Does Competition Help Drug Shortage Recovery?

The U.S. has been experiencing persistent drug shortages since early 2000, posing a significant threat to public health. Many patients cannot obtain critical drugs and doctors are forced to ration drugs [Fink 2016]. Some shortages driven by exogenous shocks such as natural disasters are unavoidable and out of drug manufacturer’s control. In contrast, 84% of shortages is driven by drug manufacturers’ business decisions [U.S. Government Accountability Office 2014]. The U.S. Food and Drug Administration (FDA) is working closely with the manufacturers to mitigate the latter type of shortages. Although the authority cannot enforce manufacturers to revise their business decisions, it has been attempting to bring more firms into market by expediting review and inspection processes for drugs with shortages [U.S. Food and Drug Administration 2013]. While this approach helps new or existing competitors to enter a new market or expand capacity, it may hamper the shortage occurring manufacturer’s recovery investment because the increased competition could lower margin of producing a drug. If the former effect is stronger, the drug shortage duration will be reduced. Otherwise, the approach may aggravate the shortage recovery. Thus, the overall impact of the FDA’s approach is ambiguous and a matter of empirical research.

To generate well-grounded hypotheses, we develop a simple yet general model to accommodate unique features in the drug shortages. Specifically, we introduce recovery complexity contingent on manufacturing scale, where the complexity decreases in manufacturing scale. We characterize how the relation between the profit and the recovery function affects the manufacturer’s recovery decision and show that drug shortage recovery time may or may not decrease in competition. In short, when the profit is more severely reduced due to increased competition than the recovery complexity, the drug shortage recovery time may increase. We empirically test our theoretical predictions.

We obtain unique drug shortage history data between 2010 and 2015 from the University of Utah Drug Information Service. The raw data consists of approximately 30,000 MS-word document files for 733 drugs. Each document has shortage drug names, their National Drug Codes (NDC), shortage causing manufacturers, available substitutable drugs, available manufacturers, shortage occurred date, and shortage resolved date. After parsing them, we remove highly seasonal
drugs such as vaccine to focus on the supply driven shortages. To control drugs’ clinical features and manufacturers' business characteristics, we relate the data with the FDA’s orange book and COMPUSTAT’s financial statement, resulting in 381 drugs with 3,029 NDC codes.

Figure 1: Regression Results

Figure 1 summarizes our empirical results with 2 by 2 conditions. Brand (Generic) means that a drug is sold under a brand (generic) name such as Tylenol (acetaminophen) and Injectable represents drugs that must be administered by injection. Since all the profitabilities of drugs cannot be observed by researchers, we use Brand and Injectable as profitability proxies. It is commonly known that a drug is more profitable when it is brand and non-injectable (Reiffen and Ward 2005, Woodcock and Wosinska 2013). We find that when the competition changes from a monopoly to a duopoly, the drugs recovery time increases in all panels except the Generic-Injectable panel, the least profitable combination, which can be plausibly explained by our model. If the competition level increases further, all panels exhibit monotonically decreasing drug shortage recovery, confirming our intuition. Nevertheless, moderate competition (e.g., Oligo1) may not be enough to drive a significant shortage recovery time reduction than a monopoly.

Our contributions are multi-fold. First, we analyze the impact of the competition level on the drug shortage recovery time by introducing the manufacturing scale dependent recovery complex-

1Oligo1 means that there are 3 to 5 firms producing the same drug. Oligo2 represents that there are more than 5.
ity. Somewhat counterintuitively, we show that an increased competition level may prolong the 
recovery time and characterize sufficient conditions for the recovery complexity. Second, we test 
the hypotheses about the impact of competition on operational decisions (drug shortage recovery 
investment) using a unique hand-collected data set and find general empirical supports. Although 
drug shortage recovery is an essential operations issue, there are only a few theoretical papers in 
the operations literature \cite{Kim2015, Jia2017}. This paper not only fills this 
important gap but also provides empirical results, in which future research can be grounded.

Our results produce academic and managerial insights. When the system recovery is considered 
under a competitive setting, the recovery complexity should be explicitly considered. Policymakers 
should recognize the subtle effect of competition on recovery and carefully setup the expedition 
rule. When competition already exists (e.g., a duopoly or an oligopoly), then increasing competition 
further will mitigate the drug shortage. However, if there is no competition, they should strive to 
increase the competition level high enough (e.g., from a monopoly to an oligopoly). Otherwise, a 
monopoly may be better than a duopoly for the shortage recovery of many profitable drugs.

References


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