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Advocacy Coalition Framework Lens on Pressing Healthcare Issues

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Abstract

In deciding how to interpret and understand public policy, many experts use theories and frameworks to justify their reasoning. One of the most common avenue of viewing policy involves the advocacy coalition framework based on its broad applicability. This popular framework consists of banding like-minded individuals together into a coalition to advance the narrative by creating acceptable policies for their group. These coalitions normally include a wide range of professional backgrounds from interest groups, elected officials, researchers in academia. These groups utilize special events to influence subfields consisting of actors who decide the solutions for policy problems. Subfields normally are made up of key players employed in government institutions and private industrial groups who willingly agree to work toward a compromise with the goal to create policy acceptable for both sides (Cairney 2014) These coalitions influence the subfield in different ways through capitalizing on their influential power or by ignoring the alliances and mergers of the groups. This paper shall explore how advocacy coalition framework works for three pressing issues facing the healthcare industry. These three policies focus on drug pricing, heath data privacy and opioid liability. This paper will explore the policy in depth, provide historical context and the major players while outlining how the specific proposals fit in the framework as well as identifying the framework's limitations with the policy.

Keywords

Drug Pricing, Health Data Protection, opioid liability

Disciplines

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Comments

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PUBLIC POLICY THEORY PAPER

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Introduction

In deciding how to interpret and understand public policy, many experts use theories and frameworks to justify their reasoning. One of the most common avenue of viewing policy involves the advocacy coalition framework based on its broad applicability. This popular framework consists of banding like-minded individuals together into a coalition to advance the narrative by creating acceptable policies for their group. These coalitions normally include a wide range of professional backgrounds from interest groups, elected officials, researchers in academia. These groups utilize special events to influence subfields consisting of actors who decide the solutions for policy problems. Subfields normally are made up of key players employed in government institutions and private industrial groups who willingly agree to work toward a compromise with the goal to create policy acceptable for both sides (Cairney 2014) These coalitions influence the subfield in different ways through capitalizing on their influential power or by ignoring the alliances and mergers of the groups. This paper shall explore how advocacy coalition framework works for three pressing issues facing the healthcare industry. These three policies focus on drug pricing, heath data privacy and opioid liability. This paper will explore the policy in depth, provide historical context and the major players while outlining how the specific proposals fit in the framework as well as identifying the framework's limitations with the policy.

Healthcare Privacy Data

One of the gravest concerns facing the Federal government involves addressing the need to safeguard personal data from cyberattacks. Over the past decade, the rise in national detected cyberattacks makes it a pressing issue for not only US business but also the average American. This concern is also especially true for the healthcare industry which loses $5.6 billion each year on this weakness according to Becker's Hospital Review. (HIM Admissions 2018) The healthcare industry has proven to be an easy mark as it has often been called a soft target with a source of valuable data with patient records. Self-

incriminating polls by healthcare organizations state less than 50% of the major providers think they can prevent and defend their organizations from cybercrime and healthcare IT spending accounts are underinvesting by one/fifth percent compared to other major industry trends (Martin 2017). Most cyber vulnerabilities are hard to identify leaving many organizations to be left unaware that they suffered a security breach for weeks and even months sometimes according to the Workgroup for Electronic Data Interchange health IT group (HIM Admissions 2018). In 2016, the Department of Human Health and Services established the Health Care Industry Cybersecurity Task Force which is comprised of representatives from all avenues of the public health and healthcare sectors including hospitals, insurers, pharmaceutical companies, patient advocate groups and medical device manufacturers (Public Health Emergency 2018). The findings of their June 2017 report called for the urgent need of a collaboration among all private and public sectors subgroups to address this growing threat (Public Health Emergency 2018). Through this massive announcement, the structure of power has shifted as coalitions create new and more effective practices in addressing the issue allowing them to dominate their subsystems.

