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EDITOR'S REPORT

Welcome to the second issue of the Chronicle for the ABA 2018-19 term. In this issue, we are pleased to present an interview and two original articles. The first piece is an interview with Ryan Kantor, former Assistant Chief of the U.S. Department of Justice's Antitrust Division, Healthcare and Consumer Products Section. The second article provides a primer on the role of pharmacy benefit managers (PBMs) in the pharmaceutical drug supply chain. And the third article reflects on the European Union's judgment in the GSK parallel trade investigation and discusses the evolution in Europe of antitrust law on parallel trade of pharmaceutical products.

If there is a topic that you would like to see covered in a Committee program or if you have any other suggestions, please contact the Committee Co-Chairs, Seth Silber (ssilber@wsgr.com) or Leigh Oliver (leigh.oliver@hoganlovells.com).

If you would like to submit an article for the Chronicle, please contact Amanda Lewis (alewis1@ftc.gov) or Robin van der Meulen (rvandermeulen@labaton.com).

In This Issue

A Publication of the Health Care and Pharmaceuticals Committee of the Antitrust Section of the American Bar Association, Co-Chaired by Seth Silber of Wilson Sonsini and Leigh Oliver of Hogan Lovells.

ENFORCER INSIGHTS: AN INTERVIEW WITH RYAN KANTOR, FORMER ASSISTANT CHIEF OF THE DOJ ANTITRUST DIVISION'S HEALTHCARE AND CONSUMER PRODUCTS SECTION

Ryan Kantor is a partner with Morgan Lewis in Washington, D.C., specializing in federal and state government antitrust investigations, antitrust litigation, and counseling on antitrust and competition issues. From 2012 to 2018, Mr. Kantor served as Assistant Chief of the U.S. Department of Justice's Antitrust Division, Healthcare and Consumer Products Section.

Ryan Kantor
Former Assistant Chief of the DOJ Antitrust Division's Healthcare and Consumer Products Section

What are the Healthcare and Consumer Products Section's areas of responsibility?

The Healthcare and Consumer Products Section (HCP) is responsible for a broad spectrum of products and conduct. Within the health insurance and health care industries, HCP reviews health insurer mergers and acquisitions, as well as potentially anticompetitive conduct by insurers. It also investigates potentially anticompetitive conduct by hospitals, doctors and other providers and occasionally reviews provider mergers and acquisitions. Outside of health care, HCP handles merger review and conduct investigations relating to consumer products – including food products and appliances – and pulp, paper and timber products.

I am often asked how the Department of Justice (DOJ) divides health care responsibilities with the Federal Trade Commission (FTC). In contrast to HCP's responsibilities, the FTC historically has taken the lead on pharmaceutical, pharmacy, pharmacy benefits manager, and medical device matters and handled most of the provider merger reviews. Vertical mergers can create complex clearance issues that need to be worked out by DOJ and the FTC.

Based on your experience at DOJ, can you give us your perspective on whether antitrust enforcement in health care evolved during your tenure?

I do not think that antitrust enforcement in health care has evolved significantly over the last ten years. If you look at older DOJ cases, you see precedent for almost everything that has happened over the last few years. For example, much was made of DOJ's decision to allege monopsony harm in the Anthem-Cigna litigation. But if you look back at Aetna-Prudential in 1999 and UnitedHealth-Pacificare in 2005, you see a common concern about harm to hospitals and doctors as a result of health insurer consolidation. And, with a few exceptions, you see consistency across product and geographic market definitions over time.

What has changed is the size and scale of the proposed transactions. Starting with Aetna-Humana and Anthem-Cigna in 2015, and moving to CVS-Aetna and Cigna-Express Scripts in 2018, the agencies are seeing more of the very large, industry-transforming mergers. An effect of these large deals is that they attract significant attention outside of the relatively narrow world that typically follows health care antitrust deals. The large deals also raise the stakes for DOJ – these types of mergers may transform the industry, but can carry significant risk of harm to consumers.

Generally, what are some best practices for advocating before HCP?

First, it is well worth developing a good working relationship with all parts of the Antitrust Division, from the Front Office to section management to staff attorneys to economists. Investigations often last six to twelve months, and there will be many points along the way when an attorney's and client's credibility will be important.

Second, from the outset, be ready to provide basic information about the competitive overlaps, key competitors and customers. This allows DOJ to get their investigation off to a smooth start, which is usually beneficial in the short and long run. It is worth keeping in mind that last year DOJ opened investigations in 2% of proposed transactions and issued Second Requests in less than 1% of proposed transactions. If you have strong arguments that are supported by market participants, there is a good chance that you will not end up with a Second Request.

Third, be upfront with DOJ about potential issues from the proposed merger. DOJ will be interviewing market participants, and they are likely to hear about every possible theory of harm. It is beneficial to have your best arguments in front of DOJ when they are having those conversations and considering the merits of the theories of potential harm.

Fourth, work hard to narrow the issues and areas of disagreement over the course of the investigation. Narrowing the issues, of course, is beneficial in terms of reducing the burdens and timing of Second Request compliance. It also is beneficial at the end of the investigation. Neither DOJ nor the parties want to waste time in the often-chaotic end stages of the investigation on non-essential issues. Both sides want to be fully focused on the key issues and the relevant evidence.

Alternatively, what are some bad, unhelpful, or unproductive practices that you recommend against engaging in?

Generally, it is the flip side of the best practices. "Hiding the ball" often results in DOJ finding out about issues later in the process, which can slow down the investigation and decision-making by DOJ. It also can hurt the credibility of the parties, resulting in DOJ double-checking every statement made by the parties. In addition, not engaging with DOJ staff regularly can result in the parties not focusing on issues that are high priorities for DOJ, and the agency spending time and resources on issues that could have been quickly addressed by the parties.

Insurance Merger Review

What are some important issues in an insurance deal that the private bar should be ready to address during the early stages of an investigation?

The first issue, as in all deals, is to identify the competitive overlap, the product and geographic markets, and the competitors in those markets. If there are areas in which the parties have significant combined market shares, the parties should be prepared to address the closeness of competition between the parties. Depending on the product, relevant information often can be found in win-loss data, switching data, and strategic planning documents. Parties should keep in mind that DOJ looks at all forms of competition, including non-price competition relating to benefits and breadth of provider networks. The parties also should consider having their business executives meet with DOJ to discuss how competition functions in those markets.

In addition, the parties should be ready to provide examples of recent entry or expansion and focus DOJ on companies with the competitive assets needed to enter or expand in the event of an exercise of market power post-acquisition. The parties also should be ready to explain any other constraints on the parties, including regulatory constraints. Finally, the parties will want to explain to DOJ from day one the reasons for the deal, particularly any benefits to consumers.

In the end, neither the parties nor DOJ want to spend any more time reviewing a merger than is necessary, so putting the parties' best arguments in front of DOJ early in the process usually benefits everyone.

Are there any publicly available sources of information that provide

insight into how HCP or DOJ evaluates insurance deals?

The first place to look for any deal is the Horizontal Merger Guidelines (Guidelines), which lay out the practices and policies for DOJ and FTC merger review. The Guidelines provide the framework that the federal antitrust agencies will use in analyzing whether the proposed acquisition violates the antitrust laws.

For health insurance deals specifically, virtually every potential issue and argument in a health insurance merger is covered in *U.S. et al. v. Anthem-Cigna* and *U.S. et al. v. Aetna-Humana*, which were litigated by DOJ in 2016. The breadth of the complaints and subsequent judicial opinions cover most products that are typically involved in a health insurer merger. The complaint in Anthem-Cigna alleged harm in the sale of commercial insurance to national and large group employers and harm in the purchase of health care services from hospitals and doctors. The complaint in Aetna-Humana addressed harm in the sale of Medicare Advantage and individual insurance on the Affordable Care Act exchanges. These cases also involved arguments about the effect of government regulation on competition, flailing divisions, and efficiencies in health insurer mergers. While the judges in these cases did not ultimately address all of the issues in their opinions, there are hundreds of pages of case filings about how DOJ analyzes potential harm in these markets.

DOJ has reviewed several insurance deals over the years. Some of which the agency has challenged, and some the agency has not, such as WellPoint Inc.'s acquisition of Amerigroup. What are some of the factors that DOJ considers in evaluating whether to challenge an insurance deal?

Each merger review ultimately is unique and dependent on the specific facts present in the markets. As discussed, DOJ will almost always start by assessing the competitive overlap, the existing market structure, and the closeness of competition between the merging parties. If the markets are not concentrated or the merging parties are not close competitors, those are likely to be significant factors.

DOJ also will look at where the markets are heading. It will investigate whether the markets have seen recent entry and expansion or whether they have been largely stable. In addition, DOJ will look at where the merging parties are heading. Sometimes DOJ finds that one or both of the merging parties are becoming a weaker competitive force. Other times a merging party is acting aggressively and growing, which increases concerns about harm from the deal.

Finally, DOJ will address potential efficiencies from the deals. While efficiencies-based arguments historically have not been successful at trial, they are part of the internal DOJ merger review process. Parties asserting efficiencies from a deal should document the efficiencies early in the process and explain to DOJ why the efficiencies are likely to be achieved and passed through to consumers.

In the context of insurance deals, if parties have a divestiture in mind that will likely resolve DOJ's concerns, how soon should the parties present the divestiture?

It really depends on the case. If the primary goal of the parties is to close the transaction as soon as possible, engaging with DOJ early is the correct strategy. On the other hand, if harm from the deal is questionable, it may make sense to let the evidentiary record develop to see whether a divestiture is necessary. But parties should keep in mind that the divestiture process takes time. DOJ will want detailed information about the proposed asset package and will want to test the viability of the package by talking to market participants. If an upfront buyer is proposed, DOJ will want to interview and possibly depose employees from the buyer about their plans for the divestiture assets. It also may want strategic planning documents from the buyer relating to its plans for the divestiture. If the merging parties have a hard date by which the deal must close, they should work backwards to ensure that the divestiture process can be completed in time.

What sort of due diligence should the parties undertake before presenting a divestiture proposal?

The primary factors that DOJ will look at in assessing a potential divestiture are the asset package

and, if known, the proposed acquirer. DOJ has a strong preference for structural, rather than behavioral, remedies. Structural remedies typically involve the sale of assets to create or enhance a competitor; behavioral remedies regulate the merged firm's conduct after the acquisition closes.

DOJ typically prefers divestiture of an intact business unit. Business units come with all of the necessary assets for competition and have been tested in the market. However, depending on the state of competition in the market and the proposed buyer, smaller asset packages may be sufficient. In the health insurance context, a divestiture to an insurer that already has contracts with providers, a brand in the relevant market, broker networks, and internal infrastructure may result in fewer assets needing to be divested. Parties also should be prepared to enter into a transition services agreement with the divestiture buyer. The agreement will cover such services as claims processing, appeals and grievances, call center support, and enrollment services.

Litigating the Fix

Litigating the fix has been a hot issue in recent merger litigation. What are some lessons learned from recent cases with regards to litigating the fix?

A key lesson is that DOJ and the court are going to analyze the divestiture asset package and proposed buyer in great detail. In a recent case, DOJ put on evidence – that the court favorably cited – about all aspects of the buyer's existing operations and history in the relevant market, including its recent struggles. In addition, DOJ highlighted the buyer's limited assets in the relevant product and geographic markets, including a limited set of provider contracts, a lack of a brand, and an absence of employees or infrastructure.

Another lesson is that the buyer's internal documents will be scrutinized. The court in a recent case noted that the parties put forward evidence of the buyer's capabilities, but that this evidence was undermined by contradictory statements made by the buyer's executives while the deal was being negotiated. These communications among senior executives expressed concerns about being successful with the divestiture, particularly because of the limited asset package and the buyer's significant needs. For parties considering litigating the fix, it is well worth developing a good relationship with the divestiture buyer so that everyone is aware of any contradictory evidence early in the process.

How can merging parties put themselves in the best posture to successfully litigate their fix?

Parties should think about their strategy in terms of three related questions. First, what is the competition between the merging parties that needs to be replicated through the divestiture? Second, what is the combination of asset package and divestiture buyer that would need to be divested to replicate that competition? Third, how do you minimize the risk that will exist in the judge's mind – the judge is making a projection about the divestiture buyer's ability after all – that the divestiture will fail? The answer to the first question will be determined throughout the trial as the parties and the government fight about the competitive effects from the acquisition. The answers to the second and third questions require a great deal of attention being paid to the specifics of the asset package being divested and the existing assets of the divestiture buyer. In addition, finding a buyer with a track record of success in other geographic markets or similar product markets can be an important factor.

Health Care Conduct Matters

While at DOJ, you also worked on a number of conduct investigations in the health care industry. How does DOJ learn about potentially anticompetitive conduct?

DOJ has many sources of leads for potential investigations. Often, customers or competitors – typically companies that claim to be foreclosed from a market or otherwise harmed by the conduct – complain to DOJ. In addition, conduct investigations sometimes arise from DOJ seeing potential violations in documents or other information provided in the course of a merger investigation.

