



HOUSE COMMITTEE ON THE JUDICIARY SUBCOMMITTEE ON ANTITRUST,
COMMERCIAL, AND ADMINISTRATIVE LAW

Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets

April 29, 2021 at 1:00 PM, [Cisco WebEx](#)

PURPOSE

The purpose of this hearing is to discuss anticompetitive conduct in the health care sector, highlighting primarily the anticompetitive practices of the pharmaceutical industry. Also under scrutiny is the anticompetitive nature of consolidation efforts of pharmaceutical companies as well as hospital entities.

KEY TAKEAWAYS

- This hearing highlighted bills and proposals intended to enhance generic and biosimilar competition and target pharmaceutical drug antitrust tactics, such as product hopping. These bills include Affordable Prescriptions for Patient Act, CREATES Act, Medicare Negotiation, the Prescription Drug Pricing Reduction Act, and importation of drugs.
- Members and witnesses underscored anticompetitive industry practices, such as pay for delay, product hopping, and ‘evergreening’ of drug patents.
- Various Congressmen and women put forth statements calling for the Federal Trade Commission (FTC) to look into consolidation and antitrust industry practices, with particular emphasis on the pharmaceutical drug industry.
- The highlighted anticompetitive actors included pharmaceutical manufacturers, insurance companies, pharmacy benefit managers (PBMs), insurance companies, as well as hospitals.

MEMBERS PRESENT

Chairman Cicilline, Ranking Member Buck, Representatives Nadler, Issa, Jones, Johnson, Raskin, Greg, Jeffries, Bishop, Jayapal, Fischbach, Deutch, Spart, Dean, Feldman, Fitzgerald, Buck

WITNESSES

Senator Klobuchar (D-MN)

U.S. Senate

Senator Cornyn (R-TX)

U.S. Senate

Senator Grassley (R-IA)

U.S. Senate

Senator Lee (R-UT)

U.S. Senate

Senator Blumenthal (D-CT)

U.S. Senate

Senator Maloney (D-NY)

U.S. Senate

Leemore Dafny, PhD*Professor*

Bruce V. Rauner Professor of Business Administration, Harvard Business School

Michael Carrier*Distinguished Professor*

Rutgers Law School

Robin Feldman*Arthur J. Goldberg Distinguished**Professor of Law**Director, Center for Innovation*

University of California Hastings College of the Law

Albert Abbot*Senior Research Fellow*

Mercatus Center at George Mason University

OPENING STATEMENT SUMMARY

Chairman Cicilline (D-RI) opened the hearing by stating that prior to the COVID-19 pandemic, the health care system was in a state of crisis. Prescription costs have increased by 200% in a short period of time. Kaiser reported that a quarter of cancer patients could not afford their drugs and resorted to cutting pills in half or skipping their doses. Despite rising costs, the US ranks last in health outcomes among developed countries. Consolidation within the health care sector has continued as cost of care skyrockets. Five mega mergers in the pharmaceutical market adding up to nearly \$100 billion occurred in the second half of 2020 alone. The FTC has not attempted to block any of these deals despite growing concerns of inappropriate behavior, especially in the pharmaceutical market. In the hospital market, the FTC has been more successful at blocking these types of mergers. One hospital administrator received \$6.17 million while they furloughed thousands and received large bail outs from the federal government. It is far more likely that monopoly prices are contributing to CEO benefits rather than bringing lifesaving medications to the market. Chairman Cicilline stated that the entry of generic drugs is needed but some companies participate in anticompetitive actions to delay the generic drugs from entering. The CREATES Act has been successful at presenting solutions to this issue however more needs to be done to address other forms of anticompetitive behavior. That's why the reintroduction of the Affordable Prescriptions for Patients Competition Act should be passed.

