FDA Must Punish Unethical Researchers

BY AGNES CAZEMIRO

In November, Public Citizen petitioned the U.S. Food and Drug Administration (FDA) to initiate serious enforcement proceedings against two researchers at Hennepin County Medical Center (HCMC) in Minneapolis, Minn., who repeatedly and deliberately violated agency regulations intended to protect human subjects.

These doctors conducted a series of clinical trials from 2014 to 2018 that tested the dangerous general anaesthetic ketamine and powerful sedatives on agitated patients without their consent. Two trials led by Dr. Jon Cole compared the safety and effectiveness of ketamine to either haloperidol or midazolam for treating patients with agitation in the community setting, and two led by Dr. Lauren Klein assessed the relative safety and effectiveness of four sedating drugs — haloperidol, midazolam, olanzapine and ziprasidone — in patients with agitation in the hospital emersee FDA, page 16



Photo of a Hennepin County Medical Center skyway in Minneapolis, Minn., courtesy of Tony Webster / Flickr.

Political Consulting Firms Working as Dual Agents

BY AGNES CAZEMIRO

In 2010, the U.S Supreme Court's ruling on *Citizens v. Federal Election Commission* made it legal for corporations and labor unions to spend unlimited sums to influence elections. That decision was based on the court's assumption that outside groups could be counted on to act completely independently of candidates and political parties and would not coordinate with them.

A report published by Public Citizen, "Dual Agents," found this to be a misguided presumption.

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According to the study, political consulting firms routinely work for a candidate or political party while simultaneously working for an unregulated super PAC or other purportedly "independent" outside entity — on the same electoral contests. During the last two election cycles, political consulting firms received a jaw-dropping \$1.4 billion for this potentially coordinated work.

"Political consulting firms are perfectly positioned to harmonize the message and strategies of campaigns and super PACs," said Taylor Lincoln, research director of Public Citizen's Congress Watch division and author of the study. "The findings in this study add to the overwhelming evidence that campaign committees and outside groups frequently are not truly independent of one another."

Payments to common vendors in the 2018 and 2020 election cycles totalled \$771.4 million from candidate and party committees and \$628.2 million from super PACs and other outside entities, according to the study. Commonvendor payments for the 2020 presidential campaign totalled \$526.7 million, equal to 38% of the spending documented in the study.

Some of the key findings of the report include:

- Ten consulting firms received nearly \$1.3 billion of the \$1.4 billion paid to these common vendors.
- A single firm, which operates under three different names, received more than \$930 million, accounting for more than 66% of the total money paid to common vendors.
- There were 210 cases of a consulting firm receiving payments from both a regulated and unregulated political entity for work on the same contest. Of these: 89 involved payments by an unregulated entity and just a candidate committee; 65 involved payments by an unregulated entity and just a party committee; and 56 involved payments by an unregulated entity and both a candidate and party committee.
- In the 2020 presidential contest, alone, 26 consulting firms were paid by both regulated and unregulated entities. They received \$526.7 million for their work on the presidential election (\$330 million from regulated committees and \$196.7 million from unregulated entities).

see **Dual Agents**, page 16

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GET TO KNOW PUBLIC CITIZEN HANNAH SAGGAU

An ongoing series profiling Public Citizen leaders and staffers



was an important piece of the climate fight, and Public Citizen was working under this umbrella.

fter graduating from the University of ANorth Carolina at Chapel Hill with a bachelor's degree in health policy and management, Saggau worked extensively with reproductive health and environmental protection. This includes her time spent as a community health volunteer with Peace Corps and campaigning for water rights alongside communities threatened by a hydroelectric company in Ecuador.

Shortly after her work in Ecuador, Saggau joined Public Citizen's Climate Program as campaign coordinator, where she continues to work on climate justice. Saggau's passion for climate justice extends to her extracurricular hobbies. An avid reader, her favorite books include works by Naomi Klein and climate fiction, like Octavia Butler's Parable of the Sower. Aside from reading, Saggau also enjoys hiking and going on runs.

How did you become involved in campaigning and what made you decide to join Public Citizen?

Saggau: I went abroad to Ecuador to work in community health after I graduated from college. The project involved advocacy and community organizing, supporting communities to elevate their demands to public figures, which is how I was introduced to campaigning. Following that experience, I was looking to bring those skills directly to work in fighting climate change. I found out about climate finance as an angle to target not the heavy emitters themselves, like fossil fuel companies, but rather the banks and asset managers and insurance companies propping up and enabling polluters. Insurance companies are a crucial pillar of the fossil fuel economy: they're both investing in fossil fuel companies, enabling them to build new operations, and providing insurance coverage, which is crucial for building new pipelines, building new fracking wells, and maintaining existing fossil fuel infrastructure. I quickly realized that it

How have your work experiences prepared you for your current role?

Saggau: My most recent experience, which was environmental and human rights in organizing and advocacy, has helped me understand how to work in very fast-paced environments and prioritize interpersonal relationships on a campaign. My experience in Peace Corps helped me learn how to build something from the ground up. I came into the AIG campaign and was tasked with getting it off the ground, building a campaign strategy and moving it forwards.

I had a similar experience when I was in Ecuador, of coming in as a community health educator, having to build new relationships from scratch, building new projects, and figuring out how to move towards my goal. One skill that's important to this role is the ability to be strategic and creative. Constantly asking yourself and your team: What can I do to push my target in the direction that we are asking, and to meet our campaign demands? Overall, my time in Ecuador taught me how to be flexible and deal with unexpected situations.

What does your typical workday consist of?

Saggau: My job is so varied that there really is no "typical" workday, but some things that I do frequently are sending digital action alerts to our email list, working on social media promotion with our fantastic digital team, writing op-eds, and planning direct actions with partners. Also, lots of outreach on recruitment and pipeline disruption. Those are just a few examples of things that I might do in a workday. Then periodically taking a step back, doing campaign planning and thinking about our broader strategy.

– Compiled by Agnes Cazemiro

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Public Citizen is a national nonprofit membership organization based in Washington, D.C. Since its founding by Ralph Nader in 1971, Public Citizen has fought for corporate and government accountability to guarantee the individual's right to safe products, a healthy environment and workplace, fair trade, and clean and safe energy sources. Public Citizen is active in Congress, the courts and government agencies.

Public Citizen does not accept government or corporate grants. Our funding comes from our supporters throughout the country, who believe there should be full-time advocates of democratic principles working on their behalf; from foundations; and from the sale of our publications. Public Citizen is an equal opportunity employer. To become a member of Public Citizen and receive the award-winning Public Citizen News, please call (202) 588-1000 or send a check payable to Public Citizen for \$20 to Public Citizen Membership Services at the address above.

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CONNECT ONLINE WITH PUBLIC CITIZEN







EDITORIAL

Public Citizen at 50 Years

We enter 2022 with some unfinished business — and lots more to do! Here's an overview of how we're looking to drive progress in the coming year.

First, while we made great progress, we didn't manage to push democracy legislation



PRESIDENT'S VIEW ROBERT WEISSMAN

or President Biden's Build Back Better package over the legislative finish line last year. Passage of neither is certain in 2022, but we're going to do everything we can. We continue to spearhead the main organizational coalition building outside support for the Freedom to Vote Act and the John Lewis

Voting Rights Advancement Act. We're organizing protests and demonstrations across the countries, placing op-eds, supporting on-theground work in West Viriginia and Arizona, driving calls and emails to senators, working with the media, lobbying intensively and more. For Build Back Better, we are focusing on our priorities in this broad and transformative legislation, including improving Medicare, lowering drug prices, and addressing the climate catastrophe.

Second, as the Biden administration moves into its second year, we will press them to accelerate the process of issuing regulations to advance health, safety, democracy, justice, and ecological sustainability. There's a huge

amount the administration can do under existing law, but it takes time to go through the rulemaking process — and there's no time to waste. We are pushing the administration and independent agencies to issue and finalize rules to: protect workers, especially immigrant farm workers, from extreme heat; require companies to disclose their political spending; prohibit risky executive pay packages to bankers; protect consumer privacy from snooping Internet firms; stop banks and financial firms from investing in fossil fuel production; and much more.

Third, having generated huge momentum on global Covid issues in 2021, we will continue to press forward in 2022. Our cutting-edge investigations have documented the degree to which U.S. government support has driven vaccine research and has ownership claims on key mRNA vaccine technology. Our advocacy has led the U.S. government to step up its vaccine donations and secured a commitment to start producing vaccines for global distribution. Yet we still need much more technology sharing with other countries, more resources for expanded manufacturing, and much more urgency. Not only is ending the global pandemic a humanitarian imperative; but, as Omicron reminds us again, we will truly leave the pandemic behind us in the United States when we have ended it everywhere.

