

ISSUE BRIEF

Potential Impacts of Advance Price Notification on the Pharmaceutical Supply Chain

Introduction

This issue brief explores the potential impact of laws mandating advance notification of medicine price increases. The U.S. pharmaceutical supply chain is based on contractual relationships between manufacturers, wholesalers, and pharmacies that involve confidential negotiations and complex transactions. Any change to the normal interactions between stakeholders without regard to those processes could result in negative, unintended consequences.

For instance, mandating advance price notification for prescription medicine could incentivize speculative purchasing to take unfair advantage of price variations. Speculative purchasing could in turn lead to downstream effects such as product stockpiling and medicine shortages, but is unlikely to produce any measurable benefit for government payers, private payers, or patients. What is more, because such laws may favor some purchasers over others, advance notification requirements can create inequities and competitive disadvantages.

As a result, patient access could be greatly compromised and private and public purchasers could see the price of medicines increase.

The Pharmaceutical Supply Chain and Advance Price Notification

The pharmaceutical supply chain allows for the safe and reliable flow of pharmaceutical products from a manufacturer to a patient. A seamless flow is critical to ensure patients have timely access to medications. Ideally, a patient can have a prescription written and immediately pick up that medicine at a pharmacy without any disruption in his or her treatment. All of this is enabled by a number of entities behind the scenes:¹

THE US COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN FUNCTIONS



PHARMACEUTICAL MANUFACTURERS

Manufacturers ship medicine through contracts with distributors and other direct purchasers, such as pharmacies, hospitals or physician's offices



WHOLESALE DISTRIBUTORS

Wholesale distributors act as the shipping centers for manufacturers and pharmacies and maintain the proper supply needed for distribution to pharmacies



PHARMACIES

Pharmacies serve as the point of sale for patients and rely on manufacturers and distributors to deliver the correct amount of product

Advance Price Notification

In an effort to bring more transparency to how prices for medicine are set, some lawmakers are pursuing provisions that would require pharmaceutical manufacturers to submit reports to the government that include proprietary information. Advance price notification provisions require manufacturers to notify payers of increases in the list price of a medicine prior to the increase taking effect, and do not take into account the other factors, such as negotiated discounts and rebates, that factor into the net price for the medicine.

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Advance Price Notification Will Not Save Money for Consumers or Government Payers

These policies would provide minimal to no benefit to patients and increase the administrative burden on state agencies responsible for enforcement.



Patients: A patient's out of pocket cost for a medicine is determined by insurance benefit design; therefore, mandatory price reporting of a medicine's list price (i.e. Wholesale Acquisition Cost) has little bearing on what customers actually pay for a medicine.



Government Payers: State and federal agencies would need to contend with the administrative burdens of constant price revisions and would not realize any benefits from speculative purchasing.

Advance Price Notification Will Likely Lead to Speculative Purchasing and Medicine Shortages