Ranking Member Buck (R-CO) stated that health care consists of one-fifth of the U.S. GDP. Health care is a very large component of the economy which has been made further complex through the actions of the Affordable Care Act (ACA), especially within the pharmaceutical industry. Ranking Member Buck stated that the ACA has been sold to the people by promising affordability and protection, but it has done the complete opposite. The U.S. has seen a loss of doctors, increased consolidation, and increased costs. Two of the largest insurers control 70% of the market. Consolidation and closing of hospitals is prevalent, especially within rural communities. This leads to fewer choices. Federal regulations and contradictions have added to complexities and difficulties of the health care sector. Ranking Member Buck stated that the web of inconsistent laws in health care makes it difficult to maneuver, which has been further exacerbated by COVID-19. The

speed with which COVID-19 vaccines hit the market was unheard of and further provides justification that the regulatory practices need to be reformed permanently. The games played by the pharmaceutical industry, such as artificially delaying drugs to the market and anti-competitive actions needs to be stopped.

Chairman Nadler (D-NY) stated that all of the bills that will be discussed in the hearing would provide patient protection from the harmful anticompetitive actions of the pharmaceutical industry. Today, one quarter of Americans report that it is difficult to afford their medications, including seniors, cancer patients, and people suffering from chronic illnesses such as diabetes. These issues have been further worsened by the coronavirus pandemic. Under both Republican and Democratic leadership, the House Antitrust Subcommittee has been focused on solving these issues in the past and seeks to continue its efforts now. A significant effort would be easing generic drugs entry to the market, which would disallow pharmaceutical companies to have monopoly powers. That's why the reintroduction of the Preserve Access to Generics and Biosimilars Act, which would ban pay to delay actions, is important to stop these growing issues. Further, this legislation passed this same subcommittee last year so hopefully it can pass this year once more.

TESTIMONY SUMMARIES

Senator Klobuchar said it is not only the technology industry that suffers from consolidation, but also the pharmaceutical industry. First, Medicare should be allowed to negotiate drug prices, which President Biden mentioned last night. Second, drug importation should be considered as an important effort. Third, protecting generics, which the CREATES Act could help provide a solution. Fourth, antitrust anticompetitive policies need to be prioritized within the pharmaceutical industry which efforts such as a merging filing-fee. Big Pharma and Big Tech cannot be taken on with band aids and duct tape.

Senator Grassley said drugs are unaffordable for millions of Americans which causes patients to not follow their treatment plan in the way they should. Through recent discovery, the relationships within the health care industry, such as PBMs and debt collectors, have further worsened the affordability issue for taxpayers. The importation of safe and affordable prescription drugs from Canada could help lower drug costs. Further, the rebate process that is currently in place needs to be reformed while the consolidation efforts need to be further researched to understand the magnitude of harm to patients, especially within the PBM industry. Many of the legislative proposals introduced today could help solve these issues.

Senator Blumenthal said the No Stalling Act and the Preserve Access to Generics and Biosimilars Act are two important bills that could solve many of the issues discussed today. Also, importing more drugs, requiring Medicare to negotiate drugs, and the Affordable Prescriptions for Patients Act, which would eliminate the abuses of product

hopping, could also be successful in solving these issues. Further, patent dancing also needs to stop. However, what needs to occur today is to break up these monopolistic predatory powers. Strong enforcement of the current laws need to be prioritized while also further policies need to be written into law to prevent these actions from occurring.

Senator Cornyn said it is important to recognize American ingenuity and creative innovation has led to life saving discoveries. However, strong public health policies are incredibly important to protect public along with supporting these discoveries. No families should have to make difficult choices in regards to the health. The Affordable Prescriptions for Patients Competition Act is strong legislation that negates patent thickening from occurring while also protecting patent rights. It is known that companies will not invest in life saving discoveries if they cannot find a return at the end of the product but bad actors cannot continue.

