About Recent Developments

Recent Developments is published six times a year by the ABA Antitrust Section Health Care and Pharmaceuticals Committee and contains summaries of recent federal and state court cases, government enforcement actions, and other “recent developments” involving antitrust and privacy issues in the health care and pharmaceutical industries.

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Medtronic Granted Summary Judgment in Surgical Bone Mill Monopoly Suit

*Lenox MacLaren Surgical Corp. v. Medtronic Inc.*, No. 10-2139 (D. Colo.)

On December 3, 2015, U.S. District Court Judge Marcia S. Krieger granted Medtronic Inc.’s summary judgment motion in a suit brought by competitor Lenox MacLaren Surgical Corp. accusing Medtronic of monopolizing the market for surgical bone mills. Lenox argued that Medtronic and its subsidiaries conspired to use a supply contract to force Lenox out of the bone mill market, giving Medtronic the opportunity to launch its own bone mill product and monopolize the market.

The litigation between Lenox and Medtronic dates back to 2007, when Lenox alleged that Med USA, a subsidiary of Medtronic, breached a distribution agreement it had entered into with Lenox. Under the distribution agreement, Med USA purchased bone mills from Lenox, rebranded them, and distributed them. In the initial suit, Lenox alleged that Med USA did not distribute the bone mills, but instead loaned them to customers. Later, according to Lenox, Med USA made the unilateral decision to recall Lenox’s bone mills after receiving customer complaints. After the recall, PS Medical, another Medtronic subsidiary, introduced its own bone mill. The 2007 suit was subject to arbitration, and the arbitration panel found partially in Lenox’s favor and awarded Lenox damages.

In 2010, Lenox brought the most recent suit, alleging that Medtronic and its other subsidiaries created a monopoly in the bone mill market in violation of Section 2 of the Sherman Act. Lenox argued that other Medtronic subsidiaries violated the antitrust laws by conspiring with Med USA to seek the exclusive deal with Lenox to sell its products, then, instead of distributing the Lenox products, using the devices to generate interest in Medtronic’s own bone mill product.

Judge Krieger determined that there was no evidence that Medtronic’s other subsidiaries were meaningfully involved in the actions of Med USA.

AbbVie and Teva Face another Niaspan Pay-For-Delay Suit

*Giant Eagle, Inc. v. Abbott Lab.*, No. 15-01608 (W.D. Pa.)

On December 8, 2015, Giant Eagle, Inc., a retail supermarket and pharmacy, filed a complaint alleging that AbbVie, Inc., and Teva Pharmaceuticals USA, Inc. engaged in a pay-for-delay scheme to delay the release of a generic version of Niaspan, causing Giant Eagle to pay higher prices for Niaspan than it would have but for the defendants’ agreement. Niaspan is the branded version of extended release niacin and used to treat lipid disorders.

In the suit, filed in the U.S. District Court for the Western District of Pennsylvania, Giant Eagle contends that several companies began filing applications with the U.S. Food and Drug Administration (FDA) to market generic niacin in October 2001, but no generic competitor entered the market until September 2013, twelve years later.

According to the complaint, in 2005, AbbVie’s predecessor Kos Pharmaceuticals, Inc. paid Teva’s predecessor Barr Pharmaceuticals, Inc. to not launch its generic niacin product until September 20, 2013, and to drop challenges to Kos’s patents covering Niaspan. As a result, Kos allegedly earned millions of dollars in monopoly
profits from the sale of Niaspan each month the
generic was delayed and Barr earned millions
from payments from Kos. Giant Eagle asserts this
arrangement constituted illegal collusion and an
unreasonable restraint of trade in violation of
Section 1 of the Sherman Act. The suit also
brought monopolization claims under Section 2 of
the Sherman Act.

On December 22, 2015, the U.S. Judicial Panel on
Multidistrict Litigation issued a conditional
transfer order sending Giant Eagle’s lawsuit to the
U.S. District Court for the Eastern District of
Pennsylvania and assigned it to District Judge Jan
E. DuBois, who is presiding over In Re: Niaspan
Antitrust Litigation, which involves similar cases.

Community Based ACO Accuses
Competitor of Sham Litigation to
Maintain Monopoly for Cardiac
Catheterization Services in Southwest
Massachusetts
Steward Health Care Sys. LLC v. Southcoast
Health Sys. Inc., No. 15-14188 (D. Mass.)