There also are referrals from other agencies, including the FTC and state agencies. Finally, potential violations can come to the attention of DOJ either through the press, particularly the trade press, or industry observers.

What are some factors in evaluating whether to open a conduct investigation?

Conduct investigations can last for multiple years and typically require a large investment of resources by DOJ. They also can cause significant burdens for the parties being investigated. As a result, DOJ makes careful decisions about which conduct to investigate. A number of factors are considered in deciding whether to open an investigation. DOJ will first consider the available evidence and the merits of the theory of harm. DOJ will also consider the likelihood of relief and the magnitude of the likely harm. In addition, DOJ will consider the precedential value of the investigation. Sometimes the conduct at issue is popping up across the country. DOJ cannot possibly investigate conduct everywhere due to a lack of resources. Instead, DOJ will choose one or two areas to investigate, hoping that the outcome will set a precedent for other areas of the country.

What are some examples of conduct by large health care entities that DOJ has focused on?

DOJ has focused on a wide range of conduct by large health care entities in the last few years. DOJ had a multi-year litigation that resulted in a recent settlement against Carolinas Healthcare System (now Atrium Health) over its use of anti-steering and anti-price transparency provisions in its contracts with health insurers. DOJ also had multiple recent settlements with health systems that had agreed to allocate territories for the marketing of competing health care services in an effort to limit competition. In addition, DOJ has focused on provider associations that jointly negotiated with insurers without financially or clinically integrating. On the health insurer side, DOJ has, on numerous occasions, litigated or reached settlement agreements with health insurers over their use of most-favored-nation provisions in their contracts with providers.

Outlook on Vertical Merger Enforcement

Can you give us your perspective on the state of vertical merger enforcement going forward in light of DOJ's clearance of CVS-Aetna and Cigna-Express Scripts? What are some of the issues that parties should think about?

I think that vertical merger enforcement is still viable and will be fully investigated by DOJ where appropriate. Parties with potential vertical issues should be prepared to address them early in the investigation. A key issue in the merger review is going to be the competitiveness of the relevant markets. For example, in CVS-Aetna, DOJ specifically said that CVS was unlikely to increase costs to Aetna's rivals because of competition from other PBMs and retail pharmacies. Related to that point, the economic analysis is likely to be important to DOJ's assessment of potential harm from a vertical merger. A critical question will be whether the parties have the economic incentive to foreclose competitors. In CVS-Aetna, DOJ concluded that CVS would not be able to offset losses from lost customers due to raising its PBM or retail pharmacy prices by capturing additional health insurance customers. For parties considering an acquisition with potential vertical issues, understanding the economic analysis should be a high priority. Another important consideration is the content of the parties' internal documents. DOJ will examine these documents carefully for any suggestion that the parties are considering taking actions that would foreclose competitors.

A PRIMER ON PHARMACY BENEFIT MANAGERS

The health care industry is changing, and the role of Pharmacy Benefit Managers (PBMs)—which are positioned at the center of the pharmaceutical drug supply chain—is changing too. Recent vertical mergers between PBMs and health insurers have thrust PBMs into the spotlight. PBMs took center stage in 2017 and 2018 when PBMs CVS Health and Express Scripts announced their respective plans to merge with health insurance companies Aetna and Cigna.[1] Both mergers closed in late 2018,[2] although the CVS-Aetna merger is still awaiting court approval.[3] The resulting entities each will control an insurance company, a PBM, and a pharmacy network, allowing them to influence various parts of the healthcare industry. Some have raised concerns about the impact of these mergers on competition, and, as these changes unfold, PBMs may find themselves to be the subject of increased oversight.

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What are Pharmacy Benefit Managers?

Pharmacy Benefit Managers are intermediaries at the center of the prescription drug supply chain. They administer the prescription drug plans for more than 266,000,000 Americans.[4] Historically, they were hired by third-party health insurers and other plan sponsors (hereinafter "insurers") to administer prescription drug programs on their behalf.[5] This was a limited administrative role, whereby PBMs would process and adjudicate beneficiaries' prescription drug claims in exchange for a fee.[6]

Over time, PBMs gained additional responsibilities. PBMs now are intermediaries between health insurers and the various entities with whom they contract to deliver pharmaceutical drugs to their beneficiaries. In the drug supply chain, pharmaceutical manufacturers create the drugs, health insurers pay drug costs, and pharmacies dispense drugs to patients. PBMs facilitate relationships between all of these components of the supply chain. They manage insurers' prescription drug programs, negotiate drug prices and rebates with drug manufacturers, negotiate reimbursement rates with pharmacies, and manage the prices and availability of drugs on insurers' formularies. In addition, some PBMs own their own pharmacy or mail-order pharmacy networks. Due to their intermediary role, PBMs are often referred to as "middle men" of the pharmaceutical drug supply chain.

Recent Developments in the PBM Industry

In recent years, PBMs have been

[1] Bruce Japsen, *Justice Department Gives Early Okay to Cigna-Express Scripts Deal*, Forbes (Sept. 17, 2018), https://www.forbes.com/sites/brucejapsen/2018/09/17/justice-department-gives-early-ok-to-cigna-express-scripts-deal/#4c91d5ca78a6; Press Release, Cigna, *Cigna to Acquire Express Scripts for $67 Billion* (Mar. 8, 2018), https://www.cigna.com/newsroom/news-releases/2018/cigna-to-acquire-express-scripts-for-67-billion; Press Release, CVSHealth, *CVS Health to Acquire Aetna; Combination to Provide Consumers with a Better Experience, Reduced Costs and Improved Access to Health Care Experts in Homes and Communities Across the Country* (Dec. 3, 2017), https://cvshealth.com/newsroom/press-releases/cvs-health-acquire-aetna-combination-provide-consumers-better-experience.

[2] Anna Wilde Mathews, *Cigna and Express Scripts Seal $54 Billion Merger*, Wall St. J. (Dec. 20, 2018), https://www.wsj.com/articles/cigna-and-express-scripts-seal-54-billion-merger-11545327979; Angelica LaVito, *CVS Creates New Health-Care Giant as $69 Billion Merger with Aetna Officially Closes*, CNBC (Nov. 28, 2018), https://www.cnbc.com/2018/11/28/cvs-creates-new-health-care-giant-as-69-billion-aetna-merger-closes.html.

[3] *See United States v. CVS Health Corp.*, No. 1:18-cv-2340 (D.D.C. filed Oct. 10, 2018).

[4] Press Release, Pharm. Care Management Ass'n, *PCMA Offers Policy Solutions to Reduce Prescription Drug Costs* (Jan. 28, 2019), https://www.pcmanet.org/pcma-offers-policy-solutions-to-reduce-prescription-drug-costs/.

[5] Samantha Liss, *Why Payers Are Gobbling up PBMs,* Healthcare Dive (Sept. 8, 2018), https://www.healthcaredive.com/news/why-payers-are-gobbling-up-pbms/532224/.

[6] *Id*.; David Balto, *CVS-Aetna Merger Is a Robber Baron's Dream Come True*, The Hill (Dec. 6, 2017), https://thehill.com/opinion/finance/363510-cvs-aetna-merger-is-a-robber-barons-dream-come-true.

consolidating.[7] Currently, the three largest PBMs—Express Scripts, CVS Health, and OptumRx—facilitate most drug transactions paid by health insurers in the United States.[8] All three PBMs are now affiliated with major health insurers.[9]

The third-largest PBM—OptumRx—was created in 1990 by the largest health insurer in the country, UnitedHealth Group.[10] Then, in 2015, UnitedHealth Group expanded OptumRx by acquiring another PBM, Catamaran Corporation.[11] At the time of the acquisition, Catamaran was the fourth-largest PBM in the country.[12]

In late 2018, the two largest PBMs—Express Scripts and CVS—merged with health insurers Cigna and Aetna, respectively.[13] Cigna and Aetna are among the largest health insurers in the nation.[14] In addition to operating PBMs, Express Scripts and CVS are also pharmacy retailers.[15]

In the fall of 2018, DOJ cleared the Cigna-Express Scripts and CVS-Aetna mergers.[16] Both mergers closed in late 2018.[17] First, on September 17, 2018, after a six-month review, DOJ announced that it was closing its investigation into the $67 billion merger of Cigna and Express Scripts.[18] DOJ explained that "[t]he merger is unlikely to lessen competition substantially in the sale of PBM services because Cigna's PBM business nationwide is small."[19] DOJ said that the likely impacts of the merger included: (1) other PBMs will remain in the post-merger market as competitors; (2) other PBMs will be able to continue to compete for Cigna's medical insurance customers; (3) Express Scripts can continue to sell PBM services to Cigna's rivals; and (4) competition from other vertically-integrated insurer-PBM rivals will constrain Cigna's and Express Scripts' ability to increase health insurance costs. The Cigna-Express Scripts merger closed on December 21, 2018.[20]

Second, on October 9, 2018, DOJ announced that it and five state attorneys general had reached a settlement with Aetna and CVS that would allow the $69 billion merger of Aetna and CVS.[21] As a condition of the settlement, DOJ required that Aetna fully divest its Medicare Part D prescription business. In announcing the settlement, Assistant Attorney General Makan Delrahim said: "The divestitures required here allow for the creation of an integrated pharmacy and health benefits company that has the potential to generate benefits by improving the quality and lowering the costs of the healthcare services that American consumers can obtain."[22] Aetna divested its Medicare Part D business to

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[7] Mathews, *supra* note 2; Jack Du, *What is the Pharmacy Benefit Management Industry? (ESRX, CVS)*, INVESTOPEDIA (July 2, 2015), https://www.investopedia.com/articles/markets/070215/what-pharmacy-benefit-management-industry.asp; Trefis Team, *What the UnitedHealth-Catamaran Deal Means for Walgreens*, FORBES (Apr. 1, 2015), https://www.forbes.com/sites/greatspeculations/2015/04/01/what-the-unitedhealth-catamaran-deal-means-for-walgreens/#df3bdc15bf07; *see also Pharmacy Benefit Manager Directory*, PHARMACY BENEFIT MGMT. INST., https://www.pbmi.com/PBMI/Directory/PBM_Directory/PBMI/Directory/Pharmacy_Benefit_Manager_Directory.aspx?hkey=3b01e5a2-1e2c-40b4-8ed5-88994303bf1f (last visited Jan. 3, 2019).

[8] COUNCIL OF ECON. ADVISERS, EXEC. OFFICE OF THE PRESIDENT, REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD (Feb. 2018), at § 2.3, https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

[9] Mathews, *supra* note 2.

[10] Liss, *supra* note 5; *America's Biggest Health Insurance Companies in 2018*, FORBES.

[11] Balto, *supra* note 6.

[12] *Id.* Catamaran previously was Catalyst Health Solutions, which included a PBM owned by Walgreens until 2011. *See* Team, *supra* note 7.

[13] Mathews, *supra* note 2; LaVito, *supra* note 2.

[14] *America's Biggest Health Insurance Companies in 2018*, *supra* note 10.

[15] Express Scripts owns a mail-order pharmaceutical delivery service, and CVS operates the largest network of brick-and-mortar pharmacy locations in the United States, with over 10,000 locations. Press Release, U.S. DEP'T OF JUSTICE, JUSTICE DEPARTMENT REQUIRES CVS AND AETNA TO DIVEST AETNA'S MEDICARE INDIVIDUAL PART D PRESCRIPTION DRUG PLAN BUSINESS TO PROCEED WITH MERGER (Oct. 10, 2018), https://www.justice.gov/opa/pr/justice-department-requires-cvs-and-aetna-divest-aetna-s-medicare-individual-part-d.

[16] *Id.*; U.S. DEP'T OF JUSTICE, STATEMENT OF THE DEPARTMENT OF JUSTICE ANTITRUST DIVISION ON THE CLOSING OF ITS INVESTIGATION OF THE CIGNA–EXPRESS SCRIPTS MERGER (Sept. 17, 2018), https://www.justice.gov/atr/closing-statement.

[17] Mathews, *supra* note 2; Reed Abelson, *CVS Health and Aetna $69 Billion Merger Is Approved with Conditions*, N.Y. TIMES (Oct. 10, 2018), https://www.nytimes.com/2018/10/10/health/cvs-aetna-merger.html.

[18] U.S. DEP'T OF JUSTICE, *supra* note 16.

[19] *Id.*; *see also* Abelson, *supra* note 17.

[20] U.S. DEP'T OF JUSTICE, *supra* note 16; Mathews, *supra* note 2.

[21] U.S. DEP'T OF JUSTICE, *supra* note 15.

