Editor’s Report

In this edition of the *Chronicle*, we are pleased to offer four original articles, including a summary of a recent committee program, that together cover antitrust issues relating to the healthcare and the pharmaceutical industries:

- The first article, by William Reiss, Principal at Robins Kaplan LLP and Ben Steinberg, Associate at Robins Kaplan LLP, discusses the recent treatment by the courts of challenges to the admissibility of expert testimony at the class certification stage, using the *In re Blood Reagents Antitrust Litigation* case and other healthcare antitrust cases as representative examples.

- The second article, by Melissa Brumer, Associate at Cahill Gordon & Reindel, provides an overview of recent pharmaceutical and health care merger reviews and related divestitures and remedies.

- The third article, by Amy Paul, Associate at Ropes & Gray, discusses the state immunity doctrine and the influence of the Supreme Court’s decision in *North Carolina State Board of Dental Examiners v. Federal Trade Commission*.

- The fourth article, by Lauren Battaglia, Senior Associate at Hogan Lovells provides a summary of the recent committee program on Anti-Kickback and FCA litigation.

As you know, we are always interested in hearing from our Committee members. 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, Jeff Brennan (jbrennan@mwe.com) or Philip Nelson (nelson.p@east.ei.com).

If you are interested in writing an article for the *Chronicle*, please contact Amanda Lewis (alewis1@ftc.gov).

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Revisiting the Applicability and Scope of Daubert at Class Certification Three Years after Comcast v. Behrend

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Introduction

The Supreme Court’s 2013 decision in Comcast Corp. v. Behrend1 generated renewed debate regarding the extent to which antitrust plaintiffs must prove damages are capable of measurement on a class wide basis at the class certification stage. Members of the defense bar argue that Comcast established a “heightened” predominance requirement making it more difficult for plaintiffs to show that damages can be measured on a class-wide basis under Rule 23(b)(3). Plaintiffs’ lawyers—and increasingly courts—have interpreted Comcast more narrowly, limiting Comcast to its holding that a plaintiff’s expert’s damages model must match its theory of liability. Notably, both sides of the debate have largely focused on Comcast’s implications under Rule 23(b)(3).2

A separate question raised by Comcast, and one that has received relatively little attention, is how Comcast affects the admissibility of expert testimony at class certification under Daubert.3 Although related, the question of whether expert testimony is admissible at class certification under Daubert is distinct from the question of whether expert testimony is sufficient for class certification under Rule 23(b)(3). Ignoring this distinction, defendants have increasingly sought to deploy Comcast in the Daubert context. Specifically, defendants have argued that expert testimony offered to demonstrate the propriety of class certification is inadmissible under Daubert because it fails to “prove” under Rule 23(b)(3) that questions common to the putative determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff’s cause of action.” Comcast, 133 S. Ct. at 1429

As a general matter, in antitrust cases, the battle at class certification is fought over whether plaintiffs can demonstrate that common issues will predominate over individual issues with respect to the fact of injury, often referred to as impact in antitrust parlance, and damages. See Marcy Hogan Greer, A Practitioner’s Guide to Class Actions 422 (2010).


2 In order to certify a class for damages, plaintiffs must satisfy the elements of Federal Rule of Civil Procedure 23(a)(1)-(4) and 23(b)(3), which requires that “questions of law or fact common to class members predominate over any questions affecting only individual members.”

3 See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). The so-called Daubert test is an application of Federal Rule of Evidence 702, which governs the admissibility of expert testimony at trial.
class predominate over questions affecting individual plaintiffs.

This attempt to repurpose Comcast as an evidentiary hurdle, in addition to a Rule 23(b)(3) hurdle, has forced courts to reevaluate Daubert’s applicability at the class certification stage, an issue the Supreme Court has yet to fully address. While most courts have held that at least some Daubert analysis is required during class certification, post-Comcast courts have largely stopped short of heightening Daubert’s traditional admissibility standards in the way defendants had hoped. A recent price-fixing case out of the Eastern District of Pennsylvania, In re Blood Reagents Antitrust Litigation, provides a useful illustration of this trend.

Given the ongoing uncertainty regarding Daubert’s role at the class certification stage, it is likely that defendants will continue to challenge the admissibility of expert testimony during class certification by raising Rule 23(b)(3) predominance arguments as part of Daubert motions. This article outlines how courts have treated such efforts to date, using the Blood Reagents case and other healthcare antitrust cases as representative examples.

**Uncertainty in the Wake of Comcast**

The uncertainty surrounding Daubert’s applicability during class certification stems from a rather odd procedural oversight by the Supreme Court. When the Supreme Court originally granted certiorari in Comcast, it sought to address a Daubert-related question: whether courts must evaluate expert testimony under Daubert when it is offered for purposes of class certification under Rule 23(b)(3). However, after granting certiorari, the Supreme Court realized that Comcast had failed to timely object to the admission of plaintiffs’ expert’s damages model at the district court level and therefore had waived the issue on appeal. Rather than dismissing the appeal, however, the Supreme Court opted to evaluate a separate question relating to class certification: whether plaintiffs failed to show that their case was susceptible to awarding damages on a class-wide basis under Rule 23(b)(3) (i.e., whether they had satisfied Rule 23(b)(3)’s predominance requirement).

The putative class in Comcast consisted of cable subscribers in the Philadelphia area who alleged that Comcast had engaged in an unlawful “clustering” strategy to eliminate competition and increase prices. “Clustering” refers to a strategy of concentrating business operations within a particular region—in this case, Philadelphia. The plaintiffs originally proposed four theories of antitrust liability. The district court rejected all but one. Nonetheless, in support of their motion for class certification, the plaintiffs relied on an expert’s regression model that calculated damages based on all four theories. The damages model failed to isolate damages based on the sole remaining theory of antitrust liability.

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6 Comcast, 133 S. Ct. at 1435–36.
7 Id.
8 Id. at 1436.
9 Id. at 1430.
10 Id.
11 Id. at 1431.
12 Id.

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Writing for the majority, Justice Scalia held that this was insufficient under Rule 23(b)(3). Specifically, the majority held that a damages model purporting to serve as evidence of class-wide damages must measure only those damages attributable to the plaintiffs’ theory of liability. Because the plaintiffs’ damages model failed to do this, the majority held that their damages model fell short of establishing that damages were capable of measurement on a class-wide basis as required under Rule 23(b)(3). More generally, the majority reiterated that courts must conduct a “rigorous analysis” to determine whether Rule 23(b)(3)’s predominance requirements have been satisfied.

Much ink has been spilled regarding what, if any, impact Comcast has on plaintiffs’ ability to certify a class. Many in the defense bar have argued that Comcast created a “heightened” predominance standard. Specifically, they argue that plaintiffs have a higher burden in demonstrating that damages are capable of being measured on a class-wide basis. This interpretation has been applied in a handful of cases in which post-Comcast courts have declined to certify classes due to predominance issues that might have escaped scrutiny before Comcast. Most courts, however, including several courts in notable healthcare-related cases, have limited Comcast to its holding that a plaintiff’s damages model must match its theory of liability. This relatively modest holding has not significantly altered the class action landscape.

As courts continue to grapple with competing interpretations of Comcast, a new set of questions has emerged regarding Comcast’s implications in the Daubert context. Specifically, courts are now being asked to address two interrelated questions: (1) whether a

13 The dissent, authored by Justice Ginsburg and joined by Justices Breyer, Sotomayor, and Kagan, concluded that, as a threshold matter, the writ of certiorari should have been dismissed due to Comcast’s failure to object to the admission of the expert report at the class certification stage. Id. at 1436. The dissent next further found that plaintiffs’ expert report was sufficient under Rule 23(b)(3) and emphasized that the majority’s ruling is good “for this day and case only” and does not disturb the “black letter rule” that a class may obtain certification under Rule 23(b)(3) when liability questions common to the class predominate over damages questions unique to class members. Id. at 1437–41.

14 Id. at 1432–33.

15 Id. at 1433.

16 Id.

17 Id.
Daubert inquiry is required at the class certification stage; and (2) if so, whether Comcast heightens Daubert’s admissibility standards during class certification. The following sections describe how courts have thus far addressed each issue.

Is Daubert Analysis Required During Class Certification?

The first Daubert-related question left unanswered by Comcast is whether a Daubert inquiry is necessary at class certification. This is not a new question. For years, courts have struggled to address the level of scrutiny that should be applied to expert testimony at class certification.21 This is likely why the Supreme Court originally sought to address the question in Comcast. While the Supreme Court was ultimately forced to shift its focus to Rule 23(b)(3) predominance considerations, Comcast’s general instruction to apply “rigorous analysis” at the class certification stage arguably weighs in favor of requiring Daubert analysis of expert testimony at class certification.22 Courts nonetheless remain split on the question of whether—and to what extent—a Daubert inquiry is required at class certification. Courts’ approaches to Daubert tend to fall into three camps: (1) courts that apply a “full” Daubert analysis at class certification, (2) courts that apply a “tailored” or limited Daubert analysis at class certification, and (3) courts that do not apply Daubert analysis at class certification at all.23 These varying approaches reflect courts’ attempts to balance their gatekeeping function against the need to avoid turning class certification into a mini-trial.