Late last year, Steward Health Care System, LLC,
filed a suit alleging that Southcoast Health
System, Inc., has engaged in exclusionary
conduct, including filing sham litigation, in an
attempt to improperly preserve its purported
monopoly of the market for cardiac
catheterization services in Southeastern
Massachusetts, all in violation of state and federal
antitrust law. Both Steward and Southcoast are
community-based accountable care organizations
(ACOs). Steward operates nine hospitals in
Massachusetts, including one in Fall River, while
Southcoast operates three community hospitals in
southeast Massachusetts. Southcoast’s Fall River
and New Bedford hospitals are the region’s only
providers of cardiac catheterization services.

In May 2008, the Massachusetts Department of
Public Health established a limited moratorium on
new cardiac catheterization centers within 30
minutes of a hospital that provides such services.
In July 2014, the Department created an exception
to that moratorium for ACOs such as Steward,
allowing an ACO to transfer a cardiac
catheterization service from one hospital to
another within the ACO, even if that transfer
would fall within the geographic limitation
imposed by the 2008 moratorium. Pursuant to the
exception, Steward proposed transferring a
cardiac catheterization service from an
underperforming hospital it was closing south of
Boston to its hospital in Fall River.

While Steward’s application for the transfer was
pending, Southcoast sued in state court,
challenging the validity of the July 2014
exception and the ability of the Department of
Health to allow Steward’s requested transfer. The
state court judge denied Southcoast’s request for a
preliminary injunction.

In its suit against Southcoast, Steward alleged that
Southcoast’s state court action is sham litigation.
Steward also alleged defamation and tortious
interference of business relations under
Massachusetts law. Steward pointed to, among
other things, the state court’s denial of
Southcoast’s request for a preliminary injunction
on the grounds that Southcoast had not
demonstrated a likelihood of success on the merits
of its claims.

Southcoast filed a motion to dismiss Steward’s
lawsuit, arguing that the Noerr-Pennington
dctrine, which conveys antitrust immunity over
non-sham petitions for government action,
protects the conduct at issue. In the complaint,
Steward charged that Southcoast’s state court
action was a sham and therefore not immunized
by the Noerr-Pennington doctrine. In its motion to
dismiss, Southcoast argued that the sham
exception is narrow, requiring that “no reasonable
litigant could realistically expect success on the
merits,” and that the complaint’s factual allegations are insufficient to meet this standard.

Retailers in Lipitor Pay-for-Delay Case Appeal to Third Circuit
In re: Lipitor Antitrust Litig., Nos. 14-4202, 14-4632 (3d Cir.)

On December 18, 2015, a group of plaintiff retailers, including Walgreens and Rite Aid, filed appeals in the U.S. Court of Appeals for the Third Circuit concerning rulings by Judge Sheridan of the U.S. District Court for the District of New Jersey to dismiss pay-for-delay allegations related to Pfizer’s cholesterol drug Lipitor. In the appeal, the retailers claim that they presented more than enough evidence in the District Court to support their allegations of illegality concerning a patent settlement agreement between Pfizer and generic product manufacturer Ranbaxy to postpone the release of Ranbaxy’s generic version of Lipitor, and that Judge Sheridan’s decisions misapply the burden of proof applicable to plaintiffs’ charges.

According to the retailers’ claims, Pfizer submitted false information to the U.S. Patent and Trademark Office (PTO) to obtain additional patent protection for Lipitor. In 2013, however, Judge Sheridan determined that Pfizer’s PTO filings were challenged in the patent process and in several international courts, making the retailers’ claims of fraud by Pfizer “implausible.” The retailers argued that it was during those international cases that some of the allegedly false information provided by Pfizer came to light, such that the fraud claims are not “implausible.”

The plaintiffs also challenged a 2014 decision that dismissed all other claims related to the suit. In his decision, Judge Sheridan ruled that the plaintiffs did not provide a detailed estimate of the amount of money that Ranbaxy had saved by settling its litigation related to Pfizer’s Lipitor patent infringement with Pfizer, and so the court was unable to determine whether the settlement resulted in a large payment to Ranbaxy. The plaintiffs argued that the detailed explanation of the noncash value of the payments was not necessary at the early stage of the suit.

