In 2012, the US Congress, faced with widespread shortages of critical chemotherapy drugs, passed the Food and Drug Administration Safety and Innovation Act. Among its provisions, the law sought improvements in the pharmaceutical supply chain, including a requirement that manufacturers provide the US Food and Drug Administration (FDA) with notice of anticipated interruptions in manufacturing. A decade later, however, the US continues to face shortages of critical products, including contrast dye for imaging, infant formula, and pediatric oncology treatments.

Although economists usually worry about the deficiencies of health services markets or the challenging trade-offs implicit in the regulation of patented pharmaceuticals, these shortage situations have arisen in markets for goods (not services) and typically involve generic products that do not have patent protection. That is, these shortages are happening in markets where, economists would argue, competition should be working effectively to maintain supply, keep quality up, and hold prices down. In fact, almost all of these markets usually work in just that way. But sometimes, in some of these markets, a perturbation—such as a failed safety inspection or a supply chain disruption—exposes a significant and often unanticipated problem.

Such markets might be described as “sclerotic.” Under ordinary circumstances, their fragility is invisible—but in a crisis, they fail catastrophically, as with the recent US national shortage of infant formula. Because of changes in the technology of medicine, market sclerosis is likely to become an increasing problem. This problem poses a daunting challenge to policy makers, as obvious policy responses could inadvertently amplify the problem.

Market sclerosis arises from both demand- and supply-side factors. The problems are most acute for products where consumer demand is relatively insensitive (ie, inelastic) to price. Most markets cope with unanticipated disruptions through consumers choosing alternatives in response to an increase in prices. In sclerotic markets, such as those for specific chemotherapies, alternatives are often infeasible or undesirable. For many of these goods, storage options are costly, limited, and complicated, so lower prices will not even induce savvy purchasers to stockpile supply. A manufacturer that produces too much product may have a very hard time placing it, even at sharp discounts.

These demand-side rigidities generate corresponding inflexibility on the production side. Offering products at a lower price might divert some demand from existing competitors, but there is little opportunity to increase the overall size of the market. Such relatively static markets can often be effectively supplied by a small number of manufacturing facilities, which eventually settle into stable market shares.

Supply-side responsiveness is further circumscribed by the standardization and regulation imposed to maintain the quality of products that are typically hard for consumers to evaluate. Although there may be few legal barriers to entering these generic markets, a new producer cannot quickly and easily enter (and then exit) to take advantage of a market opportunity when something has gone awry. The producer must make substantial investments and obtain certification from the FDA that it meets Current Good Manufacturing Practice (CGMP) standards, investments that will be prohibitively costly unless the producer plans to stick around. These requirements mean that the supply side of these markets also shows limited responsiveness to increases in prices.

Most of the time, markets for complex, highly regulated products for which demand is not very responsive to price appear perfectly healthy. In these markets, a handful of firms compete for market
share assiduously enough to keep prices close to the costs of production, and they meet quality standards that are certified through routine inspections.

But if a disruption occurs in one of these markets—because one of the plants fails an inspection or a supply chain breaks, for example—the consequences can be calamitous. Margins in low competitive markets make it uneconomical for firms to maintain excess capacity at CGMP levels or stockpile inputs in case of a disruption. Potential new entrants are often many months or years from coming online. Competitor firms have optimized production schedules for their anticipated market share and can do little to fill the gap. Consumers—whether hospitals, physicians, or patients—have few acceptable substitutes. High demand drives up prices, but these high prices neither reduce demand nor induce new supply.

What can be done to address the risks posed by fragile markets? One option is to build a buffer into prices to induce manufacturers to maintain extra capacity and improve safety processes. The practical challenges of doing this are enormous, beginning with the problem of devising an efficient way to diagnose sclerosis in markets without creating an incentive for manufacturers to claim it as an argument in support of higher prices.

Another idea is to increase the size of the market by permitting importation of product from manufacturers whose plants meet quality standards established by peer regulatory institutions in other countries. The downside is that although a larger market might enable more firms to thrive, it could equally drive global consolidation. That could happen if the worldwide market is small enough that it can be served by a small number of producers.

A better option might be to enhance the FDA's regulatory discretion to accept products certified by peer regulatory agencies, such as the European Medicines Agency, in the event of a shortage. Currently, the FDA has very limited authority to allow importation of drugs, mainly restricted to drugs certified in Canada (which often shares a supply chain with the US for these products, making this authority of limited value in this circumstance). The FDA has used its temporary regulatory enforcement discretion to address the infant formula crisis. Congress should consider how it might provide the FDA with temporary regulatory authority to permit importation of peer-certified products in the event of a significant shortage of a generic product. This approach could preserve a diversity of producers globally, each primarily catering to its own market, while offering a more automatic fail-safe mechanism in case of an emergency.

As health care moves increasingly in the direction of personalized medicine, the problem of sclerotic markets is likely to intensify. By better matching treatments to patients, personalized medicine further reduces the number of alternatives available for individual patients, reducing the size of markets. Markets, left alone, are unlikely to cure their own sclerosis. Rather, regulatory policy needs to increase the FDA's agility and discretion to respond when market rigidities generate crises.