For the Record

Biden's Antitrust–Buybacks Contradiction

Reading Richard West and James Largay's recent article challenging criticisms of corporate stock buybacks ("Against Taxing Corporate Stock Buybacks," Summer 2023), I found myself wondering about the contradiction between the Biden administration's buybacks crackdown and its expansionist antitrust efforts.

On the one hand, the administration says it wants to tax buybacks so that companies will invest more in new opportunities. But if those opportunities bear fruit, the firms presumably will grow bigger. On the other hand, the administration (particularly Federal Trade Commission chair Lina Khan) clearly wants to dissuade companies from getting bigger, e.g., the recent lawsuit against Microsoft to block its acquisition of a game developer and other, more recent guidelines. Given this, one would think the administration would prefer the Apples and Microsofts and Googles spin-off cash so it can be invested in entities outside the firms' control.

To be clear, I don't think I'm in favor of much change in antitrust law. I do, however, understand why very large corporations represent some degree of risk to society. It is conceivable that the combined effects of (1) traditional economies of scale and (2) the newer data virtuous cycle could catalyze extreme growth in some situations. However, this is a very nuanced topic that does not admit to easy answers, and I only scratch the surface of it a recently co-authored book, *Data Science in Context* (Cambridge University Press, 2022).

—Alfred Z. Spector
Pelham Manor, NY

BRIEFLY NOTED

Limiting Federal Regulation of Cannabis

BY VICTORIA LITMAN

A change in the federal status of cannabis plants that are considered psychoactive—legally called marijuana—appears to be inevitable. A vast majority of states have passed legislation to regulate marijuana use in medical or recreational settings. On the federal level, numerous bipartisan pieces of legislation have been introduced in recent years, including several that would remove it from the federal Controlled Substances Act (CSA) and regulate it at the federal level.

However, no major changes to federal marijuana prohibition have yet gained passage. Federal acceptance of cannabis extends only to so-called "industrial hemp," which is produced for its fiber and contains minimal amounts of the psychoactive chemical tetrahydrocannabinol (THC).

Last October, the White House issued a "Statement from President Biden on Marijuana Reform." It announced a pardon of all prior federal offenses of simple marijuana possession, urged governors to do the same, and asked the secretary of health and human services and the attorney general to initiate an administrative process to review how cannabis is currently scheduled. The statement contemplated federal law change but noted that if those changes happen, "important limitations on trafficking, marketing, and under-age sales should stay in place."

Most of the proposed congressional legislation and Biden's statement presume that a federal law change, even a scheduling change initiated by the Drug Enforcement Administration, must be accompanied by significant federal regulation of cannabis. However, the best federal policy to develop a successful national cannabis marketplace would be to remove it from the CSA and regulate it in a manner akin to alcohol.

Priorities/ Over 90 percent of states have passed some form of cannabis liberalization legislation. So far, it has been impossible to judge the success of the myriad state policies in creating a functioning legal cannabis market because of significant continued barriers resulting from federal prohibition. Under Internal Revenue Code Section 280E, cannabis businesses are disallowed ordinary business deductions except for the Cost of Goods Sold, resulting in an effective tax rate that can exceed 70 percent even if they are legal in the state.

Cannabis companies also have difficulties in obtaining bank accounts. Although banks can provide financial services to state legal cannabis businesses, they are disincentivized from doing so by regulatory burdens imposed by the U.S. Treasury's Financial Crimes Enforcement Guidance, including the requirement to file Suspicious Activity Reports for activities that are legal under state law.

Continued federal illegality has resulted in state siloed markets and no legal interstate markets. That artificially inflates the value of each state license to sell cannabis, especially in states that severely limit the number of licenses. This state siloed outcome creates a market with significant economic and environmental inefficiencies.

Finally, federal prohibition itself results in a great deal of uncertainty and instability in the industry, deterring investment, creating perverse incentives, and limiting growth. The Food and Drug

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Administration claims jurisdiction over all the state legal activity but has not regulated any of it, relying on Warning Letters to intimidate operators into unclear compliance. An arbitrary and non-global THC standard for hemp products has led to enforcement challenges and ongoing litigation. The continued federal illegality of Delta-9 THC has led to the development of unregulated cannabinoids like Delta-8 THC to circumvent federal illegality.

Any law that changes the federal status of cannabis should aim to reduce the barriers that have stunted the development of state legal cannabis markets. All these issues would be alleviated with a piece of federal legislation that removes cannabis from the CSA. However, without clear limits on the reach of federal regulation, a change in federal law would not necessarily stop ongoing battles between state operators and the DEA and FDA, especially as relates to the existing state medical cannabis programs that all violate FDA drug law.

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What should Congress do? / Congress should defer the bulk of the power to regulate cannabis to the states, which have been the primary regulators of cannabis for almost three decades. Starting in 1996, California voters passed Proposition 215, making it the first state to legalize the use, possession, and cultivation of cannabis by medical patients. The California State Legislature supplemented Prop. 215 with legislation in 2004 that more formally regulates medical marijuana patients in the state. In 2010, Colorado became the first state to have a formal access program for medical patients. In 2012, Washington joined Colorado in permitting cannabis use for all adults.

It took almost two decades from when California first passed Prop. 215 for Congress to address the burgeoning state legalization trend. In 2014 it passed the Rohrabacher–Farr Amendment, which limited the use of federal enforcement dollars against state legal medical cannabis businesses. By then, 29 states had passed some form of cannabis liberalization. Despite adult-use cannabis being legal in 21 states in 2023, there has been no congressional legislation addressing the issue.

