THE WEB OF CONFLICT

January 17, 2019

Abstract

What has evolved, especially as it relates to the horrific ramifications of the opioid crisis, is the undisputed control of corporate America, and for purposes of this paper, the opioid supply chain. It's everywhere, in powerful lobbies like PhRMA, in non-profits and foundations, in our government agencies staffed with ex-corporate executives, and in PACs and private interest groups. It's protected by Bills and Acts of Congress being passed without proper vetting and public knowledge. Big business runs the entire political infrastructure and "Big Money" is the weapon of choice to keep everyone in line. This paper summarizes the issues and introduces some key questions we, a united coalition of advocacies need to address.

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Table of Contents

The WEB of CONFLICT

INTRODUCTION

Most people agree that the opioid crisis as we know it started around 1996 with the approval and subsequent distribution of massive quantities of Purdue Pharma's powerful opioid painkiller OxyContin. Today, nearly 500K are dead from overdoses and over two million either actively fighting substance use or in recovery. And with overdose deaths steadily increasing, there's little evidence the opioid epidemic will be ending anytime soon. *The question is why, and can we stop the spread of this incomprehensible disease?*

The cynical view of why is to follow the money and its source because the biggest source usually translates to the most power and influence. Our elected, and some say purchased, political representatives fight it out to control lawmaking, policy and the direction of the agencies ostensibly created as the protectors of our health, safety and well-being. The agencies may halfheartedly argue on behalf of the public but generally capitulate to the demands of political power.

But what has evolved, especially as it relates to the horrific ramifications of the opioid crisis, is the undisputed control of corporate America, and for purposes of this paper, the opioid supply chain. It's everywhere, in powerful lobbys like PhRMA, in non-profits and foundations, in our government agencies staffed with ex-corporate executives, and in PACs and private interest groups. It's protected by Bills and Acts of Congress being passed without proper vetting and public knowledge. Big business runs the entire political infrastructure and "Big Money" is the weapon of choice to keep everyone in line.

These words are not intended as an accusation, there are many within our elected officials who enter office with the full intent to push the necessary changes to enable our country to emerge from this devastating man-made epidemic. Unfortunately, many either become mired in the politics of big business and back door deal-making or are drummed out of office through the dedicated efforts of Pharma money and calculated last minute negative campaigning. But compared to years past when Purdue Pharma and the Sackler's set the stage for rampant distribution of painkillers, progress is being made.

In fact, one of the first initiatives undertaken by the newly sitting House of Representatives was to introduce the **For the People Act**, a bill with solid provisions meant to enforce campaign finance transparency and minimize the influence of big money donors. This bill, if passed, could help end the confusion surrounding many of the contradictory and legal machinations of other finance campaign reform and countermeasures.

This is a bill that requires immediate response on a national level to ensure as much support as possible. Those loyal to the current status quo will fight this bill and without the public's support it is conceivable it will become either bogged down in controversy or watered down in bipartisan rhetoric. This bill is extremely important to ending the political influences contributing to the opioid crisis.

FOLLOW the MONEY

Follow the money and find its source and eventually the real influence position will be exposed and disabled.

Dark Money

The term dark money, or as it is sometimes referred to as blood money, is the primary tool of choice that enables donors to ensure the pharmaceutical industry thrives and controls all aspects of the drug industry. It continues to permeate all aspects of public policy and is a huge obstacle to ending the opioid crisis. We find donors hidden in literally all aspects of lobby activities, non-profits and foundations, PACS and special interest groups. OpenSecrets.org refers to it as the **Influence Industry**, an appropriate term for the flow of money and machinations that control our futures.

But more often than not, WE, the public, are unaware of all these machinations going on right under our noses, right smack in the middle of the opioid crisis. The info is all there, if you have the time and tenacity to find it. But why should we have to do the research, identify the issues, outline the dangers and fight for our own supposed rights of citizenship? Where are our protectors, the guardians of our most precious asset, our people? The backbone of our democracy is to rely on our elected representatives to keep on top of issues that can directly hurt our health and well-being. Somewhere along the line we got lost in the bigger picture of corporate greed, funding expectations and back room deals. We are losing the battle to protect our legacy and it's not getting better, it's getting worse

2010 Citizens United Ruling

A seminal event that gave corporations a clear path to campaign and subsequent public policy domination was the Supreme Court ruling in 2010 in which justices voted 5-4 to reject corporate spending limits in support of political influence. Basically, the court held that *corporations* had the same rights as individuals to the protections of the free speech principal found in the First Amendment and therefore the government had no right to regulate political speech. This one ruling today shapes the way elections are conducted. At the time, President Obama called it, "a major victory for big oil, Wall Street banks, health insurance companies and other powerful interests that marshal their power every day in Washington to drown out the voices of everyday Americans." The connection between donor money and political action was not only established, it was soundly protected by the Constitution.

While charities and foundations organized under Section 501(c)(3) of the U.S. tax code — the types of nonprofits to which you may make tax-deductible contributions — are still prohibited from engaging in electoral politics, the Citizens United ruling allowed certain other nonprofits — most notably 501(c)(4) "social welfare" organizations and 501(c)(6) trade associations (the powerful PhRMA lobby is a 501(c)(6))— to spend heavily in elections. Unlike political candidates, parties or political action committees, these nonprofits are generally not required to disclose their donors, meaning the public is frequently left in the dark about who is funding the ads that are trying to influence their votes.

Treasury Eliminates Donor Information Disclosures

In addition to the 2010 ruling, a recent tax rule was passed that eliminates one method of access to donor contributions. After significant corporate lobbying of the new administration, as of fiscal year 2019, Treasury will no longer require certain non-profit organizations, including 501c4s and 501c6s, to disclose the names of large donors to the I.R.S. And since the majority of dark money is funneled through only fifteen donor organizations of which the PhRMA lobby is eighth with an estimated $13,329,825 funding as of 2016, this rule not only increases donor privacy and reduces compliance costs for qualifying non-profits, it closes the door to assessable I.R.S. disclosures of donor amounts already difficult to find. This is a significant setback to donor transparency. (See: List of Dark Money donors, 2016, Open Source in bibliography)

It's always the money and it will continue until the voters send a united message that our political system has evolved way beyond compromise and bipartisan negotiation. Our system operates almost

entirely on donor response negotiations and until this stops, our political representatives will not be working in our best interests, regardless of party and intent. Our efforts must include focus on creating the majority voice that motivates challenging Big Pharma influenced laws and regulations. As we organize efforts to minimize the flow of Big Pharma money to our elected officials we must keep pace with the constantly evolving donor strategies of the members of the opioid supply chain. In addition, we need to be as cognizant of where ex politicians go after they leave office as we are diligent in tracking existing recipients of drug money.

