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tagline

NEWS ON THE FIGHT TO END HIV/AIDS, VIRAL HEPATITIS, AND TUBERCULOSIS



A LUTA CONTINUA!

By Tim Horn

With every major election, particularly one that secures or fortifies Republican control of the White House, Senate, or House of Representatives, a certain amount of worry and strategy realignment is to be expected from public health activists and civil society. Following one of the biggest upsets in political history, in which Donald Trump rode a wave of populist and nationalist sentiments to become the 45th president of the United States and all but guaranteed a right-wing trifecta, the concern among health justice leaders has been unprecedented.

And rightfully so. Anxieties regarding government underinvestment in public health—basic and clinical research, international aid, domestic healthcare infrastructure, and various federally funded programs needed to support health outcomes—are heightened once again. In addition, we must now contend with executive and legislative branches bent on scaling back statutes and regulations that are key to human wellness and survival on the basis of, in no small part, willful disregard for science and evidence-based policy making.

Progress made in the arenas of HIV, tuberculosis (TB), and hepatitis C virus (HCV) over the past several years has been significant, to the point at which strategies to end all three epidemics have not only been envisioned, but actualized. But these gains are incredibly fragile and will diminish swiftly in the absence of federal nurturing and support (page 3).

TAG remains committed to the capacity building, coalition strengthening, and direct advocacy required to maintain forward momentum in a federal political climate that isn't merely indifferent to public health, but is ultimately hostile to its efforts and the communities that it benefits.

In this issue of *TAGline*, we touch on five of our overarching priorities in the months and years ahead:

1) ensuring strong investments in HIV, TB, and HCV research and buttressing scientific independence and public trust from the malevolent forces of 'alternative facts' (page 5);

2) moving toward reforms that recognize drugs and biologics as a global public good, and not luxuries of a market economy (page 8);

3) protecting and strengthening health systems that are intended to prevent and treat pathologies of poverty and marginalization, including a worsening opioid epidemic in states likely to be disproportionately affected by continued assaults on Medicaid (page 12);

4) pushing back against an anti-immigrant agenda that is fundamentally racist and xenophobic and the antithesis of good public health (page 14); and

5) defending against deregulation of the U.S. Food and Drug Administration and other stringent regulatory agencies charged with ensuring the safety and efficacy of the world's medicines (page 17).

We remain in solidarity with our allies who have long fought battles to secure funding for basic and clinical research, reverse stigmatizing and discriminatory policies, stare down pharmaceutical industry greed, and push for programs to ensure equitable access to treatment and care. Although the challenges now go broader and deeper than ever before, we stand stronger than ever in a fight that has yielded monumental victories in the past and will continue to do so in the future. *A luta continua, a vitória é certa.*

LESSONS **from** HISTORY **for** TODAY'S HIV RESPONSE

Maintaining and expanding the accomplishments of the past depend on a **fight for their survival and growth** – now more than ever.

By Mark Harrington

Today's political situation with respect to the struggle to end HIV/AIDS, to treat all of those infected, and to reduce new transmission of the virus to zero, is facing new and unprecedented challenges. In this situation—particularly in the United States, where over 1.2 million people are living with HIV, where approximately 40,000 people are newly infected each year, and where over 6,720 people died of AIDS in 2014—HIV care, treatment, prevention, and support programs are likely to come under unprecedented threat from adverse political forces that are now overwhelmingly predominant in all of the branches of the federal government and in at least 33 states, which are marked by single-party dominance of the governors' and legislative houses.

The HIV community is facing a political emergency unparalleled since the epidemic's earliest years, in the early 1980s, when there was no prevention, little research, no effective treatment, no government funding, no public supportive services, few or no legal rights and protections, and massive fear, stigma, and discrimination, and ongoing violations of human rights of people with HIV and those at risk for HIV.

Looking more broadly on the potential effect of the new presidency and Congressional majorities on health, a recent article in *The Lancet* asked "What will [the current] presidency mean for health? A scorecard" (see table on page 4).

However, our current knowledge and the scientific discoveries of the past 35 years amount to a revolutionary improvement from the unstudied state of the HIV pandemic in the 1980s: the enormous progress that has been made in understanding the science of HIV, how it is transmitted, and how it may be prevented, how it can be treated, as well as ongoing research efforts to define better prevention, treatment, a cure, and a vaccine.

There is as well an extensive, nationwide and global network of expert practitioners and providers, educated and empowered communities, and strong and diverse funding streams that support both domestic HIV treatment and care, such as the Ryan White CARE Act and the Housing Opportunities for Persons with AIDS (HOPWA) program; and global programs, such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria and the President's Emergency Plan for AIDS Relief (PEPFAR). There are large and well-organized research programs such as those administered by the National Institutes of Health (NIH) and many other research agencies.

As a result of the billions of dollars invested in research, political mobilization, and institutional growth and development that have accompanied the advent of effective prevention and treatment for HIV, death rates from AIDS have dropped almost 90 percent in the U.S. from the early 1990s (>50,000 per /year) to 2014 (6,720/year), with new infections dropping from >140,000 (1984) to <40,000 (2014). While major work remains necessary to bridge the diagnosis/treatment gap, treat everyone earlier, and scale up pre-exposure prophylaxis (PrEP) and other prevention methodologies, the US could be on a trajectory to end AIDS as an epidemic by 2025 if the most ambitious programs – such as those in New York, San Francisco, and Washington, D.C. – are expanded and emulated.

Globally, more than 18.5 million people—or about 50% of those in need—currently receive life-saving anti-HIV treatment. As reported by Jon Cohen in the December 9, 2016 issue of *Science*, recent data from high-burden southern African countries such as Malawi, Zambia, and Zimbabwe indicate that treatment success (measured as virologic suppression) in PEPFAR-supported programs exceeds 85 percent—comparable to the most favorable levels in developed countries.

Proposed scorecard for the stated policies of the [current] Presidency

Universal health coverage	Red	Plans to repeal the Affordable Care Act
Evidence-based health policy	Red	Rejection of scientific consensus
Reproductive health	Red	Opposition to abortion rights; possible Supreme Court of the United States reversal of Roe v. Wade
Vulnerable populations	Red	Increased prison/detainee population
Climate action	Red	Plans to reject Paris Accord; nomination of Pruitt to lead EPA; defunding of NASA climate monitoring
Social determinants of health/health inequities	Red	Tax/benefit policies to reduce taxes on (super) rich, reducing safety net funding for the poor
Gun violence	Red	Weakening of existing limited gun-control measures
Security and foreign policy	Pink	Statements on areas of actual and potential for conflict raise concerns about unintended consequences
Aid and global health	Pink	Pledges to reduce support for international aid
Trade/market integration	Pink	Isolation and protectionism
Employment/job security	Pink	... anti-union policies may weaken job security

Adapted from figure, McKee M, Greer SL, Stuckler D. What will [the current] presidency mean for health? A scorecard. The Lancet 2017 Feb 18;389(10070):748–754. [http://dx.doi.org/10.1016/S0140-6736\(17\)30122-8](http://dx.doi.org/10.1016/S0140-6736(17)30122-8).

INDICATORS: Red = high risk to health; Pink = medium risk to health.