Among courts applying a full Daubert analysis are the Third Circuit,24 Seventh Circuit,25 Eleventh Circuit,26 and select district courts in other jurisdictions.27 These courts require a Daubert analysis when an expert’s report or testimony is critical to class certification. The Sixth Circuit has also approved of Daubert analysis at the class certification stage, but has not formally mandated that it be performed.28 Notably, several of the leading antitrust cases


22 Also supporting the applicability of Daubert at class certification is dicta from the Supreme Court’s decision in Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541, 2554 (2011) in which Justice Scalia, speaking for the majority, observed that while “[t]he District Court concluded that Daubert did not apply to expert testimony at the certification stage of class-action proceedings[,] [w]e doubt that is so.”


24 See In re Blood Reagents Antitrust Litig., 783 F.3d 183, 187 (3d Cir. 2015).

25 Am. Honda Motor Co. v. Allen, 600 F.3d 813, 816 (7th Cir. 2010).

26 Sher v. Raytheon Co., 419 F. App’x 887, 890-91 (11th Cir. 2011).


requiring a *Daubert* analysis have arisen in the healthcare context.  

Courts falling into the second category also apply *Daubert* principles at class certification, but require something less than full *Daubert* scrutiny. The Eighth Circuit and several district courts have adopted a so-called “tailored” *Daubert* test requiring courts to evaluate the reliability of expert testimony in light of the criteria for class certification and the current state of the evidence. While the Ninth Circuit has also approved of this “tailored” approach, recent district court decisions suggest that at least some courts within the Ninth Circuit may be moving towards a more robust standard. District courts in other jurisdictions have articulated a similar “limited” form of *Daubert* analysis focusing on whether expert testimony is reliable and relevant to the Rule 23 class certification requirements.

Courts in the third and final category do not require *Daubert* analysis at all during class certification. This is the least common approach, particularly after *Dukes* and *Comcast*. Nonetheless, a limited number of courts continue to hold that it is not necessary to conduct a *Daubert* analysis at the class certification stage. Several commentators have taken issue with this approach, arguing that *Comcast* undermined all of the arguments against conducting a *Daubert* analysis. Apart from the Third Circuit, however, the extent to which courts will adjust their approaches following *Comcast* remains to be seen.

**Does Comcast Heighten *Daubert’s* Admissibility Standards?**

The second question left unanswered by *Comcast* is whether *Comcast*’s “rigorous analysis” mandate requires courts to apply something beyond *Daubert*’s traditional admissibility requirements during class certification. In other words, assuming a

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30 *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 627-28 (8th Cir. 2011) (affirming the district court’s use of a “tailored” *Daubert* analysis to admit a class certification expert report submitted by Minnesota homeowners who alleged that the brass fittings used in plumbing systems were defective).

31 *Sirko v. IBM*, No. CV 13-03192, 2014 U.S. Dist. LEXIS 130407, at *17 (C.D. Cal. Sept. 3, 2014) (applying a tailored *Daubert* test and striking portions of an expert report that relied on a survey to prove commonality in an employment class action); *In re Visa Check/Mastermoney Antitrust Litig.*, 192 F.R.D. 68, 76-77 (E.D.N.Y. 2000) (applying a tailored *Daubert* test and admitting an expert report of class of retailers who alleged they were illegally forced to accept both debit cards).

32 *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011). (affirming the district court’s application of a tailored *Daubert* analysis in admitting class certification expert reports of female employees who sued Costco for gender discrimination).

33 See, e.g., *Stemple*, 2014 U.S. Dist. LEXIS 125313, at *16 (“The court is required to apply the evidentiary standard set forth in *Daubert* to expert testimony at the class certification stage.”).

34 See *Messer*, supra note 21 at 310–15; see also *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015).


36 See *Messer*, supra note 21 at 310–15; see also *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015).
Daubert inquiry is necessary, does the arguably heightened level of scrutiny Comcast applied in the Rule 23(b)(3) context carry over into the Daubert context? Or, are courts merely required to apply Daubert’s traditional requirements with traditional scrutiny when assessing expert testimony at the class certification stage?37

Thus far, the few courts that have directly addressed the issue have opted for the latter approach, rejecting defendants’ arguments that expert testimony should be excluded under Daubert because it fails to “prove” that questions affecting putative class members predominate over questions affecting individual plaintiffs. In In re NJOY Consumer Class Action Litig., for example, the Central District of California expressly rejected a defendant’s attempt to raise predominance arguments as part of a Daubert motion.38 The defendant, NJOY, sought to exclude an expert’s damages methodology under Daubert, citing several post-Comcast cases holding that similar damages models were insufficient under Rule 23(b)(3).39 The court rejected NJOY’s arguments, finding that the cases were inapplicable in the Daubert context. As the court explained, “Admissibility turns on whether [an expert’s] methodology is sufficiently reliable; whether it satisfies Comcast and shows that a class should be certified is another question altogether—one which the court will address infra in conducting a Rule 23(b)(3) predominance analysis.”40 Other courts have echoed this sentiment.41 In In re Mushroom Direct Purchaser Antitrust Litig., the court rejected defendants’ attempt to rely on Comcast to argue that plaintiffs’ damages model was inadmissible under Daubert.42 The court suggested that the scrutiny applied to damages models in Comcast should not be applied in the Daubert context.43 Similarly, in In re High-Tech Emp. Antitrust Litig., the court explained that “it is not at all clear that Comcast's holding concerning Rule 23 predominance . . . is applicable to the Daubert stage when courts are evaluating whether an expert's model is admissible under Rule 702.”44 And, in In re Processed Egg Products Antitrust Litig., the court also distinguished between the two types of analysis, holding that plaintiffs’ damages model was admissible under Daubert “without making any pronouncements about the ultimate ability of [plaintiffs] to clear the Comcast bar.”45

To be sure, there have been numerous post-Comcast cases in which courts have granted Daubert motions to exclude expert testimony at the class certification stage, including two notable antitrust cases in the healthcare context.46 However, these cases do not suggest


39 Id.

40 Id. at 32–33.


43 Id.


that courts have heightened *Daubert’s* traditional admissibility requirements post-*Comcast*. Rather, these cases serve as a reminder that, irrespective of *Comcast*, *Daubert* serves as a legitimate barrier that plaintiffs seeking class certification must overcome.

**In re Blood Reagents**

A recent decision from the Eastern District of Pennsylvania recertifying a class of direct purchasers of blood reagents exemplifies the ongoing battle over whether *Comcast* necessitates application of a heightened *Daubert* analysis to expert testimony at class certification. By way of background, blood reagents are blood testing products typically used by hospitals and blood donor centers to determine the compatibility between blood donors. In 2009, a group of direct purchasers of blood reagents filed a putative class action against the two leading manufacturers of blood reagents alleging that the manufacturers had engaged in a horizontal price-fixing conspiracy in violation of Section 1 of the Sherman Act.50

The plaintiffs moved for class certification in 2012.49 In support of their motion, plaintiffs offered the expert report of Dr. John C. Beyer, who provided market structure analysis and a damages model estimating class-wide damages.50 Ortho, the remaining defendant in the case,51 attacked the reliability of Dr. Beyer’s report under Rule 23, but did not make a formal *Daubert* motion.52 Relying largely on Dr. Beyer’s report, the district court certified the class, finding that the plaintiffs had satisfied the predominance requirements under Rule 23(b)(3). Notably, the district court did not rule on the admissibility of Dr. Beyer’s report under *Daubert*. Instead, it held that the report was sufficient under the then-applicable standard that his report “could evolve to become admissible evidence.”53

The Supreme Court issued its decision in *Comcast* seven months later.54 On appeal, Ortho argued that the district court erred by certifying the class without first subjecting Dr. Beyer’s report to a *Daubert* analysis.55 The Third Circuit agreed, finding that while the district court had applied the correct standard at the time, *Comcast* now required the district court to determine whether the aspects of Dr. Beyer’s report offered to satisfy Rule 23 were admissible under *Daubert*.56 Specifically, the Third Circuit held that “a plaintiff cannot rely

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47 In re Blood Reagents Antitrust Litig., 783 F.3d 183, 185 (3d Cir. 2015).

48 Id.


50 Id.


52 Id. at n.1.

53 Id. at 240.


55 In re Blood Reagents Antitrust Litig., 783 F.3d 183, 188 (3d Cir. 2015).

56 Id.
on challenged expert testimony, when critical to class certification, to demonstrate conformity with Rule 23 unless the plaintiff also demonstrates, and the trial court finds, that the expert testimony satisfies the standard set out in Daubert.” The Third Circuit vacated the class certification order and remanded to the district court to conduct a Daubert inquiry.57

On remand, Ortho repurposed many of the arguments it had previously made in opposing class certification under Rule 23(b)(3) seeking to reject the admissibility of plaintiffs’ expert under Daubert. Citing Comcast, Ortho broadly argued that Dr. Beyer’s report was inadmissible because it failed to reliably bridge the difference between supracompetitive prices attributable to market consolidation and supracompetitive prices attributable to price fixing. Ortho also argued that Dr. Beyer’s damages model was unreliable because it used a start date for the conspiracy that differed from the start date alleged in the Complaint.58 Despite the parallels to Comcast, the district court rejected this argument, citing several other post-Comcast cases and finding that Ortho’s critique did not implicate the reliability of plaintiffs’ expert testimony under Daubert.59

Ortho also argued that Dr. Beyer’s damages model was unreliable because it used a price benchmark rather than regression analysis, used averaged but-for prices, failed to account for changes in demand and costs, and arbitrarily limited the damages period.60 The court generally held that these alleged flaws were either non-existent or insufficient to warrant exclusion under Daubert.61 While the court did not directly address Comcast’s implications on Daubert’s admissibility factors, it cited several post-Comcast cases that did and which largely excluded Comcast considerations from the Daubert context.62 Based on this finding, the court admitted Beyer’s expert report and re-certified the class.

