

glargine pens won't exceed \$55, as compared with a list price of \$425 for Lantus, \$404 for Semglee, and \$148 for unbranded Semglee.^{2,5}

This plan is straightforward: sell a drug at cost and at the same price to all buyers. Having no profit motive is one key ingredient. Another is targeting a high-volume, high-rebate drug: there is enough margin being captured by intermediaries and plan sponsors to enable Civica to cover its



An audio interview with Dr. Dafny is available at [NEJM.org](https://www.nejm.org)

costs and still give patients a good deal.

Civica will face important barriers to executing this plan, though. In addition to the usual implementation and regulatory challenges, intermediaries threatened by its approach may introduce new obstacles; for example, they might pressure phar-

macies not to carry Civica's insulin products. It's also possible that intermediaries won't try to block Civica's end run and will instead promote new diabetes agents that would be subject to the existing system. If Civica does deliver on its plan, however, it will disrupt the status quo for an important set of drugs and establish a path for reducing prices for other biologic medications whose market-exclusivity periods have passed.

Disclosure forms provided by the author are available at [NEJM.org](https://www.nejm.org).

From Harvard Business School, Boston, and the Kennedy School of Government, Harvard University, Cambridge — both in Massachusetts.

This article was published on April 6, 2022, at [NEJM.org](https://www.nejm.org).

1. Fein AJ. Why PBMs and payers are embracing insulin biosimilars with higher

prices — and what that means for Humira. Philadelphia: Drug Channels Institute, November 9, 2021 (<https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html>).

2. Civica to manufacture and distribute affordable insulin. Salt Lake City: Civica, March 3, 2022 (<https://civicarx.org/wp-content/uploads/2022/03/Civica-Affordable-Insulin-Press-Release-03.03.22.pdf>).

3. Pharmacy benefit managers and their role in drug spending. New York: Commonwealth Fund, April 22, 2019 (<https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending>).

4. Insulin: examining the factors driving the rising cost of a century old drug. Staff report. Washington, DC: Senate Finance Committee, January 14, 2021 ([https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf)).

5. Kansteiner F. Viatris launched 2 versions of its interchangeable insulin biosimilar. Why? Fierce Pharma. November 16, 2021 (<https://www.fiercepharma.com/pharma/viatris-launches-two-versions-its-interchangeable-biosimilar-semglee-bid-to-tackle-pricing>).

DOI: 10.1056/NEJMp2203001

Copyright © 2022 Massachusetts Medical Society.

The Tobacco Wars' Lessons for the Vaccination Wars

Robert Bazell, C.Phil., Howard Koh, M.D., M.P.H., and Barry R. Bloom, Ph.D.

Covid-19 will soon have killed 1 million Americans. When vaccines first became available in late 2020, surveys indicated that about one third of U.S. adults were keen to be vaccinated, 15% expressed strong resistance to vaccination (a proportion that has stayed fairly constant), and the remainder didn't harbor strong ideological resistance.¹ About 27% of U.S. adults remain unvaccinated.¹ An important challenge involves reaching the undecided — an issue for booster doses, future pandemics, and all vaccines. In the midst of deafening noise,

much of it hateful, filled with falsehoods, and purely political, we believe public health shouldn't lose its voice.

Lessons from the tobacco wars can provide perspective. In the case of tobacco, preventable deaths were fueled by an industry that influenced millions of people with messages suggesting that using its products was glamorous and normal. Nearly half of U.S. adults smoked cigarettes in the 1960s.² The current rate of about 12.5% reflects decades of multifaceted public health efforts to deglamorize and denormalize

tobacco use and make it less socially acceptable. The science of tobacco's harms was initially summarized in the first U.S. Surgeon General's report on smoking and health in 1964; the tobacco industry attacked the data, and the report's effects were minimal. C. Everett Koop's 1986 report, a massive compilation of epidemiologic and biologic data, overwhelmingly established tobacco use as a major preventable cause of cancer and death and, most importantly, highlighted the harm associated with involuntary smoking.

Koop and others were vilified by the tobacco industry, which mounted a sustained campaign that aggressively raised doubts about this science, publicized misinformation about smoking, emphasized tobacco's economic importance, and warned against restricting individual freedom. Industry leaders lied to Congress and the public about their long-standing knowledge that nicotine was addictive and that tobacco use could be lethal. Although the initial debate over tobacco control was focused on individual choice, two 1981 studies changed the conversation by documenting that nonsmoking wives of smokers had a higher risk of lung cancer than nonsmoking wives of nonsmokers. At least a dozen other studies in the next few years proved the dangers of secondhand smoke. What was initially a concern specific to smokers became everyone's problem when the public understood that one person's actions endangered other people's lives.

Congress has never enacted a federal smoking ban. Efforts of former Food and Drug Administration (FDA) commissioner David Kessler and others to have the FDA restrict nicotine and tobacco products were rejected by the Supreme Court in 2000.³ Congress granted the FDA limited authority to regulate tobacco in 2009, enabling restriction of marketing and sales to youth and requiring warning labels on smokeless tobacco. Nevertheless, broad-based strategies at all levels of society have been important. Cessation messages from health professionals have reached millions of smokers. Policies restrict smoking in public places,

workplaces, schools, restaurants, bars, and airplanes. These efforts have made the importance of clean air, not just a reduction in smoking, part of the message behind the goal of broadening the social norm. Also important have been public information messages delivered by athletes, artists, and actors, as well as hard-hitting, sometimes graphic counter-advertising that features smokers debilitated by tobacco use who are expressing regret over smoking and urging others not to start. The Centers for Disease Control and Prevention (CDC) Tips from Former Smokers campaign, which began in 2012 and is still airing on television, has triggered more calls to smoking "quit lines" and led to increased cessation rates. Strategies such as taxation, advertising restrictions on tobacco products, and actions to counter the tobacco industry's efforts to recruit young people to use its products have contributed to reductions in smoking. Legal battles initiated by state attorneys general, arguing for tobacco companies to be held liable and compensate states for Medicaid costs for people harmed by smoking, resulted in the 1998 Master Settlement Agreement, the largest civil-liability settlement in U.S. history.