In addition to creating the taskforce, HHS has been actively working toward viable solutions as well as being influenced by coalitions groups on this subject. Beyond the taskforce, one of HHS main goal is to raise awareness about cybersecurity in the healthcare sector by providing grants to promote information sharing with key leaders in the industry and offering online resources as they continue to work with the National Academics and the private sector on cyber infostructure (Public Health Emergency 2018). From this collaboration, the HHS and these coalition groups strive to create effective educational programs which will be adopted throughout the industry. For example, this initiative includes educating employees about falling prey to phishing emails which the Health Insurance Portability and Accountability Act (HIPAA) journal says account for 91% of all cyber-attacks (HIM Admissions 2018). The research institutions chosen in this study will help control the policy-oriented learning which ACF serves as the center hub for changing belief and deciding the top coalitions (Weible 151).

HIPAA

Most of the Federal laws pertaining to protecting healthcare data occurs through complaints with the HIPAA. Citizens can also protect their data through the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 which called for rapid secure adaptation of electronic medical records (Lord 2018). HIPAA's role is crucial as it represents the baseline for protecting a patient's sensitive healthcare data through the Privacy Rule. This ruling determines the specific information classified as sensitive and whether that information can be disclosed or not. With the rising trend of data breaches including large tech giants, Google and their newly entrance into the healthcare field, lawmakers are calling for a sweeping update for HIPAA. Lawmakers have expressed concerned over HIPAA lack of regulations regarding new healthcare technology and the practice of sharing the data from these devices. In order to fill these gaps, lawmakers have started to push their own agenda through legislation. One bill called the Smartwatch Data Act regulates how consumer health information is used and shared through tech companies' devices like fitness trackers (Ravindranath 2019). In this instance, the external shocks of the misappropriation of the tech giants using our data without express consent threatens the relatively stable parameter of the system as many government legislators calling for dramatic changes in updating HIPAA. To arrive at this end goal, they are attempting to appeal to minority coalitions such as the voter base. If these endeavors hit major roadblocks, the legislators will attempt to pass their own legislations.

FDA Involvement

The HHS does not represent the only Federal organization involved in pushing for stronger healthcare data protection. The FDA has also been extremely active in setting new policies in this field. The first policy involved updating the guidance terms on protecting data connected to medical device. Creating applicable guidelines for this field is difficult due to the wide spread of applicability with medical devices. A good example concerns insulin pumps which utilize an app on the phone. This type of

electronic method allows hackers to not only gain patient information, but the bigger implication involves giving hackers the ability to manipulate medical dosages, alter drug dosages as well as create false medical records which could impact what a doctor would prescribe (HIM Admissions 2019). Another common practice with medical officials includes the use of portable tablets on patient rounds to uploaded to their electronic charts. Security on these devices needs to be addressed as information can be easily altered or stolen. Many of the proposed FDA guidelines include installing a layer of data encryption when data is transferred between devices as well as creating security features that would detect breaches (Delgado 2014). Even though many of these policies should be standard commonplace practices, the FDA guidelines are not implemented as formal regulations. Rather they serve as an incentive for healthcare organizations to embrace and voluntarily practice. The FDA cannot enforce this policy as a legal regulation under the ACF coalition hypotheses 4, within a coalition, administrative agencies will usually advocate more moderate positions than their interest groups allies (Weible 148).

The pharmaceutical companies have also added their own insights about healthcare cybersecurity. The industry has been more forceful in creating regulations that ensure product safety and data integrity. Driven by their own experience problems within clinical trials and the supply chain process has ensured pharmaceutical companies take on an active role in this process. Their new regulations based on recommendations of industry consultants include a pre-approval inspection of systems used to store and handle data. They also shed light by questioning the upkeep of medical devices and advocate for additional testing for system changes with manufacturing updates. This is important as many medical devices are not designed to handle software updates. Also, the FDA have tightened the appeal process for CGMP (Current Good Manufacturing Practices) tests, as currently a retest only consists of needing a valid scientifically reason. Lastly, the FDA has created or expanded their contacts in international subfields and coalitions by partnering up with international regulatory agencies to exchange best practices and violations

of data security (Kent 2018). Having the FDA regularly informed and updated about international trends allows for foreign coalitions to join previously dominated American subfields in creating policy.