**Conclusion**

The court’s decision in Blood Reagents serves to illustrate two primary trends that have emerged following Comcast relating to the scope and applicability of Daubert at class certification: (1) bolstered by Comcast, defendants are increasingly repackaging Rule 23(b)(3) predominance arguments as reliability arguments and asserting them as part of Daubert motions during class certification, and (2) courts have largely rejected such arguments, finding them inapplicable in the Daubert context. As these trends continue to play out in courts across the country, plaintiffs can take comfort in the fact that most courts have avoided applying Comcast-like scrutiny in the Daubert context. Defendants, on the other hand, must grapple with the realization that Comcast is not the “game changer” they hoped it would be.

61 Id.

Introduction

In 2015, like in recent years, the health care industry has experienced a high volume of pharmaceutical mergers and acquisitions, with the industry experiencing record deal activity in the second quarter of the fiscal year. 1 The health care sector had the most merger and acquisition transactions valued at $10 billion or more in 2015. 2 The announcement of the largest health care acquisition yet, Pfizer Inc.’s $160 billion acquisition of Allergan plc (expected to close in the second half of 2016), 3 suggests that this trend is poised to continue.

As the number of mergers and acquisitions in the health care industry has grown, the Federal Trade Commission’s enforcement actions against such transactions have likewise increased. The FTC frequently resolves such actions through consent orders that contain remedial measures to prevent perceived anticompetitive effects from the proposed merger. The FTC is currently studying the effectiveness of such remedies. 4

Consistent with current antitrust enforcement practices, almost every health care-related final consent order approved by the FTC in 2015 required the parties to divest part of its business to a third party. Some consent orders also appointed interim monitors to oversee the divestitures in instances where the divestiture required an ongoing relationship between the acquisition parties and the buyer of the divested assets. Interim monitors were also appointed where the divestiture was for a product that had not yet received regulatory approval in the relevant market. A few FTC challenges did not result in divestitures.


Pharmaceuticals and Medical Devices

In 2015, the FTC often required divestitures as a part of settlements to alleviate allegations of anticompetitive effects that the FTC contended would result from certain pharmaceutical and medical device mergers and acquisitions.

On November 18, 2015, the FTC approved a final order settling charges that an $8 billion merger between Endo International and Par Pharmaceuticals would negatively impact competition in the pharmaceutical market for generic glycopyrrolate tablets, which are used with other drugs to treat certain types of ulcers. The FTC alleged that the acquisition would combine the two most significant suppliers for these tablets in the U.S. The FTC further contended that the acquisition would combine two of only four active suppliers in the market for generic methimazole tablets that treat the body’s production of excess thyroid hormone.

Through the settlement, Endo and Par agreed to divest all of Endo’s rights and assets to generic glycopyrrolate tablets and generic methimazole tablets to New Jersey-based generic drug marketer Rising Pharmaceuticals. Endo also agreed to provide technical assistance, training, and other transitional services to help Rising establish manufacturing capabilities. Despite these divestitures, the merger will add nearly 100 products, including a number of expensive injectable medicines to Endo’s line of more than 700 generic medicines, and nearly double Endo’s revenue for generic products.

On November 17, 2015, the FTC finalized its settlement order addressing concerns that the $3.3 billion merger between Wright Medical Group and Wright’s closest competitor, Tornier N.V. would likely harm competition in the U.S. markets for the relevant products. The FTC alleged that the merger would combine: two of only three significant suppliers for total ankle replacements; the only significant suppliers of silastic big toe joint replacements; and the most significant suppliers of total silastic lesser toe joint replacements. Wright and Tornier are the only U.S. suppliers of fixed bearing technologies used for revision ankle replacement surgeries; the third significant U.S. supplier uses a different, mobile bearing system.

Through the settlement, Wright and Tornier agreed to sell Tornier’s rights and assets related to its total ankle replacements and total silastic

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8 Id.


10 Wright Medical Group, Inc. and Tornier N.V.; Analysis to Aid Public Comment, 80 Fed. Reg. 195, 60902 (Oct. 8, 2015).
toe joint replacements to Integra Lifesciences Corporation. The parties also agreed to provide Integra with intellectual property, manufacturing technology, and existing inventory, as well as other assets and assistance to ensure that Integra can effectively compete in the relevant product markets. The parties must provide Integra with total ankle replacements for up to three years and total silastic joint replacements for up to one year.11

On November 3, 2015, the FTC accepted a proposed consent order to settle allegations that Mylan N.V.’s unsuccessful hostile takeover offer of Perrigo Company plc would harm competition in the U.S. markets for seven generic drugs.12 Despite this, Mylan failed in its $26 billion hostile bid for Perrigo, when only approximately forty percent (instead of the required fifty percent13) of Perrigo shareholders tendered their shares to Mylan.14 Mylan unsuccessfully attempted to acquire Perrigo earlier in the year as well.15

Although the transaction never went forward, the FTC’s analysis is instructive. The consent agreement would have required Mylan to divest its interests in seven generic pharmaceutical products to New Jersey-based Alvogen Group.16 The FTC complaint alleged that the proposed acquisition would have likely harmed competition in the U.S. market for four generic drugs that Mylan and Perrigo either currently sell or have approval from the U.S. Food and Drug Administration to sell.17 The proposed transaction would have combined: two of only three suppliers of generic bromocriptine sesylate; the only supplier of generic clindamycin phosphate 1% benzoyl peroxide 5% gel (Mylan) with an FDA-approved and likely supplier entrant of the same product (Perrigo); two of only three suppliers of generic liothyronine sodium; and two of only three active suppliers of generic polyethylene glycol 3350.18

The settlement also resolved FTC concerns regarding future competition in three generic drug markets: acyclovir ointment, a topical product used to slow the growth and spread of the herpes virus; hydromorphone hydrochloride,


15 Id.


17 In re Mylan N.V., Complaint, Dkt. C-4557 (Federal Trade Commission, Nov. 2, 2015). These drugs include: bromocriptine mesylate, a dopamine agonist used to treat Type 2 diabetes, pituitary tumors, Parkinson’s disease, neuroleptic malignant syndrome, and hyperprolactinemia; clindamycin phosphate/benzoyl peroxide gel, a combination antibiotic and drying agent used to stop the bacterial infection that causes acne; liothyronine sodium, a synthetic thyroid hormone used to treat hypothyroidism and to treat or prevent enlarged thyroid glands; and polyethylene glycol 3350, a laxative oral solution packet used to treat occasional constipation. Mylan, N.V.; Analysis to Aid Public Comment, 80 Fed. Reg. 217, 69675 (Nov. 10, 2015).

18 See supra n. 15
an analgesic used to treat moderate to severe pain in narcotic-tolerant patients; and scopolamine transdermal patches, used to prevent nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery.\textsuperscript{19} The proposed transaction would have combined: one of three suppliers of generic acyclovir 5% ointment (Mylan) with one of a limited number of suppliers likely to enter that market (Perrigo); one of three generic suppliers of hydromorphone hydrochloride extended release tablets (Perrigo) with one of a limited number of suppliers likely to enter that market (Mylan); and the only approved supplier of generic scopolamine transdermal patches (Perrigo) with one of a limited number of suppliers likely to enter that market (Mylan).\textsuperscript{20}

The consent order would have required Mylan to divest the rights to these seven generic drugs to Alvogen. FTC said Alvogen has the resources, financial and technical capabilities and marketing experience to replace successfully the competition that would have been lost through the acquisition, but the consent order nonetheless would have also required Mylan to provide Alvogen with transitional services, including technical assistance.\textsuperscript{21}

The FTC, on October 19, 2015, approved an order settling charges that Pfizer’s $16 billion acquisition of Hospira would harm competition.\textsuperscript{22} According to the complaint, the proposed acquisition would have reduced the number of suppliers from three to two in the U.S. market for acetyl cysteine inhalation solution – a mucolytic therapy used to treat certain respiratory disorders – and from four to three in the U.S. market for clindamycin phosphate injections, an antibiotic used to treat lung, skin, blood, bone, joint, and gynecological infections.\textsuperscript{23} The proposed acquisition would have also eliminated Hospira as one of an allegedly limited number of suppliers capable of entering the market for voriconazole injection, an antifungal medication; Pfizer was already one of two suppliers of the drug at the time.\textsuperscript{24} In addition, the FTC alleged that the transaction would have combined two potential future suppliers that were developing melphalan hydrochloride injections, a chemotherapy agent used to treat multiple myeloma and ovarian cancer.\textsuperscript{25}

