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A Smarter Way to Provide Epinephrine at School

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Despite the years-long public outcry over high prescription drug prices, public concern has not yet coalesced into major policy change. As a result, Americans remain uncomfortable with pharmaceutical prices, spending, and pharmaceutical manufacturers' profits.¹

In large part, the absence of significant policy change to rein in drug prices or spending is attributable to the inherent political challenges of altering the market of a large, profitable industry. But it also reflects the complexity of the issue



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of high drug prices. Drug prices can be high or rise quickly for many reasons.

The quintessential case is that of the on-patent drug with years of monopoly protection in a market willing (or even required) to pay exorbitant prices through third-party payers. It is precisely this mechanism that underlies the 12% annual growth rate in the launch prices of new cancer drugs, for example.² But, for other reasons, we have also seen some drugs with competitors, even generics, offered at ever-higher prices.

The EpiPen is one such example. An EpiPen is an epinephrine autoinjector for patients experiencing a severe allergic reaction. Although epinephrine autoinjectors have been available since the 1970s, the price of the EpiPen has continued to go up over time, not down, as would be expected of a mature technology. When Mylan acquired the decades-old EpiPen in 2007, a 2-pack retailed for less than \$100. By 2016, Mylan had raised the price to more than \$600.³ Even though the EpiPen is an old product, Mylan was able to continually increase its price for at least 3 key reasons. First, although the drug contained within the EpiPen is old and off-patent, the newer versions of the autoinjector device are still under patent,⁴ and Mylan can exclude competitors from making the same device. Second, the regulatory process to develop a challenger to the EpiPen is long and complex, especially in cases in which the existing product is seen as highly safe and effective. Third, even in periods when there have been other autoinjectors on the market, their mode of operation is different enough that it creates barriers to switching for patients and other health care actors.

Although there are now more EpiPen alternatives on the market, it is not clear that prices for many patients have come

down meaningfully. In response to the public criticism of their price increases, Mylan introduced an authorized generic version of the EpiPen for \$300. This is still 3 times the 2007 price, but since the generic version may not come with the same discounts as the branded product, it may not save money for insurers. Patients may obtain an authorized generic version of Adrenaclick, a rival product with a similar injection mechanism, for closer to \$100,⁵ but the barriers to switching mean that few patients have chosen to change. In 2018, the US Food and Drug Administration approved a generic version of the EpiPen made by Teva, but since its price is also \$300, it may not save money for similar reasons.⁶

The rise in the price of the EpiPen was coupled with a rise in the prevalence of high-deductible plans, which means that more patients were exposed to the product's full price.⁷ The cost to families is higher still if they provide units for dedicated at-school use. This is a burden borne by a large number of families. An estimated 6 million children (8%) younger than 18 years in the United States have food allergies and could be at risk for anaphylaxis.⁸ Because delays in care could be fatal, it is prudent that epinephrine be available at school, where children spend a great deal of time and are easily exposed to food allergens. About 18% of school-aged children with food allergies have had a reaction at school within the last 2 years.⁹

However, it does not follow from these facts that the socially optimal way to protect children from anaphylaxis is for families to provide epinephrine for use in schools. As shown by Shaker and Greenhawt,¹⁰ it is both lower cost and more effective when schools do so instead. It is easy to see why: some autoinjector units expire unused. Therefore, when families take on the cost of in-school anaphylaxis directly, resources are more likely to be wasted on unused units. This approach is also more effective because some students do not always have epinephrine devices available for in-school use.¹¹ Additionally, some students and staff may be unknowingly at risk for anaphylaxis (eg, undiagnosed allergies); 55% of in-school epinephrine use by students is for first-time incidents.¹² Therefore, when epinephrine is provided by schools, it addresses both known and unknown risks, something family provision alone cannot accomplish.

These 2 arguments point to the rather sensible conclusion that it is more efficient for schools solely to provide

epinephrine for in-school use for their students and staff, in effect socializing the treatment as well as its costs. Indeed, as shown by Shaker and Greenhawt,¹⁰ for a low enough price per unit, such an approach is cost-effective even when families continue to supply their own epinephrine as well.

Although school provision may be more cost-effective, it does shift the burden of bearing the cost from the families of the students in question to public sector actors, a shift that raises additional issues. Many school districts have highly limited resources, and it may be challenging for them to absorb the cost of any EpiPens beyond the 4 they are eligible to receive for free from Mylan through its EpiPen4Schools program.¹³ Small school districts in particular may lack the bargaining power to bring down the price of the product, whereas the size of the Chicago Public Schools (the school system considered by Shaker and Greenhawt¹⁰) gives them greater ability to use their procurement process to negotiate a deal on the EpiPen.

It may be that states (particularly the 11 that require rather than simply permit schools to independently stock epinephrine¹⁴) should assist individual school districts with the negotiation process, with reimbursement for these products or with both aspects of the deal.¹⁴ Massachusetts has recently developed a bulk purchasing program designed to help pool the bargaining power of school districts statewide, although the new program is not financed by the state.¹⁵ It may be that state Medicaid or Children's Health Insurance Programs could be brought in to assist as well, given that school districts already use Medicaid to provide health-associated services to students with disabilities. However, at present, shifting to a school-only model is likely to be prohibitively costly for at least some school districts.

