CORPORATE CRIME REPORTER

PHILLIP ZWEIG ON LEGALIZED KICKBACKS IN HEALTHCARE

Why in America, land of the free, home of the brave, are hospitals struggling with drug shortages?

Two words – legalized kickbacks.

At the center of the crisis are for profit corporations known as group purchasing organizations. The big four are Vizient, Premier, HealthTrust and Intalere.

The group purchasing organizations control purchasing of \$300 billion annually in drugs, devices and supplies for the nation's healthcare system.

If you pay the GPO a big enough fee, you get the sole source contract to the hospitals.

But aren't kickbacks like this criminal? In every other industry, yes.

In this one, no. Why?

Because Congress, in its wisdom, in 1987, created a safe harbor for the group purchasing industry.

In other words, no longer could the government criminally charge the group purchasing organizations for taking kickbacks.

This has led to a reduction in the number of suppliers and drug shortages for hospitals.

It's so bad that the United States now imports sterile saline solution from Spain, Norway and Germany.

How to fix the problem?

Repeal the 1987 law and reimpose criminal penalties for kickbacks.

That's the take of Phillip Zweig, a business journalist who now heads a group called Physicians Against Drug Shortages. In his career, Zweig worked for a number of news outlets including the *Wall Street Journal, Business Week* and *Bloomberg.* He is the author of two books – *Belly Up: The Collapse of Penn Square Bank* (Ballantine Books, 1985) and *Walter Wriston, Citibank, and the Rise* and Fall of American Financial Supremacy (Crown Publishers, 1996).

He now has a laser focus on legalized kickbacks in healthcare.

"Group purchasing organizations were originally founded in 1910 as cooperatives," Zweig told Corporate Crime Reporter in an interview last week. "Hospitals found they could band together and by buying supplies in bulk, they could save everyone money. This cooperative arrangement, which started down First Avenue from me in Manhattan at Bellevue Hospital, worked fine for 80 years."

"In 1972, Congress passed anti-kickback laws that prohibited kickbacks of this sort. In the mid-1980s, the hospital lobby and the group purchasing lobby went to Congress and sought a safe harbor. They said – we need to codify what's already going on. Manufacturers had been paying kickbacks to the group purchasing organizations, obviously illegally. The lobbyists said – let's just put this into statute."

Who are the major players?

"The major lobbying group is the Healthcare Supply Chain Association. They represent all of these group purchasing organizations. Their primary function is to preserve the safe harbor."

The GPOs make money doing what?

"They make money selling sole source contracts to the highest bidder. They make money off of these legalized kickbacks. As far as I have been able to tell, this is the only industry in America that has a blessing from the United States Congress to take kickbacks."

And they are taking kickbacks from whom?

"From suppliers. Every company that supplies goods to American hospitals, outpatient clinics, nursing homes, most every product that is purchased by 5,000 American hospitals."

You pay us and we will get your products into hospitals?

"That's the long and short of it yes. Because of the safe harbor, it's the principal agency problem. Under the old cooperative model, the purpose was to save money for hospitals. The GPOs were working for the hospitals. As soon as the rules were implemented in 1991, the business model changed 180 degrees to where the GPOs were in the business of selling market share to the suppliers. They have said this in print – we deliver market share. The more market share that a company wants, the more it pays to the GPO."

(See ZWEIG, page three)

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(ZWEIG, from page one)

If the law is repealed, how does that relieve the shortages?

"The shortages have resulted from the fact that the GPOs have awarded sole source contracts to many of these large suppliers, eliminating competitors. If you know that your competition has a sole source contract with two group purchasing organizations that control the marketplace, why would you want to enter this business?"

What role do hospitals play in the kickback game?

"There are all of these drug shortage stakeholders – the American Hospital Association, the American Medical Association, the American Society of Health System Pharmacists, the American Society of Clinical Oncology. Many are conflicted."

"Take the American Hospital Association. This is the clearest example. The GPOs are for profit organizations. Vizient, formerly Novation, is owned by major shareholder members. As institutions, they get the profits from the kickbacks. Premier is a publicly held GPO. How do you grow shareholder revenue and market value while saving money for hospitals? There are two classes of stock. One class is owned by their hospital members. And another class is owned by institutions and whoever wants to buy it."

"We had known for years that the shareholder hospitals get what is called patronage fees from the GPOs. The GPOs admit that the CEOs of member hospitals count on what are known as sharebacks as part of their annual compensation."

What is a shareback?

"A percentage of the kickback goes to the CEOs. That's how they keep this system in place."

"Have there been any books written on this?" "Yes back in 2009 by S. Prakash Sethi. It's called Group Purchasing Organizations: An Undisclosed Scandal in the U.S. Healthcare Industry."

Is there legislation in Congress?

"There was a discussion draft bill that was introduced in 2005 but never made it out of the subcommittee," Zweig says. "Last year, we met with Congressman Mark Meadows (R-North Carolina). He drafted a bill based on the 2005 bill that would repeal the safe harbor. That is circulating. He never introduced it."

Why not?

"Two months later, we get an email from Congressman Meadows' legislative assistant saying that Freedom Works and Heritage Foundation don't support it, so that's the end of that."

Senator Richard Blumenthal (D-Connecticut), when he was Attorney General in Connecticut in 2006, testified before the Senate Antitrust Committee saying that group purchasing organizations amounted to a "pay-to-play scheme" and an "insidious, incestuous, insider system," that created "a myriad of conflicts of interest and anti-competitive behavior that must be regulated if not prohibited."

At the time, Blumenthal called for "immediate Congressional action" and "more aggressive federal action to investigate and prosecute" antitrust violations.

Blumenthal's investigation ended landed him on the front page of the New York Times.

But as Senator, Blumenthal has refused to introduce legislation to correct the problem.

Zweig took to the pages of the *New Haven Register* in 2016 with an op-ed piece titled "Blumenthal's Silence Deafening on Root Cause of Surging Generic Drug Prices."

"Somewhere on the road from Hartford to Washington, Senator Richard Blumenthal seems to have lost the pugnacity and sense of outrage over corporate wrongdoing that marked his 20-year tenure as Connecticut's attorney general," Zweig and co-author Dr. Rob Campbell wrote.

"The Obama administration and Congress are well aware of these abuses," they wrote. "But they haven't intervened because of the formidable political clout of the GPO cabal."