All of these gains are fragile. In spite of Congress' inability to repeal the Affordable Care Act (ACA), continuing efforts to undermine domestic health programs—particularly those serving marginalized populations including people with or at risk for HIV—have the potential to severely damage HIV prevention and treatment programs. Current levels of support for Ryan White AIDS Drug Assistance Programs are vulnerable. Rewriting regulations to weaken Medicaid or to impose employment requirements where, in many places, jobs are unattainable, could hurt people with HIV and other vulnerable populations. Cuts to the U.S. Centers for Disease Control and Prevention (CDC) and NIH will damage HIV research as well as research on emerging pathogens, while cuts to the U.S. Food and Drug Administration would weaken rigorous regulatory oversight of product development. Cuts to PEPFAR and the Global Fund could throw millions off of HIV treatment, with corresponding increases in progression to AIDS, death, and new infections.

The most relevant history lesson from the 1980s, however, is that community mobilization and activism are essential for mobilizing national and state leadership, funding, resources, and political will to respond to the pandemic, protect the uninfected, treat those living with HIV, and invest in the domestic and global research, prevention, and treatment programs that ultimately have the potential to end the epidemic.

These are monumental historical accomplishments and we must fight for their sustained survival and growth with all our might.

All the progress we've made in the past 35 years of the global AIDS pandemic has been built on a strong foundation of community responses. We will need to be smart, agile, rapid-reacting, flexible, and willing to build new alliances and coalitions to defend all of the lives now at stake, and to ensure that we build on scientific progress to move HIV and AIDS closer than ever to their endgame.

JUST **the** FACTS: TRUMP **and the** DEVALUATION **of** SCIENCE

Mobilizing to defend biomedical research investments and scientific integrity as essential for public health, safety, and well-being

By Kenyon Farrow and Mike Frick

One of the more memorable moments of resistance to the Trump administration's and GOP-controlled Congress' attempted plan to repeal the Affordable Care Act (ACA) took place on February 9, 2017, in Murfreesboro, Tennessee, at a town hall meeting organized by Republican Representative Diane Black. Jessi Bohon, one of Representative Black's constituents, rose and gave a powerful defense of the ACA and the idea of expanding Medicaid to all by reminding Black that healthcare is about uniting the sick and the healthy to lift up everyone in their moment of need. Bohon located her comment in her Christian faith, but it just as easily could have been spoken by a human-rights activist articulating the right of everyone to the highest attainable standard of health, or by a health economist explaining why insurance schemes must include both sick and healthy to stay solvent. Bohon's testimony was powerful because its logic transcended concerns about healthcare to raise bigger questions of what we owe to each other and what obligations our government owes to us.

The fight to save the ACA is fundamentally about preserving and expanding healthcare access. But the threat of ACA repeal is deeply entangled in debates about the role of government in biomedical research that advances healthcare and informs public health. Do people who see their government attempting to take away their access to healthcare have any reasonable expectation to benefit from government-funded research? Can people without assured healthcare be mobilized to defend medical research as being indispensable to health? Is it easy to imagine a constituent such as Jessi Bohon rising at a town hall meeting and articulating a similarly impassioned, clear-eyed defense of federal funding for research?

That the answer to these questions is likely 'no' reveals how advocacy for biomedical research is not well connected to broad-based social justice movements fighting for access to healthcare, housing, a clean environment, and safe working conditions. The result is a public that feels disconnected from science despite the innumerable ways

Do people who see their government attempting to take away their access to healthcare have any reasonable expectation to benefit from government-funded research? Can people without assured healthcare be mobilized to defend medical research as being indispensable to health?

good science improves their everyday life and underpins their good health. This disconnect has to end for research advocates to have any hope of defending scientific research under Trump's presidency.

Most health research advocacy is focused at the federal level, and on federal funding in particular. One of the interesting things about

the politics in Washington under the Trump administration and the GOP-controlled Congress is that advocates for research have taken solace in the feeling that biomedical research remains a rare area of bipartisan support. This theory has been put to the test by Trump's March 16th "skinny" budget proposal, which included a \$5.8 billion (20%) cut to the U.S. National Institutes of Health (NIH). Advocates will need to mobilize to hold the common ground that Democrats and Republicans have found on NIH funding in the past. But biomedical research

One of the very first actions the Trump administration took after the inauguration was to muzzle what information could come out of key agencies responsible for research and regulatory functions, including Health & Human Services, the Environmental Protection Agency, and the Department of Agriculture.

is more than NIH funding, and research advocates must be prepared to fight for more than money. More insidious threats to the research required to end the HIV, tuberculosis (TB), and hepatitis C virus (HCV) epidemics are likely to come from Trump administration policies that weaken publicly funded research or harm the ecosystem in which good science happens. Elements of this ecosystem include civil, political, economic, social, and cultural rights, such as academic freedom, the right to seek and impart information, freedom of movement, the university tenure system, and evidence-based review and regulation of research results.

Barely two months into Trump's presidency, all of these elements have come under attack. One of the very first actions the Trump administration took after the inauguration was to muzzle what information

could come out of key agencies responsible for research and regulatory functions, including Health & Human Services (HHS), the Environmental Protection Agency, and the Department of Agriculture. Specifically, these agencies were barred from releasing any public-facing documents, communicating with other public officials, or posting on their official social media channels, among other actions. The ability to communicate freely is central to science's public mission, and these orders, although described by some observers as standard for an incoming administration, have raised fears about whether the new administration will respect government scientists' right to seek and impart information. For example, since the Trump administration has demonstrated its intent to undermine the Affordable Care Act (and has an HHS Secretary in place who's also committed to its demise), any research or reports showing benefits of ACA components not favored by the administration or the GOP in Congress may be prevented from publication.

Trump has also taken aim at systems designed to support the impartial, outside review of research in the public interest. In his first address to Congress on February 28th, 2017, President Trump spoke to the need to cure rare diseases, but what he really presented was a policy agenda that will undermine the regulatory authority of the Food and Drug Administration (FDA) (see "The New War on Drugs" by Horn and Madoori in this issue of TAGline for how the FDA may suffer under Trump, page 17). During his address, Trump told the story of Megan Crowley, a 20-year-old woman who suffers from a rare disease and whose father started a biotech firm to help find a cure for her condition. The television cameras focused in on Crowley, who was in the audience and is wheelchair bound. This was a classic bait and switch technique; instead of announcing a plan to create new NIH research funds to study rare diseases, Trump used Crowley's illness to play on the sympathies of the American public to propose policies that will weaken public accountability over medical science by stripping the FDA of its regulatory power. In the long run, such a move could erode public trust in science if drugs that haven't met rigorous review standards harm patients.

President Trump's initial executive order banning immigrants from an arbitrary list of seven countries with large Muslim populations took aim at another right that is central to science: freedom of movement. The order prevented several researchers from entering

the U.S. to conduct work and attend conferences and other meetings. Importantly, the lawsuit that reversed the January 27th executive order, *University of Washington v. President Donald J. Trump*, cited both students and researchers who had been provided visas, but were not allowed entry into the country, as the issue that gave the states standing to file the lawsuit; the states successfully argued that the teaching and research missions of their public universities were harmed by the order. Undeterred by massive protests and this court decision that blocked the initial order, the Trump administration has issued a new executive order that, despite allowing current visa holders in six predominantly Muslim countries to enter or re-enter the U.S., will still affect the ability of scientists to travel to this country.