THE POLITICAL INFLUENCE

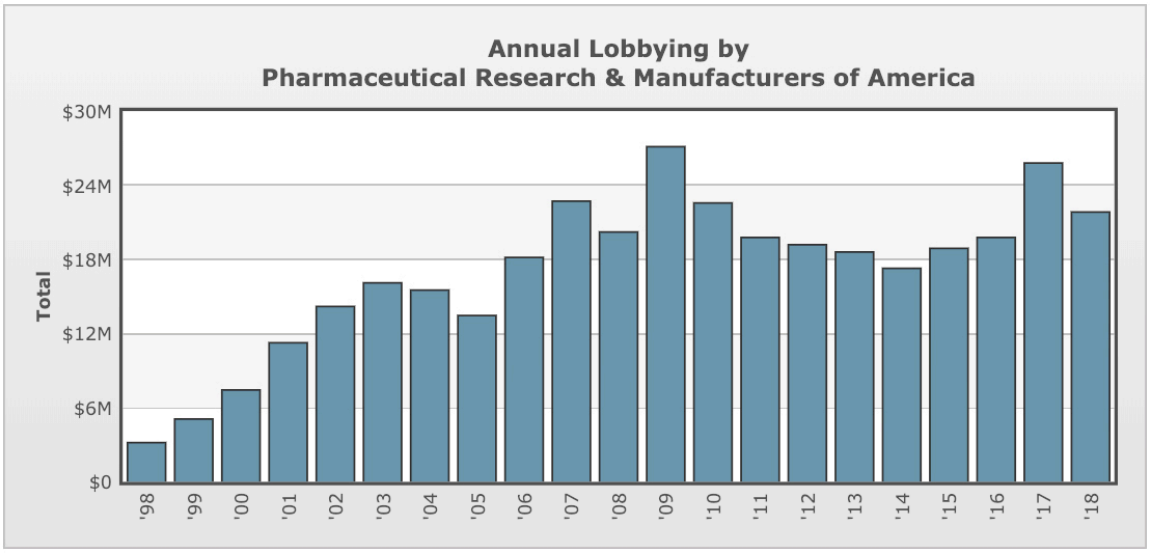
Big Pharma

Pharmaceutical companies and medical device makers, collectively Big Pharma, spend far more than any other industry to influence politicians. Big Pharma has poured close to 2.5 billion into lobbying and funding members of Congress over the past decade with hundreds of millions of dollars flowing to lobbyists and politicians on Capitol Hill each year to shape laws and policies that keep drug company profits growing. The pharmaceutical industry, which has about two lobbyists for every member of Congress, spent 152 million on influencing legislation in 2016, according to the Center for Responsive Politics. Drug companies also contributed more than 20 million directly to political campaigns in that same year. About 60 % went to Republicans. Senator Paul Ryan, the former speaker of the House of Representatives was the single largest beneficiary, with donations from the industry totaling $228,670. What makes that interesting is Senator Ryan sat on an important committee investigating the issues of the opioid crisis.

PhRMA Lobby

The major lobby group behind the massive pharmaceutical industry influence is the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group 501(c)(6), trade Association.

Chart Source: Center for Responsible Politics



PhRMA Lobby Losing Clout?

But it looks like the tide may be turning for the once invincible PhRMA lobby which has just suffered one of the biggest losses of its politically influencial existence. Last February Congress laid out a plan to force drug makers to pay far more into Medicare, a cost of approximately 11 billion. And it came from a Republican controlled House and Senate who, working with Democrats managed to slip a provision about a paragraph in length into an almost 400 page bill behind PhRMA's back. The timing couldn't be better, especially with a new Democratic House which will do everything it can to stop Congress from rolling back the policy as it often does under PhRMA lobby pressure.

This is the perfect storm for advocacy coalitions looking to make an impact against the opioid industry. We have a House introducing bills on behalf of the people, a weakened PhRMA lobby and a growing public awareness of the back door political influences that allowed opioid manufacturers to flood the market with addictive painkillers under false pretenses. This Bill should be considered a priority for our organized support.

Non-Profits, Foundations and Philanthropic Influence

"We have an entire legal code devoted to defining a private foundation, a community foundation, charitable trusts, the perpetual hand of the donor after death in guiding the cause of the philanthropic project, tax incentives for giving money away. These are all in the ordinary landscape of policies, and almost no attention has been paid to whether these are good policies or bad policies, whether they support or undermine democracy" .That's the quote of Rob Reich, Stanford University political science professor and his comments really hit home as we follow the enormous "blood money" that flows through these various non-profits.

There are 100s of these non-profits representing advocacy groups for all aspects of pro and con relative to opioid issues. Most operate independently of pharmaceutical money but some have capitulated to the often huge dollars offered with ostensibly no strings attached. Accepting donations from any members of the pharmaceutical supply chain, especially when representing an interest in direct contradiction to that of the donor, is a slippery slope.

Foundations Created as an Act of Congress

Many people do not realize that approximately ten years ago Congress established a non-profit called the Reagan-Udall Foundation for the FDA. The foundation is supposed to act as a liaison between the FDA and drug companies, researchers, nonprofits, or other businesses with regulated products who might want to support a project to make the agency's job easier. Perhaps fortunately, the foundation hasn't achieved its fundraising goals, probably due to factors such as timing, the public's growing awareness of monetary conflict of interest issues and perhaps even a reluctance of of Congress to affiliate with its own foundation in today's climate.

Reagan-Udall's funding troubles underscore its position in the broader debate about how closely a regulator should work with the industry it regulates, a debate that has shadowed the FDA itself as policymakers consider how much of the agency's funding should come from taxpayers and how much from drug makers. It's difficult to justify no influence after the first $150,000 of the foundation was seeded by the PhRMA lobby. More concerning is the fact that the FDA itself has contributed to the foundation, approximately $5 million since 2012.

