

HEALTH LAW

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INTRODUCTION

At the state level, the Court of Appeals delivered a blockbuster decision expanding the duty that health care providers owe to third-parties, a decision that will likely have long-term impacts on medical malpractice litigation in New York State.¹ The Second Circuit waded into a controversial issue with its decision upholding New York’s mandatory vaccine requirements.² On the statutory and regulatory front, there are new rules governing telehealth and Office of the Medicaid

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1. *Davis v. S. Nassau Cmty. Hosp.*, 26 N.Y.3d 563, 46 N.E.3d 614, 26 N.Y.S.3d 231 (2015).

2. *Phillips v. City of New York*, 775 F.3d 538 (2d Cir. 2015).

Inspector General (OMIG) compliance programs.³ Additionally, experienced nurse practitioners have been granted new levels of autonomy in their dealings with licensed physicians.⁴ Finally, the Supreme Court delivered the latest in a seemingly never-ending cycle of cases involving the Affordable Care Act.⁵

I. NEW YORK STATE CASE LAW

A. *New York State Court of Appeals*

1. *Davis v. South Nassau Communities Hospital*

The most impactful and wide-ranging decision handed down by the Court of Appeals this year was *Davis v. South Nassau Communities Hospital*.⁶ Although this case was handed down after the expiration of the *Survey* year, the authors and the editors of the *Syracuse Law Review* agreed that this case was significant enough that it warranted an inclusion in this year's *Survey*.

The facts as alleged by the plaintiffs in this case are fairly straightforward.⁷ In March of 2009, non-party Lorraine A. Walsh presented at South Nassau Communities Hospital's emergency room, where she was treated by the various defendants in this case.⁸ During the course of her treatment at the hospital, the defendants prescribed and administered Dilaudid, an opioid narcotic painkiller, and Ativan, a

3. See Act of March 13, 2015, ch. 6, 2015 Sess. Laws of N.Y. 8 (McKinney) (codified at N.Y. PUB. HEALTH LAW § 2999 (McKinney Supp. 2016); N.Y. INS. LAW § 3217-h (McKinney Supp. 2016); N.Y. SOC. SERV. LAW §367-u(2) (McKinney Supp. 2016)); OFFICE OF THE MEDICAID INSPECTOR GEN., MANDATORY COMPLIANCE PROGRAM REQUIREMENT: HOLDING COMPANY AND JOINT VENTURE STRUCTURES: EMPLOYEE VESTED WITH RESPONSIBILITY FOR DAY-TO-DAY OPERATION OF THE COMPLIANCE PROGRAM COMPLIANCE GUIDANCE 3 (2015) [hereinafter COMPLIANCE GUIDANCE]; Letter from N.Y. State Dep't of Fin. Servs., Insurance Circular Letter No. 7 to All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, and Health Maintenance Organizations (Dec. 11, 2014).

4. N.Y. EDUC. LAW. § 6902 (McKinney 2015).

5. *King v. Burwell*, 135 S. Ct. 2480 (2015).

6. 26 N.Y.3d 563, 46 N.E.3d 614, 26 N.Y.S.3d 231.

7. Please note that this case was dismissed by the New York supreme court for failure to state a cause of action pursuant to N.Y. C.P.L.R. 3211(a)(7) (McKinney 2006). *Id.* at 571, 46 N.E.3d at 617–18, 26 N.Y.S.3d 234–35. The appeals in this case have been based upon the supreme court's order of dismissal. *Id.* Therefore, the facts of this case have not been litigated at all. In consideration of the procedural posture, the Court assumed the facts as pleaded in the complaint as true and decided the case purely as a matter of law. *Id.* at 572, 46 N.E.3d at 618, 26 N.Y.S.3d at 235. Additionally, a full description of the facts is limited at best as they stem from the pleading itself.

8. *Id.* at 570–71, 46 N.E.3d at 617, 26 N.Y.S.3d at 234.

benzodiazepine, to Ms. Walsh.⁹ According to the plaintiffs' expert, Dilaudid has a significant analgesic effect, several times stronger than morphine, which is more prominent in ambulatory patients.¹⁰ The plaintiffs' expert also noted that the package insert for Dilaudid specifically warns that the drug may impair the patient's ability to perform hazardous tasks, including driving and operating machinery.¹¹ Furthermore, the half-life of Dilaudid administered intravenously, as was the case for Ms. Walsh, is two to four hours.¹² Ativan, similarly, has common side effects that include "sedation, dizziness, weakness, unsteadiness, and disorientation."¹³