Cannabis legalization is incredibly popular among Americans. According to the Pew Research Center, about 90 percent of Americans think cannabis should be legal. This reality, plus the perceived potential to reap additional tax revenue, has motivated state and some federal lawmakers to move forward with regulatory and tax schemes that move beyond making cannabis legal to imposing significant taxes on businesses and consumers. Consequently, in the states that have legalized cannabis, the unlicensed and untaxed market has not disappeared. (See "Why Regulation Will Likely Keep Illegal Weed Dominant," p. 44.) This is partially due to the challenges described above, but it is also an inevitable outcome of the states and localities imposing steep excise tax rates on marijuana, sometimes hovering over 30 percent. Merely passing legislation that legalizes cannabis at the federal level will not change that dynamic.

If Congress's goal is to create a safer national marketplace for cannabis and effectively reap potential tax revenue, federal law must support the transition into a market that does not just compete with, but merges with, the existing state markets and booming illicit markets. Even though a sizable federal excise tax would make it more difficult to reduce the presence of the illegal market, most proposed legislation includes significant marijuana taxes to be imposed on top of state and local taxes.

The Constitution / It should not be assumed that Congress has broad powers to comprehensively regulate cannabis at the federal level, and it is very plausible that such legislation would be challenged by an industry group. In *Gonzales v. Raich* (2005), the Supreme Court upheld the federal CSA as a permissible exercise of Congress's Commerce Clause powers. The Court found that Congress's powers over interstate commerce extend to medical marijuana grown by patients in California, despite that being a completely intrastate activity. To arrive at that conclusion, the Court relied on the aggregate doctrine, developed in its 1942 decision *Wickard v. Filburn* involving wheat cultivation. In both cases, the Court relied on the idea that, although the activity in question itself is not interstate, it has the potential, in the aggregate, to substantially affect interstate commerce.

Thanks to *Gonzales*, it is often presumed that Congress's Commerce Clause

powers necessarily include the power to pass a comprehensive cannabis law. These assumptions ignore that central to the Court's reasoning in *Gonzales* is the CSA's status as a comprehensive federal criminal regulatory scheme with no exceptions. Allowing a state-level exception would make the entire system unenforceable. By comparison, the development of the cannabis industry has not been the result of comprehensive federal coordination, but rather each state has its own unique regulatory scheme.

A more recent case involving the constitutionality of the Affordable Care Act (ACA) may be more instructive. In *National Federation of Independent Business v. Sebelius* (2012), the Court found that regulating health care—an interstate activity—is not a permissible exercise of Congress's Commerce Clause power because it is not regulating existing commerce but rather compelling commerce. Although many states have legalized cannabis, some have not, and some have only a limited medical market. The anti-commandeering principle disallows the federal government from forcing states to pass laws against their will. A federal law that mandates comprehensive federal regulation of cannabis could violate this principle by forcing states to legalize cannabis.

The Court's jurisprudence is inconsistent and largely depends on the Court's makeup. Still, it's not hard to imagine that the current Court would be more inclined to limit federal overreach and be more willing to uphold a law under Congress's taxing clause, as it did in the ACA case. Debates about possible federal cannabis legislation must consider how the law may be evaluated under Congress's Commerce Clause powers. Passing a law that would likely be challenged and may be found unconstitutional would further frustrate the development of a national marketplace and unified federal policy for cannabis.

Conclusion / The most promising piece of comprehensive legislation that has been introduced is the States Reform Act (SRA). It imposes the lowest federal excise tax, limits the FDA's jurisdiction to no more than what it has over alcohol, legislatively fixes several FDA-related problems, and includes some criminal justice measures such as expungement of prior cannabis-related records. But the SRA would still require state legal medical cannabis operators to apply for a nebulous FDA certification to sell their medical products in interstate commerce.

Federal movement on cannabis reform may be an inevitability, but it is still likely several years away because of a lack of unanimity among industry operators and lawmakers about what it should entail. Despite the continued challenges for state operators from federal illegality, a delay in comprehensive legalization may be for the best: it may be as difficult to fix a federal law legalizing cannabis that has many shortcomings as it would be to pass such a law in the first place. *R*

More Airline Regulations?

BY SHIH-HSIEN CHUANG

This summer marked the unofficial end to the travel industry's post-pandemic recovery. Airlines, in particular, carried an all-time-high number of passengers in the summer of 2023, with millions of travelers taking to the skies for the first time in several years.

With a record number of travelers comes heightened public—and political—scrutiny. Recently, there has been a spotlight on airlines' customer service, operations, and performance, with some in Washington calling for new laws and regulations.

In May, the U.S. Department of Transportation announced plans for a new rulemaking that would require airlines to compensate passengers when the airlines are responsible for delays or cancellations. Also, Congress is considering legislation that would address a variety of airline practices that lawmakers deem objectionable. The FAIR Fees Act, introduced by Sens. Richard Blumenthal (D–CT) and Ed Markey (D–MA), would eliminate "unreasonable or disproportionate" cancellation or change fees, all but abolish checked or carry-on baggage fees and seat assignment fees, and implement a process for the government to evaluate whether other fees are "reasonable."