Fourth, however, the federal legislative fights turns out, we know that we have an immense challenge in this calendar year - and afterwards — in defending and deepening our democracy. We will be doubling down against the threats of Trump's Big Lie and a proto-fas-

cist movement, concerted voter suppression and ongoing Big Money dominance of our elections – addressing each of these challenges will be a long-term project but also necessitating urgent action. To protect the integrity of the 2022 election, we will be involved on a state-by-state basis in supporting independent election officials, recruiting poll workers and ensuring the candidates who receive the most votes are declared victorious. To counter voter suppression, we will undertake a voter turnout program beyond anything we've ever done. And to address Big Money dominance, we will push for executive action, advance local initiatives for small donor, public financing of elections, and intensify our campaign to win a constitutional amendment to overturn Citizens United.

Last, we will be celebrating our 50th anniversary! We're planning on holding a series of online and, if possible, in-person events with leading regulators, elected officials, and authors, both to reflect on our achievements and look forward to the next 50 years. We're going to hold a series of you-won't-want-tomiss conversation with Public Citizen's founders. We aim to produce a series of think pieces and books on how to meet the great challenges ahead. And, pandemic permitting, we will gather supporters in Washington, D.C., in September (for those who can't make it to D.C., we'll gather online), to celebrate our achievements, reconnect with old friends, and reaffirm our commitment to continuing bold advocacy for justice, democracy, and a better world.

Public Citizen Celebrates 50 Years
People. Power. Progress.

To mark this special occasion, we are creating a Memory Bank where we are collecting stories, anecdotes, and memories from our supporters, allies and alumni about the work of Public Citizen.

Share your memory via email to afleming@citizen.org or visit www.anniversary.citizen.org.

For more information, visit www.anniversary.citizen.org.

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"I support Public Citizen because it champions the foundational principles and practices that enable government to be truly of the people, by the people, and for the people. So many forces are at work today to serve those with power and money. Public Citizen is one of the few organizations fighting back. Public Citizen helps keep hope alive for democracy."

-Jay McClelland, Palo Alto, Calif.

Are your medicines SAFE?

Many drugs that come to market have risks that outweigh their benefits. Others, found to have risks only after they are approved, are left on the market for dangerously long periods of time. Find out which drugs are safe—and which you should avoid—with Public Citizen's WorstPills.org and Worst Pills, Best Pills News.

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IN THE SPOTLIGHT

The following are highlights from our recent media coverage.

Robert Weissman, Public Citizen president

On U.S. Senate Democrats' agreement over lowering prescription drug prices: MSN Money, CNN International, The Los Angeles Times, The Seattle Times, Common Dreams. On the Jan. 6 insurrection: The Washington Post. On the director of Consumer Financial Protection Bureau, Rohit Chopra, scrutinizing the business practices of Big Tech companies: The Seattle Times, Kansas City Star, Common Dreams. On the \$778 billion military budget approval: Salon, Common Dreams.

Lisa Gilbert, vice president of legislative affairs

On Biden not filling the Office of Management and Budget director role: CNN, MSN. On the meeting between U.S. Vice President Kamala Harris and pro-democracy organizations to pass stalled federal voting rights bills: Yahoo News. On harmful Facebook algorithms: Tech Crunch. On legacy rider policies harmful to civil rights still in Congress' annual federal spending package: MSN News, The Hill. On 208 U.S. House of Representatives Republicans voting against the Protecting Our Democracy Act: Common Dreams.

Peter Maybarduk, director of Public Citizen's Access to Medicines Program

On the U.S. drug company Merck granting a royalty license for its experimental COVID-19 drug to a **United Nations-backed nonprofit:** The Washington Post, Yahoo Finance. On the White House expanding U.S manufacturing capabilities for COVID-19 vaccine doses to reach poorer parts of the world: The New York Times, The Washington Post. On the World **Health Organization announcing the** first royalty-free, transparent, global, and non-exclusive vaccine licensing agreement with the Spanish National **Research Council:** Politico, Common Dreams. On Johnson & Johnson prioritizing vaccine doses to wealthy coun**tries:** Common Dreams.

Lori Wallach, director of Public Citizen's Global Trade Watch

On the World Trade Organization's (WTO) intellectual property issues: CNN International, The Hill. On a letter to Biden on WTO Big Pharma intellectual property barriers: Common Dreams. On the 1999 WTO activist shutdown: Democracy Now!

Dr. Michael Carome, director of Public Citizen's Health Research Group

On the U.S. Food and Drug Administration (FDA) warning consumers about benzene in hand sanitizers: MSN News, Yahoo News, NBC News. On Biden's nomination of Robert Califf as FDA commissioner: MSN News, The Washington Post, Scientific American. On Medicare's 15% premium increase for hospital outpatient services: Medscape, Common Dreams. On the sale of COVID-19 medical exemptions: The Raw Story, News Break.

David Arkush, managing director of Public Citizen's Climate Program

On Jerome Powell's renomination to Federal Reserve chairman: Yahoo Finance, Politico, The Hill, News Break, Common Dreams. On climate change as a threat to America's financial system: Mother Jones.

Public Citizen Litigation Group

On Public Citizen Litigation Group's lawsuit against the state of Tennessee over the denial of public access to a report recommending how to respond **to COVID-19:** SFGate, Associated Press. On the Daily Kos' legal victory against Robert Kennedy Jr.: Daily Kos. On **Public Citizen's friend-of-the-court** brief on behalf of former Occupational Safety and Health Administration administrators supporting the lifting **of the vaccine rule hold:** *Government* **Executive.** On Public Citizen's lawsuit victory against U.S. Postal Service delivery delays: Federal News Network, Government Executive.

Adrian Shelley, director of Public Citizen's Texas office

On cryptocurrency miners migrating to Texas due to formal incentives such as a 10-year tax abatement: Bloomberg, Yahoo Finance, CNBC, SFGate. On power grid vulnerability after the Texas freeze: NBC News, Chron, News Break, Dallas Morning News, The Texas Tribune.

Craig Holman, government affairs lobbyist with Public Citizen's Congress Watch division

On U.S. Sen. Joe Manchin III (D-W. Va.)'s ties to the coal industry: The Washington Post, CNN International, MSNBC, The Seattle Times. On Capitol Hill townhouses owned by business groups and lobbyists: Politico. On 182 congressional staffers violating federal conflict-of-interest law: The Washington Post, Business Insider. On the Bureau of Alcohol, Tobacco, Firearms, and Explosives' \$85 million contract behind unsolved gun crimes: The Daily Beast. On nominee to be FDA Commissioner Robert Califf's profitable health care industry ties: Politico.

Bartlett Naylor, financial policy advocate of Public Citizen's Congress Watch Division

On the Biden administration's recommendation that Congress pass legislation regulating stablecoin: Roll Call. On the unclear regulation of cryptocurrency: Roll Call.

2021 Year in Review

2021 was a turbulent year. It began with the January 6 insurrection and was marked by efforts in states across the nation to deny people of color and others the right to vote and even to pave the way for legislatures to overturn legitimate election results. Public Citizen was ready to respond - and we have. We continued to spearhead the major coalition pushing for democracy and voting rights legislation. We helped pull together hundreds of local protests, drive hundreds of thousands of emails and calls to Congress and much more in order to build support for transformative democracy legislation and place it atop the Congressional agenda. By the end of the year, we were on the cusp of winning passage of the Freedom to Vote Act and the John Lewis Voting Rights Advancement Act - but with the ultimate outcome very much uncertain.

Throughout the year, Public Citizen worked to undo the Trump administration's disastrous policies and attacks on consumers, workers, the environment and civil rights. As you'll see in the following pages, we notched a number of victories, expanded our staff, committed to alleviating the effects of systemic racism and launched new initiatives.

Working with Imperial College process engineers, we came up with a detailed, \$25 billion plan to produce enough Covid vaccines for the entire world. for We released a report showing how to rapidly scale up new production lines at 14 mRNA facilities how governments can source materials, retrofit facilities, and train staff to make billions of doses. This proposal has won widespread endorsement - though not uptake from the U.S. government. Nonetheless, this proposal and our advocacy has focused attention on global vaccine inequity and forced the United States and other rich nations to do more - though still far too little - to deliver vaccines to developing countries.

In response to a global advocacy campaign spearheaded by our Global Trade Watch team, the Biden administration made a historic decision to support waiving World Trade Organization (WTO) intel-

lectual property rules to help fight COVID-19.

This year also saw us leading the charge for aggressive drug pricing measures to be included in budget reconciliation - savings from which could be used to improve and expand Medicare. We worked closely with the offices of U.S. Sen. Bernie Sanders (I-Vt.) and U.S. Rep. Pramila Jayapal (D-Wash.) to build support for Medicare for All, including securing a record number of original House cosponsors and organizing a virtual town hall with members of Congress and health justice champions.