Ms. Walsh was discharged from the emergency department approximately an hour and a half after she initially presented herself.¹⁴ Ms. Walsh drove herself from the hospital.¹⁵ Nineteen minutes later, Ms. Walsh's vehicle crossed a double yellow line and struck the plaintiffs' automobile.¹⁶ According to the allegations in the complaint, the defendants did not warn Ms. Walsh of the effects of the medication nor instruct her that she should not have operated a motor vehicle.¹⁷ The plaintiffs further allege that, as Ms. Walsh was still under the influence of her medication when the accident occurred, the defendants should now be liable to the plaintiffs for the injuries they sustained as a result of the defendants' alleged medical malpractice in treating Ms. Walsh.¹⁸

After answering, the defendants moved to dismiss the action for failure to state a cause of action.¹⁹ The defendants based their motion on long-standing New York precedent that medical providers do not owe a duty of care to third parties for treatment rendered to their patients.²⁰ The Court of Appeals had, in previous cases, specifically refused to extend the physician's duty beyond individual patients to also cover members of the community at large.²¹ The plaintiffs cross-moved for, among other relief, leave to file an amended complaint to add a cause of

9. *Davis*, 26 N.Y.3d at 570, 46 N.E.3d at 617, 26 N.Y.S.3d at 234.

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.* (quoting from the record on appeal).

14. *Davis*, 26 N.Y.3d at 570, 46 N.E.3d at 617, 26 N.Y.S.3d at 234.

15. *Id.*

16. *Id.* at 570–71, 46 N.E.3d at 617, 26 N.Y.S.3d at 234.

17. *Id.* at 571, 46 N.E.3d at 617, 26 N.Y.S.3d at 234.

18. *Id.*

19. *Davis*, 26 N.Y.3d at 570, 46 N.E.3d at 617, 26 N.Y.S.3d at 234.

20. *Id.* at 571, 46 N.E.3d at 617–18, 26 N.Y.S.3d at 234–35.

21. *Id.* at 572, 46 N.E.3d at 619, 26 N.Y.S.3d at 236.

action for common law negligence.²² The supreme court granted the defendants' motion and denied the plaintiffs' cross-motion.²³ After the appellate division affirmed the supreme court, the plaintiffs requested and were granted leave to appeal by the Court.²⁴

Plaintiffs' attorney, Joseph Dell, essentially argued that policy considerations require the Court to reconsider its position on duty of physicians to third parties.²⁵ Mr. Dell noted in an interview with the *New York Law Journal* that, under the existing law, "if [the plaintiffs] were confined to suing only Walsh, she could have been absolved of all liability if a jury found her impairment was the fault of the hospital and Mr. Davis would have recovered nothing."²⁶

In an opinion by Judge Fahey, the Court agreed with the plaintiffs' argument, overruled its earlier decisions, and determined that the defendants did, in fact, owe a duty to the plaintiffs to warn Ms. Walsh that the medications they administered could have impaired her ability to safely operate a motor vehicle.²⁷ After outlining the underlying law governing appeals of a motion to dismiss and recognition of a duty of care, the Court outlined the policy considerations New York courts use to resolve legal duty questions, including "common concepts of morality, logic and consideration of the social consequences of imposing the duty."²⁸ Specifically, the Court noted that "our calculus is such that we assign the responsibility of care to the person or entity that can most effectively fulfill that obligation [to avoid injury] at the lowest cost."²⁹

The Court began its analysis by noting that it has historically proceeded carefully and with reluctance whenever expanding a duty of care, in particular in the realm of the duty of care owed by physicians to their patients.³⁰ The Court noted that it had declined in early cases to impose on medical providers a broad duty of care to the community at large, which the Court described as "an indeterminate, faceless, and

22. *Id.* at 571, 46 N.E.3d at 618, 26 N.Y.S.3d at 235.

23. *Id.*

24. *Davis*, 26 N.Y.3d at 571, 46 N.E.3d at 618, 26 N.Y.S.3d at 235.

25. Ben Bedell, *Court Says Third Party Can Sue Hospital in MedMal Case*, N.Y.L.J., December 17, 2015, at 2.

26. *Id.*

27. *Davis*, 26 N.Y.3d at 577, 46 N.E.3d at 622, 26 N.Y.S.3d at 239.