Limitations

Along with all frameworks, there are certain limitations that can allow this policy matter to be interpreted in other lights. First, coalitions activities can be difficult to monitor and evaluate. Since it can be an extended time before a company finds out about their breach, it is difficult to decipher which coalition represents the top level. Next, the ability of a single coalition dominating this policy field is very easy due to the power not naturally distributed. As seen indicated after the HHS created their task force, the federal government decided which industry partners to work with while ensuring that minority voices will not be heard. Smaller companies who practice strong data protection measures can be easily overlooked due to their lack of contacts. This missed opportunity does not allow their procedures to be adopted amongst the rest of the industry. Another occurrence involves smaller companies being overtaken by larger entities to stop their innovation thus eliminating the threat and ensuring no change in the coalitions (Economic and Social Council of the UN 2017).

Opioid Liability

The greatest danger leading coalition faces happens when their subsystems are distributed, and stability cannot be fixed no matter how much power they have**.** This credibility problem can be seen through the developing policy field deeply affecting the healthcare industry involving opioid liability trials. Major lawsuits are being filled by states, countries and cities in federal and state courts asking for comprehension by the largest pharmaceutical manufacturers and distributors of opioids (Bruno 2018). Due to the lack of accountability put forth by the Federal government to regulate opioid distribution, over 400,000 people has died of opioid overdoses since 1998. In the past few years, the amount of overdose opioid deaths has surpassed deaths caused from traffic accidents. The economic impact of this opioid crisis

is astounding. In 2018, the Society of Actuaries estimated $179. 4 billion represented the cost of the opioid epidemic which includes costs incurred by the government, employers, insurance companies and private individuals (Duffin 2019). This $179 billion figure can be categorized into several key expenses including lost productivity, health care, criminal justice, child/family assistance to actual overdoses. Since the lawsuits were filled, the number of defendants and plaintiffs are increasing as other healthcare sectors such as clinics, pharmacists and individual physicians are being accused. Even individual pharmacists are being targeted in lawsuits for having the most impact on encouraging patients to prescribe to opioids and received the most money from manufacturers (Hals 2020). For plaintiffs now include non-governmental entities such as individuals who are combining into class action groups with a wrongful death in their family (Bruno 2018). Based on the staggering statistics of the opioid epidemic, all these court cases are being compared to the tobacco litigation which was forced to pay out $250 billion in 1998 (Quinn 2019). Consequently, litigation will primarily turn their focus to the opioid manufacturers with their deep financial pockets whose industry makes over $13 billion in profit each year (Ott 2018). These events will generate a massive subsystem change as companies doling out of billions of dollars deal with the tainted image with the public and a loss in market share. But the companies with no wrongdoing will rise to the top and surpass many previously dominant subfield healthcare leaders.

Litigation Concerns

Convicting the largest pharmaceutical manufacturers and distributors of opioids for their pivotal role in this epidemic will prove to be much harder than the tobacco litigation due to legal policy involving the loose interpretation of bodily injury. Municipalities can claim that the drug companies did engage in fraud, conspiracy, and violated RICO and the Controlled Substance Act along with consumer protection laws (Bruno 2018). To gain evidence to prove this occurrence, 41 states have banded together to subpoena information from select drug manufacturers about the misrepresentation in the marketing and failure to recognize the frequency and quantity of prescription orders (Ott 2018). Coalitions are forming like

ASHRN (American Society for Healthcare Risk Management) with chapters all across the country keeping members informed on current legislation and law proposals by legislators and ensuring necessary funding is made available (Ott 2018). This coalition is crucial to prevent less frivolous claims gets processed which could jeopardize claims with big payouts. One such example involves concerns raised by law enforcement about the possibility of being sued if they administer Naloxone. Naloxone is currently the best drug on the market to treat opioid overdose. It has been claimed to be a lifesaver by the FDA in numerous articles and press talks. To protect themselves, police coalitions are lobbying to change state laws for police and first responders to receive civil immunity through the Good Samaritan laws (Collins 2015). Additionally, the Department of Justice has weighed in on this concern stating the low possibility that these lawsuits against police will be taken seriously in a court of law. The concerns expressed by the police fits into the advocacy coalition frame. Actors behaving rationally can find themselves in situations where they feel conflicted with their core beliefs to save individuals based on the possibility their actions might get them in trouble if no clarification is provided.