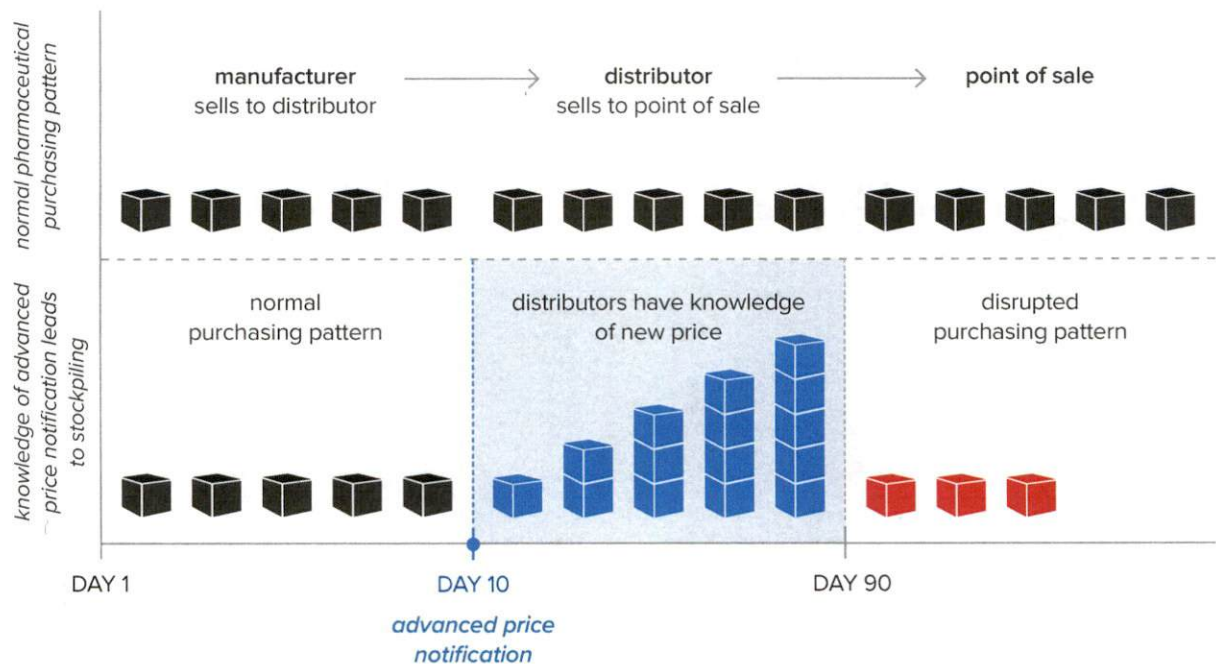
Notifications based on costs and future price increases could incentivize new speculative purchasing and problematic stockpiling that both industry and the federal government have fought to eliminate in recent years.

In the past, speculative purchasing was a practice used by distributors to profit from fluctuations in medicine prices. Manufacturers and primary distributors (wholesalers who purchase medicines directly

from manufacturers) enter into agreements that manage the volume of medicines a distributor can hold. These arrangements enable the primary distributor to earn greater inventory management fees if they manage their inventories to pre-defined target service levels, and thus discourage arbitrage or stockpiling of inventory in amounts in excess of end customer need.

Advance price notification creates a new incentive for some distributors — especially those that do not enter into contractual agreements with manufacturers — to profit from purchasing medicine at the 'old' price and selling them at the 'new' price once the increase is made public.²