Through the settlement, Pfizer agreed to sell to Alvogen the rights and assets related to its generic acetylcysteine inhalation solution and to Hospira’s clindamycin phosphate injection, voriconazole injection and melphalan hydrochloride injection. The settlement required Pfizer to supply Alvogen with the clindamycin phosphate injection for three years while Pfizer transfers the manufacturing technology.\textsuperscript{26}

\textsuperscript{19} Id.
\textsuperscript{20} Id.
\textsuperscript{21} See supra n. 12.
\textsuperscript{23} In re Pfizer Inc. and Hospira, Inc., Complaint, Dkt. No. C-4537 (Federal Trade Commission, Aug. 21, 2015).
\textsuperscript{24} Id.
\textsuperscript{25} Id.
On April 27, 2015, the FTC announced an order settling allegations that Impax Laboratories’ $700 million acquisition of CorePharma, LLC would likely harm competition in the U.S. market for certain generic drugs. The FTC alleged that the transaction was anticompetitive because Impax and CorePharma are the only likely entrants in the market for generic pilocarpine tablets (used to treat dry mouth), which has only two incumbent suppliers. This market recently experienced supply shortages, which the FTC said could diminish competition among suppliers. The FTC also alleged that the transaction would have harmed the market for generic ursodiol tablets, which are used to treat biliary cirrhosis and gall bladder diseases. At the time of the settlement, Impax was one of four competitors in this market and CorePharma was one of a limited numbers of likely entrants. The parties agreed to divest all of CorePharma’s rights and assets in the foregoing products to Perrigo. Impax and CorePharma must also provide transitional services and take all actions that are necessary for Perrigo to obtain FDA approval to manufacture and market these products.

On April 8, 2015, the FTC approved a settlement order regarding Novartis AG’s $16 billion acquisition of GlaxoSmithKline’s portfolio of cancer-treatment drugs. The FTC alleged that Novartis’ acquisition would negatively impact competition in the U.S. BRAF- and MEK-Inhibitor drug market. These drugs are orally administered targeted oncology products that inhibit molecules associated with the development of cancer. At the time of the settlement, GlaxoSmithKline was one of only two BRAF-Inhibitor drug sellers in the market. Novartis was allegedly the only company whose BRAF-Inhibitor drug in development was likely to enter the market.

In addition, GlaxoSmithKline was the only U.S. seller of a MEK-Inhibitor drug, and Novartis was one of only a small number of companies that held the rights to MEK-Inhibitor drugs with an MEK-Inhibitor in the late stages of clinical development. GlaxoSmithKline sells the only FDA-approved BRAF/MEK combination therapy. In the consent agreement, the FTC

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30 Id.

31 Id.
said it sought to prevent delay or termination of the development of these drugs, as well as other products. Novartis agreed to divest all assets related to its BRAF- and MEK-Inhibitor drugs currently in development to Array BioPharma, and to provide transitional services to Array to ensure that the development of these drugs continue uninterrupted.  

On January 20, 2015, the FTC approved a final order settling charges that Novartis’s consumer health care products joint venture with GlaxoSmithKline would likely harm competition by combining the only two suppliers of branded nicotine replacement therapy transdermal patches in the U.S. The consent order requires Novartis to divest Habitrol, its branded nicotine replacement therapy patch, and its private-label patch business to Dr. Reddy’s, an India-based seller of private-label over-the-counter health products. The FTC alleged that without the divestiture, the joint venture would have substantially reduced competition in both the branded nicotine replacement therapy and private label nicotine replacement therapy patch markets.

The FTC settled charges that Eli Lilly and Company’s $5.4 billion acquisition of Novartis Animal Health would eliminate head-to-head competition between the companies’ rival canine heartworm products. According to the FTC, Eli Lilly’s Trifexis products are particularly close substitutes for Novartis’ Sentinel product line, which allegedly are the only products that treat heartworm disease in dogs and are given orally once a month, contain the same active ingredient, also treat fleas and other internal parasites in dogs. Under the consent agreement approved on March 4, 2015, Eli Lilly agreed to divest its Sentinel product line to the French pharmaceutical company, Virbac, S.A.

Appointment of a Monitor Trustee

Although most settlement agreements involving divestitures reserve the FTC the right to appoint a monitor trustee to oversee the divestiture process, the FTC utilized that right in only some of the health care-related settlements in 2015. According to the FTC, a monitor trustee is appointed to oversee orders that impose “obligations on the respondent of a specialized nature that may result in a temporary


44 See supra, n. 42.


relationship between the respondent and the buyer of divested assets. . . . The Commission has also required a monitor in connection with respondent’s obligations in a hold separate order or an order to maintain assets.\footnote{47} The FTC appoints monitors in a minority of required divestitures. The agency may require a monitor to oversee health care divestitures where an ongoing relationship between respondent party and a buyer of divested assets is necessary or where the assets divested by health care companies have not yet gained regulatory approval to be sold in the relevant market.

On August 20, 2015, the FTC announced its approval of a final order settling charges that Zimmer Holdings’s $13.35 billion acquisition of Biomet would likely harm competition in the markets for unicondylar knee implants, total elbow implants, and bone cement.\footnote{48} According to the complaint, the acquisition would have combined two of the three substantial competitors for unicondylar knee implants, two of the three main suppliers of total elbow implants, and two of the four significant competitors in the market for bone cement.\footnote{49} The companies agreed to divest Zimmer’s U.S. ZUK unicondylar knee implant rights and assets to London-based Smith & Nephew, and Biomet’s U.S. Discovery total elbow implant and Cobalt bone cement rights and assets to DJO Global, Inc. (“DJO”). The consent agreement required Zimmer to provide Smith & Nephew the U.S. intellectual property, manufacturing technology, and existing inventory relating to Zimmer’s unicondylar implant, and provide transitional services to help Smith & Nephew establish manufacturing capabilities and secure necessary FDA approvals. It also required Zimmer was to waive any non-compete employment clauses and assist in facilitating employment interviews between key Zimmer employees and sales representatives of the ZUK unicondylar knee product.\footnote{50}

The consent agreement requires Biomet to divest its intellectual property, manufacturing technology, and existing inventory relating to its total elbow implant and bone cement products to DJO, and to facilitate DJO’s hiring of sales representatives and other staff who work with these products.\footnote{51} The FTC appointed a monitor trustee to oversee the divestitures.\footnote{52} Although the reason for the monitor is not specifically stated in the FTC’s complaint or settlement order, the monitor appears to serve to assist during the ongoing relationship between Zimmer and DJO required by the order. The monitor may assist not just in the divestiture of the relevant assets, but also in DJO’s interview and hiring processes for new employees.

To settle FTC allegations that their planned merger would be anticompetitive, Sun Pharmaceutical Industries and Ranbaxy


\footnote{50} Zimmer Holdings, Inc. and Biomet, Inc.; Analysis of Proposed Consent Order to Aid Public Comment, 80 Fed. Reg. 125, 37259 (June 30, 2015).

\footnote{51} Id.

Laboratories agreed to divest Ranbaxy’s interest in three dosage strengths of generic minocycline tablets, used to treat a wide array of bacterial infections, to Torrent Pharmaceuticals, an India-based drug company. The FTC alleged that the proposed merger would have eliminated Sun as a likely entrant into the generic minocycline tablets market in the near future. Ranbaxy was currently one of only three suppliers in the market for the generic drug. The consent order also requires divestiture of Ranbaxy’s generic minocycline capsule assets to Torrent. The FTC said this was required to enable Torrent to obtain regulatory approval for a change in ingredient suppliers for its minocycline tablets as quickly as Ranbaxy would have been able to do so, by allowing Torrent to use the same active pharmaceutical ingredient supplier for both the minocycline tablets and capsules. The parties must also supply Torrent with generic minocycline tablets and capsules until Torrent establishes its own manufacturing infrastructure.

The FTC appointed a monitor to oversee the divestiture process. The agency explained that the monitor would “assure that Sun and Ranbaxy expeditiously comply with all of their obligations and perform all of their responsibilities pursuant to the Consent Agreement.” The FTC added that Sun and Ranbaxy must file reports with the monitor, who would then report to the FTC regarding the parties’ transfer of rights and assets to Torrent. The FTC appears to have appointed a monitor to attempt to ensure that Torrent gains regulatory approval and enters the generic minocycline market as quickly as Ranbaxy would have done so in the absence of the transaction.

As part of a consent agreement approved by the FTC on January 21, 2015, the medical technology company Medtronic, to obtain FTC clearance to acquire Covidien plc, agreed to divest its rights to certain products to a third party. The FTC alleged that Medtronic’s $42.9 billion dollar acquisition of Covidien would likely be anticompetitive without the divestitures, because it would have combined the only companies with products advanced to clinical trials in the FDA approval process for drug-coated balloon catheters for the fem-pop artery, an artery located above the knee. Drug-coated catheters for the fem-pop artery are used to treat peripheral artery disease, and the market had only one incumbent supplier.

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55 Id.