Senator Lee said the CBO estimated that the CREATES act will save 3.8 billion for taxpayers and has already been successful in supporting generic drugs to enter the market. Because of the success of this bill, other bills should follow this pathway through incremental targeted fixes rather than a one-size fits all approach. If there is anything worse than a monopoly using its power to squeeze citizens, it's when that monopolist power is a product of the democratic process. At the state level, incumbent hospitals have veto power from allowing other hospitals to be successful while nurse practitioners also have restrictions that both hurt citizens and the economy as a whole. Government intervention at the federal level has hurt the system in many ways such as Medicare strong arming lower reimbursement rates. As such, Medicare for all would result in everyone to suffer since no one would exist to pay out subsidies that the system currently requires. Providers and patients deserve a free market approach.

Senator Maloney said the late Chairman Cummings first enacted an extensive research project of the largest pharmaceutical companies in the nation, which has continued after his passing. While the country is reliant on the pharmaceutical industry for life saving drugs, they too frequently have abused the system by engaging blatantly anti-competitive behavior. While Medicare has not been allowed to negotiate drugs, pharmaceutical companies have targeted the country to charge high prices while the rest of the world lowers their prices. By allowing these anti-competitive tactics to continue, the country is paying more money for negative behavior. For example, Teva participates in product hopping which experts estimate this one hop cost the country approximately \$1.4 billion. Experts also estimate that Novartis delay in a generic drug cost the country over \$1 billion. The investigation also discovered patent thickens, the misuse of the Orphan Drug Act, and harmful relationships with PBMs. These deceitful efforts need to be addressed.

Dr. Dafny said the United States spends a larger share of its GDP than any other country. High prices, not the type or quantity of services or the health of the country, have to do with the rising costs. Health care providers such as hospitals and physicians account for

roughly half of the country's expenditures. In the late 1990s, private practices were 10% higher than Medicare costs where in 2012, the cost rose 75%. Rising costs equate to higher premiums, which mean smaller paychecks, and higher deductibles, which mean more out of pocket costs. Consolidation of the health care sector is a reason for increased spending, in particular after hospitals acquire other hospitals in the same state or of other practices. The bad guys are not hospitals, doctors, or insurers. The bad guy is a lack of competition. Three solutions to these issues are first, strengthen the federal enforcement agencies to identify potentially harmful mergers. Second, amend and strengthen the antitrust statutes. Third, ask the agencies to issue health care guidelines.

Mr. Carrier said the CREATES Act is a strong piece of legislation that would be a targeted solution to the anti-competitive nature of the pharmaceutical industry. The first thing Congress can do is address product hopping. H.R.2883 would address the issues of soft switches of drugs. The second effort Congress should address is the pay for delay action to work against generic drugs. Third, citizen petitions, which would also be addressed by H.R.2883, need to be assessed. Fourth, Congress can address biosimilar disparagement. It is harmful and is furthered by inaccurate advertisement efforts. Fifth Congress can address mergers. A presumption should be made against mergers since there is no good reason for large-sized mergers to occur. Additionally, generic mergers deserve more attention as well since not all generics are doing what they are supposed to do.

Ms. Feldman said it is known pharma markets aren't working due to its anti-competitive behaviors while they are repeatedly gaming the system. This is included by delaying generics from entering the market. Many of the games, including product hopping, involve some modification of an existing drug, which can be seen in the market of opioid use disorder. Often, these modification patents are very weak which has resulted in generics winning most cases against the patent. However, these cases take a very long time so the company is allowed to continue to accrue profits. These gaming activities also include reviving older drugs, pushing for drugs on the market that already exist. All of these activities reduce competition in the industry. The antitrust laws haven't kept up, which has resulted in many courts only focusing on one specific action of a company, which misses many of the harmful actions. These issues have only really blossomed over the past 15 years, so they are not very old which allows for the potential of solutions positive impact.