In our effort to achieve Medicare expansion in a reconciliation bill, we coordinated a letter with nearly 50 groups and Hill letters with over 150 U.S. House of Representatives members and nearly 20 senators. This year alone, we won Medicare for All resolutions in a number of cities, including Long Beach, Calif.; Princeton, N.J.; Prince George's County, Md.; Andover, N.H.; Windham, Conn.; and Dane County, Wis.

In 2021, we also helped craft the Nullifying Opportunities for Variants

to Infect and Decimate (NOVID) Act, led by U.S. Reps. Raja Krishnamoorthi (D-IL) and Jayapal and U.S. Sens. Jeff Merkley (D-Ore.) and Elizabeth Warren (D-Mass.), which would make our plan law. Other milestones: We inspired Oxfam and UNAIDS to form the People's Vaccine Alliance, and now help organize more than 70 groups challenging pharma greed together and calling on governments to make vaccines public goods. We testified before the U.S. Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee and encouraged emergency authorization for the Pfizer, Moderna/NIH, and Johnson & Johnson vaccines.

In other health news, we testified before FDA advisory committees several times to oppose the approval of several dangerous drugs. We urged the FDA to not approve an ADHD oral amphetamine product that is intended to be abuse-deterrent, on the grounds that it would not reduce abuse. By a 19-2 vote, the committees recommended against approval. Similarly, we testified before FDA advisory committees to oppose approval of the combination drug olanzapine/samidorphan for treating schizophrenia and bipolar disorder, since it increased the risk of opioid overdose. The FDA rejected the drug.

Texas and its energy infrastructure gained national attention after the deadly winter storms in February 2021 decimated its under-regulated and un-winterized power grid. In response to the devastating Winter Storm Uri, we established a statewide messaging partnership to counter misinformation about the energy crisis. In Texas, we also succeeded in getting an amendment added to SB 3, the modest reform Texas legislation passed after Uri, to require consideration of climate impacts. This is the first positive climate legislation to pass in Texas in many years. We continue to help drive climate and energy advocacy in San Antonio, Houston, and Austin.

In March, we released a Climate Roadmap for U.S. Financial Regulation, the most comprehensive and in-depth set of recom-

mendations on "climate-finreg" policy to date. We also launched a campaign to push AIG to stop insuring and investing in fossil fuels. Our decade-long advocacy to create an Office of Public Participation that would finance public interest advocates' regulatory work at the Federal Energy Regulatory Commission (FERC) has succeeded. FERC will be required to report in June on how it will set up the Office.

Finally, in a year that has seen devastating weather events, in June, the U.S. Occupational Safety and Health Administration announced it would begin the process of issuing a rule to protect workers from extreme heat - a decade after we first petitioned for such a rule.

In 2022, we will celebrate Public Citizen's 50th anniversary. Even as we look back on the past fifty years of being on the frontlines of advancing consumer protection, health and safety, and justice and democracy rights, we are redoubling our efforts to move us closer to a nation of opportunity and justice for all.



A mobile billboard circles the U.S. Capitol in Washington, D.C., during "Democracy Week" to underscore the importance of the For the People Act to ensure a robust democracy. Photo courtesy of the Declaration for American Democracy Coalition.



A votercade wends its way through Los Angeles, Calif., on the National Jewis Lewis Voting Rights Advancement Action Day. Photo courtesy of Jed Pauker.

DEMOCRACY

We headed into the new Congress and Biden administration with a lot of energy. Our coalition's strong advocacy throughout 2020 led to the For the People Act being introduced again as H.R.1 on Jan. 4, 2021, indicating that it was a top priority for House leadership.

On Jan. 6, 2021, we watched in stunned disbelief as the president of the United States incited an insurrection and sought to block certification of the 2020 election results. After the dust settled, we strongly supported Trump's impeachment (successful) and conviction (not successful, but with significant Republican support). Even after skulking away from the White House, Trump clung to the Big Lie that he actually had won the election — a claim that served as organizing principle for authoritarian and anti-democratic forces.

All this threw into stark relief the imperative of winning democracy legislation. The Declaration for American Democracy (DFAD) coalition — which Public Citizen leads and which includes a diverse coalition of more than 240 democracy, environmental, labor, faith-based, good government, women's rights, civil rights, and other groups — led the charge for passage.

Following introduction of H.R. 1, billed as "National Democracy Week," national and state coalition partners participated in coordinated social media activities, socially-distanced stunts, a letter to the editor campaign, and a day of action in which grassroots leaders in over 65 cities hosted virtual rallies, telepress conferences, car caravans, and other events to call on Congress to pass the For the People Act. It was to be the first of many coordinated nationwide actions.

In March, the House of Representatives passed the bill. Our coalition hosted a livestream to celebrate the House passage of the For the People Act, featuring more than five hours of coalition member-led panels, discussion, videos, and special guests, including several senators and representatives. We led a letter to Congress signed by over 300 organizations calling on the Senate to urgently pass the For the People Act. In April, DFAD hosted the "For the People Week of Action," including local visibility actions. Members of DFAD hosted a dozen democracy trainings throughout the week to teach over 1,300 attendees about S1.

On May 8, 2021, Public Citizen, the Transformative Justice Coalition, DFAD, and the Leadership Conference on Civil and Human Rights led an effort where thousands of activists took to the streets in 150 cities for nationwide John Lewis "votercades" to support passage of S1. Most of these actions were led by people of color, helping to sharpen focus on the assault on voting rights and the urgent need for a legislative fix.

We kept the heat on through the summer. With U.S. Sen. Joe Manchin, (D-W.Va.), demanding revisions to the For the People Act, a group of senators negotiated a modified bill. In September, it was introduced as the Freedom to Vote Act.

We continued the pressure with calls, protests, press conferences, webinars, texts, social media, editorials, letters to the editor, in-state lobbying, paid advertisements and much more. With all 50 Democratic-aligned senators supporting the bill — and Republicans repeatedly filibustering it — the issue became whether the 50 Democrats (plus Vice President Kamala Harris) would support changes to Senate rules to enable passage.

We kept the pressure on. Public Citizen President Robert Weissman and other Public Citizen staff were arrested at the White House urging President Biden to demand passage of the Freedom to Vote and John Lewis Voting Rights Advancement acts and to demand changes to Senate rules, if needed. Manchin and U.S. Sen. Kyrsten Sinema (D-Ariz.),

resisted agreement on Senate rules reform, however, and the issue remained undecided at the end of the year.

Our efforts were not focused only on the Freedom to Vote and John Lewis Voting Rights Advancement Acts. We mobilized activists to help protect elections and encourage high turnout in the Georgia runoff election in January 2021. We engaged 27 Georgia students who interned with us to reach out to other students on their campuses and support community-based efforts to turn out voters of color. We helped to build a relentless call program that called more than half a million voters of color with more than 1,500 volunteers that we helped to recruit and train, sending email and text reminders and organizing a team of interns who phone-banked reminders to daily callers through weekends and holidays.

In 2021, we also helped lead grassroots planning and efforts to win a Jan. 6 commission, filling two large town halls with congressional speakers and coordinating national call-in days. We organized meetings and town halls, helped build grassroots engagement nationally and in key Senate districts, and were part of the broader push to move forward Trump's second impeachment.

We recruited sponsors for, and led grassroots campaigning for, the Protection of Democracy Act, which would cure many of the Trump presidential power abuses (for example, by requiring presidents to disclose their tax returns, limiting the pardon power, and enhancing the enforceability of congressional subpoenas).

In 2022, we will continue to defend democracy from rising authoritarian movements and, simultaneously, work for the transformative democracy reforms our nation needs to deliver on its best ideals.



OTHER ACCOMPLISHMENTS

- In January, we led an open letter to corporate America calling on companies to stop their political giving following the Jan. 6 insurrection.
- We published two reports, "The Corporate Sponsors of Voter Suppression" and "Bankrolling the Disenfranchisers," highlighting the role of large corporations in supporting state legislators pushing voter suppression legislation.
- We helped draft and promote legislation like the Executive Branch Comprehensive Ethics Enforcement Act (S. 1546), which was reintroduced by U.S. Sen. Richard Blumenthal (D-Conn.), and the Presidential Appointee Accountability Act, by Blumenthal that would strengthen the Hatch Act.

GOVERNMENT & FINANCIAL REFORM

In the first year of the Biden administration, Public Citizen led the efforts to clean up the messes the Trump administration left behind — with an emphasis on rebuilding federal watchdog agencies with better leadership, addressing critical budgetary needs, and pressuring lawmakers to hold Big Tech monopolies accountable.

Regulatory Reform, Federal Agencies, and Enforcement

At the start of 2021, Public Citizen and its allies in the Coalition for Sensible Safeguards urged Congress to use the Congressional Review Act — an expedited process for repealing regulations — to strike down several harmful Trump era rules. Congress repealed a bad methane rule as well

as harmful deregulatory actions at the

Equal Employment Opportunity Commission and the U.S. Treasury Department.

