

these plans when they misdiagnose fetuses, switch samples, or misrepresent donors.⁵ Doctors who have purposefully misled patients in order to propagate their own genes engaged in misconduct that goes far beyond thwarting efforts to select for offspring traits. This grave abuse of trust makes fertility fraud a fitting point of departure for policymakers and judges to consider extending protections under informed-consent doctrine.

Until now, the requirement that patients show evidence of tangible harm to prove a breach of informed consent has largely closed the courthouse doors to people who have been subject to misconduct that can be classified as procreation deprived, imposed, or confounded. Fertility-fraud laws could herald an

expansion of informed-consent doctrine to provide recourse against other wrongful nondisclosures that harm patients in real and serious — albeit not tangible — ways.

Such reforms could have effects beyond reproductive medicine, shielding patients from breaches of informed consent that upend interests central to their individual agency, personal identity, or moral dignity. This shift invites a risk, however, that excessive liability could deter well-meaning clinicians from performing high-risk procedures that represent patients’ best options or could drive specialists out of certain fields, thereby making care less available and more expensive. Legislatures and courts would do well to weigh trade-offs between justice and access as they

consider loosening informed-consent doctrine’s tangible-harm requirement.

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1. *Canterbury v. Spence*. 464 F.2d 772 (D.C. Cir. 1972).
2. Hard AD. Artificial impregnation. *Med World* 1909;27:163-4.
3. Fox D. Reproductive negligence. *Columbia Law Rev* 2017;117:149-241.
4. Fox D. Birth rights and wrongs: how medicine and technology are remaking reproduction and the law. New York: Oxford University Press, 2019.
5. Fox D. Donor 9623: One man. 36 kids. The biggest hoax in reproductive history. Audible. August 31, 2020 (<https://www.audible.com/donor>).

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Updated Health Warnings for Alcohol — Informing Consumers and Reducing Harm

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In April 2022, the Centers for Disease Control and Prevention (CDC) released new mortality statistics showing that alcohol consumption now accounts for more than 140,000 deaths per year in the United States, or more than 380 deaths per day. The Covid-19 pandemic has exacerbated alcohol-associated harm in the United States, with alcohol-related deaths increasing by 25% during the first year of the pandemic as compared with the previous year.¹ Yet many Americans are not aware of some of alcohol’s most serious health risks.

Requiring new, well-designed warning labels on alcohol containers could be a commonsense strategy for providing information to consumers and reducing the burden of alcohol-related harm.

The risks associated with alcohol consumption are now well documented. Although the alcohol industry has worked to spread the idea that alcohol consumption has health benefits, research suggests that its risks outweigh potential benefits, on average.² In addition to the data on fatal and nonfatal injuries resulting from acute intoxication (includ-

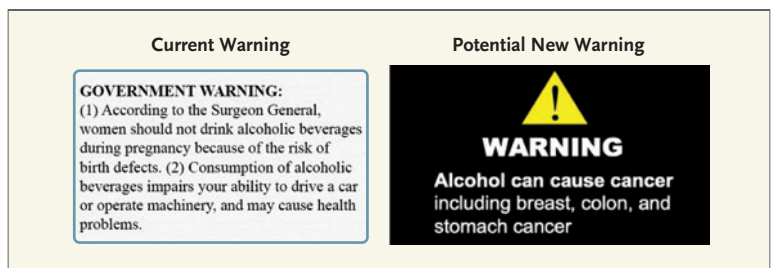
ing injuries caused by motor vehicle crashes), mounting research links longer-term alcohol consumption to chronic diseases including hypertensive heart disease, cirrhosis, and several types of cancer.² Even light or moderate drinking increases the risk of these conditions, particularly cancer.² Yet according to the CDC, two thirds of U.S. adults report drinking alcohol.

The alcohol industry spends more than \$1 billion each year to market its products in the United States; as a result, the most readily available information about

alcohol comes from alcohol companies themselves. The industry has also actively suppressed efforts to educate consumers about the health risks associated with alcohol, including by thwarting attempts by various governments to adopt more transparent alcohol-labeling policies. This information asymmetry may explain why Americans are so poorly informed about some of alcohol's health risks. A national survey of U.S. adults, for example, found that nearly 70% are unaware that alcohol consumption increases the risk of cancer.³

One strategy for addressing gaps in knowledge could be to update the required warning labels on alcohol containers. Warning labels are a core public health strategy for providing information to consumers and encouraging healthier behaviors, in part because they permit broad and sustained reach of health messages at low cost. More than 150 countries require warning labels on cigarette packages, for example, and these warnings have contributed to decreases in smoking rates over the past several decades. Building on the success of tobacco warnings, nine countries have adopted policies requiring warning labels for unhealthy foods and sugar-sweetened beverages.

Regulators have a large body of evidence available to guide them in developing effective, engaging warning labels for alcohol. Warning labels are most effective when they are displayed prominently on the front of product packaging, include pictorial elements such as photographs or icons, and rotate the content of their messages to avoid any one



Current U.S. Alcohol Warning and an Example of a Potential New, Evidence-Based Warning.

message becoming “stale.” A randomized trial involving 2149 smokers, for example, found that large, front-of-pack, pictorial warning labels for cigarettes increased smoking quit rates by 50% (from 3.8 to 5.7%) over 4 weeks as compared with smaller, side-of-pack, text-only warning labels.⁴ Similar benefits have been documented in longitudinal studies examining smoking behaviors after countries implemented well-designed cigarette-package warning labels and in quasi-experiments evaluating grocery purchases after implementation of prominent front-of-package warning labels for unhealthy foods and beverages.

