New FDA Head Led Flawed Clinical Trial

The blood thinner Xarelto may be familiar to Americans from television commercials featuring comedian Kevin Nealon and golfer Arnold Palmer. The drug has generated billions of dollars of sales for Johnson & Johnson and Bayer, which makes and markets Xarelto.

Xarelto was approved by the Food and Drug Administration (FDA) in 2011 to prevent blood clots and strokes in patients with atrial fibrillation, a condition that involves the irregular beating of the heart. But evidence uncovered by POGO indicates that a clinical trial for the multi-billion dollar drug was problematic and potentially fatally flawed.

Last year, POGO discovered that an FDA staff review found the clinical trial for Xarelto, called ROCKET AF, was biased in favor of the experimental drug. At the time, a senior FDA official wrote that a “lack of care” in ROCKET AF’s design and execution might have led to avoidable strokes among test subjects. The trial involved more than 14,000 patients in 45 countries over several years.

Later, POGO exclusively reported that ROCKET AF suffered from another, potentially crippling flaw: it relied on a blood-testing device with a history of malfunctioning and delivering false results. Records show that the Xarelto trial used “INRatio” blood-testing devices and that the reliability of those devices was the subject of two FDA warning letters before the trial began in late 2006. In 2014, four years after the trial ended, a recall notice warned that certain INRatio devices could deliver false test results and that use of those devices may “cause severe or life-threatening injuries, including death.”

The executive committee of the clinical trial was co-chaired by Dr. Robert Califf, the recently-confirmed head of the FDA who, at the time, was the director of the Duke Clinical Research Institute.

Given POGO’s investigations detailing Dr. Califf’s problematic oversight of the Xarelto trial, POGO Executive Director Danielle Brian said, “We are concerned about his strong ties to the pharmaceutical industry and question his ability to act independently and in the public interest.”

She noted that during his confirmation hearings, Dr. Califf pledged to keep the agency’s distance from the pharmaceutical industry. But, she said, it’s important for POGO and other groups to “carefully monitor the FDA to ensure that he keeps that pledge and that the agency puts the health and concerns of the American people ahead of the bottom lines of the drug industry.”

POGO publicly praised Senators Kelly Ayotte (R-NH), Richard Blumenthal (D-CT), Joe Manchin (D-WV), Ed Markey (D-MA), and Bernie Sanders (I-VT) for opposing Dr. Califf’s nomination.
Dear Friend,

You may have heard that the highly regarded Center for Effective Government (formerly called OMB Watch) is integrating most of its operations into POGO.

We are saddened to see this great organization close its doors after 33 years, and I’d like to recognize the stellar work and dedication of CEG’s staff, interns, partners, and allies from over the years. We’re honored and excited that they chose us to build on what they have been doing for more than three decades: strengthening democracy by connecting national policy debates with the concerns of everyday Americans.

But what does this mean exactly?

It means that POGO is scaling up its commitment to fighting the undue influence of special interests in between elections. As you know, there are a lot of groups working to fix the problem of money in politics, but we will be redoubling our efforts to fix the problem of money in policy.

After elections, the money spigot doesn’t turn off once the ballots are in and the people are home listening to the politicians’ acceptance speeches. Billions of dollars are spent each year by powerful special interests in order to gain access to decision-makers in government in an attempt to influence their policies. One of the most vulnerable places they exert this pressure—too often outside the view of the public—is on the rulemaking process at government agencies.

Just because a law is passed doesn’t mean it’s going to be carried out effectively or as intended by legislators. Often, it’s up to the various federal agencies to interpret the law and write rules for its implementation. During that process, it’s too easy for a good law to become twisted into something that’s more beneficial for special interests than American taxpayers.

This undue influence is a threat to democracy and effective government. We look forward to building upon CEG’s work to tackle this issue, and I’m grateful to its Board of Directors for entrusting POGO to carry on that legacy.

Sincerely,

Danielle Brian
Executive Director
Pentagon’s 2017 Budget is Mardi Gras for Defense Contractors

Mardi Gras is an occasion for gluttony, masks, and general revelry. In February, the Pentagon celebrated Fat Tuesday with the release of its fiscal year 2017 budget request, tossing out a variety of goodies for defense contractors.