[22] *Id.*

WellCare Health Plans, Inc. on November 30, 2018.[23]

The CVS-Aetna merger closed on November 28, 2018, while it was still subject to public comment (until December 17, 2018) and still awaiting court approval as required under the Tunney Act, 15 U.S.C. § 16(b)–(h).[24] Although court approval ordinarily is granted routinely, the CVS-Aetna merger came under unusual scrutiny, with Judge Richard Leon of the U.S. District Court for the District of Columbia stating in a December 2018 order: "At this stage, I am less convinced of the sufficiency of the government's negotiated remedy than the government is."[25] Judge Leon also suggested that CVS and Aetna should pause integration of their companies until after he concluded his Tunney Act review of the merger agreement.[26]

Pursuant to the Court's order, CVS filed a brief explaining that it should not be required to hold its newly-acquired Aetna business separate because CVS was taking adequate precautions during the pendency of the Court's Tunney Act review.[27] The Court was satisfied with the measures that CVS described in its brief and ordered CVS to continue to use those measures during the Court's review.[28]

Potential Effects on Competition

In merging vertically with health insurers, PBMs say that they will achieve numerous procompetitive benefits, including "improving patient engagement, improving health outcomes, and lowering total healthcare costs."[29] In particular, CVS says that its merger with Aetna "will lead to better access to healthcare and lower costs for patients."[30] PBMs say that they will lower drug prices by creating tiered drug formularies, encouraging patients to use generic drugs, negotiating with drug manufacturers for volume discounts (also referred to as rebates), negotiating with retail pharmacies for reduced reimbursement rates, and encouraging beneficiaries to use cost-effective mail order delivery.[31]

Yet, pharmacists, competitors, and other critics say that, even before the mergers, PBMs caused anticompetitive harms to consumers. Noting that three PBMs are involved in most insurer-covered prescription drug transactions,[32] critics have accused

[23] CVS Health Corporation's Memorandum in Response to the Court's December 3, 2018 Order to Show Cause ("CVS Response"), at 15 n.19, ECF No. 33, *United States v. CVS Health Corp.*, No. 1:18-cv-2340 (D.D.C. Dec. 14, 2018).

[24] *Judge Accepts CVS Offer on Aetna While Reviewing Consent Decree*, CNBC (Dec. 24, 2018), https://www.cnbc.com/2018/12/24/judge-accepts-cvs-offer-on-aetna-while-reviewing-consent-decree-.html; LaVito, *supra* note 2.

[25] Order to Show Cause, at 2–3, ECF No. 27, *United States v. CVS Health Corp.*, No. 1:18-cv-2340 (D.D.C. Dec. 4, 2018); *see also* Diane Bartz, *U.S. Judge Concerned Over Government Nod for CVS-Aetna Deal*, REUTERS (Dec. 4, 2018), https://www.reuters.com/article/us-aetna-m-a-cvs-health/u-s-judge-concerned-over-government-nod-for-cvs-aetna-deal-idUSKBN1O32EC.

[26] Order to Show Cause, at 2–3, ECF No. 27 ("Because the Tunney Act procedures have not yet been completed, neither I, nor the public, has had a chance to evaluate whether the proposed final judgment adequately remedies the harm alleged in the complaint and, more importantly perhaps, whether the complaint as drafted is actually in the public interest or is drafted so narrowly as to 'make a mockery of judicial power' as prohibited by our Court of Appeals."); Angelica LaVito, *Here's What a Judge Can—and Can't—Do in Ruling on the Justice Department's Deal with CVS and Aetna*, CNBC, (Dec. 3, 2018), https://www.cnbc.com/2018/12/03/how-a-judge-can-rule-on-justice-departments-deal-with-cvs-aetna.html.

[27] CVS Response, at 15–16, ECF No. 33.

[28] Memorandum Order, ECF No. 44, *United States v. CVS Health Corp.*, No. 1:18-cv-2340 (D.D.C. Dec. 21, 2018) (noting that CVS had taken measures including "1. Aetna's health insurance business is being operated as a separate and distinct unit from CVS retail pharmacy and pharmacy benefit manager CVS Caremark within the CVS Health enterprise. . . . 2. Aetna will maintain its historical control over the pricing and product offerings brought to market. 3. Aetna personnel will retain their current compensation and benefits. 4. CVS Health has and will maintain a firewall to prevent the exchange of competitively sensitive information between CVS Health and Aetna").

[29] CVS Response, at 6, ECF No. 33; *see also Cigna to Acquire Express Scripts for $67 Billion*, *supra* note 1; *CVS Health to Acquire Aetna; Combination to Provide Consumers with a Better Experience, Reduced Costs and Improved Access to Health Care Experts in Homes and Communities Across the Country*, *supra* note 1.

[30] CVS Response, at 1, ECF No. 33.

[31] *See, e.g.*, Joshua Cohen, *Cigna And Express Scripts Deal: Virtues Of Vertical Integration*, FORBES (Oct. 3, 2018), https://www.forbes.com/sites/joshuacohen/2018/10/03/cigna-and-express-scripts-deal-virtues-of-vertical-integration/#426db78a6a0b; Ike Brannon, *Pharmacy Benefit Managers Are Not the Cause of High Prescription Drug Prices*, FORBES (June 6, 2018), https://www.forbes.com/sites/ikebrannon/2018/06/06/pharmacy-benefit-managers-are-not-the-cause-of-high-prescription-drug-prices/#268db4d06b9a.

[32] *See, e.g.*, Team, *supra* note 7 ("The PBM market was already controlled by few players, with CVS and Express Scripts Holding Co. together controlling about 50% of the market. With this deal, another similar sized company is formed resulting in more than 70% of the market to be controlled by just 3 players. The creation of larger healthcare enterprises gives them greater bargaining power, which in turn results in greater pricing pressures for drug retailers. This is why we think this acquisition and, hence large [sic] the large benefit managers,

PBMs of increasing drug prices by collecting unnecessary fees, pocketing rebates, and artificially inflating costs as they perform their intermediary functions.[33] In addition, some believe that the PBMs that own pharmacy networks have a conflict of interest in negotiating drug prices.[34]

While PBMs say that the mergers will help to address these concerns, critics contend that these anticompetitive harms will be amplified by the mergers. The President of the American Medical Association believes that the merger of CVS and Aetna will "substantially lessen competition in many health care markets, to the detriment of patients."[35] Likewise, Food and Drug Administration Commissioner Scott Gottlieb has cautioned that "[c]onsolidated firms—the PBMs, the distributors, and the drug stores" will "team up with payers" and "use their individual market power to effectively split monopoly rents with large manufacturers and other intermediaries; rather than passing on the saving garnered from competition to patients and employers."[36] In moving to intervene in *United States v. CVS Health Corp.*, multiple pharmacist groups argued that the mergers would "exacerbate the concerns associated with an already concentrated and anticompetitive PBM market."[37] The pharmacist groups warned that "[w]hen the PBM is commonly owned with the entity it is supposed to bargain with, or one that has its own mail-order operations, there is an inherent conflict of interest which can lead to deception, anticompetitive conduct, and higher prices."[38]

These concerns are outlined below.

Competitive Concerns that Pre-Date the Mergers

First, critics say that PBMs take advantage of the rebates offered by drug manufacturers to reduce the list prices of their drugs. Here's how it works. While pharmaceutical drug manufacturers create drugs for patients to use, they typically do not sell their drugs directly to patients. Instead, manufacturers contract with PBMs to put those drugs on the insurers' prescription drug benefit plans. Before a PBM agrees to list a manufacturer's drugs on the formularies that it manages for insurers, the PBM typically negotiates with the manufacturer for a rebate, that is, a discount on the list drug price. Manufacturers offer rebates in exchange for favorable placement of the drug on the insurers' formularies. Manufacturers hope to be placed on a lower-cost tier—with a lower co-pay—where more patients will be able to afford to purchase the drugs.

According to PBMs, this is a good thing. PBMs use their negotiating power to induce manufacturers to offer rebates that bring the cost of the drugs below the list price.[39] PBMs have a lot of negotiating power because they manage the prescription benefit plans for so many people.

Critics disagree. They say that it is unclear whether the rebates paid by manufacturers to PBMs are passed on to patients.[40] While PBMs

could be a potential threat to Walgreens' profits in the future."); *PBM Resources*, NAT'L CMTY. PHARMACISTS ASS'N, https://www.ncpanet.org/advocacy/the-tools/pbm-resources ("[T]hree large companies—Express Scripts, CVS Health and OptumRx—control as much as 89% of the market: 238 million lives out of 266 million lives."); *The Anti-Competitive Nature of Mergers*, PBM WATCH, http://www.pbmwatch.com/problems-in-the-market.html ("Three PBMs control 78% of prescription drug benefit transactions in the United States.").

[33] COUNCIL OF ECON. ADVISERS, *supra* note 8, at § 2.3 ("[T]he PBM market is highly concentrated. Three PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves. . . . Policies to decrease concentration in the PBM market and other segments of the supply chain (i.e., wholesalers and pharmacies) can increase competition and further reduce the price of drugs paid by consumers.").

[34] *Id.*; *The Anti-Competitive Nature of Mergers*, *supra* note 32.

[35] Kevin B. O'Reilly, *Anticompetitive CVS-Aetna Merger Should Be Blocked*, AM. MED. ASS'N (June 19, 2018), https://www.ama-assn.org/delivering-care/patient-support-advocacy/anticompetitive-cvs-aetna-merger-should-be-blocked.

[36] Morgan Haefner, *Dr. Scott Gottlieb: PBMs, Payers Use 'Rigged Payment Scheme' to Block Biosimilars,* BECKERS HOSP. REVIEW (Mar. 7, 2018), https://www.beckershospitalreview.com/supply-chain/dr-scott-gottlieb-pbms-payers-use-rigged-payment-scheme-to-block-biosimilars.html.

[37] Pharmacists United for Truth and Transparency and Pharmacists Society of the State of New York's Motion for Leave to Intervene, or in the Alternative, to Participate as Amicus Curiae ("Pharmacists' Motion to Intervene"), at 16, ECF No. 35, *United States v. CVS Health Corp.*, No. 1:18-cv-2340 (D.D.C. Dec. 14, 2018).

[38] *Id.*

[39] Vidya Ramesh & Sandip Shah, *Middlemen Are Not Passing on All Drug Discounts Intended for Patients*, FORBES (May 26, 2017), https://www.forbes.com/sites/realspin/2017/05/26/middlemen-are-not-passing-on-all-drug-discounts-intended-for-patients/#1ea89bbe516c.

[40] *Id.*

typically keep a portion of the rebates for themselves and pass the remainder to the insurers,[41] it is not known whether insurers pass on any of the benefits of those rebates to patients.

In fact, critics suspect that PBMs' rebate negotiations actually may *increase* the prices paid by patients.[42] On this theory, because PBMs keep a portion of the rebate, PBMs have an incentive to ensure that the drug prices build in a rebate. In other words, drug list prices may be higher than necessary to build in a rebate that manufacturers can offer to PBMs in exchange for favorable placement on their formularies.[43] Critics say that this practice is problematic for patients because co-pays and PBM fees are calculated based on the drug's list price, not the discounted price.[44] In addition, it may encourage PBMs to place drugs that offer a rebate on more preferential tiers than competing drugs. This can artificially inflate the prices that consumers pay for generic drugs if generic drugs are placed on more expensive tiers than the brand name drugs that offered the PBM a rebate.

In apparent response to these critiques, in December 2018, CVS announced a new pricing model that would allow plan sponsors to receive 100% of rebates offered by drug manufacturers to CVS.[45] The new model promises a guaranteed net cost, which simplifies costs and shifts the burden of price inflation to CVS.[46] CVS says "[t]his new model more closely aligns PBM incentives with plan sponsors' objectives than current pricing models by providing net cost predictability."[47] The new model may encourage CVS to promote cheaper generic drugs rather than drugs with higher rebates.[48]

Second, PBMs have been accused of building a "spread" or profit for themselves into the drug price when negotiating reimbursement rates with pharmacy networks. PBMs negotiate with pharmacies to determine the *reimbursement rate* that the pharmacies will receive when patients purchase a drug. PBMs also separately set a *formulary price* for the drug, which is the price that patients and insurers pay for the drug. Critics say that PBMs set the formulary price higher than the pharmacy reimbursement rate, creating a hidden spread for the PBM.[49] In other words, PBMs charge insurers and patients a rate greater than necessary to reimburse the pharmacy that supplied the drug and then pocket the difference between the rates. This practice allows the "PBM [to] make[] money off the difference between what it charges insurers, employers or patients and what it pays the pharmacy for dispensing the medication, which can inflate list prices, critics argue."[50] Consumers fund the spread either in their co-pays or in their monthly insurance premiums.

Competitive Concerns Following Mergers

It remains to be seen whether the recent mergers between Cigna and Express Scripts as well as Aetna and CVS will exacerbate or diminish these concerns. Some say that by merging with insurers, PBMs may

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[41] *Id.*

[42] *Id*.

[43] *Id*.