That figure pales in comparison to the sums raised by similar congressionally chartered nonprofits that support the Centers for Disease Control and Prevention and the National Institutes of Health, each of which, just last year alone, raised more money than Reagan-Udall has over its entire lifetime. In the past five years, the CDC and NIH foundations together raised about half a billion dollars.

But unlike Reagan-Udall, the FNIC has been much more transparent about its sources of funding, but that doesn't mean there would be no potential conflicts if pharmaceutical donors find the need to call in a return on investment favor. The FNIC website states that it is a research foundation dedicated to forming partnerships between the NIH and private companies, university researchers and even other agencies like the FDA to form and conduct science.

But the donor list reads like a who's who of the opioid supply chain which includes McKesson Corporation, one of the top four opioid distributors, CVS Caremark, named defendant in opioid lawsuits and the PhRMA foundation, a major source of funding for both foundations. In fact, one of the major donors and long standing member of the board is Jillian Sackler, President and CEO of the Dame Sackler and Dr. Arthur M. Sackler Foundation for the Arts, Sciences and Humanities.

The concept of enhancing an agency budget with outside private money may have been a good idea in the past but over the years it has diluted the effectiveness of partner agencies and, as a result, created a negative impact on public health.

Political Non-Profits

It is the political nonprofits that have developed and effectively leveraged the concept of "Dark Money." These organizations have an uncanny ability to be so nimble and reactive to any unfavorable rulings that it has become almost impossible to curb their vast influence on our political process. Establishing public transparency and insisting ethical considerations are translated into enforced regulations is only option left to public advocacy. Efforts are already underway to build a voting block across the nation that is focused on the issues of political influence and diminishing the hidden control over our supposed representatives.

The Center for Responsible Politics defines political donor organizations as follows;

501(c) Groups — Nonprofit, tax-exempt groups organized under section 501(c) of the Internal Revenue Code that can engage in varying amounts of political activity, depending on the type of group. For example, 501(c)(3) groups operate for religious, charitable, scientific or educational purposes. These groups are not supposed to engage in any political activities, though some voter registration activities are permitted. 501(c)(4) groups are commonly called "social welfare" organizations that may engage in political activities, as long as these activities do not become their primary purpose. Similar restrictions apply to Section 501(c)(5) labor and agricultural groups, and to Section 501(c)(6) business leagues, chambers of commerce, real estate boards and boards of trade.

527 Group — A tax-exempt group organized under section 527 of the Internal Revenue Code to raise money for political activities. These groups are typically parties, candidates, committees or associations organized for the purpose of influencing an issue, policy, appointment or election, be it federal, state or local. Such organizations can raise unlimited funds from individuals, corporations or labor unions, but they must register with the IRS and disclose their contributions and expenditures.

Hybrid PACs (Carey Committees) — A Carey committee is a hybrid political action committee that is not affiliated with a candidate and has the ability to operate both as a traditional PAC, contributing funds to a candidate's committee, and as a super PAC, which makes independent expenditures. To do so, Carey committees must have a separate bank account for each purpose. The committee can collect unlimited contributions from almost any source for its independent expenditure account, but may not use those funds for its traditional PAC contributions.

Political Action Committee (PAC) — A political committee that raises and spends limited "hard" money contributions for the express purpose of electing or defeating candidates. Organizations that raise soft money for issue advocacy may also set up a PAC. Most PACs represent business, such as the Microsoft PAC; labor, such as the Teamsters PAC; or ideological interests, such as the EMILY's List

PAC or the National Rifle Association PAC. An organization's PAC will collect money from the group's employees or members and make contributions in the name of the PAC to candidates and political parties. Individuals contributing to a PAC may also contribute directly to candidates and political parties, even those also supported by the PAC. A PAC can give $5,000 to a candidate per election (primary, general or special) and up to $15,000 annually to a national political party. PACs may receive up to $5,000 each from individuals, other PACs and party committees per year. A PAC must register with the Federal Election Commission within 10 days of its formation, providing the name and address of the PAC, its treasurer and any affiliated organizations.

Tax exempt political donor groups will continue to play an influential role in candidate elections, especially with the 2010 Supreme Court ruling protecting donors under the first Amendment and empowering donors to spend unlimited dollars on campaign ads.

Private/Corporate Philanthropic Foundations

Unlike politically motivated nonprofits or foundations created to further a market agenda like Purdue's many funded chronic pain educational foundations, these corporate and special interest groups want their donor records made public.

Consider the Sacklers, the family who developed and flooded our country with OxyContin, who for years were perceived as generous, public minded philanthropists. They funnel their money through many trusts, foundations and direct donations. They take their tax entitlements and put their names on famous buildings and everything is perfectly legal as defined by code and public policy.

Likewise, we now have numerous foundations created by the named defendants in the opioid lawsuits such as Purdue, McKesson and AmerisourceBergen as a means to launder criminally aquired "blood money" through the tax deductible donations and investments in good works. Much of the foundations' initiatives are meant to divert the public's attention away from the corporations' contributions to the opioid crisis and to rebuild tarnished reputations.

But is it moral or good for democracy to accept money because it's earmarked for a good cause or should money from private and corporate philanthropists be held to a moral standard, tied to the donor, as well as a legal one? Philanthropy is defined as the desire to promote the welfare of others, expressed especially by the generous donation of money to good causes. Do we allow the Sackler family and other opioid related corporations continue to manipulate public perceptions and set a precedent that donations can serve as reparations for criminal and harmful acts to society? So why does their tainted blood money qualify under the definition of philanthropy? Why are we accepting the funding of causes in lieu of criminal guilt?

The only good news is if legal code and policy currently dictates the process of donations then we can demand modifications to those policies to add a well defined ethical component. We, as the final beneficiaries, should have the right to determine if a donation meets the standards of *ethics* as defined by regulation. Perhaps we need to look at tax benefits not as a means to launder blood money but as an opportunity to define eligibility based on where the money originated. There are laws today that allow seizure of assets as reparation for money acquired unlawfully. Perhaps non-profits, foundations and other philanthropic tax shelters should be assessed for eligibility under the same seizure penalties. At the very least such a bill would force increased scrutiny by recipients.

