TO: **Federal Trade Commission**
Office of the Secretary

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DATE: **September 26, 2023**

RE: **16 CFR Parts 801-803—Hart-Scott-Rodino Coverage, Exemption, and Transmittal Rules, Project No. P239300. Comments submitted to the FTC regarding Proposed Amendments to the HSR Rules and Form**

We are researchers and faculty members at Harvard Medical School and the University of Utah.[1] Our research intersects industrial organization economics and antitrust law with a focus on the pharmaceutical market. We have studied *the effect of the U.S. pre-merger notification program on pharmaceutical prices.* Our comments are based on this work and closely related accumulated experience.

I. PRE-MERGER NOTIFICATIONS IN THE PHARMACEUTICAL MARKET

Our research shows that the pre-merger notification program plays a critical role in moderating the anticompetitive effects of consolidation in the pharmaceutical market. In a recently posted study, we analyze how the price of branded, patent-protected pharmaceutical products changes after they are acquired by another pharmaceutical company, either through a merger or a targeted asset acquisition.[2] We find that, while most acquisitions are not followed by price increases, acquisitions exempted from disclosure requirements because their value falls below the HSR Act thresholds are followed by significant price increases. On average, drugs

[1] The opinions expressed here are our own and may not reflect the views of Harvard Medical School or the University of Utah.
[2] See Feng, Josh, Thomas Hwang, Yunjuan Liu, and Luca Maini. "Mergers that Matter: The Impact of M&A Activity in Prescription Drug Markets." Available at SSRN 4523015 (2023).

acquired in these "stealth" acquisitions experience a 65 percent price increase in the years following the acquisition.[3]

Our estimates suggest that the impact of these acquisitions on spending is large. Even though only eight drugs were acquired through stealth consolidation, we calculate that price increases to these drugs and their direct competitors led to over $500 million in excess spending in the year immediately following the acquisition alone.

II. DISCLOSURE OF PRIOR ACQUISITIONS

Section III.C.6 of the NPRM proposes changes to Item 8 of the Form. In particular, the changes expand the scope of prior acquisitions that would need to be disclosed and extend the requirement to the acquired entity.

Our examination of pharmaceutical M&A activity supports this change to the pre-merger notification rules and suggests that further expansion of these requirements may be warranted.

In the pharmaceutical market, there are several instances of serial acquirers. Valeant Pharmaceuticals (currently Bausch Health) acquired 86 on-patent, branded drugs through twenty-one separate acquisitions between 2010 and 2015.[4] More broadly, our analysis shows that between 2007 and 2019, eight companies completed at least four separate acquisitions. One of these companies, Horizon Therapeutics, is responsible for two "stealth" acquisitions that were followed by large increases in prices:

1. In 2013, Horizon acquired the marketing rights to Vimovo (naproxen/esomeprazole magnesium) from AstraZeneca.[5] Vimovo is a pain reliever used to manage symptoms of osteoarthritis and rheumatoid arthritis. At the time of the acquisition, Horizon already owned Duexis (ibuprofen/famotidine), another pain reliever commonly used by patients with osteoarthritis and rheumatoid arthritis. In 2014, Vimovo's estimated net-of-rebate prices increased 10-fold relative to its 2012 price. Its posted list price increased by 750%.

2. In 2015, Horizon acquired the marketing rights to Pennsaid 2% (diclofenac sodium topical solution) from Nuvo Research Inc.[6] Like Duexis and Vimovo, Pennsaid 2% can also treat osteoarthritis pain. In 2016, Pennsaid 2%'s estimated net-of-rebate price increased 20-fold relative to its 2014 price. Its posted list price increased by 650%.

[3] The term "stealth consolidation" was first used in Wollmann, Thomas G. "Stealth consolidation: Evidence from an amendment to the Hart-Scott-Rodino Act." *American Economic Review: Insights* 1, no. 1 (2019): 77-94.
[4] Numbers based on our own review of publicly available press releases.
[5] See https://www.genengnews.com/news/horizon-pharma-buys-u-s-rights-to-vimovo-from-astrazeneca/, accessed 9/26/2023.
[6] See https://www.prnewswire.com/news-releases/nuvo-research-sells-pennsaid-2-us-rights-for-us45-million-to-horizon-pharma-279541812.html, accessed 9/26/2023.

In both cases, Horizon likely did not disclose the acquisition to the FTC under the pre-merger notification program because the deal's value was below the HSR Act thresholds.[7]

Horizon's case is relevant because the company is the target of a soon-to-be-completed acquisition by Amgen.[8] Under current regulations, Horizon would not be required to disclose either deal. Moreover, because both acquisitions were structured as licensing deals, it is likely that they may not need to be disclosed even if the changes proposed by the NPRM are implemented. However, even a cursory examination of our data clearly shows that these deals had an enormous impact on prices. Hence, **we recommend that the pre-merger disclosure requirements explicitly include previous licensing deals of all parties involved in the acquisition.**

III. DISCLOSURE THRESHOLDS

The NPRM does not propose any changes to the current disclosure thresholds. However, our work suggests that **lowering the HSR thresholds would help reduce the amount of anticompetitive consolidation activity at no great cost to the regulatory authorities**.

Our research uncovers two related insights pertinent to HSA thresholds. First, as discussed in Section I of this comment, in the absence of regulatory oversight, firms will engage in consolidation activity that leads to higher prices.

Second, when regulatory oversight exists, very little enforcement action is necessary to prevent anticompetitive deals from being carried out. In our sample of analysis, we observe over 100 acquisitions of branded drugs whose reported value exceeds the HSR thresholds. Even though the FTC presumably received a pre-merger notification for all these acquisitions, it did not challenge a single one—only investigating ten and requiring divestitures on eight occasions. Yet, we find almost no evidence that these acquisitions led to higher prices.

We interpret these numbers to imply that lowering notification thresholds would result in fewer anticompetitive acquisitions being *proposed*. In other words, **the threat of close regulatory scrutiny can be sufficient to deter anticompetitive activity**. As a result, the additional burden to the FTC of reviewing acquisitions below the threshold would likely be low.

We note that our evidence applies to the overall impact of stealth consolidation in the pharmaceutical market, where stealth consolidation activity is rare because the HSR Act thresholds are quite low relative to the average size of a deal between pharmaceutical companies—which, in our data, exceeds $1 billion. However, the same may not be true in other markets. Other research shows that acquisitions below the threshold are widespread.[9] Therefore, our results may have limited external validity when applied beyond the pharmaceutical market.

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[7] Because we do not have access to FTC data on disclosures we cannot know for sure whether these deals were disclosed. However, the publicly released information on deal value suggests the deal did not have to be disclosed.

[8] See https://www.ftc.gov/news-events/news/press-releases/2023/09/biopharmaceutical-giant-amgen-settle-ftc-state-challenges-its-horizon-therapeutics-acquisition, accessed 9/26/2023

[9] See Wollmann, Thomas G. "Stealth consolidation: Evidence from an amendment to the Hart-Scott-Rodino Act." *American Economic Review: Insights* 1, no. 1 (2019): 77-94.

IV. CONCLUDING REMARKS

We conclude by expressing our sincere appreciation to agency staff for their willingness to engage with and improve existing procedures. Our research shows that regulatory oversight works well to deter anticompetitive activity. Expanding it, whenever feasible, is a worthwhile cause, especially in healthcare markets, where consolidation can lead to higher prices and reduced access to treatments for patients with critical medical needs.