In biomedical research, clinical trials often have to occur in multiple countries, with research teams that include people from around the world. Freedom of movement is essential for enabling international collaboration in science and is a necessary ingredient for building a diverse scientific labor force. The labor rights of researchers have come under attack in other ways. There have been attempts to end the university tenure system in three states with GOP-controlled legislatures (Iowa, Missouri, and Wisconsin), with more likely to follow. If academic professors lose the protections of tenured positions, the potential for research to become even more politicized becomes much higher. They may be subject to the whims of the administration, board of directors, or student groups, and could be fired for studying things that are unpopular or controversial. Researchers may be dis-incentivized to study rare diseases that affect small numbers of people or stigmatized groups (people of color, sex workers, drug users, LGBT, etc.).

Current threats to the academic freedom afforded by the tenure system, tightening immigration to the U.S., and the undermining of federal agencies' ability to communicate with the public and use their authority to regulate industry and protect the public interest constitute just some of the looming threats to research under the GOP-led Congress. Activists who are concerned about the future of scientific research and its ability to help save lives and solve major global health pandemics will need to connect the fight for funding to other social justice issues, such as labor, immigration, and de-regulation of big business, to engage and mobilize the public. This will require forging new alliances, taking

the fight to new arenas of action, and developing a fuller appreciation for the multiple ways that research can come under attack.

Treatment Action Group is working on this front. We are working with our national and local efforts to fight the gutting of the ACA. We are still organizing to build local strategies to end HIV and HCV as epidemics nationwide. We will be actively opposing all efforts to strip the

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FDA of the authority to protect the public from drugs approved with shoddy evidence. We are also very strongly advocating for continued support for HIV, TB, and HCV funding at the Centers for Disease Control and Prevention, NIH, the President's Emergency Plan for AIDS Relief, and the U.S. Agency for International Development, and for those efforts to remain free of the politics of bigotry and ideology that are not supported by evidence.

We are doing this work firm in our belief that research policy is human rights policy, and with the understanding that policies that attack human rights also undermine research by weakening the social ecosystem in which it takes place.

WRANGLING AFFORDABLE DRUG PRICING **and** HCV ELIMINATION **under** **the** NEW WHITE HOUSE ADMINISTRATION

Trump's early tough talk on drug pricing is now a **pro-industry, anti-regulation** GOP dreamscape

By Bryn Gay

Unaffordable drug prices were a hot-button topic on the 2016 U.S. presidential campaign trail and remain a significant source of frustration among Democrats and Republicans in Congress. This common ground, backed by public opinion (see sidebar), can be leveraged to steer drug-pricing legislation and regulations toward truly bold initiatives that prioritize affordable treatment access.

Within his first two weeks in office, Trump met with pharmaceutical executives and regurgitated classic capitalist remedies for high drug pricing. Rather than consulting with patient groups or health policy specialists, the administration has primarily focused on meeting with the pharmaceutical industry. Trump's initial stance of empowering the U.S. government to step up its ability to negotiate drug prices, notably for Medicare, have since shifted toward fast-tracking drug approval and rolling back regulations.

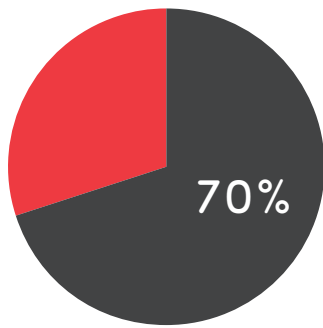
Trump's proposals fall short of and diverge from popular demands because they lack the ambition of approaches used in other countries to rein in drug cost expenditures: consolidation of purchasing power and other initiatives that would contribute to lower prices and earlier generic competition, such as shortened patent life; increased transparency in research and development (R&D) costs and pricing; and open-source research that discloses scientific findings, deprioritizes patent protection, and avoids monopolistic pricing. Executive action on drug pricing, however, appears unlikely.

Value-based drug-pricing regulations, such as those established by Germany's AMNOG law, are another model that could potentially guide U.S. drug pricing reform and reward scientific innovation without bankrupting payers or patients. AMNOG determines pricing decisions on the basis of independent assessment of a new drug's additional clinical benefits over existing drugs, relies on full transparency in all negotiation steps, and negotiates directly with pharmaceutical companies and key stakeholders, rather than involving government intermediaries. However, value-based pricing raises additional significant questions. Is a market-based economic system the best way to value drugs and human lives? Is the methodology of value-based tendering in itself transparent and does it reflect patients' concerns? Does it address true innovation, or could 'value' be potentially rigged by the pharmaceutical industry?

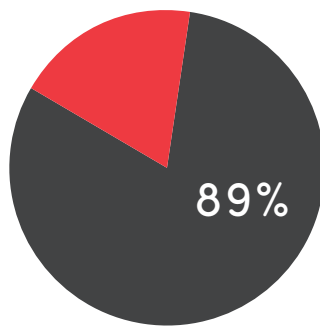
U.S. Congressional attempts to permit pharmacies and patients with prescriptions to import low-cost medicines from Canada and other countries have popular support. However, federal initiatives, such as the bipartisan Safe and Affordable Drugs from Canada Act, face pushback from PhRMA, the pharmaceutical industry's formidable lobbying group.

State houses are also taking up legislation to control drug costs. If these initiatives pass and prove to be effective, they could provide a template for other states and ultimately create a network of state-based resistance to high drug pricing. Maryland's bill would require companies to

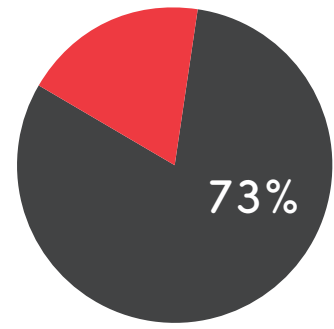
U.S. Surveys Say



Agree the government should do more to regulate drug prices so that they are affordable for everyone.¹



Think medicines developed with taxpayer funding should be made affordable for all.¹



Support giving the U.S. government the right to negotiate Medicare Part D prices.²

1. Lake Research Partners/ASO Communications. Effective messaging on prescription drug pricing. Survey Report. 2016 June.

2. Blendon RJ, et al. Health care in the 2016 election – a view through voters' polarized lenses. *N Engl J Med*. 2016 Oct 27;375(17):e37. doi:10.1056/NEJMs1606159.

disclose their R&D, manufacturing, and other costs, and would grant the state attorney general the authority to prosecute companies that price gouge 'essential generics' (for example, in the cases of Daraprim and Epipen). New York's Governor has introduced legislation supporting value-based determinations (including R&D costing) for high-priced specialty drugs, along with provisions targeting the anti-competitive practices of pharmacy benefit managers—insurance intermediaries that collect rebates from manufacturers while passing exorbitant out-of-pocket costs on to consumers.