Chronic Pain Advocacy Groups

There is a large and growing coalition of patient advocacy groups dedicated to ensuring the availability of opioid prescriptions for chronic pain patients. One of the most influential and heavily funded groups in active advocacy is the US Pain Foundation. This well organized advocacy promotes the continued use of prescription opioids and actively works to minimize regulations that combat the

flow of painkillers. The foundation has an impressive media and communication reach and a bill tracking software that follows bills by name, sponsors, status and state. Recently, the foundation replaced its CEO and admitted misappropriations of funds, however, the issue does not appear to have limited this organizations reach and influence.

One of the most consistent achievements of pain advocacy is the successful blocking of repeals to the 2016 Ensuring Patient Access and Effective Drug Enforcement Act. There have been at least five repeal legislative bills introduced to no avail. Much of the coalitions success is its nationally and statewide organized support of Senator Hatch and Senator Whitehouse, both sponsors of the bill and supporters of pain advocacy initiatives.

There are many who believe a coordinated effort between advocates for pain and the recovery community would give an incredible momentum and lobby for change. So far the perceived cross purposes of our separate initiatives have thwarted the efforts of either position. If we could find compromise and unite our voices the combined political influence would go far to halt the control Big Pharma currently holds.

The Sacklers, Biggest Political Influence of All

Purdue and other opioid-makers spent $900 million on lobbyists and political contributions—eight times more than what the gun lobby spent, according to a recent series by the Associated Press and the Center for Public Integrity.

The Sackler family and Purdue Pharma, which is widely blamed for playing an essential role in starting the opioid epidemic, have given more than $1.3 million to U.S. candidates and another $1 million to political organizations since OxyContin's creation, according to Center for Responsive Politics data, but that's just the surface of how deep the pharmaceutical titans' influence runs. The Sacklers have disbursed $2.3 million to nearly 300 U.S. candidates and political organizations since 1996, and the OxyContin-backed politicians often held leadership positions, chairmanships, or served on committees that have oversight of the pharmaceutical industry. Just over one-third of the money went to only five recipients.

- Former Sen. Joe Lieberman (R-Ct) took the most funding from the Sacklers and Purdue and accepted more than $220,000, according to a DCNF's analysis. The Democrat-turned Independent served Connecticut, where the company is headquartered.
- Former Sen. Chris Dodd, (D-CT) took the second most from the Sacklers and Purdue, raking in more than $85,000. He served on the Committee on Health, Education, Labor and Pensions (HELP) — a panel that that held hearings on the opioid epidemic — and chaired one of its subcommittees. He also chaired the Banking, Housing and Urban Affairs committee. Dodd sponsored legislation that called for research on pain in America, and a group tied to Purdue spent $19 million lobbying in favor of the bill according to a joint investigation by The Associated Press and The Center for Public Integrity. Nearly half the experts recruited to author the resulting 364-page report had pharmaceutical industry ties.
- The Sacklers and Purdue gave former Republican Rep. Christopher Shays, who represented the district where Purdue is headquartered, the third-most funding with nearly $84,000.
- Colorado Democratic Sen. Michael Bennet took the fourth most, and was the biggest recipient among the legislators currently serving with $54,000 in contributions. Bennet serves on the Senate HELP committee and voted against legislation that reportedly would have helped lower drug prices.
- Rep. Jim Himes of Connecticut — the Democrat who replaced Shays — took more than $35,000 from the Sacklers and Purdue, making him the second biggest recipient among sitting lawmakers.

- The Sacklers and Purdue also gave $245,200 to the Republican National Committee — more than any other recipient.
- Purdue's lobbying arm was the second biggest recipient, having received $140,000, followed by the Democratic Congressional Campaign Committee, which took more than $109,000.

Purdue and the Sacklers donated to Democrats and Republicans nearly evenly. About 47 percent of the funding went to Republican candidates and organizations, while around 41 percent went to Democrats — a difference of about $133,300.

Purdue and the Guiliani Factor

In 2002, Purdue retained Giuliani Partners, a newly formed consulting firm Rudy Guiliani intended to leverage based on his reputation for being America's "straight shooter." Celebrated on Oprah and Time Magazine's Person of the Year for his exemplary work during 9/11, his job was to mitigate political and medical fears regarding The FDA's "Black Box Warning" and more importantly, stop the DEA's evolving consideration of limiting the right to prescribe opioids to only pain specialists. Guiliani knew that within the DEA there were high level officials tied to the interests of congressional and state leader's pushing to ensure OxyContin would not be limited, even as their states were being ravaged by a growing epidemic. Giuliani raised thousands for the DEA museum and cut the ribbon alongside Hutchinson, DEA Chief and then Attorney General, John Ashcroft.

With less fanfare, another Giuliani firm partnered on a Department of Justice contract to evaluate the DOJ's Organized Crime Drug Enforcement Task Force. The task force, which included the DEA, investigated trafficking in OxyContin and other prescription drugs. Among the goals, evaluate how the task force should focus its resources. The apparent conflict of interest between Giuliani advising a DOJ task force charged with investigations of illegal street sales of OxyContin and the DEA project by Guiliani Partners (funded by Purdue Pharma) had either been ignored by Congress or actively kept from public scrutiny.

Guiliani's lobbying efforts were successful. The DEA's own OxyContin-related investigations dropped by 49 percent, to 71 in 2003. Arrests fell by 21 percent. All this came at a time when OxyContin theft, measured in doses of the drug, was up 78 percent.

Guiliani continued to support Big Pharma and Purdue and in 2007 was again brought in as an ally to Purdue and a trusted negotiator for the Justice Department to hash out charges and settlement negotiations in a case brought by Virginia U.S. Attorneys. Based on overwhelming evidence, the U.S. Attorneys recommended felony charges that could have sent top Purdue execs to prison if they were convicted. However, top Justice Department officials in the George W. Bush administration did not follow the Virginia prosecutors' recommendations, and refused to indict the executives as recommended, instead pursuing lesser misdemeanor charges for them, and no jail time.

But Guiliani may be getting his wings clipped or at the very least be maneuvered into a position whereby to save himself he might trade useful information about the Sacklers and Purdue. Sens. Maggie Hassan, D-N.H., and Sheldon Whitehouse, D-R.I., are requesting documents detailing info about Purdue Pharma's interactions with the agencies in the 2000s when it was under investigation for its OxyContin promotions. The senators seek to learn whether "potential conflicts of interest" secured the company's "inappropriately lenient treatment."