Mr. Abbott said additional funding for the fed antitrust enforcement is a bipartisan endeavor and should be further prioritized. The other effort that needs to be furthered is that the FTC should be given authority over nonprofits. Additionally, the far reaching statutory efforts could be harmful but targeted statutory amendments can be appropriate in the right circumstances, which is also why the CREATES Act is a strong piece of legislation. Lastly, enhancing competition in the health care market should continue to remain as a nonpartisan effort.

QUESTION AND ANSWER SUMMARY

Chairman Cicilline asked why there has been so much consolidation in the health care industry. **Mr. Feldman** said the closer the country gets to a free market, the better the country will be. A far greater response for mergers is needed. **Chairman Cicilline** asked what are some examples of mergers that are harmful that go unchecked. **Dr. Dafny** said examples are both when hospitals are buying nearby hospitals and when a hospital acquires a physician practice, which increase hospital facility fees. One could require the parties that are proposing the acquisition to demonstrate why the purchase won't be harmful. **Chairman Cicilline** asked why product hopping is so harmful and how the Affordable Prescriptions for Patients Competition Act would solve these issues. **Dr. Carrier** said product hopping hurts patients and only raises prices. The legislation would help courts understand that soft switches are harmful.

Rep. Issa (R-CA) asked if there is any reason why the committee couldn't revoke the right of anyone having a patent that isn't useful. **Mr. Carrier** said not every patent is valid and the concern with product hopping is it is an invasion of the regulatory regime. **Rep. Issa** asked why the patent abuses do not exist in the generic drug market. **Mr. Carrier** said while trade secrets are important, it is hard for generics to access a patent if it is under lock and key. **Rep. Issa** asked if the trade secrets shouldn't be allowed to create a barrier if a company wants the patent. **Mr. Carrier** said yes, most areas have to choose.

Rep. Jones (D-NY) asked for an example of a pharmaceutical merger that has been harmful. **Mr. Carrier** said the Abbvie and Allergan merger could be an example. Both companies had a significant amount of blockbuster drugs while the tough rebate laws made it difficult for any other competitors to go against them. **Rep. Jones** asked why a presumption against mergers is important. **Mr. Carrier** said the key element of size makes a very big difference where there is no good reason for two large companies to merge. **Rep. Jones** asked how it would help patients to make some mergers presumptive. **Dr. Dafny** said it would save substantial regulatory resources.

Rep. Johnson (R-LA) asked what the certification of need is. **Mr. Abbott** said the certificate of need is a state law provision that requires that any hospital investment needs to be justified. But in reality, they are harmful since a larger hospital can veto a smaller hospital from its investments. **Rep. Johnson** asked how reforming this would improve the experience for patients. **Mr. Abbott** said it would allow new entry into the market and prevent rural monopolies from entrancing the market power.

Rep. Raskin (D-MD) asked how the antitrust law has developed to deal with monopolies. **Ms. Feldman** said the antitrust laws are an essential partner but they haven't caught up with the sophistication of the health care sector. **Rep. Raskin** asked how an antitrust system could be created to solve the issues being discussed today. **Ms. Feldman** said legislation needs to pass that consist of examples of specific targeted behaviors that are inappropriate and that include sophisticated language to give agencies the space to

respond. **Dr. Dafny** said there can't be incentives for these games to occur. Preventing them can arise by strengthening enforcement's hands and reduce the burden of proof in transactions will result in better outcomes.

Rep. Greg (R-FL) asked which state policies could be marked as anti-competitive. **Mr. Abbott** said occupation licensing restrictions are an example, such as restrictions for nurse practitioners. While these are state policies, Congress could make an impact. **Rep. Greg** asked how the ACA's acceleration of consolidations has been harmful. **Mr. Abbott** said incentives were created for consolidation, but the causation of them by the ACA is not necessarily true. **Rep. Greg** asked how the problems discussed today could be addressed in a targeted way. **Mr. Abbott** said health care is unusual because there is a combination of state and federal complexities. Broad laws have created incentives for further gaming.