The scale of lawsuits emerging is astounding to say the least. For example, in Pennsylvania 16 counties plus the city of Philadelphia have filed lawsuits against big pharmaceutical companies and manufacturers and this trend is spreading in other states like Ohio hit hard by the epidemic (Ott 2018). To expediate the process and establish order to the legal lawsuit chaos, the Federal Government has decided to bound cases together in multi-district litigation (Bruno 2018). 2,300 of these lawsuits will be heard under a Federal Judge in the Northern Ohio District. Once the judge determines a recommendation on how to settle the cases, the cases will return back to their original courts. Judge Dan A. Polster presides over this lawsuit gaining the attention of all the coalitions involved in the subfield. Despite showing bias with his first day announcement indicating his clear preference for a global settlement deal rather than go to trial, Judge Polster's actions have been called "novel" and "unorthodox" by policy and legal experts (Hoffman 2019). His predictions for a speedy resolution have not materialized as the case has lingered in

the federal court for the past two years. The goal changed to a "negotiation class" which would allow 49 local governments to establish settlements with the companies. If the majority of these 49 municipalities agree to terms, it will be applied to every local and state government with lawsuits unless they opt to drop out of the case. Once the judge legally authorizes the settlement, drug companies cannot be sued in the future at the federal level by city and countries. Through the advocacy coalition framework, these local government entities gain bargaining power and stronger leverage while the companies save significant money by ensuring prevention of future lawsuits (Duffin 2019).

By advocating a moderate position, the single federal judge combs through many of the coalition hypothesis before reaching his final verdict. This concentrated approach protects the interest group allies of both the defendants and plaintiffs except both actors will give up secondary aspects of their belief systems in order to prevent a never-ending litigation case that many municipalities cannot afford (Weible 148). The case took an unexpected turn in late 2019 when the defendants comprised of Walgreens, Rite Aid, CVS, Cardinal Health and McKesson filed a motion to disqualify the judge based on his continued biases to settle in order to financially relieve state and local governments. Judge Polster has made numerous comments in the courtroom, public appearances and to the media. This recusal of the federal judge is a rare occurrence especially this late in the overall process. The ramifications of this verdict could set off an astounding chain of events as many attorney generals include the Ohio AG where the case is being heard is attempting to get the US 6th Court of Appeals to end the case on the grounds it violates the power of the states (Hoffman 2019).

Just this week, after months of additional litigation involving opioid lawsuits observed 21 states reject an $18 billion opioid ligation settlement by the three largest drug distributers as the states wanted a larger settlement offer in the range of $22-32 billion (Hals 2020). The pharmacies and drug makers are not included in this offer and this movement also fits in the advocacy coalition framework as the drug

distributors are appearing to break from their coalition in order to settle so that they can regain relatively stability parameters (Weible 144).

Limitations Public Image Ramifications or Polishing their Public Image (would use different subtitle

Some limitations to this theory would include controlling a positive public narrative which would be hard based on the high prevalence of deaths and destruction caused by the opioid epidemic. Even though these companies belong to the Fortune 500 and the most influential lobbying coalition presence in DC, the public scrutiny might not be enough to save their image. Secondly there are many cultural and emotional connotations that clash with this theory. It would work better under the IAD Framework. These connotations guarantee that the traditional stability of the system will disappear for a while.