The current alcohol warning in the United States lacks all the key elements of evidence-based warning design: it uses small text, typically appears on the back or side of product packaging, and doesn't include any pictorial elements (see figure). The warning message is also static, having remained unchanged since the label was first implemented more than three decades ago. Given these limitations, it's perhaps unsurprising that studies suggest the warning has had a limited effect on overall alcohol consumption. By contrast, when large, pictorial warnings about cancer risk were temporarily add-

ed to the front of alcohol containers in some stores in Yukon, Canada, alcohol sales dropped by 6 to 10%.⁵ Given the high burden of alcohol-related harm in the United States, a reduction of this size in alcohol consumption could have meaningful population health benefits.

We believe warnings should also reflect the strongest available research on product harms, meaning that policymakers should regularly update label requirements when new data warrant making changes. The current U.S. warning label reflects outdated science regarding alcohol's harms. Its language was written more than a generation ago, when evidence of the harms associated with alcohol consumption was still emerging. Since that time, alcohol has been classified by the International Agency for Research on Cancer as a group 1 carcinogen, meaning that it is known to cause cancer in humans. A growing body of prospective cohort studies have also linked alcohol consumption to a wide range of diseases that the current warning label doesn't mention — from liver disease to pancreatitis to some types of heart disease.² Instead, the existing label focuses on risks during pregnancy and the risks associat-

ed with operating machinery and ends by noting that alcohol “may cause health problems,” language that is so understated that it borders on being misleading.

Multiple regulatory and legislative pathways exist for adopting new alcohol warning labels. For example, the Alcoholic Beverage Labeling Act of 1988 instructs regulators (in consultation with the U.S. Surgeon General) to recommend that Congress revise alcohol warnings if available scientific information justifies changes. Congress can also independently choose to require new warnings on alcohol products, much as it adopted a policy requiring pictorial warnings on cigarette packages in 2009. Legislation requiring new alcohol warning labels would need to garner support from lawmakers and regulators, which could be challenging in the current political environment. It’s worth noting, however, that two thirds of Americans support requiring new, specific health-related warning labels for alcohol.³

Once a policy mandating new alcohol warnings is adopted, the alcohol industry might try to block its implementation on First Amendment grounds, as the tobacco industry did in the case of pictorial warnings for cigarette packages. Despite these challenges, we believe policies requiring updated warning labels are worth pursuing. Unlike other strategies for educating consumers about product harms, accurate and up-to-date warning labels would provide people with information

at the exact moment they need it to make reasoned decisions about alcohol purchases and consumption. Warnings could also raise awareness of alcohol’s harms, which could increase public support for additional alcohol-control policies, such as taxes and marketing restrictions.

Because updated alcohol warnings would provide new risk information to many Americans, we believe implementing such warnings would be a sensible policy for addressing industry dominance over alcohol-related information, even if warnings’ effects on consumption are fairly small. Consumers have a right to know about any serious health harms associated with products they might buy. They can then do their own calculations to determine the amount of risk they are willing to tolerate, just as all people do as part of the many decisions we make every day. In the absence of government intervention, however, the alcohol industry has little incentive to communicate these risks. Some alcohol companies even seek to link their products to health campaigns. Several companies, for example, have sold seasonal, pink ribbon-themed alcoholic drinks during October to promote their efforts to raise funds for breast-cancer research — despite compelling evidence that alcohol increases the risk of developing breast cancer.

Alcohol consumption and its associated harms are reaching a crisis point in the United States.

Evidence suggests that new alcohol warnings could empower consumers to make more informed decisions and reduce alcohol-related harm. We believe Americans deserve the opportunity to make well-informed decisions about their alcohol consumption. Designing and adopting new alcohol warning labels should therefore be a research and policy priority.

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1. White AM, Castle IP, Powell PA, Hingson RW, Koob GF. Alcohol-related deaths during the Covid-19 pandemic. *JAMA* 2022; 327:1704-6.
2. Griswold MG, Fullman N, Hawley C, et al. Alcohol use and burden for 195 countries and territories, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet* 2018;392:1015-35.
3. Seidenberg AB, Wiseman KP, Eck RH, Blake KD, Platter HN, Klein WMP. Awareness of alcohol as a carcinogen and support for alcohol control policies. *Am J Prev Med* 2022;62:174-82.
4. Brewer NT, Hall MG, Noar SM, et al. Effect of pictorial cigarette pack warnings on changes in smoking behavior: a randomized clinical trial. *JAMA Intern Med* 2016;176:905-12.
5. Zhao J, Stockwell T, Vallance K, Hobin E. The effects of alcohol warning labels on population alcohol consumption: an interrupted time series analysis of alcohol sales in Yukon, Canada. *J Stud Alcohol Drugs* 2020;81:225-37.

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