It is a well-established fact that language is not only our servant, when we wish to express—or even to conceal—our thoughts, but that it may also be our master, overpowering us by means of the notions attached to the current words. This fact is the reason why it is desirable to create a new terminology in all cases where new or revised conceptions are being developed. Old terms are mostly compromised by their application in antiquated or erroneous theories and systems, from which they carry splinters of inadequate ideas not always harmless to the developing insight. Therefore I have proposed the terms “gene” and “genotype” and some further terms, as “phenotype” and “biotype,” to be used in the science of genetics.

Drug Purchasing Strategies to Treat People With Hepatitis C in the Criminal Justice System

More than a half million incarcerated people are estimated to be living with HCV in the United States.\(^1\) One in three individuals with HCV passes through a US correctional facility each year.\(^2\) HCV is the leading cause of cirrhosis, end-stage liver disease, and hepatocellular carcinoma. As of 2006, the number of deaths from HCV surpassed those from HIV.\(^3\) These statistics are not new; yet correctional health care systems face significant structural barriers in treating the most common blood-borne infection in the United States.

PEOPLE WITH HCV IN CORRECTIONS

A tremendous opportunity exists to treat HCV in correctional settings. Following the US Supreme Court ruling in Estelle v Gamble (429 US 97; 75-929 [1976]), incarcerated individuals have a legal right to medical care during confinement. However, the constitutional rights set forth in this case have yet to be realized at a great personal cost to incarcerated individuals and society. If current practices do not change, then tens of thousands of individuals with chronic HCV in correctional settings who require treatment will go untreated, and a significant number will develop fibrosis leading to end-stage liver disease, hepatocellular carcinoma, transplant, and ultimately death. In addition, on return to the community, untreated

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This editorial was accepted February 2, 2018.

doi: 10.2105/AJPH.2018.304362

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individuals with chronic HCV can contribute to ongoing disease transmission. Current HCV treatment standards published by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America recommend direct-acting antiviral treatment for all patients with HCV except those with a short life expectancy. However, very few detainees receive HCV treatment during incarceration. Treatment is limited, in part, by case identification. National guidelines now recommend universal opt-out screening; however, this is not being performed in most states. Furthermore, not all correctional systems have the infrastructure in place to provide HCV treatment. The most significant barrier, however, is the budgetary challenge associated with costs that supersede overall correctional health care budgets in certain states.

“BEST PRICE”

Discounts or alternative payment strategies clearly are required in the correctional system, but what form these will take is unclear. Manufacturers are disincentivized to offer better pricing on direct-acting antiviral agents as a result of two federal laws—section 1927 of the Social Security Act and section 340B of the Public Health Service Act—requiring them to give their “best price” on brand name outpatient drugs (bit.ly/2BzSums). A manufacturer’s “best price” is one of the factors used to calculate the rebates a company owes to state Medicaid agencies under section 1927 and the up-front discounts it must provide to certain statutorily defined safety-net hospitals and federally funded clinics under section 340B. The “best price” mechanism ensures that, except in a few narrow instances defined by law, no purchaser in the US drug market receives a better price than Medicaid or a 340B hospital or clinic. This means that if state and local correctional institutions pool their volume with other government purchasers of drugs in an effort to negotiate lower prices, they cannot hope to negotiate a price better than “best price.” If they could, their discounted prices would, by definition, become the new “best price,” forcing the drug’s manufacturer to give larger rebates to Medicaid and deeper discounts to 340B participants.

The net effect is that for each brand name drug marketed in the United States, “best price” becomes a floor on price negotiations for every purchaser except those whose prices have been statutorily excluded from “best price.” Recognizing that manufacturers are unlikely to discount their prices below “best price,” Congress established “best price” exemptions for several government purchasers and programs. Unfortunately, purchases by state and local correctional facilities are not among those excluded from a manufacturer’s “best price” calculations. Establishing such an exception would require an act of Congress. But because the Congressional Budget Office generally scores “best price” exemptions as increasing federal costs, members of Congress may be reluctant to help, especially those focused on reducing the federal deficit.

340B OR STATE MEDICAID

Correctional institutions can overcome the “best price” problem by partnering with 340B safety-net providers or state Medicaid programs. Several state prisons and county jails have partnered with 340B-covered entities (including Federally Qualified Health Centers and Disproportionate Share Hospitals) as a way to lower the cost of drugs they purchase. 340B Hospitals are ideally suited as potential partners because many are owned by the same state or local government that oversees the relevant correctional institution(s). Medicaid programs are increasingly looking for value-based purchasing opportunities, making them potential partners. In an effort to increase the volume of drugs subject to their discount negotiations with manufacturers, state Medicaid agencies may be interested in purchasing on behalf of correctional institutions and other state-owned purchasers of drugs. They likely would need to apply for a federal waiver to ensure that the jointly negotiated Medicaid and correctional pricing was exempt from the “best price” calculation. This strategy was recently proposed by an Oregon research team charged with strengthening the ability of Medicaid programs to manage prescription drugs through alternative payment methodologies.

Without action, incarcerated individuals may endure unnecessary morbidity and mortality, correctional health providers will remain frustrated by delaying care for patients seeking treatment, correctional health care systems will remain open to litigation, and the cost of treating preventable medical conditions will burden taxpayers in our public health system. The need for HCV treatment in correctional settings must be actively communicated to decision-makers at city, state, and national levels. Such discussions may be facilitated by the recent emergence of lower-cost direct-acting antiviral treatment options. Whether through price reductions on the part of pharmaceutical industry, “best price” exemptions for state and local correctional systems, policy changes on Medicaid pricing for correctional settings, or decisions by policymakers that treating HCV is a worthwhile investment, action is urgently needed to address the public health imperative of the HCV epidemic in the criminal justice system.

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