(For the complete Interview with Phillip Zweig, see page 12.)

ROTECH TO PAY \$9.95 MILLION TO SETTLE WHISTLEBLOWER CASE

Rotech Healthcare will pay a total of \$9.95 million dollars to the federal government and certain states to settle a whistleblower lawsuit that alleged the homecare medical equipment company defrauded government healthcare programs through a fraudulent billing scheme.

The alleged billing fraud involved oxygen equipment and oxygen supplies provided for homecare use by Medicare and Medicaid patients.

Out of the total settlement amount, \$9.68 million is attributable to claims on Medicare and \$273,000 is attributable to claims on the Medicaid programs in approximately 20 states.

Phillips & Cohen, together with O'Connell & Soifer, filed the qui tam complaint under seal on behalf of their client in 2014 in federal district court in Plano, Texas.

The court lifted the seal, making the case public, when it approved the settlement agreement last week.

"This was a case where a company tried to grab as much money as it could from Medicare and Medicaid regardless of patients' needs," said Molly Knobler, a whistleblower attorney at Phillips & Cohen who represented the whistleblower. "Without our client, the government would have been unaware that millions of dollars were being siphoned off of Medicare and Medicaid."

Medicare Part B and Medicaid cover the cost of renting certain portable and stationary oxygen equipment as well as the oxygen that is used with that equipment. Starting in 2009, the government placed a 36-month cap on equipment rental payments.

After that period, for the remainder of the useful life of the equipment – generally an additional two years – suppliers may bill for medically necessary oxygen contents, but not for the equipment.

According to the whistleblower lawsuit and the settlement agreement, Rotech programmed its software in 2009 to automatically bill Medicare and Medicaid monthly for portable oxygen for all of its patients after the 36-month billing cap, including those who did not need or use portable oxygen.

"Rotech's programmers programed the software pursuant to the specifications approved by Rotech's management," says the settlement agreement.

The healthcare programs were billed for oxygen equipment that was never delivered.

Durable medical equipment suppliers are required to maintain proof of delivery for the equipment and supplies, and Rotech acknowledged in the settlement agreement that it failed to verify that equipment was delivered.

The whistleblower, a former Rotech employee, reported her concerns to the federal government about the company's billing system before she filed a qui tam lawsuit alleging violations of the False Claims Act.

After the government began an investigation into the matter, Rotech's chief compliance officer ordered the company in 2012 to turn off its automatic billing system.

The company then sent out letters and refunds to contractors responsible for administering the Medicare program, claiming the billing system was "inadvertently programmed with a flaw."

The letters also claimed the company discovered the flaw by "examining adjustment reports and consultation with the Corporate Compliance Department."

"Our client was deeply troubled by how government healthcare programs were being cheated," said Claire M. Sylvia, a whistleblower attorney and partner at Phillips & Cohen. "Because of her concerns, she decided to speak up and pursue her case despite the stress it caused her."

This is at least the third time that Rotech has paid millions to the federal government to settle billing fraud allegations.

In 2002, Rotech Medical Corp. paid \$17 million to settle allegations of billing fraud involving respiratory equipment.

Six years later, Rotech paid \$2 million to settle a whistleblower lawsuit alleging the company suppressed disclosure of billing issues in three states.

The False Claims Act allows private citizens to sue companies that are defrauding the government and recover funds on the government's behalf. If the government joins the case, the whistleblower is entitled to 15 percent to 25 percent of the amount recovered.

FALSE CLAIMS ACT CASE AGAINST CVS HEALTH CAREMARK UNSEALED

A False Claims Act case against CVS Health Corporation (Caremark) was unsealed last week by a federal court in Philadelphia.

The government has not yet determined whether it will intervene in the action, but instead filed a notice on April 2, 2018 that it is not intervening at this time.

The case involves drugs dispensed to beneficiaries under Medicare Part D.

The lawsuit alleges that Caremark, as a Pharmacy Benefits Manager reported to CMS higher prices than what Caremark was actually paying the pharmacies, despite CMS regulations that require the reporting of "pass-through" prices.

The scheme involves separate sets of contracts with Part D Plans on one side and pharmacies on the other.

Pharmacies were paid lower drug prices than the government-insured Part D Plans were charged.

The whistleblower in the case estimates that this deliberate fraud has cost CMS and beneficiaries well over one billion dollars.

CMS changed its regulations in 2010 to require the reporting of "negotiated prices" and to eliminate any PBM spread in the reported drug costs. In addition to wanting to eliminate PBM spread from drug costs (and pay administrative expenses and profits separately), CMS was pushing to have lower prices for beneficiaries and more transparency overall.

Caremark continued the same manner of price reporting that it had used prior to the change.

Consequently, not only CMS but also Medicare beneficiaries have unwittingly paid higher prices for their drugs than what Caremark was actually paying the pharmacies.

Caremark's price reporting caused CMS to overpay Reinsurance and Risk-corridor payments under Part D, and for premiums to be inflated, based on Caremark's fraudulent reporting of the prices "actually paid" to the pharmacies.

The fraud was uncovered by the head actuary, Medicare Part D, at Aetna, which contracted with Caremark to serve as its PBM.

The complaint alleges that when Aetna realized that Caremark was seemingly not obtaining competitive prices for Aetna's Part D plans, Aetna confronted Caremark about the pricing practices. Caremark confirmed that Aetna wasn't getting competitive prices, leading Aetna to ask if Caremark could go back to renegotiate with the pharmacies.

In those discussions, the complaint alleges, Caremark admitted that it had better prices with pharmacies, but it didn't have to pass those prices through to Aetna's Part D Plan.

From the government's perspective, those "better prices with pharmacies" were NOT being reported to CMS, despite the pass-through price reporting requirements and the definitions of "actually paid" prices.

"We believe this is a massive fraud, carefully orchestrated to keep hidden a substantial PBM spread on generic drugs in the Part D program," said Susan Schneider Thomas of Berger & Montague, one of the lead lawyers on this case. "Some beneficiaries were charged higher co-pays at point of sale, and CMS overall was grossly overcharged for drugs in its important Part D program. Although many people focus on the fact that generic drugs are much cheaper than brand drugs, and therefore not a lot of attention is paid to generic drug prices, in fact there are many opportunities for cheating on the generic side as well – and participants in Part D take advantage of the fact that the government might not be paying as much attention as on the brand side."

