Legal Lens

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, executive director, supervised contributions by Caela M. Camazine (J.D./M.P.H. anticipated 2024) and Mary Schnellmann (J.D. anticipated 2024).

DRAFT BILL WOULD BAN CDC, NIH FROM FUNDING LAB RESEARCH IN CHINA

Jocelyn Kaiser, Science, July 12, 2022. https://www.science.org/content/article/draft-bill-would-ban-cdc-nih-funding-lab-research-china

Following the speculation that the Wuhan Institute of Virology (WIV) released the coronavirus that started the current pandemic, as well as objections to other potentially risky biomedical experiments, Congress is looking to bar the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) from funding research laboratories in China, Russia, or any country the U.S. government has designated a foreign adversary. If signed into law, the measure could cut off millions of dollars of U.S. funds flowing to collaborative research projects in several areas. These include HIV/AIDS, cancer, mental health, and flu surveillance. Supporters say that "taxpayers shouldn't be forced to fund … cruel, wasteful, and dangerous animal experiments in hostile countries … where there's no real transparency and accountability." Though, the proposed measure does not mention animal studies. Some scientific organizations are concerned by the proposal's expansive scope, calling it extreme, and say there may be better ways than blocking all NIH funding to foreign countries. International collaboration is essential for scientists to understand disease threats and protect public health. The ban's potential impact isn't clear because WIV is largely funded by the Chinese government, and researchers there have not received U.S. funding since July 2021. But the NIH supports other research in China, with grants totaling $5.6 million this year, making some projects headed by Chinese investigators vulnerable. The ban would need to survive in the Senate to become law.

HOUSE PASSES BILL TO EXPAND HEALTH BENEFITS FOR BURN PIT EXPOSURE

Stephanie Lai and John Ismay, The New York Times, July 13, 2022. https://www.nytimes.com/2022/07/13/us/politics/burn-pits-veterans-care.html?searchResultPosition=2

The House of Representatives passed a bill that is one of the largest expansions of veterans' benefits. The bill would put forth a projected $285 billion over the next decade to streamline veterans' access and cover their treatment for burn pit exposure. This legislation would presume that any American service member stationed in a combat zone for the last 32 years could have been exposed to toxic substances by being near trash burn pits on U.S. military

bases. Open-air burn pits were standard on American military bases in Afghanistan and Iraq. When existing sanitation services were destroyed by combat, soldiers would use jet fuel to burn all unneeded items. These fires, as well as contaminated drinking water on bases in the United States, have been estimated to have exposed 3.5 million veterans to toxic substances, leading to many conditions, respiratory illnesses, and cancers. The legislation would modify the definition of "toxic exposure" to determine veterans' eligibility for medical care, nursing home care, and mental health services. It would require the Department of Veterans Affairs to recognize dozens of cancers and respiratory illnesses linked to toxic exposure. It would also order the department to include such exposure in patient questionnaires to reach patients unaware that their conditions could be linked to these burn pits. Opponents of the legislation objected to its cost, complaining that due to the expensive nature of the bill, there would be cuts to other programs to compensate. However, they have cut a deal to phase in the benefits over a series of years, meaning that those who served earliest would be eligible for care in 2024.

THE NEW 988 MENTAL HEALTH HOTLINE IS LIVE. HERE'S WHAT TO KNOW

Rhitu Chatterjee, NPR, July 16, 2022
https://www.npr.org/sections/health-shots/2022/07/15/1111316589/988-suicide-hotline-number

Starting July 16, individuals can call or text the National Suicide Prevention Lifeline's 988 phone number for crisis assistance as an alternative to calling 911. The purpose of the lifeline is to connect people in crisis with appropriate mental health services, rather than deploying 911 to the scene of each call. Mental health crises are unique among medical emergencies because they overwhelmingly result in a law enforcement response, which is not always appropriate. The 988 initiative was signed into law in 2020 by then-President Trump and is a joint initiative by the Department of Health and Human Services (HHS), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Department of Veterans Affairs. The lifeline will be funded as a joint federal-state partnership, with the Biden administration contributing more than $400 million to help bolster crisis call centers, many of which have closed due to lack of funding or labor. Additionally, the legislation permits the addition of a small fee on cellphone bills as a permanent source of funding for 988 and associated mental health services. The lifeline comes as the United States is grappling with an unprecedented rise in suicide rates. Currently, the rate of suicide is highest in middle-aged White men. As of 2020, suicide is a leading cause of death for people ages 10 – 14 and 25 – 34.