28. *Id.* at 572, 46 N.E.3d at 618, 26 N.Y.S.3d at 235 (quoting *Tenuto v. Lederle Lab., Div. of Am. Cyanamid Co.*, 90 N.Y.2d 606, 612, 687 N.E.2d 1300, 1302, 665 N.Y.S.2d 17, 19 (1997)).

29. *Id.*

30. *Id.*

ultimately prohibitively large class of plaintiffs.”³¹ Previously, the Court had only extended a physician’s duty to warn and advise in situations where a special relationship existed sufficient to supply a predicate for that extension.³² For example, the Court found that physicians had a duty of reasonable care to members of a patient’s immediately family or household who may suffer harm as a result of any medical care rendered by the physician.³³ The Court declined, however, to extend the duty to friends or acquaintances who may contact diseases from a physician’s patients.³⁴

In particular, the Court reviewed its decision in *Purdy v. Public Administrator of Westchester*.³⁵ In *Purdy*, the Court had considered the question whether a defendant nursing home and a defendant physician, who was the admitting physician at the home, owed a duty of care to a plaintiff who was struck by a car driven by one of the nursing home residents who had a medical condition that made her unsuitable to drive.³⁶ The Court determined that no special relationship between the defendants and the resident existed such that the defendants were legally obligated to control the resident’s conduct and limit her ability to drive.³⁷ Concluding that the defendant physician owed no duty to the plaintiff, the Court noted that the defendant doctor

was not [the resident’s] treating physician, and therefore was under no legal obligation to warn [the resident] of possible dangers involved in activities in which she chose to engage off the premises of the facility. Nor [, we added,] ha[d] [the] plaintiff demonstrated that [the resident’s] impaired driving ability was attributable to any medication prescribed by [the physician] without appropriate warnings.³⁸

However, the Court also acknowledged in its *Purdy* decision that circumstances could exist where a defendant had sufficient authority and ability to control the conduct of another party such that a duty would extend to prevent that other party from causing harm to others.³⁹

Under the Court’s analysis, those earlier decisions, even when they

31. *Id.* at 573, 46 N.E.3d at 619, 26 N.Y.S.3d at 236.

32. *Davis*, 26 N.Y.3d at 573–74, 46 N.E.3d at 619–20, 26 N.Y.S.3d at 236–37.

33. *Id.* at 574, 46 N.E.3d at 620, 26 N.Y.S.3d at 237.

34. *Id.* at 574–75, 46 N.E.3d at 620, 26 N.Y.S.3d at 237.

35. 72 N.Y.2d 1, 526 N.E.2d 4, 530 N.Y.S.2d 513 (1988).

36. *Id.* at 6, 526 N.E.2d at 6, 530 N.Y.S.2d at 515.

37. *Davis*, 26 N.Y.3d at 574, 46 N.E.3d at 620, 26 N.Y.S.3d at 237.

38. *Id.* at 576, 46 N.E.3d at 621, 26 N.Y.S.3d at 238 (alterations in original) (quoting *Purdy*, 72 N.Y.2d at 10, 526 N.E.2d at 8, 530 N.Y.S.2d at 517).

39. *Id.* at 573–74, 46 N.E.3d at 619–20, 26 N.Y.S.3d at 236–37 (citing *Purdy*, 72 N.Y.2d at 8, 526 N.E.2d at 7, 530 N.Y.S.2d at 516).

declined to extend the duty of care for medical providers, left open the possibility of recognition of a duty of care in cases such as this.⁴⁰ The Court had observed in an earlier decision that “[i]n the limited circumstances where we have expanded the duty [of care of a treating physician so as to include a third party], the third party’s injury resulted from the physician’s performance of the duty of care owed to the patient.”⁴¹ Expanding on that reasoning, and specifically referring back to its analysis in *Purdy* and its failure to foreclose the prospect of an expansion of duty involving a failure to warn of the dangers of operating a motor vehicle, the Court concluded that the defendants in this case would owe a duty to the plaintiff.⁴²

Here, put simply, to take the affirmative step of administering the medication at issue without warning Walsh about the disorienting effect of those drugs was to create a peril affecting every motorist in Walsh’s vicinity. Defendants are the only ones who could have provided a proper warning of the effects of that medication. Consequently, on the fact alleged, we conclude that defendants had a duty to plaintiffs to warn Walsh that the drugs administered to her impaired her ability to safely operate an automobile.⁴³

The Court concluded its analysis of this question with three observations. First, the Court noted that the cost of this duty should be small, as medical providers already have a pre-existing duty to warn patients of the potential effects of medication they administer.⁴⁴ Second, the Court stressed that a physician can meet its duty under this decision by simply advising a patient to whom medication is administered what the dangers of that medication are.⁴⁵ Third, the Court instructed that its decision should not be construed as an erosion of the underlying principle that courts should proceed cautiously and carefully in recognizing a duty of care.⁴⁶

Finally, the Court affirmed the courts below and denied the plaintiff’s request for leave to add a cause of action for common law negligence.⁴⁷ Under the facts as pleaded, the alleged misconduct constituted medical treatment; therefore, the Court noted, the claim

40. *Id.* at 575–76, 46 N.E.3d at 621, 26 N.Y.S.3d at 238.