Caremark owns both CVS pharmacies (where many of these drugs are dispensed) and SilverScript Insurance Company, a major Part D Plan Sponsor.

Caremark (now CVS Health Corp.) and Aetna are presently planning to merge.

That transaction is currently being scrutinized by the Antitrust Division of the United States Department of Justice.

Legislatures, investigators and industry analysts have long lamented the lack of transparency in the PBM market.

Indeed many have placed much of the blame for higher drug costs on the PBMs. Fortune magazine, for example, titled a 2014 article about PBMs "Painful prescription: Pharmacy benefit managers make out better than their customers."

"These middlemen can accomplish this by claiming inflated costs (or negotiated prices) incurred from reimbursing pharmacies without properly disclosing the various chargebacks and other payments that PBMs receive from pharmacies as a condition of contract terms imposed by the PBM," said one industry analysis, B. Douglas Hoey.

The State of Ohio just announced an inquiry into complaints that private pharmacy benefit managers appear to be profiting excessively by slashing reimbursement rates paid to retail pharmacies.

"We are excited about the prospect of bringing these costly PBM practices into the public eye, and breaking the conspiracy of silence that the PBMs have long imposed on other participants in the industry," said Thomas.

CALIFORNIA AG SUES SUTTER HEALTH FOR ANTI-COMPETITIVE PRACTICES

California Attorney General Xavier Becerra has filed a lawsuit against Sutter Health, the largest hospital system in Northern California, for anticompetitive practices that result in higher healthcare costs for Northern Californians.

The action aims to stop Sutter Health from unlawful conduct under state antitrust laws and restore competition in the California healthcare market.

"Sutter Health is throwing its weight around in the healthcare market, engaging in illegal, anticompetitive pricing that hurts California families," said Attorney General Becerra. "These tactics are risking Californians' lives by driving up the cost of healthcare for everyone. Big business should not be able to throttle competition at the expense of patients. The California Department of Justice is dedicated to ensuring that all families in our state can access quality, affordable healthcare no matter where they live."

The complaint alleges that Sutter Health engaged in anticompetitive behavior. These illegal practices resulted in higher prices for health care in Northern California by establishing, increasing and maintaining Sutter Health's power to control prices and exclude competition, foreclosing price competition by Sutter Health's competitors and enabling Sutter Health to impose prices for hospital healthcare services and ancillary products that far exceed the prices it would have been able to charge in an unconstrained, competitive market.

The complaint alleges that the excess profits Sutter Health received from illegal pricing practices went toward waves of acquisitions, extreme levels of executive compensation, and financing its own insurance arm.

Sutter Health consists of at least 24 acute care hospital facilities, 31 ambulatory surgery centers, nine cancer centers, six specialty care centers, nine major physician organizations, 8,200 physicians and 48,000 employees located in 19 counties in Northern California.

Sutter Health also negotiates contracts on behalf of a variety of other affiliated physician groups, the largest being the Palo Alto Medical Foundation.

In California, multi-county hospital systems have charged higher prices for their services than other providers.

Attorney General Becerra called for action in light of a new report by University of California Berkeley's Petris Center on Health Care Markets and Consumer Welfare.

The report documents how the rapid consolidation of healthcare markets in California has led to rising healthcare costs for consumers throughout the state.

Market consolidation in Northern California was especially glaring.

The cost of the average inpatient hospital procedure in Northern California \$223,278 exceeded that in Southern California \$131,586 by more than \$90,000.

PUBLIC CITIZEN: CPSC FAILING TO ALERT CONSUMERS TO DANGER

The Consumer Product Safety Commission (CPSC) should invest in technology and data to advance its mission and remove obstacles to releasing more public safety information, Public Citizen told the commission last week.

Remington A. Gregg, Public Citizen's counsel for civil justice and consumer rights, testified before the CPSC to urge the commission to enhance its online product safety database and update an agency rule to place consumer safety above protecting manufacturers.

Gregg urged the CPSC to work with Congress to eliminate a statute that restricts the CPSC from disclosing information to the public about specific products until the manufacturer or other authorized entity gives the agency permission.

No other federal health and safety agency is

bound by such a law.

The law, Section 6(b) of the Consumer Product Safety Act, along with agency rules implementing the statute, requires the commission to negotiate with a manufacturer or company so that they can weigh in on – or even object to – product safety information before it's disclosed to the public.

"While corporations try to block the release of vital safety information, people – including children – are being hurt by dangerous products still allowed on store shelves," Gregg said.

The hearing comes as Public Citizen and the media highlight growing concerns that commissioners and senior agency staff are becoming too cozy with the industries they are regulating.

Acting Chair Anne Marie Buerkle has consistently opposed strong health and safety regulations throughout her tenure on the commission, Public Citizen said.

Dana Baiocco, who has been nominated to a seat on the commission, has spent her professional career defending corporations from product safety claims. And the agency's new top lawyer previously worked for one of the nation's leading makers of gasoline engines, that consistently has opposed stronger safety standards.

"Sadly, we see an agency that is increasingly more partisan, hiring senior staff with ties to industry, and a White House intent on nominating commissioners who seem eager to protect corporate interests, said Gregg.

"The mission of the nation's chief product safety agency is to protect consumers from unnecessary risk, injury and death – not do the industry's bidding."

Gregg also urged the CPSC to invest in improvements to SaferProducts.gov, an online database that allows the public to search for and report product safety hazards. And he encouraged the commission to make the database more visible to the public on social media and other platforms, and explore innovative ways to convey information about product recalls, among other modifications to the website.

Gregg said the CPSC should implement recommendations that Public Citizen, the Consumer Federation of America and Kids in Danger submitted to the agency in June 2017 to make voluntary recalls more effective. And the agency also should speed up its response time to Freedom of Information Act (FOIA) requests to ensure a timely response that is consistent with its statutory obligations.

SEC AWARDS WHISTLEBLOWER MORE THAN \$2.1 MILLION

The Securities and Exchange Commission has awarded a whistleblower more than \$2.1 million to a former company insider whose information led to multiple successful enforcement actions.

The whistleblower's information strongly supported the findings in the underlying actions and the whistleblower provided ongoing assistance to the staff during the investigation.

