 CCR 96070.
[17] Cal. Health & Safety Code § 127679(e).

than the reference to the pending case, hence good cause has not been shown to waive or reduce the penalty on that issue.

8. As to the constitutionality of the penalty itself, the case cited by the Appellant concerned a punitive damages award by a jury that was substantially larger than the statutory fines available in the state or elsewhere.[18] The civil penalty calculation at issue here is explicitly set forth in statute.[19] Even if reasoning in the case cited was applicable to the present matter, the Appellant has not provided the necessary facts and analysis to determine if the penalty is unreasonable or excessively punitive in relation to the harm.[20] The Appellant concedes that there is a public interest in providing information around drug cost increases, but does not quantify the value of that interest as it relates to products it failed to report on. It does not explain why the penalty is unreasonable or excessively punitive given the harm from its failure to provide reports related to eleven WAC increases for nearly a year. The Appellant simply suggests that the harm was minimal and therefore the penalty of $2,849,000 is unconstitutional. It has not shown good cause to reduce or waive the penalty as unconstitutionally excessive.

CONCLUSION

For the reasons set forth above, the Appellant has failed to establish good cause for waiver or reduction the assessed penalty of $2,849,000.

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[18] *Bmw of N. Am. v. Gore* (1996) 517 U.S. 559, 584.
[19] Cal. Health & Safety Code § 127679(e).
[20] *Bmw of N. Am. v. Gore* (1996) 517 U.S. 559, 580.

ORDER

The appeal is denied and the assessed penalty is sustained.

Dated: March 25, 2021

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ELIZABETH A. LANDSBERG
Director
Office of Statewide Health Planning and Development