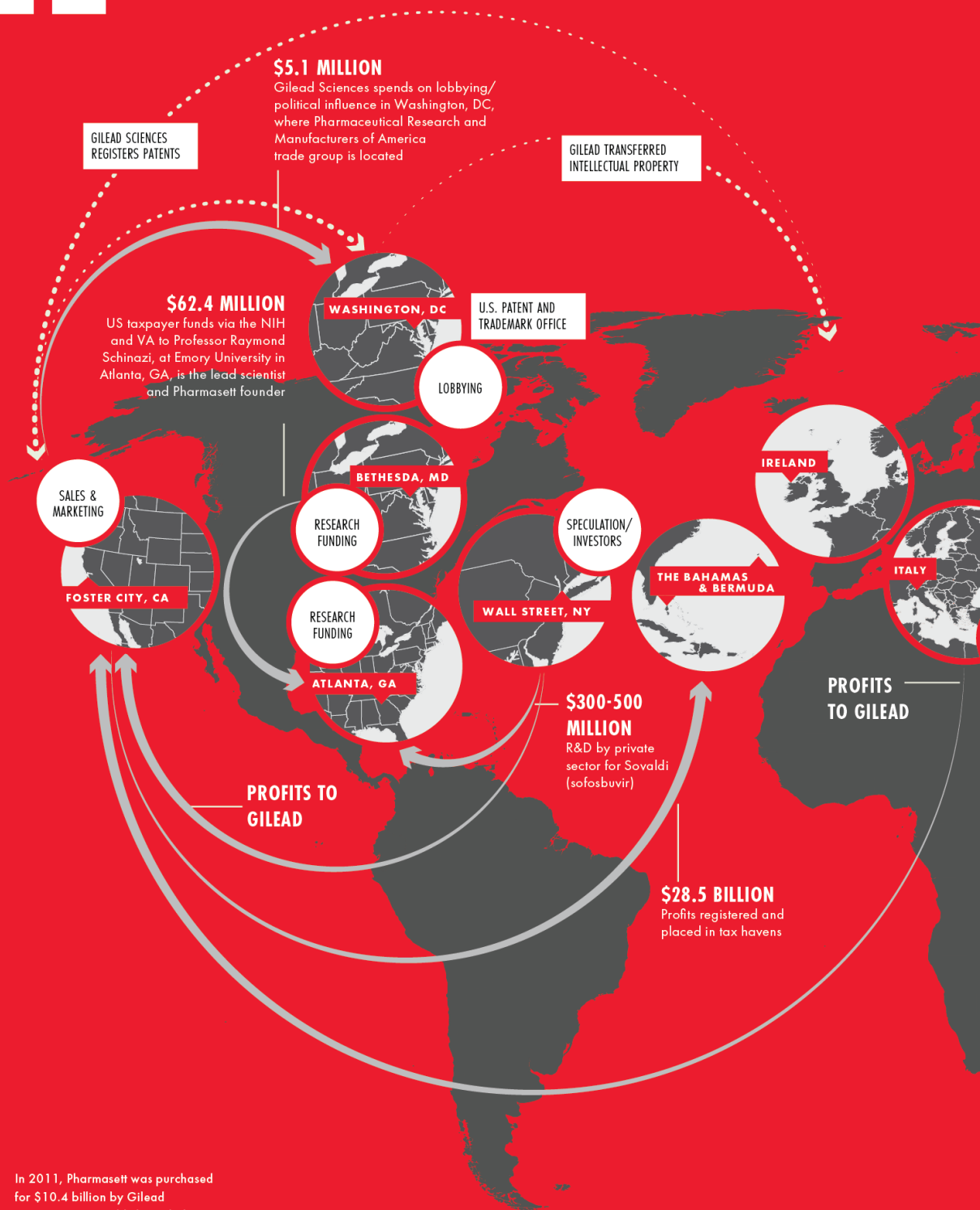
There may be opportunities at the international level that expand generic access to hepatitis C virus (HCV) treatments, including to the pangenotypic sofosbuvir/velpatasvir. Recent patent oppositions in India and Argentina have shown the strength of solidarity and economic cooperation in ensuring generic production of these medicines for countries in the global South. During the Trump years, we can anticipate the rise of fast-growing countries such as Brazil, Russia, India, China, and South Africa (BRICS) to finance drug development as well as to scale up their generic manufacturing and pooled procurement for medicines to get better pricing deals (for a review of other drug pricing strategies, see the Spring 2016 issue of *TAGline*).

Another notable strategy, put forth by Peter Bach of Memorial Sloan Kettering Cancer Center and Mark Trusheim of Massachusetts Institute of Technology, recommends that the U.S. government buy Gilead for \$156 billion to reduce spending on HCV drugs by one-third. Although certainly provocative, it does not consider actual R&D and production costs and is unsustainable for creating a more equitable drug development system.

The complexity of funding drug development socializes the costs through taxpayers funding the bulk of biomedical research and privatizes profits through legal loopholes such as corporate tax havens and monopolistic pricing through strict intellectual property ownership. The pharmaceutical industry misleads the public by arguing that it needs to set high benchmark prices to recoup R&D expenses. In the case of Gilead, R&D expenses were already recouped in the first quarter of 2014 when sofosbuvir hit the market. Data from the research firm GlobalData revealed that the industry spent the majority of revenue on sales, marketing, advertising, and lobbying. Meanwhile, Dr. Andrew Hill and colleagues at the University of Liverpool showed that the actual cost to produce a drug, with a 50% profit, is often significantly less. The supply chain of sofosbuvir illustrates the pharmaceutical industry charade that prioritizes shareholders and profits over patients' lives (see *Pharma Shell Game*, page 10-11).

U.S. commitments to eliminate HCV will require affordable treatment for all patients, particularly those in the baby boomer and younger injection-drug-user cohorts. Evidence-based health policy that integrates drug-pricing solutions will be vital for overcoming treatment barriers. TAG will use this lens to engage in drug-pricing debates under the new White House administration. Our domestic and international networks, technical expertise, commitment to treatment literacy and inclusion of patients in policy-making, and critical voice will contribute to advocacy that informs state and federal legislation and regulation, debunks pharmaceutical industry myths, and rallies the base for securing affordable, high-quality medicines.

THE PHARMA SHELL GAME



FINANCIAL FLOWS

FUNDING FOR DRUG DEVELOPMENT starts in Bethesda, MD, at the National Institutes of Health (NIH), which awards taxpayer funded grants to scientists in the U.S. A researcher employed by the Veterans Affairs (VA), also funded by taxpayers, used NIH grants to discover sofosbuvir, a direct-acting antiviral (DAA), and a breakthrough drug for hepatitis C. The lead scientist (again, a public employee) and partners formed a private corporation, Pharmasett, to continue development with private investment. Pharmasett was first registered as a corporation in Atlanta, GA (home of the lead scientist), then in the tax haven of Barbados, then Delaware, to avoid state corporate income tax, and finally Princeton, NJ, where their physical offices are now located.

In 2011, Pharmasett was purchased for \$10.4 billion by Gilead Sciences, Inc, a publicly traded company listed on the New York Stock Exchange (Wall Street) with global investors, including public pension funds. Gilead, based in Foster City, CA, funded the final required clinical trials.

The global system for funding drug development socializes the costs and privatizes the profits through a system of taxpayer-funded research, legal corporate tax havens, and intellectual property registrations to guarantee exclusive access to markets and to reduce corporate taxes, while selling identical formulations at wildly different prices.