56 Id.


58 See supra n. 54.

59 Id.


62 Id.
Medtronic agreed to divest Covidien’s drug-coated catheter business to The Spectranetics Corporation, which, according to the FTC, manufactures and markets a range of devices to treat peripheral and coronary arterial disease and has the industry and regulatory experience to obtain FDA approval for the product to enter the U.S. market. As part of the consent agreement, Covidien must allow Spectranetics to take over the manufacturing facility where Covidien coated the balloon catheters, grant Spectranetics a worldwide license to produce the balloon catheters incorporated into the drug-coated balloon catheters and supply Spectranetics with balloon catheters for up to three years. The FTC explained that this is intended to ensure that the drug-coated balloon catheters would continue to be available for ongoing clinical trials, while Spectranetics works to obtain FDA approval.

The order required the parties to enter into a transitional services agreement with Spectranetics and provide Spectranetics access to employees who possess confidential business information as the company seeks FDA approval. The parties agreed to appoint a monitor to oversee the divestiture. The FTC likely required that a monitor be included in the consent order to ensure that Medtronic supplies Spectranetics with all necessary resources, such as manufacturing facilities and employees, to facilitate Spectranetics’ FDA approval and entry into the drug-coated balloon catheter market.

Mergers and Acquisitions among Health Care Providers

FTC actions in 2015 relating to hospital, physician practice group and other healthcare service provider mergers and acquisitions included attempts to block proposed transactions as well as consent agreements to resolve charges that transactions either likely had or would have anticompetitive effects. Divestitures were ordered in some but not all of the latter actions. It is apparent from these actions that the availability of a competent buyer is required for a divestiture remedy.

In a consent agreement, the FTC settled charges under Section 7 of the Clayton Act and Section 5 of the FTC Act concerning a 2011 merger by six independent orthopedic practice groups in Berks County, Pennsylvania, into a single new practice group named Keystone Orthopaedic Specialists, LLC (“Keystone”). The merger allegedly combined 19 of the 25 orthopedists in Berks County. The complaint alleged that the merger eliminated competition and led to higher prices because it enabled Keystone to negotiate rates with health plans on behalf of all of its formerly independent member practices. The FTC did not require a divestiture. In 2014, prior to the FTC investigation that preceded the consent agreement, one of the six merging practices, Orthopaedic Associates of Reading


65 Id.

66 Id.
(“OAR”), separated from Keystone for business reasons, reducing the number of Keystone orthopedists to eleven70 and becoming a major player in the market.71 The settlement, among other things required Keystone and OAR to (i) obtain prior approval from the FTC before acquiring any interests in each other, another orthopedic practice in Berks County, or hiring or offering membership to another orthopedist who has provided services in the county; (ii) refrain from any anticompetitive, illegal activity, such as coordinating their prices with other orthopedists in the market or jointly negotiating or refusing to deal with payors; and (iii) take certain steps to facilitate new contracts with health plans.72

In 2013, the U.S. Supreme Court decided in favor of the FTC when it held that a consummated hospital merger in Albany, Georgia did not qualify for immunity from the antitrust laws under the state action doctrine, because Georgia law did not clearly articulate and affirmatively express a policy authorizing the respondent state hospital authority to make competition-reducing acquisitions.73 Following and notwithstanding this legal victory, the FTC did not require a divestiture when it entered into a consent agreement to resolve its charges that the merger, involving Phoebe Putney Health System, Inc. (“Phoebe Putney”), the Hospital Authority of Albany-Dougherty County (“Hospital Authority”) and HCA Inc., created an illegal monopoly.74

After the Supreme Court ruling, the FTC proposed a consent agreement that did not include a required divestiture.75 The FTC said Georgia’s certificate of need (“CON”) law effectively precluded that relief.76 Instead, the consent order requires that Phoebe Putney and the Hospital Authority give the FTC prior notice before acquiring any part or controlling interest in other healthcare providers in the geographical area for the next ten years.77 It also prohibits the parties from objecting to regulatory applications made by potential new hospital providers in the area for up to five years.78 The FTC continues to believe that the acquisition has a negative impact on competition in the relevant market.79


78 Id.

79 See supra, n. 86.
The consent agreement settled FTC charges that U.S. Renal’s proposed $640 million acquisition of DSI Renal would lead to a significant increase in market concentration and anticompetitive effects in the Laredo, Texas area market for outpatient kidney dialysis services. U.S. Renal must transfer to Satellite the medical director agreement and leases for the divested clinics and provide Satellite with transitional financial, information technology, and purchasing services. Firewalls and confidentiality agreements must be instituted to ensure that U.S. Renal and Satellite do not exchange competitively sensitive information. The FTC may appoint a monitor to oversee the transition.

Implications for Future FTC Consent Agreements

Practitioners should carefully evaluate the antitrust risk in health care related mergers and the implications of this risk for the possibility the FTC will require consent agreements to allow the transaction to close. Most FTC merger challenges, unless the parties abandon the transaction or successfully defend a challenge, are likely to settle by consent agreement, typically including divestitures and sometimes with a monitor to oversee the compliance with terms of the consent order. Most consent orders allow the FTC to appoint a monitor trustee to oversee divestitures. In 2015, the FTC appointed monitors in certain health care-related divestitures, often in situations where the divested product had not yet gained regulatory approval to enter the relevant market and an ongoing relationship was required among the divesting parties and the buyer of the divested assets. Practitioners can expect the FTC to follow these patterns in the upcoming years.


81 Id.

82 Id.
State Action Immunity: The State of Play Since *NC Dental*

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**Introduction**

Since *North Carolina State Board of Dental Examiners v. Federal Trade Commission*¹ (“NC Dental”), the Federal Trade Commission’s (“FTC”) second Supreme Court victory in three years on state action immunity, legislatures, district courts and private citizens have begun to grapple with how the ruling should be applied to specific state professional boards, and what kind of antitrust liability these boards are likely to face should they continue to operate under the current status quo. The result of these efforts is a closer review of how state regulatory boards are constituted, as well as numerous lawsuits being filed in federal courts across the country, spanning a variety of industries and professions.

This flurry of activity is largely unsurprising given the breadth of the Court’s decision that boards may no longer presume they are entitled to state action immunity merely because the state has established it to regulate the industry in which its members participate. Rather, the board must now plead immunity as an affirmative defense and must prove why actions that would otherwise be anticompetitive should be shielded from federal antitrust scrutiny.

Numerous lawsuits and legislative reform could begin to shape the authority regulatory boards will have to govern their professions and the state supervision that will trigger antitrust immunity.

**Brief History of Recent FTC State Action Enforcement**

The state action immunity doctrine stems from a long line of federal court cases, the first of which was the U.S. Supreme Court’s 1943 decision in *Parker v. Brown*, which held that the sovereign acts of a state are not subject to Sherman Act liability.² The doctrine expanded in subsequent case law to immunize anticompetitive actions by non-sovereign entities such as political subdivisions and private actors. To qualify for antitrust immunity, political subdivisions must show that their anticompetitive actions are taken pursuant to a clearly articulated and affirmatively expressed state policy to supplant competition with regulation. Private actors must meet not only that standard but also a second one: that their anticompetitive actions will be actively supervised by the state to ensure compliance with the underlying state policy.³

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² 317 U.S. 341, 351 (1943) (the “Sherman Act makes no mention of the state as such, and gives no hint that it was intended to restrain state action or official action directed by a state”).

In 2013 and 2015, respectively, the FTC prevailed in two state action cases decided by the Supreme Court concerning whether certain allegedly anticompetitive actions should be subject to antitrust liability or held immune under the foregoing standards. These decisions clarified each prong of the two-part immunity test and in doing so, narrowed the types of actions that can be shielded from federal antitrust scrutiny.

The first of these two FTC victories was FTC v. Phoebe Putney, which concerned the agency’s challenge to a merger between the only hospitals in Albany, Georgia. In 2010, Phoebe Putney Memorial Hospital (“Phoebe Putney”) and Palmyra Health Center (“Palmyra”) merged. In 2011, the FTC challenged the merger as a monopoly in violation of the Section 7 of the Clayton Act. The hospitals defended the merger on the grounds that it was immune pursuant to the state action doctrine. They relied on Georgia statutes that authorize each county to establish hospital authorities to ensure patients’ access to quality health care services. Georgia law grants certain powers to hospital authorities that are similar to those held by private corporations, such as the power to lease and acquire. Phoebe Putney was first run by the Albany Hospital Authority (“the Authority”) and subsequently leased to Phoebe Putney Health System, a private corporation established by the Authority. To acquire control of Palmyra, the Authority purchased Palmyra from Hospital Corporation of America then leased Palmyra to Phoebe Putney for one dollar.

In the lower courts, Phoebe Putney successfully argued that the transaction qualified for state action immunity because the Georgia legislature gave the Authority the powers to lease and acquire, and in so doing contemplated and foresaw acquisitions like this one that were between competitors in highly concentrated areas and therefore likely to violate the antitrust laws. The Supreme Court unanimously rejected this argument, holding that anticompetitive mergers were not the foreseeable result of the applicable Georgia statutes. The Court held that the Georgia hospitals failed to show a “clearly articulated and affirmatively expressed” state policy to authorize anticompetitive hospital mergers, and rejected the hospitals’ immunity defense.

With the first state action prong clarified, the Supreme Court addressed the second prong in 2015 – whether active state supervision is required to confer federal antitrust immunity on a regulatory board. In a 6-3 decision, the Court ruled in NC Dental that the North Carolina Dental Board (“the Board”), which was comprised in the majority of active market participants (i.e., practicing dentists), was not a state actor for purposes of antitrust immunity, and therefore, active state supervision was required.