[44] Laurie Toich, *How Does PBM Involvement in the Supply Chain Impact Drug Costs?*, AM. JOURNAL OF PHARMACY BENEFITS (Mar. 9, 2017), https://www.ajpb.com/news/how-does-pbm-involvement-in-the-supply-chain-impact-drug-costs ("These co-pays are based off a list price that's been artificially inflated because of involvement by middlemen, like pharmacy benefit managers, that are demanding these rebates. In the end, patients are not better off, as their co-pays are based off those list prices.").

[45] Max Nisen, *CVS Hears Trump, But Don't Count on Lower Drug Prices*, WASH. POST (Dec. 5, 2018), https://www.washingtonpost.com/business/cvs-hears-trump-but-dont-count-on-lower-drug-prices/2018/12/05/3045fe14-f8d0-11e8-8642-c9718a256cbd_story.html?utm_term=.fe8a92bac783.

[46] Press Release, CVS Health, *CVS Health Introduces New Approach to Pricing of Pharmacy Benefit Management Services*, (Dec. 5, 2018), https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-new-approach-pricing-pharmacy-benefit-management.

[47] *Id.*

[48] Nisen, *supra* note 45.

[49] Brittany Hoffman-Eubanks, *The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1*, PHARMACY TIMES (Nov. 14, 2017), https://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1.

[50] Alex Kacik, *Express Scripts Looks to Limit Rebate Model, Lower Drug Costs in 2019*, MODERN HEALTHCARE (Nov. 13, 2018), https://www.modernhealthcare.com/article/20181113/NEWS/181119986?ite=41183&ito=1156&itq=4f3d65fd-8d0f-4501-8c51-e48ca3e99a1d&itx%5Bidio%5D=&itx[idio]=10228220; *see also* Megan Thompson, *Why a Patient Paid a $285 Copay for a $40 Drug*, PBS (Aug. 19, 2018), https://www.pbs.org/newshour/health/why-a-patient-paid-a-285-copay-for-a-40-drug.

cease to be middlemen that capture unnecessary fees.[51] An integrated PBM-insurer-pharmacy may do away with inefficiencies and be more willing to pass on rebates, eliminate administrative fees, and reduce its share of the drug price spread.

On the other hand, critics say that the combined entities will exacerbate pre-merger anticompetitive effects and cause additional anticompetitive effects. Post-merger, critics are concerned that the new entities will push other pharmacies out of the market, require people covered by the affiliated insurer to use the PBM's pharmacies, raise drug prices, cut other PBMs out of the market, and cause further consolidation within the healthcare industry. In addition, they say that any efficiencies from consolidation may undermine other "free-standing" insurers' or PBMs' abilities to compete.[52]

First, one of the primary fears is that the post-merger companies will use their strengths as insurers and PBMs to prevent smaller pharmacies from competing with their pharmacy networks.[53] CVS and Express Scripts already were among the largest pharmacies in the country before the mergers.[54] With the mergers, CVS and Express Scripts pharmacies now wield the backing of insurers Aetna and Cigna, respectively. The post-merger entities could use that power to decide which unaffiliated pharmacies are in-network for their insurers' beneficiaries, how much they will reimburse unaffiliated pharmacies, and which prescriptions are covered by the plan formulary. In particular, some are concerned that PBM-insurers may engage in self-dealing, requiring beneficiaries of their insurers' health plans to use pharmacies owned by the PBM-insurers.[55] For example, pharmacist groups warn that CVS might "design the benefit to offer patients a lower co-pay for medications obtained at their own mail-order pharmacy or retail stores and a higher co-pay at non-CVS community pharmacies in their network."[56]

Second, there are fears about the impact of the mergers on drug prices and availability—particularly specialty drugs, which treat rare diseases and are not available in most retail pharmacies.[57] Many of the largest specialty pharmacies are owned by PBMs, including CVS and Express Scripts.[58] Post-merger, the combined PBM-insurers could attempt to leverage higher list prices for specialty and non-specialty drugs, building in a rebate that the PBM-insurer can capture.

Of course, this also could cut the other way. PBMs say that they will be able to use their increased leverage to negotiate with drug manufacturers for lower prices and improved delivery of specialty drugs post-merger. A combined PBM-insurer may be able to more efficiently coordinate medical and pharmaceutical benefits for certain specialty drugs.[59] And, as already mentioned, CVS recently announced a new pricing model that would allow plan sponsors to receive 100% of rebates offered by drug manufacturers to CVS.[60]

Third, there are concerns that Aetna, Cigna, and United may stop working with other PBMs now that they each own a PBM.[61] This would undermine the bargaining power of

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[51] Cohen, *supra* note 31; Brannon, *supra* note 31.

[52] Balto, *supra* note 6; Steven Pearlstein, *Why CVS-Aetna May Be Bad for Your Health*, WASH. POST (Dec. 15, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/12/15/why-cvs-aetna-may-be-bad-for-your-health/?utm_term=.688daf097dad; O'Reilly, *supra* note 35; David Balto, *Why DOJ Must Block the Cigna-Express Scripts Merger*, THE HILL (Mar. 27, 2018), https://thehill.com/opinion/healthcare/380522-why-doj-must-block-the-cigna-express-scripts-merger.

[53] Pharmacists' Motion to Intervene, at 16–19, ECF No. 35.

[54] Linette Lopez, *What CVS Is Doing to Mom-and-Pop Pharmacies in the US Will Make Your Blood Boil*, BUSINESS INSIDER (Mar. 30, 2018), https://www.businessinsider.com/cvs-squeezing-us-mom-and-pop-pharmacies-out-of-business-2018-3.

[55] Balto, *supra* note 6; Pearlstein, *supra* note 52.

[56] Pharmacists' Motion to Intervene, at 19, ECF No. 35.

[57] Jacob Passy, *Cigna's Express Scripts Deal Could Lead to Higher Prices for Consumers*, MARKET WATCH (Aug. 7, 2018), https://www.marketwatch.com/story/cignas-latest-deal-could-spell-trouble-for-consumers-2018-03-09; Sally Welborn & Pramod John, *Imagine There Are No PBMs. It's Easy if You Try*, STAT NEWS (Aug. 23, 2018), https://www.statnews.com/2018/08/23/pbms-rebates-drug-purchasing/ ("The controversy surrounding rebates is that they would traditionally be considered 'kickbacks' from drug manufacturers to pharmacy benefit managers to drive formulary positioning.").

[58] Adam J. Fein, *The State of Specialty Pharmacy in 2018*, ASSEMBIA (May 1, 2018), http://drugchannelsinstitute.com/files/State-of-Specialty-Pharmacy-2018-Fein-Asembia.pdf.

[59] *Id.*; Liss, *supra* note 5.

[60] Nisen, *supra* note 45.

[61] Passy, *supra* note 57.

PBMs that are not affiliated with insurers and could lead to higher prices. Notably, DOJ found this this was unlikely to happen in closing its investigation into the Cigna-Express Scripts merger.[62]

Finally, further vertical integration of the healthcare industry may be on the horizon. Anthem, the second-largest health insurer in the United States, has announced plans to launch its own PBM by 2020.[63] In pursuit of the efficiencies of vertical integration, insurers may next move to acquire hospital networks and physician groups.[64] In addition, hospitals may follow the lead of PBMs and insurers, by creating or acquiring their own pharmacies or PBMs.[65]

Regulatory Oversight of PBMs

Like pharmaceutical drug manufacturers,[66] PBMs often have been subject to public and governmental scrutiny.[67] In 2018, scrutiny increased with the high-profile mergers of CVS and Aetna as well as of Express Scripts and Cigna. Those mergers coincided with an increased regulatory focus on PBMs.[68] Proposals for reform seek increased transparency, aiming to shed light on the role that PBMs play in the prescription drug supply chain and the fees that they collect.[69]

In 2018, Congress passed two Acts aimed at so-called "gag clauses," which kept pharmacists from informing patients that their co-pay for a particular drug was greater than the cost of the drug itself.[70] The Patient Right to Know Drug Prices Act and Know the Lowest Price Act became law on October 10, 2018.

These laws prohibit group health plans, health insurance issuers, and PBMs from barring pharmacies from providing information about this price differential to consumers.[71]

A number of states also have passed laws prohibiting gag clauses and enacted other regulations aimed at transparency in PBM and insurer billing, rebates, and savings.[72] For example, the Ohio Medicaid department is taking steps to make PBM contracting more transparent after finding that CVS and OptumRx billed Ohio a $223.7 million spread over the amount they paid to pharmacies for the drugs. The Ohio Medicaid department wants to renegotiate the contracts

[62] U.S. DEP'T OF JUSTICE, *supra* note 16; Mathews, *supra* note 2.

[63] Mathews, *supra* note 2; *America's Biggest Health Insurance Companies in 2018*, *supra* note 10; Bruce Japsen, *Anthem to Launch PBM Earlier, Ending Express Scripts Deal in March*, FORBES (Jan 30, 2019), https://www.forbes.com/sites/brucejapsen/2019/01/30/anthem-will-launch-new-pbm-earlier-than-expected/#1927f3341320.

[64] Gregory A. Freeman, *Insurance Consolidation May Soon Include Hospitals, Create Powerhouses*, HEALTHLEADERS (May 23, 2018), https://www.healthleadersmedia.com/finance/insurance-consolidation-may-soon-include-hospitals-create-powerhouses.

[65] Adam J. Fein, *Why Manufacturers and PBMs Should Worry About the Growth of Hospital-Owned Specialty Pharmacies*, DRUG CHANNELS (Sept. 12, 2017), https://www.drugchannels.net/2017/09/why-manufacturers-and-pbms-should-worry.html; https://www.businesswire.com/news/home/20180820005586/en/RxBenefits-Launches-Enhanced-Pharmacy-Benefits-Solution-Hospital.

[66] *See, e.g.*, Christopher Rowland, *Investigation of Generic "Cartel" Expands to 300 Drugs*, WASH. POST (Dec. 9, 2018), https://www.washingtonpost.com/business/economy/investigation-of-generic-cartel-expands-to-300-drugs/2018/12/09/fb900e80-f708-11e8-863c-9e2f864d47e7_story.html?utm_term=.15cbcffc57d1.

[67] *The PBM Story*, NAT'L CMTY. PHARMACISTS ASS'N (2017), http://www.ncpa.co/pdf/PBM-Storybook-6pg.pdf.

[68] Toich, *supra* note 44.

[69] Mathews, *supra* note 2.

[70] The Patient Right to Know Drug Prices Act, S. 2554, 115th Cong. (2018); Know the Lowest Price Act, S. 2553, 115th Cong. (2018); Brittany Shoot, *Trump Signs 2 Drug Pricing Bills, HHS Secretary Promises 'More to Come'*, FORTUNE (Oct. 11, 2018), http://fortune.com/2018/10/11/trump-administration-gag-clause-compare-prescription-prices/.

[71] These laws aim to prevent patients from paying more to use their insurance plan with a co-pay to purchase a drug than the drug would have cost the consumer without using insurance. Patients pay more for a drug using their insurance plans 25% of the time, according to a March 2018 study published by the University of Southern California's Schaeffer Center for Health Policy and Economics. On average, consumers were charged $7.69 more for the drug than the pharmacy was reimbursed, leading to millions in overpayments in 2013. Thompson, *supra* note 50.

[72] Jay Phillips, *A 50 State Scan: States Move to Protect Healthcare Consumers by Prohibiting Gag Clauses on Pharmacists*, COUNCIL OF STATE GOV'TS (July 3, 2018), https://knowledgecenter.csg.org/kc/content/50-state-scan-states-move-protect-healthcare-consumers-prohibiting-gag-clauses-pharmacists; Richard Cauchi, *States Regulating Pharmaceutical Benefit Managers*, NAT'L CONFERENCE OF STATE LEGISLATURES (Dec. 1, 2018), http://www.ncsl.org/research/health/pbm-state-legislation.aspx. However, some say that some state laws may be preempted by ERISA, which preempts state regulation of ERISA-governed plans, as well as state regulation of third-party administrators of those plans. M. Miller Baker & Sarah Hogarth, *ERISA Preempts State Regulation of PBM–Pharmacy Pricing Agreements*, JDSUPRA (July 27, 2018), https://www.jdsupra.com/legalnews/erisa-preempts-state-regulation-of-pbm-81742/; Du, *supra* note 7.

that its five managed care plans hold with PBMs to include a more transparent "pass-through" pricing model.[73] The pass-through pricing would eliminate the spread PBMs collect above the pharmacy reimbursement rate and ensure that managed care plans pay the discounted pharmacy price.[74]

Regulation of PBMs could be an area of bipartisan action in the new Congress, as Democrats, Republicans, and the President have all raised concerns about pharmaceutical drug prices.[75] As Politico noted, Democrats introduced a "flurry of bills" after the 2018 midterm election proposing to regulate pharmaceutical drugs, suggesting "that the powerful pharmaceutical industry will be a major populist target during the Democratic presidential primary and possibly the general election."[76]

Finally, the Department of Health and Human Services Office of Inspector General has proposed a new rule that would impact the way PBMs do business. The proposed rule entitled "Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" would make it unlawful for drug manufacturers to provide rebates to PBMs under the Federal Anti-Kickback Statute.[77] The proposed rule was published in the Federal Register on February 6, 2019, and the public comment period for the proposed rule ended on April 8, 2019.[78]

Alternatives to PBMs

Regulatory action is not the only avenue for potential reform. Large employers—which share the costs of health insurance premiums with their employees—have taken steps to address their concerns about PBMs.[79] The costs of health insurance are important to employers because, "[a]fter compensation and real estate, employer-sponsored health insurance is often the next-highest expense for a business."[80] To keep costs down and cut unnecessary spending, some employers, such as Walmart, have decided to purchase healthcare directly from providers, thereby forgoing engaging with insurers and PBMs altogether.[81]

[73] Columbus Dispatch Editorial Board, *Guest View: New Year Will Not Fix Ohio Medicaid Drug Pricing*, THESUBURNABITE.COM (Jan. 3, 2019), http://www.thesuburbanite.com/opinion/20190103/guest-view-new-year-will-not-fix-ohio-medicaid-drug-pricing; Karen Kasler, *Ohio Medicaid Orders Managed Care Plans To Break Contracts With PBMs Using "Spread Pricing"*, STATEHOUSE NEWS BUREAU (Aug. 14, 2018), http://www.statenews.org/post/ohio-medicaid-orders-managed-care-plans-break-contracts-pbms-using-spread-pricing; *see also* Alison Kodjak, *States Question Costs of Middlemen that Manage Medicaid Drug Benefits*, NPR (Aug. 8, 2018), https://www.npr.org/sections/health-shots/2018/08/08/636603636/ohio-medicaid-pushes-for-more-transparency-in-prescription-drug-plans.

