

**THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

v.

KWAME RAOUL,
in his official capacity as Attorney
General of the State of Illinois,

Defendant.

Case No.

DECLARATION OF TIMOTHY DE GAVRE

I, Timothy de Gavre, declare as follows:

1. I am the Chief Commercial Officer for Sandoz Inc. (“Sandoz”). I joined Sandoz on February 1, 2010, and since June 1, 2021, I have overseen the wholesale distribution of Sandoz’s generic and biosimilar prescription drugs in my role as CCO. I am knowledgeable about Sandoz’s distribution system, including its sales arrangements with wholesalers and other customers.

2. Sandoz is a corporation organized and existing under the laws of Delaware with a principal place of business in Princeton, New Jersey.

3. Sandoz is a pharmaceutical company engaged in the manufacture, sale and distribution of, among other things, generic drugs and biosimilars.

4. In the vast majority of cases, Sandoz sells its products to large national wholesale distributors, which are located outside Illinois. The wholesale purchasers then re-sell Sandoz’s products, including its generic and biosimilar products, to retail pharmacies, hospitals, or other

healthcare facilities, some of which are located in Illinois. Sandoz does not control the prices at which its drugs are resold by other entities in the supply chain, nor does it control where those drugs are resold. In rare circumstances, Sandoz sells its products to hospital systems, physicians, or specialty pharmacies with a physical presence in Illinois.

5. Sandoz's large wholesale-distributor purchasers typically purchase Sandoz's products in bulk via negotiated multi-drug contracts, rather than on a drug-by-drug basis.

6. Sandoz also sells its generic and biosimilar products directly to some retail pharmacy chains that maintain their own warehouse facilities, which are also located outside Illinois. Sandoz's large pharmacy-chain purchasers also typically purchase Sandoz's products in bulk via negotiated long-term, multi-drug contracts, rather than on a drug-by-drug basis.

7. Sandoz's sales to wholesale distributors and retail pharmacy chains take place outside Illinois.

8. Sandoz markets an [REDACTED], a generic prescription medication that [REDACTED]. Sandoz sells its [REDACTED] product in a [REDACTED] dosage. [REDACTED] is manufactured for Sandoz in [REDACTED], and Sandoz markets [REDACTED] for sale throughout the United States. Sandoz's sales of [REDACTED] to wholesale distributors and retail pharmacy chains take place outside Illinois. Sandoz does not sell [REDACTED] directly to consumers in Illinois.

9. The reference listed drug for [REDACTED] is [REDACTED]. There are [REDACTED] listed for [REDACTED] in the U.S. Food and Drug Administration's Orange Book.

10. [REDACTED] is on the World Health Organizations most recent model list of essential medicines. Sandoz is one of only three companies that markets [REDACTED] for the

United States, and Sandoz has struggled to [REDACTED] for its product. [REDACTED] is currently on the [REDACTED].

11. Sandoz sells [REDACTED] in [REDACTED]. An adult receiving a maintenance dose of [REDACTED] receives [REDACTED]. [REDACTED].

12. The process for producing [REDACTED] is [REDACTED] expensive, requiring the use of [REDACTED] and the implementation of [REDACTED], for example, requiring product-specific [REDACTED], specific [REDACTED], and even requiring [REDACTED]. Failure to maintain any of these costly processes could [REDACTED]. As a result, manufacturing [REDACTED] requires its own product-specific capital investment.

13. Over the past years, the cost of manufacturing Sandoz's [REDACTED] product has increased in multiple respects: production cost increases, product ingredient cost increases, increased costs associated with product validation (including inspection and testing), and changes to its active pharmaceutical ingredient that required additional expensive tests. Other costs that are not directly associated with production have also increased, such as regulatory approval costs and costs incurred due to product inventory loss. Additionally, as Sandoz recently [REDACTED] where [REDACTED] is manufactured, Sandoz expects that overhead costs related to [REDACTED] may continue to increase when compared to [REDACTED]. And, should Sandoz decide to [REDACTED], it estimates that the [REDACTED] will cost upwards of \$2,000,000. As a result, Sandoz has faced and expects in the future

to face significant new production hurdles requiring increased processes and investment at almost every stage of production.

14. For all of calendar year 2023, the wholesale acquisition cost of [REDACTED] was [REDACTED]. In the first quarter of 2024, Sandoz intends to increase the wholesale acquisition cost of [REDACTED] for certain customers by [REDACTED]. The wholesale acquisition cost for [REDACTED], both before and after the planned price increase goes into effect, will exceed \$20 for a course of treatment lasting 30 days. Moreover, the planned increase of [REDACTED] in the wholesale acquisition cost for [REDACTED] constitutes a [REDACTED] increase over the calendar year 2023 wholesale acquisition cost for [REDACTED]. Even after Sandoz's planned price increase for its [REDACTED] product, the wholesale acquisition cost of its [REDACTED] will be [REDACTED] below the current wholesale acquisition cost for branded [REDACTED] and [REDACTED] below the current wholesale acquisition cost for the nearest competing generic [REDACTED].

15. A majority of the [REDACTED] increase in the wholesale acquisition cost of [REDACTED] is attributable to factors other than an increase in the cost of producing [REDACTED], or the cost of expanding access to [REDACTED] to promote public health. These factors include regulatory approval costs, costs incurred due to product inventory loss, and inflation. In addition, a portion of the price increase is attributable to Sandoz's assessment of current market dynamics for [REDACTED], including the pricing of competing generic products.