The question is who is the next Rudolph Guiliani? Is there someone well-known and respected by the public ready to represent the opioid supply chain and have the same degree of influence as Guiliani? Should we be tracking ex-politicians, especially those who were advocates for Big Pharma while in office? Should we be lobbying for a "revolving door bill?

JUDICIAL ADVOCACY

Criminal v Civil/ The Opioid Lawsuits

Executives of a certain financial institution were indicted in 2015 for making false statements in securities filings and to U.S. governmental agencies. The 18-count indictment included charges of conspiracy to commit fraud related to the purchase and sale of securities; conspiracy to defraud the United States; and with making false statements to regulators. These executives had done the unthinkable, they had committed fraud against the people and LOST PEOPLE'S MONEY. In four years the executives were convicted and given prison sentences.

The above is a real case and it took only four years to put these executives in jail for losing money but we can't get an executive of a pharmaceutical company in jail for losing PEOPLE's LIVES. It's true, the specifics of the law are not the same but the message is clear, the politics of opioid lawsuits do not advocate jail time for corporate executives, not when the government has implemented revenue producing alternatives to imprisonment. And despite recent rulings ordering that fraud and RICO criminal charges should be allowed in certain opioid lawsuits and the *almost* felony convictions precedent set in the 2007 Purdue case, the general concensus is that these lawsuits will be settled by monetary reparations and not criminal incarceration.

In a New York Times article by Barry Meier, author of "Pain Killer" some very important points are presented, most of which center around decisions whether to settle the cases or pursue criminal charges and expose the complete disregard for the public health by the opioid industry's guilty parties.

- There are good reasons to settle the cases quickly, certainly the government sponsored MDL cases are eager to settle. And the settlements could be used to fund much needed recovery initiatives. But what is the tradeoff? Quick settlements generally are more favorable to the defense.
- It is an uncomfortable truth that by not holding Purdue executives accountable in the 2007 case, Purdue's corrupt business practices not only continued, the government's failure to hold the executives criminally accountable allowed a containable crisis to mushroom into catastrophe. In addition, without a trial, doctor's remained unaware of the deceptive and erroneous claims and continued to increasingly prescribe opioids.
- Lastly, by settling and agreeing to seal documents that would have clearly made public the degree in which Purdue disregarded the public's safety and disclose beyond a doubt the danger of opioids, thousands of innocent lives were lost. One such document is the deposition of Richard Sackler, Purdue's President during the time period under complaint. Although not publically released, many believe Sackler confirms he was briefed about Oxy's life-threatening abuse years before public officials were aware of it.

After years of legal haggling it looks like the sealed documents, especially the apparently incriminating deposition of Richard Sackler, President and CEO of Purdue taken during one of the small southern cases in the early 2000's, is going to be released in the near future. This deposition was taken long before judges around the country had ruled on cases that opened up the floodgates of nuisance and fraud violations. It's ironic that the arrogance of the deposed Sackler, sitting in a small county court in a case that was settled with pocket change, might be the downfall of a dynasty that caused the deaths and destruction of so many innocent souls. If this deposition contains the incriminating details of guilt that many legal experts believes it does, it will be a huge windfall for the current cases, especially the cases looking to link Sackler wealth to Purdue's actions.

Insys Therapeutics

There has been a recent flurry of postings and interest in Insys Therapeutics and the 2016 indictments of founder John Kapoor and selected executive and sales employees. This is an incredibly important case because the evidence of guilt is irrefutable and the corporation is a publicly held company subject to shareholder fraud laws, unlike Purdue, which is privately held by the Sackler family. Twelve years ago it would seem inevitable that the guilty parties serve prison time but today, that may not be the case.

What is concerning is the way in which our governments' view of guilty executives has seemingly shifted. More and more, our government prosecutorial efforts, even for blatant criminal actions resulting in deaths, end up going away under agreements for large sums of blood money.
We'll most likely find out Kapoor's outcome next year but under the existing climate, it is improbable he or other executives will serve time unless we put the full force of our advocacy efforts behind holding opioid executives proven to be criminally accountable to their crimes. And if the law doesn't cover the Pharmas like it does the banks, we need our political representatives to EXPAND the interpretation of the law.

The Settlement Dilemma

As we progress through the opioid litigation we need to consider what went wrong in terms of the tobacco settlement monies that never went where it was earmarked. This time around we need to carefully monitor every penny by organizing "watchdog" coalitions by state to be prepared to expose any state administration or representative that attempts to divert funds from it's settlement mandated intent. We also need to exert pressure on Attorney Generals who are negotiating settlements to secure clearly articulated language in the settlement documents regarding compliance with any state mandated special opioid funds that each state may establish for receipt of lawsuit settlements. Ideally those state funds are administered by a committee with at least one recovery advocate as a member. We must make it clear to our state reps if you want to be re-elected don't mess with our opioid funds!

The Joint Commission Lawsuit

Finally, we are seeing lawsuits that demand accountability from nonprofit boards. According to Stat, local officials in West Virginia, the state with the nation's highest drug death rate, have taken aim at a different target; the medical experts who recommended their use. This past week the cities and towns of Huntington, Charleston, Kenova, and Ceredo filed a class-action lawsuit against the Joint Commission (JCAHO), the influential nonprofit that both inspects hospitals' performance and sets practice standards for their physicians. This is the commission that wrote, under Purdue's direction and authorship, the Fifth Vital Sign requiring physicians to prescribe opioids if the patient expressed pain. To this day, hospitals must abide by the group's standards, on opioids or anything else, in order to get reimbursed for care provided to Medicaid and Medicare patients.

The lawsuit claims the nonprofit, responsible for accrediting more than 20,000 health organizations nationwide, has spread "misinformation" about the risks of opioid addiction dating back to the early 2000s, including in published materials underwritten by opioid manufacturers such as Purdue.

The lawsuit is based on the Joint Commission's pain management standards, first issued in 2001, and the alleged cozy financial ties the nonprofit had with pharmaceutical firms. According to the lawsuit, the nonprofit produced materials that downplayed the evidence "that addiction is a significant issue when persons are given opioids for pain control." It also says that similar materials claimed that patients who used opioids rarely became addicted, even though that was underpinned by scant evidence.