"The SEC has issued nearly \$90 million in whistleblower awards in the past month alone," said Jane Norberg, Chief of the SEC's Office of the Whistleblower. "As these awards demonstrate, we continue to receive high-quality information from whistleblowers, which we use to detect and prosecute securities violations and safeguard investors."

Since issuing its first award in 2012, the SEC has awarded more than \$266 million to 55 individuals under the whistleblower program. In that time, almost \$1.5 billion in monetary sanctions have been ordered against wrongdoers based on actionable information received from whistleblowers, including more than \$740 million in disgorgement of ill-gotten gains and interest, the majority of which has been or is scheduled to be returned to harmed investors.

All payments are made out of an investor protection fund established by Congress that is financed entirely through monetary sanctions paid to the SEC by securities law violators. No money has been taken or withheld from harmed investors to pay whistleblower awards.

Whistleblowers may be eligible for an award when they voluntarily provide the SEC with original, timely, and credible information that leads to a successful enforcement action. Whistleblower awards can range from 10 percent to 30 percent of the money collected when the monetary sanctions exceed \$1 million.

BANNER HEALTH TO PAY OVER \$18 MILLION TO SETTLE FALSE CLAIMS CHARGES

Banner Health will pay over \$18 million to settle allegations that twelve of its hospitals in Arizona and Colorado knowingly submitted false claims to Medicare by admitting patients who could have been treated on a less costly outpatient basis.

Headquartered in Arizona, Banner Health owns and operates 28 acute-care hospitals in multiple states.

"Taxpayers should not bear the burden of inpatient services that patients do not need," said Acting Assistant Attorney General Chad A. Readler for the Justice Department's Civil Division. "The Department will continue its efforts to stop abuses of the nation's health care resources and to ensure that patients receive the most appropriate care."

The settlement resolves allegations that 12 Banner Health hospitals knowingly overcharged Medicare patients unnecessarily.

Federal officials alleged that from November 1, 2007 through December 31, 2016, Banner Health billed Medicare for short-stay, inpatient procedures provided at the 12 hospitals that should have been billed on a less costly outpatient basis.

The settlement also resolves allegations that Banner Health inflated in reports to Medicare the number of hours for which patients received outpatient observation care during this time period. Banner Health also entered into a corporate integrity agreement with the U.S. Department of Health and Human Services – Office of Inspector General (HHS-OIG) requiring the company to engage in significant compliance efforts over the next five years.

Under the agreement, Banner Health is required to retain an independent review organization to review the accuracy of the company's claims for services furnished to federal health care program beneficiaries.

The settlement resolves a lawsuit filed in the U.S. District Court for the District of Arizona by Cecilia Guardiola, a former employee of Banner Health, under the qui tam or whistleblower provisions of the False Claims Act, which permit private citizens to bring lawsuits on behalf of the United States and obtain a portion of the government's recovery. Guardiola will receive roughly \$3.3 million. Guardiola is a registered nurse, compliance professional and law school graduate with extensive nursing and compliance experience.

She was hired by Banner Health in October 2012 as its Corporate Director, Clinical Documentation.

Her role was to improve the quality of medical documentation to support improved billing with the goal of identifying positive revenue for Banner hospitals.

The position required Guardiola to observe and evaluate compliance efforts at multiple Banner hospitals and throughout the Banner Health corporate system.

Quickly recognizing that her efforts to bring ethical compliance efforts to Banner were and would continue to be ineffective, Guardiola resigned her position in December 2012.

Once hired, Ms. Guardiola's first priority was to evaluate Banner's existing clinical documentation program and identify opportunities for improvement.

She assessed randomly chosen medical records to develop baseline measurements from which to evaluate the quality of existing medical documentation efforts.

Upon completing her assessment, Guardiola identified many ways in which Banner could improve its revenue streams.

When senior Banner administrators repeatedly expressed concerns that Banner was failing to capture inpatient stays properly, Guardiola expanded her evaluation to include short-stay inpatient claims, an effort which led her to uncover Banner's wrongdoing.

Guardiola discovered that all Banner hospitals were billing an inordinate and improper number of short-stay claims, particularly those for expensive cardiac procedures.

In her complaint, Guardiola identified over 650 instances where Banner billed Medicare for an inpatient claim, even though the patient was admitted to and discharged from the hospital on the same calendar day.

Guardiola discovered that two Banner hospitals, Boswell and Del Webb, intentionally falsified documentation to ensure payment of fraudulent claims.

She found that they devised a means of

circumventing the Medicare Administrative Contractor's review process by mischaracterizing certain claims for cardiac procedures – such as implantable defibrillators, pacemakers and stents – as "urgent" on Medicare claim forms when the claims should have been characterized as "elective," which is what was done by all of Banner's other hospitals.

By labeling the claims as "urgent," Boswell and Del Webb were able to prevent a large number of financially lucrative claims from being denied.

Guardiola also found that Banner systematically inflated the number of hours for which patients received outpatient observation care.

Because Medicare reimburses such care on a per-hour basis, the inflated figures caused Banner to receive payments higher than it was entitled to claim.

When she raised her concerns with Banner administrators, she was met with resistance to change and an undue emphasis on revenue enhancement through inpatient admissions. Compliance was treated as an afterthought.

"Banner provides quality healthcare to many residents of Arizona and other states, and I wanted them to focus on the long-term benefits of acting with integrity. But they were unwilling to do that," Guardiola said.

"Thanks to Ms. Guardiola's honesty and courage, taxpayers have been reimbursed for the misconduct alleged in her complaint," Guardiola's attorney, Mitch Kreindler said. "Ms. Guardiola recognized the wrongdoing and called it to the attention of Banner's most senior management. She pursued the fight for what she knew was right."

"I can only hope that this settlement is the 'change agent' that allows Banner to bring its focus back to where it belongs," Guardiola said.

"While Banner will likely try to downplay these allegations as 'technical billing issues,' the fact is that Ms. Guardiola encountered resistance to fixing systemic problems that caused the billings to regularly recur," said Kreindler. "Everyone knows the difference between right and wrong. But it takes a person of integrity, like Ms. Guardiola, to stand up and say, 'I'm not going to allow this to happen.' She is the true hero in this story."

PRESIDENT TRUMP TO NOMINATE DAN BERKOVITZ TO CFTC

President Trump to nominate Dan Michael Berkovitz of Maryland, to be Commissioner of the Commodity Futures Trading Commission, for the remainder of a five year term expiring April 13, 2023.

