BEFORE THE

DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION

STATE OF CALIFORNIA

In the Matter of the Penalty Issued to: **SECURA BIO** Appellant.	HCAI No. 21-008-Q2

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, Secura Bio, failed to establish 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 Tuesday, August 31, 2021, beginning at 10:30 a.m. PDT.

HCAI was represented by Ty Christensen, Health Program Audit Manager II, Accounting and Reporting Systems Section, over the Cost Transparency in Prescription Drug Pricing

("CTRx") program, Rodney Garcia, Associate Governmental Program Analyst for CTRx, and Geoffrey Trautman, Attorney.

Secura Bio, "Appellant," was represented by Mark Spring, Chief Financial Officer, and Daren Esposito, in-house counsel (not licensed with California) appearing for Appellant as an employee.

Both documentary and testimonial evidence were received. The matter was submitted for decision and the record was closed on Tuesday, August 31, 2021, at 10:50 a.m. PDT.

PROCEDURAL HISTORY

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

1. On March 4, 2021, HCAI assessed a penalty against Appellant in the amount of $58,000 for its two delinquent quarterly Wholesale Acquisition Cost ("WAC") Increase Reports.

2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated March 8, 2021 and received by the HCAI Hearing Office on March 16, 2021.

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 6 to be authentic and relevant, and admitted then into the record.

6. Appellant submitted a written statement to the Hearing Office and HCAI representatives at the time of appeal. The Hearing Officer found the written statement to be

[1] Health & Saf. Code, § 127681(f).

authentic and relevant, and admitted them into the record.

FACTUAL FINDINGS

1. In 2018, four experienced pharmaceutical managers formed Secura Bio ("Appellant").

2. On September 30, 2020, Appellant acquired the rights to Copiktra, which is approved to treat lymphocytic leukemias (chronic and small), and follicular lymphoma. Appellant claims the market for Copiktra is niche. Appellant produces Copiktra in two dosages: 15mg and 25 mg. Both dosages are produced as 56 capsules per package.

3. On September 30, 2020, at the time of acquisition, the Wholesale Acquisition Cost ("WAC") of both dosages was $12,390. On December 4, 2020, the Appellant increased the WAC by $1226.61 (for a total WAC of $13,616.61) for both the 15mg and 25mg dosages.

4. Section 127679 of the Health and Safety Code required Appellant to file its WAC Increase Quarterly Reports for the drug Copiktra by January 31, 2021.[2]

5. Penalties accrued from February 1, 2021, until March 1, 2021, 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 29 days, resulting in a total penalty amount of $58,000 for the late reports for both dosages. On March 4, 2021, 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 March 4, 2021, and addressed to Mark Spring.

6. HCAI noted Appellant had no previous or subsequently late report filings, at the time of the hearing. The subsequent reporting shows a second WAC increase for Copiktra. Appellant stated that it believed that it had a quarter to report its WAC increases. Appellant knew of the filing requirements under CTRx.

[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).

7. HCAI stated that it did not send a courtesy reminder notice to the Appellant. Appellant stated that the courtesy reminders help it report in a timely manner. However, Appellant admitted that the lack of a reminder was not the sole cause of its late reports.

8. Appellant stated that it has a small staff of 21, and the company is relatively inexperienced.

9. Appellant's late reporting did not impact the scheduled public release of the CTRx data, as the scheduled public release was at the end of March.

10. Appellant stated that it operates at a loss, and a penalty of $58,000 would be a material cost. Additionally, COVID-19 contributed to financial pressure as representative could not market its drugs. Appellant, however, stated that Copiktra had experienced modest increases during the pandemic, while its other drug witnessed decreased sales.

11. The only reason that the Appellant articulated for waiver of the penalty is its financial impact on the company.

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 Secura Bio's quarterly WAC Increase Reports for the 15mg and 25mg dosages of Copiktra by January 31, 2021, 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

[5] *Waters v. Super. Ct. of Los Angeles County* (1962) 58 Cal.2d 885, 893.
[6] *Ibid*.

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 aware of the CTRx program when it increased the WAC for Copiktra on December 4, 2021. Appellant stated that it did not realize that the reports were due on January 21, 2021. Appellant stated that HCAI's courtesy reminders played a role in timely reporting, and the lack of a reminder may have played a role in the late reporting. Mere ignorance is not a strong showing of good cause.[9] Even the excuse of ignorance is undermined by the fact the Appellant had previously filed reports in a timely manner. The Appellant cannot rely on HCAI sending courtesy reminders (nor does the statute require such a reminder). In this situation, it appears that rather than ignorance, the late reporting was due to a lack of diligence. The diligence of the party is a factor in determining good cause.[10]

3. The Appellant stated that it is a small company and is relatively inexperienced. 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] 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 its diminutive stature as good cause to gain exception in the California regulatory environment relative to its larger peers. Moreover, the argument that the Appellant lacks experience is undermined by its own statement, which noted that the Appellant was formed "by four experienced pharmaceutical managers." (Statement for Appeal of Late WAC Increase Report, March 8, 2021.)

4. The Appellant stated that COVID-19 primarily impacted its commercial operation by limiting access to oncologists to give them information about Farydak and Copiktra, and secondarily caused administrative and communication inefficiency across the organization. The Appellant did not claim that COVID-19 caused major business disruption resulting in significant

[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] Health & Saf. Code, §127677(a).

operational impacts though January 2021. In fact, Appellant stated that Copiktra had moderate increases in sales during the pandemic.

5. Both parties noted that the late reports did not impact HCAI's public reporting under the CTRx program. The fact that late reports arrived when they could be included in a public report is fortunate but not material for determining good cause. The statute is clear on its reporting requirements, and a late report is sanctioned without regard to its inclusion or not in the applicable public report. If late reports included in the applicable public report are not penalized, then the will of the legislature is thwarted.

6. Lastly, the Appellant contends that the penalties are too high given its limited financial resources. 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.[12] 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 during 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. The Appellant stated that Copiktra is a niche drug for specific forms of cancers. Here, the Appellant provides no information to determine costs and profits, and the sales of the drugs either within the United States, or California. Without the Appellant providing information on all sales (for both 15 mg and 25 mg regimes) 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 monetary impact of penalties. The Appellant claims that it operates at a loss. However, it does not provide any information on either its commercial activity, or the financial reasons for operating at a loss. The Appellant noted that Copiktra saw an increase in sales during the pandemic, and documents indicate that the WAC increased twice after the start of the pandemic. Consequently, it is not possible to assess either the impact that the penalty will have on the

[12] *Simon v. San Paolo U.S. Holding Co., Inc.* (2005) 35 Cal.4th 1159, 1179-1180.

Appellant, or the benefit derived from Copiktra during the time the Appellant failed to comply with its reporting requirements.

8. The Appellant submitted the mandated reports on its WAC increases 29 days late. Based on the statutory requirement, HCAI determined that the Appellant incurred a penalty of $58,000. 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 cannot be calculated, as neither testimony, nor documentary evidence provided sales information, or use. Therefore, any claim of good cause for relief cannot be confirmed.

9. While Appellant requests waiver of the penalty, it does not make a case for good cause to do so as required by law.

CONCLUSION

For the reasons set forth above, the penalty assessed against the Appellant for failure to report the WAC increases on 15mg and 25mg doses of Copiktra remains at $58,000.

ORDER

The assessed penalties are upheld.

Dated: May 23, 2022

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