And those standards were developed in collaboration with the very drug makers positioned to profit from them, the suit alleges. Dr. Gary Franklin, a neurology professor at the University of Washington and vice president of state regulatory affairs for the advocacy group Physicians for Responsible Opioid Prescribing, said the research supporting the original standards was "developed in collaboration with University of Wisconsin" pain researchers who accepted drug money funding while pushing the industry's agenda.

Advocacy beyond the Opioid Lawsuits

CREW, Citizens for Responsibility and Ethics put a case before the Supreme Court entitled Merk, Sharp & Dohme v Doris Albrecht. Although this case does not involve an opioid pharmaceutical it is important because historically all pharmaceuticals have minimized their liabilities regarding warning the public of an on the market drug's newly discovered dangers. Currently the FDA doesn't allow newly identified warnings by updating FDA approved labels. Hence, Big Pharma is handed a credible "not my fault" defense that CREW hopes to remove.

On another CREW case, the Supreme Court declined to intervene with a federal judge ruling that threw out a decades old Federal Election Commission (FEC) regulation allowing nonprofit groups to keep their donors secret unless they had earmarked their money for specific purposes. The FEC is now required to create a new rule for the effected nonprofits. The intent is to appeal the win but until then many political groups will turn to super PAC rules as an alternative.

The Pharmaceutical Manufacturing Research Services (PMRS), not to be confused with the PhRMA lobby, has repeatedly requested the FDA to set a higher standard for New Drug Applications (NDA) for abuse-deterrent opioids for treatment of chronic pain, which has been repeatedly declined. As a result, PMRS is resorting to a calculated submission for its own abuse-deterrent opioid which the FDA also denied based on multiple failures (not a surprise to PMRS), which subsequently filed a lengthy complaint and sued the FDA. The 22 page complaint reads like an anti-opioid advocacy report and dedicates 15 pages to discussion of the opioid epidemic, FDA's reliance on abuse – deterrent guidelines largely crafted by opioid manufacturers, chronic use labeling and the scientific evidence supporting long term opioid effectiveness for chronic pain. The entire suit appears to be a clever bully pulpit to expose the FDA's wrongful approval of opioids in a legal record.

These are just four examples of many that leverage the courts against the ineffective acts of the FDA and other agencies such as the NIH and HHS. Our opioid community of advocates needs to consider an organized process to track and support key pieces of litigation beyond the opioid lawsuits. Likewise as the courts render their rulings on a particular matter we need to be prepared to lobby the drafting and submission of bills to solidify key decisions.

AGENCIES THAT PROTECT US?

HHS

Health and Human Services (HHS) the government agency that directs the FDA, also includes the CDC, NIH, SAMHSA, and Medicare/Medicaid, among others. HHS also oversees the Pain Management Best Practices Inter-Agency Task Force which has recently come under scrutiny for member financial conflict of interest. Congress created this task force to *objectively* analyze the state of pain management and to make recommendations to fight the opioid epidemic, not to hand opioid manufacturers and their affiliates a new avenue to spread their influence. Yet, out of 21 task force members, hand- picked by HHS, 10 received payments totaling nearly $180,000 from drug makers, including companies that sell opioids, between 2013 and 2017.

On December 18th, 2018, The US Senate, Committee on Finance issued a comprehensive letter to Alex Azar, Secretary of the Health & Human Services, outlining its concern over the conflicts within the task

force. The letter is included in the attached bibliography. It's obvious that Big Pharma's influence is imbedded within the HHS. But the important question is how much influence does the Pharma friendly HHS have regarding the objectivity of one of its' most important agencies, The FDA? And How did the dis-connect between our public right to be protected and the agency charged with our safety get so vast it's downright criminal?

FDA

According to the mission statement found on the FDA website, **"The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products, and medical devices.** The bottom line is the FDA has become so far removed from its original charter to "protect the public health" especially with the opioid crisis, that it has become a necessity for the public to directly challenge its value in its current state.

As advocates we need to consider whether to coordinate our support for the ex- Commissioners in their quest to separate the FDA from the Influence Industry and by doing so we can ensure the public's proper representation relative to critical opioid issues. So much that has contributed to the opioid epidemic began, ***and continues,*** *with the approval process and the clinical efficacy study methods that rely on the integrity of the very drug companies the FDA is evaluating. At the very least our advocacy efforts should consider the following;*

- The codependence between the drug industry and the HHS and the trickle- down effect that has on FDA objectivity.
- The refusal to set opioid abuse-resistant standards that protect the public.
- The conflict between rapid approval directives found in the FDA Prescription Drug User Fee Act (PDUFA) and the dependence on those fees allowed under the Act to subsidize the FDA's budget.
- The resistance of the FDA to voluntarily allow box drug labels to be revised after approval. The drug industry has consistently used this FDA directive as a culpability defense against the public's lack of timely awareness when a problem with a drug occurs.
- The need to repeal or modify certain drug industry favorable Acts such as the 21st Century Cures Act which appears to be written to save drug and device companies millions in bringing products to market by short circuiting FDA testing.
- The conflict between the potential and promise of lucrative career opportunities within the drug industry and maintaining an objective perspective on drug approvals.

Should the FDA Separate?

Recently the big issue surrounding the operations of the FDA, especially in regards to drug approvals is whether the agency has lost the clout to truly represent the health and safety of the public or has it become subservient to the whims of political, pharmaceutical and career opportunity pressures. In response to this theory, a bipartisan group of seven former FDA Commissioners are uniting to advocate for breaking the Food and Drug Administration out of the Department of Health and Human Services and making it an independent agency.

The idea is to make the FDA less vulnerable to political pressure so it can focus instead on protecting public health. While FDA's mission has always been politicized, the issue is particularly critical due to the FDA's contribution to the opioid crisis. But now, seven of eight of the former commissioners who ran the agency since 1984, are breaking rank. "There's horse-trading going on at higher levels and

some of the things that you are deeply committed to as part of the Food and Drug Administration get caught up in that," former Commissioner Margaret Hamburg said at an FDA conference.