While capping or abolishing the fees that many passengers love to hate might seem like a populist exercise that would be difficult to oppose, such legislation would be a pyrrhic victory for passengers. It would not save them money, and it would almost inevitably engender a more regressive fare structure.

The reality is that deregulation has allowed airlines to become fiercely competitive, driving down the cost of airfares, allowing more people to travel, and encouraging airlines to invest in new technology. Requiring airlines to provide a level of service dictated by the priorities of a few politicians would work against those achievements and result in higher fares for everyone.

Delays and cancellations / Despite the calls for more compensation for flight delays and cancellations, U.S. airlines currently have plenty of incentive to avoid those nuisances. Delays and cancellations lead to disrupted schedules for fleet and crew members, which cost airlines money and vastly complicate their logistics. Airlines want repeat customers, and delays and cancellations hurt their reputations and customer trust. Minimizing delays or cancellations is the profit-maximizing outcome for airlines.

Airlines actively try to minimize delays that are under their control. They cannot, however, prevent operational challenges like

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extreme weather, which was the cause of more than half of flight cancellations in 2022. Severe weather can significantly derail flights and cause a domino effect across the air transportation system. There are also situations where weather causes initial delays and subsequent flights are canceled at the behest of the Federal Aviation Administration to streamline operations at airports. For example, on July 9, 2023, the FAA issued a ground stop and employed ground delay programs for many airports on the East Coast because of "a long line of sparse to medium convective weather."

The FAA's own shortcomings have been a growing cause of passenger delays and is something the Transportation Department could address. Of particular concern is the slow progress toward technology modernization. For example, earlier this year a computer failure caused 11,000 flights to be delayed or canceled, the first national grounding of domestic flights in nearly two decades. Another example: the FAA's NextGen project, which promises to greatly expand airport capacity, is a decade behind schedule. While some airport infrastructure upgrades were included in the Infrastructure Investment and Jobs Act passed by Congress two years ago, the FAA's aging aviation infrastructure received no funding, and lawmakers refuse to consider widespread privatization of airports and air traffic control even though it has proven enormously successful in countries that have adopted such a system.

FAA staffing challenges are also affecting airport capacity. One of the most important air traffic control facilities in New York is only 54 percent staffed, and it has forced airlines to reduce their schedules to alleviate pressure on the National Airspace System. According to a Transportation Department inspector general report, the FAA has not done enough to ensure adequate controller staffing at the busiest air traffic control facilities. Some 77 percent of critical air traffic control facilities are staffed below the FAA's 85 percent threshold, and 26 percent of total air traffic controllers are trainees.

Returning to the broader issue of penalizing airlines for delays and cancellations, it should be noted that no other passenger industry is required to provide compensation and cover passenger expenses following operational disruptions. For example, Amtrak has no requirement to compensate passengers for delays from an extreme weather event. Given that its on-time performance outside the Northeast Corridor is beyond abysmal, why does Amtrak escape scrutiny? These regulations are also not proposed for bus companies, ferry companies, and other major methods of transportation that also subject their passengers to delays and cancellations.

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Junk fees? / While these bills and proposed regulations were designed to help consumers, the likely outcome will be the opposite. Low-income flyers will be one of the groups that suffer the most if any of the proposed rulemaking or legislation moves forward.

Specifically, if Congress or the Transportation Department prevents the airlines from charging ancillary fees, that will inevitably push up ticket prices. Allowing fliers to pay to check a bag, obtain a preferred seat assignment, or have more flexibility in changing the date of a flight allows airlines to create competitive pricing models where people who are cost sensitive can choose the plans and options that best fit their individual needs. Treating the abolition of fees as an unabashed win for flyers completely misconstrues the reality of what would occur. If airlines cannot charge fees, they will fold the costs into higher ticket prices.

The beneficiaries of a cap on in-flight fees would be those people who tend to pay for better seats or bring a carry-on. These people are more likely to be flying on a business account, frequent flyers with status, or willing to pay for good seats. But if they can no longer purchase them outright, they will use their experience to navigate the system to get better seats, ensure they have space for their bags, and benefit from other accouterments that would be rationed instead of sold—all while the broader flying public subsidizes their preferences through higher ticket prices. Any benefits that accrue to passengers would inevitably be regressive, defeating the intent of the regulations.

Abolishing all fees would also be inefficient. Banning fees for things like carry-on bags would inevitably result in needless and costly queues. When carriers do not charge for extra carry-on bags, more people bring carry-on bags, forcing the airline to check some bags during the boarding process. The delays this exercise regularly causes are a top reason why airlines began charging for additional carry-on bags in

the first place. Using prices to allocate scarce services is the central organizing principle in a market economy, and rejecting it because some people do not like it represents a step in the wrong direction.

These ancillary fees are not "junk fees," as some have suggested. They are fees for a service that consumers choose. Besides, there are other fees that are included in ticket prices—including government-imposed taxes and fees—that rarely receive scrutiny, yet they also contribute to ticket prices.

Airline economics / The argument that airlines can afford to keep prices low with these regulations in place fails to understand the economics of aviation. In this labor- and capital-intensive, highly competitive industry, even in years of record revenue, typical profit margins consistently fall below the U.S. inter-industry average. From 2010 to 2019, pretax margins averaged 7 percent in the airline industry. That means that for every $300 in ticket revenue, an airline would keep $21 in profit. The catastrophic drop in travel driven by the pandemic grounded most commercial aircraft, forcing airlines to take on unprecedented levels of debt to survive. In the last five years, airlines have recorded $12 billion in pretax losses.