CONSERVATIVE BLOCS UNLEASH LITIGATION TO CURB PUBLIC HEALTH POWERS

Lauren Weber and Anna Marie Barry-Jester, Kaiser Health News, July 18, 2022. https://khn.org/news/article/conservative-blocs-litigation-curb-public-health-powers/

Conservative and libertarian think tanks, Republican state attorneys general, and religious liberty groups have been attacking

public health mandates and the government agencies charged with protecting community health, rolling back public health authority at the local, state, and federal levels. Through lawsuits or simply wielding the threat of legal action, these loosely affiliated groups have targeted individual counties and states, and in some cases, set a broader legal precedent. The Wisconsin Institute for Law & Liberty has filed a flurry of COVID-related litigation. It won a Supreme Court case stripping local health departments of the power to close schools to stem the spread of disease. The Missouri state attorney general levied dozens of cases against school mask mandates and set up an email address where parents could report schools that imposed such mandates. In California, religious groups challenged a health order that limited the size of secular and nonsecular in-home gatherings and drew in religious liberty groups that gained traction after Amy Coney Barrett was confirmed as a U.S. Supreme Court justice. By no means have the blocs won all their challenges. The Supreme Court declined to hear a lawsuit on behalf of employees challenging a vaccine mandate for health care workers in New York that provides no exemption for religious beliefs. For now, the legal principles that for nearly 120 years have allowed governments to require vaccinations in schools and other settings with only limited exemptions remain intact. However, all of these lawsuits have chipped away at the power of federal and state authorities to mandate COVID vaccines for employees or a governor's ability to declare emergencies. Public health experts say these groups have altered the government response to this pandemic and have endangered the fundamental tools public health workers have used for decades.

BGOV BILL SUMMARY: H.R. 8373, CONTRACEPTION ACCESS

Christina Banoub, Bloomberg Law, July 19, 2022. https://news.bloomberglaw.com/health-law-and-business/bgov-bill-summary-h-r-8373-contraception-access

In response to the Supreme Court's decision to overturn *Roe v. Wade* in *Dobbs v. Jackson Women's Health Organization*, the U.S. House of Representatives created House Resolution 8373, which provides a statutory right to obtain contraception and to engage in the use thereof. The legislation also protects a health care practitioner's right to provide and counsel on contraception; empowers the Justice Department, individuals, and entities to take civil action against parties carrying out state or local law in violation of the measure; and prohibits (1) limitations on access to contraception and (2) restrictions on facilities and practitioners providing contraception. If passed, state laws are preempted by H.R. 8373, and federal district courts have jurisdiction over such disputes and, as such, would be instructed to "liberally construe" the bill's provisions. Under H.R. 8373, states' and officials' immunity from 10th Amendment suits is removed, as are similar protections for such parties under the 11th Amendment. The bill comes at a time when twelve states have laws allowing practitioners to refuse to provide contraception, and several other states have attempted to block access to contraceptives. When introduced by Rep. Kathy Manning (D-NC 06) on July 14, the bill had 55 Democratic cosponsors. The measure is further supported by the National Women's Law Center, NARAL Pro-Choice America, Planned Parenthood Federation of America, and the National Family Planning and Reproductive Health Association.

BGOV BILL SUMMARY: H.R. 4040, MEDICARE TELEHEALTH AUTHORITIES (1)

Christina Banoub, Bloomberg Law, July 26, 2022. https://news.bloomberglaw.com/coronavirus/bgov-bill-summary-h-r-4040-medicare-telehealth-authorities

Medicare could continue to offer telehealth services through Dec. 31, 2024, under a modified version of House Resolution 4040. Originally authorized during the COVID-19 public health emergency, telehealth service use is growing among elderly and rural populations. The bill's sponsor, Liz Cheney (R-WY At-large District), is optimistic that this legislation will "permanently cut burdensome red tape" and allow Medicare to adapt to "ever-changing innovation in medical technology." H.R. 4040 aims to reduce the Medicaid Improvement Fund trust by nearly two million dollars and will allow: (1) Medicare patients to receive authorized telehealth services regardless of location; (2) federally qualified health centers (FQHCs) and rural clinics to continue providing telehealth services; (3) telehealth for mental health services, including audio-only services for office visits and office psychiatry services; (4) hospice physicians and nurse practitioners to use telehealth services in emergency situations; and (5) occupational and physical therapists, as well as speech language pathologists and audiologists, to provide telehealth services. Ultimately, supporters of the legislation, including the American Medical Association and the Connected Health Initiative seek to address disparities in health care that persist between urban and rural communities, as well as in elderly populations.

WHAT'S IN JOE MANCHIN AND CHUCK SCHUMER'S RECONCILIATION DEAL ON CLIMATE, HEALTH AND TAX POLICY?

Amara Omeokwe and Siobhan Hughes, The Wall Street Journal, August 5, 2022. https://www.wsj.com/articles/whats-in-joe-manchin-and-chuck-schumers-reconciliation-deal-on-climate-health-and-tax-policy-11658973323?mod=Searchresults_pos3&page=1

After months of negotiations over a crucial piece of President Biden's agenda, two Democrats have created the Inflation Reduction Act of 2022. Senate Democrats report that the measure would reduce the budget deficit by roughly $300 billion over a decade. The nonpartisan Congressional Budget Office found the package would reduce the deficit by about $102 billion over a decade. The proposal would implement a 15% corporate minimum tax aimed at large companies that report significant profits but pay little or nothing in income taxes. The deal would dedicate $64 billion to extending the Affordable Care Act subsidies, sparing nearly 13 million people who get federal subsidies from higher health-insurance premiums. The measure would also allow Medicare to negotiate the cost of some prescription drugs with pharmaceutical companies, predicted to save the government $288 billion. More than 100 economists are in support, saying the proposal "addresses some of the country's biggest challenges at a significant scale by cooling inflation by reducing aggregate demand in the economy. Republicans have argued the deal would have little impact on inflation, pointing to an analysis from the Penn Wharton Budget Model. GOP lawmakers have said this would hurt American families and companies. Democrats hope to approve the bill in the Senate via reconciliation, allowing it to

pass with a simple majority. Republicans are likely to oppose the measure unanimously.