FINANCIAL, INTELLECTUAL PROPERTY AND PRODUCT FLOWS



INTELLECTUAL PROPERTY FLOWS

GILEAD HOLDS THE MYRIAD OF PATENTS associated with sofosbuvir through the US Patent and Trademark Office in Washington DC, granting them exclusive rights to the US market. Gilead also registered a subsidiary (Gilead Biopharmaceutics Ireland Corporation) and its patents in Ireland. By registering the intellectual property (IP) on Sovaldi in Ireland, Gilead's subsidiaries need to pay an Irish company for

the right to manufacture the drug. Sales generated by the Irish company incur taxes at the Irish tax rate of 12.5% rather than the US tax rate of 35%. The favorable tax rate leads many multinational corporations to claim revenues there to avoid paying billions in taxes. Gilead had \$21.7 billion pre-tax profits and \$28.5 billion in untaxed offshore profits in 2015 and would owe \$9.7 billion to the U.S. if those sums were repatriated. Gilead has tax residency in the Bahamas and Ireland, using a "Double Irish" loophole, avoiding taxes in Ireland on profits mostly generated in the U.S.

HEPATITIS C CURE GLOBAL SUPPLY CHAIN

DRUG PRODUCTION ORIGINATES in China, where active pharmaceutical ingredients (APIs) are manufactured. APIs for brand name and generic drugs are synthesized in the same factories. The APIs are sent to India or Bangladesh to be combined into the medicines that patients take. Some medicines are sold as generics in low- and middle-income countries — as long as the "originator" pharmaceutical corporation (for example, Gilead is the "originator" of sofosbuvir) that holds the exclusive patents gives permission to these countries. Some medicines are sent to Western Europe — Italy in the case of Gilead's hepatitis C cures — to be packaged for sale in high-income countries like the U.S. and Canada.

SOVALDI: \$0.35/MONTH;
PACKAGED DRUG: (GENERIC)
\$41/DRUG FOR FULL COURSE



HEPATITIS C VIRUS PREVALENCE WORLDWIDE



TOTAL GENERIC COST
12-week course of Sovaldi:
\$62 INCLUDING 50% PROFIT MARGIN
12-week course of Harvoni:
\$96 INCLUDING 50% PROFIT MARGIN
12-week course of Eplclusa (cures all hepatitis C virus genotypes):
\$181-216

LIST PRICE OF SOVALDI
\$84,000
CURRENTLY AROUND \$50,000 IN THE U.S.

WHAT ABOUT THE PATIENTS?

The \$9.7 billion in owed taxes could, at \$62 per 12-week course, treat over 150 million people with hepatitis C in the world. We can only eliminate hepatitis C if national budgets can afford the treatments.

RESISTING **the** COMING AUSTERITY: MEDICAID **in the** CROSSHAIRS

Lingering Republican **threats** to the ACA and Medicaid do **no favors** for America's working **poor**

By Annette Gaudino

The 2016 election is in large part a story of the failure of existing health policy to adequately address a health crisis among the working class. The largest voter margins in favor of Trump comprise many people in poor health. This includes the opioid overdose epidemic currently occurring among predominantly white, suburban, and rural communities battered by deindustrialization and dimmed economic prospects. Affordable Care Act (ACA) repeal and replace

individual and \$33,000 for a family) is key. Roughly half of the 22 million Americans who receive health insurance coverage under the ACA are covered under Medicaid expansion.

Medicaid is currently a federal entitlement, meaning the U.S. government is committed to at least matching state funding to guarantee coverage for all Americans meeting eligibility requirements. Wealthy states with large tax bases, such as New York, split Medicaid costs 50/50 with the federal government. States with a lower GDP and smaller tax base are in effect subsidized by federal tax dollars. For example, approximately 70% of red-state Kentucky's costs are paid with federal funds.

In recent years, many states have moved to managed care Medicaid programs, with patient care being increasingly budgeted on a per-capita basis and delivered with per-capita costs in mind. In the best cases, this provides strong incentives towards preventive care, but managed care can also be used to limit access to expensive treatment options, as we've seen with restrictions to HCV curative treatments based on disease progression or sobriety.

The introduction of AHCA in early 2017 initiated the next great battle in U.S. healthcare reform. The bill, pulled from the floor of the House of Representatives after it became clear the Republican Party did not have the votes to pass the measure, maintained the most popular provisions of the ACA, while providing generous tax refunds to those who need it least and sought to end the entitlement to health care under Medicaid. Where the bill succeeded was in providing a clear view of the GOP's political goal: relieve the federal government of the burden to fund health care for the poor.

Where the American Health Care Act succeeded was in providing a clear view of the GOP's political goal: relieve the federal government of the burden to fund health care for the poor.

legislation, presently defeated with the fall of the American Health Care Act (AHCA) but still an ambition of the White House administration and Republican Congress, threaten to make a bad situation worse.

The federal government has a large role to play in funding the public health response to the ongoing opioid crisis and its sequelae, including hepatitis C virus (HCV) and HIV. The expansion of Medicaid under the ACA to cover individuals living at 138% of the federal poverty level (approximately \$16,000 for an

If AHCA had passed, the proposed per-capita caps would have cut \$880 billion in federal funding for all state Medicaid programs and resulted in 14 million people losing Medicaid coverage by 2026. Per-capita caps or block grants would have also left Medicaid programs with even fewer financial resources to cover exorbitantly priced curative hepatitis C treatments and comprehensive HIV care.

For the low-income individuals and families who would have been thrown into the for-profit insurance marketplace, the AHCA proposed replacing income-based premiums and subsidies with fixed age-based refundable tax credits, regardless of the actual cost of insurance where they live, which varies significantly across states. Additionally, AHCA would have allowed insurers to charge older enrollees up to five times what they charge younger ones (up from 3:1 under the ACA), effectively wiping out the value of the slightly larger tax credit for those 60 years of age and older. Those that managed to remain on Medicaid were at risk of losing essential benefits coverage, including mental health and substance use treatment—a particularly short-sighted change given the opioid epidemic.

As was evident with AHCA, however, the road to replacing the ACA is rocky for GOP leadership. The House bill effectively alienated all stakeholders: voters would have seen their subsidies to purchase insurance cut significantly, hospitals and other providers would have faced reduced funding and more unreimbursed care, private insurers would have been left with sicker enrollees, and Congressional members ideologically committed to free market solutions would have been left wanting. The split between Republicans in Congress and in State Houses remains particularly difficult to bridge—the former don't have to balance budgets under the additional public health burden of hundreds of thousands of potentially uninsured residents.

The big question that remains, particularly now that ACA remains the law of the land, is whether there is a way to repair the features of the original legislation signed by President Obama in 2010 that provide no benefit to the working poor and middle class. For example, under current formulas, ACA subsidies max out for annual incomes above \$48,000 for individuals and \$97,000 for a family of four. The resentment among those who are too well off to qualify for expanded Medicaid, but too strapped to feel secure under high-deductible, unsubsidized plans, contributed to the election results. Will both major parties once again miss the opportunity to address the needs of working people?

Even in the darkest political times, persistent advocacy and activism has resulted in concrete, permanent wins for public health. The Ryan White CARE Act and PEPFAR were both enacted under Republican administrations that were otherwise hostile to evidence-based public health approaches to the HIV pandemic. Likewise, AHCA faltered under GOP control of the White House and Congress. There is no reason to think significant movement toward ending the HIV and HCV epidemics isn't achievable under Trump.