And even as fuel and labor costs have skyrocketed, airlines are still investing in technology and hiring. From the end of 2020 to May 2023, U.S. passenger airlines have added 118,000 jobs. In total, U.S. passenger and cargo airlines now employ an all-time-high 800,000 workers. The nation's largest airlines spent $6.8 billion on information technology in 2022. Airlines want to ensure a seamless travel experience for their customers and are not incentivized to provide a poor travel experience, especially given the number of competitors in the industry.

Because of fierce airline competition, airlines have continued to offer low fares, even amidst the post-COVID travel spike. Adjusting for inflation, fares for the first half of 2023 were 10.2 percent lower than in the first half of 2019 and 2.2 percent lower than in the first half of 2022. Low prices are a strong signal that an industry is competitive, with pricing being one tool that airlines use to attract new customers and retain current ones.

Without reregulation, airlines are keeping air travel accessible and making sustainable investments in technology and the workforce to reduce delays and cancellations when the reasons behind the operational difficulties are within their control. The nearly 50 years since the government deregulated the industry have shown that the freer market has been a boon for travelers, and we should continue to allow the market and air travelers to pick and choose what's best for their experience.

Conclusion / Competition is the bedrock of the U.S. economy, and historically competition has incentivized airlines to keep prices low and investments in their employees and technology high. Competition also helped fuel a dramatic recovery following the COVID-19 pandemic. However, the regulations and bills currently proposed against the airline industry would dampen competition, hurting consumers the most.

The Transportation Department's proposed rules would push airlines into adopting responses that would be less efficient and cost-effective than what they would do on their own. Congressional proposals to sharply curtail most ancillary fees would fail to save fliers money while reducing the ability of low-income passengers to afford tickets.

There is no such thing as a free lunch: the more that Congress or the Transportation Department dictates how airlines run their business, the higher ticket prices will be. While these bills and regulations may sound like they would be a victory for consumers, the reality is that consumers would suffer the most from a reregulation of the airline industry. *R*

The Costs of the New Weight Loss Hope Could Be Very High

BY CHAD COTTI

There has been a great deal of interest in a relatively new class of diabetes drugs known as GLP-1 agonists. Better known by such brand names as Ozempic, Rybelsus, and Mounjaro, these medications help treat type 2 diabetes by stimulating insulin production after eating, which lowers blood sugar levels. What makes them of special interest, though, is that they also promote a feeling of fullness and act to reduce appetite, which promotes weight loss. The results of GLP-1s as weight-loss drugs have been remarkable, with the Mayo Clinic noting studies showing that people on a weight loss program who used one of these drugs, semaglutide, lost about 33.7 pounds versus 5.7 pounds for those who didn't use the drug.

This has led to the hope that GLP-1 medications could be used broadly to treat the obesity epidemic afflicting the United States. In fact, it appears that many people began taking these drugs to lose weight even before the Food and Drug Administration gave formal approval for that purpose, to the extent that drug shortages have been reported.

There is little doubt that the demand for a drug that could help a person lose weight would be high. The obesity crisis in the United States has been spiraling for decades, and it has caused or contributed to a variety of afflictions as well as early deaths

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for millions of Americans while costing the health system hundreds of billions of dollars each year. More than 40 percent of U.S. adults are considered clinically obese.

Costs and concerns / Given the effects that obesity has on our society, it is understandable that so many have put their hope into these drugs as a solution for drastically improving health outcomes. For instance, there are now calls for health insurance to cover these drugs when used as a weight loss treatment, and there is bipartisan legislation—the Treat and Reduce Obesity Act—that would authorize Medicare Part D to cover GLP-1 medications.

However, authorizing the coverage of GLP-1 drugs for weight loss would be extremely expensive. A recent study in the *New England Journal of Medicine* estimated that the annual cost to Medicare could be $13 billion to $26 billion a year, which at the high end would increase the total annual cost of Medicare Part D spending by approximately 25 percent. The cost to private health insurers would be even greater: one estimate is that total annual U.S. spending, private and public, on this class of drugs could exceed $100 billion by the next decade.

This proposed spending is poised to occur despite the fact that some groups are raising concerns about some of the unknown effects of GLP-1 medications. While randomized control trials and real-life studies have shown the efficacy of GLP-1s on weight loss, diabetes, and other valuable health outcomes of interest, more research is needed to fully appreciate the long-term effects of the drugs on the body, both in terms of successfully treating weight loss and the health consequences of long-term use.

If GLP-1s' short-term success in helping aid weight loss can be translated to sustained weight loss, the high costs of covering the care could be well worth the money. However, there are concerns on this front. For example, a 2023 study by the pharmacy benefit manager Prime Therapeutics investigated claims data and found that GLP-1 adherence was poor, with just 32 percent of members persistently using the drugs at one year and 27 percent adherence to therapy during the post-year. Another study found that people tend to regain the weight lost after stopping these drugs. This is worrisome given the high cost of covering these drugs and the tradeoffs in covering them instead of other uncovered health care needs.