Drug Pricing

In times of overcoming ominous threats, coalitions will often become stronger or break apart dealing with adversity. In order to free themselves, coalitions break apart through the devil shift as groups place the blame for the problem on other subsystems instead of resolving the issue. A healthcare policy where this effect clearly evident involves drug pricing and the ongoing battle to lower prescription drug prices. Many Americans struggle daily to pay for prescription drugs and our nation pays more for medicines than anywhere else in the world. The resulting frustration has led to surprising bipartisan support in forming coalitions to reform the industry at the state and national level. These coalitions are also exerting massive pressure for biopharmaceutical companies to work with the US government in controlling pricing as well as creating more transparency in the industry as a whole. With this goal in mind, these coalitions cannot discount the U.S. important role as the world's foremost innovator for drug development and all that entails with the expensive investment of drug research (Jena 2018).

Due to the complex nature of the highly regulated healthcare industry, many factors contribute to the price discrepancy of prescription medicine not being transparent to the general public. All coalitions

involved agree that medicines are one of the most effective tools in improving patients' medical conditions and that those who need medicines should have access to it. But society cannot find common ground on how this health benefit gets translated to an actual price value. This is where the most disagreement happens between government and private industry coalitions on attempting subsystem affairs (Weible 139). Value is currently evaluated by amount of drug supply, the ability to create new innovative medicines and successful patient outcomes. It is not only the pharmaceutical industry receiving pressure to reform by outside coalition groups. The very identity of value is shifting in healthcare from a fee-for-service mentality to value-based healthcare system where doctors get paid based on outcomes instead of the previous system where they get paid by the number of patients saw. As a result, costs skyrocketed under the old value practices as doctors were more liberal in requesting unnecessary tests and procedures on patients in order to gain money. Instead, this new system brings accountability to doctor groups decreasing their power in the medical subfields as patients will have influence in removing bad doctors and more flexibility with their insurance planes. Along with doctors' coalitions, pharmaceutical companies are changing their business model for new products based on safety and effectiveness. For example, if a patient with diabetes takes medicine that does not lower their blood sugar level by a certain percentage over time, the patient can receive a full refund or price reduction (Andrade 2019). Since 2015, Medicaid and Medicare along with medical facilities run by the department of human and health services started operating in a value-based system which has improved patient out per dollar on treatment (Lapointe 2018).

Single Payer System

Another major change some coalition groups are attempting to bring to healthcare is to establish price limits similar to other developed countries with a single payer system. These countries can achieve these prices by setting price caps with drug companies and not covering certain medicines which could lead to rations and shortages of medicines (Jena 2018). Aside from creating an equal payer system for all,

these groups want the government to have the ability to negotiate with pharmaceutical companies even though the government is the largest prescription drug buyers in US through the VA, Department of Defense and Medicare. Pharmaceutical company's advocacy coalitions do not use enough policy-oriented learning to educate coalitions outside the healthcare subfield as other country's systems relay on the US to subsidize heavily in global research for drug development. It is not feasible to expect medical innovations in other developed countries as there is small investor return on investment and high developmental costs. This can be proven as US biopharmaceutical companies' funds 44% of the world's medical R&D (National Science Foundation 2018). The gap is increasing and the financial responsibility to uphold high standards on clinical drug trials hinders U.S biopharmaceutical companies to maintain profits for their shareholders (Goldman, 2018). As seen through the advocacy coalition framework, this financial burden puts pharmaceutical companies in a tough position especially with the external subsystem events to adopt a single payer system. This will end the stable parameters of their industry leading them to become more aggressive in using resources and strategies to overcome this threat.

Roles of Insurance Companies and PBMs

The insurance companies have been effective in using the devil shift to direct public anger toward pharmaceutical companies for their profits made by drug pricing. By keeping the attention on the high drug prices allows the insurance industry to avoid scrutiny even though out of every dollar spent on healthcare has 12% tied to the industry (Axene Health Partners 2019). Negotiations between drug and insurance companies for the final listed prices without insurance discounts are largely hidden from public eyes. Pharmaceutical coalitions and their advocacy groups are pairing up with the government to bring more transparency to the process. In these decisions, the insurance companies have immersive power as they decide what medicines can be used by patients and what medical services will be covered. More often than not, this ensures that the patient takes the more expensive drug brand instead of the cheaper generic alternative (Thomas 2017). From there, additional negotiations happen with the vendor companies who

actually sell the drug to the consumer. If an insurance company questions the pharmaceutical company's price listing, they can reject it and the billions of dollars the company spend investing in the drug could lead to substantial financial losses. Smaller policy entrepreneurs and companies face the daunting task to align with primary coalition groups in hopes to get their drugs to reach the market. This ensures stability to the system but prevents outsiders from gaining power in pharmaceutical subsystems.