[74] Columbus Dispatch Editorial Board, *supra* note 73.

[75] Max Ritchman, *A Dem-Controlled House Could Work with Trump to Lower Drug Prices*, THE HILL (Oct. 25, 2018), https://thehill.com/opinion/healthcare/413129-a-dem-controlled-house-could-work-with-trump-on-lowering-drug-prices.

[76] *See, e.g.*, Alex Thompson & Sarah Karlin-Smith, *Warren Bill Would Get Feds into Generic Drug Manufacturing*, POLITICO (Dec. 17, 2018), https://www.politico.com/story/2018/12/17/elizabeth-warren-bill-drug-manufacturing-prices-1067916; Press Release, Bernie Sanders, U.S. Senator, *Sanders, Khanna to Introduce Legislation to Drastically Lower Prescription Drug Prices* (Nov. 20, 2018), https://www.sanders.senate.gov/newsroom/press-releases/sanders-khanna-to-introduce-legislation-to-drastically-lower-prescription-drug-prices; Hector Ramirez, *Senator Blumenthal Introduces CURE High Prices Drug Act at Harford Hospital*, WTNH (Dec. 17, 2018), https://www.wtnh.com/news/health/senator-blumenthal-to-introduce-cure-high-prices-drug-act-at-hartford-hospital/1662771416; Press Release, Richard Blumenthal, U.S. Senator, *Blumenthal, Harris, Merkley & Klobuchar Introduce Bill To End Predatory Price Gouging on Lifesaving Drugs* (Dec. 13, 2018), https://www.blumenthal.senate.gov/newsroom/press/release/blumenthal-harris-merkley-and-klobuchar-introduce-bill-to-end-predatory-price-gouging-on-lifesaving-drugs.

[77] Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (Feb. 6, 2019) (to be codified at 42 C.F.R. 1001).

[78] *Id.*

[79] Mathews, *supra* note 2 (explaining that a 2018 survey "by the National Business Group on Health found that only 26% of employers were optimistic about mergers between PBMs and insurers, while 56% were skeptical they would lead to improvements and 18% actually felt they would raise costs").

[80] Simeon Schindelman, *The Cure for Health Care Is Competition*, FORBES (Dec. 5, 2017), https://www.forbes.com/sites/realspin/2017/12/05/the-cure-for-health-care-is-competition/#3356d48a52a1.

[81] Bruce Japsen, *Walmart's Health Plan Is Way Ahead of Amazon's Buffett-JPMorgan Project*, FORBES (Dec. 28, 2018), https://www.forbes.com/sites/brucejapsen/2018/12/28/walmarts-health-plan-is-way-ahead-of-amazons-buffett-jpmorgan-project/#7e5278c65589; Michelle F. Davis et al., *Harvard's Gawande Chosen to Lead Berkshire-Amazon-JPMorgan Health Initiative*, INS. JOURNAL (June 21, 2018),

Other employers have entered into coalitions to increase their bargaining power when negotiating with PBMs.[82] More than 40 major corporations have joined the Health Transformation Alliance, which was formed in 2016 to contain drug costs for members by contracting with PBMs at lower, more transparent prices.[83] Members include American Express Co., BNSF Railway Co., Johnson & Johnson, Macy's Inc., JPMorgan Chase, Shell, and Verizon, among others. The Alliance aims to limit fees collected by PBMs to administrative service fees, thereby eliminating hidden fees added by PBMs to the costs of drugs themselves. The Alliance has threatened to create its own PBM if it is unable to contract with current PBMs on favorable terms. So far, the Alliance has successfully reduced costs for its members by about 15%.[84]

Likewise, in January 2018, Amazon, Berkshire Hathaway Inc., and JPMorgan Chase announced plans to create a non-profit healthcare joint venture that will serve their employees.[85] According to the announcement, the "[g]oal is to improve U.S. employee satisfaction while reducing overall costs."[86] Since then, they hired several high-profile executives who will lead the initiative and announced that the venture will be called "Haven."[87] The venture will seek to eliminate fees that contribute to the excessive costs of prescription drugs.[88]

There also is speculation that Amazon may launch its own PBM, after Amazon purchased an online pharmacy startup.[89] The startup—PillPack—has licenses to distribute mail-order pharmaceutical drugs in every state as well as relationships with most Medicare Part D plans.[90]

Conclusion

PBMs are in the midst of significant changes brought about by mergers, regulations, and alternatives proposed by other market actors. Regulators and competitors alike will keep a close eye on the competitive impacts as those changes occur.

https://www.insurancejournal.com/news/national/2018/06/21/492882.htm.

[82] Anna Wilde Mathews & Joseph Walker, *Health Efforts by Amazon, Others Aims to Succeed Where Others Have Failed*, WALL ST. J. (Feb. 1, 2018), https://www.wsj.com/articles/employers-struggle-to-make-a-dent-in-health-costs-1517502768.

[83] *Id.*

[84] Kevin Ricaurte Knebel & Jasmine Ye Han, *Amazon Health Alliance's Secret Sauce Will Be Technology*, BLOOMBERG LAW (Feb. 2, 2018), https://www.bna.com/amazon-health-alliances-n73014474966/.

[85] *Id.*

[86] Press Release, Berkshire Hathaway, *Amazon, Berkshire Hathaway and JPMorgan Chase & Co. to Partner on U.S. Employee Healthcare*, (Jan. 30, 2018), http://www.berkshirehathaway.com/news/jan3018.pdf; Abelson, *supra* note 17.

[87] Jon Kamp & Anna Wilde Matthews, *New Details on Amazon, Berkshire Hathaway, JPMorgan Health Venture Emerge in Court Battle*, WALL ST. J. (Jan. 30, 2019), https://www.wsj.com/articles/new-details-on-amazon-berkshire-hathaway-jpmorgan-health-venture-emerge-in-court-battle-11548899146; Christina Farr, *The Health Care Venture from Amazon, Berkshire and JP Morgan Just Hired Its First Female Exec, and She Comes from a Big Insurance Company*, CNBC (Nov. 19, 2018), https://www.cnbc.com/2018/11/19/amazon-berkshire-jpm-health-jv-hiresdana-gelb-safran-from-blue-cross.html; Zachary Tracer, *Amazon-Berkshire-JPMorgan Health Venture Picks Operating Chief*, BLOOMBERG (Sept. 4, 2018), https://www.bloomberg.com/news/articles/2018-09-04/amazon-berkshire-jpmorgan-health-venture-picks-operating-chief; Angela LaVito, *Amazon's Joint Health-Care Venture Finally Has a Name*, CNBC (Mar. 6, 2019), https://www.cnbc.com/2019/03/06/amazon-jp-morgan-berkshire-hathaway-health-care-venture-named-haven.html.

[88] Knebel & Han, *supra* note 84; LaVito, *supra* note 87.

[89] Joshua Cohen, *Amazon Could Still Disrupt the Prescription Drug Market*, FORBES (June 8, 2018), https://www.forbes.com/sites/joshuacohen/2018/06/08/amazon-could-still-disrupt-the-prescription-drug-market/#1f0e6cd02035; Robert Langreth, *Amazon to Buy Online Pharmacy Startup PillPack as Entry into Health Care*, INS. JOURNAL (June 28, 2018), https://www.insurancejournal.com/news/national/2018/06/28/493514.htm; Casey Ross, *In Prescription Drug Business, Will Amazon Partner with PBMs, or Seek to Conquer Them?*, STAT (July 16, 2018), https://www.statnews.com/2018/07/16/will-amazon-partner-or-conquer-pbms/.

[90] Langreth, *supra* note 89.

THE END OF THE 20-YEAR PARALLEL TRADE GSK SAGA - NIHIL SUB SOLE NOVUM? WHAT ARE THE LESSONS FOR THE PHARMACEUTICAL INDUSTRY?

On September 26, 2018, the EU General Court[1] handed down its judgment in European Association of Euro-Pharmaceutical Companies (EAEPC) v. European Commission (Commission),[2] laying to rest the EU's seminal parallel trade investigation into the pharmaceutical sector. The investigation, spanning over two decades, concerned the alleged "dual pricing" practices of GlaxoSmithKline (GSK) in Spain, which involved GSK charging parallel traders more than those who sold on the domestic market in Spain. This case culminated in the EU Court of Justice (ECJ) ruling in 2009 that the Commission had failed to conduct a full examination of GSK's arguments on potential efficiencies from limiting parallel trade.[3] On remittal from the court, the Commission concluded in 2014 that the case was no longer a priority and declined to reinvestigate the matter.[4] Ending the investigation, the EU General Court has now confirmed that the Commission had lawfully de-prioritised the case because GSK's conduct had long since ceased. This was notwithstanding the parallel traders' claim that this was a critical opportunity for the EU Courts to, once and for all, provide guidance on parallel trade restrictions. This case raises the issue of whether further guidance in this area is needed or not.

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The brevity with which the Commission brushed aside the EAEPC's request to re-open the investigation belies the huge resources devoted by the EU to pursuing such cases over the past two decades. The Commission stated that it "is unable to pursue every alleged infringement of EU competition law which is brought to its attention. The Commission has limited resources and must set priorities."[5] The General Court's approval of the Commission's de-prioritisation could be seen as the end of an era. It suggests that the Commission's fixation on pursuing parallel trade infringements — and in particular dual pricing — in the pharmaceutical industry has fizzled. Indeed, recent statistics published by the European Commission show that between 2009 and 2017, only 9 percent of investigations carried out by the European competition authorities into pharmaceutical companies related to alleged parallel trade restrictions.[6]

One could perhaps even argue that this ruling signals the final nail in the coffin for further intervention from European competition regulators into parallel trade practices by pharmaceutical companies. But is this truly a watershed moment? This is a timely point at which to reflect on parallel trade enforcement across the decades, and whether EU antitrust law on parallel trade of pharmaceutical products can now be considered settled.

Free Movement of Goods and the Economics of Parallel Trade

The free movement of goods is one of the fundamental objectives of

[1] The European courts consist of two courts: the General Court and the Court of Justice. The General Court acts, notably, as a court of first instance and hears and determines challenges against acts of the EU institutions while the Court of Justice hears and determines appeals on points of law against judgments and orders of the General Court.

[2] *EAEPC v. European Commission* (T-574/14) (http://curia.europa.eu/juris/liste.jsf?language=en&num=T-574/14).

[3] *GSK, et al. v. European Commission* (C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P) (http://curia.europa.eu/juris/liste.jsf?language=en&num=C-501/06P).

[4] *Glaxo Wellcome* (Case AT.36957), (http://ec.europa.eu/competition/antitrust/cases/dec_docs/36957/36957_612_6.pdf).

[5] *Glaxo Wellcome* (Case AT.36957), Rejection Decision, paragraph 19.

[6] European Commission, *Competition Enforcement in the Pharmaceutical Sector*, 2019, p. 10.

European Union law and, as such, has been a key element in creating and developing a single market for goods without regulatory barriers or restrictive practices across the EU (known as the Single Market or Internal Market). It is one of the economic freedoms established by the Treaty on the Functioning of the EU (TFEU). Articles 28-30 of the TFEU define the scope and content of the principle by prohibiting unjustified restrictions on intra-EU trade.