It's also unclear whether all the health maladies that derive from patients' obesity will quickly disappear with their excess weight after taking a GLP-1 regime. A recent study in *Medical Decision Making Policy & Practice* suggests that senior citizens with diabetes and generally fair or poor current health may not see any health benefits from the drug regime even if they were to lose weight. Conversely, early clinical evidence indicates that one of the drugs, Wegovy, may reduce the relative risk of heart attack, stroke, or heart-related death, suggesting a potentially high value of these drugs for other non-weight loss purposes.

In general, GLP-1 medications hold tremendous potential to become an important tool in fighting the obesity epidemic and improving health outcomes in America and globally. But there are potentially large financial, health, and adherence costs that need to be better understood. It will take time to appreciate the long-term effects and more completely access the tradeoffs of this costly investment. As a result, careful and diligent study is prudent at this time, so we can assure that Americans are investing in a well-understood and best-use option for the long run. *R*

READINGS

- "Anti-Obesity Drug Discovery: Advances and Challenges," by Timo D. Müller, Matthias Blüher, Matthias H. Tschöp, and Richard D. DiMarchi. *Nature Reviews: Drug Discovery* 21: 201–223 (2022).
- "Expected Health Benefits of SGLT-2 Inhibitors and GLP-1 Receptor Agonists in Older Adults," by Rahul S. Dadwani, Wen Wan, M. Reza Skandari, and Elbert S. Huang. *Medical Decision Making Policy & Practice* 8(2): 2381468323118756 (2023).
- "Medicare Part D Coverage of Antiobesity Medications—Challenges and Uncertainty Ahead," by Khrysta Baig, Stacie B. Dusetzina, David D. Kim, and Ashley A. Leech. *New England Journal of Medicine* 388(11): 961–963 (2023).
- "Real-World Analysis of Glucagon-Like Peptide-1 Agonist (GLP-1a) Obesity Treatment One Year Cost-Effectiveness and Therapy Adherence," by Joseph Leach, Marci Chodroff, Yang Qiu, et al. Prime Therapeutics and Magellan Rx Management, July 11, 2023.
- "Weight Regain and Cardiometabolic Effects after Withdrawal of Semaglutide: The STEP 1 Trial Extension," by John P.H. Wilding, Rachel L. Batterham, Melanie Davies, et al. *Diabetes, Obesity, and Metabolism* 24(8):1553–1564 (2022).

BRIEFLY NOTED

Will the *Harvard* Ruling Make Discrimination in Admissions Worse?

BY DENNIS L. WEISMAN

Last June, in *Students for Fair Admissions v. Harvard*, the U.S. Supreme Court mostly banned the use of racial preferences in college admissions. The Court found such preferences violate the Equal Protection Clause of the Fourteenth Amendment that prohibits discrimination on the basis of race. The decision is likely to be well received by the public because nearly three-fourths of those surveyed indicate they do not believe that race or ethnicity should be a factor in college admissions decisions.

If you were to ask those opposed to racial preferences the basis for their opposition, most would probably say something to the effect that the "best and the brightest" should be admitted into elite colleges and race should not be a factor in those decisions. The question then is whether it is necessarily the case that more of the "best and brightest" will be admitted to elite universities now that racial preferences are prohibited. The surprising answer is "not necessarily."

Other preferences / Racial preferences constitute only one of several types of preferences that elite universities regularly employ in making their admission decisions. There are also preferences for legacy admissions (family of alumni), athletes, and the offspring of faculty. (See "What Constitutes 'Discrimination' in College Admissions?" Summer 2019, and "College Admissions Preferences Are Not Justified," Fall 2019.) While racial preferences are now prohibited, these other types of preferences that allow for non-merit admissions were not before the court in the *Harvard* case and remain in place for the time being.

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This is worrisome because minorities do not have the same access as whites to these other types of preferences. To wit, upwards of 36 percent of the students in Harvard's Class of 2022 are descendants of previous Harvard students and only 5 percent of Harvard's tenured faculty are black. The Court's decision discriminates against blacks because the only preferences that remain in place are those that disproportionately favor whites. Was the Court judicious in eliminating racial preferences when the case before it did not allow it to eliminate all preferences?

There is a self-perpetuating dimension to legacy preferences that is eerily reminiscent of *hereditary succession*, with all the trappings this entails. In contradistinction to racial preferences that have been adjudicated through a convoluted process over the course of more than 50 years, legacy preferences have received only limited scrutiny because the courts have not previously been asked to rule on their constitutionality.

Implicit in the aforementioned survey results is the assumption that universities would respond to a prohibition on racial preferences by increasing the number of merit-based admissions, but there is no guarantee this is what will occur. Elite universities may respond to the Court's ruling by replacing more-able race-based admissions with less-able legacy admissions who are willing and able to contribute generously to university coffers. The outcome could well be the opposite of what is expected: a less able student body.

Disproportionate impact / This outcome, however unfortunate, is not completely unexpected. In the case of Harvard and other elite educational institutions, the

Supreme Court's decision may have served only to change how the price of admission is denominated. Race is no longer an accepted currency, but dollars can still be used as a medium of exchange to compensate for a lack of academic merit.

Employment discrimination law may offer some insight into how the courts could potentially find that these other types of preferences raise constitutional questions. The 1971 Supreme Court ruled in *Griggs v. Duke Power Co.* that an employer cannot augment the educational requirements for a position of employment if (1) the stated educational requirements are not necessary to perform the particular job function in a competent manner, and (2) the educational requirements would have a *disproportionate impact* in excluding minorities from due consideration even if there is no discriminatory intent. The Equal Employment Opportunity Commission has similarly taken the position that a requirement for a high school diploma is discriminatory under Title VII of the Civil Rights Act if it has a *disparate impact* on a protected group and is not job related or consistent with business activity.

