

## P E R S P E C T I V E

**Why Sole-Supplier Vaccine Markets May Be Here To Stay**

Vaccine markets tend to evolve toward a single dominant supplier, which has advantages as well as disadvantages.

**by Patricia Danzon and Nuno Sousa Pereira**

**ABSTRACT:** Given the structure of costs, demand, and competition, vaccine markets reach long-run equilibrium with one or very few suppliers at any point in time. Sole suppliers are less likely to exit and may have lower total social costs. Vaccine markets are dynamically competitive, with new, superior products displacing older, inferior products. Measures to address short-run supply disruptions include inventories, foreign sourcing, and improved technologies. Increasing the relative prices paid for new vaccines to levels that more closely reflect their social value compared to other new drugs and biologics is essential to achieving appropriate incentives for allocation of pharmaceutical R&D.

**M**ARK PAULY PROVIDES a thorough review of the factors that contribute to the perceived inadequate supply of existing vaccines and the development of new ones.<sup>1</sup> On the demand side, he concludes: “The real limit on state and local spending on vaccines is the willingness of... taxpayers to set a high-enough priority on this type of service by being willing to pay the price of expanding it.” On the supply side, he notes that “the production of existing vaccines has been characterized by major exit of firms and shortage of investment (relative to other drugs)” and concludes that “this is circumstantial evidence that returns on investment are below normal” and that there is strong evidence of inadequate spending on inputs to prevent errors and disruptions of supply. His tentative policy conclusion is that “shifting to more public provision of demand-side financing can be combined with greater

reliance on markets to invent, produce, and distribute vaccines, as the [Institute of Medicine] report suggested.”

Our analysis of vaccine supply elsewhere in this volume reaches some similar conclusions but with some important differences in the diagnosis of the problems and tentative policy implications.<sup>2</sup> We argue that given the cost and demand conditions of most vaccine markets, long-term equilibrium is likely to be one supplier or at most a few suppliers of each vaccine type at any point in time. Having a sole supplier of each vaccine type does not necessarily imply suboptimal investment or that the expected return on investment is below normal. For older products for which research and development (R&D) has presumably been fully amortized, prices must be sufficient to cover long-run marginal cost, including the costs of any plant or product upgrades required by regulation. But it is unrealistic to an-

---

*Patricia Danzon (danzon@wharton.upenn.edu) is the Celia Moh Professor of Health Care Systems at the Wharton School, University of Pennsylvania, in Philadelphia. Nuno Sousa Pereira is an assistant professor in the Economics Department at the Universidade do Porto, Portugal.*

anticipate investment in new “me-too” forms of old vaccines. Rather, new entrants into older vaccine markets tend to produce superior products, and this has precipitated the exit of the older, inferior products. Thus, inactivated poliovirus (IPV) drove out active oral poliovirus (OPV), acellular pertussis drove out whole-cell pertussis, and thimerosal-free products drove out thimerosal-containing products.

The anticipation of new, superior technologies can contribute to short-run supply problems of established products, by undermining incentives for producers to invest in upgrading or expanding their existing plants. Thus, as we describe in our longer paper, the anticipation of new, superior cell-based forms of flu vaccine is one reason why existing suppliers who use the old egg-based technology are unwilling to invest in expanding their capacity, since this capacity may be rendered obsolete once the superior product is approved.

### Dynamics Of Vaccine Markets

■ **Emergence of superior products.** This pattern of dynamic competition and subsequent single-product dominance of vaccine markets is not necessarily suboptimal, given the high fixed costs of regulatory approval and production, compared with the relatively small market size and concentrated demand. This concentration of demand is greatest for pediatric vaccines and is attributable not just to governmental purchase of more than half of pediatric vaccines, but also to governmental recommendations that apply equally to private as well as public purchasers. Thus, once the recommendation of the Advisory Committee on Immunization Practices (ACIP) switched from OPV to IPV, demand evaporated for OPV products, and they all exited the market. Such exits are not necessarily cause for concern, if the recommendations do in fact identify the superior product.

■ **Prices.** Of course, the entry of a superior product type need not imply a sole producer. In fact, new classes of vaccines often initially attract several suppliers. But the continued co-existence of multiple suppliers is likely only if

they produce differentiated products, each of which is preferred by some group of purchasers. If the products are identical, or if one is superior for the great majority of purchasers, then competition is likely to drive prices down to marginal cost, leading ultimately to the exit of all but one producer—in the absence of tacit or explicit agreement on price and market allocation, which is unlikely to be condoned by purchasers or antitrust authorities. Thus, vaccine prices for older vaccines may be low not just because consumers and government purchasers undervalue vaccines, but also—and perhaps mainly—because competition between firms with large sunk costs and low marginal costs drives prices below purchasers’ maximum willingness to pay. In economic terms, purchasers capture the consumer surplus. Anticipating such competition, potential entrants have little incentive to invest in developing similar products since they could not hope to recoup their R&D costs unless they have a sufficiently superior product to command a higher price or capture a dominant market share.

