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**IN THE LAST 18 MONTHS, SEVEN companies and four executives in the generic pharmaceuticals manufacturing sector were charged with antitrust violations, amassing penalties of over \$426m. And this month, the Department of Justice Antitrust Division brought its first ever criminal charges for a conspiracy to lower wages to workers against the former owner of a physical therapist staffing company. With enforcement efforts ramping up – and COVID-19 adding additional scrutiny – health care companies will need a comprehensive antitrust compliance program to avoid enforcement actions. Months, should be possible post-pandemic.**



Even the most casual observer of the health care industry can see that it faces enormous challenges in light of the COVID-19 pandemic. From accessing sufficient supplies of personal protective equipment and medication to the financial strains caused by the reduction or suspension of non-emergent treatment and care, medical providers, hospital systems, and health care suppliers are staring down tremendous financial and logistical pressures.

What may have escaped notice, though, is that the industry is at the same time confronting a wave of enforcement by the US Department of Justice (DOJ)



Antitrust Division and other antitrust enforcers. For instance, in the last 18 months, seven companies have been criminally charged in the DOJ's investigation of antitrust violations in the generic pharmaceutical manufacturing industry, with monetary penalties thus far totaling over \$426m. But these amounts are just the tip of the iceberg in terms of the financial exposure these companies face. Not only are there follow-on civil damages actions claiming trebled damages and other penalties, but also debarment and securities litigation threats, all arising from the same conduct. Four former and current executives from several generic pharmaceutical companies were also criminally charged in connection with this investigation.

The modern history of the health care industry is, of course, characterized by regulation and government scrutiny: from HIPAA to the Anti-Kickback Statute, the Affordable Care Act to workplace and patient safety regulations. But, until recently, the DOJ generally did not pursue criminal enforcement of the federal antitrust laws in the health care industry. Times have changed, and companies in the health care sector often operate in a manner that can make them vulnerable targets for antitrust enforcers, so special care should be taken in this environment. In Vivo has explored the history of antitrust enforcement in the health care industry, how

it has evolved, and what steps health care companies can take to protect themselves from future enforcement actions.

### **Antitrust Enforcement In The Health Care Industry**

While the DOJ has only recently fully deployed its criminal enforcement powers in the health care industry, it has historically been anything but hands-off in terms of civil enforcement of antitrust laws. In 2004, the DOJ and Federal Trade Commission (FTC) issued an in-depth report addressing the important role competition law and policy play in shaping the health care industry. Since then, the Division's Healthcare and Consumer Products Section has brought over 25 civil merger and conduct cases in the industry and resolved several others without filing suit.

Most of the Division's activity in the health care sector has focused on enjoining mergers it deemed anticompetitive and policing agreements between various industry players, as well as exclusionary conduct by those companies with market power. For instance, the DOJ recently brought suit to enjoin central Pennsylvania health care provider, Geisinger Health, from acquiring its close rival, Evangelical Community hospital, alleging that the transaction is likely to lead to higher prices, lower quality and reduced access to high-quality inpatient services for patients in central Pennsylvania. And in 2018, along with five states, the DOJ sought to enjoin CVS from acquiring Aetna, alleging that the merger would substantially lessen competition in the sale of individual prescription drug plans, in violation of Section 7 of the Clayton Act. The lawsuit resulted in a settlement involving an Aetna divestiture. In 2016, the Division and several states filed suit to stop Anthem, the nation's second-largest health insurer, from acquiring Cigna, the nation's fourth largest insurer. The merger was enjoined after a seven-week trial. And a merger between two other health insurance giants, Aetna and Humana, was entirely blocked in 2017.

The FTC has been similarly active in the health care industry, blocking mergers and enjoining allegedly anticompetitive practices through civil consent decrees. However, because the FTC does not have jurisdiction to prosecute the antitrust laws criminally, the risk of crimi-

nal prosecution in the health care industry is limited to the DOJ.