Provigil Plaintiffs Can’t Argue Per Se Liability Theory at Trial

On December 14, 2015, District Court Judge Mitchell S. Goldberg, who is overseeing several antitrust actions relating to alleged pay-for-delay deals concerning Cephalon’s brand name drug Provigil, ruled that plaintiffs may not argue a per se theory of liability against the remaining generic defendants at trial.

The plaintiffs sought to assert the per se standard to their argument to the jury that Cephalon and the generic defendants entered into patent settlement agreements despite knowing the Provigil patent at issue was obtained by fraud and was invalid. Since both Cephalon and the generic defendants were aware that the fraudulent patent had no potential to exclude the generics, according to plaintiffs, their settlement agreements were equivalent to naked agreements not to compete and subject to per se liability.

In the U.S. Supreme Court’s 2013 decision in FTC v. Actavis, the Court held that pay for delay allegations are subject to the rule of reason and that the per se rule does not apply. Plaintiffs in the instant case argued that the Court’s analysis in FTC v. Actavis did not address fraud allegations and therefore application of the per se rule was appropriate based upon older cases concerning fraudulently obtained patents.
Judge Goldberg rejected plaintiffs’ argument. He held that although *FTC v. Actavis* did not involve allegations of a fraudulently procured patent, it also did not provide an exception to the rule of reason standard for situations in which generic manufacturers may have been aware of fraud in the underlying patent case. Continuing, Judge Goldberg noted that because the generic defendants asserted fraud only as a theory in the underlying patent case prior to any judgment, this allegation could not be used as evidence against the generic manufacturers that they definitely knew of the fraud when they entered into settlement agreements with Cephalon. The Judge pointed out that adopting plaintiffs’ reasoning would create a situation where a generic manufacturer faced with patent litigation must choose between: (1) declining to raise potential defenses for fear that those defenses could later be used to establish a per se violation of the antitrust laws; or (2) raising the defenses and litigating the case to conclusion without considering settlement.

Several of the cases were slated to go to trial in the beginning of February 2016, but the U.S. Court of Appeals for the Third Circuit recently entered a stay that will likely delay the start of the trial.

### Ninth Circuit Allows Access to Patient Data in Unfair Trade Practices Suit

*Pac. Radiation Oncology v. The Queen’s Med. Ctr.*, No. 14-17050 (9th Cir.)

The United States Court of Appeals for the Ninth Circuit affirmed that a group of oncologists accusing a medical center of unfair trade practices could not bar the medical center from accessing patient data, because the plaintiffs sought injunctive relief based on claims not pled in the complaint.

Plaintiff Pacific Radiation Oncology (PRO) is a group of physicians providing radiation services to patients at defendant The Queen’s Medical Center (QMC) and at The Cancer Center of Hawaii (TCCH), one of QMC’s competitors. QMC is the only facility on Oahu with an operating room licensed by the Nuclear Regulatory Commission (NRC) for specialized radiation services to treat cancer. According to PRO, for the past 40 years, QMC allowed PRO physicians to meet with and treat their patients at QMC if requested by the patient.

In 2011, however, QMC transitioned to a closed-facility model, meaning PRO physicians could not practice at QMC unless they accepted exclusive employment agreements with QMC and divested any interests they held in TCCH. Without access to QMC, PRO physicians would no longer hold hospital privileges for Oahu’s only NRC-licensed operating room where they have been treating certain patients.

PRO filed suit in January 2012, alleging ten claims for relief focusing on unfair trade practices and other competition-related claims. Prior to PRO’s filing, QMC administrators identified 133 patients from QMC’s medical records system who had initial consultations with PRO physicians at QMC but did not return to QMC for radiation therapy. After litigation commenced, QMC brought counterclaims against PRO, alleging that PRO physicians were unlawfully transferring patients from QMC to TCCH and failing to inform patients of PRO’s financial interests in TCCH. QMC then served a subpoena on TCCH seeking documents regarding those 133 patients. The subpoena identified 132 of the 133 patients by name and included patient numbers and treating physicians. However, QMC accidentally filed the subpoena on the public docket with the complete, unredacted list of the patient’s names. Four days later, the mistake was corrected.