Overall, the Pentagon requested $582.7 billion—a $2.4 billion increase over last year. The request includes $58.8 billion for a “war spending” account named the overseas contingency operations (OCO) account, which is often used as a slush fund for a myriad of programs that have little to nothing to do with America’s wars. The proposed budget continues a trend of Pentagon spending well above historical norms, with our total national security spending for next year near reaching a whopping $1.1 trillion.

There is some good news in the proposed defense budget. For one, the Air Force has issued a temporary stay on its campaign to retire the A-10, admitting that it is too useful against Syria and the Islamic State to mothball just yet. The Pentagon is also proposing to cut one ship from the Littoral Combat Ship (LCS) program—whose many problems have been documented by POGO over the years—saving taxpayers $206 million.

As for the bad news, the budget includes $46 million for the Army blimp made infamous when it broke loose this past fall and sailed over the fields of Pennsylvania. POGO has documented the program’s numerous deficiencies, but it’s unclear what it will take to actually kill this wasteful program.

The $1.4 trillion F-35 program continues to experience significant problems, performing worse than the legacy aircraft it is supposed to replace. The Pentagon’s testing office recently released the most damning report to date (POGO’s analysis of the report was widely reported). Instead of slowing down production, the Pentagon is asking Congress to fund an additional 63 F-35 planes at an astonishing $10.1 billion. Fortunately, the Pentagon did not include a proposal for a block buy of the aircraft in its budget request, and the Air Force deferred purchasing five of the planes this year.

It should be noted that it’s not uncommon to see a spending spree at the end of an administration, but it doesn’t make it any less disappointing for taxpayers when it happens.

Meet the New Comms Director

Since December, there’s been a new Communications sheriff in POGO town. Ari Goldberg came to POGO following more than a decade of experience inside the Beltway. On Capitol Hill, Ari was Representative Jerry Nadler’s Press Secretary and a Journalism Fellow for then-Representative Howard Berman. Off the Hill, Ari was the head of media relations for Radio Free Europe, the American Israel Public Affairs Committee, and, most recently, the ONE Campaign (the global anti-poverty group founded by U2 frontman Bono). Ari has written more than two dozen op-eds on foreign policy, global development, and US politics.

Ari is a native of El Paso, Texas, and studied journalism at the University of Texas at Austin. He also holds a Master’s in Hebrew Literature from Cambridge University, where he heroically captained its fledgling baseball team in a place where cricket reigns supreme. These days, Ari has little time for extracurricular activities as he spends most of his free time playing with (and refereeing) his five (!) children.
Are Taxpayers Getting Fleeced by Companies Drilling and Mining on Public Lands?

In January, American taxpayers won a small victory when the Interior Department announced plans to temporarily halt new coal leases on federal land while it undertakes an in-depth review of the coal leasing program for the first time in 30 years.

According to POGO Executive Director Danielle Brian, it’s a review that’s long overdue.

“Public lands belong to the American people and they deserve a fair share of coal revenue from these areas,” she said. “They also have a right to know how the federal coal program is administered, which has been far too opaque for far too long.”

POGO reported in 2015 that loopholes in the federal coal leasing program mean that taxpayers could be missing out on millions of dollars in potential revenue each year. POGO had called on the Interior Department to modernize its regulations to ensure taxpayers get their fair share.

Following the Interior Department’s January announcement, POGO and Taxpayers for Common Sense brought together a panel of natural resource revenue experts in a roundtable public discussion at the Carnegie Institute for Science in Washington, DC. Ali Zaidi, Associate Director for Natural Resources, Energy, and Science Programs at the Office of Management and Budget, gave the keynote address.

“If you care about the federal taxpayer, there is strong evidence we’re undercharging [for natural resources extracted from public lands],” Zaidi said.

“The regulations and administrative process that govern the leasing of coal, for example, were put in place in the 1970s and 80s,” he said. “Since then, the whole American energy landscape has changed and we haven’t caught up. Given this backdrop, [Interior] Secretary Sally Jewell announced that we’re undertaking a comprehensive review of the federal coal program and pausing new leases. There’s a lack of true competition when we make federal coal leases and that’s a big deal since [the federal government] is responsible for 40 percent of coal produced in the US.”