Outside the merger context, the DOJ has not hesitated to investigate and file complaints when it suspects antitrust violations have occurred. In 2011, the Division filed suit to prohibit a large hospital from entering into exclusionary contracts with insurers, alleging a monopolization violation of Section 2 of the Sherman Act. But, until recently, the Division has used its civil – and not criminal – enforcement powers to police anticompetitive agreements under Section 1 of the Sherman Act in the industry, even where similar agreements have been subjected to criminal enforcement in other, non-health care industries. Under Section 1 of the Sherman Act, the Division prosecutes price-fixing, bid-rigging and market allocation agreements, as well as certain group boycotts, as per se criminal violations with limited exceptions. In the past, however, we have seen those exceptions more often applied in the health care industry, for example:

- In 2016, the Division filed suit against two West Virginia hospital systems for agreeing to allocate marketing territories. The Division pursued similar claims against four Michigan hospital systems in 2015, resulting in civil settlements and a consent decree.
- Pricing agreements have also garnered scrutiny, but again, resulted in civil and not criminal enforcement. In 2013, DOJ filed suit to enjoin a chiropractic association from negotiating prices and contracts with insurers on behalf of competing chiropractors in South Dakota. The Division brought a similar case in Oklahoma.
- In 2010, the Division brought suit against five individual orthopedists for alleged agreements with competitors to engage in group boycotts to obtain higher fees.

At the time of the FTC and DOJ 2004 joint report, the DOJ had pursued only “a few criminal health care antitrust cases,” but noted that it was “continuing to consider carefully the appropriateness of criminal sanctions in particular health care cases.”

## DOJ's Changing Approach To The Industry

As recent criminal case filings reflect, the DOJ is now aggressively using its criminal enforcement authority to root out and prosecute so-called 'hard-core' antitrust violations in the health care industry. The first wave of the Division's criminal enforcement efforts in health care markets started with several criminal actions involving price-fixing of generic pharmaceuticals. In December 2016, the DOJ charged two pharmaceutical executives with antitrust violations. They entered guilty pleas in January 2017. Then in May 2019, Heritage Pharmaceuticals Inc. entered into a deferred prosecution agreement (DPA) after being charged with fixing prices, rigging bids, and allocating customers for a medicine used to treat diabetes. In a separate civil action, Heritage agreed to pay \$7.1m to resolve allegations under the False Claims Act related to the price-fixing conspiracy. Since then, the DOJ has charged several other pharmaceutical companies and four current and former executives as part of the same investigation of the generic drug market.

### DPA

Deferred prosecution agreements allow DOJ to enforce against alleged antitrust violations without securing felony convictions. In the medical sector, deferred prosecutions allow DOJ to quash suspect conduct without disqualifying medical professionals and companies from serving their communities.

The DOJ recently charged Glenmark Pharmaceuticals USA for conspiring with Apotex Corp. (which previously entered into a DPA) to fix the prices of prevastatin, a medication that reduces cholesterol, and other generic drugs. The DOJ alleges that the gain to conspirators and the loss to victims is at least \$200m, meaning that Glenmark faces a potential fine of \$400m. On 23 July 2020, the DOJ filed a two-count felony charge against Taro Pharmaceuticals U.S.A., Inc. for fixing prices, allocating customers, and rigging bids of numerous generic drugs. The DOJ then announced a DPA resolving the charges against Taro, whereby Taro agreed to pay a \$205,653,218 criminal fine and admitted that the sales affected by the charged conspiracies exceeded \$500m.

Taro is the fifth of seven companies charged to admit its role in the conspiracies. Former Taro executive, Ara Aprahamian, is one of four executives charged and is now awaiting trial. Teva Pharmaceuticals was then charged, with Glenmark, in August 2020.

In April, a large south Florida oncology group agreed to pay a \$100m criminal fine to resolve a single felony antitrust charge under a deferred prosecution agreement. The oncology group and its co-conspirators allegedly agreed to allocate chemotherapy and radiation treatments to cancer patients in Southwest Florida.