The resentment among those who are too well off to qualify for expanded Medicaid, but too strapped to feel secure under high-deductible, unsubsidized plans, contributed to the election results. Will both major parties once again miss the opportunity to address the needs of working people?

We must engage at all levels of government, including state and local, to amplify the political cost of not further expanding Medicaid, link Medicaid and the opioid crisis, and build coalitions to fight back, particularly alongside the harm reduction movement and those fighting to dismantle mass incarceration and white supremacy.

A broad, intersectional social justice movement has been ignited as a result of the 2016 election. It is led by those who never paused their struggle during the Obama years—the movements for black lives, indigenous rights, and immigrant rights. The huge influx of new people into existing activist movements, and the formation of new direct action groups such as Rise and Resist in New York City, and countless others nationwide, creates a unique opportunity to share knowledge and skills across generations, follow and foster new leaders, and bring public health issues to new audiences and spaces. As we have just witnessed, when we fight, we win.

BREAKING DOWN WALLS **in** TRUMP'S ANTI-IMMIGRANT RHETORIC

How the Trump administration's **anti-immigrant stance** threatens **human rights**, **public health**, and the **lives** of people living with TB

By Erica Lessem and Suraj Madoori

Perhaps the most recognizable symbol of the current presidential administration and the campaign that led Donald Trump to the White House is *the wall*. In 2015, then-candidate Trump first announced his intention to build a wall between the United States and Mexico. Now his administration is implementing its even broader anti-immigrant agenda, with grave consequences for human rights and public health.

Stephen Bannon's closeness to the White House and his association with the controversial travel bans is of critical concern to the TB advocacy community.

After activists' hard-fought victories to remove a pernicious travel ban against people with HIV and to stop the quarantining of Ebola response workers, the United States is once again on a dangerous path of implementing stigmatizing immigration and migration policies that threaten to undermine public health and well-being. In particular, those affected by tuberculosis (TB) are at major risk of poor health outcomes and discrimination because TB is an airborne infectious disease and because existing policies and attitudes relating to immigration and TB are already heavily biased against people with TB.

The notoriously alt-right Breitbart Media, formerly helmed by White House chief strategist Stephen Bannon, is already positioning TB as a public health and economic

threat to fuel nationalist anti-immigrant rhetoric. Bannon's closeness to the White House and his association with the controversial travel bans is of critical concern to the TB advocacy community. Despite TB being a relatively rare disease in the United States that receives little attention in the mainstream media, Breitbart has propagated stigmatizing and sensational coverage of TB among foreign-born individuals in the United States, with more than 25 of those stories posted in the six-month period spanning the final months of the election cycle and the presidential transition.

In years past, these stories could have been dismissed simply as the baseless rhetoric of nationalist fringe groups. But with Bannon's newfound influence on policy as chief strategist to the President, the impact of these stories riding the wave of "alternative facts" must be taken as serious threats to the health and safety of immigrants. Such prejudiced attitudes severely compromise our ability to engage vulnerable populations in prevention work.

"TB should never be used as a pretext to stigmatize migrants or justify discriminatory policies," clarifies Peter Davidson, president of the National Tuberculosis Controllers Association (NTCA). "People migrating to the U.S., including and especially refugees, are not arriving to the U.S. sick or infectious and do not pose a risk to the communities in which they settle. TB is a major threat in the U.S., but one that can be best addressed through a robust public health response, not through immigration controls."

However, people migrating to the United States have long been subject to cumbersome and often archaic TB screening and control policies (see table). TB is still a quarantinable disease according to U.S. law, a fact that can easily be exploited to deny people affected by TB to stay in the United States.

Archaic TB-related immigration policies and practices and how they should be updated

Existing policy/practice	Recommended change	Rationale
People seeking residency in the United States are required to undergo testing for TB infection. However, approved clinicians almost exclusively use tuberculin skin test (TST)	Provide low-cost interferon gamma release assays (IGRAs)	IGRAs are the standard of care for testing for TB infection in people who have received BCG vaccination. The majority of immigrants with TB come from countries that routinely use BCG vaccination, which can cause a false-positive result when the traditional TST is used
People seeking residency in the United States are required to, when indicated, take therapy for TB infection. However, approved clinicians almost exclusively prescribe nine months of daily isoniazid (9H) as therapy	Provide low-cost short-course therapy—12 once-weekly doses of isoniazid and rifapentine (3HP)—with proper consent for (rather than mandated) therapy	3HP allows higher rates of adherence and treatment completion than the grueling 9H
HIV-positive immigrants undergoing green card processing abroad must undergo lengthy, invasive sputum-based TB testing that requires several appointments and weeks or months of laboratory visits	Test HIV-positive immigrants with GeneXpert MTB/RIF, for which results are available in just two hours	Immigrants who must leave the United States for their visa processing get stuck in a potentially unsafe country, separated from their families, with limited medication for 90 days or more. GeneXpert MTB/RIF is the most rapid, sensitive, and specific test for TB in people with HIV
TB is a quarantinable disease	Prioritize accurate testing to determine whether people with TB are currently infectious, and if so, give them effective treatment with accompanying counseling and education, and practice infection control measures	Active TB is no longer transmissible after ≤ 2 weeks of effective treatment, and infection control is highly effective at preventing transmission. In contrast, quarantine has the potential for grave human rights abuses that are not only unjust but unnecessary from a public health perspective

Indeed, the evidence indicates that the most effective and economical path toward eliminating TB as a public health threat in the United States would be an aggressive, two-pronged approach that mobilizes public health resources and deploys the latest scientific advances. First, we must empower TB controllers with more resources to focus on TB prevention—identifying those individuals most at risk for developing active TB among the millions in the United States with latent TB infection and providing them with safe, effective, and easy treatment. The Division of Tuberculosis Elimination (DTBE) of the U.S. Centers for Disease Control and Prevention and the NTCA have created a robust prevention plan, but though the plan costs only an estimated \$40 million per year, which would be rapidly offset by projected savings from cases averted, the sorely underfunded DTBE does not currently have resources to support this work. Second, increased U.S. leadership on and investment in global health security for TB would help reduce the global burden of disease and the resulting impact of TB on the United States. Modeling by Schwartzman and colleagues showed that investing in other countries' infrastructure to respond to TB would ultimately save costs in the United States.

The implications of anti-immigrant policies on both science and health care are frightening. Over half the biomedical researchers in the United States are foreign born; travel bans and other policies that deter migration

to the United States will be a huge blow to science. On the delivery side, stigmatizing noncitizens, isolating them through fear, and removing access to social services not only violates individual rights but also creates a breeding ground for public health threats that could actually cost taxpayers much more than providing services up front would. The continued unchecked proliferation of anti-immigrant messaging could allow for the use of discriminatory immigration policy as a "public health" strategy, justifying the shirking of U.S. commitments to support global TB elimination and other diseases.

One of the paradoxes of TB is that the body walls off the bacteria to sequester the infection, but this creates conditions in which TB can multiply, damage tissues, and spread. Now consider the political and social conditions: the Trump administration's isolationist immigration and foreign policies also foster the conditions for TB to flourish, transmission rates to worsen, and stigma to thrive. We must not mimic the body's perverse attempt at disease control by creating political or actual walls that will cut people off from needed services. Leading with science and strengthening public health defeated nonsensical travel bans for people with HIV and halted the knee-jerk policy response to the Ebola crisis; these will be the same strategies needed to protect the rights and fight the stigmatization of communities vulnerable to TB.

