Addressing the Lack of Competition in Generic Drugs to Improve Healthcare Quality and Safety

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A lack of access to critical drugs in the USA, either due to exorbitant prices or shortages, has become a troubling norm that threatens the quality and safety of healthcare. In 2017, there were shortages of 146 commonly used drugs including electrolytes, chemotherapy, cardiovascular, and antibiotic agents. For example, there currently exists a shortage in intravenous fluids and injectable opioids (both in chronic short supply for years) that has been respectively ascribed to disruptions in pharmaceutical manufacturing by Hurricane Maria and manufacturing delays. These explanations, however, mask a more fundamental and avoidable cause: a lack of healthy competition in the generic drug market which is likely contributing to price hikes and shortages. By understanding this underlying cause, we hope to illuminate a pathway from our current state of complacency, where drug price hikes and shortages are routine, to a future state of effective action, where patients have reliable access to vital drugs. This article outlines a roadmap to influence incentives, regulations, new drug development, and ultimately stakeholder (i.e., patients, providers, and drug makers) behavior to enhance competition, with the ultimate aim of improving the quality and safety of healthcare for our patients.

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A lack of access to critical drugs in the USA, either due to exorbitant prices or shortages, has become a troubling norm that threatens the quality and safety of healthcare. In 2017, there were shortages of 146 commonly used drugs including electrolytes, chemotherapy, cardiovascular, and antibiotic agents.[1] For example, there currently exists a shortage in intravenous fluids and injectable opioids (both in chronic short supply for years) that has been respectively ascribed to disruptions in pharmaceutical manufacturing by Hurricane Maria and manufacturing delays. These explanations, however, mask a more fundamental and avoidable cause: a lack of healthy competition in the generic drug market which is likely contributing to price hikes and shortages. By understanding this underlying cause, we hope to illuminate a pathway from our current state of complacency, where drug price hikes and shortages are routine, to a future state of effective action, where patients have reliable access to vital drugs.

The lack of competition for some generic drugs has roots in small market sizes, difficult regulatory requirements, and possibly, iniquitous drug manufacturer practices. For example, some pharmaceutical companies are under investigation by the Federal Trade Commission for refusing to provide samples of their products to generic drug companies, in an effort to "preserve a brand firm's monopoly indefinitely."[2]

This has led some pharmaceutical companies to acquire generic drugs for which there are no alternatives, limiting payer options when prices are increased. A widely publicized example involved pyrimethamine, a toxoplasmosis drug, whose price was increased by over 5000% after being acquired by a new pharmaceutical company. Far from an isolated example, price increases ranging from 200 to 2100% have occurred after various pharmaceutical companies acquired generic drugs. Further complicating the issue, a widening lawsuit alleges that some pharmaceutical companies have colluded to fix prices for those generic drugs that do have competitors.[3]

Regulations play a nuanced role in influencing competition in the generic drug market. On the one hand, excessive regulation may dissuade some companies from entering a small generic drug market, thereby deterring healthy competition. On the other hand, a general lack of oversight may open the door for predatory price hikes and market manipulation. Such behaviors may be compounded by a lack of clear internal or external financial incentives that align pharmaceutical company behaviors with consumer interests. For example, while investments to improve manufacturing infrastructure may

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have benefits to the consumer (by enhancing system resiliency to drug shortages), such investments are unlikely to occur unless they make sense to the financial bottom line for the companies involved.

Ultimately, an absence of healthy competition in some areas of the generic drug market means that one or a few companies exclusively create particular generic drugs or classes of drugs. The adage "don't keep all your eggs in one basket" sums up why this is a problem. We should not be surprised when the company that holds all the eggs decides to increase the price or is unable to meet demand.

The recent shortages in intravenous fluids and opioids exemplify why urgent action is needed. Loss of patient access to critical generic drugs, whether due to shortages or price hikes, may adversely impact patient health.[4]

Concrete solutions, such as mandating manufacturing redundancy for critical products and changing transparency requirements, have been recommended.[5] There is value in such symptom management. To get to a cure, however, we must collectively address the competition problem ailing the generic drug market.

INCREASE INCENTIVES AND MODIFY REGULATIONS TO IMPROVE COMPETITION

We should consider financial incentives to entice new companies to enter a small market and careful pruning of regulatory barriers to avoid deterring new entrants. Increasing competition in this way spreads out drug manufacturing, which adds redundancy and protects against greedy price hikes.

Conversely, reasonable drug price controls may act as a safety net for when normal market mechanisms fail and may help curb the out-of-control rate increases in health care costs. It also aligns the USA with other industrialized countries successfully using price control strategies.

REDIRECT OVERINVESTMENT IN NEW DRUG DEVELOPMENT TO THE GENERIC DRUG MARKET TO FOSTER COMPETITION

A recent report by the Brooking Institute[6] questions the premise that more innovation is always a good thing. They describe the current situation as an "arms race" of pharmaceutical "overinvestment," that evades "normal market self-correction mechanisms" and yields diminishing returns. This race to develop new (but rarely better) drugs ultimately draws resources away from the already floundering but high-value generic drug market.

We recommend three general strategies to address this problem: (1) Dis-incentivize overuse of high-cost low-value brand drugs; (2) Incentivize use of low-cost high-value generic drugs (e.g., by reducing co-payments); (3) Ensure equitable access to rare high-cost high-value breakthrough drugs that do not have a generic peer. Such an approach recalibrates pharmaceutical attention around proven treatments (i.e., cheap generic drugs) and advances that matter (i.e., breakthrough drugs).

PIVOT FROM SHORT-TERM SURVIVAL MODE TO LONG-TERM ORGANIZED RESPONSE

Our responses to these crises tend to be short-term solutions that sometimes exacerbate the problem, such as when hospitals build up reserves during a shortage. Other tactics show ingenuity, as when hospitals barter for supplies. What is missing as we jump from one crisis to the next, however, is attention to the deeper causes fueling this state of perpetual emergency. We cannot deliver on our mission to provide high quality care when patients go without necessary pain medications or intravenous fluids. We must continue to shift away from a survival mode culture and begin organizing our responses around long-term, sustainable solutions for patients.

ACTIVATE OUR PATIENTS BY TALKING ABOUT DISEASE (I.E., LACK OF COMPETITION), NOT JUST SYMPTOMS (I.E., PRICE HIKES AND SHORTAGES)

As trusted members of the community, we have an obligation to educate patients on issues relevant to their health. Many organizations have developed and communicated clinical action plans to patients, in response to drug price hikes and shortages. This is an excellent first step, but we can do more by educating our patients on the disease rather than the symptoms.

For example, many organizations attributed the recent intravenous fluid shortage to the effects of Hurricane Maria. This explanation is akin to attributing angina to heavy exertion, without addressing underlying risk factors for heart disease. A discussion of the symptoms without the disease leaves patients with an incomplete understanding; one that ultimately renders them less effective to advocate for their own interests and health. Helping patients understand their role in maintaining the status quo is an important step in the right direction.

THINK OUTSIDE THE BOX

There are more novel approaches being considered. Intermountain Healthcare and partners aim to address the "often unwarranted shortages and high costs of lifesaving generic medications"[7] by forming a not-for-profit generic drug company. There is also speculation that Amazon and partners are forming a new health care business to tackle rising drug costs. We should watch these experiments closely, to see what lessons we can bring back to our own organizations.

The generic drug market is not so broken as to be irreparable. By influencing incentives, regulations, new drug development, and ultimately stakeholder (i.e., patients, providers,

and drug makers) behavior to enhance competition, we can improve the quality and safety of healthcare for our patients.

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