Here, the North Carolina legislature enacted a statute that established the Board and directed it to regulate the “practice of dentistry” in the State. The Board was comprised of six licensed dentists, one licensed dental hygienist, and one private consumer – a majority of active market participants, i.e., practicing dentists. In an effort to regulate the “practice of dentistry,” the Board, initiating the action that led to the FTC’s antitrust challenge, issued almost fifty cease-and-desist letters to non-licensed dentists who were providing teeth-whitening services, a service the Board deemed “practicing dentistry.”

In challenging this restriction, the FTC argued that the Board’s concerted action to exclude non-dentists from delivering teeth-whitening

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5 Phoebe Putney, 133 S.Ct. at 1003.
services impeded competition and consumers’ access to lower-cost services. The Fourth Circuit agreed with the FTC, and the Supreme Court affirmed, holding that because the Board’s members were active market participants, it was not a state actor, and therefore active state supervision was required to confer federal antitrust immunity on the Board’s actions.

The Court’s message to regulatory boards is loud and clear and has broad implications for future board actions. The antitrust laws will not shield otherwise anticompetitive actions merely because the state established the board and empowered it to regulate the profession in which the board members participate. FTC Commissioner Maureen Ohlhausen gave remarks following the decision and praised the Court for applying its ruling to all regulatory boards controlled by active market participants.

**FTC Guidance to State Legislators**

Now that state regulatory boards face an increased risk of potential antitrust liability, some observers contend that market participants, who arguably may be most knowledgeable and qualified to serve on professional boards, will be deterred from participating on licensing boards due to concern about antitrust liability. To counterbalance this potential risk and incentivize professionals to participate, state legislatures are likely to begin enacting legislation to define the broad powers that have been granted to professional boards. Such modifications could include changes to the board selection process and composition, its power to unilaterally approve regulations and impose disciplinary measures, and the extent to which the state will be involved in the board’s more routine procedures.

Legislative efforts to implement these revisions have been slow since the *NC Dental* decision. Connecticut is the only state that has taken formal legislative action to address the new standard for antitrust immunity. Under its Public Act 15-05, the Connecticut General Assembly has now made board decisions subject to final approval or denial by a Connecticut Department of Public Health employee, which demonstrates the need for active state supervision.

Other state officials, however, appealed to the FTC for further guidance. FTC Staff responded in October 2015, issuing guidance for when professional regulatory boards may require active state supervision to potentially provide federal antitrust immunity for board action. The FTC believes a fact-intensive review of the purported state supervision is necessary before granting antitrust immunity to a board’s actions. Acknowledging that there is no universal rule for what precisely constitutes sufficient active state supervision, the FTC’s guidance does not encourage state legislatures to require state supervision for every board decision. Rather, the FTC suggests that states could “avoid all conflict with the federal antitrust laws by creating regulatory boards that serve only in an advisory capacity,” meaning, limit the board’s abilities and power to interfere with competition.

In its guidance, the FTC defines “active market participant” broadly to include anybody who participates in any professional specialty or subspecialty that is regulated by the board, even if that person is not directly impacted by the board’s decision. The same is true for board

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7 See id. at 7 (For example, the FTC explains that even if the members of the North Carolina Dental Board did not provide teeth-whitening services (e.g., orthodontists),
members who temporarily cease participating in their given professions in order to serve on the board. As with the board composition, the FTC also broadly defines what it means for market participants to “control” the regulatory board, saying that a numerical majority is not required in order for a board to be “controlled” by market participants and thus require active state supervision. Instead, the FTC advises that determining whether the board is “controlled” by market participants is a fact-based inquiry and the Commission will consider numerous factors, including the specific rules governing the board’s decision-making power and whether the market participant board members have the power to veto board decisions.

Finally, using illustrative scenarios, the FTC assesses whether there is satisfactory active supervision under two sets of facts. Many of the factors considered relate to the extent to which the state supervisor has taken the necessary steps to gather adequate information to appropriately evaluate the board’s actions. Such steps could include conducting public hearings, evaluating certain market conditions, or inviting public comments prior to approving a board decision. Again, the FTC’s emphasis was on the quality of the state’s review of the board decisions and whether state supervisors have undertaken sufficient effort to ensure that any such decisions are not hindering competition in the regulated profession.

**Judicial Follow-On**

As legislatures digest and begin to apply the FTC’s guidance, private lawsuits are being filed in rapid succession. These cases concern challenges across a variety of board actions, including (1) disciplinary proceedings and decisions; (2) rules that require certain qualifications to practice a profession; and (3) rules that limit who can practice in a particular profession. While many of these cases are in relatively early stages of litigation, one federal district court in Texas denied a medical board antitrust immunity, applying the Supreme Court’s decision in *NC Dental* for the first time.

**“Practice Limitation” Cases**

In *Teladoc, Inc. v. Texas Medical Board*, the plaintiff, Teladoc, a large telehealth provider, brought an action against the Texas Medical Board (“the Medical Board”) challenging regulations requiring an in-person meeting between a patient and doctor for certain services, such as prescribing certain medications. As a telehealth provider, Teladoc utilized many technologies in order to provide health care services to patients outside non-traditional settings such as the emergency room or physician offices. Originally, under the Medical Board’s 2003 regulation, certain dangerous or controlled substances could only be prescribed upon establishing a “proper professional relationship” with the patient. Such relationships could be established through a variety of means, such as reviewing the patient’s medical history or conducting a mental evaluation. In 2010, the Medical Board amended that regulation to require telemedicine providers to conduct a physical examination of a patient in order to establish the “proper professional relationship” required to prescribe certain medications. In 2011, the Medical Board sent a letter to Teledoc, citing the language that requires a “face-to-face” examination prior to prescribing dangerous drugs or controlled substances. Teledoc filed an antitrust suit against the Medical Board alleging that requiring in-person physical examinations

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8 See id. at 8.

9 See id. at 10.

was a mechanism to prevent telehealth providers from competing with traditional physician providers and the Medical Board sought to dismiss the complaint, arguing that it was immune to antitrust liability.

A majority of the Medical Board members were market participants, with 12 of the 19 members being licensed physicians. As such, both Teledoc and the Medical Board agreed that there must be active state supervision in order to avoid antitrust liability. Citing *NC Dental*, the court stated that there are “few constant requirements of active supervision,” including (1) the state supervisor must review the *substance* of the Medical Board’s decision, not merely the *procedures* followed; (2) the state supervisor must have the ability to veto or revise a decision to accord with state policy; and (3) there must be *actual* state supervision, not merely the potential for it.

The Medical Board contended that they satisfied the supervision requirement because its statutory framework permitted review of the validity of regulations and procedural irregularities by numerous state bodies, including the Texas Legislature as well as judicial review by the courts and the State Office of Administrative Hearings. The district court disagreed that this review sufficed as active state supervision, because while the Medical Board’s decisions could be reviewed for procedural validity, they could not be reviewed for whether the substance of the regulation aligned with state policy. Because state officials did not have the power or mechanism to review the *substance* of board regulations and decisions and could only review the *procedural* aspects, the court found that the Medical Board failed to meet its burden to show active state supervision and denied its motion to dismiss. The Medical Board has filed a notice to appeal this decision.

Teledoc illustrates that the burden rests with the defendant board to establish actual evidence of state supervision. Here, the court determined that the mere possibility of judicial or legislative review is not enough to trigger antitrust immunity. The court did not provide, however, an example of what *would* constitute sufficient active supervision under the presented facts. Instead, it merely cites to *NC Dental*’s “constant requirements,” requiring actual state supervision.

Numerous cases currently being litigated in other jurisdictions may afford courts the opportunity to evaluate specific examples of state supervision and determine whether they are sufficient to confer antitrust immunity to board actions and decisions. A few such cases are discussed in brief detail below.

**“Practice Qualification” Cases**

Several cases challenging various state professional boards’ powers to establish certain qualifications to participate in that profession have been challenged in district courts across the country. The two highlighted below are ones in which professional boards instituted certain requirements in order to participate in the profession, and the plaintiffs argued these requirements were anticompetitive because they restricted the number of participants and services in the market.

In April 2015, Axcess Medical Clinic (“Axcess”) filed a complaint against the Mississippi State Board of Medical Licensure (“the Licensure Board”), arguing that its rule that any pain management clinic must be owned by a hospital or licensed physician was anticompetitive. A “pain management clinic” was designed as a facility for which the majority

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11 *Axcess Medical Clinic v. Mississippi State Board of Medical Licensure*, No. 3:15-cv-00307 (S.D. Miss. April 24, 2015).
(greater than 50%) of the patients are issued, on a monthly basis, a prescription for opioids, barbaturates, benzodiazepines, carisoprodol, butalbital compounds, or tramadol. The Licensure Board was comprised of nine practicing physicians. Axcess, a pain management clinic, was owned and operated by Kenneth Charles Knight, a non-physician. Upon passage of the physician ownership rule, Mr. Knight transferred his ownership interest to a practicing physician, Dr. Neal. The Licensure Board, however, found that Dr. Neal had failed to provide sufficient proof of pain management training or certification, and thus was not compliant with its rules. The Licensure Board then instructed him to immediately reduce the percentage of his pain management patients to a number below 50% of his total patients. Because nearly 100% of Dr. Neal’s patient portfolio was pain management patients, Axcess was forced to close its clinic.