Berkovitz is a partner and co-chair of the futures and derivatives practice at the law firm of WilmerHale.

From 2009 to 2013, Berkovitz served as General Counsel of the U.S. Commodity Futures Trading Commission (CFTC).

While at the CFTC, he was the agency's Deputy Representative to the Financial Stability Oversight Council.

Prior to the CFTC, Berkovitz was a senior staff lawyer for the Senate Permanent Subcommittee on Investigations.

He also served as Deputy Assistant Secretary in the Department of Energy's Office of Environmental Management.

Berkovitz is an Adjunct Professor at Georgetown University Law School, and vice-chair of the American Bar Association Committee on Futures and Derivatives.

Berkovitz obtained an A.B. in Physics from Princeton University and a J.D. from the University of California, Hastings College of the Law.

T-MOBILE TO PAY \$40 MILLION TO SETTLE FCC CASE

T-Mobile will pay \$40 million to settle an investigation brought by the Federal Communications Commission into whether T-Mobile violated the Communications Act when it failed to correct ongoing problems with delivery of calls to rural consumers and whether it violated the FCC rule that prohibits providers from inserting false ringtones with respect to hundreds of millions of calls.

"It is a basic tenet of the nation's phone system that calls be completed to the called party, without a reduction in the call quality – even when the calls pass through intermediate providers," said FCC Chairman Ajit Pai. "The FCC is committed to ensuring that phone calls to all Americans, including rural Americans, go through."

The FCC's Enforcement Bureau opened an investigation following rural carrier and consumer complaints that T-Mobile callers were unable to reach consumers served by three rural carriers in Wisconsin.

Although T-Mobile reported to the FCC that the problems had been "resolved," the Commission continued to receive complaints that calls were failing.

Call completion complaints filed directly with T-Mobile showed patterns of problems with call delivery to consumers in at least seven other rural areas.

The investigation also revealed T-Mobile's practice of injecting false ringtones into certain calls.

T-Mobile reported that it had done so on hundreds of millions of calls and admitted that its actions violated the Commission's prohibition of injecting false ringtones on any calls.

CONSUMERS UNION URGES TOUGH LIMITS ON ARSENIC IN RICE-BASED FOOD

Consumers Union last week called on the Food and Drug Administration (FDA) to finalize its guidance limiting the permissible levels of inorganic arsenic in infant rice cereals, and for Congress to set tough limits on inorganic arsenic in all rice-based food.

Consumers Union is urging the FDA to issue its final guidance in light of a new Government Accountability Office report that found the agency has not done enough to limit the risks to consumers of arsenic in food.

Infants and children are especially vulnerable to exposure to arsenic, a known carcinogen that has been linked to damage to the brain, cardiovascular system, and nervous system.

Tests by Consumer Reports have found worrisome levels of arsenic in rice cereals.

The FDA proposed a limit for inorganic arsenic in infant rice cereals two years ago but has yet to formally adopt it.

The GAO recommended that the FDA finalize its guidance by the end of 2018, which the FDA agreed it would do.

However, the FDA has not yet shown it has

taken concrete steps to reach that goal.

"The health risks of inorganic arsenic are well established and a serious concern, especially for small children," said Jean Halloran, Director of Food Policy Initiatives for Consumers Union. "The FDA should finalize its guidance limiting inorganic arsenic in infant rice cereals without further delay to protect vulnerable children from this dangerous contaminant. We also urge Congress to pass the RICE Act so that the FDA is required to address the risks from arsenic in all rice-based food."

The RICE (Reducing food-based Inorganic Compounds Exposure) Act, sponsored by Representative Rosa DeLauro (D-CT), would require the FDA to set mandatory limits on the amount of inorganic arsenic contained in rice and rice-based foods.

Consumers Union first called for the FDA to set limits on the maximum levels of inorganic arsenic allowed in rice in 2012. In September 2012, Consumer Reports released the results of its tests that found varying levels of inorganic arsenic in more than 60 rice and rice products.

No federal limit exists for inorganic arsenic in most foods, but the standard for drinking water is 10 parts per billion (ppb). That level is twice the 5 ppb that the EPA originally proposed and that New Jersey actually established.

Using the 5-ppb standard, Consumer Reports found that a single serving of some rices could give an average adult almost one and a half times the inorganic arsenic he or she would get from a whole day's consumption of water, about 1 liter.

Consumer Reports also discovered that some infant rice cereals, which are often a baby's first solid food, had levels of inorganic arsenic at least five times more than has been found in alternatives such as oatmeal.

According to federal data, some infants eat up to two to three servings of rice cereal a day. Eating rice cereal at that rate, with the highest level of inorganic arsenic Consumer Reports found in its tests, could result in a risk of cancer twice as high as its experts calculated to be acceptable.

FTC COMMISSIONER TERRELL MCSWEENY TO RESIGN

Terrell McSweeny, who has served as a Commissioner of the Federal Trade Commission since April 2014, has issued a statement announcing her resignation later this month.

"Commissioner McSweeny has been a steadfast advocate for consumers and competition at the Federal Trade Commission," Acting FTC Chairman Maureen K. Ohlhausen said. "Her expertise and enthusiasm have been important assets to the agency. She has been an exemplary Commissioner and we wish her well in the future."

McSweeny has served as an FTC Commissioner since April 28, 2014, following her appointment by President Barack Obama. Her last day at the Commission will be April 27.

Prior to joining the FTC, Commissioner McSweeny served as Chief Counsel for Competition Policy and Intergovernmental Relations for the U.S. Department of Justice Antitrust Division.

She joined the Antitrust Division after serving as Deputy Assistant to the President and Domestic Policy Advisor to the Vice President from January 2009 until February 2012, advising President Obama and Vice President Biden on policy in a variety of areas, including health care, innovation, intellectual property, energy, education, women's rights, criminal justice and domestic violence.

McSweeny's government service also includes her work as Senator Joe Biden's Deputy Chief of Staff and Policy Director in the U.S. Senate, where she managed domestic and economic policy development and legislative initiatives, and as Counsel on the Senate Judiciary Committee, where she worked on issues such as criminal justice, innovation, women's rights, domestic violence, judicial nominations and immigration and civil rights.

She also worked as an attorney at O'Melveny & Myers LLP.