For interactions between companies, as opposed to measures adopted by member states, competition law is one of the instruments available to attack alleged or perceived restrictions on the free movement of goods. Indeed, many of the early competition law cases concerned restrictions of free movement of goods,[7] including in the pharmaceuticals industry.[8] As parallel trade of medicines increasingly became a lucrative and, hence, more widespread activity, it started to have a significant impact on pharmaceutical companies' supply forecasting and also affected access to medicines in some countries. This led to some companies introducing supply quota schemes. As long as these schemes were strictly unilateral and, consequently, did not involve any kind of agreement, or even acquiescence, on the part of the wholesaler, they could not be defined as anti-competitive agreements within the scope of Article 101 of the TFEU.[9] Nor could a refusal to supply extraordinary orders (*i.e.*, orders that were out of the ordinary in terms of historical order levels and patient demand) be defined as an abusive refusal to supply within the scope of Article 102 of the TFEU.[10]

Free movement continues to be a fundamental premise of the quest to create a fully integrated common market and, as such, will continue to attract the interest of competition regulators. Over the last 20 years or so, there have been several high-profile cases in a variety of industries applying competition law to free movement of goods restrictions. Lately, competition regulators' interest in promoting the principle of free movement has turned to so-called geo-blocking arrangements, which broadly involve a supplier restricting retailers from online advertising and selling cross-border to consumers in other member states.[11] However, this article focuses on the competition law aspects of parallel trade in pharmaceutical products, a market that arguably differs from other unregulated markets due to its national price regulations.

There is consensus that parallel import and export of pharmaceutical products is a lawful form of trade within the European Single Market. This is consistent with the EU's founding principles of creating a Single Market across the trading bloc based on free movement of goods, which, in theory, promotes uniform pricing across member states. However, in reality, considerable variations in pharmaceutical prices persist between member states of the European Economic Area (EEA)[12] depending on a variety of factors. There are also different regulatory requirements regarding the ability of pharmaceutical companies to supply medicines and, ultimately, it is for each member state to ensure that there are sufficient medicines available to protect public health. Thus, there is arguably no single European market for pharmaceuticals in the same sense

[7] See, *e.g.*, *Societe Technique Miniere* (C-56/65) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61965CJ0056); *Grundig/Consten* (C-56/64) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61964CO0056).

[8] See, *e.g.*, the *de Peijper* cases (C-15/74 and C-16/74), dating back to 1974, which were fundamental in establishing the principle of exhaustion, as applied to patents (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61974CJ0015) and (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61974CJ0016).

[9] *European Commission v. Bayer / Adalat,* (Joined Cases C-2/01 P and C-3/01 P) (http://curia.europa.eu/juris/liste.jsf?language=en&num=C-2/01P). See also the European Commission Guidelines on Vertical Restraints (VBER Guidelines) (C(2010)2365), paragraph 25.

[10] *Sot. Lelos et al. v. GlaxoSmithKline* (Joined cases C-468/06 to C-478/06).

[11] See, *e.g.*, *Guess* (AT.40428). Apart from *Guess*, the Commission also launched three investigations into geo-blocking by *Nike* (AT.40436), video game suppliers, *Focus Home* (AT.40413); *Koch Media* (AT.40414)*; ZeniMax* (AT.40420)*; Bandai Namco* (AT.40422)*; and Capcom* (AT.40424), and holiday companies, including Kuoni, Rewe, Thomas Cook (AT.40308). Additionally, there are a number of similar cases being brought forth or investigated by the national competition authorities. See also the recent geo-blocking regulation, "Regulation (EU) 2018/302 of the European Parliament and of the Council of February 28, 2018 on addressing unjustified geo-blocking and other forms of discrimination based on customers' nationality, place of residence or place of establishment within the internal market and amending Regulations (EC) No 2006/2004 and (EU) 2017/2394 and Directive 2009/22/EC (Text with EEA relevance)".

[12] The European Economic Area is comprised of the EU member states as well as Iceland, Liechtenstein and Norway.

as there is for other unregulated products.

It is a paradox that EU competition law is held out as a means of obtaining lower prices, despite the fact that health policy remains a national competence in the EU. Each member state is typically responsible for regulating its own pharmaceutical prices, which one must assume represents the approach that the member state believes is appropriate. The overlay of EU competition law has been criticised as requiring one member state's pricing laws to have extraterritorial effect on another, because pricing regulation is exported via parallel trade.

In this complex and fragmented regulatory situation, the commercial rationale for parallel trade of pharmaceutical products is straightforward — "price differentials between Member States create the opportunity for arbitrage, *i.e.*, the purchase of pharmaceutical products in low-price Member States and subsequent resale in high-price areas. It is from this price differential that parallel traders derive their profits."[13]

Parallel traders exploit the price differentials caused by the regulatory fragmentation, buying pharmaceutical products in one member state (typically states such as Greece and Spain, where they are sold at a lower price), and selling into other member states (such as Denmark, Sweden and the U.K., where prices typically are higher) without having to take into consideration the regulatory obligations of the marketing authorisation holders.[14] This practice was described by the ECJ in *GSK Greece*, in which it stated:

> *[T]he producers of medicines are subject to precise obligations with regard to their distribution. While pharmaceuticals companies are required by law to deliver their products in all Member States where they are authorised to do so, parallel exporters are free to shift their activities from one product or market to the next if the latter product or market offers a higher profit margin, which can lead to shortages in some exporting Member States. Thus parallel trade has negative consequences for the planning of production and distribution of medicines.*[15]

Parallel trade is no small business. In its 2009 sector inquiry, the Commission estimated that the turnover of parallel traders accounts for between 2-3 percent of the overall pharmaceutical market, with approximately 100 companies employing between 10,000 and 15,000 people, engaged in parallel trade.[16] In 2016 alone, parallel trade in pharmaceuticals across the EU was estimated to be €5,202 million,[17] with some countries, in particular, Denmark, Sweden, Germany and the U.K., relying on parallel imports to satisfy between 8.5-25.5 percent of domestic demand.[18]

Supporters of parallel trade of pharmaceutical products cite its benefits in promoting price competition, which should, in turn, reduce prices and increase consumer welfare. However, from the perspective of pharmaceutical companies whose products are subject to this arbitrage, parallel trade may undermine their ability to determine the prices at which their products are bought and sold in different markets. This may result in artificially low profits and, more importantly, it creates disruption in the supply chain of medicines, leading to potential shortages of critical medicines in "export markets." Such shortages jeopardize public health and, therefore, also become an issue of national interest.[19]

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[13] European Commission, "Pharmaceutical Sector Inquiry Final Report (2009)," paragraph 116 (http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html).

[14] The marketing authorisation holder is the pharmaceutical company that has been granted a marketing authorisation, which allows it to market a specific pharmaceutical product in one of the EU member states.

[15] *Sot. Lelos et al v. GlaxoSmithKline* (Joined cases C-468/06 to C-478/06), paragraph 43.

[16] European Commission, "Pharmaceutical Sector Inquiry Final Report (2009)," paragraph 117 (see supra note 12).

[17] European Federation of Pharmaceutical Industries and Associations (EFPIA), "The Pharmaceutical Industry in Figures(2018)." Values are stated at ex-factory prices.

[18] EFPIA member associations (estimate): Denmark 25.5 percent, Sweden 12.9 percent , United Kingdom 9 percent and Germany 8.5 percent.

[19] This is evidenced by the introduction of temporary export bans in several member states to ensure national access to critical medicines, which are exempted from the free movement of goods principle under Article 36 of the TFEU protecting public health.

Competition Law and Parallel Trade – A Brief History of Enforcement

From a competition law enforcement perspective, the Commission's stance has — as briefly noted above — been that agreements with the objective or effect of restricting parallel trade violate Article 101 of the TFEU (formerly Article 81 of the EC Treaty) by fragmenting the single market. Abuse of dominance under Article 102 of the TFEU (formerly Article 82 of the EC Treaty) also can come into play when the company seeking to restrict parallel trade has market power (*i.e.*, a "dominant position") in the relevant market and abuses this dominant position by restricting supply of a product indispensable to the parallel trader's business. Over the past two decades, pharmaceutical companies have therefore adopted many and varied initiatives, ranging from pricing mechanisms and "direct to pharmacy" models to repackaging restrictions and stock management programs, in an attempt to find ways to control their supply chains whilst staying on the right side of EU antitrust law.

Article 101 of the TFEU — Anti-Competitive Agreements

For there to be an agreement within the meaning of Article 101 of the TFEU, at least two independent parties must have expressed their joint intention to conduct themselves in the market in a specific way. The form in which that intention is expressed is irrelevant as long as it constitutes a faithful expression of the parties' intention. Though no explicit agreement expressing the concurrence of wills is needed, it needs to be clear that the unilateral policy of one party receives the acquiescence of the other party.[20] The two leading Article 101 TFEU parallel trade cases significantly differ in that one case was clearly about an agreement within the meaning of Article 101 of the TFEU and the other was not.

Bayer/Adalat — Stock management programs and what constitutes an agreement under Article 101 of the TFEU

Stock management programs involve pharmaceutical companies taking unilateral measures to limit or restrict the supply of their products to certain wholesalers to curtail the risk of stocks being exported and sold in another member state. One of the first cases concerning parallel trade in the pharmaceutical industry arose in this context in the mid-1990s. The Commission found that Bayer's policy of limiting supplies of its best-selling medicine – Adalat - to wholesalers in France and Spain constituted an agreement with these wholesalers to restrict parallel trade. This unlawfully distorted competition in the Single Market contrary to Article 101 of the TFEU.[21]

The stock limits had been set by Bayer at the amounts required to service France's and Spain's national markets (both relatively low-priced countries), fearing that excess volumes would be exported to higher-priced countries (*e.g.*, the U.K.), thereby eroding Bayer's margins. On appeal to the General Court (formerly the Court of First Instance), Bayer maintained that because it had implemented the supply limit unilaterally the practice could not be in breach of Article 101 of the TFEU, which only applies to agreements or concerted practices between companies. The appeal was successful, with the General Court and the ECJ (following an appeal by the Commission) finding that there was no evidence of a "concurrence of wills" between Bayer and its wholesalers (in fact, the wholesalers had objected to the cap) and therefore no breach of Article 101 of the TFEU. The General Court found that the documents submitted by the Commission contained no evidence proving either that (i) Bayer had the intention of imposing an export ban on its wholesalers; or that (ii) supplies to wholesalers were made conditional on compliance with the alleged ban. The Commission also failed to prove that the wholesalers adhered to the policy, their reaction showing, on the contrary, an attitude of opposition. The General Court (with the ECJ agreeing) found that the Commission had therefore failed to prove the existence of either an express or tacit acquiescence by the wholesalers in the policy adopted by the manufacturer. The Court of First Instance also rejected the Commission's argument that it was sufficient in order to prove the existence of an agreement to

[20] See the VBER Guidelines, paragraph 25.

[21] *Bayer Adalat,* Decision 96/478/EC (Case IV/34.279/F3-Adalat).

establish that the parties continued to maintain their business relations. To the contrary, it held that the very concept of an agreement rests on a meeting of minds between economic operators.[22]

The rationale of *Bayer* subsequently was adopted in the VBER Guidelines which sets out the four main elements to a vertical agreement: (i) an agreement or concerted practice, either express or implied through acquiescence. In the case of the latter, this either can be deduced from the powers conferred upon the parties in a general agreement drawn up in advance or deduced tacitly through showing that one party requires (explicitly or implicitly) the cooperation of the other party for the implementation of its unilateral policy and that the other party complied with that requirement by implementing that unilateral policy in practice; (ii) two or more undertakings; (iii) agreements operating at different levels of the production chain; and (iv) agreements or concerted practices that relate to the conditions under which the parties to the agreement, the supplier and the buyer, "may purchase, sell or resell certain goods or services."[23]

Dual Pricing—GSK in Spain

Bayer/Adalat tells us that an outright agreement between a supplier and a wholesaler in which the wholesaler may not export the medicines will be regarded as an infringement under Article 101 of the TFEU. However, what if the parties agreed to two separate price lists depending on the end-destination of the medicines?

This was the starting point of the "GSK Spanish dual-pricing case," which went on for 20 years, in which Spanish legislation distinguished between medicines going into the Spanish reimbursement system[24] and medicines sold to other buyers. In essence, the law provided that manufacturers were free to determine the prices of their pharmaceuticals except where certain conditions for government intervention were met. In such instances, pharmaceutical manufacturers were obliged by law to replace the freely set price with the price established by the national authorities. However, applying an upfront differentiation of customer groups with different price lists raised some concerns, in particular, when this differentiation was part of an agreement between the supplier and the wholesalers and quite obviously was designed to make the business case for parallel export less attractive.