PRO subsequently filed a motion for a temporary restraining order or, alternatively, a preliminary injunction, arguing that QMC’s conduct violated
HIPAA and the Hawaii Constitution. PRO challenged the public filing of the patient list and QMC’s right to review its own medical records that were the basis of the list. PRO also sought to preclude QMC’s review of the records requested from TCCH in the subpoena.

The Ninth Circuit affirmed the district court’s denial of PRO’s motion. Citing to Eighth Circuit precedent, the Ninth Circuit held that there must be a “sufficient nexus between the claims raised in a motion for injunctive relief and the claims set forth in the underlying complaint itself.” In this case, PRO’s motion for injunctive relief was based on misconduct unrelated to its unfair trade practice claims. PRO’s privacy claims did not have a relationship or nexus to the unfair trade practices claims in the original complaint, so the district court properly dismissed the motion.

Contact Lens Manufacturer Sues Valeant for its Acquisition of Competitor


Tru-Form Optics, Inc., a manufacturer of orthokeratology (OrthoK) lenses, filed a class action suit against Valeant Pharmaceuticals, Inc. in December 2015, alleging that Valeant acquired Paragon Vision Sciences, Valeant’s only competitor in the market for the material used to manufacture OrthoK lenses, known as OrthoK buttons, and then increased the price of OrthoK buttons between 61 and 143 percent.

OrthoK lenses are a kind of gas-permeable contact lens used to slowly reshape the cornea and improve vision. Patients wear the lenses only at night while sleeping and the effects of the lenses last throughout the next day. Prior to Valeant’s acquisition in May 2015, Paragon and Valeant’s subsidiary Bausch & Lomb were, according to the complaint, the only competitors in the market for the manufacture of OrthoK buttons.

Tru-Form and other OrthoK lens manufacturers purchase OrthoK buttons to manufacture OrthoK lenses for patients. Tru-Form alleges that because of Valeant’s purchase of Paragon and Valeant’s price increase, Tru-Form and others similarly situated are forced to pay higher prices for OrthoK buttons.

Supreme Court Declines to Hear Long-Running Aggrenox Work Product Dispute


On January 19, 2016, the Supreme Court denied Boehringer Ingelheim’s petition for a writ of certiorari, ending the drug company’s dispute with the Federal Trade Commission concerning whether certain documents analyzing a patent settlement and co-promotion agreement were fact work product or the more highly protected opinion work product.

The dispute goes back to a subpoena the FTC served on Boehringer in 2009 during an investigation into a patent settlement agreement between Boehringer and generic manufacturer Barr Industries involving the former’s branded drug Aggrenox. Boehringer certified compliance with the FTC subpoena but withheld hundreds of responsive documents under the work product doctrine and attorney-client privilege. The FTC disagreed that Boehringer complied with the subpoena. The agency focused its objections on withheld financial analyses and forecasts related to the patent settlement agreement and to a co-promotion agreement between Barr and Boehringer that was entered into at the same time that the manufacturers entered the patent settlement agreement.
The district court reviewed a sample of the documents and concluded that they were properly withheld. The district court noted that documents analyzing litigation outcomes and settlement terms were plainly work product because they were prepared “in anticipation of litigation.” Further, the district court held that the co-promotion agreement was “integral” to the settlement and therefore also qualified for work product protection. The district court also held that the materials were highly protected opinion work product, because they were prepared at the request of Boehringer’s in-house counsel and implicitly reflected the mental impressions of Boehringer’s counsel as to what was important concerning the settlement and co-promotion agreement.

The FTC appealed to the U.S. Court of Appeals for the D.C. Circuit, which largely affirmed the district court’s determination that the documents were work product (except for certain documents that were created after the settlement agreement was executed) but disagreed with the district court’s characterization of the materials as opinion work product. The D.C. Circuit noted that many of the documents appeared to be fact work product in that they were the types of documents that one would expect to be generated under the circumstances of analyzing a potential patent settlement. The D.C. Circuit further noted that the mere fact that the documents were prepared at the request of in-house counsel did not automatically transform them into opinion work product. Thus, the D.C. Circuit held that the district court should have required Boehringer to explain specifically how each document was opinion work product and how disclosure would reveal counsels’ mental impressions. The D.C. Circuit also took the opportunity to clarify the standard for opinion work product.

