

## VIEWPOINT

## Pharmaceuticals and Public Health

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**The national debate** over increasing costs and spending for pharmaceuticals has reached a fever pitch. Special concern has focused on new “specialty” drugs, for which per-patient treatment costs often exceed \$1000 per month or more than \$10 000 for a course of a therapy. The most commonly discussed solutions include approaches to pricing these drugs based on their value to individual patients.<sup>1</sup> However, for pharmaceuticals vital to public health, such as immunizations and drugs to treat communicable diseases, policy makers should broaden their perspective to consider the population as a whole.

For example, for new drugs used to treat hepatitis C infection, manufacturers have set prices in excess of \$40 000 per course of treatment, and payers have responded with a variety of policies limiting patient access. In addition, many patients who need treatment are uninsured. As a result, only about 10% of an estimated 3 million US residents with hepatitis C are receiving care for a life-threatening and contagious infection.<sup>2</sup> This constitutes a national crisis in access that is causing unnecessary morbidity and is anticipated to result in significant preventable mortality.

Under such circumstances, rather than try to find the right price one patient at a time, policy makers should focus on the public interest, for which price cannot be separated from the amount of medication needed to treat the population.

In the case of hepatitis C, a committee of the National Academy of Medicine has articulated the objective: the virtual eradication of viral transmission in the United States.<sup>2</sup> The committee has noted that success will require a national campaign, widespread disease screening to detect undiagnosed patients infected with the disease, and “near universal access to treatment” that includes a focus on persons with infection who are uninsured, underinsured, and incarcerated. In other contexts, such as a breakthrough treatment or vaccine for Zika virus infection, or a lifesaving therapy for pandemic influenza, public health recommendations might support treating a relatively small number of patients or nearly the entire population, depending on the evidence.

If manufacturers offer treatments at affordable prices, policy makers and the health care system can turn their focus to the challenges of outreach and clinical care. However, manufacturers may alternatively choose a different path: setting high prices based in part on projections that assume that only a small fraction of the target population will be able to access care. In such a scenario, as with hepatitis C, treating all patients recommended for care becomes prohibitively expensive, leaving the health care system unable to meet the public health need. It then becomes necessary for policy makers to consider alternative approaches to pricing.

One option is for the federal government to allow a subset of payers to join together, commit to a broad treatment strategy as part of a public health campaign, and obtain lower prices. Legislation is needed to facilitate this approach—just as it was to provide access to human immunodeficiency virus (HIV) treatment. The AIDS Drug Assistance Program, authorized by the Ryan White Act, has allowed states to provide access to essential medications to uninsured and underinsured individuals via special discounts and opportunities for negotiation that generate hundreds of millions of dollars in savings each year.<sup>3</sup> Hundreds of thousands of US residents have received lifesaving treatment for HIV, and the program has not slowed the pace of innovation for new HIV treatments. A strength of the Ryan White approach is that it ensures access to care for those least likely to have resources; a weakness is that it can leave considerable variation in coverage in the private sector, causing an overreliance on public programs.

An alternative option is for the federal government to conduct the price negotiation and purchase large quantities of the pharmaceuticals. In 1994, after a major measles outbreak that resulted from low vaccination rates, Congress and the Clinton administration created the Vaccines for Children Program. Under this program, the federal government conducts a single negotiation with the manufacturer to purchase universally recommended vaccines for about half of all US children, including those uninsured and those covered by Medicaid. The government also funds an extensive effort to educate parents and pediatricians about the value of vaccines. Since enactment of the Vaccines for Children Program, childhood vaccination rates have improved substantially.<sup>4</sup> Many new vaccine candidates addressing these and other childhood diseases are moving through the development pipeline.<sup>5</sup>

A third option is more aggressive: the government can use its own facilities or commission other manufacturers to make the pharmaceutical without regard to the manufacturer’s patents. This is a type of government-exercised “eminent domain,” in which the government takes private property for public use and compensates the property owner at a reasonable rate but a rate that can be much lower than the price set by the manufacturer. In 2001, during the anthrax attacks, Secretary of Health and Human Services Tommy Thompson threatened this action for ciprofloxacin, a pharmaceutical still under patent by Bayer.<sup>6</sup> Such a step would have allowed a generic company to make ciprofloxacin at a far lower price. Rather than accept such a scenario, Bayer reduced the price of ciprofloxacin, and the federal government negotiated a deal to purchase 12 million doses. There is additional authority under the Bayh-Dole Act for the federal government to

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seek lower prices for pharmaceuticals for which discovery began with a federal research investment.

Government action on medicines to achieve a public health objective may be justified by a quid pro quo. On one hand, the United States provides a highly favorable environment for pharmaceutical manufacturers by funding basic science research and by routinely guaranteeing better access and paying higher prices for pharmaceuticals than other developed countries. In exchange, the pharmaceutical industry should recognize the need to lower prices as part of an all-out public health campaign to protect the welfare of the US population, now and in the future. The guarantee of a much larger market in the short term, with publicly funded outreach and marketing by health officials, can help reduce the disadvantages of a lower unit price for manufacturers.

Yet policy makers should still take care not to seek such low prices that there is little reward for manufacturers. For new treatments meeting vital public health needs, manufacturers should be able to recoup their costs, make new investments in research and development, and earn a generous return. Achieving this goal, however, requires a commitment to transparency by manufacturers as well as a process of mutual understanding that might build on efforts under way to support the development of therapies for low-income countries.<sup>7</sup>

The logic of pricing for a population—and not just a patient—is most clear for infectious diseases, in which broad treatment strategies help protect those who are uninfected. But population-based pricing also may apply to common conditions for which inadequate access to care places a tremendous burden on society. For example, it is recommended that pregnant women who have had a prior preterm birth should receive injectable progesterone to reduce the chance of another early delivery. However, pricing of this drug, in excess of \$10 000 per pregnancy, means that many uninsured or inadequately insured women do not receive treatment. The result is infants born prematurely with a broad set of lifelong needs. Looking ahead, manufacturers are developing pharmaceuticals to delay the onset of Alzheimer disease. Failure to provide reasonable access to such breakthrough treatments would accentuate health disparities, leaving some communities disproportionately burdened with unnecessary morbidity, disease, and substantial care needs.

Some treatments are simply too important to public health to leave their distribution to the private interests vying against each other in the US health care system. Taking a broad, public health perspective on access to medications may provide a better context for policy discussions regarding the pricing of breakthrough pharmaceuticals and create opportunities for a virtuous circle for manufacturers, payers, and patients.

#### ARTICLE INFORMATION

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