16. By implementing this price increase in the first quarter of 2024—after HB 3957 went into effect on January 1, 2024—Sandoz will be exposed to significant penalties and other monetary liability under HB 3957. Sandoz will have no way to recoup the revenue it may lose as a result of the enforcement of HB 3957 if the law is not enjoined.

17. At its current price, Sandoz's internal projections predict [REDACTED] will no longer be profitable given increased input costs. Withdrawing [REDACTED] from Illinois specifically would not be feasible. If it were, and if Sandoz were to withdraw [REDACTED] from Illinois to avoid HB 3957's price control, Sandoz would lose significant revenues.

18. Sandoz's anticipated pricing decisions constitute confidential and proprietary information. Sandoz does not publicly disclose the identities of any of the products for which it intends to make price changes, or the amount of any anticipated price change. Instead, Sandoz has internal safeguards and policies in place to ensure that its pricing plans do not become publicly known to its competitors or any third party.

19. Sandoz maintains the confidentiality of its internal pricing decisions to protect the integrity of its business operations, to maintain its competitive position in the market, as well as to ensure compliance with all applicable laws, including federal and state antitrust laws.

20. The public disclosure of Sandoz's confidential pricing decisions, including the identity of any product for which Sandoz intends to make a price change and the amount of that price change, would harm Sandoz and its competitive position. Sandoz's competitors would have the opportunity to make adjustments to their own pricing or other business strategies in response to Sandoz's non-public pricing plans. Even disclosing the identity of a product whose price Sandoz intends to increase (or intends not to increase), without disclosing the details of the increase, would harm Sandoz by providing its competitors for that product with otherwise confidential information regarding Sandoz's pricing plans they can use to compete with Sandoz.

21. Sandoz does not make drug pricing decisions on a state-by-state level. A number of national and regional stakeholders, including wholesale distributors, pharmacy benefit managers, retail pharmacy chains, health insurers, Medicaid and Medicare contractors, hospital

networks, and others, play a role in determining the national prices of the company's products. Sandoz has no ability to specify the price at which its products will be resold in Illinois specifically.

22. Cost is a significant factor in the pricing of Sandoz's generic and biosimilar medicines. The market for many generic medicines is highly competitive, with a dozen or more generic products competing for market share, including on price. Even where only one generic or biosimilar is available, the generic or biosimilar will generally be priced lower than the brand-name counterpart. As a result, Sandoz generally realizes significantly lower profit margins on each generic product than a brand company realizes on a brand product.

23. Under HB 3957, price increases on Sandoz's generic and biosimilar products could subject Sandoz to substantial liability. However, price increases for these products may be necessitated by numerous reasons unrelated to Sandoz. For example, prices are affected by the actions of market players that supply Sandoz with raw materials and other supplies and utilities used in the manufacture of Sandoz's generic and biosimilar drugs. Moreover, end customer prices are affected by the actions of additional market players other than Sandoz, such as wholesale distributors, pharmacy benefit managers, retail pharmacy chains, health insurers, Medicaid and Medicare contractors, hospital networks, and others. Prices also are affected by market forces in states other than Illinois. Moreover, prices for biosimilar products may also be affected by increased costs of marketing, as well as a need to recoup the costs of clinical or other studies undertaken to obtain FDA approval.

24. Sandoz already faces significant economic risks associated with its manufacture of generic and biosimilar products. Even after overcoming the difficulties in obtaining FDA approval and avoiding or defeating claims of patent infringement, Sandoz faces significant risk and uncertainty after its generic and biosimilar products enter the market, particularly when there are

multiple other products for the same medicine. The threat of liability posed by HB 3957 exacerbates the financial and other risks that Sandoz already currently faces in producing and marketing generic and biosimilar products, which will make it even more difficult to bring and maintain affordable drugs to patients. In addition, Sandoz will face increased, unrecoverable costs due to being required to comply with HB 3957's mandatory notice-and-reporting regime.

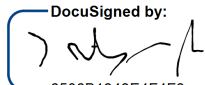
25. A cost increase of any kind could make it unprofitable for Sandoz to manufacture its generic and biosimilar prescription products. If Sandoz faces increased costs of any kind but is unable to increase its prices due to HB 3957, then Sandoz's already thin profit margins could be erased or the product rendered unprofitable.

26. If Sandoz's thin profit margins disappear, there is a real risk that Sandoz will be forced to withdraw the relevant generic or biosimilar products it currently sells nationwide, as that is the only way for it to avoid the Act's price regulation. Product withdrawal would significantly harm Sandoz, resulting in a loss of revenues, which Sandoz could not regain in the event HB 3957 were invalidated.

27. Thus, under any scenario, Sandoz will be injured by HB 3957. Each time increased costs of production or other separate factors require Sandoz to consider a price increase like those described above for [REDACTED], Sandoz will have to either (1) forgo the price increase, thus sacrificing some or all of its already low profit margin; (2) raise prices to maintain profitability, but risk severe civil penalties and other monetary liability in Illinois court; or (3) if the product is no longer profitable without the covered price increase, potentially withdraw the product from the market, suffering a loss of revenue. Sandoz will never be able to recover any of these monetary damages.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 19, 2024.

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Timothy de Gavre, CCO Sandoz Inc.