Most recently, in December 2020, the DOJ announced the indictment of the former owner of a health care staffing company for allegedly conspiring to suppress wages paid to physical therapists and physical therapy assistants in North Texas. The former owner was also charged with obstruction of justice for allegedly making false and misleading statements and concealing information during an earlier Federal Trade Commission (FTC) investigation into the same conduct giving rise to the DOJ's criminal charges. According to the indictment, both the former owner of the staffing agency and, at his direction, the Clinical Director, exchanged text messages and reached agreements with competing physical therapy staffing agencies about lowering rates paid to contracting physical therapists and physical therapist assistants suggesting, among other things, that each of the agencies "collectively should move together." The indictment is especially notable because it marks the first time that the DOJ has brought a criminal case for so-called "wage-fixing," something the Division has been signaling was a possibility for several years. The indictment is unlikely to be the last of its kind given that, according to their April 2020 Joint Statement Regarding COVID-19 and Competition in Labor Markets, the DOJ and FTC "are on alert for employers, staffing companies (including medical travel and locum agencies), and recruiters, among others, who engage in collusion or other anticompetitive conduct in labor markets, such as agreements to lower wages or reduce salaries or hours worked."

The Division is also ramping up its involvement in the health care space by intervening in private civil lawsuits alleging anticompetitive conduct in the industry. In a

September 2019 Senate subcommittee address, Assistant Attorney General Makan Delrahim emphasized the importance of private litigation and the Division's role in providing guidance to courts "to ensure they reach sound interpretations of the antitrust laws." Not long before, the Division had filed a statement of interest in a private antitrust class action suit regarding an alleged agreement between Duke University, the University of North Carolina, and related defendants to not compete for each other's medical faculty. The Division's statement addressed the appropriate standard for reviewing alleged no-poach agreements under Section 1 of the Sherman Act. In an unprecedented step, the DOJ subsequently intervened in the case and joined the settlement, which gives the US the right to enforce an injunction against Duke and which prohibits no-poach agreements and compels various other compliance measures. And then in October 2020, a district court granted DOJ's motion to intervene in a private antitrust case against Teva Pharmaceuticals on the grounds that that the civil case may bring to light information that could be useful in the criminal prosecution.

### **COVID-19 Could Increase Criminal Enforcement In Health Care**

These trends in the Division's recent health care enforcement activity are reason enough for industry players to brace for increased scrutiny. But the COVID-19 pandemic and intense public interest and press attention on health care generally also increases the chances that antitrust enforcers will set their sights on allegedly anticompetitive conduct in this critically important sector. Indeed, as Deputy Assistant General Barry Nigro said in a 2018 speech, "Few, if any, segments of our economy merit higher priority [than health care] when it comes to antitrust enforcement, and health care has long been an enforcement priority for the Antitrust Division and our friends at the Federal Trade Commission."

The DOJ emphasized this focus in a March 2020 joint statement with the FTC's Bureau of Competition. In addition to describing how the agencies were advancing their timelines for responding to COVID-19-related requests (e.g., the Division's Business Review Process and the FTC's Advisory Opinion Process) and recognizing that collaboration among competitors can be procom-

petitive and essential to fighting COVID-19, the agencies emphasized that they "will not hesitate to seek to hold accountable" those who use COVID-19 as an "opportunity to subvert competition or prey on vulnerable Americans." The Division specifically stated that it "will prosecute any criminal violations of the antitrust laws," while also noting that DOJ more broadly "is addressing actions by individuals and businesses to take advantage of COVID-19 through other fraudulent and illegal schemes."

There are also features of this industry that make health care companies and their employees especially vulnerable to criminal antitrust enforcement:

- Industry consolidation and barriers to entry create tempting opportunities to successfully collude without losing market share;
- Collaborations and business transactions between competitors (e.g., joint ventures) can easily exceed their intended legitimate scope to achieve anti-competitive goals;
- Informal information exchanges between employees and executives who have contacts through industry relationships (e.g., former employment) and events (e.g., trade associations) are commonplace but very high risk; and
- Discussions with third parties such as mutual customers relating to pricing, market share, and employee recruitment, as well as benchmarking activities, often occur and can facilitate collusion.

### **What Should Health Care Companies Be Watching For?**

**Illegal coordination with competitors to fix prices, allocate markets or rig bids.** The most significant risk of criminal antitrust enforcement involves agreements between competing hospitals, medical equipment and product suppliers, or medical providers to set prices, allocate or divide markets, or discuss and coordinate bids. As we saw with the ongoing generic pharmaceuticals investigation and the Florida oncology case, agreements to fix prices or allocate medical services among competitors can result in substantial multi-million-dollar fines and prison sentences for individuals.