Efforts undertaken by the anti-vaccination movement, which is hardly new but is thriving during the Covid-19 pandemic, bear many similarities to strategies used during the tobacco wars. Although not financed by a single industry, the movement is well supported by certain political figures, physicians, and media companies, and it sows doubt and distrust in science and government. Vast

amounts of misinformation about vaccine safety and effectiveness are readily available online. Whereas the tobacco wars initially involved massive advertising and public relations campaigns, social media and right-wing media channels now promote conspiracy theories that vaccines deliver microchips to control behavior, render vaccinees sterile, or harm fetuses. The vilification of scientific leaders such as Anthony Fauci is a replay of attacks on Koop and others. Once again, important decisions affecting the public's health are being made not by public health experts, but by the courts — including the Supreme Court.

Of course, there are important differences between tobacco control and vaccination; for example, the effects of interventions to prevent smoking initiation and chronic disease often take decades to materialize, whereas vaccinations usually reduce hospitalizations and acute viral illness within days or weeks. CDC data clearly show that approved Covid-19 vaccines have reduced hospitalizations and deaths in the United States, and household-transmission studies have shown that vaccination reduces SARS-CoV-2 transmission.⁴ Vaccination also prevents indirect harm to the health care system.

We believe it's necessary to counter misinformation about vaccines with a compelling public information campaign modeled on the successes of the tobacco wars — one that illustrates the harm caused by Covid-19 and the power of vaccines. Getting vaccinated and boosted should be the accepted social norm during a pandemic. An adaptation of the Tips campaign for vaccina-

tion could feature many of the real patients in intensive care units who, just before being intubated, express deep regret over failing to get vaccinated. Many of these patients only then request vaccination and are told it's too late. Unvaccinated people often assume that doctors and hospitals will always be available to them if they get sick. Messages could therefore also feature health care workers attesting to the strain that Covid-19 places on clinicians and on patients requiring treatment for any condition. There is an opportunity to mount a serious effort to provide accurate vaccination information using the same media channels on which people currently consume misinformation.

Vaccine mandates have helped boost vaccination rates in some places by making being vaccinated a social norm, similar to wearing a seat belt and pausing for security checks in airports. Regulations at the local and community levels, such as requiring proof of vaccination to enter public spaces and maintain local business functions, may be even more effective than federal mandates. Liability litigation seeking compensation for harm caused by businesses that don't require

their workers to be vaccinated merits consideration, even though the Supreme Court rejected private-employer vaccine mandates from the Occupational Safety and Health Administration.

Trusted personal physicians remain the best source for the effective transmission of health information. But many people at risk of remaining unvaccinated have had less-than-optimal access to and experiences with the health care system, which has engendered mistrust. Furthermore, despite the extraordinary efforts of most physicians during the pandemic, not all physicians provide truthful information, and states have inadequately regulated the licenses of those who spread harmful misinformation.⁵

Public health practitioners knew for years that tobacco use causes cancer, but scientific knowledge alone had a minimal effect on smoking behavior. Just as the awareness that smokers endanger others marked a turning point for tobacco control, conveying the message that unvaccinated people endanger their family members, communities, and the health care system may be effective. A well-funded, multifaceted communications effort will again be required to change

the behavior of some people who are still undecided.

Freedom of choice remains; people can still smoke cigarettes and decline vaccinations. But the roadmap drawn by tobacco-control efforts shows that the public mindset can be tilted toward public health and social good. With vaccination, this work shouldn't take decades; it needs to begin immediately.

Disclosure forms provided by the authors are available at NEJM.org.

From the Department of Molecular, Cellular, and Developmental Biology, Yale University, New Haven, CT (R.B.); and the Harvard T.H. Chan School of Public Health, Boston (H.K., B.R.B.), and the Harvard Kennedy School, Cambridge (H.K.) — both in Massachusetts.

This article was published on April 13, 2022, at NEJM.org.

1. Kaiser Family Foundation. KFF COVID-19 vaccine monitor. 2022 (<https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor-dashboard>).
2. Brandt AM. The cigarette century: the rise, fall, and deadly persistence of the product that defined America. New York: Basic Books, 2007.
3. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 120 S. Ct. 1291 (2000).
4. Shah ASV, Gribben C, Bishop J, et al. Effect of vaccination on transmission of SARS-CoV-2. *N Engl J Med* 2021;385:1718-20.
5. Rubin R. When physicians spread unscientific information about COVID-19. *JAMA* 2022;327:904-6.

DOI: 10.1056/NEJMp2202618

Copyright © 2022 Massachusetts Medical Society.

Physicians as Political Pawns — The Texas Directive on Gender-Affirming Care and Other Moves

Anna Kirkland, J.D., Ph.D.

On February 21, 2022, Texas Governor Greg Abbott (R) directed his Department of Fam-

ily and Protective Services (DFPS) to treat as child abusers all parents seeking gender-affirming

care for their transgender children. One targeted family sued, and on March 11 — after a court