Dan Bucks, former Director of Revenue for the State of Montana, said “the real problem is secrecy.”

“Royalties from public lands are underpaid and undervalued. The public has no idea what the value is of the [resources] they own. Secrecy has never served the American people well,” he added, citing examples from what he said are 95 years-worth of underpaid and undervalued royalties.

POGO’s work to increase transparency around federal natural resource management is ongoing.

In December, POGO celebrated the release of a groundbreaking report that gives Americans access to data that documents how much individual companies pay to extract natural resources from public lands, as well as a more accurate picture of job creation and economic impact in states with the most drilling and mining activity. The report was released by the U.S. Extractive Industries Transparency Initiative (USEITI), a federal advisory committee comprised of industry, government, and civil society representatives. Brian serves as chair of the civil society sector, representing the interests of taxpayers, labor unions, environmental organizations, tribal communities, academics, and other non-governmental stakeholders.

According to Ryan Alexander, the head of Taxpayers for Common Sense, greater transparency about natural resource revenues is clearly in the public interest.

“Who doesn’t have an interest in transparency?” she asked. Answering her own question, Alexander said, “The companies who’ve learned to game the system.”
This is a story about the biggest, baddest earmark of all time.

It all began with good intentions. Back in 2000, the US and Russia agreed to dispose of 34 metric tons of plutonium. The US decided to build a facility to convert the weapons-grade material into fuel for commercial nuclear reactors. The plant, located in South Carolina, was called the Mixed Oxide Fuel Fabrication Facility (MOX), and was expected to be completed within three years and cost $1.6 billion.

Fast forward to today and the facility still has not been finished. The Department of Energy has sunk $4.5 billion into construction alone and estimates for finishing the job range between $25 billion and a staggering $114 billion. Not only is the project more than one-thousand percent over cost and years behind schedule, the MOX facility lacks even a single US utility customer for its commercial reactor fuel.

It is the very definition of a boondoggle.

As former Chairman and Ranking Member of the House Appropriations Energy and Water Subcommittee, and as a conservative, it was my duty to spend taxpayer dollars on projects that move our country forward. I worked to advance defense research and development at Wright-Patterson Air Force Base and improve management practices at the Department of Energy.

But when I raised concerns about the MOX facility during hearings a dozen years ago and tried to stop the project, I was met with resistance by the Energy Department, the Bush Administration, and many of my fellow Republicans. They told me canceling the project would hurt then-South Carolina Governor Mark Sanford’s chances of being reelected, and would damage our relations with Russia.

Thirteen years later, everything I was afraid of happening is now unfolding. The project was never about good policy—just politics.

My biggest regret from my time in Congress is not finding a way to thwart the project.

Beyond the exorbitant price tag, the MOX facility also suffers from alarming safety and security problems, according to watchdog groups like the Project On Government Oversight and Taxpayers for Common Sense.

They discovered, for example, that the contractor in charge of the project was granted an exemption from an important security standard before construction of the facility began. Places like MOX must be able to verify the location of all special nuclear materials within 72 hours. The logic is straightforward: if a terrorist claims to have stolen nuclear material from a facility like MOX, it is essential to be able to verify or disprove such a claim as soon as possible.

Instead of 72 hours, the MOX contractor estimates it could take 180 days (!) to physically verify the presence of all nuclear materials—60 times the safety requirement.

It should be acknowledged that the US can continue to uphold its agreement with Russia without the MOX facility. The Department of Energy has identified several alternative strategies to dispose of the plutonium that have been independently verified to be more cost effective, timely, and safer. We also should question the current status of our relationship with Russia, and the progress being made on their side of the plutonium disposal agreement.

Now that my party is in control of both chambers of Congress, we should demonstrate to the American people that we are, in fact, champions of fiscal restraint and willing to cut wasteful spending.

I implore my successors in Congress to put an end to the wasteful MOX facility once and for all.

David Hobson is a former Republican Representative from Ohio and former Chairman and Ranking Member of the House Appropriations Energy and Water Subcommittee.
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