**Illegal labor agreements.** DOJ has been saying since at least 2016 that so-called ‘no poach agreements’ are ripe for criminal prosecution. In its 2016 Antitrust Guidance for Human Resource Professionals, DOJ stated that going forward, it “intends to proceed criminally against naked wage-fixing or no-poaching agreements.” As the Duke/UNC case demonstrates, DOJ seems to have an appetite for bringing these cases in the health care industry. Medical industry employees may also bring private litigations, including class actions, alleging the same or similar conduct.

**Unjustified price increases on scarce supplies.** Investigations of conduct not traditionally within the ambit of antitrust and competition law – such as investigations of ‘price gouging’ of medical supplies and services – may nevertheless reveal evidence of antitrust violations.

**Increased consolidation.** As health care companies respond to micro- and macro-economic effects of the COVID-19 pandemic, the industry will likely see an increase in mergers and acquisitions, leading to more DOJ and FTC merger reviews. These transactions will be closely scrutinized for competition concerns. Merger-related investigations can sometimes reveal evidence of criminal antitrust violations that can torpedo the intended transaction and expose the companies to years of investigations and litigation.

**Reduced budgets for legal compliance.** When an industry is under pressure, whether because it is facing unprecedented challenges in the form of a pandemic or dire financial straits, even well-meaning people make mistakes. Conditions like these that can tempt people to cross lines that they would not otherwise. The DOJ and other antitrust enforcers know this.

### **What Can Health Care Companies Do To Reduce Their Risks?**

If a company does not yet have a comprehensive antitrust compliance program, there is no time like the present to introduce one. First, robust compliance programs allow corporate leadership to be explicit about their expectations that employees will abide by both the letter and spirit of antitrust laws, establishing a corporate culture of compliance. Second, a solid compliance

program prevents misconduct by educating employees about how to avoid antitrust pitfalls and minimize risk to themselves and their company. Third, a well-designed program helps companies identify and address possible antitrust violations early so that they can determine whether to self-report to antitrust enforcers and take advantage of the DOJ’s Leniency Program and the Antitrust Criminal Penalty Enhancement and Reform Act, which could reduce civil exposure. And finally, the DOJ evaluates the quality of companies’ compliance programs in determining whether to bring charges and negotiating plea or other agreements.

Engage skilled antitrust counsel before venturing into collaborative ventures, joint ventures, or mergers with competitors. As noted above, certain industry collaborations can be procompetitive and advance important medical priorities. But because they often involve sharing potentially sensitive information with actual or potential competitors, and provide opportunities for competitors to communicate, companies should not treat these arrangements casually.

Given the DOJ’s current criminal enforcement priorities, health care companies should take a fresh look at their compliance programs and conduct a risk assessment. As the saying goes, “an ounce of prevention is worth a pound of cure.”

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### **About The Authors**

- **Niall E. Lynch** is a partner in the Global Antitrust & Competition Practice at Latham & Watkins LLP. A former prosecutor and assistant chief in the San Francisco Field Office for the Antitrust Division of the US Department of Justice, Lynch has deep experience in cartel matters, representing companies and individuals defending criminal and civil price-fixing investigations and litigations in the US and abroad.

- **Elizabeth Prewitt**, a partner in the Global Antitrust & Competition Practice at Latham & Watkins LLP, defends corporations and executives facing complex and often cross-border antitrust investigations by federal, state, and foreign competition enforcement agencies. She is a former prosecutor and assistant chief in the New York office of the Antitrust Division of the Department of Justice.
- **Ashley M. Bauer**, a partner in the Global Antitrust & Competition Practice at Latham & Watkins LLP, has represented leading companies in antitrust litigations and cartel investigations, white collar criminal defense and class action litigations. She has extensive experience as coordinating counsel on matters involving investigations and private actions spanning the globe.
- **Meaghan Thomas-Kennedy** is an associate in the Global Antitrust & Competition at Latham & Watkins LLP. Thomas-Kennedy advises clients – including health care companies – facing domestic and international cartel investigations and related class actions and counsels clients on internal investigations and compliance programs.
- **Gabriella Kapp**, an associate in the Litigation & Trial Department of Latham & Watkins LLP, focuses on civil antitrust litigation, cartel matters and complex commercial disputes, representing US and international companies in a wide variety of industries.