To fight the so-called alternative facts that sensationalize TB among the foreign-born in the United States, it is more important than ever to highlight the actual facts about TB:

- TB is preventable and curable;
- TB is rapidly rendered noninfectious upon the start of appropriate therapy;
- Numerous personal and environmental controls (ventilation, UV light or sunlight, the wearing of respirators) are highly effective at preventing TB transmission;
- Recent transmissions of TB in the United States are mostly connected with U.S.-born, rather than foreign-born, individuals;
- Refugees make up just 4.3% of the total number of people diagnosed with TB and only 6.4% of the foreign-born people diagnosed with TB;
- Foreign-born individuals are most likely to be diagnosed with TB over 10 years after their arrival in the United States.

Source: Centers for Disease Control and Prevention. Reported tuberculosis in the United States (tables 22, 36, 37). Atlanta: 2016. Available from: https://www.cdc.gov/tb/statistics/reports/2015/pdfs/2015_surveillance_report_fullreport.pdf

THE NEW WAR ON DRUGS

The 21st Century Cures Act and a right-wing war on regulations are **direct threats** to FDA evidentiary requirements for drugs, biologics, and devices

By Tim Horn and Suraj Madoori

What could possibly be wrong with legislation beamishly called the 21st Century Cures Act? Signed by President Obama during his final days in office, the bill's appeal and broad bipartisan support are understandable. It promises significant funding for the National Institutes of Health, genomics and cancer research, and opioid dependency prevention and treatment. However, it also contains some deeply troubling provisions in the name of developing and delivering novel therapies: it relaxes standards of evidence used by the U.S. Food and Drug Administration (FDA) to determine that drugs and devices are safe and effective for approval.

Much of the Cures Act language focusing on approval processes will be up to the FDA to translate into guidance and regulations. But while this legislation came into being under the evidence- and public-health-minded Obama administration, the still-unconfirmed FDA commissioner in the Trump administration—already committing itself to undo the “administrative state” across all branches of government—will be overseeing much of this work.

In a January 31 meeting with pharmaceutical executives, Trump said that regulations are impediments to drug development and fair pricing, adding “we’re going to be cutting regulations at a level that nobody’s ever seen before.” In March, Trump tapped Dr. Scott Gottlieb to serve as FDA commissioner. While arguably a more suitable pick than other rumored contenders, Gottlieb—a venture capitalist, senior fellow of the conservative American Enterprise Institute, and former FDA deputy commissioner under George W. Bush—is a longtime critic of the FDA’s current stringency and marketing requirements, arguing that they stifle competition, and has robust ties to the drug industry.

TAG is among several organizations concerned not only that the Cures Act will allow the new FDA commissioner to begin dismantling regulations widely considered critical to evidence-based medicine but that it is the first of several possible pieces of legislation aiming to curtail vital

FDA stringency requirements that protect and advance public health both within and outside the United States. Key to advocacy resistance will be challenging the false narrative that the FDA’s drug and device approval processes are a primary obstacle keeping affordable treatments and cures out of the hands of the people who need them most.

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The ultimate irony is that the FDA’s authority to ensure drug safety and efficacy was born of legislation seeking to rein in drug pricing. Beginning in 1959, Senator Estes Kefauver’s (D-TN) Antitrust and Monopoly Subcommittee held hearings on the pharmaceutical industry’s dubious marketing practices, including the aggressive promotion of drugs without safety warnings or proof of efficacy. In the wake of the 1962 thalidomide tragedy—thousands of infants worldwide were born with malformed limbs to women who were prescribed the drug as a mild tranquilizer during pregnancy, in the absence of any supporting safety and efficacy data—Congress ultimately (and unanimously) passed legislation strengthening the Federal Food, Drug, and Cosmetic Act, introduced earlier in the year by Kefauver and Rep. Oren Harris (D-AR).

Chopped from the Kefauver Harris Drug Amendments, due in part to pharmaceutical industry objections, was

language supporting Kefauver's broader desire to end drug monopolies and egregious pricing. He pushed for a compulsory licensing provision whereby exclusivity on new drugs proven to be clinically advantageous would be limited to three years (vs. 17 years under existing law), after which the manufacturer would be required to share its patents with competitors in exchange for royalty payments.

What ended up being signed into law by President John F. Kennedy in October 1962 was still profound: fundamental protections requiring manufacturers to provide supportive data from adequate and well-controlled studies as a condition of approval, along with FDA empowerment to ensure proper clinical trial conduct, drug production controls, and veracity in marketing. Not only does such rigorous premarket development provide a strong foundation of safety to protect healthcare consumers, it provides the efficacy outcomes required to make critical risk-benefit decisions in clinical practice.

Political criticism of the FDA begins with Kefauver Harris, which unquestionably added both cost and length to the drug development and approval processes. The extent to which this heightened stringency has prevented safe and effective treatments from reaching the market, particularly for rare and neglected diseases, continues to be hotly debated, along with claims that it drives up drug prices.

Claims of regulatory overreach and financial strangulation of biomedical ingenuity omit evidence showing that: 1) manufacturers probably spend far less on drug development and FDA-required trials than the numbers touted by industry supporters; 2) healthcare systems increasingly depend on rigorous data, made available as close to product launch as possible, to make cost-effectiveness determinations; 3) more, not less, oversight is required to minimize residual uncertainty following approval; and 4) the FDA has a great deal of flexibility to speed the availability of essential new medicines.

Critics have long argued that the FDA review and approval process can best be summed-up as a "gray zone"—too fast for some and too slow for others. But the FDA has both more than doubled the number of New Active Substances (NASs) approved annually since 2005 and reduced its review and approval time of New Drug Applications (NDAs) to a median of 10.1 months (compared with 20.8 months in 1993), effectively leading its European counterpart, the European Medicines Agency. Review times could potentially be reduced further with expansion of the FDA workforce—a

feature of the Cures Act—but this runs counter to a Trump executive order instituting a federal hiring freeze.

A common thread in both the Cures Act and the mounting political rhetoric of FDA overreach is the potential for phase II studies, along with the use of "real-world" patient testimony and unvalidated surrogate markers, to be suitable stand-ins for phase III trial approval requirements. Though not yet peer reviewed, a January 2017 analysis by the FDA should temper these arguments. The analysis included 22 drugs, vaccines, and medical devices since 1999 that yielded promising phase II results that later were not confirmed in phase III trials. There were 14 cases of unconfirmed efficacy, one case of safety concerns documented in phase III but not phase II trials, and seven cases of important safety and efficacy concerns arising in phase III studies. The phase III failures occurred even when the phase II studies were relatively large and even when the product was already approved for another indication (6/22 drugs).

No less disingenuous are claims that the FDA is overly rigid in its approval processes. Due in large part to the influence of AIDS activism in the early 1990s, the FDA has demonstrated itself amenable to novel pathways allowing expedited access to unique new treatments without compromising the science required to confirm safety and efficacy. Many such processes also incentivize industry investments in research and development, particularly for rare and neglected diseases and diseases with limited treatment options.