We were extremely pleased to see President Joe Biden issue an executive order on his Inauguration Day calling for progressive regulatory reform, one of Public Citizen's longtime priorities. Unfortunately, there has been no further action since then.

So in early December, the Coalition for Sensible Safeguards urged the administration to proceed with the reform process — calling for steps that would make the rulemaking more transparent, accountable, efficient, and responsive to the public instead of corporate lobbyists. At the same time, U.S. Rep. Pramila Jayapal (D-Wash.) introduced legislation — the Stop Corporate Capture Act — to do just that, which Public Citizen was proud to endorse.

Closely related to the regulatory process is the issue of enforcement. Biden's Justice Department issued a new policy this year, pledging to get tough on corporations that repeatedly break the law — especially those that have done so while operating under a leniency agreement. Public Citizen published a report in November identifying several of the worst offenders and sent a letter to the U.S. Justice Department urging its leadership to follow through.

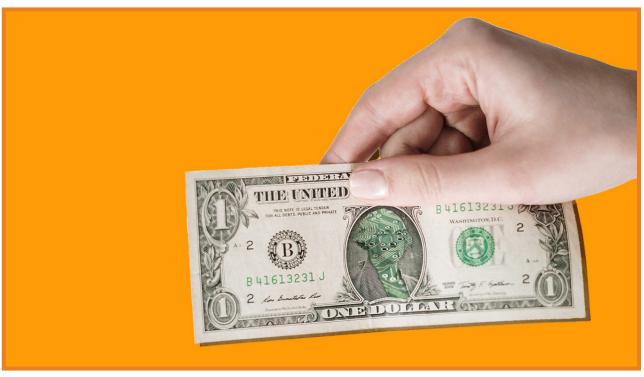
Big Tech Accountability

It was a very busy year for Public Citizen's Big Tech accountability efforts. In the early months of 2021, Public Citizen and its allies insisted that President Biden avoid revolving-door appointments. We were particularly pleased with the nomination of Lina Khan to head up the Federal Trade Commission, since she is a noted proponent of breaking up Big Tech companies and other corporate monopolies.

In March, Public Citizen published a report which found that Facebook and Amazon are now the two biggest corporate lobbying spenders in the country, according to data from the Center for Responsive Politics.

And in the late spring, Public Citizen, the Center for American Progress Action Fund, and Change Research conducted and released a poll that found support from nearly 90% of voters for "rules to ensure that all internet companies, regardless of size, don't take advantage of consumers by abusing their data, using deceptive and unfair practices, or violating their civil rights."

We led an international coalition that spent the first half of 2021 pushing back on a set of privacy-violating data collection practices Facebook



Graphic courtesy of Zach Stone.

intended to implement on its messaging platform WhatsApp. That effort spurred governmental investigations in eight countries. Facebook eventually backed down.

And in July, Public Citizen led one of its first direct actions since the beginning of the pandemic: a protest in front of Facebook's national lobbying headquarters in downtown D.C. calling attention to the tech giant's litany of abuses.

This fall, we called for the regulation of cryptocurrencies, particularly as some of the Big Tech platforms began to branch out into setting up their own payments systems and stablecoins. We also put a spotlight on how tech monopolies stifle competition through anti-competitive practices. And we finished out the year by calling on Congress to pass legislation holding tech companies — particularly Facebook — accountable.

Tax and Budget

Throughout the year — but especially following the conclusion of the War in Afghanistan in August — Public Citizen repeatedly pushed Congress to slash military spending and reallocate the funding to human needs priorities such as education, health care, and vaccine production. We led the campaign to cut spending by at least \$25 billion. An amendment to do that failed, but received 146 votes — a highwater mark in recent years in opposition to endless increases for Pentagon spending.

One crucial and partial victory came on the fight to remove long-standing poison pill policy riders from the annual appropriations package. Many such measures were taken out of the draft spending bills in both chambers of Congress, including three secret money riders Public Citizen has fought for years to remove. Two of the riders blocked rules requiring corporations and government contractors, respectively, to disclose their political spending; and the third blocked rules that would clarify what kind of political activity is legally permissible for nonprofits and churches.

To remove these and many other harmful legacy riders, Congress must finish appropriating — rather than pass a long-term continuing resolution that just continues Trump-era funding levels for another year. Public Citizen and its allies in the Clean Budget Coalition ran an ad in a *Politico* newsletter urging lawmakers to finish the appropriations process, and groups are asking voters in key states to call their senators and urge them to come to the negotiating table.

Congress has until Feb. 18 to act, so we expect significant developments very early in the new year. ■

"I support Public Citizen because I'm happy that it keeps the pressure on Washington power holders to put citizens' rights first."

-Kate Thill, Ashland, Ore.

CONSUMER HEALTH & SAFETY



Supporters hang signs commemorating family and friends who have died of COVID-19 at the Rally for Vaccine Access for Everyone, Everywhere on May 5 in Washington, D.C. Photos throughout courtesy of Eric Kayne/AP Images for Social Security Works.

Vaccine Apartheid

Nearly 5.5 million people worldwide have died from COVID, most of them *after* introduction of the first vaccine one year ago. Many leaders of powerful nations have accepted and even encouraged vaccine apartheid, forcing Black and Brown people living in the Global South to wait at the back of the line for vaccines and a path to safety. The U.S. government hoarded supplies while failing to share the doses or knowledge needed to end the pandemic quickly.

During year two of the global pandemic, Public Citizen showed leaders an alternative to vaccine scarcity. Countries can teach one another to make highly effective mRNA vaccines, share knowledge, and equip vaccine manufacturing facilities on every continent. Our work with many partners has helped improve the global response and save lives. The world is on a flawed but slowly improving course, thanks in significant part to our work.

Build Back Better

Thanks to our advocacy, the Build Back Better Act passed by the U.S. House of Representatives includes \$1.3 billion that may be used to support global vaccine manufacturing. If the U.S. Senate preserves that investment, it can help to rapidly increase developing country manufacturing capacity while committing valuable U.S. technical capacity. Public Citizen will continue to press for increased resources dedicated to global vaccine manufacturing.

Inclusion of funds for global vaccine manufacturing springs from a new Global Vaccination Caucus that Public Citizen helped inspire, chaired by U.S. Reps. Raja Krishnamoorti (D-Ill.), Pramila Jayapal (D-Wash.), Mark Pocan (D-Wis.), Jake Auchincloss (D-Mass.), and U.S. Sen. Edward Markey (D-Mass.). We worked hand-in-glove with key congressional champions, including Sen. Elizabeth Warren (D-Mass.), to press the administration to use its contractual and statutory authorities to support technology transfer to developing countries in order to boost vaccine manufacturing.

To generate support for Congress providing funding for global vaccine manufacturing, we mobilized academics, organized global health and development groups to sign letters, and activated people around the nation to phone and email the White House and key members of Congress. Faith groups wrote letters to the president and helped with op-eds and targeted messages.

Voters Support Vaccines Leadership

We commissioned a poll of U.S. likely voters to assess support for U.S. global vaccine leadership. The poll found that Americans in both parties

want the U.S. to step up. Seven in 10 support Public Citizen's proposal to fund global vaccine manufacturing and share knowledge about how to manufacture vaccines. A majority of Democrats identifies global vaccine leadership as a core value.

We identified many opportunities where more decisive U.S. leadership could reshape the pandemic response. For example, the government could release mRNA vaccine manufacturing information to the World Health Organization (WHO) to teach qualified manufacturers to make COVID-19 vaccines. We found that the National Institutes of Health likely has the NIH-Moderna vaccine recipe on its computers and has rights to share information with vaccine makers. When this news went public, President Joe Biden's vaccine czar David Kessler responded to media pressure. Kessler told Rachel Maddow that he would "hold Moderna's feet to the fire" to ensure Moderna delivers more doses to low-income countries.

He also publicly contemplated using the government's authority to force Moderna to share the recipe for the publicly funded NIH-Moderna vaccine. Shortly thereafter, Moderna announced it would sell 110 million doses to nations in the African Union. Now mainstream development and foreign policy think tanks are joining our call for Moderna to transfer technology.

Biden's Global COVID-19 Summit

In September, the White House convened a global COVID Summit that yielded modest new vaccination targets. Public Citizen helped shape expectations in major media and worked again with senators and 60 advocacy groups to press for an actual plan to vaccinate the world. For the first time, Biden and other world leaders endorsed transferring vaccine technology and locating production within developing countries.

The analysis we shared with journalists created a catalytic media moment with five articles in The New York Times, two in The Washington Post, and a BBC broadcast, all within thirty-six hours. These reports elevated the announcement that WHO will help establish the first mRNA technology transfer hub in South Africa and

invite manufacturers worldwide to learn how to make mRNA vaccines. Techniques developed at the site will be shared openly. We are pressing the U.S. to accelerate the timeline with funding, expertise, and leverage with Moderna.