In its complaint, Axcess argued that the Licensure Board’s definition of “pain management clinic” created a “previously non-existing separation” between physicians whose pain management patient population falls under the fifty percent limit and ones whose population exceeds it. Further, Axcess argued that excluding non-physicians from owning pain management medical practices is anticompetitive and does not qualify for state action immunity.

In September 2015, the St. Louis Metropolitan Taxicab Commission (“the MTC”) filed a motion to dismiss a suit brought by an Uber Technologies unit of drivers. The complaint asserted that the MTC adopted certain regulations to prevent such companies from expanding into the city, specifically targeting the decision to require Uber drivers to (1) obtain a separate license from MTC, (2) obtain a Missouri chauffeur’s or commercial driver’s license, (3) pass criminal background checks beyond Uber’s own background checks, (4) submit to fingerprinting, (5) provide a physician statement supporting the driver’s ability to handle passenger luggage, and (6) publicly disclose the driver’s personal telephone numbers and email addresses. The plaintiffs contended that these types of requirements prevent Uber drivers from providing rideshare services within St. Louis, thus preventing competition to entrenched taxicab companies, including companies in which MTC commissioners had financial stakes. Because four of the nine commissioners are members of the taxicab profession, the complaint alleged that they are market participants who require active state supervision.

**Disciplinary Proceedings Cases**

Other cases have been filed challenging various disciplinary actions such as license suspensions or revocations taken by professional state boards. The common question is whether these disciplinary proceedings and decisions amount to anticompetitive conduct. Central to resolving the question will be a deep factual inquiry into the procedures undertaken before taking such actions, and whether any state supervisor oversaw the proceedings and had sufficient information and opportunity to review the substance of these decisions.

In *Robb v. Connecticut Board of Veterinary Medicine*, Dr. Robb, a practicing veterinarian and owner of a pet hospital franchise in Connecticut, alleged that the Connecticut Board

12 *Axcess* at ¶ 35.


14 *Wallen* at ¶ 90.

of Veterinary Medicine ("the Veterinary Board") wrongfully disciplined him over his vaccination procedures. In his complaint, Robb contended he altered his vaccination protocols to offer smaller-than-recommended doses to smaller dog breeds based on what he believed to be sound medical research and judgment. The Veterinary Board, comprised of three practicing veterinarians and two attorneys, brought a disciplinary procedure to force Robb to follow manufacturers’ recommended doses. Robb alleged that because 70% of all canine visits are for vaccinations, the Veterinary Board was motivated by their own financial stake when bringing a disciplinary action against him, and as a result, certain small breed pet owners were foreclosed from seeking his vaccination approach. While the judge denied Robb’s request for a temporary restraining order, the court has yet to rule on the preliminary injunction ruling. The Veterinary Board has filed a motion to dismiss the case, asserting state action immunity as one of its defenses.

In August 2015, nursing student Kourtney Shari Rodgers filed a complaint against the Louisiana State Board of Nursing ("the Nursing Board") for terminating Grambling State University’s School of Nursing Baccalaureate of Science Degree in Nursing (BSN) programs. The school previously had been accredited for more than 20 years. The Nursing Board, which is comprised of eight registered nurses, one certified registered nurse anesthetist, and two ex officio non-voting physician advisors, based its decision to terminate the programs on the University’s failure to maintain an “80% First Time Taker Pass Rate” (FTTPR) on the National Council Licensure Examination for Registered Nurses. Rodgers claimed that reliance on and application of the “arbitrary” FTTPR metric restricts competition for nursing services in Louisiana. Rodgers also alleged that the Nursing Board is not subject to any state supervision and thus should not be immune from antitrust liability.

**Conclusion**

Nearly one year after the Supreme Court handed down its decision, *NC Dental* continues to influence a variety of professional boards, state legislatures, and district courts, with questions remaining to determine the application of the decision to unique fact patterns. While we await further state legislative reform to clarify the powers and procedures conferred upon state professional boards, we can expect district courts to begin tackling the complex issue of what actually constitutes sufficient state supervision to warrant antitrust immunity.

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16 *Robb* at ¶¶ 55-57.
On January 13, 2016, the Health Care and Pharmaceuticals Committee hosted a panel discussion regarding recent developments and trends in health care Anti-Kickback and False Claims Act litigation. Moderated by Sally Woodhouse, a Vice President at Cornerstone Research, the panel featured speakers representing a range of perspectives. Ashley Hardin, a partner with Williams and Connolly LLP in Washington, D.C., offered views from a private practice and defense perspective. Representing the enforcement side was Sara Winslow, an Assistant U.S. Attorney with the U.S. Attorney’s Office in the Northern District of California. Rounding out the panel was Professor Daniel Kessler of Stanford University, who offered economic insights into the issues. The panel addressed a range of issues including enforcement trends and developments, the legal challenges involved in proving liability and damages in the course of litigation, and the current circuit split regarding the doctrine of implied false certification.

Introduction

Moderator Sally Woodhouse opened the discussion by briefly recounting the history of the False Claims Act and the Anti-Kickback statute, and tracing the growth of related litigation in the health care sector. Passed during the Civil War, the False Claims Act (FCA), together with its more recent counterpart, the Anti-Kickback statute (Anti-Kickback), continues to generate significant amounts of litigation—with annual judgments peaking at $3 billion in FY2009. Although judgments in FY2015 were $2 billion, 423 new cases were filed—the third highest ever. Health care-related cases have been a major driver of this growth—accounting for an average of two-thirds of all new qui tam cases filed.

Despite its traditionally active role in bringing FCA and Anti-Kickback cases, the U.S. government recently declined to intervene in two cases in which plaintiffs obtained very large awards. According to Sara Winslow we should

2 “In a qui tam action, a private party called a relator brings an action on the government’s behalf. The government, not the relator, is considered the real plaintiff. If the government succeeds, the relator receives a share of the award.” Legal Information Institution, Cornell University, https://www.law.cornell.edu/wex/qui_tam_action.
not necessarily expect government inaction to become a trend. In Winslow’s view, at least two factors likely explain the government’s decision not to get involved in these two high recovery cases and neither factor signals a trend.

First, although health care fraud has long been a priority of the Department of Justice (DOJ), significant agency resources have been focused in recent years on mortgage fraud cases arising from the financial crisis. Many of these cases are coming to a resolution soon, which will free resources for health care fraud cases. Second, Winslow attributed the relative lull in recent fraud litigation to the fact that a new category of cases has yet to emerge to replace off-label pharmaceutical cases as the major driver of litigation volume in this space.

Ashley Hardin agreed that the underlying dynamics of the FCA and Anti-Kickback statutes are such that health care fraud is likely to remain a very active area for federal action. Noting that treble damages are available to prevailing plaintiffs, Hardin said the stakes for health care companies in these cases can be so high that if a plaintiff can survive a motion to dismiss, it can likely expect some kind of settlement offer regardless of the underlying merits of the case.

Health Care Fraud Litigation

Defining what constitutes a “kickback”

The discussion shifted to the mechanics of FCA and Anti-Kickback litigation and how these cases relate to issues of competition. Prof. Kessler explained that for competitive markets to function well, participants need accurate information. This is particularly true in the health care industry where payers, including the government, depend on providers to identify the appropriate care for patients. This can make fraud simultaneously more harmful and more lucrative.

Winslow and Hardin explained the difficulty in defining what constitutes a “kickback” given the broad definition provided in the statute, which states:

any remuneration (including any kickback, bribe, or rebate) [received] directly or indirectly, overtly or covertly, in cash or in kind—(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.4

According to Hardin, few kickbacks that result in litigation take the form of a straightforward “cash payment in an envelope.” Instead, she said, they often involve sophisticated schemes such as discounts or medical directorships. For this reason, determining what constitutes an illegal kickback is almost always a fact-based inquiry that should take into account the purpose of Anti-Kickback statute. Hardin predicted that the new frontier of cases under the Anti-Kickback statute is likely to involve patient referral systems. However, because many patient referral systems may be justifiable under the statute, these cases present interesting challenges. For example, Prof. Kessler discussed a situation in which a pharmaceutical manufacturer subsidizes a pharmacy patient adherence program. A challenger could argue that such a program is merely a scheme by the

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4 42 U.S.C. § 1320a-7(b)(1).
manufacturer to persuade the pharmacy to prescribe more of its drug, but if the program improves patient adherence, both payers and patients benefit. Winslow agreed that defining what constitutes a kickback can be difficult, but, in her view, the fact that the statute requires knowing and willful conduct greatly reduces the risk of over-enforcement.

Winslow then discussed the avenues through which parties can receive advice from the government. She highlighted that parties can request an advisory opinion from the Office of Inspector General at the U.S. Department of Health and Human Services (OIG). Winslow stressed that although the OIG has issued opinions on a range of different practices—including patient adherence programs—parties should not simply rely on previously issued opinions because even small factual changes can alter the analysis. Instead, it is critical that parties seeking to rely on OIG advice request an advisory opinion through the disclosure of specific facts related to the practice at issue.