Invoking similar logic, retaining all types of preferences with the exception of racial preferences in the college admissions calculus could be expected to have a *disproportionate impact* on excluding minorities from admission at elite universities. Chief Justice John Roberts, in an oft-quoted phrase, observed in his plurality opinion in the 2007 case *Parents Involved in Community Schools v. Seattle School District No. 1* that "the way to stop discrimination on the basis of race is to stop discriminating on the basis of race." The question the courts will ultimately have to engage is whether retaining preferences in college admissions to which minorities do not have equal access constitutes a form of race-based discrimination.

The Supreme Court's long-awaited decision in the *Harvard* case has been hailed as a victory for constitutional principles. But it may not eliminate race-based discrimination in higher education. R

We Need an FDA Office of Preparedness and Response

BY ENLLI LEWIS

Operation Warp Speed revolutionized vaccine development. By cutting red tape, the Food and Drug Administration enabled the deployment of life-saving COVID-19 vaccines in record time. It showed how removing unnecessary and time-consuming regulatory barriers can have immense public health and economic value. However, using this approach solely in a time of crisis is an enormous error.

Tenacity and innovation / Prior to Operation Warp Speed, the fastest vaccine to be developed—a mumps vaccine back in the 1960s—took four years. For COVID-19, it took less than one. This success was in large part due to the tenacity and innovation of the FDA's Center for Biologics Evaluation and Research (CBER). In recognition of the urgent need to deploy vaccines and the dire consequences of delay, CBER adopted a streamlined regulatory approach and identified bureaucratic hurdles that could be removed with little detrimental effect on safety and efficacy.

Developing a vaccine is usually a cumbersome process, taking on average 10 years to go from initial vaccine research and development through preclinical and clinical trials. Under Operation Warp Speed, CBER greenlit initial Phase I human testing of vaccine candidates on an accelerated basis (often in the absence of animal data) and enabled large-scale Phase II and III human testing to begin before a full readout of Phase I results became available. Also, CBER quickly issued guidance for pharmaceutical companies that established the evidentiary threshold for demonstrating the suitability of their candidates for Emergency Use Authorization (EUA). By doing so, CBER provided clear expectations to developers regarding the safety and efficacy standards they were required to meet, which reduced regulatory uncertainty for developers and eased the review process by standardizing evidence packages.

To ensure data from vaccine developers were reviewed as quickly as possible, CBER exercised rolling review, examining the data as they became available instead of waiting for the trials to conclude and having the developers submit all their results as a complete package. CBER expanded its review capability, with staff working around the clock to review submissions in real time. These efforts allowed CBER to authorize the Pfizer vaccine within 21 days of its EUA request and Moderna within eight. In comparison, the FDA's existing Priority Review designation aims for action on an application within six months.

Using regulatory acceleration to promote medical innovation isn't unique to COVID-19 vaccines. Other FDA accelerated programs have shown promising results. Its Breakthrough Therapy Designation, which accelerates the development and evaluation of medications that show significant enhancements over existing therapies, has cut clinical development times by 23 percent without any statistical effect on safety or efficacy. However, CBER's handling of the COVID-19 vaccines completely eclipses the existing accelerated programs, with huge implications for medical innovation.

Despite its results, Operation Warp Speed's legacy is barely noticeable within the FDA today and stories of stagnating approvals have begun to reappear. A particularly frustrating example is the new interferon drug to treat COVID-19 patients that has been shown to cut hospitalizations

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in half in a large clinical trial. Despite its promise, it's likely to take years until the drug receives FDA approval.

Making Warp Speed permanent / To reverse this, the FDA should create an Office of Preparedness and Response within CBER. This office would embrace the Warp Speed approach to authorizing vaccines and other biologics by fostering an expedited and flexible approach toward the authorization of medical countermeasures and other socially valuable medical products. In ordinary times, this office would support developers of medical countermeasures against potential emerging threats through the publication of proactive guidance, an expedited review of proposed clinical studies to prepare "prototype" countermeasures that can be quickly adapted and deployed if a pandemic starts, and undertaking rapid review of medical products whose social value appears to greatly exceed their market value.

As with Operation Warp Speed, where CBER insisted that "the general safety evaluation of COVID-19 vaccines [...] should be no different than for other preventive vaccines for infectious diseases," this office would make no tradeoff between safety and speed. On the contrary, additional safety and efficacy measures would be implemented to complement expediency. For the COVID-19 vaccines, CBER increased the usual number of required clinical trial participants to 30,000. In the new office, additional safety measures could take the form of stricter deadlines on developers for conducting confirmatory trials following initial authorization and concrete plans for the collection of real-world evidence to verify a product's safety and effectiveness.

Public acceptance / Regardless of additional safety measures, a challenge facing any accelerated approach to authorization is the effect it could have on vaccine hesitancy. Whereas the FDA's earlier accelerated programs drew far less attention from vaccine skeptics prior to the pandemic, vaccine hesitancy has increased substantially in the wake of COVID-19.

At root, this skepticism is the product of miscommunication. By socializing accelerated approval during ordinary times and dedicating resources to improving post-market data generation, this new office's normalization of accelerated research and testing could make great headway in building public confidence in advance of the next pandemic. By improving standards of verifiability through the better collection of real-world evidence, it could create better information to address skeptics' concerns.