Manufacturing Delays

The international consortium COVAX initially pledged to deliver more than 2.3 billion shots worldwide by the end of the year. But by late December, it was struggling to deliver well under half that figure. Public Citizen closely monitored global vaccine delivery schedules, highlighting pharmaceutical companies' repeated failure to deliver. We exposed how pharma's manufacturing projections neglected to account for regulatory failures, production errors, raw material shortages, and more. This analysis bolstered our assertion that urgent new manufacturing is needed.

Wealthy nations' primary strategy for assisting developing countries get the vaccines they need is donating surplus doses. President Biden has committed to donate 1.1 billion doses to low- and middle-income countries by September 2022. Yet countries need vaccines now and they need them on predictable and reliable delivery schedules to plan successful vaccination campaigns. Logistical challenges have been a massive problem that are slowing efforts to get shots in arms. Many African countries report that donations have arrived too near their expiration dates to be usable, leading some to turn away donations. We have pressed the Biden administration to resolve these operational challenges and senior officials have made

public commitments to improve coordination.

U.S. Government Announces mRNA **Production Plan**

In November, the Biden administration announced that it will invest several billion dollars to produce one billion doses of mRNA vaccine per year. Public Citizen long has called for a \$25 billion investment to make eight billion doses of mRNA in one year, enough to meet global need. While not the ambitious and transformative action we called for the U.S. government to take twelve months ago, the administration plan still represents a major investment to boost mRNA production that can help save many lives, and potentially even shorten the pandemic.

Moderna Backs Down

Public Citizen exposed Moderna's failure to include National Institutes of Health (NIH) scientists as co-inventors on key patent applications, jeopardizing the government's ability to license and share the vaccine with developing nations. After the media widely covered this news, NIH Director Francis Collins told the press the government was prepared to take Moderna to court, and Moderna retreated. The company announced it had decided not to pursue the patent application, and instead was filing a continuation allowing it to make that decision later.

Global Access Campaign

For the Tokyo 2020 Olympics, we devised a campaign urging leaders to "StopPlayingGames with our lives and livelihoods." We wrote Jill Biden, head of the U.S. delegation, and produced a video that was viewed 700,000 times and shared by former Olympians. We supported protests outside the United Nations, at the **European Commission** in Washington, D.C., and at Pfizer headquarters in New York City. Public Citizen also built connections among many different groups campaigning for global vaccine access and shaped the dialogue on how most effectively to prese governments and vaccine manufacturers to accelerate vaccine supply. We see huge challenges ahead to ensure everyone in the world has equitable access to effective COVID-

> In 2022 Public Citizen will build on our progress made as we continue fighting for vaccine justice.

FDA

- In June, in one of the agency's worst decisions, the U.S. Food and Drug Administration (FDA) approved aducanumab for treatment of Alzheimer's disease. We have previously testified before the FDA to oppose approval since there is not sufficient evidence showing that the drug is effective for treating Alzheimer's disease. The potential patient population for this drug which poses serious side effects is 2 million. Biogen aims to charge more than \$50,000 per patient. We called for interim FDA Commissioner Janet Woodcock to resign.
- On July 14, we submitted comments to the FDA urging the agency not to approve the new drug application (NDA) for roxadustat for treatment of anemia due to chronic kidney disease in adult patients. The agency subsequently decided not to approve the NDA and issued a response
- We wrote a letter to the FDA urging the agency to convene an external expert advisory panel to evaluate whether the approval of the antiviral COVID-19 treatment remdesivir should be rescinded, given doubt about its efficacy
- We testified before FDA advisory committees to oppose a hydrocodone combination product because the product had an unfavorable risk-benefit profile. By a 14-7 vote, the committees recommended against approval of the drug and the FDA subsequently rejected the drug.
- We testified before FDA advisory committees against approval of an osteoarthritis drug, arguing that the risks of the drug far outweigh its benefits. By a 19-1 vote, the committee recommended against approval of the drug.
- We petitioned the FDA to promptly add the weight loss drug lorcaserin and injectable forms of the antibiotic bacitracin to its official list of drugs withdrawn or removed from the market because they were deemed unsafe or ineffective, in order to prevent pharmacy compounding of these banned drugs.



"Everything depends on who you trust. Public Citizen is one of the groups I trust. They haven't let me down yet."

—Michael Beer, Richmond, Calif.

19 vaccines.

JUSTICE

Successful Resolution of Lawsuit Against USPS

In August 2020, Public Citizen Litigation Group and the NAACP Legal Defense and Educational Fund filed a lawsuit against the U.S. Postal Service (USPS) in a case called *NAACP v. United States Postal Service* to challenge delays in mail delivery and inadequate measures to ensure prompt delivery of mail-in ballots.

In December 2021, we settled the case. The settlement helps to guard against the politicization of mail delivery and facilitates citizens' ability to exercise the fundamental right to vote by putting in place mechanisms to ensure that USPS has procedures to handle election mail.

Under the settlement, USPS will have to meet with the NAACP in the months before each national primary and general election through 2028 and to provide reports on service performance during the six weeks leading up to general elections. USPS will also issue guidance documents to address its plans for prioritizing the monitoring and timely delivery of election mail for the national general elections through 2028. These measures will be similar to the measures used in the weeks leading up to the 2020 general election. Those measures, which the court required USPS to implement in response to our motions, helped to ensure that the vast majority of mailed ballots were delivered to the boards of elections in time to be counted.



Photo of Tyson products courtesy of Shutterstock.

Essential Workers Impacted by Pandemic Safety Measures

In March, Public Citizen obtained a cache of documents from the U.S. Department of Agriculture (USDA) that painted a grim picture of the meatpacking industry's efforts to avoid safety measures during the pandemic. The documents, obtained in response to a Freedom of Information Act (FOIA) request, showed that, at the start of the pandemic, the industry rebuked common-sense reporting and public-health measures designed to stop the spread of the deadly virus. Documents previously obtained by Public Citizen and released in February showed that the Trump administration did not involve the U.S. Occupational Safety and Health Administration in its response until nearly a month after outbreaks began and, even then, did so reluctantly.

Through litigation, we continued to advocate for the interests of workers at poultry and meatpacking plants. In one case, we are handling an appeal o behalf of the families of several workers who died after contracting COVID at a Tyson Foods meatpacking facility in 2020. The lawsuit, filed in Iowa state court, alleges that Tyson and management that operated the plant violated Iowa tort law by acting negligently and making fraudulent misrepresentations to workers. Contesting Tyson's claim that it could move the case to federal court because it was acting under the direction of a federal officer, we explained to the court of appeals there was no evidence of delegation of federal authority or

control of Tyson's operations by any federal officer. In December, the U.S. Court of Appeals for the Eighth Circuit ruled in our favor, agreeing with us that Tyson's receipt of assistance from the federal government did not entitle it to remove the families' claims to federal court. The cases will now return to Iowa state court for litigation on the merits.

FOIA Victory for Immigrants and Open Government

In a significant victory for open government advocates, the U.S. Court of Appeals for the Second Circuit ruled in February that people can sue to enforce the Freedom of Information Act (FOIA) requirement that federal agencies post certain documents online so that they are accessible to the public. Public Citizen Litigation Group serves as lead counsel in the case, *New York Legal Assistance Group v. Board of Immigration Appeals*. We brought the case to compel the Board of Immigration Appeals to post all its opinions online, so that attorneys like NYLAG who represent immigrants have access to them.

Protecting Disability Rights

This fall, Public Citizen Litigation Group helped defend the rights of individuals with disabilities in a case before the U.S. Supreme Court called *CVS v. Doe.* CVS was asking the court to hold that two laws that allow people to sue for discrimination against people with disabilities — the Rehabilitation Act and the Affordable Care Act — do not allow claims based on the discriminatory impact of policies that are not discriminatory on their face, but do have discriminatory impacts. Public Citizen served as Supreme Court co-counsel for the plaintiffs. After briefing was completed, CVS dismissed its petition to the Supreme Court in the face of outcry from disability rights groups. As a result, legal protections against policies that have the effect of excluding for individuals with disabilities from access to publicly funded programs remain in place.

Scourge of COVID in Nursing Homes

Nearly one-third of all coronavirus deaths in the United States have been linked to nursing homes. When the coronavirus started to spread throughout the United States, numerous nursing homes flouted infection-control regulations and guidance from state and federal public health authorities. In so doing, they put the lives of their residents and staff at risk.

In appeals from cases filed in California, Kansas, New York, Pennsylvania, and Texas, Public Citizen Litigation Group represented the families of residents who died of COVID-19 in Spring 2020 in nursing homes. In each case, the nursing home failed to take common-sense measures to protect their residents, such as isolating residents known to have been exposed to COVID-19 and preventing symptomatic staff from interacting with patients. In one case, the nursing home even barred the use of masks. These cases are among more than 70 cases across the country in which nursing homes have argued that they cannot be held responsible for the spread of coronavirus in their facilities because they participate in the Medicare and Medicaid programs and because the federal government had issued guidance on infection control in nursing homes.