Dentists Propose Class Actions in New York and Texas Accusing Leading Supply Distributors of Colluding to Keep Prices High


On January 25, 2016, and days afterward, dentists from across the country filed five proposed class actions in New York and Texas federal courts that accuse leading dental supply distributors of colluding to keep prices high. Among the named defendants are suppliers Henry Schein, Inc., Patterson Cos. Inc., and Benco Dental Supply, which allegedly control approximately 80 percent of distribution channels for dental supplies.

The complaints’ allegations are largely identical and include charges that defendants threatened state dental associations with trade-show boycotts and refusals to sell the products of dental supply manufacturers that did business with startup distributors. One complaint allegation states: “If new, low-cost distributors had not been unlawfully prevented from partnering with state dental associations and/or dental supplies manufacturers, they would have emerged as significant competitors.” The complaints also allege that the FTC is investigating one or more of the distributors concerning the alleged conduct.
By conditionally approving the transaction, the Attorney General concluded a review process that included a public comment period, six public meetings, and five Health Care Impact Statements by independent health care experts.

FTC Responds to Senators’ Call for Saline Shortage Investigation

Last October, a bipartisan group of U.S. Senators urged the FTC to open an investigation into possible illegal collusion among saline solution manufacturers. In December, FTC Chairwoman Ramirez reportedly responded by letter to Senator Richard Blumenthal (D-Conn.), stating that the FTC would not disclose whether it was investigating the matter. In the letter, which Senator Blumenthal shared with the media, Chairwoman Ramirez wrote, “the commission is dedicated to protecting competition and consumers and will take appropriate action against any act or practice in the marketplace that violates any statute we enforce.” Chairwoman Ramirez also noted that the FTC had forwarded the Senators’ letter to the Food and Drug Administration since it also has authority over drug manufacturers.

In their October 2015 letter, Senators Blumenthal (D-Conn.), Mike Lee (R-Utah), Amy Klobuchar (D-Minn.), and Orrin Hatch (R-Utah) sought an investigation into whether saline suppliers were violating the antitrust laws by taking advantage of the shortage that began in 2013. The Senators observed that the shortage has persisted while the three saline manufacturers—Baxter, Hospira, and B. Braun—have increased prices by 200 to 300 percent.
percent. Hospitals had also reported that all three saline suppliers were imposing even greater price increases on customers who did not purchase non-saline products, and thus allegedly tying saline sales to sales of other products such as pumps, tubing, and catheters. The Senators contended that these additional price increases were not justified by natural market forces. The Senators also suggested that the length of the saline shortage raises questions about the incentives of the saline manufacturers to solve the issue and the possible coordination among them. Last, the Senators questioned whether, even if there was no coordination, the suppliers’ ability to significantly raise prices and to enter into long-term contracts with their customers reduced their incentive to address the shortage.
FEDERAL AND STATE COURT CASES

FTC Moves to Block Proposed Merger of Chicago-Area Hospitals

*FTC. v. Advocate Health Care Network, No. 15-11473 (N.D. Ill.)*

The FTC moved to block the merger of two Chicago-area hospital systems, alleging that the combined entity would significantly harm consumers through increased healthcare costs and lower quality of care. This is the FTC’s third challenge to a proposed hospital merger since November 1, 2015, along with actions against transactions in Pennsylvania and West Virginia.

According to the FTC’s complaint, Advocate Health and Hospitals Corporation (Advocate) and NorthShore University HealthSystem (NorthShore) are the two leading providers of general acute care inpatient hospital services in the northern suburbs of Chicago, Illinois. Advocate operates twelve hospitals in the Chicago area, employs approximately 1,375 physicians as part of its employed physician group, and clinically integrates an additional 3,825 non-employed physicians. The Commission contends that NorthShore is Advocate’s close competitor in the geographic market. NorthShore operates four hospitals in the Chicago area, employs about 900 physicians, and clinically integrates an additional 1,200 non-employed physicians. The FTC estimates that the combined systems would control 55 percent of the general acute care inpatient hospital services market, while the next largest hospital would have only 15 percent of that market.