This new office could also function as a proving ground for innovative approaches to enhance the FDA's regulatory framework, surpassing the measures used by CBER during Operation Warp Speed. One pathway for improvement would be the integration of alternative clinical trial designs, such as the human challenge trials that my organization advocates, in which compensated volunteers are deliberately exposed to an infectious disease as part of a clinical trial. Human challenge trials are uniquely positioned to accelerate vaccine development: challenge models can help researchers gain a better understanding of how diseases work and establish correlates of protection for clinical trials to allow for rapid regulatory approval. While challenge studies have been used historically for developing treatments and vaccines for a range of pathogens (including malaria, influenza, typhoid, and cholera), their use to accelerate vaccines has been sporadic and no regulatory incentives exist to advance their effective utilization. An Office of Preparedness and Response would be perfectly suited to build the FDA's experience with using human challenge trials, creating the necessary regulatory structures to best utilize challenge studies for accelerated approval.

By practicing rapid review, this office would create a template for Warp Speed decision-making across the FDA. This rollout could take place in the form of a new type of FDA award, analogous to its current Priority Review Voucher (PRV) program for neglected and rare diseases. Under standard review times, the FDA aims to make a decision on a new drug application within 10 months, while priority review decreases this to six. If a developer secures approval, it is awarded a sellable voucher that can be applied to another new drug that becomes eligible for priority review, buying four months' faster decision time. When first offered, the vouchers typically sold for about $300 million, though subsequent wider availability has reduced the price to around $100 million—still a valuable incentive.

The new office could also develop a discovery award for developers that make discoveries or develop tools that advance their respective fields. The award would be a sellable voucher that would make a product eligible for "warp speed" treatment by the FDA. In doing so, discovery awards could one day potentially disseminate process improvements throughout the FDA while incentivizing the improvement of regulatory science.

Conclusion / Recent events have reinforced the urgency of establishing this office. The upcoming reauthorization of the Pandemic and All-Hazards Preparedness Act is instigating a reevaluation of the U.S. pandemic strategy in light of the lessons learned from COVID-19. The FDA's proposal for an Emerging Pathogens Preparedness Program to "enhance regulatory capabilities and readiness to respond to emerging pathogens" parallels this proposal. It is precisely the kind of change we should be seeking because it would institutionalize the successes of Operation Warp Speed for the benefit of future medical products.

Also, the Biden administration's recent launch of Project Next-Gen—a $5 billion program to accelerate next-generation coronavirus vaccines and monoclonals—offers a perfect case study for a new FDA program. Details regarding the program are scarce, leading to calls for Project Next-Gen to replicate the Operation Warp Speed model, especially its speeding up of regulatory processes. Allocating just 1 percent of the Project Next-Gen budget to fund the FDA's proposed Emerging Pathogens

Preparedness Program to authorize these next-generation vaccines at a similar pace to Operation Warp Speed could be critical to the program's success.

After years of calls for regulatory process reform at the FDA, the COVID-19 pandemic has expanded the realm of possibilities and provided a glimpse of what can be achieved through regulatory innovation. *R*

READING

■ "Regulatory Incentives for Innovation: The FDA's Breakthrough Therapy Designation," by Amitabh Chandra, Jennifer Kao, Kathleen L. Miller, and Ariel D. Stern. NBER Working Paper no. 30712, December 2022.

The Inhibition of Innovation

BY DAVID J. BERTIOLI AND HENRY I. MILLER

The adage "Follow the science" when formulating public policy has much to recommend it, but it's not as straightforward as it sounds. Let us explain.

Astrophysicist and science writer Ethan Siegel recently wrote, "Science is a way of thinking about the world, the process of inquiry and investigation, and also the full suite of relevant knowledge that we know, collectively, about an enterprise." It is based on "the scientific method," a rigorous process that reveals new information, or knowledge, that enables us to know what we know.

But simply saying that scientific knowledge, not science itself, should guide policy is insufficient. An essential ingredient is missing: value judgments. Knowledge created by science tells us, with ever-increasing accuracy, what the world *is*, but it does not tell us what the world *ought* to be. This gap between "is" and "ought," which cannot be filled by logic or reason, was articulated by Scottish philosopher David Hume. It can only be filled by value judgments, be they moral, religious, or political.

Value judgments are needed because of tradeoffs. Decisions can be informed by scientific knowledge, but they are not dispositive because differing values can lead to different decisions based on the same accepted body of scientific knowledge. Consider, for example, California's High-Speed Rail Project, which would link San Francisco and Los Angeles. Although it is technically achievable, whether the cost is worthwhile is a value judgment, and it has changed over the years. As of March 2023, according to a California High Speed Rail Authority project update report, the price tag for the system had risen to $128 billion. That's a nearly 22 percent increase from last year's estimate of $105 billion and a far cry from the $33 billion voters approved in 2008. That massive outlay inevitably diverts government resources from other projects—and from taxpayers' pockets—and what is cost-effective and societally advantageous is a matter of value judgment.

Genetic engineering / The interplay of scientific knowledge and value judgments also applies to opinions about innovative technologies, from nuclear power and fracking to genetic engineering. Let us focus on the last of these, a particular interest of ours.

When it comes to certain activists' decades-long objections to societally important advances in "genetic engineering," or "genetic modification," we would argue that they have been wrong on both the science and the value judgments.