Rep. Jeffries (D-NY) asked if there is reason to believe if brand names have abused citizen petitions towards delaying the entry of generics to the market. **Mr. Carrier** said yes, most are found to be frivolous. 92% of these petitions have been filing these petitions while almost no citizens have filed them. **Rep. Jeffries** asked how this impacts the consumer. **Mr. Carrier** said citizen petitions are used with other conducts to make it harder for consumers to afford the services they need. Companies claim they are raising safety concerns but frequently it is a sham.

Rep. Bishop (R-NC) asked if it is true that the ACA has increased consolidation. **Dr. Feldman** said the closer the system can get to competition, the better the country will be. **Dr. Dafny** said there is no data to prove the causation of consolidation from the ACA. However, incentives have been created for these types of transactions. **Rep. Bishop** asked if consolidation of insurers would be good for consumers. **Dr. Dafny** said consolidation of insurers would be concerning.

Rep. Jayapal (D-WA) asked if a lack of unfair competition has resulted in issues. **Dr. Dafny** said yes, the growth of prices that has coincided with the increased consolidation of the health care sector in undeniable. **Rep. Jayapal** asked how hospital consolidated effect consumers. **Dr. Dafny** said it impacts spending and reduces consumer experiences through lowering access to services. **Rep. Jayapal** asked how nonprofit and for-profit hospitals engage in similar behaviors. **Dr. Dafny** said they are in the same industry. Even if nonprofits aren't seeking profits, they are at least seeking to break even. There shouldn't be a difference in enforcement of these entities and they both require antitrust scrutiny. **Rep. Jayapal** asked how antitrust laws can be strengthened to prevent non-horizontal transactions. **Dr. Dafny** said more reporting and justification as to why the transaction is not harmful.

Rep. Fischbach (R-MN) asked what the federal role is in relation to state anticompetitive policies. **Mr. Abbott** said the federal role is competition advocacy. Additionally,

occupational licensing should be a no-brainer but it is not. **Rep. Fischbach** asked how regulatory costs that health care providers experience create barriers to entry. **Mr. Abbott** said it is a very complicated topic but there are many barriers to entry.

Rep. Deutch (D-FL) asked what anti-competitive activities Suboxone participated in to extend its patent. **Mr. Carrier** said it first participated in patent hopping and then citizen petition. These actions were not justified exclusively outside of hurting generic drug's entry to the market.

Rep. Spart (R-IN) asked if there are any approaches from the bottom up to solve these issues. **Mr. Abbott** said while it may simplistic, regulatory reform and competition advocacy are very important.

Rep. Dean (D-PA) asked how the orphan drug exclusivity has been used. **Ms. Feldman** said the Orphan Drug Act was originally intended for companies that couldn't recoup their finances from creating niche drugs. Closing the loophole currently being abused by the Orphan Drug Act would be very beneficial. **Rep. Dean** asked what the lack of competition does more broadly. **Ms. Feldman** said the problem is the access of affordable medications for patients. The Orphan Drug Act is intended to only reach small populations so companies slice up their populations to apply for serial Orphan Drug Applications.

Rep. Fitzgerald (R-WI) asked if there are any examples of laws that should be considered before reinstating licensing laws. **Mr. Abbott** said there are many licensing laws that have prevented inter-state movement. Certificate of need laws should be considered and any subsidies from the ACA could be provided more to patients rather than providers. **Rep. Fitzgerald** asked how antitrust laws can go too further. **Ms. Feldman** said it is important that antitrust can keep pace with innovations. COVID-19 vaccines are wonderful examples of the scientific collaboration and innovation in the country and are good reminders that patents aren't the only way to increase competition.

Rep. Buck asked if it is an issue that the high ranking executives in health care companies are treated like a shareholder and receive high compensation. **Dr. Dafny** said just with the case for regular for profit companies, there are market prices for someone for that skill. The issue is more so about the total amount that is being charged, not the specific compensation of the executive.