The FTC alleged that Advocate and NorthShore compete for inclusion in commercial payers’ hospital networks, and, without either system, it would be “very difficult” for commercial payers to market a plan in the Chicago area. The FTC hypothesized that, post-transaction, the combined entity would have greater bargaining leverage with commercial payers, likely leading to more favorable reimbursement terms for the hospital system. The commercial payers would then pass the higher healthcare costs on to employers and employees. Furthermore, the FTC asserted that the combined system would have a diminished incentive to improve its quality of care or increase its service offerings to patients.

Advocate and NorthShore denied the Commission’s allegations, claiming the transaction would lower the cost of health care and enhance the quality of care for patients. The FTC responded that such defenses are neither substantiated nor merger-specific. The hospital systems also attacked the FTC’s definition of the relevant market, stating that it was based on no known boundaries and constituted an “attempt to gerrymander a market and is inconsistent with market realities.”

Kidney Dialysis Provider U.S. Renal Care to Divest Assets in its Acquisition of DSI Renal


On December 30, 2015, the FTC announced a proposed consent order requiring kidney dialysis provider U.S. Renal Care, Inc. to divest three clinics as part of its acquisition of a competing provider, DSI Renal.

Founded in 2000, U.S. Renal Care has more than 400 dialysis programs across the country. In addition to outpatient care, the Texas-based U.S. Renal Care also provides home and specialty dialysis programs. It had previously acquired another dialysis provider, Ambulatory Services of America, Inc., in 2013. Acquisition target DSI Renal operates 91 dialysis locations and has
explored possible deals since as early as 2014. The acquisition is valued at approximately $640 million.

As stated in the FTC complaint, patients receiving kidney dialysis services typically require frequent treatment—about three times a week. Many patients do not have a substitute for dialysis services because the only medical alternative is a kidney transplant, which can take three years to complete. The FTC defines the geographic market as the Laredo, Texas area in the complaint, based on limitations on the ability of patients to travel for treatment.

The FTC complaint also asserts that the Laredo market is highly concentrated and the acquisition would reduce the number of local providers from three to two. It notes there are high barriers to entry as dialysis service providers must find a medical director with a reliable referral network. Also, there is little incentive for new companies to enter into markets with a large number of Medicare recipients and few commercial patients.

Under the proposed consent order, the firms will divest three DSI Renal outpatient clinics located in Laredo to competitor Satellite Healthcare, Inc. Satellite Healthcare is smaller than U.S. Renal Care but has eight locations in the Austin and San Antonio, Texas areas. In addition to financial assets and purchasing services, the divestiture will transfer the medical director agreements from DSI Renal to Satellite Healthcare.

Joint Statement on CON Laws Issued by FTC and DOJ

The FTC and the Antitrust Division of the Department of Justice submitted a joint statement on the competitive implications of certificate-of-need (CON) laws and South Carolina House Bill 325—a legislative proposal to eventually repeal South Carolina’s CON laws.

In their letter, FTC and DOJ told South Carolina’s Governor Nikki Haley that CON laws limit innovation and competition. “By interfering with the market forces that normally determine the supply of facilities and services, CON laws can suppress supply, misallocate resources and shield incumbent health care providers from competition from new entrants,” said the letter. “The best empirical evidence suggests that greater competition incentivizes providers to become more efficient,” the Agencies said in their statement. “Recent work shows that hospitals faced with a more competitive environment have better management practices. Consistent with this, there is evidence suggesting that repealing or narrowing CON laws can reduce the per-patient cost of health care.”

The Commission’s vote approving the comment was 3-1.

UnitedHealth and NY AG Reach Settlement to End Antitrust Inquiry

On January 7, 2016, New York State Attorney General Eric T. Schneiderman announced a settlement with UnitedHealth Group (United) resolving concerns related to United’s business practices in the alleged market for certain elder and long-term care insurance products. In addition to agreeing to pay $100,000, United agreed (i) not to condition participation by skilled nursing facilities (SNFs) in United’s broader insurance network on participation in United’s institutional special needs plan (I-SNP); and (ii) not to penalize SNFs that do not participate in United’s I-SNP by offering them reimbursement rates lower than those offered to similarly-situated
SNFs. United neither admitted nor denied the findings in the settlement.