First, the science. Genetic modification refers to a continuum of techniques that have been used over millennia. These include hybridization, mutagenesis, somaclonal variation, wide-cross hybridization (movement of genes across "natural breeding barriers"), recombinant DNA, and, most recently, gene-editing. The primary distinction between the last two and the others is that they are far more precise and predictable than the earlier techniques, which often introduced off-target mutations. And yet, some organizations such as Greenpeace and Friends of the Earth have singled out the newer, more precise, more predictable techniques for sui generis, excessive regulation that has boosted research and development costs and delayed or prevented important advances.

Because of the continuum alluded to above, and the fact that the newer techniques are more precise and predictable, science is against the activists and so, we would argue, are the value judgments. Activists have teamed up with companies that sell organic and "natural" food products to denigrate crops crafted with molecular techniques, which they have dubbed "Frankenfoods." This anti-genetic-engineering industry and its lobbyists contribute significantly to the public apprehension toward this technology. They then exploit that fear to sell alternative food products to consumers.

Now, this same industry is lobbying globally for stringent regulation of plants and animals that have been modified with state-of-the-art gene editing techniques such as CRISPR–Cas9. One prominent genetic engineering skeptic, North Carolina State University professor Jennifer Kuzma, said about gene editing, "We need a mandatory regulatory process: not just for scientific reasons, but for consumer and public confidence." The latter claim, especially, is a fallacy: Thirty years of excessive regulation of genetic engineering has neither reduced public anxiety nor quieted the critics. If anything, these gratuitous regulations have fanned public concerns about this safe, superior technology. As Barbara Keating-Edh, representing the consumer group Consumer Alert, testified before the U.S. National Biotechnology Policy Board three decades ago:

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Regulation was first published in July 1977 "because the extension of regulation is piecemeal, the sources and targets diverse, the language complex and often opaque, and the volume overwhelming." Regulation is devoted to analyzing the implications of government regulatory policy and its effects on our public and private endeavors.

> For obvious reasons, the consumer views the technologies that are *most* regulated to be the *least* safe ones. Heavy involvement by government, no matter how well intended, inevitably sends the wrong signals. Rather than ensuring confidence, it raises suspicion and doubt.

Precautionary Principle / Decades of large-scale use—millions of acres cultivated and trillions of meals consumed without a single mishap—undermine activists' concerns. However, there remains one particularly resistant formulation of risk analysis that rejects evidence-based considerations of overall benefit and harm. That is the "Precautionary Principle," which posits that regulatory action should be taken to avoid risks even when there is incomplete scientific evidence as to their magnitude or potential effects. Advocates of the Precautionary Principle portray it as a neutral tool for assessing risks. But it oversimplifies the complex processes of risk analysis and risk management, allowing regulators to assume that new technologies have infinite risks but uncertain benefits. A new technology is thus assumed to be guilty until it can be proven innocent to a safety standard dictated by its antagonists—a practical impossibility. (See "The Paralyzing Principle," Winter 2002.)

The Precautionary Principle has now been incorporated into legislation in the European Union and elsewhere.

As a tool of public policy, the primary shortcoming of the Precautionary Principle is that it incorporates neither coherent evidentiary standards nor any clear limits. It stipulates that hypothetical risks should take precedence over substantive demonstrated benefits and effectively frees regulators to arbitrarily require any amount and kind of testing they wish. Likewise, it permits them to ignore overwhelming evidence of a product's (or a technology's) safety and benefits, and to prevent or delay its use. It functions independently of "what the science says" and penalizes innovation. It ensures that wherever it is applied, progress—especially in agriculture—will be stunted for the foreseeable future.

The Precautionary Principle is especially perverse when it is applied to the genetic engineering of plants and animals because, without any scientific basis, it discriminates against the use of the newest, most precise, and most predictable techniques by subjecting them to the most intense, stultifying regulation. The negative societal effects of such policies are discussed eloquently in a recent *Nature Plants* article by Daniel Jenkins et al.:

> Regulation based on process will not advance common goals of nutrition, sustainability or consumer preference. On the contrary, process-based regulation will only delay or prevent the achievement of these goals. Differential requirements lead to a confusing system with higher burdens, lower utility and increased time to market. This only creates disincentive to fund research and business investment, and ultimately throws up barriers to reaching consumers and improving diets for even the simplest and most-familiar of characteristics. When science cannot distinguish one seedless grape from another, neither should regulation.

The Precautionary Principle is not the only tool of anti-genetic-engineering activists, who also invoke opposition to certain new products based on resentment of corporate entities' profits or on the fact that most agricultural innovation comes from industrialized countries and therefore somehow represents "colonialism" when transferred to developing countries. Such factors obviously should have no bearing on regulation to assure safety and efficacy.

If we are to realize the potential of the newest techniques of genetic engineering, we need to fend off the sophistry and mendacity of anti-innovation activists, both within and outside governments. Public policy, including regulation, should be dictated by science and common sense. *R*

READINGS

- "Regulation of Plants Developed through New Breeding Techniques Must Ensure Societal Benefits," by Daniel Jenkins, Nicole Juba, Brian Crawford, et al. *Nature Plants* 9: 679–684 (2023).
- "What All Scientific Experts Wish Non-Experts Knew," by Ethan Siegel. *Big Think*, May 31, 2023.

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