The calculation of damages and the use of sampling

One of the more controversial issues the panel addressed is how damages should be assessed in a kickback case. Hardin argued that the government and private plaintiffs are only entitled to so-called “benefit of the bargain” damages. Prof. Kessler explained that the critical question is how much the payer would have spent on the treatment but for the illegal behavior. In his view, to measure this one must consider two effects: price and quantity.

The price effect occurs when moving to a treatment that provides the same care, but is more expensive (e.g., receiving the same care from a higher priced provider where there was an inducement to choose that provider over a lower priced provider). The quantity effect occurs when an inducement causes delivery of more treatments than would otherwise be necessary. According to Hardin, unless there is a claim that patients received services that they did not need, the government would have paid for those goods or services regardless of the alleged scheme and therefore has not suffered damages (assuming prices were not inflated).

Winslow explained that the statute does not prescribe how damages should be calculated, and thus that this is not the only method that has been used to calculate damages arising from kickbacks. She offered a different approach. In prosecuting health care fraud cases, the government routinely takes the position that because in many cases the provider would not have been paid anything but for the kickback, the damages are the entire amount paid to the provider. Under this approach, any offset to damages based on the value of services actually provided by the defendant would only be applied after trebling. According to Winslow, this is supported in both FCA and Anti-Kickback case law and is a well-established principle outside the health care context.5

One point on which Hardin and Winslow agreed, however, is that we are likely to see an uptick in FCA cases brought on the basis of Anti-Kickback violations. This is due in large part to the Patient Protection and Affordable Care Act of 2010 (PPACA), that made it easier to bring these cases.6 PPACA overturned Ninth Circuit case law that had previously required the government to prove that a defendant knew

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5 See United States v. Rogan, 517 F.3d 449 (7th Cir. 2008).

6 PPACA amends the Anti-Kickback statute to clarify that “a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” PPACA Section 6402(f)(2). PPACA also provides that Anti-Kickback violations are deemed to be FCA violations. Id. at Section 6402(f)(1).
about the Anti-Kickback statute and specifically intended to violate it in order to establish a violation of the FCA.\footnote{See e.g., United States v. Bornstein, 423 U.S. 303 (1976); United States v. Eghbal, 548 F.3d 1281 (9th Cir. 2008).}

**The potential impact of the Affordable Care Act**

Prof. Kessler predicted that PPACA, by forging closer ties between different types of providers, may complicate Anti-Kickback issues and potentially result in more litigation. He explained that although some guidance has already been provided in anticipation of this, it is inevitable that there would be more “friction” in terms of providers forming relationships with one another.

**The doctrine of implied certification**

The panel also addressed a topic that is currently before the U.S. Supreme Court: whether a claim for payment constitutes an implicit representation that the person submitting the claim has complied with all applicable statutes and contract terms, which could constitute a false representation for purposes of the FCA if the submitter knows that it has not done so.

An FCA violation has four elements: (1) a claim for government money or property that (2) is false and (3) material to the government’s decision to pay, and (4) made with knowledge of its falsity. In some cases, plaintiffs are able to show that a claim was false by demonstrating that the claimant had not complied with a certain statute, regulation, and/or contract term after it expressly certified compliance. In recent years, some courts have allowed FCA claims to proceed even absent the an express false certification, so long as plaintiff can show that the defendant made a claim and knowingly withheld information regarding its noncompliance with a material statute, regulation or contract provision.\footnote{See e.g., United States v. Bornstein, 423 U.S. 303 (1976); United States v. Eghbal, 548 F.3d 1281 (9th Cir. 2008).} The rationale underlying the implied certification doctrine is that by seeking payment from the government, a claimant is impliedly asserting that it has complied with applicable laws and contracts.

U.S. Courts of Appeals have disagreed on multiple levels regarding the doctrine of implied certification. At a broad level, numerous Courts of Appeals have recognized the doctrine—including the First, Second, Fourth, Sixth, and D.C. Circuits. But in June 2015, the Seventh Circuit explicitly rejected it, resulting in a circuit split.\footnote{United States v. Sanford-Brown, Ltd., No. 14-2506, 2015 WL 3541411, at *12 (7th Cir. June 8, 2015).} Even among the courts that recognize the doctrine, however, there is little consensus as to how it should be applied. The Second and Sixth Circuits have held that a claimant only impliedly certifies compliance with those laws, regulations, and contractual provisions upon which the government expressly conditions payment.\footnote{Mikes v. Strauss, 274 F.3d 687, 700-02 (2d Cir. 2001); Chesbrough v. VPA, P.C., 655 F.3d 461, 468 (6th Cir. 2011); United States v. Triple Canopy, Inc., 775 F.3d 628, 636 (4th Cir. 2015); United States v. Sci. Apps. Int’l Corp., 626 F.3d 1257, 1269 (D.C. Cir. 2010).} The First, Fourth, and D.C. Circuits, on the other hand, do not require that a legal obligation be clearly identified as a condition of payment.\footnote{United States ex rel. Hutcheson v. Blackstone, 647 F.3d 377, 386-88 (1st Cir. 2011); United States v. Triple Canopy, Inc., 775 F.3d 628, 636 (4th Cir. 2015); United States v. Sci. Apps. Int’l Corp., 626 F.3d 1257, 1269 (D.C. Cir. 2010).}

In the wake this Circuit split, the Supreme Court agreed to take up the issue of implied
certification in *Universal Health Service v. United States ex rel. Escobar*. Specifically, the Court has certified two questions for its consideration. First, is the doctrine of implied certification a viable theory by which to establish legal falsity under the FCA? Second, if it is a viable theory, can a claim be deemed legally false under the theory, “if the provider failed to comply with a statute, regulation or contractual provision that does not state that it is a condition of payment?” Oral arguments in this case are expected in the spring of 2016.

The panel discussion reflected the significantly differing views as to the validity and utility of this doctrine. Hardin explained that the issue many defendants see with implied certification is that it has the potential to sweep in a range of conduct, including run-of-the-mill breach of contract claims that the FCA as a fraud statute was not intended to address. In Hardin’s view, other remedies are available for many of the types of claims that are captured by the doctrine of implied certification, but not by other more traditional legal theories. According to Winslow, however, the only concern for enforcers and courts is whether the elements required under the FCA are met, and any concerns like those expressed by Hardin are concerns about the statute, which is designed to be broad. Furthermore, in Winslow’s view, there is little risk of a minor violation being inappropriately brought under the FCA because of the materiality and scienter requirements.

**The use of sampling to establish liability**

The panel closed its discussion by addressing the use of sampling to establish liability under the FCA and the Anti-Kickback statute. Although courts have long accepted the use of claims data sampling to estimate damages, until recently sampling was not used to establish liability. This changed in 2014 when a federal district court in the Eastern District of Tennessee denied a motion for summary judgment by finding that statistical sampling and extrapolation were sufficient to satisfy the elements of FCA liability. In that case, the government planned to present evidence regarding a sample of four hundred patient admissions, which it would then use to extrapolate both liability and damages as to a total of 54,396 patient admissions. The district court judge refused the defendant’s request for interlocutory appeal to the Sixth Circuit. But, in *U.S. ex rel. Michaels et al. v. Agape Senior Community Inc.*, the Fourth Circuit has agreed to hear an appeal on the same issue, which will make it the first appeals court to weigh in on the issue. In *Michaels*, the district court rejected sampling as a means of proving liability or damages because the parties had access to the underlying files for each contested claim and so a claim-by-claim review was possible.

Prof. Kessler offered a brief overview of sampling and explained how proper sampling methodology can minimize the probability of an incorrect conclusion that a defendant submitted false claims and/or that damages were incurred. A proper sample should be both randomly selected and representative. To ensure the representativeness of the sample, it is critical

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12 Petition For Writ of Certiorari, Universal Health Services, Inc. v. U.S. ex rel. Escobar (June 30, 2015).


15 *Id.* at *6-8 (stating that “some cases are suited for statistical sampling and, indeed, in many cases that method is the only way that damages may be proved. This civil action, however, is not such a case.”).
that the sample is drawn from the same population that formed the basis for the case. The validity of sampling may also vary depending on the degree of diversity in the claims at issue (e.g., the types of procedures, patient backgrounds, etc.). If the claims involve a patient population that is homogenous, cover a limited time period, and involve the same providers, then the sampling is likely more reliable than if the allegations stretch across a range of geographic locations, providers, and time, in which case effective sampling is far more difficult.

Hardin argued that in addition to the technical issues involved with sampling, significant due process issues are associated with finding a defendant liable for claims that were not individually proven to violate the law. She believes that taken together, these issues make sampling an inappropriate means of establishing FCA liability.

Winslow agreed that the government and any relator must prove the falsity of claims in order to establish FCA liability, but noted that the statute does not require claim-by-claim proof; instead, the burden of proof is merely a preponderance of the evidence. Winslow pointed to the government’s track record of successfully establishing liability based solely on a defendant’s policy as further support for the fact that the government does not need to prove that each individual claim was false. Moreover, the defendant is also able to attack the validity of extrapolating from the sampling evidence because the jury has the option of only awarding damages for the sampled cases.
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