After investigating complaints, the Attorney General’s Office found that, in some instances, United effectively required SNFs to participate in its I-SNP—a health insurance plan designed for patients with chronic health conditions—in order to participate in United’s other insurance plans. According to the Attorney General’s Office, SNFs must remain “in-network” with commercial insurance providers commanding a significant market presence, as United does in a number of New York counties, because the higher reimbursement rates typically available through commercial and Medicare Advantage insurance providers enable SNFs to remain economically viable while accepting patients with Medicaid and other types of coverage with generally lower reimbursement rates.

According to the Attorney General’s Office, the settlement will preserve competition among New York State I-SNP providers and ensure freedom of choice for SNFs and their patients.

**Penn State Hershey and PinnacleHealth to Fight FTC’s and Pa. AG’s Move to Block Penn State Hershey Merger**


On December 9, 2016, the FTC filed a complaint in U.S. District Court for the Middle District of Pennsylvania, seeking a preliminary injunction to block the merger of Penn State Hershey Medical Center and PinnacleHealth System. The Commission contends that the combined hospital system would control 64% of the market, affecting 500,000 residents across four Pennsylvania counties, and harm competition. Days later, the Pennsylvania Attorney General joined the FTC by filing a separate complaint for a temporary restraining order and preliminary injunction to prevent the merger. Attorney General Kathleen Kane said in a written statement, “We have learned the hard way in Pittsburgh what happens when a health system has a large market share. The continued competition between Pinnacle and Hershey will ensure that the greater Harrisburg area will continue to have a vibrant and competitive health care market.” The defendant hospitals jointly responded that the merger will keep costs down and expand access to care.

**Pay-for-Delay Deals Decreased Substantially after Actavis Decision Says FTC Report**


On January 13, 2016, the FTC released a report finding that pharmaceutical companies entered into substantially fewer potential pay-for-delay patent dispute settlements in fiscal year 2014—the first year after the Supreme Court held in *FTC v. Actavis* that a branded drug manufacturer’s reverse payment to a generic competitor to settle patent litigation can violate antitrust laws.

The FTC report summarized data on patent settlements filed with the FTC and the Department of Justice pursuant to the Medicare Modernization Act of 2003. The report states that potential pay-for-delay agreements decreased from 40 in FY 2012, prior to the Actavis decision, to 29 in FY 2013, and 21 in FY 2014. This decrease occurred as the number of filed settlements increased from 145 in FY 2013 to 160 in FY 2014. Patent dispute settlements are deemed potential pay-for-delay agreements when the branded manufacturer compensates the generic manufacturer and the generic manufacturer is restricted from marketing its product in competition with the branded product for some period.
“Consumers are better off when there is more competition from lower-priced generic medicines,” said Debbie Feinstein, Director of the FTC’s Bureau of Competition. “So although it is too soon to know if these are lasting trends, it is encouraging to see a significant decline in the number of reverse payment settlements.”

**FTC Staff Letter Supportive of Georgia Bill Regarding Dental Hygienists**


On January 29, 2016, FTC staff responded to an invitation to comment on a Georgia House Bill that would expand the settings where dental hygienists may work without direct supervision of a dentist. Georgia law currently requires that, in most circumstances, a dentist must be physically present in the location where the dental hygienist is working.

The exceptions for the direct supervision requirement is for services provided in state and county public health facilities and within the department of corrections. In addition, dental hygienists currently may provide dental screenings, or visual assessments of the mouth and teeth to determine whether an examination by a dentist is required, at schools, hospitals, clinics, and public health programs. Georgia House Bill 684 would expand the exceptions of the direct supervision requirement to allow hygienists to provide care at nonprofit clinics, health care facilities, school programs, and other safety-net provider facilities. In addition, hygienists could provide dental screenings in any setting.

The FTC Staff concluded that the proposed legislation would likely enhance competition in the provision of preventive dental care services and would expand access to care, benefiting Georgia consumers.

