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The Tragedy of the Commons — Drug Shortages and Our Patients' Health

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There has been, rightfully, a great deal of controversy related to the EpiPen pricing issue[1]; a preparation sold for $83 by Merck (Rockville, Md) a decade ago is now priced at $600. The fury directed at the company now marketing this drug-delivery device — Mylan (Canonsburg, Pa) — came from patients, families, and legislators; lives are on the line, people suffering from anaphylaxis will die if they do not have rapid access to epinephrine. The response of Mylan was, initially, to shrug their shoulders: it is capitalism after all. Their secondary response, outlined by Fromer[2] in this issue of ***The American Journal of Medicine*** — and commented upon by us[3] — was to shift this obscene cost to employers, insurers, and our government. This is truly a tragedy of the commons: an entity benefitting from the commons without contributing to it.[4] Mylan's final response to the increasing public outcry and governmental scrutiny is the release of a "generic" EpiPen at half the current price, $300 for 2 injectors as opposed to $600, still nearly triple the price charged for the EpiPen as recently as 2007.[5]

Why is this happening? Those of us who practice medicine know, intimately, about drug shortages (detailed updates at http://www.ashp.org/menu/DrugShortages/CurrentShortages).[6] The literature is replete with discussion of these[7-9] and include: 1) Competition forcing weaker generic manufacturers out of the market, leaving a stronger company — such as Teva (Petah Tikva, Israel) — in control of 20% of the world's supply of generic drugs; 2) The Food and Drug Administration (FDA) approval process for each generic drug is slow, creating barriers to new entrants; 3) Manufacturing problems, supply chain issues, FDA compliance problems, and business failures have decreased the numbers of suppliers; 4) Finally, the emergence of companies with avaricious pricing strategies — such as Mylan, Turing, and Valeant — are illustrative of a new pharmaceutical business model in which research and development are not performed. Rather, the company acquires rights to an old drug with a natural monopoly and engages in price gouging.

The issue of drug unavailability where the reason is not regulation, primary material shortage, or manufacturing mishap, but price — or price gouging, in the case under discussion — is different. Health care economics is not the same as automobile manufacturing economics. Customers purchase cars from dealers, have a series of options to choose from, and live within a stable construct to execute the purchase in a well-thought-out way; our patients are not — in the sense of having choice when they are acutely ill — "customers." Health care is different in as much as its receipt — including drugs — may involve the very *being* of the person under consideration. Furthermore, the market approach to health care breaks down the moment a patient enters a health care system. No one suffering from acute illness is able to "shop around" for his or her care. Similarly, when one company — Mylan — through a legal monopoly, controls the only epinephrine injector presently marketed, some patients are forced to carry expired injectors due to cost-associated barriers[10]; others do not have the device at all.

We need to be able to reward individuals and companies who innovate to create new drugs, especially if at a lower cost. We must not, however, allow the health of our patients to be held hostage to individuals or companies who hoard a drug through its patent/production, and then gouge the commons. This is not modern regulated capitalism; it is a monopoly capitalism that has gone off the rails. When Adam Smith wrote about an "invisible hand of the market," he was not referring to some pricing self-correction mechanism. Instead, the context was "the market" preventing industrialists from moving to lower-cost countries to maximize profit[11]; that this was a mistaken concept is self-evident. Centrally, there must be appropriate regulation to prevent this abuse from occurring.

Mylan's strategy dictates the Chief Executive Officer's plan, who frankly admits, "I am running a business."[12] Yet this strategy betrays the rules of modern capitalism. In a true competitive environment — at least in theory and when

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multiple firms produce similar products — the market price is beyond the control of any individual firm, and there is no need for anyone, government or private, to set a fair price. Steady increases in anaphylaxis-related diagnoses or hospitalizations, representing increased "customer" demand, would result in firms entering the market, increasing production of the epinephrine delivery device and putting downward pressure on the device's price. A *lack* of competition — as in this case — informs the conditions for a firm's profit maximization. The monopolist raises the price — gouging "customers," the government, and insurers — as long as it can recruit consumers, and regardless of the device quantity. The result is, as we have seen, a troublesome clash between the individual pharmaceutical company's bottom line and our health system. We acknowledge that a firm investing significant capital in drug research and development should recover their cost and make a profit; this is not the case with Mylan or the EpiPen.

The data on anaphylaxis reported in the article under Fromer's name[2] are clear. He calls for access to the EpiPen for all in need; we applaud this call. Less laudatory is his suggestion that, while Mylan increases the price almost eightfold, availability be funded through the commons — employers, insurance companies, and our government.

We suggest a slightly different plan of action to deal with the issue under discussion and each of the above-cited problems causing drug shortages. Firstly, in a critical area (emergent treatment of anaphylaxis) the FDA can, through regulation, eliminate Mylan's monopoly. An epinephrine delivery device for anaphylaxis is available in Britain, Canada, and the European Union; these should be given expedited approval for import to the US. Secondly, the FDA can, and should, provide expedited review of abbreviated new generic drug applications for which only one manufacturer exists. Thirdly, the FDA should eliminate user fees for evaluation of selected drugs/manufacturers to encourage new market entrants once patent protection has expired. Fourthly, the Centers for Medicare & Medicaid Services should be empowered to negotiate drug prices. Finally, our drug market should be opened to drugs regulated by the European Medicines Agency and Health Canada.

This may result in more, different, or even less regulation, but it will not result in the enrichment of the few at the expense of the many; the classic tragedy of the commons.

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