An increase in legislation and regulations on the state and local levels are being passed as these entities are trying to intervene for the patient but these best intentions have only deepened the complexity and loopholes of price transparency. Last year 33 states implemented 51 laws as recorded by the National Academy for State Health Policy (Findley 2019). For example, Vermont now requires pharmaceuticals companies to provide justification when they raise prices (Ramsey 2017). But the states in taking this stand has put them against the power pharmacy benefit managers who have consolidated power in their subfield by getting concessions on pricing by pharmaceuticals and also manage the benefits for large corporations. Pharmacy Benefit Managers (PBMs) representing the middlemen between pharma companies and the retailers as well as 16 states have banded together to create regulation for these entities (Findley, 2019). Pharmaceutical companies at great risk or within the shadows are helping these state entities as they frequently point out PBMs are contributing factor for high drug costs.

President Trump's Initiatives

President Trump has repeatedly denounced the high cost of prescription drugs. He has struggled to fulfill his campaign promise to lower drug pricing especially through several high profile failed policy attempts. The first failed initiative includes importing cheaper prescription drugs from Canada. This bill's concept presents a logistical nightmare for the FDA to ensure drug safety and eliminate the threat of counterfeit drugs. Another failed initiative involved having all pharmaceutical's television advertisements include the list price of the drug in their marketing. This policy got blocked by a federal judge who ruled

in favor of the pharmaceutical companies' lawsuit (Allyn 2019). As a result, coalitions are now pushing to criticize the president and lobby Congress to pass their legislation. One such advocacy group includes the Patients for Affordable Drugs who fund multi-million advertising campaigns (Jensen 2020) These media campaigns come at a critical time in drug pricing as there are two different versions of drug pricing bills being pitched in the Senate and the House of Representatives. The House bill proposes an aggressive resolution to allow Medicare to directly negotiate with pharmaceutical companies while the Senate bill also addresses the Medicare Part D plan which represents its prescription drug program by placing inflation caps for drug makers if they raise drug prices higher than the inflation rate. These two bills have been stalled in a deadlock since early September 2019. Out of the two proposals, the White House has endorsed the Senate version called the Grassley-Wyden Bill. The Congressional Budget Office (CBO) estimates that the Grassley-Wyden Bill would save over $85 billion for Medicare over the next 10 years (Cancryn, 2019).

In addition, the Trump administration has also explored the option of an international pricing index through executive order. This proposal would cap payments for drugs to average the lowest prices offered in developed countries (Facher 2019). Recently, 53 conservative and libertarian organizations sent a letter to HHS Secretary Alex Azar to not continue with the proposal as it would add price controls harming patents and innovations (Hendrie 2020). Along with these political groups, they are being joined by healthcare coalitions including the HHS Secretary himself who stated in a Senate Hearing that companies will raise prices abroad to increase prices or avoid foreign markets (Facher 2019).

Conclusion

Normally it remains very difficult in healthcare to describe three policies under one framework due to the complexity of the regulations and existing laws. But in this insistence, the advocacy coalition framework fits perfectly due to the utility it provides in this case. Whether it ranges from drug pricing to

opioid liability lawsuits, each scenario involves many coalitions from the private sector all interacting with forces in the government sphere to achieve their goals. Coalitions with the most success of protecting their data, finding new and innovative ways of bringing down prices and not getting tangled up in costly opioid litigations will emerge as the new coalition leaders in their subfields. Surviving these potential landmines is crucial, as each policy has the potential to change the stable parameters of the whole Healthcare subfield in dramatic ways but they can also provide great opportunity for advancement if the situation is handled properly.

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