NICHICON PLEADS GUILTY FINED \$42 MILLION

Nichicon Corporation plead guilty for its role in a conspiracy to fix prices for electrolytic capacitors sold to customers in the United States and elsewhere and will pay a \$42 million fine.

Nichicon conspired with others to suppress and eliminate competition for electrolytic capacitors from as early as November 2001 until December 2011.

"The Antitrust Division has now charged seven companies and ten individuals for participating in a long-running conspiracy to fix the price of a critical component in electronic devices used by millions of American consumers," said Director of Criminal Enforcement Marvin Price of the Justice Department's Antitrust Division. "But our investigation is not over. We are continuing to pursue the companies and executives who conspired to undermine competition in this vital industry."

Electrolytic capacitors store and regulate electrical current in a variety of electronic products, including computers, televisions, car engines and airbag systems, home appliances and office equipment.

INTERVIEW WITH PHILLIP ZWEIG, EXECUTIVE DIRECTOR, PHYSICIANS AGAINST DRUG SHORTAGES, NEW YORK, NEW YORK

Why in America, land of the free, home of the brave, are hospitals struggling with drug shortages?

Two words.

Legalized kickbacks.

At the center of the crisis are for profit corporations known as group purchasing organizations. The big four are Vizient, Premier, HealthTrust and Intalere.

The group purchasing organizations control purchasing of \$300 billion annually in drugs, devices and supplies for the nation's healthcare system.

If you pay the GPO a big enough fee, you get the sole source contract to the hospitals.

But aren't kickbacks criminal? In every other industry, yes. In this one, no.

Why?

Because Congress, in its wisdom, in 1987, created a safe harbor for the group purchasing industry.

In other words, no longer could the government criminally charge the group purchasing organizations for taking kickbacks.

This has led to a reduction in the number of suppliers and drug shortages for hospitals. It's so bad that the United States now imports sterile saline solution from Spain, Norway and Germany.

How to fix problem?

Repeal the 1987 law and reimpose criminal penalties for kickbacks.

That's the take of Phillip Zweig, a business journalist who now heads a group called Physicians Against Drug Shortages.

We interviewed Zweig on April 16, 2018.

CCR: Give us a bit about your professional history from college on.

ZWEIG: I graduated from Hamilton College in 1968. I wound up in the Peace Corps in Hawaii. Didn't like the program I was in. I was always interested in sailing. Did some sailing around the world.

One of my fellow crew members became editor of a boating magazine called *American Boating*. He asked me to write an article about one of my adventures in the South Seas. I started writing about sailing and then shipping. I wrote a front page article on containerization for the *New York Times*.

I was then hired as a consultant for Manufacturers Hanover Trust, which has long since been merged into JP Morgan Chase.

I then started writing about banking freelance while working at the bank. I joined the American Banker in 1980 as a staff reporter. I stumbled on a story about a crazy bank in Oklahoma City that was making loans that nobody else would touch to wildcatters.

I did a story for the American Banker on this bank – Penn Square Bank.

My articles in the *American Banker* prompted the government to shut the bank down on July 5, 1982.

A year later, Seattle First collapsed. It created a major crisis in the American banking system. And it gave rise to the too big to fail doctrine. I won most of the major journalism awards for my reporting.

I went on leave to write a book – Belly Up: The Collapse of Penn Square Bank (Ballantine Books, 1985). That was a bestseller, got rave reviews in Fortune, the New York Times, the Wall Street Journal.

By that time I was at the *Wall Street Journal*. I spent two years there. I then got a contract to write a biography of the former chairman of Citicorp. It was called *Walter Wriston, Citibank, and the Rise and Fall of American Financial Supremacy* (Crown Publishers, 1996).

I worked for a couple of other magazines at the time. I did a couple of stints at *Bloomberg*.

In 1993, I joined *Business Week* as corporate finance editor. That led me to the story that we will talk about today.

At *Business Week*, I wrote one of the first stories about how the Koch Brothers started to use their wealth to gain political influence.

I wrote a piece in 1997 that highlighted the minefields of credit default swaps, which nobody wrote about for another ten years until they brought down the global financial system.

In June 1997, I was in Oklahoma City to give a talk on the lessons of Penn Square Bank fifteen years later.

I got together with a former United States Attorney who had prosecuted the first Penn Square criminal case. We had become kind of friends.

We got together for breakfast. I was poking

around for good stories for Business Week.

And I asked him what he was up to. He starts telling me about this guy in Texas who had developed a retractable syringe that prevented needle stick accidents.

I knew nothing about this. He told that there were something like 600,000 to 800,000 needle stick accidents a year. Nurses often were infected with HIV and Hepatitis C.

And this guy came up with this revolutionary needle that had been funded with support from the NIH. He got FDA approval. Nurses and doctors loved it.

Then he found out he couldn't sell it because of what my friend the federal prosecutor referred to as the buying cartels. These are large group purchasing organizations that set themselves up as the gatekeepers and marketmakers to award exclusive contracts to their favorite dominant suppliers.

These were multi-year, sole source contracts that basically kept better, safer and cheaper medical devices and other products out of the marketplace.

I started poking around. And I found that many other small companies with innovative, better, safer and cheaper products were in the same boat. I collaborated with my Dallas bureau chief on a story titled – Locked Out of the Hospital.

It was published in *Business Week* in March 1998. We wrote about a whole range of different devices and products that these cartels had blocked from the market so that they could get huge fees and kickbacks from the bigger suppliers.

Shortly thereafter, I left *Business Week* to take care of my aging parents. I freelanced a bit. Then a year and a half later, I had a conversation with the CEO of the company that was exhibit A in the *Business Week* article.

I asked him about the story and whether it had an impact. He said it did, but they still had this terrible problem. He asked me if I would consider taking a sabbatical from my journalism and try to help reform the system.

I figured – piece of cake. Spend a year or two doing that and go back to reporting.

I ultimately agreed. I had a chat with an old friend of mine from the *Wall Street Journal* – Walt Bogdanich.

I asked for his advice and thoughts on whether this was a good career move. He thought it was. He was at the time a senior producer at 60 Minutes. I took the job. I wound up working with him and Mike Wallace on a segment called *Needles*. That segment exposed the corruption among the nefarious parties blocking hospitals from getting access to safer needles.