Districts courts around the country have rejected these arguments, and the nursing homes have appealed in numerous cases. We serve as lead appellate counsel in nine cases, seeking to return the litigation to state court and end the delays caused by the baseless removals.

Hazards of Herbicide Roundup

We filed an amicus brief opposing a proposed class action settlement that would have resolved the claims of anyone exposed to the herbicide Roundup who had not already sued Monsanto. Our brief explained that, among other problems, the proposed settlement would be unfair to individuals who had been exposed to Roundup, had not been diagnosed with Non-Hodgkin's Lymphoma, but might develop the disease in the future, as well as to their families.

The U.S. District Court in the Northern District of California held a hearing on May 21, in which we participated, and the court subsequently denied preliminary approval of the proposed settlement. ■

HOLDING CORPORATIONS ACCOUNTABLE

Taking on Big Oil

After four years of nonstop Trump-era giveaways to fossil fuel corporations, the Biden administration has pledged to get behind a transition to clean energy. But Biden's progress has been limited, and the oil and gas industry has done whatever it can to perpetuate a corrupt system that allows them to profit by exploiting public lands and water for drilling at artificially low costs.

Throughout 2021, Public Citizen worked to expose how oil and gas CEOs and their political allies on Capitol Hill have worked to put oil and gas industry profits over the future of human civilization. Public Citizen also advocated for policy changes to force dirty energy companies to ensure they can clean up their own mess or pay higher royalties for the privilege of extracting resources from public lands. For too long, inappropriate federal subsidies and tax breaks have supported fossil fuel development, exploration, and production costs, making expensive drilling projects feasible that would not otherwise turn a profit. Belowmarket leasing rates, royalties, and fees encourage oil and gas companies to exploit our public lands without reflecting the environmental costs. Public Citizen's research found that:

- Oil companies bankrolled lawmakers who tried unsuccessfully to disenfranchise Americans' votes after the 2020 election, with 65 fossil fuel company political action committees contributing millions to members of Congress who voted to challenge the electoral college outcome.
- House Republican lawmakers who opposed Biden's order to pause new oil leasing on federal lands and offshore waters received millions over their careers from fossil fuel interests. Many of these same lawmakers touted a misleading, industrygroup-promoted study exaggerating the job market impact of Biden's oil leasing pause.
- The oil industry paid lavish bonuses to executives who presided over a surge in corporate bankruptcies. Public Citizen analyzed the 25 largest U.S. oil and gas bankruptcy cases from 2018 to 2020, finding that 76 executives from these companies received a total of nearly \$200 million in cash bonuses, retention payments, and severance. Fossil fuel executives are getting these exorbitant payouts regardless of whether they lead their companies to success or failure. Meanwhile, workers lose jobs, shareholders lose money, and taxpayers may wind up footing the bill for environmental cleanup.
- Even under Biden, the dirty energy industry has been able to keep on drilling on public lands at a rapid pace. While the oil industry has attempted to link high gasoline prices to Biden's public lands policies, federal data shows that the Biden administration has been unable to make a major dent in the Trump administration's



Graphic courtesy of James Yang.



Graphic courtesy of Zach Stone.

oil binge. The federal Bureau of Land Management, which leases public lands to oil and gas drilling companies, has approved an average of about 333 drilling permits per month from February 2021 through November, higher than three out of four years of the Trump era.

Fighting Corporate Crime

In early 2021, Public Citizen research revealed that Trump's final year in office marked a quarter-century low in corporate crime enforcement — and urged the Biden administration to adopt policies to reverse the trend and hold corporate criminals accountable. Subsequently, Biden administration appointees reversed some of the Trump administration's worst soft-on-corporate-crime policies and adopted a tougher stance against corporate wrongdoers.

Announcing a strengthened U.S. Department of Justice (DOJ) focus on corporate crime, Deputy Attorney General Lisa Monaco shared internal DOJ findings that nearly one in five cases the department brings against a corporation is against a big repeat offender company — findings which echo Public Citizen's own research. Similarly, Federal Trade Commission Chair Lina Khan cited Public Citizen research into corporate repeat offenders when announcing her agency's new criminal enforcement initiative against corporations that violate consumer protection and antitrust law.

Public Citizen will continue to track federal enforcement activities against corporate crime to ensure that big businesses and responsible executives are held accountable when they break the law.

Public Citizen's research found that:

- The number of federal prosecutions of corporate criminals plummeted to a new low of just 94 in fiscal year 2020, according to data released by the U.S. Sentencing Commission, a decline of 20% from 118 in 2019. This decline means that only 94 corporations either pled or were found guilty of crimes, down by two thirds from the peak of 296 corporate prosecutions in 2000 and the lowest on record since the U.S. Sentencing Commission started releasing corporate prosecution statistics in 1996. The year-over-year decline in corporate criminal prosecutions is greater than the 15% pandemic year decline in federal criminal cases overall.
- Jeffrey Bossert Clark, the ex-BP oil spill defense attorney who became the DOJ's environmental enforcement chief under Trump and, later, a key figure in efforts to overturn the 2020 election, took soft-on-corporate-crime policy to the extreme. Before Biden's inauguration, Clark attempted to lock in a policy memo that would have permanently hobbled enforcement against environmental crimes. Biden's DOJ rescinded the memo.
- Twenty big corporations that resolved criminal investigations through DOJ leniency agreements merit close scrutiny from prosecutors under new Biden administration policies. Public Citizen sent a letter to Attorney General Merrick Garland with the list of corporations to be scrutinized. The first corporation on Public Citizen's list, Monsanto, was subsequently prosecuted for breaching its agreement with DOJ. ■

GLOBALIZATION & TRADE



Protesters arranged body bags outside the White House during a protest on July 15 calling on German Chancellor Angela Merkel to stop blocking an emergency waiver of intellectual property rules needed to increase global production of COVID-19 vaccines. Photo courtesy of AP Images for Citizen Trade Campaign.

The Global Trade Watch (GTW) division of Public Citizen spent most of 2021 fighting World Trade Organization (WTO) rules that artificially restrict the availability of vaccines and treatments around the world. GTW has been rallying support for an emergency COVID-19 waiver of WTO Trade-Related Aspects of Intellectual Property (TRIPS) rules that require countries to guarantee pharmaceutical firms monopoly control of how much medicine is made and where it is sold. The waiver would make clear that WTO rules do not stand in the way of governments and manufacturers worldwide ramping up production of the COVID-19 vaccines, treatments, and tests necessary stop the rise of variants like Omicron and finally end the coronavirus pandemic.

In a shift that made headlines worldwide and changed the dynamic of the global effort, on May 5, 2021 President Joe Biden announced support for a WTO waiver for COVID-19 vaccines. But eight months later, the waiver is still not enacted, and GTW is pushing for Biden to lead to deliver it.

Some highlights of the "TRIPS Waiver" campaign include:

- Through public education and outreach to Congress, we helped get the majority of U.S. House of Representatives Democrats to support the waiver and urge Biden to do so.
- We organized several press conferences with U.S. Sen. Bernie Sanders (I-Vt.), Sen. Tammy Baldwin (D-Wis.), Rep. Jan Schakowsky (D-Ill.), Rep. Rosa DeLauro (D-Conn.), Rep. Earl Blumenauer (D-Ore.), Rep. Jesús "Chuy" Garcia (D-Ill.), and other representatives and dozens of organizational leaders.
- We had our staff or materials quoted in The New York Times, The Washington Post, The Wall Street Journal, The Los Angeles Times, USA Today, Bloomberg, The Associated Press, Reuters, and other outlets, in addition to appearances on Democracy Now! and the Thom Hartmann show.
- Together with Avaaz, Oxfam, and 40 other allied organizations, we secured 3 million petition signatures demanding a comprehensive TRIPS waiver.
- We helped spotlight dozens of global protests for the waiver with an activist website where people could find events near them and press could see our global movement.
- We created a series of new fact sheets explaining how the waiver could make a difference and debunking Big Pharma myths about it.
- We produced dozens of podcast episodes and videos as well as hundreds of graphics and social media posts to educate the public.

Some other achievements in 2021:

- We earned major newspaper coverage for our report detailing the disproportionate damage to Black and Latino workers from corporate-rigged U.S. trade policies.
- We helped raise awareness of Big Tech's attempts to push so-called "digital trade" proposals that have little to do with trade, but instead create binding international rules to limit governments worldwide from regulating online platforms in the interest of workers, consumers, or smaller business competitors.
- We joined the AFL-CIO, SEIU, and independent Mexican union SNITIS in filing the first complaint under the new NAFTA's Rapid Response Mechanism for violations of workers' rights.