This is why Glaxo Wellcome (now GSK), under the Spanish rules, planned to introduce two separate price lists depending on the destination of its medicines and manifest this in its wholesaler contracts. In 1998, Glaxo Wellcome sought approval from the Commission for its new general sales conditions.[25] GSK proposed to introduce a dual pricing scheme for the Spanish market, whereby wholesalers would be charged one of two prices for the same medicine: a lower price for medicines sold into the Spanish reimbursement system (set at the maximum price established by the Spanish health authority) and a higher price for medicines sold outside of the Spanish reimbursement system—by and large for export. Glaxo Wellcome argued that the agreement was either non-restrictive of competition, and outside Article 101(1) of the TFEU, or merited "exemption" under Article 101(3) of the TFEU because of its countervailing benefits.

In reality, a very small portion of the medicines sold in Spain outside the Spanish reimbursement system were destined for other patients in Spain — so most of what was sold outside the system would have been destined for export. In 1999, the European parallel traders association, EAEPC, lodged a complaint requesting that the Commission find that Glaxo Wellcome's dual pricing infringed EU competition law. In 2001 the Commission agreed,[26] but the decision was partially annulled in 2006 when the General Court found that the Commission had not adequately considered whether the

[22] *Bayer AG v. Commission* (Case T-41/96).

[23] See the VBER guidelines, paragraph 25.

[24] In Spain, pharmaceutical assistance is jointly financed by the national health system and patients. The government may adjust a patient's contribution through reimbursement.

[25] The possibility of applying for a finding of non-infringement (negative clearance) or finding that a restrictive agreement is exempt due to its countervailing benefits (exemption) was a procedure available in 1998 to seek legal certainty for legal agreements. It was abolished in 2003 by Regulation 1/2003.

[26] *Glaxo Wellcome* European Commission prohibition decision (COMP/36.957/F3).

conditions for an exemption under Article 101(3) of the TFEU had been fulfilled.[27]

Before the Commission, GSK argued that parallel trade predominantly served the interests of parallel traders. Furthermore, GSK argued that parallel trade reduced manufacturers' capacity to finance essential R&D initiatives. The Commission refused any exemption on the basis that "a pricing policy which makes it economically uninteresting for wholesalers to indulge in parallel trade must be considered to be at least as effective as an outright contractual export ban,"[28] and held that GSK had failed to prove that the criteria for an exemption under Article 101(3) had been fulfilled. The General Court found that the Commission had not sufficiently examined GSK's justifications for the practice. GSK argued that the pharmaceutical sector was characterised by strong innovation competition. This competition needed R&D funded by profits obtained globally despite significant differences between member states' health systems and price controls. Profits lost to parallel trade therefore impeded innovation competition. The General Court held that the Commission was required to look into whether the disadvantages to intra-brand competition were offset by efficiency advantages through improved inter-brand competition at the R&D level.

In October 2009, the ECJ dismissed an appeal of the General Court's judgment, confirming the General Court's assessment of the criteria for an exemption under Article 101(3) of the TFEU. Although the ECJ found that the General Court erred in its assessment of the agreement as an effects-based restriction, rather than an object-based restriction, the ECJ considered that the operative part of the General Court's judgment — confirming the Commission's finding that the pricing system infringed Article 101(1) of the TFEU — need not be set aside. GSK formally withdrew its application for an exemption in January 2010, based on the outcomes of the General Court and ECJ's findings and the lapse of time, without having applied the dual-pricing scheme.

In May 2014, the Commission formally rejected the EAEPC's initial 1999 complaint,[29] which by this point had undergone multiple revisions, finding that the conduct under investigation (GSK's general sales conditions) had ceased in 1998, there were no persisting effects of GSK's conduct, and national courts and authorities could deal with the issues.

The EAEPC brought a further appeal to the General Court, which, in September 2018, finally resolved the dispute, finding that the Commission had correctly concluded that there was no longer continued interest in a European Union investigation.[30] In particular, the General Court found that the long-standing and pervasive dual-pricing practices in Spain could not be attributed to the relatively short-lived system that GSK implemented in 1998. The General Court also found that the Commission did not make an error of assessment in finding that "the purchase prices and volumes that Spanish wholesalers currently face in order to export those 82 medicines are determined by today's market dynamics rather than by GSK's conduct."[31] The Commission, in this regard, was therefore justified in doing nothing about the pervasive dual-pricing systems, endemic in Spain's pharmaceutical industry, which were linked *inter alia* to the operation of national regulation (by this time, Article 90 of Spanish Law 29/2006).

From the GSK decision, and a series of other investigations opened by Spain at the member-state level over the past 20 years, it is clear that the Spanish authorities take the view that pharmaceutical companies lawfully may implement pricing arrangements akin to "dual pricing." Perhaps, therefore, pharmaceutical companies can take comfort from the fact that certain types of dual-pricing programs have been approved by national authorities, and (at least for now) the Commission has deprioritised further inquiry. Indeed, apart from the investigation opened into alleged dual-pricing practices in Spain shortly before the rejection of EAEPC's complaint, the EU has not

[27] *GlaxoSmithKline Services v. Commission* (T-168/01).

[28] *Glaxo Wellcome,* European Commission prohibition decision (COMP/AT.36957), paragraph 118.

[29] *Glaxo Wellcome,* European Commission rejection decision (COMP/AT.36957).

[30] *EAEPC v. Commission* (Case T-574/14).

[31] *EAEPC v. Commission* (Case T-574/14), paragraph 117.

pursued any other dual-pricing case since 2001.

'Single Pricing' Distribution

Whilst the GSK case was passing through the layers of Spanish and EU legal enforcement, Pfizer also had fallen under scrutiny in Spain. The practice at issue was Pfizer's introduction of pricing mechanisms that enabled Social Security-financed pharmaceutical products being marketed in hospitals and pharmacies to be sold at a discount; whereas pharmaceuticals not financed through Social Security and not being marketed in Spanish hospitals and pharmacies would *de facto* be subject to a higher price.

In 2004, Pfizer announced its intention to undercut wholesalers and sell directly to pharmacies. Following objections from wholesalers, a revised pricing system approved by Spanish officials was adopted whereby the initial pricing of pharmaceuticals sold to distributors was to be set at a price freely decided by Pfizer rather than the regulated price set by the state. Once the wholesaler was able to prove that the product had been sold in Spain, the initial price would be adjusted downward to meet the regulated price. In 2017, the Spanish Competition Authority (CNMC) focused on the latter part of this system, *i.e.*, the downward adjustment of the price via a rebate to domestic wholesalers.

In 2017, the CNMC approved Pfizer's distribution system.[32] It held that Pfizer had not established a dual-pricing mechanism of the sort that previously had been subject to EU antitrust enforcement (*i.e.*, prices of drugs determined by destination). To the contrary, the CNMC found that Pfizer instead had established a single price that would only change once a wholesaler had proven that the drug had been sold in Spain, and this change would arise by operation of national law, rather than Pfizer's commercial choice.

The CNMC reasoned that Pfizer must be allowed to fix its own price freely, and only where Pfizer was unable to do so must it adjust to the regulatory obligations on pricing. In effect, therefore, the CNMC seems to have made a case that Pfizer set a single price for its products, charging an alternative price only when national regulations required it to do so.

The CNMC also dismissed analogies made between Pfizer's pricing mechanism and the GSK mechanism described above—which, at the time, was pending before the General Court. The CNMC maintained that when GSK introduced its dual-pricing policy, the regulated cap pricing in Spain applied to any publicly financed pharmaceuticals, whereas when Pfizer introduced its policy, the law had been amended to limit cap pricing to those publicly financed pharmaceuticals sold in Spain. Therefore, as far as the CNMC was concerned, whereas GSK's decision to introduce dual pricing was a voluntary decision, Pfizer's system was introduced as a result of a regulatory obligation, and therefore could not be considered anticompetitive.

Article 102 of the TFEU—Stock Management Programs and Abuse of Dominance

In *Bayer*, the Commission confined itself strictly to the examination of Article 101 issues, meaning that it did not consider the issue of dominance. However, later case law suggests that dominant companies implementing stock management programs could be subject to closer scrutiny, based on the allegation that the stock management program is an abusive refusal to supply in violation of Article 102 of the TFEU. Similar to Bayer, in the early 2000s, Glaxo (now GSK) imposed measures to limit the volumes of certain pharmaceuticals sold to Greek wholesalers, where prices are some of the lowest in the EU/EEA. The Greek court sought a ruling from the ECJ as to the correct interpretation of EU competition law. The ECJ found that dominant pharmaceutical companies are permitted to protect their commercial interests through stock management programs, on the condition that any such measures are "reasonable and proportionate." In its guidance on what may be considered "reasonable and proportionate," the ECJ recognised that pharmaceutical companies may refuse orders from wholesalers that are "out of the ordinary" and essentially destined for parallel export, in order to protect a company's legitimate commercial interests.

[32] *Pfizer/Cofares,* Spanish Competition Authority decision (Case S/DC/0546/15).

Other than vaguely referring to historic order volumes and market demand, no precise guidance was provided as to how "out of the ordinary" should be measured, and this has been left to national courts to decide.[33] The ruling is important, however, in showing that certain restrictions imposed by pharmaceutical companies may be permitted, as long as they are reasonable and proportionate to the underlying objective of protecting the company's commercial interests.

Ultimately, in July 2018, Greece's Competition Commission (HCC) fined GSK more than €4 million for its stock management program, finding that certain restrictions imposed between 2000 and 2004 constituted an Article 102 TFEU violation, referencing the ECJ's "out of the ordinary" guidance. The HCC did, however, find that GSK's actions to limit the sale of one drug to a small number of wholesalers was justified, on the grounds that the quantities demanded were disproportionate to the Greek patient demand.

France

Whilst much of the recent parallel trade action has focused on Spain, case law suggests that in France quantitative restrictions on supplies to wholesalers may be considered lawful as well, provided certain conditions are met. In a series of decisions adopted in 2007, the French Competition Authority (FCA) analysed the quota restrictions imposed by pharmaceutical companies in France. The FCA recognised that such restrictions may be legal, provided that they are strictly necessary for a sound and optimal supply of the French market, while maintaining real competition opportunities between wholesalers, including an opportunity to export the products.[34]

Other Measures Aimed at Restricting Parallel Trade

Repackaging/Relabeling

Another method by which pharmaceutical companies have sought to make it harder for parallel traders to export products is controlling the repackaging and relabeling of its products. The packaging and labeling of pharmaceuticals is highly regulated both at the EU and member state level, and a product acquired in one member state usually will need to be repackaged before entering the market of another member state.

The seminal case on repackaging, *Bristol-Myers Squibb* from 1996, provided guidelines (the BMS guidelines) on the reasons why a brand owner (*i.e.*, a pharmaceutical manufacturer) may oppose the repackaging of its product.[35] In its judgment, the ECJ clarified that one of the key conditions, that the repackaging may not harm the reputation of the trademark owner, should be interpreted broadly and thus not limited only to cases where repackaging is considered untidy, defective or of poor quality. In practice, the EU courts have identified a relatively broad range of practices that may harm the manufacturers' mark. In *Boehringer II*, the ECJ found a parallel importer might damage the trademark's reputation while applying its own logo or house-style design.[36]

'Direct to Pharmacy' Distribution Models

In 2007, in an attempt to more tightly control supply chains (and thereby minimise parallel trade), Pfizer introduced a new distribution model in the U.K. Many other large pharmaceutical companies have since followed suit in an attempt to gain more direct control of the supply of their medicines and better ensure that the medicines actually reach the patient. Known as Direct to Pharmacy (DTP), the model refers to the practice of pharmaceutical manufacturers supplying medicines directly to pharmacies, thereby cutting out the "middlemen" wholesalers, and reducing the risk of pharmaceuticals being sold across borders because regulations in many countries restrict pharmacies from exporting medicines.

[33] *Sot. Lelos et al v. GlaxoSmithKline* (Joined Cases C-468/06 to C-478/06), particularly paragraph 73, stating that it is for the referring court to establish if the orders "are ordinary in the light of both the previous business relations between the pharmaceuticals company holding a dominant position and the wholesalers concerned and the size of the orders in relation to the requirements of the market in the Member State concerned."

[34] See Conseil de la concurrence (Paris), Decision 07-D-22, July 5, 2007.

[35] *Bristol-Myers Squibb* (Joined Cases C-427/93, C-429/93 and C-436/93).

[36] *Boehringer Ingelheim KG and Others v. Swingward Ltd and Others* (C-348/04).

From an antitrust perspective, a company is essentially free to set up and arrange the distribution of its products as it sees fit. Setting up a DTP system from the outset should not be problematic. However, in most cases, the manufacturer will have established relationships with wholesalers, which will need to be terminated to implement a DTP system. If it can be argued that the manufacturer is dominant and, hence, the supply is indispensable to the wholesaler's business, it may be abusive. It would, however, be unusual for a wholesaler to be totally dependent on only one supplier, so the argument that the supply from a specific manufacturer is indispensable for the wholesaler may be difficult to prove. An in-depth study by the U.K. Office of Fair Trading (OFT) (the predecessor to the U.K. Competition and Markets Authority)[37] recognised these anti-competitive risks, but ultimately concluded that, provided changes are made to the Pharmaceutical Price Regulation Scheme, it did not recommend further action be taken against DTP models.[38] More recently, the DTP model has been reviewed by the Romanian Competition Council, which concluded that it could not find any competition law arguments against DTP at this time, but would continue to monitor the market.[39]

Looking Forward—The Future of Parallel Trade in the EU?