Certainly the actions of the past two decades indicates a pattern of corporate influence and conflict of interest, beginning with the staged approval of Purdue Pharma's OxyContin in 1995 during which the agency provided blatant assistance, led by Curtis Wright, the FDA official in charge of OxyContin's approval process. Wright was very instrumental in getting the drug positioned for the mass market and even made recommendations that limited competition, including the completely unsubstantiated declaration written into Purdue's box labelling which read, ***"Delayed absorption is believed to reduce the abuse liability of a drug."***

This sentence, included as an important piece of the FDA-approved label, became the basis of Purdue's product launch and sales mantra. And the sentence was written by the FDA under Curtis' direction. Two years after leaving the FDA, Wright took a job at Purdue. The revolving door of members of the FDA moving to more lucrative careers in the pharma industry continues today. Nearly 340 former congressional staffers now work for pharmaceutical companies or their lobbying firms, according to data analyzed by KHN and provided by Legistorm, a nonpartisan congressional research company.

The Opioid Generics

With so much attention focused on the original opioid manufacturers like Purdue Pharma, it's important to be diligent regarding the significant growth of the opioid generics market. Generic opioids, which now represent 90% of opioid production are being approved at an alarming rate. And typical of the Sacklers' forsight and political influence, the establishment of Rhodes Pharmaceuticals, a wholly owned subsidiary of Purdue Pharma, is meant to capture the opioid generics market. In addition, not only do current regulations allow for rapid approval of these generics but also protects the generics producers like Rhodes from the liabilities of lawsuits against the original manufacturers, including so far, it's parent company. The FDA's repeated approval of generic opioids for chronic pain with insufficient evidence of efficacy is a major factor behind the continued momentum of the opioid epidemic.

Dsuvia, Public Trust Betrayal?

The FDA situation is even more critical with the recent approval of the AcelRX Pharmaceutical companies' Dsuvia opioid, a Sufentanil based drug, released in a tiny pill form, and purported to be dangerously more potent than any other opioid on the market. With this approval, the FDA has truly demonstrated a loss of control of its mission objectives and a capitulation to political and corporate pressures.

Those of us on the ground trying to build awareness, effect change and fight this opioid crisis wonder; how could the FDA approve such a dangerous drug right in the middle of this epidemic? Perhaps it was because approval of this drug was basically a done deal from the start. Gottlieb, perceived by many a friend of Wall Street, stated immediately following approval that the drug would be offered in limited, heavily monitored release and was intended primarily for the military.

But most of the public is not aware that in May 2015, AcelRX entered into an award contract with the Research and Material Command of the Department of Defense (DoD) whereby the DoD agreed to provide around 17 million (and more if needed) to support the development of Dsuvia, then known as ARX-04. Under the terms of the DoD Contract, the DoD has and continues to reimburse AcelRX for costs incurred for development, manufacturing, regulatory and clinical costs in preparation of submitting a qualifying NDA to the FDA, including reimbursement for certain personnel and overhead expenses. Once Dsuvia is approved by the FDA, the contract provides for the DoD to purchase 112,000 units of the commercial drug.

The ability of the DoD to literally override FDA approval authority caused a lot of tension between the FDA and the Pentagon, so much that the President signed Public Law (PL) 115-92 allowing the DoD to use unapproved drugs under certain circumstances. The bottom line is, if the Pentagon asks for it, the FDA had better approve, and fast. The framework under which the DoD and the FDA implemented the law was previously passed by Congress in 2017 for engagements between the DoD and the FDA and cover;

- The FDA will work closely with the DoD to evaluate how best to foster access to safe and effective medical products that serve the military's medical needs.
- The FDA will give the highest level of attention to and expedite review of priority DoD medical products.
- The FDA will provide ongoing technical advice to aid in the rapid development and manufacturing of medical products for use by the military.
- The FDA will examine products currently under development to determine opportunities to streamline review and expedite their availability.

Little by little, as more facts are exposed, it's understandable the ex-FDA Commissioners want the FDA to defect. Despite Gottlieb's assurances to the public that Dsuvia was only approved for the military, SEC filings indicate that to meet Wall Street's expectations Dsuvia will need to be expanded into ER's, ambulatory surgeries and most likely the chronic pain population.

"Clearly the issue of the safety of the public is not important to the Commissioner, despite his attempts to obfuscate and misdirect," said Dr. Raeford Brown, the FDA panel chair and a professor of anesthesiology and pediatrics at the College of Medicine at the University of Kentucky. Brown, who was not available during the panel vote to approve Dsuvia and who vehemently disapproves of the drug's release, stated, "I will continue to hold the agency accountable for their response to the worst public health problem since the 1918 influenza epidemic."

DOJ

The Justice Department (DOJ) mission statement states:

"The mission of the Department of Justice is to enforce the law and defend the interests of the United States according to the law; **to ensure public safety** against threats foreign and domestic; to provide federal leadership in preventing and controlling crime; to seek just punishment for those guilty of unlawful behavior; and **to ensure fair and impartial administration of justice for all Americans."**

Before his departure Attorney General Sessions submitted a comprehensive strategic plan which is available in its entirety on the AGC website. It focused on four key areas of concern to our nation that need to be addressed for the 2018 – 2022 period. The four Strategic Goals of the Department of Justice will be:

1. Enhance National Security and Counter the Threat of Terrorism
2. Secure the Borders and Enhance Immigration Enforcement and Adjudication
3. Reduce Violent Crime and Promote Public Safety
4. Promote Rule of Law, Integrity, and Good Government

There's no reason to believe that the acting Attorney General replacing Sessions will modify the strategy and how that mission statement and strategic plan applies to the opioid crisis remains to be seen. But one point is blatantly obvious, despite the hundreds of thousands of lives lost to the opioid crisis and the huge economic and societal cost to our nation, at the time of the plan being written, it did not make the cut of the top strategic initiatives from 2018-2022. This leaves no question if we expect the opioid crisis to get under control we'll have to increase our advocacy in the political and public policy arena.

The False Claims Act

The DOJ has launched criminal indictments and prison terms for a number of physicians, client brokering organizations and insurance fraud violators but what is lacking is the criminal prosecution of executives and board members tied to the manufacturers and distributors responsible for the huge toll on society. So far it has been up to the state Attorney Generals and U.S. Attorneys to build criminal indictments and it doesn't appear that the new Attorney General intends to reverse the pattern.

In fact, The DOJ's latest crime fighting tool, The False Claims Act (FCA), traditionally a civil enforcement tool (read fines) has become the remedy of choice to combat the opioid epidemic and prosecute fraud cases.