A Message from Lori Wallach

Twenty-five years ago, with your help, I created Global Trade Watch to fight against the corporate rigging of "trade" policies. Together, we created a new movement and we have so much to be proud of. Thanks to inspiring policymaker, labor, civil society, thought leader and activist partners with whom GTW has had

the honor of working in the U.S. and around the world, we avoided the damage of U.S. entry into the Trans-Pacific Partnership (TPP), as well as WTO expansion, the hemisphere-wide Free Trade Area of the Americas spread of NAFTA, the Multilateral Agreement on Investment, many years of Fast Track, and so much more.

Even better, we are beginning to turn this ship around, gutting special multinational corporate rights ("investor-state dispute settlement" or ISDS) and new Big Pharma monopoly rights in the revised NAFTA, and strengthening labor rights and enforcement. There is much more to come, where we can build a better world instead of just stopping the bad stuff! We have achieved so much together. Thank you!

It is bittersweet to announce that, after 30 amazing years at Public Citizen, I will continue the "trade" work that I love and to which I remain committed — in a different role. Instead of managing a big team, I will focus on high-level advocacy, analysis, writing, and press work on the next generation of trade fights as director of the ReThink Trade program at the American Economic Liberties Project.

And the work continues. Public Citizen is committed to preserving Global Trade Watch as an important institution that supports the work of many here and around the world. Working together for decades, we have created today's unique window of opportunity to generate new rules for the global economy and trade that put people and the planet first — and to remove the myriad non-trade corporate protections and public interest policy constraints imposed by our "trade" policies.



ENERGY & CLIMATE

Climate change threatens to swamp the global and U.S. economies with increased burdens on health and infrastructure, disruption of agriculture and industry, violence and political destabilization, and a cascade of acute crises, presenting innumerable threats to financial stability. Big banks, insurers and financial firms are actually making the problem worse, however, by providing a financial pipeline for Dirty Energy projects.

Over the past year, Public Citizen, with coalition partners, has taken a lead role in developing and advocating a broad, ambitious agenda to use the tools of financial regulation to move money away from dirty energy and toward investments in equitable, clean energy. We are working to incorporate climate considerations into market rules, including in disclosures for investors, fiduciary duties, credit ratings, claims that products or services are "green," and more, with the primary effect of empowering investors to avoid climate-related risk and vote their dollars.

Putting the Spotlight on Insurance Companies

At the beginning of 2021, we launched a campaign to hold insurance giant American International Group (AIG) accountable for its role in enabling the climate crisis. AIG is a multinational insurer that helped cause the 2008 financial crisis with risky bets on subprime mortgage loans. The company has been engaging once again in risky business: funding and insuring climate chaos.

As we pointed out, insurance companies are fueling climate change. AIG and other insurers provide coverage to fossil fuel companies, enabling continued coal, oil, and gas production. Additionally, AIG invests billions into fossil fuels: at least \$26.8 billion as of 2017. Activists across the globe added their voices to our calls for AIG to end insurance for, and investments in, fossil fuels. We staged a protest outside of AIG headquarters during the company's Annual General Meeting in May, and we engaged AIG's sustainability director in an ongoing dialogue, producing an analysis that exposed the greenwashing in the company's first ever Environmental, Social, and Governance report.

In August, we partnered with activists in Scotland to highlight climate at the AIG Women's Open, an international golf tournament. In addition to posters and banners calling on AIG to end its support for fossil fuels, we posted digital ads to tournament attendees, including high-level AIG employees.

Our work targeting AIG culminated in a December protest at AIG's headquarters to focus attention on the company's role in insuring coal. Over 35 insurers globally have restricted the support they provide to coal companies, but AIG has taken no steps to decrease coal cover, despite warnings from UN climate scientists and energy policy experts. Activists reimagined AIG President and CEO Peter Zaffino as the Grinch, while Cindy-Lou Who delivered over 25,000 petition signatures to him.

Public Citizen also worked with an international coalition to fight the Trans Mountain Pipeline, which transports tar sands oil from Alberta, Canada to the Salish Sea on the Pacific Northwest coast. The pipeline is currently under construction and crosses unceded Indigenous lands. The plan to expand its capacity would add 71,100,000 metric tons of carbon pollution annually, so we worked with frontline communities and allies to secure five new commitments from insurers not to insure the existing pipeline and its expansion. AIG refused to publicly rule out insurance support for the project, so we will continue to pressure the company.

Financial Regulators Acting on Climate Risk

Throughout the year, our advocates engaged with financial regulators across federal agencies to provide policy recommendations and guidance on climate action. The financial industry currently bankrolls climate change, with large banks and asset managers investing billions in fossil

fuel projects — even though climate-related risks increasingly threaten the stability of individual financial institutions and the financial system. Damage from increasingly frequent and intense weather events becomes more expensive each year, and many loans to fossil fuel companies will never be paid off in a world safe for humanity. Fossil fuel loans are the new toxic assets that Wall Street is spreading throughout the financial system.

With partner Americans for Financial Reform, we issued a climate finance roadmap for regulators laying out the policies they should pursue. This roadmap is by far the most comprehensive policy manual on climate-finreg. We also briefed more than 20 congressional offices interested in financial services and climate issues.

Public Citizen played a main role in coordinating the activist community's response to the Securities and Exchange Commission's (SEC) Request for Information on climate risk disclosure. We hosted six lis-

tening sessions with experts, provided a database of resources, and offered sample comments for activists and organizations to submit. The SEC can require public companies, including big banks and asset managers, to disclose their climate-related risks and their climate pollution the public and their shareholders. We recruited 59 organizations and over 3,400 activists to submit comments in favor of strong disclosure requirements.

After we advocated for banking regulators to issue supervisory guidance on climate-related risks, and issued detailed recommendations on the subject, the national bank regulator (the Office of the Comptroller of the Currency) issued a strong proposed guidance in December. We are advocating to improve the proposal before it is finalized and pushing other banking regulators to join it.

With U.S. Reps. Mondaire Jones (D-N.Y.), Rashida Tlaib (D-Mich.), and Ayanna Pressley (D-Mass.), we helped author and have introduced the Fossil Free Finance Act in September. Our advocates recruited 15 additional cosponsors in the U.S. House of Representatives. Sens. Jeff Merkley (D-Ore.) and Ed Markey (D-Mass.) then introduced a companion bill in the Senate in November.

The legislation requires big banks and financial institutions to write and follow plans align their financing with science-based climate targets under the supervision of the Federal Reserve. Before introducing the bill, we sent a letter with over 60

partner organizations to Federal Reserve Chair Jerome Powell asking that he take strong action to protect our financial system from climate-related risks.

We also worked to advance climate-related insurance regulation in the states. In Connecticut, we drafted, advised on, and supported a landmark bill that orders the state insurance regulator to require insurers to align their investments and underwriting with science-based climate targets. The bill passed in June.

We are now working with Connecticut groups to implement it. In New York, we worked with 20 local organizations to ask the New York Department of Financial Services (NYDFS) to improve guidance for insurers on managing and reducing climate risk. Our advocates also met with staff at the department to engage them in dialogue and detail our recommendations. The guidance, released in November, was heavily influenced by our policy suggestions. NYDFS became the first regulator in the nation to recommend that insurance companies decrease their support for fossil fuels to protect their own industry, which is financially vulnerable to natural disasters.

Along with partner organizations, we also influenced the creation and execution of the Executive Order on Climate Related Financial Risk, which President Joe Biden issued in May. The president directed the U.S. Department of the Treasury to issue a report on climate-related financial risk, which we worked to influence and strengthen.



In October, Public Citizen and other groups delivered more than 40,000 petition signatures to U.S. Treasury Secretary Janet Yellen demanding climate action. Photo courtesy of Elise Peterson-Trujillo.

TEXAS

Public Citizen's Texas office had a busy and productive year in 2021, notching victories in the battle to hold polluters accountable, protect utility ratepayers, and mitigate the damage that climate change inflicts on communities.

Houston

In October, after months of pressure from Public Citizen and other Houston-area environmental advocates, the Port Commission of the Port of Houston Authority agreed to take an important step toward reducing pollution from a \$1.1 billion project to widen and deepen the Houston Ship Channel. The massive dredging project, scheduled to break ground in March 2022, now includes air quality as one of its scoring mechanisms for contract proposals. Public Citizen led the push to convince port officials to prioritize clean, low-emission equipment to help protect neighboring communities.

Stephanie Thomas, Public Citizen's researcher and organizer in Houston, said Port Houston's willingness to make the change was a major breakthrough in ongoing efforts to stem pollution around the Ship Channel.

"Port Houston took an important first step to reduce the environmental impact," Thomas said. "This new approach of considering pollution during the bidding process should extend beyond this project and into

all future requests for proposals as the Port evaluates contractors who use heavy-duty equipment as part of their work."