The starting point of this paper was that the General Court's dismissal of the parallel traders' request to have the Commission re-open the GSK Spanish dual-pricing case suggests that case law on parallel trade of pharmaceutical products is settled and that there is no appetite for revisiting the question from a competition law point of view.[40] The appetite for revisiting the issue of parallel trade appears to be limited even outside the sphere of competition law — in January 2018, the Commission (Directorate General Internal Market) dismissed a complaint from the EAEPC regarding restrictive measures on intra-EU export of human pharmaceutical products adopted by the Slovakian government.[41] In May 2018, the Commission formally closed infringement proceedings against Poland, Romania and Slovakia, citing issues with shortages of medicines in certain member states and stating that "[r]econciling the respect to the free movement of goods with the right of access to healthcare to patients is a fine balancing act. After careful assessment, the Commission has concluded on the need to look for other ways than infringements to adequately solve this complex situation in order to swiftly and efficiently deal with an issue that might have negative impact on the health of European citizens."[42]

Returning to competition law, this leaves us where we started. Aside from dual pricing, the law on parallel trade in pharmaceuticals appears to be largely settled. There

[37] "Medicines distribution," OFT Market Study, 2007 (https://webarchive.nationalarchives.gov.uk/20140402181405/http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft967.pdf).

[38] However, see also AstraZeneca in Poland (https://www.independentpharmacist.co.uk/dtp-thwarted-in-poland), in which the Supreme Administrative Court concluded that AstraZeneca's model of supplying Polish pharmacies directly from the UK did not comply with national pharmaceutical legislation (June 21, 2012).

[39] See also a report by the Romanian Competition Council, published in June 2016 (http://www.consiliulconcurentei.ro/uploads/docs/items/bucket11/id11122/utila_farma_iun_2016_english.pdf), referring to the introduction of DTP systems and stating that *"Given the changing of distribution systems implemented by certain producers lately, there was analysed the impact of DTP systems (direct-to-pharmacy) and restricted by distribution. Whatever the distribution system is, if the producer is dominant, the advantages at the pharmacy / hospital level and patient must be similar to those previously recorded and must be measurable at all levels: quality, service level, financial advantages and availability just the change of the distribution system not to be regarded as abuse of dominant position. In conclusion, the Competition Council does not recommend the use of a distribution system in the detriment of another, but will intervene on certain markets opening investigations in the event that there are clues on distortion of competition.*

[40] Concern for the effects on parallel trade were expressed by the Danish Competition Authority (DCA) in *CD Pharma*, an excessive pricing case (Konkurrencerådet's decision of January 31, 2018). As parallel imports are an important source of medicines in Denmark, the DCA was concerned that the allegedly excessive prices charged by CD Pharma in Denmark could deter parallel importers from participating in domestic tenders due to the risk that if they were unable to source products and had to honor their commitments, they would be forced to purchase the medicine in the more expensive Danish market. Similarly, in the ongoing *Aspen* (AT. 40.394), the European Commission is currently investigating whether Aspen Pharmacare Holdings Limited charged excessive prices for chlorambucil, melphalan, mercaptopurine, busulfan and tioguanine, thereby hindering, *inter alia*, parallel trade between member states. The DCA's decision was confirmed by the Danish Competition Appeal Tribunal on November 29, 2018 (sag nr. KL-2-2018).

[41] CHAP(2016)3764, Jan. 30, 2018. This issue was also raised (and dismissed) in questions to the European Parliament. See, *e.g.*, Question for written answer P-006245-15, April 20, 2015; Answer June 3, 2015.

[42] European Commission, Press Release "Infringement: Parallel trade of medicines: Commission closes infringement proceedings and complaints against Poland, Romania and Slovakia," (May 17, 2018).

do, however, remain many important and difficult challenges on a practical level. Given this conclusion, it is prudent to turn briefly to how the settled law should be interpreted and applied in practice by pharmaceutical companies and parallel traders alike.

In recent years, unilateral stock management schemes have become industry standard in order to retain control of the management of the company's supply chain and to ensure continuous supply of medicines to patients across the EU. As discussed above, *Bayer/Adalat* and the VBER Guidelines provide that as long as there is no agreement or acquiescence between the pharmaceutical company and the wholesaler, Article 101 of the TFEU does not come into play. As demonstrated in *Bayer/Adalat*, it helps if the wholesalers express some discontent with the allocations to demonstrate that there is no acquiescence. However, the industry should not be complacent. Free movement of goods remains central and the case law is clear that an agreement between two or more independent companies expressing a concurrence of will to restrict parallel trade of pharmaceutical products will be viewed as an object violation of Article 101 of the TFEU.

The practical challenge with running a stock management system is therefore to ensure that the program remains fully unilateral: At no time can any agreement or acquiescence be sought or anticipated by the business, and all communication between the company and its business partners (*e.g.*, wholesalers and distributors) must be closely monitored. Whilst on the face of it, this all sounds relatively straightforward, one can imagine many scenarios in which the lines quickly could become blurred. Take, for example, a unilaterally imposed stock management policy that provides for a certain number of units of drug X to be provided to a wholesaler per month. If demand for drug X falls one month, should the wholesaler be entitled to roll over its surplus allocation to a subsequent month when demand increases? On the one hand, this seems unproblematic, as the overall supply is still managed unilaterally by the pharmaceutical company. However, a clear argument could be made that the ultimate supply received by the wholesaler was a result of interaction with the pharmaceutical company, amounting to an agreement under Article 101 of the TFEU. Such a case is yet to be tested, but it certainly provides food for thought to those on the front lines of stock management. Learning from *GSK Greek*, great care also must be taken when designing stock allocations to ensure that they correspond to market demand and historic order levels.

Another concern for those responsible for stock management policies within pharmaceutical companies will be to determine not only the quota of medicines to be supplied to each country, but also which particular wholesalers within these countries will be supplied. Recently, there has been a move by some large pharmaceutical companies to establish local operating companies (LOCs) to assist with distribution challenges; however, such business models come with challenges of their own, notably, finding a way to ensure that supply and sales to these LOCs remain reflective of local demand.

Concerning a potentially abusive refusal-to-supply scenario, in violation of Article 102 of the TFEU, the legal situation is more complex, primarily because a competition regulator would have to define dominance. As *Servier* demonstrates, defining dominance requires close consideration of the economic, regulatory and therapeutic contexts. A recent case from the Swedish competition authority provides an interesting take on the definition of the relevant market in a parallel trade case: Swedish wholesaler ApoEx, wanting to purchase various medicines for the purpose of exporting them, argued that the manufacturers' refusal to supply was an abuse of dominance, referring to a narrow product-based market definition per some recent cases relating to generic entry. The Swedish Competition Authority, however, held that this way of defining the relevant market was not appropriate in this case, stating, "In its wholesale trade, which constitute[s] an intermediate level between the manufacturing level and the retail level, ApoEx requests several different pharmaceuticals which the company then sells on either to other wholesalers or retailers. ApoEx has, in its wholesale trade operations, primarily sold on various pharmaceuticals for export

to other countries. This suggests that the relevant product market in which ApoEx operates consists of wholesale trade with several different pharmaceuticals that can be sold on at a profit. In these operations, different products from different pharmaceutical companies are substitutable."[43] With such a market definition, it becomes very difficult for the parallel trader to argue that a certain manufacturer is dominant and that access to certain products is indispensable for continuing the wholesale business. However, a different view was adopted by the Hellenic Competition Commission (HCC) in finally resolving *GSK Greek*. The HCC found that GSK had abused its "dominant position in the market of migraine medicines in Greece from 2000 to 2004 with the aim of reducing parallel exports, a) (unanimously) by initially refusing to meet all orders of the pharmaceutical product IMIGRAN in their entirety and b) (by majority) subsequently by refusing to meet 'ordinary' orders of wholesalers and reducing substantially the quantities supplied to them."[44]

In this context, the definition of relevant product market in the abuse of dominance part of the EU General Court's ruling in *Servier* is interesting, perhaps indicating a more realistic approach. The approach in *Servier* moves away from the rather simplistic assumptions that the relevant market automatically can be defined on the molecular level and that one has to consider the options available to the prescribing physician. Although this case did not concern parallel trade in general, or wholesaler activity in particular, it is worth noting that it is possible to overturn a Commission decision on the point of market definition, and time should be dedicated to thorough economic, regulatory and therapeutic analysis.[45] The *Servier* ruling appears to raise the bar for establishing dominance in the context of an alleged abuse by refusal to supply.[46]

Final Remarks – Nihil Sub Sole Novum?

To conclude, *Bayer/Adalat* and *GSK Greece* set well-established and robust precedents relating to both Articles 101 and 102 of the TFEU in terms of how pharmaceutical companies can manage their supply chains and ensure continuous supply of medicines to patients across the EU by way of unilateral stock management schemes and controlling supply volumes to existing customers. The outlier remains the dual-pricing proposition, which is specific to the relevant Spanish legislation and, in any event, something of an anomaly as pricing of pharmaceutical products is complex and not very transparent — although pharmaceutical companies presumably would have a list price in most markets. The reality is, however, that this list price is rarely of any major significance for the payers: Most medicines sold are subject to special deals with significant discounts or rebates, in tenders where prices are agreed separately — so the concept of one (or two) prices for all customers depending on status may exist only in theory.

Therefore, we conclude that there were no new outcomes as a result of the General Court dismissing the parallel traders' request to re-open the GSK Spanish dual-pricing case.

As long as there is money to be made on the arbitrage of pharmaceutical products, parallel traders will continue to seek to make a profit — and continue to challenge pharmaceutical companies that, in the parallel traders' opinions, attempt to restrict parallel trade. As such, parallel trade of pharmaceutical products remains a challenge for the pharmaceutical companies striving to set up reliable supply chains to ensure continuous supply of medicines across all member states of the European Union. This is also true for some of the member states struggling to maintain their obligation to ensure

[43] *ApoEx*, Swedish Competition Authority decision (Case No. 791/15, decision November 10, 2016). See also *Chemistree Homecare Ltd v, Abbvie Ltd* [2013] EWCA Civ 1338, judgment of Nov. 7, 2013 (finding no evidence of a dominant position by Abbvie in relation to refusal to deal with parallel trader).

[44] Hellenic Competition Commission Press Release, "Decision concerning Glaxosmithkline SA and Glaxosmithkline plc's supply policy of medicinal products Lamictal, Imigran And Serevent in the Greek market, following the partial referral of the case back to the Hellenic Competition Commission (HCC) by the Athens Administrative Court of Appeals and the Council of State," (July 11, 2018).

[45] A 2015 article by Miguel Sousa Ferro concluded that "applicants have only succeeded in persuading the Court that the Commission erred in its delineation of the market in 6.7% of the cases where the issue was raised." (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2529419).

[46] *Servier and Others v. Commission* (T-691/14).

patient access to medicines and, as a consequence thereof, have had to take extraordinary measures, such as export bans, to keep medicines on the national market. These countries have had to do so with reference to the exemption of the free movement of goods principle in order to protect public health.[47]

In *GSK Greece*, the ECJ stated that "a producer of pharmaceutical products must be in a position to protect its own commercial interests if it is confronted with orders that are out of the ordinary in terms of quantity."[48] With a careful consideration on how to meet market demand and historic order levels, *i.e.*, to continue to supply orders from business partner with whom an established business relationship exists and that are ordinary in terms of quantity, even a dominant manufacturer should be able to steer clear of Article 102 TFEU infringement. As mentioned with regard to the maintenance of a stock management system, this requires careful monitoring at all times, closely following trends in the market so that it can be established at an early stage whether an increase in demand is based on a local demand surge or parallel export.

It is for the member states to ensure sufficient supply of medicines, but pharmaceutical companies have obligations as market authorisation holders as well as a strong patient focus. They therefore have legitimate interests in ensuring that the supply chain is well managed across the European Union. In order to do this, supply quota schemes have become a critical tool and hence standard industry practice. As long as these schemes are set up and managed within the boundaries set by *Bayer/Adalat* and *GSK Greece*, pharmaceutical companies should be able to operate within the boundaries of EU antitrust law.

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[47] *See* IHS Markit, "Parallel-export bans: Member States in collision course with EU regulations, Dec. 11, 2014 (https://ihsmarkit.com/research-analysis/parallel-export-bans-member-states-in-collision-course-with-eu-regulations.html).

[48] *Sot. Lelos et al v. GlaxoSmithKline* (Joined cases C-468/06 to C-478/06), paragraph 76.

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