**FEDERAL AND STATE LEGISLATIVE TOPICS**

**Senate Investigates Generic Drug Price Hikes**


The Senate Special Committee on Aging held its first hearing into rapid price increases of certain off-patent prescription medicines. The hearing is part of a Senate investigation performed in conjunction with the efforts of the House of Representative’s Affordable Drug Pricing Task Force. Congress has focused on the topic as early as October 2014, when Senator Bernie Sanders (D-Vt.) and Representative Elijah Cummings (D-Md.) sent letters to generic drug manufacturers seeking information. However, increased media attention on the issue is likely at least partly responsible for prompting the more-recent Senate investigation. Also, remarks made by Turing Pharmaceuticals’s embattled founder and former CEO, Martin Shkreli, have only instigated further scrutiny. Shkreli’s attorneys have reported that Turing Pharmaceuticals is also being investigated by the Federal Trade Commission.

In her opening remarks, Committee Chairman Senator Susan Collins said that the Senate investigation is aimed at obtaining a better understanding of the market forces that facilitate price hikes of off-patent prescriptions and to also further explore policy responses. Senator Collins recognized the large investments and risks made by pharmaceuticals in developing new medications, but also stressed the need to balance the incentives of innovation against the need to protect payors—both individuals and government programs. In so doing, Senator Collins (R-Maine)
appeared to single out those pharmaceutical firms that “do comparatively little or no R&D, or expensive clinical trials, for prescription medicines.”

Ranking Member Senator Claire McCaskill (D-Mo.) also made reference to the absence of competition in the market for certain generic drugs. She stated, “So even though these drugs no longer have the legal monopoly granted by a patent, they end up having a de facto monopoly in the marketplace . . . . This is market failure, and when there’s a market failure, the government has a role in addressing it.”

Witnesses at the hearing included academics in the Pharmacotherapy, Pediatrics, and Health Policy fields, as well as the President of the Pharmaceutical Care Management Association. Dr. Gerard Anderson, a Johns Hopkins University professor, cited empirical studies confirming that off-patent drugs compete almost exclusively on price because the chemical compounds are identical. He linked the rapid increase in prices to increased consolidation in the generic drug market.
INTERNATIONAL

Brazil’s Council for Economic Defense Conducts Dawn Raids of Medical Device Companies
http://www.cade.gov.br/Default.aspx?95a8798091869a996cd96dc399a0

On December 1, 2015, Brazil’s Administrative Council for Economic Defense (CADE) deployed “Operation Merchant of Venice”. Operation Merchant of Venice, named for Shakespeare’s play, was a coordinated dawn raid of several currently non-disclosed manufacturers and retailers of implantable medical devices due to CADE’s concerns about collusion in the markets for orthoses and prostheses. Specifically, the alleged collusion appears to have occurred during public bids, although collusion may have also affected private transactions made by hospital networks and health insurance plans.

To execute the operation, CADE, with the support of the Federal Police, fulfilled search and seizure warrants in eight municipalities in four states due to their suspicions of collusion. CADE has only published limited details about the raids due to the ongoing investigation, so the exact reasons for the suspicions are currently unknown; however, Cade disclosed that their investigation is based on “the analysis of data on public bids ..., complaints of public procurement agencies, contributions from private buyers, and analyses of the Federal Court of Accounts.”

CADE’s use of procurement data to initiate a collusion investigation is a strategy that the agency has been developing since 2013 when it implemented an intelligence unit. The intelligence unit, rather than solely relying on leniency requests from self-reporting colluders, works with other government entities to collect data acquired through the procurement process, analyzes the data, and then attempts to use the data to launch investigations.

In this case, CADE believes that the anticompetitive conduct may include “agreements among competitors regarding bids, market division, and price fixing.” Now that CADE has utilized big data and the cooperation of other government agencies and private buyers to initiate the raids, they will review the seized materials as part of an ongoing confidential administrative inquiry within the General Superintendence. If CADE finds strong evidence to confirm the existence of the suspected activities, a public administrative proceeding will be opened against the suspected companies and individuals.

To the extent that medical device companies are eventually found to have engaged in collusion through this investigation, such companies may be facing fines that range from .1% to 20% of the company’s or group of companies’ pre-tax turnover in the economic sector affected by the conduct. CADE may also apply sanctions such as publicizing a company’s wrongdoings, debarring a company from participating in public procurement for up to five years, recommending the blocking of tax benefits, and recommending that intellectual property rights be granted to competitors. On an individual level, in addition to jail time, those found to have engaged in collusion could face fines and personal prohibitions from exercising market activities for up to five years.