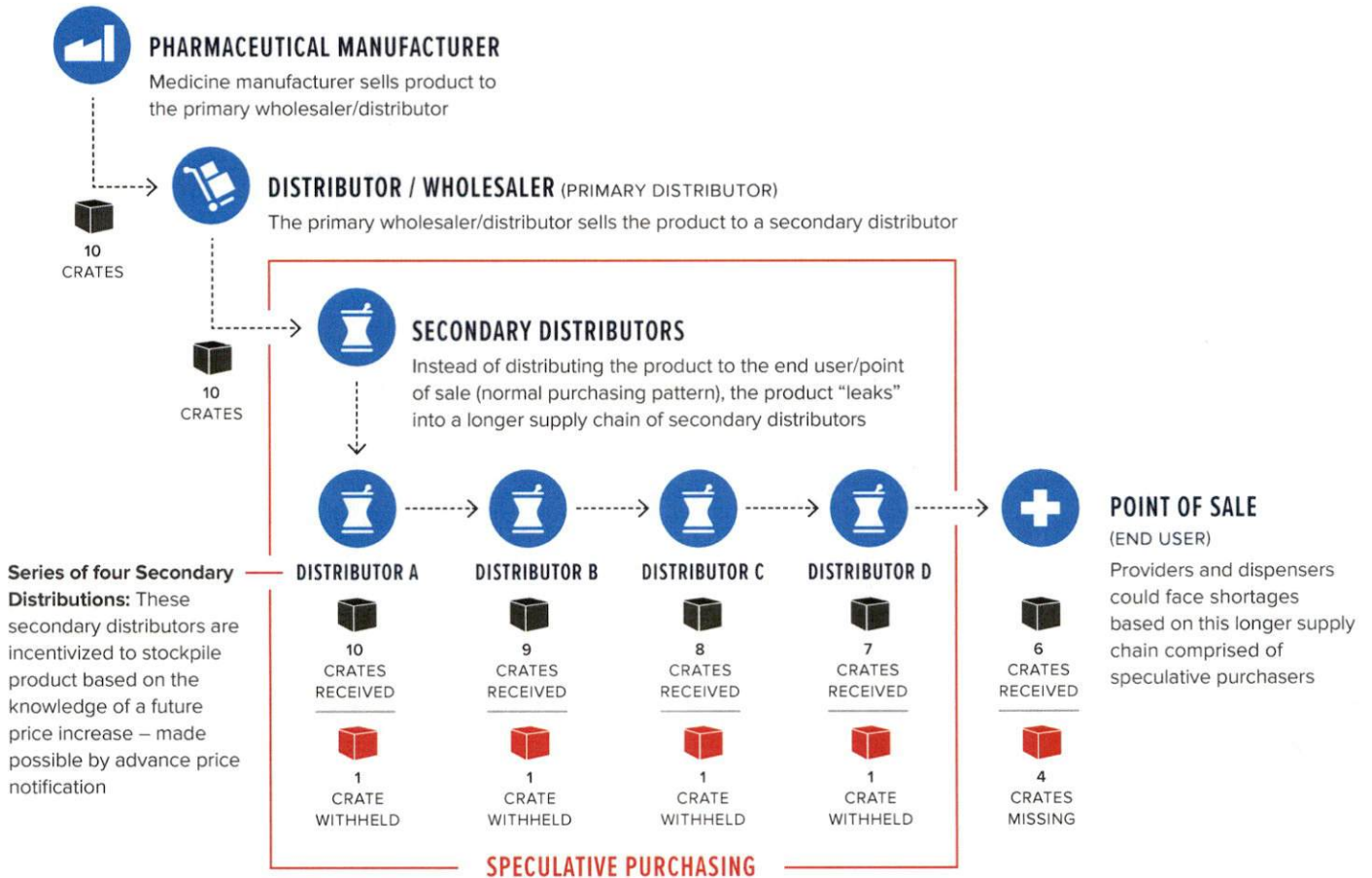
HOW SECONDARY DISTRIBUTORS PROFIT FROM ADVANCE PRICE NOTIFICATION



While medicine shortages can be caused by a variety of factors including production delays due to a lack of raw materials and components from suppliers,³ or discontinuations of medicine, they can also be caused by disturbances within the pharmaceutical supply chain. Those disturbances are often the result of distribution methods that restrict or deviate from the usual pharmaceutical supply chain.⁴ A prime example of these atypical distribution methods is the practice of stockpiling medicine in advance of a price increase or hoarding in response to an impending shortage.⁵ In this scenario, a supply chain entity may be incentivized to re-sell a medicine to another intermediary.

In the event this happens, product supply may be stretched thin and downstream prices may increase, exacerbating a medicine shortage.⁶

HOW SPECULATIVE PURCHASING CREATES A MEDICINE SHORTAGE



*This graphic is based on a Congressional investigation into drug shortages which resulted in a bicameral report titled: “Shining Light on the Gray Market”

Conclusion

The U.S. pharmaceutical supply chain system combines regulatory and market forces to ensure that medications are available to patients in a timely and safe manner.

While price transparency requirements, such as advance price notification, aim to provide the public with pertinent information on medicines, the potential consequences could become obstacles to the goals of access and affordability:

ADVANCE PRICE NOTIFICATION	
Provides No Tangible Benefit to Patients or Government Payers	Could Incentivize Speculative Purchasing between Distributor and Dispensers — Leading to Stockpiling and Shortages

1 <https://www.congress.gov/bills/113/congress/house-bill/3204/text?q=%7B%22search%22%3A%5B%22H.R.+3204%22%5D%7D&r=1>

2 <http://www.drugchannels.net/2017/10/thanks-california-sb17-will-trigger.html>

3 <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q4>

4 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/>

5 Fox E, Birt A, James K, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. Am J Health Syst Pharm. 2009;66:1399–1406.

<https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/managing-drug-product-shortages.ashx?ia=en&hash=5A30054CFE9BC74FE82F562C669F2C6BE0BDAB45>

6 Wholesale Drug Distribution: Protecting the Integrity of the Nation’s Prescription Drug Supply. National Association of Boards of Pharmacy. August 2013

7 <https://nabp.pharmacy/wp-content/uploads/2016/07/Wholesale-Drug-Distribution-08-2013.pdf>

7 <https://democrats-oversight.house.gov/investigations/investigation-of-the-gray-market>