CCR: It was a 60 Minutes version of your original Business Week article?

ZWEIG: It advanced the ball considerably. It ran on February 25, 2001.

We did a sting operation. It was the third highest segment of the season. It exposed aspects of this system that I wasn't aware of.

Then Walt left 60 Minutes for the New York Times and did a year long series called Medicine's Middlemen that took the issue even further. That ran in 2002. Those articles exposed this pay to play system.

My Business Week story only got two pages. It laid out the problem of the obstacles to small medical device companies with better, safer and cheaper products.

But the two pages was kind of limiting. I knew there was a lot more to it. *Business Week* was not the best place to write original investigative stories.

But Walt and two other reporters spent almost a year on this, almost exclusively. And their reporting resulted in four Senate Antitrust Committee hearings. Many investigations by federal and state investigators. More media. Exposes. Some successful antitrust lawsuits against some of these dominant suppliers and major purchasing organizations.

This was a bipartisan effort in the Senate. Senators Herb Kohl (D-Wisconsin) and Mike DeWine (R-Ohio) introduced bipartisan legislation that would have repealed the underlying law that gave rise to this fiasco.

But the group purchasing lobby and the American Hospital Association, with the help of Senator Chuck Schumer (D-New York), made sure that bill never saw the light of day.

I worked for Retractable Technologies from 1999 to September 2007. I then left. I worked for about six months with another company. I did some freelance reporting for the next few years.

In October 2011, I picked up the New York Times. President Obama had announced an executive order to the FDA to do something about drug shortages.

I had no idea there were drug shortages in the United States. They hadn't gotten a lot of coverage

in the *Times*, which was my major source of news. It just hadn't registered.

My first reaction was – how could this happen? We are not supposed to have shortages in a market economy, period. The article did refer to the purchasing organizations.

It took me about fifteen minutes to figure out that these same people who had kept the better, safer and cheaper medical devices out of the market had basically applied the same anti-competitive contracting and pricing practices to the generic drug industry.

I co-authored a paper called *Connecting the Dots.* And we threw it up on the web. And surprisingly, it got a lot of traction.

In early 2012, I found a website in Canada run by a Canadian hematologist at Queen's University in Kingston, Ontario. She had a web site devoted to drug shortages in Canada. I contacted her.

She told me about a conference that was being held at Emory University sponsored by an anesthesiologist – Joel Zivot.

He was holding a conference in June 2012 on the ethics of rationing drugs in a time of shortage. I called him up and left a voicemail saying - Dr. Zivot, you really ought to be looking at the underlying questionable ethics that gave rise to this fiasco in the first place and not accept as the new normal that there should be drug shortages and figure out how to ration drugs. You should be looking at the underlying cause and address that.

He called me back the next day and said – you got my attention. Most of these doctors know nothing about economics. They are focused on medicine, which is what they should be focused on. They are doctors. But they know nothing about economics and how markets work.

I gave him a quicky course in Adam Smith economics and the fact that we are not supposed to have shortages. This is not the ex Soviet Union or Venezuela. It's just not supposed to happen in a market economy. End of story.

He got into this. There was a panel on drug shortages at the Annual Society of Anesthesiologists' annual meeting in Washington, D.C. in October 2012. I was there.

The press people said they would let me attend, but I couldn't say anything. There was a panel of FDA people. There was the leadership of the American Society of Anesthesiologists. They were basically handing out the party line that this problem was complex and multifactorial. And there was no single solution. It's hopeless.

I'm sitting there seething.

CCR: Because you know the problem is what? ZWEIG: I knew there was a cause and there is a solution.

CCR: And the cause is?

ZWEIG: A bizarre statute was passed in 1987. It was called the Medicare Anti-Kickback Safe Harbor Provision. That's the short title.

It exempted group purchasing organizations from criminal prosecutions for taking kickbacks from suppliers. It awarded these cartels a get out of jail free card.

CCR: This legislation was driven by industry influence and power over Congress. What was the stated purpose of the legislation?

ZWEIG: Let me go back a bit further. Group purchasing organizations were originally founded in 1910 as cooperatives. Hospitals found they could band together and by buying supplies in bulk, they could save everyone money. This cooperative arrangement, which started down First Avenue from me in Manhattan at Bellevue Hospital, worked fine for 80 years.

In 1972, Congress passed anti-kickback laws that prohibited kickbacks. In the mid-1980s, the hospital lobby and the group purchasing lobby went to Congress and sought a safe harbor.

They said – we need to codify what's already going on. Manufacturers had been paying kickbacks to the group purchasing organizations, obviously illegally. The lobbyists said – let's just put this into statute.

CCR: The government wasn't criminally prosecuting anyway, let's just codify the safe harbor?

ZWEIG: Yes. The statute included a number of other safe harbors which were mostly innocuous. I don't know how much money changed hands to get that done. But it is preposterous on its face. Congress, for whatever reason, signed off on it. **CCR:** Who are the major players?

ZWEIG: The major lobbying group is the Health Care Supply Chain Association. They represent all of these group purchasing organizations. Their primary function is to preserve the safe harbor. **CCR:** Who are the major GPOs?

ZWEIG: The largest is Vizient. It used to be called Novation. The second largest is Premier. There is another one called HealthTrust. Another one is

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Intalere.

CCR: They make money doing what? ZWEIG: They make money selling sole source contracts to the highest bidder. They make money off of these legalized kickbacks. As far as I have been able to tell, this is the only industry in America that has a blessing from the United States Congress to take kickbacks.

CCR: And they are taking kickbacks from whom? ZWEIG: From suppliers. Every company that supplies goods to American hospitals, outpatient clinics, nursing homes, most every product that is purchased by 5,000 American hospitals. CCR: You pay us and we will get your products

into hospitals?

ZWEIG: That's the long and short of it yes. Because of the safe harbor, it's the principal agency problem. Under the old cooperative model, the purpose was to save money for hospitals.

The GPOs were working for the hospitals. As soon as the rules were implemented in 1991, the business model changed 180 degrees to where the GPOs were in the business of selling market share to the suppliers. They have said this in print – we deliver market share. The more market share that a company wants, the more it pays to the GPO. **CCR:** If we repeal the law, how does that relieve the shortages?

ZWEIG: The shortages have resulted from the fact that the GPOs have awarded sole source contracts to many of these large suppliers, eliminating competitors. If you know that your competition has a sole source contract with two group purchasing organizations that control the marketplace, why would you want to enter this business?