In the early 1990s, the FDA formalized mechanisms for compassionate-use and parallel-track programs, providing patients with access to experimental drugs that have cleared phase II and are undergoing investigation in phase III trials. There is also the accelerated approval pathway, which permits lifesaving therapies to become commercially available based on validated surrogate marker data, intermediate clinical endpoints, and company commitments to provide gold-standard clinical trial results. A number of priority review designations are also possible—qualified infectious disease product (QIDP), fast track, and breakthrough therapy—and can reduce NDA review times to six months. Other incentives include additional years of marketing exclusivity awarded to drugs that receive QIDP or orphan drug designations.

With the Cures Act now codified into law, TAG and its advocacy partners will be keeping close tabs on draft guidance and other plans to operationalize one of the most significant legislative

rollbacks of FDA authority. No less essential will be coalition efforts pressing for a Commissioner open to fresh regulatory thinking, while maintaining a course that unapologetically values evidence-based medicine over the profit-seeking interests of one of the wealthiest industries in the world.

FDA stringency is not just a function of regulations. Funding made available under the Prescription Drug User Fee Act (PDUFA) is a critical factor. The PDUFA allows the FDA to collect fees directly from manufacturers to expand and support the agency's drug approval processes. Set to expire in September 2017, the law is now up for its sixth reauthorization, which would extend its fiscal security through 2022. PDUFA and the Generic Drug User Fee Amendment (GDUFA) currently supplement the FDA budget by \$1 billion. Trump's "skinny" budget sent to Congress in March proposes doubling this, though this is likely to be met with fierce resistance by the pharmaceutical industry and may result in costs being shifted to consumers in the form of higher launch prices for new drugs.

FDA reauthorization commitments include faster review times for drugs and biologics (e.g., 90% of approval applications to be reviewed in 10 months or less) and increased attention to surrogate-marker and real-world-evidence considerations. But it is worrying that the reauthorization process is occurring in the wake of the Cures Act and is being taken up by a Congress bent on scaling back regulations of all stripes. The potential for legislative add-ons designed to cripple the FDA or prevent the PDUFA reauthorization from passing, which would be all but fatal to the agency, is considerable.

The Cures Act may also be the catalyst needed by deregulation hawks to usher in additional problematic legislation. The Reciprocity to Ensure Streamlined Use of Lifesaving Treatment Act of 2015 (S. 2388), which may be revived under its lead cosponsor Senator Ted Cruz (R-TX), would limit the FDA to 30 days for review of requests from manufacturers of drugs or devices that have been approved by stringent regulatory agencies in other countries. Most concerning isn't that it would most likely benefit only a small number of U.S. patients receiving treatment for rare diseases, according to a February 2017 *British Medical Journal* paper, but that the bill empowers Congress to override the agency if approval is denied. There is a sizeable chance that the possible benefits of this legislation will be offset by its possible harms.

There is also the Lowering Drug Costs Through Competition Act (H.R. 749), introduced by Kurt Schrader (D-OR) and Gus Bilirakis (R-FL). The bill aims to incentivize generics manufacturers to either shore up U.S. drug shortages or compete with other generics manufacturers engaged in monopolistic drug pricing. In addition to speeding FDA review, the bill would award manufacturers introducing needed generics with priority review vouchers (PRVs). PRVs are intended to motivate companies to invest in the research and development necessary to bring drugs for neglected tropical and rare pediatric diseases to market; vouchers can be applied to future drugs being developed by the manufacturer or sold to other manufacturers for millions of dollars.

The FDA has both more than doubled the number of new active substances approved annually since 2005 and reduced its review and approval time.

Unfortunately, PRV program loopholes have already been exploited. Marathon Pharma's Emflaza (for Duchenne muscular dystrophy), Novartis's Coartem (for malaria), and Knight Therapeutics's Impavido (for leishmaniasis) all received PRVs following U.S. approval, despite the fact that they were originally brought to market through other public or private ventures and are available generically in other countries for a fraction of the U.S. price. Before it expands the PRV program, Congress must fix loopholes to ensure that the United States is rewarding ingenuity, not opportunism.

The paradox of the Trump administration's war on regulations, already catalyzed by the Cures Act, is that more targeted regulation is what's needed to solve a range of treatment access issues, from developing and approving novel therapies for neglected or rare diseases to addressing egregious drug pricing. As president-elect, Trump emphatically stated that the pharmaceutical industry is "getting away with murder." A war against regulations intended to hold manufacturers accountable, protect drug safety and the health of the American public, and advance evidence-based and cost-effective care is questionable at best—and dangerous at worst.

RECENT PUBLICATION & WEBSITE UPDATES

TAG's HCV Project maintains a set of fact sheets in English & en Español, including a new fact sheet focusing on HCV genotypes. Available at: <http://www.treatmentactiongroup.org/hcv/factsheets>.

The Michael Palm Basic Science, Vaccines, and Cure Project blog remains active and recently featured a comprehensive review of cure research data reported at the annual Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle. Available from: http://tagbasicscienceproject.typepad.com/tags_basic_science_vaccin/2017/03/capsules-from-croi-2017.html

Nearly half of people with TB—over 4 million per year—are undiagnosed, leaving them ill and at risk of death and with the potential to transmit disease to others. Closing this massive gap will require much better use of the current diagnostic methods, as well as research into faster, simpler, more accurate, and less expensive options. *An Activist's Guide to Tuberculosis Diagnostic Tools* provides an overview of the different tests and strategies for detecting TB, with recommendations for how activists and clinicians can contribute to improved TB diagnosis. Available from: <http://www.treatmentactiongroup.org/tb/diagnostic-tools>

The success of recent local and state initiatives to end HIV as an epidemic will hinge on community mobilization efforts to inspire engagement in care and services, along with meaningful involvement at all levels of advocacy and policy, according to *Community Mobilization: An Assessment of Mechanisms and Barriers at Community-Based and AIDS Service Organizations in Nine U.S. Metropolitan Areas*, a new report by TAG's HIV Project (TAG). Available from: <http://www.treatmentactiongroup.org/hiv/community-mobilization>

SUPPORT TAG

As TAG works to advance its campaigns to end the HIV, TB, and HCV epidemics while defending against new and unprecedented political challenges, your support is needed now more than ever before. Donate online: www.treatmentactiongroup.org/donate.

Does your company have a matching gifts program? If so, you can double or even triple your donation. Just complete the program's matching gift form and send it in with your donation to TAG.

When you shop on Amazon, enter the site at smile.amazon.com. Choose TAG Treatment Action Group as your designated charity, and 0.5 percent of the price of your eligible purchase will benefit TAG.

ABOUT TAG

Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus.

TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information.

We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions.

TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

TAG

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Suraj Madoori

ADMINISTRATOR

Joseph McConnell

TB/HIV SENIOR PROJECT OFFICER

Lindsay McKenna

FINANCE MANAGER

David Zwany

Treatment Action Group

90 Broad St, Suite 2503
New York, NY 10004
Tel 212.253.7922
Fax 212.253.7923
tag@treatmentactiongroup.org
www.treatmentactiongroup.org

TAG is a nonprofit, tax-exempt 501(c)(3) organization. EIN 13-3624785