Austin

In Austin, Public Citizen celebrated the city council's near-unanimous (10-1) vote to approve the new Austin Climate Equity Plan, which puts the city on a more ambitious path to curbing climate warming emissions and firmly establishes the city as a national leader in battling the climate crisis. The plan sets a new goal of reducing local climate pollution to net-zero by 2040, with a strong emphasis on cutting emissions by 2030. The plan also puts equity at the center of climate action in

Austin to ensure that all residents — especially those most likely to be harmed by the climate crisis — have a role in implementing the plan.

Kaiba White, energy policy and outreach specialist for Public Citizen's Texas office, said the ambitious new goals for reducing emissions are a victory for Austin residents and the planet. Public Citizen will closely monitor implementation of the Austin Climate Equity Plan in 2022.

"The plan's vision will only become reality if city leaders, businesses, and individuals can work together to implement it. Budgets, policies, programs, practices, and habits must change to reflect the dire state of the climate crisis, and we must be willing to listen to those who have been ignored or discriminated against in the past."

Dallas

In Dallas, Public Citizen was instrumental in convincing the city council in September to approve nearly \$4 million to begin implementing the Comprehensive Environmental & Climate Action Plan the city adopted — also with Public Citizen's encouragement — in 2020.

"The Dallas City Council's decision to invest almost \$4 million in air monitors, rooftop solar, bike lanes, urban agriculture, and weatherization programs is great news for Dallas residents and our ailing climate,"

said Adrian Shelley, director of Public Citizen's Texas office. "But the city can and should do more."

San Antonio

In San Antonio, Public Citizen also was instrumental in establishing a new rate advisory committee that will advise city-owned utility, CPS Energy, on how best to protect ratepayers. The committee, which began meeting in January, is comprised of 21 members, including 10 people appointed by the CPS Energy board members and 11 appointed by City Council. The group's creation was the result of advocacy by DeeDee Belmares, Public Citizen's climate justice organizer in San Antonio, in cooperation with Mayor Ron Nirenberg, who supported efforts to push CPS Energy for more transparency in its governance.

Texas Legislature

The Republican-dominated Texas Legislature is typically difficult to persuade when it comes to protecting public health and the environment from the oil and gas industry and related climate change dangers. But after Winter Storm Uri left thousands of Texans freezing in the dark during a multi-day electricity blackout in February, Public Citizen's Texas office and other advocates convinced the legislature to take at least modest action. Shelley worked with Texas Sen. Donna Howard (D-Austin) on

the specific language of a bill that would force consideration of climate crisis implications in Texas when planning for the state's electricity grid. After the bill stalled, Public Citizen successfully lobbied the legislature — especially members of the relevant committees — to attach the amendment to a larger grid resilience bill during the final days of the legislative session in May.

The new law directs the newly created Texas Reliability Council to take into consideration the projections of the Texas State Climatologist when planning for the resiliency of the grid and its fuel supply. Specifically, the law says regulators should "take into consideration predictions on severity of future weather

winter Storm Uri courtesy of Shutterstock.

Says regulators should "take into consideration predictions on severity of future weather events over the next 15 years produced by the state climatologist." The climatologist's predictions about the likelihood of extreme weather during the next 15 years must also be considered by gas supply chain facility operators, electric cooperatives, municipally-owned utilities, and transmission and distribution utilities" to "maintain service quality and reliability during a weather emergency."

"I appreciate advocates like Public Citizen, who provided valuable suggestions throughout the legislative session," Howard said in a statement after the new law was adopted.

Thanks in part to the efforts of Public Citizen and our allies, the final version of a broad energy policy bill, which mostly protected the status quo of oil and gas in the state, was stripped of language that would unfairly impose new costs on clean energy. Specifically, the bill would have forced wind and solar farms to pay for services to ensure the flow of power on the grid remained consistent.

As we've said many times, wind and solar energy — a linchpin of the new Texas energy economy — should not be a partisan issue. A majority of Texas lawmakers, including some Republicans whose districts have benefited from thousands of new clean energy jobs, agreed in this case. They opposed efforts to lay the burden of these additional costs onto wind and solar power producers.



Photo of Austin, Texas, covered in snow during Winter Storm Uri courtesy of Shutterstock.

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"Public Citizen uses whatever investments we are able to make in its work to address some of our country's and the world's most pressing problems, especially preserving democracy in the face of very real threats."

-William Richter, Manhattan, Kan.



Dual Agents, from page 1

Many consulting firms that have worked for both regulated and unregulated entities claim to have established "firewalls" that block the flow of information between people working for the different entities. These firewall policies, however, are rarely, if ever, shared with the public, so the public has no

means to confirm the existence or the effectiveness of these systems.

Despite rampant and blatant evidence that candidates have worked in cahoots with super PACs, the FEC has not taken a single enforcement action for illegal coordination since *Citizens United* was upheld. The Freedom to Vote Act, a proposal pending in the U.S. Senate to protect voting rights in the United

States, would take several steps to prevent coordination between regulated and unregulated entities.

The bill would define cases in which vendors work for candidates and super PACs on the same contests as coordinated activities and, therefore, subject to normal campaign finance limits and restrictions. It would not offer exceptions to firms claiming to have segregated

their work with "firewalls."

"The activities of these common vendors underscore what a mockery *Citizens Unite*d has made of our campaign finance system," said Lisa Gilbert, executive vice president of Public Citizen. "We need to pass the Freedom to Vote Act to stop consultants from acting as coordinators between candidates and super PACs."

▶ FDA, from page 1

gency department setting. Public Citizen also asked the FDA to take similar harsh action against the HCMC institutional review board (IRB) for violating federal human subjects protection regulations by approving these trials without ensuring that informed consent requirements for such experiments were implemented.

Failure to take stronger compliance actions would send a signal to the research community and the public that the FDA is not serious about protecting the rights and welfare of human subjects, Public Citizen said in its petition to the agency.

"The pattern of repetitive egregious violations by the HCMC researchers and IRB over a four-year period that was thoroughly documented by the FDA demand the most serious punishment to hold those responsible accountable and to deter similar serious noncompliance by others," said Dr. Michael Carome, director of Public Citizen's Health Research Group. "A slap-on-the-wrist approach

for violations that significantly endangered the health and safety of human subjects and violated their rights will not suffice."

In July 2018, Public Citizen, alongside 64 doctors, bioethicists, and academics, submitted a complaint letter to the FDA, which prompted the agency in August 2018 to conduct an inspection of the HCMC IRB's records related to the review and approval of Cole and Klein's clinical trials.

Then, in April 2019, the agency inspectors examined Cole and Klein's research records for these trials. Serious regulatory violations observed during these inspections were detailed in FDA inspection reports and in subsequent warning letters that the agency sent to Cole and Klein in last May.

Findings described in FDA inspection documents and warning letters affirmed the allegations detailed in Public Citizen's July 2018 complaint letter to the FDA. The FDA found that both Klein and Cole had conducted their clinical trials without having submitted an investigational new drug application (IND) to the agency. An IND

is a detailed written request to the FDA to obtain authorization from the agency to administer experimental drugs to humans in a clinical trial.

The FDA's warning letters found that both Cole and Klein each had previously submitted INDs to the FDA to conduct clinical trials that were "substantially similar" to the trials of the same experimental drugs that they subsequently conducted.

However, the submitted INDs had been withdrawn (in the case of Cole) or placed on hold (in the case of Klein) because of serious deficiencies that posed unacceptable risks of harm to patients eligible to enroll in the proposed trials.

Shockingly, according to the FDA, both Cole and Klein then proceeded to repeatedly conduct substantially similar clinical trials testing the same experimental drugs without submitting an IND and without addressing the FDA-identified deficiencies that posed unacceptable risks to subjects.

Additionally, the FDA found that both researchers and the HCMC IRB failed to comply with FDA regulations requiring informed consent for clinical trials.

FDA inspectors also cited the HCMC IRB for failing to ensure that additional safeguards were implemented in the four trials to protect subjects considered to be vulnerable to coercion or undue influence.

"There is clear evidence that Cole and Klein deliberately sought to circumvent the FDA's IND and informed consent requirements for clinical trials," said Carome. "The case for the FDA disqualifying them and the HCMC IRB is overwhelming."

Public Citizen urged the FDA to promptly initiate clinical-investigator disqualification proceedings against Cole, Klein, and the HCMC IRB.

Under these disqualifications, Cole and Klein would be prohibited from conducting clinical trials testing experimental drugs or devices for a specified period of time.

Likewise, disqualification of the HCMC IRB would effectively make it ineligible to review such FDA-regulated clinical trials.

"Having spoken truth to power for 50 years, Public Citizen has been a critical vanguard for democracy on countless health, safety, and consumer issues."





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