CCR: If I come up with the biggest kickback, I get the business?

ZWEIG: Yes.

CCR: A competitor could pay more and get the contract?

ZWEIG: The suppliers are paying for protection from competition. It's sort of like organized crime, where small business pay the mob to prevent goon squads from busting up their businesses.

CCR: What role do hospitals play in the kickback game?

ZWEIG: There are all of these drug shortage stakeholders – the American Hospital Association, the American Medical Association, the American Society of Health System Pharmacists, the American Society of Clinical Oncology.

Many are conflicted.

Take the American Hospital Association. This is the clearest example. The GPOs are for profit organizations. Vizient, formerly Novation, is owned by major shareholder members. As institutions, they get the profits from the kickbacks. Premier is a publicly held GPO.

How do you grow shareholder revenue and market value while saving money for hospitals? There are two classes of stock. One class is owned by their hospital members. And another class is owned by institutions and whoever wants to buy it.

We had known for years that the shareholder hospitals get what is called patronage fees from the GPOs. The GPOs admit that the CEOs of member hospitals count on what are known as sharebacks as part of their annual compensation.

CCR: What is a shareback?

ZWEIG: A percentage of the kickback goes to the CEOs. That's how they keep this system in place. **CCR:** Have there been any books written on this? **ZWEIG:** Yes back in 2009 by S. Prakash Sethi. It's called *Group Purchasing Organizations:* An Undisclosed Scandal in the U.S. Healthcare Industry.

CCR: Do Pharmacy Benefit Managers (PBMs) play a role in this story?

ZWEIG: Yes. GPOs control the hospital, outpatient clinics, nursing home, surgical center supply chain. Virtually all of the drugs used in hospitals, notably sterile injectables, go through GPO contracts. Eighty percent of the drugs in short supply are sterile injectables.

Fentanyl, sterile saline, sterile water. We are now importing sterile saline from Spain, Norway, Germany, Brazil and Mexico. Saltwater sterilized. This has forced production of both the active pharmaceutical ingredients as well as the manufacture of these drugs offshore to India and China. This has become a national security concern.

PBMs work on behalf of insurers, unions, employers to manage their pharmacy benefits for members. They operate very much like the GPOs except the supply chain is different. The PBMs don't distribute sterile injectables. They are distributing pharmaceuticals.

There is no regulation or oversight over PBMs and GPOs.

In 2003, the HHS Inspector General extended the GPO safe harbor for kickbacks to PBM rebates. Prior to that, drug manufacturer rebates paid to

PBMs were considered illegal. HHS in April 2003 explained to drug makers how they could comply with the law by using the GPO safe harbor.

They extended protection of the GPO safe harbor to PBM rebates. It's the PBM rebates that have driven the escalating prices of drugs sold to individuals through PBMs.

The drug makers compete with each other to get favored treatment on the PBM formularies by paying higher and higher rebates. To offset the rebates, they increase their prices. It's a never ending upward spiral. That's precisely what has gotten us to where we are today.

Repeal of the safe harbor would return us to the status quo ante restoring competition and integrity to this entire supply chain. It would recriminalize GPO kickbacks, recriminalize PBM rebates and restore competition to this industry.

CCR: Who are the big PBM players and industry association?

ZWEIG: There is the Pharmaceutical Care Management Association. There are three large PBMs – Express Scripts, CVS Caremark and UnitedHealthcare has a PBM called Optum. **CCR:** Other than Physicians Against Drug Shortages are there any other players working with you to get this done?

ZWEIG: The most important development on this is the adoption by the American College of Emergency Physicians of a resolution to repeal the safe harbor and to lobby for repeal of the safe harbor. Dr. Rick Bloom, who was the past president, introduced and sponsored this resolution. That passed in early November 2017 at their annual meeting.

CCR: Is there legislation in Congress? **ZWEIG:** There was a discussion draft bill that was introduced in 2005 but never made it out of the subcommittee.

Last year, we met with Congressman Mark Meadows (R-North Carolina). He drafted a bill based on the 2005 bill that would repeal the safe harbor. That is circulating. He never introduced it. **CCR:** Why not?

ZWEIG: In our meeting with him, my friend Bill Price – the former U.S. Attorney who got me interested in this back in the 1990s – he had gotten Senator Coburn interested back in 2007.

In 2012, he got Senator Coburn interested in examining the role of the GPOs in causing the shortages. Senator Coburn endorses repeal of the safe harbor. Bill Price got on the speaker phone and mentioned that former Senator Tom Coburn endorses repeal of the safe harbor. Congressman Meadows said – that's all I need to know. We are going to get this done.

He drafts this bill. It would have repealed the safe harbor. Two months later, we get an email from Congressman Meadows' legislative assistant saying that Freedom Works and Heritage Foundation don't support it, so that's the end of that.

CCR: Any major news stories breaking on this that will put it front and center again before the American people?

ZWEIG: There is considerable interest from 60 *Minutes*.

CCR: What about antitrust enforcement? **ZWEIG:** We have been to the Senate Antitrust Committee. There have been investigations but they have never gone anywhere. Senators have asked former Federal Trade Commission chairman Jon Leibowitz to conduct an investigation. He refused. Now he's a partner at Davis Polk.

He co-authored a study claiming that GPOs save billions for hospitals – bought and paid for by the Healthcare Supply Chain Association. **CCR:** Who funds your organization?

ZWEIG: Nobody. We have no money. It's a non profit. It's all pro bono. I pay the hosting fees for the web site and travel expenses.

CCR: Have you ever had a face to face debate with the other side?

ZWEIG: There was a FTC conference on drug market competition on November 8, 2017. There was a panel on group purchasing organizations. There were representatives there from the group purchasing industry.

There were no questions from the floor. After the meeting, I went up to the CEO of the Healthcare Supply Chain Association.

His name is Todd Ebert.

I said you know Mr. Ebert, you are even slicker than your predecessor and we are going to take away your kickbacks.

And I turn around and there is another guy, a senior vice president for Premier. He's the lobbying genius of this whole operation. His sole purpose in life is to maintain the kickbacks and the safe harbor.

I turn around and say – you are Blair Childs. You are responsible for the destruction of American healthcare. That was my one and only face to face with them.

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