■ **Dominant supplier.** By contrast, a single-supplier equilibrium is less frequently the norm in pharmaceutical markets because those markets are generally larger relative to fixed costs; differentiated products can coexist because they often differ in safety or efficacy for major groups of consumers; demand is less concentrated; and there are no governmental recommendations that steer utilization toward the single preferred product.

If this model is correct—that vaccine markets tend to evolve toward a single dominant supplier—the good news is that this supplier is unlikely to exit, at least until replaced by a superior product, in which case the exit is less problematic. For example, there has been only one producer of measles-mumps-rubella (MMR) vaccine since 1978, two producers of IPV since 1980, and a single one after 2000.

■ **Supply interruptions.** Given high and potentially increasing fixed costs of regulatory compliance and production, total costs may be lower with a single producer. Of course, the full social cost of adding additional suppliers

depends not only on effects on production costs but also on any reduction in the risk of supply interruptions. Nevertheless, it seems likely that any desired reduction in the risk of supply disruption could be achieved at lower cost if the sole supplier maintained excess and separate production capacity; however, imposing such a requirement or expectation on vaccine manufacturers would add to costs and hence might further reduce the number of new entrants.

### Policy Considerations

■ **Inventory priorities.** If the sole-supplier equilibrium is likely to be the norm in vaccine markets, then policies to address the risk of temporary shortages are obviously critical. In the short term, there is a strong case for maintaining inventories, to the extent possible given vaccines' limited shelf life. Longer-term high priority should be given to technologies that reduce the risk of plant contamination and hence of product interruptions, and technologies that increase shelf life or shorten the lead time required to expand production, or both. The new cell-based flu vaccine technologies are expected to demonstrate the benefits of such improvements and provide some encouraging evidence that vaccine markets are providing incentives and firms are responding with improved products.

■ **Accelerated approval.** Perhaps the most promising approach to dealing with shortages is collaboration between the Food and Drug Administration (FDA) and other regulatory authorities, to facilitate accelerated approval for the U.S. market of vaccines that have met similar regulatory requirements in other jurisdictions, if serious shortages occur. As we show in our longer paper, a number of vaccines are approved in European and Canadian markets but not licensed in the United States, presumably because the expected costs of clinical trials and other requirements for U.S. approval are high compared with the expected revenues, given the relatively small market size and the competitive risks of taking on established producers in the absence of a clearly superior product. Using these foreign

suppliers may be the least costly approach to handling temporary shortages. Compared with simply delaying scheduled vaccines, this strategy reduces inconvenience to patients and implies a greater financial penalty to incumbent manufacturers, thereby increasing their incentives to invest to avoid supply disruptions. But this strategy is also not without cost and risk, so the best approach is vaccine specific, depending on the expected duration of the shortage, costs, and health effects of delaying vaccine schedules and risks associated with foreign sourcing.

■ **R&D incentives.** We have argued that competition may drive vaccine prices for older vaccines below consumers' maximum willingness to pay, and hence that actual prices for these older vaccines do not provide unambiguous evidence that they are undervalued by consumers, nevertheless. However, although a detailed analysis is beyond the scope of this paper, current prices for new vaccines seem low relative to prices for some other new drugs and biologics, with some new oncology products costing \$20,000–\$40,000 per year of patient treatment. Thus, although considerable R&D is under way to develop new vaccines, these sorts of price differentials are likely to skew R&D investments toward the higher-price drugs and biologics, such as cancer treatments, even if vaccines offer greater potential benefits in expected life years saved. If this observation is accurate, then increasing the relative prices paid for new vaccines to levels that more closely reflect their social value compared with other new drugs and biologics is an essential step toward achieving appropriate investment in vaccines and maximizing the health benefits from pharmaceutical R&D.

### NOTES

1. M.V. Pauly, "Improving Vaccine Supply and Development: Who Needs What?" *Health Affairs* 24, no. 3 (2005): 680–689.
2. P.M. Danzon, N.S. Pereira, and S.S. Tejawani, "Vaccine Supply: A Cross-National Perspective," *Health Affairs* 24, no. 3 (2005): 706–717.