Epinephrine is not the only emergency drug for which school provision might be sensible, although the class of drugs that might be sensible seems to us to be rather small. Such drugs must be for emergency use, making it unreasonable to presume children and staff could be transported to an emergency department, and there must be a subset of students and staff that lack their own supply of those drugs and yet have a nontrivial probability of needing them.

Apart from epinephrine, only 2 other drugs meeting these conditions come to mind. One is albuterol for treatment of acute asthma symptoms. As with epinephrine, families of children at risk often provide albuterol inhalers for school use. Yet many inhalers likely go unused or are not used to completion before expiration and so are fully or partially wasted. Instead, schools could stock nebulizers and albuterol for in-school emergency use, relieving families of asthmatic children from sending inhalers to school.

Another example is naloxone. Because the opioid epidemic continues to rage in the United States and can affect students as well as school staff, it would be prudent for schools to be prepared to treat cases of overdose. Whether school provision of either albuterol or naloxone would be cost-effective is an empirical question that we cannot answer.

Changes in how health care is organized or provided are rarely both cost-saving and more effective. Provision of epinephrine by schools and not by families for in-school use is a rare example of such, although not without the complication of the shifting of financing from families to school budgets. Even if that complication is overcome and such an organizational change is made, it would do little to address the demand by the public for substantial changes to drug pricing.

ARTICLE INFORMATION

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Corporal Punishment and Children's Report Cards—Failing Our Children

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Corporal punishment, defined as “the use of physical force with the intention of causing a child to experience pain, but not injury, for the purpose of correcting or controlling the child’s behavior,”¹ causes lasting harm to a developing child. No studies have shown that the use of harsh physical discipline or corporal punishment had the desired effect of positive behavioral changes in children.²

Around the world, corporal punishment is being eliminated as a disciplinary method. As of 2010, 112 countries have banned corporal punishment in schools, and 24 countries have passed laws banning the use of corporal punishment against children in the home.³ Notably, the United States is not one of the countries with a ban on corporal punishment.

“Spare the rod and spoil the child” is unfortunately still a strongly held tenet in the United States among some parents. Remarkably, corporal punishment is still practiced in some schools. A 2016 study found that corporal punishment is still legal in schools in 19 states, mostly in the South,⁴ and parents are still allowed to use this method of discipline against their children, so long as it does not leave a “lasting injury.”

Legal bans on corporal punishment have been clearly demonstrated to result in the decreased use of physical discipline against children.⁵ Nationally, the use of corporal punishment has decreased owing to changing attitudes among parents.⁶ Differences seen in the use of corporal punishment are associated with socioeconomic status and maternal education.

Any form of hitting or striking a child could be deleterious to their physical and mental health; however, 1 recent study⁷ suggested that parents who use physical disciplinary strategies do not consider specific disciplinary methods to be corporal punishment. Often they differentiate based on the location of a strike and whether or not an object was used to hit the child.⁷ In 1998, the American Academy of Pediatrics issued a statement on guidance for effective discipline that states, “Spanking and threats of spanking lead to altered parent-child relationships, making discipline substantially more difficult when physical punishment is no longer an option, such as with adolescents.”^{8(p726)} Furthermore, it is known that as corporal punishment loses its effectiveness in eliciting the desired behavioral change in the child, more extreme forms of physical discipline may be used to cause the child to respond in the way the caregiver wishes.⁹ These extreme forms lead to an increased likelihood of injury to a child, which constitutes physical abuse.

Parents who use spanking against their young children often do not change their disciplinary strategies as children enter school and their teen years.¹⁰ In this issue of *JAMA Pediatrics*, Bright et al¹¹ report on the manifestation of this type of escalating physical discipline against school-aged children. In their study¹¹ of verified physical abuse cases against children aged 5 to 11 years in Florida schools in a single academic year, Bright et al find that after adjusting for clustering effects and county effects (ie, demographic data and child population size), report cards released on Fridays had an associated increase in physical abuse cases. This increase in verified cases of physical abuse was not seen for release of report cards on any other day of the week. Bright et al posit that a policy level change made by the school districts or the state could potentially have the beneficial effect of reducing the rate of physical abuse, a noble goal indeed.

Bright et al¹¹ use a complex method to analyze a relatively large data set that included data for nearly every county in the state of Florida and nearly every child during a normal school year. The unadjusted analysis suggests that Monday was the worst day for children in terms of verified physical abuse, but after applying their model, they found that the incident rate ratio for verified physical abuse on a Saturday after a Friday report card release was 3.75, nearly 300% higher than on Saturdays that did not follow a Friday report card release. This certainly seems like a meaningful finding and one with a logical solution to the problem of reducing physical abuse among school-aged children. However, the 95% CI for this incident rate ratio is quite large, at 1.21 to 11.63. This size could be owing in part presumably to the actual number of verified cases of physical abuse (n = 1943) in the total data set and their distribution across a large number of days with no verified cases and a small total number of release and postrelease days. This possibility of course does not negate the study’s findings but should cause the reader to consider whether a systematic policy change will likely result in a safer environment for children.

Although rates of corporal punishment are decreasing in the United States, corporal punishment is still legal, parents still report using it, and parents who use corporal punishment against younger children will likely continue to use it against older, school-aged children. The increased likelihood of injury within families using corporal punishment as discipline for poor academic performance is alone perhaps enough to explain an increase in abuse after report card release. The increase after a Friday report card release is more troubling. Parents who cause physical injury to their children owing to



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