- Between October 1, 2016, and September 30, 2017, the DOJ obtained more than 3.7 billion in settlements and judgements from civil FCA cases. More than 64% of these recoveries (2.4 billion) involved the health care industry, including the complete opioid supply chain from drug development through final receipt by the patient.
- Deputy Associate Attorney General Stephan Cox echoed the DOJ's commitment to continue to apply the Civil Claims Act as a major opioid *crime-fighting (*his words) approach to opioid crime.
- An internal OAG memo written in January 2018 by associate attorney general Rachel Brand (now known as the Brand memo) indicated that DOJ lawyers should focus its energy on the most significant or impactful False Claims Act cases, and dismiss those cases that do not warrant investigative services.

What is apparent is the DOJ does not intend to expend resources on criminal charges that would result in prison time for the perpetrators except at the disposable levels of the opioid supply chain. Cox gives an example of the proper use of the FCA in a case against Galena Biopharma, manufacturer of the pain medication Abstral. The DOJ alleged, and sufficiently proved, the company repeatedly paid kickbacks in multiple forms to induce doctors to prescribe its drug. Galena paid a 7.5 million settlement and went back to business. Two of the doctors who received kickbacks were tried and sentenced to prison.

The message here is clear, the DOJ looks at manufacturers, distributors, pharmaceutical chains and similar big business as revenue. Doctors are the low hanging fruit because they are the guilty party who shouldn't have listened to the politically influenced FDA and prescribed the pills. It's all neat and tidy but does not serve the best interest of the public. History has proven that until the big guys go down, nothing will change.

DEA

The DEA mission is to: "Enforce the controlled substances laws and regulations of the United States and to bring to the criminal and civil justice systems of the United States, or any other competent jurisdiction, those organizations, and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of and demand for illicit controlled substances on the domestic and international markets.

Due mostly to the publicity from the 60 Minutes interview of ex-DEA agent Joe Rannazzisi, the DEA has found itself under increased public scrutiny. Joe Rannazzisi was a supervising agent in charge of a DEA department, entitled the Office of Diversion.

"The Office of Diversion consists of diversion investigators, special agents, chemists, pharmacologists, program analysts, and others. The office's activities include: **program priorities and field management oversight; coordination of major investigations; drafting and promulgating of regulations; establishment of national drug production quotas; design and execution of diplomatic missions; U.S. obligations under drug control treaties; design and proposal of national legislation; advice and leadership on state legislation/regulation; legal control of drugs and chemicals not previously under federal control;** control of imports and exports of drugs and chemicals; computerized monitoring and tracking the distribution of certain controlled drugs; providing distribution intelligence to the states; industry liaison; and program resource planning and allocation."

According to Rannazzisi, members of Congress acting on behalf of a pharmaceutical and lobby influence campaign passed Bill HR 471, the Ensuring Patient Access & Effective Drug Enforcement Act in 2016. The Act stripped the DEA of significant prosecutorial powers against opioid distributors and weakened the nation's drug laws at a time of unprecedented crisis. The most telling comment from Rannazzisi that echoes the sentiments of the public is; "the one thing I wanted to do, the one thing that I thought would have the most impact, is to lock up, arrest one of these corporate officers that's involved in the decision process, knowing what the law is you make that arrest, then everybody sits up and takes notice because three piece suit guys just don't do well in prison. They just don't."

In the end, both the DEA and DOJ are credited with agreeing to the Bill, however, the DOJ has since questioned the effectiveness of its provisions and prior to relinquishing her office Senator McCaskill wrote and submitted a well substantiated repeal with little response.

What is the most startling about HR 471 is the fact that Senator Marino (R-Pa), the bill's sponsor and a well-known friend of Big Pharma, and Senator Hatch (R-Utah) managed to get unanimous passage of the Bill with virtually no inquiry into its effect on the DEA or the growing opioid crisis. As citizens who rely on our elected officials to stay on top of actions that could harm the safety of the public, the unanimous unquestioned acceptance of HR471 should be of greater concern than even its harmful contents. What happened with this bill is indicative of the evolving disparities between public need and corporate need.

The DEA began as the brainchild of Richard Nixon with an original charter of cutting off the supply of drugs on the black market, both here and abroad. The agency's charter was expanded to include enforcement of the Controlled Substances Act of 1970. The DEA has been the subject of political pressure and persuasion as far back as 2003 when it attempted to take opioid prescriptions out of the hands of the general practitioners and back to pain and specialty practice physicians. The Pharma industry immediately retaliated with the hiring of Guiliani and a full court press on political "friends of family." That was the beginning of the end of the DEA's power to stop the horrific expansion of the opioid epidemic.

The reality is the DEA is simply not structured or provided the regulatory and legal tools with enough teeth to stop a crisis that for all intents and purposes is both American made and legal. Likewise, it does not have the resources or competencies to operate deep in the dark net where so much international illegal substance trafficking occurs. Sometimes it is necessary to completely reengineer an entity from scratch to be in compliance with current issues. It may be time for the DEA to undergo a complete overhaul of its resources, skill sets and organization.

WHAT NOW?

The time is critical for us, as advocates to unite our competencies and voices to bring about the change necessary to facilitate the end to the opioid crisis and enable the public to begin the process of healing. *As previously mentioned*, w*e are in the perfect storm of timing to make more progress changing the paradigm of the opioid crisis response than any other time in the past twenty years.*

- Public awareness of the societal devastation and huge economic losses brought about by the opioid crisis is growing.
- The science supporting addiction as a disease is becoming more established and accepted by the medical establishment.
- Pressure is being put on the government to accept empirical data that establishes the cost benefit for recommended responses to opioid issues.
- The overwhelming number of lawsuits and the increasingly favorable Plaintiff

  rulings by judges across the U.S. make it clear there is growing public demand for justice.
- The Supreme Court's pattern of rulings favorable to corporate and political transparency indicates the Court's reaction to the public's rights as citizens to be informed.
- The recent bipartisan efforts to diminish the PhRMA lobby's influence sends a message that even politicians friendly to big Pharma recognize the position may not be as favorable as it once was.

It is our responsibility to continue advocating for the end to this horrible epidemic and to remove the Web of Influence line by line.

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