NEW WEIGHT-LOSS DRUGS CAN FATTEN DRUGMAKERS' PROFITS

David Wainer, The Wall Street Journal, August 5, 2022.
https://www.wsj.com/articles/new-weight-loss-drugs-obesity-treatment-obese-11659646078?mod=Searchresults_pos5&page=1

Novo Nordisk and Eli Lilly have repurposed drugs developed for diabetes into weight loss drugs. Although Eli Lilly's tirzepatide hasn't been approved for weight loss yet, Novo Nordisk's Wegovy received Food and Drug Administration (FDA) approval last year for obesity. In studies, tirzepatide helped obese people lose as much as 22.5% of their body weight. Expecting similar results in future studies, Eli Lilly is working with the FDA to assess whether it can submit the drug for approval earlier based on the current data. Novo Nordisk's approved Wegovy, which mimics the effects of gut hormones that work to increase satiety, shows patients can lose about 15% of their body weight. However, usage is limited due to supply constraints and reimbursement challenges since many insurers hold that weight loss is a vanity project rather than a legitimate medical treatment. With 40% of American adults being obese, government-sponsored insurance plans deciding to cover these drugs would be pivotal. Morgan Stanley analysts expect Congress to pass a bill in the future that would expand Medicare and Medicaid coverage of prescription drugs for obesity. Ultimately, private insurers will take their cue from Medicare and Medicaid.

CONGRESS POISED TO EXTEND ENHANCED MARKETPLACE SUBSIDIES THROUGH 2025

Katie Keith, Health Affairs, August 9, 2022.
https://www.healthaffairs.org/content/forefront/congress-poised-extend-enhanced-marketplace-subsidies-through-2025

On August 7, 2022, the U.S. Senate approved the Inflation Reduction Act (IRA). The bill aims to bolster investment in health care, climate change, and deficit reduction through a $740 billion budget reconciliation package. The IRA includes policy implications for Medicare and for marketplace subsidies enacted under the American Rescue Plan Act (ARPA). Changes to Medicare include (1) a new requirement for federal officials to negotiate some prescription drug prices, (2) a cap on overall out-of-pocket spending for seniors, (3) a copay cap of $35 on all insulin products, and (4) rebates if drug prices rise too quickly. Additionally, the IRA extends the temporary marketplace subsidies adopted under ARPA to make premium tax credits (PTCs) more available. Under ARPA, individuals are eligible for PTCs if the cost of premiums exceeds 8.5 percent of their household income. Previously, individuals and families above 400 percent of the federal poverty level were not eligible for PTCs, leaving many middle-income individuals — especially those who are older and live in rural areas — with high premiums. This policy ensures that self-insured middle-income people do not pay more than 8.5% of their income toward premiums. Moreover, the IRA keeps enhanced subsidies for insurers available under the Affordable Care Act (ACA) available. Insurers that assumed the ARPA subsidies

would expire may have set their rates higher than what will be true of the actual risk pool now that the IRA has extended ARPA subsidies for another three years. Allowing insurers to proceed with the ARPA subsidy rates will drive down out-of-pocket premiums for individuals. Without the ARPA subsidy rates, out-of-pocket premiums will be higher. This may lead some enrollees to disenroll in coverage, leaving a sicker — and therefore costlier — marketplace risk pool.

U.S. ALLOWS ALTERNATE MONKEYPOX VACCINE INJECTION METHOD TO BOOST SUPPLY

Ahmed Aboulenein and Ankur Banerjee, Reuters, August 9, 2022. https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-authorizes-bavarian-nordics-jynneos-emergency-use-against-monkeypox-2022-08-09/

To respond to growing concerns about monkeypox and low vaccine supplies, the U.S. Food and Drug Administration (FDA) has authorized intradermal injection of a monkeypox vaccine, instead of subcutaneous administration. This change comes after the United States and the World Health Organization (WHO) declared monkeypox a public health emergency. This change is to maximize availability of the monkeypox vaccine, because the intradermal method only uses a fraction of a subcutaneous dose but provides the same protection. Bavarian Nordic's JYNNEOS monkeypox vaccine is approved for use in adults and people younger than 18 years if they are determined to be at high risk of infection. With the intradermal method, the standard protocol will be two doses of the vaccine given four weeks apart. Currently, the United States has 441,000 vials of the vaccine in the strategic national stockpile, which translates to more than 2.2 million intradermal doses. To support the response, the U.S. Centers for Disease Control and Prevention (CDC) will provide training and educational support to health care workers on how to administer the vaccine intradermally. The first case of monkeypox was reported in the United States on May 18, 2022. Since then, there have been more than 10,700 cases reported in the country.