The article by Dickson and Reynolds reveals a paradoxical consequence of the mechanism by which the United States seeks to ensure access to expensive medical treatments for underserved populations. The 340B Program, a US federal drug pricing program created in 1992, is an attempt to ensure access to cutting edge treatments while at the same time maintaining commitment to a market-based approach to setting drug prices. This study demonstrates that the nontransparent nature of the transactions under 340B result in unintended consequences that benefit pharmaceutical manufacturers and raises questions about the 340B system's ability to accomplish its primary goal of improving access to care.

There are 3 major parties to all transactions under the 340B system:

1. Hospitals and clinics that serve a high proportion of uninsured or underinsured people. Such clinics are designated “340B entities” under the law.
2. Pharmaceutical manufacturers.
3. Pharmacy benefit management firms (PBMs), which are corporate entities whose business is managing the pharmacy benefit for large health insurers. Pharmacy benefit managers typically manage the benefits of millions of subscribers. They leverage their large patient volume to negotiate price rebates from pharmaceutical manufacturers. When a PBM reimburses a pharmacy for dispensing a pharmaceutical product, the PBM receives the negotiated rebate from the manufacturer.

Figure 1 of the article by Dickson and Reynolds provides a clear illustration of the 340B process. First, a 340B entity purchases pharmaceuticals directly from pharmaceutical manufacturers at a discounted price, the so-called 340B price. Second, the 340B pharmacy submits a reimbursement claim to the payer, which is a PBM. The PBM then reimburses the claim at the full retail price for the drug. The margin between the list price and the 340B price generates revenue for the 340B entity. Those margins incentivize and support expanding access to new treatments at 340B entities.

After the PBM reimburses the 340B pharmacy, the PBM itself turns to the manufacturer and secures its negotiated rebate for the drug. This last transaction is somewhat counterintuitive, as the PBM is effectively a third party to the transaction between the 340B entity and the manufacturer but, because the PBM reimbursed the claim and because the PBM has a negotiated rebate for every pharmaceutical claim it pays, the manufacturer is contractually obligated to pay the rebate to the PBM.

Dickson and Reynolds point out that under the payment structure of 340B, pharmaceutical manufacturers are hit with a double cost—both the discount to the 340B entity and the rebate to the PBM. By lowering the list price for a drug, the manufacturer lowers its gross revenue but also reduces both costs. With some insightful arithmetic, Table 3 in the article demonstrates how lowering list price paradoxically results in greater net revenue for pharmaceutical manufacturers, while at the same time depriving the 340B entity of much of its revenue. Notably, this price change has little impact outside of the 340B market. For commercial insurance claims, rather than pay a high list price for a drug and then secure a rebate later, PBMs simply pay a lower list price and receive no rebate. In net, there is no difference. Effectively, all of the excess revenue for the drug comes at the expense of revenue to the 340B entity.

The central insight of this article, that manufacturers are manipulating drug prices at the expense of community health care organizations, raises serious challenges to the entire approach to
pharmaceuticals pricing in the United States. The 340B system focuses on 2 important, but independent, goals: (1) controlling the cost of pharmaceuticals and (2) subsidizing the revenue of 340B entities such that they can continue to provide care to underserved populations. At first glance, 340B appears to combine these 2 goals into one elegant, market-based solution. The system of discounts and reimbursement to 340B entities both controls cost and generates 340B entity revenue, largely on the dime of the manufacturers. But not surprisingly, pharmaceutical manufacturers are both smart and profit motivated. These new data make it clear that motivated firms will find every leak to maximize profit. Indeed, that is their job, at least in our current understanding of fiduciary duty.

Arguably, 340B is working toward its goal of controlling drug costs. The rebates that pharmaceutical companies pay to PBMs, combined with the discounts to 340B entities, effectively impose a fine on the pharmaceutical companies for keeping their prices high and their rebates opaque. The 340B system makes it more profitable for the pharmaceutical manufacturers to simply lower their list prices, rather than continue with the system of nominal, very high list prices and opaque rebates. Overall, this likely maintains downward pressure on drug prices across the board. List prices are public knowledge and contribute to market transparency, whereas rebates are negotiated in secret and create imperfect information about what other firms are paying for drugs. It is important to note that this finding contradicts what has been the dominant narrative about 340B—that forcing discounts in the 340B market creates upward pressure on prices because firms need to recuperate their losses.4 Here we see that at least in the hepatitis C virus (HCV) pharmaceuticals market, 340B is likely keeping prices lower.

However, this article also demonstrates that going forward, 340B may fail to accomplish its second goal—using pharmaceutical revenues to subsidize the work of clinics that provide care to underserved populations. Perhaps this should not be surprising, given the paradoxical goals of 340B. The 340B program seeks to simultaneously redirect revenue generated by high pharmaceutical costs back to resource-limited settings, while at the same time applying pressure to lower the very margins that it is using to create revenue. When HCV drug prices were close to $100 000 per treatment course, 340B redirected some of that inflated revenue back to communities with limited access.5 Now that drug costs have decreased and are closer to the true cost of production, there is less excess revenue to redistribute. Pharmaceutical manufacturers seem to have found the “golden ticket” that allows them to recapture nearly all of the revenue that had been flowing toward 340B entities.

Ensuring equitable access is a fundamental requirement of any health care system and a human rights mandate. In economic terms, health care equity is a good to which we attach value. Things with value have a cost. We should not be surprised, therefore, that ensuring equity comes with a cost. We need to be willing to make such investment. Revenue from HCV drugs, even at the new, lower list price, remains high.6 Tapping some of those profits to support care for underserved populations is one attractive option, but doing so will require a more direct tax on pharmaceutical manufacturers. Alternatively (or in addition), perhaps it is time to reconsider the structure of reimbursements from health insurers to ensure that they adequately reimburse the true cost of delivering HCV care. Most 340B entities use their revenues to support wraparound services like case management, pharmacy support, and patient navigation for patients with low health care literacy. These services are not reimbursed by commercial or public payers, but they are integral to the operation of a successful HCV treatment program.5,7 Supporting those services by making them reimbursable may also establish general infrastructure that could benefit health care generally in the communities that 340B entities serve. To be clear, however, there is no free lunch. Reimbursing wraparound services will have substantial cost. At some point, there is no way around the real question—are we ready and willing to invest in health care equity?
REFERENCES