41. *Id.* (alterations in original) (quoting *McNulty v. City of New York*, 100 N.Y.2d 227, 233, 792 N.E.2d 162, 166, 762 N.Y.S.2d 12, 16 (2003)).

42. *Davis*, 26 N.Y.3d at 576, 46 N.E.3d at 621, 26 N.Y.S.3d at 238.

43. *Id.* at 577, 46 N.E.3d at 622, 26 N.Y.S.3d at 239.

44. *Id.* at 579, 46 N.E.3d at 623–24, 26 N.Y.S.3d at 240–41.

45. *Id.* at 580, 46 N.E.3d at 624, 26 N.Y.S.3d at 241.

46. *Id.*

47. *Davis*, 26 N.Y.3d at 581, 46 N.E.3d at 625, 26 N.Y.S.3d at 242.

sounded in medical malpractice and not negligence.⁴⁸

In a dissent, in which Judge Abdus-Salaam concurred, Judge Stein essentially charged that the majority has conflated foreseeability of harm with the existence of a duty.⁴⁹ Judge Stein cited to several cases where the Court emphasized that foreseeability of harm limits the scope of a duty, once one is determined to exist, under the doctrine of proximate cause.⁵⁰ Judge Stein vigorously disagreed with the majority that the recognition of a duty under the circumstances of this case is merely an extension of existing precedent.⁵¹ Analyzing the same line of cases cited by the majority, Judge Stein synthesized the rule of law those cases created as follows:

In New York, a physician's duty to a patient, and the corresponding liability, may be extended beyond the patient only to someone who is both a readily identifiable third party of a definable class, usually a family member, *and* who the physician knew or should have known could be injured by the physician's affirmative creation of a risk of harm through his or her treatment of the patient.⁵²

Judge Stein noted that, even if the Court concluded that the majority's extension of duty is implied by the prior decisions, the Court would still be obligated to balance certain relevant factors, including, "the reasonable expectations of the parties and society generally, the proliferation of claims, the likelihood of unlimited or insurer-like liability, disproportionate risk and reparation allocation, and public policies affecting the expansion or limitation of new channels of liability."⁵³ Judge Stein argued that the majority's decision does not conform with the expectations of the parties or society, as physicians have never previously owed a duty to the community at large.⁵⁴ Judge Stein felt that the majority's extension of the duty did not create any additional benefit.⁵⁵ As the majority noted, medical providers already possess a duty, under the actions, to prevent future harm.⁵⁶ Thus, Judge Stein argued that the extension of that duty would have little to no

48. *Id.*

49. *Id.* at 581, 46 N.E.3d at 625, 26 N.Y.S.3d at 242 (Stein, J., dissenting).

50. *Id.* at 583–84, 46 N.E.3d at 627, 26 N.Y.S.3d at 244.

51. *Id.* at 584, 46 N.E.3d at 627, 26 N.Y.S.3d at 244.

52. *Davis*, 26 N.Y.3d at 587, 46 N.E.3d at 630, 26 N.Y.S.3d at 247.

53. *Id.* at 589, 46 N.E.3d at 631, 26 N.Y.S.3d at 248 (citing *Palka v. Servicemaster Mgmt. Servs. Corp.*, 83 N.Y.2d 579, 586, 634 N.E.2d 189, 611 N.Y.S.2d 817 (1994)).

54. *Id.* at 590, 46 N.E.3d at 632, 26 N.Y.S.3d at 249.

55. *Id.* at 591, 46 N.E.3d at 632, 26 N.Y.S.3d at 249.

56. *Id.* at 590–91, 46 N.E.3d at 632, 26 N.Y.S.3d at 249.

additional deterrent effect.⁵⁷ At the same time, however, the financial and social costs of the new rule, including defensive medical practices, increased medical malpractice insurance premiums, and increased litigation, outweighed any benefits, in Judge Stein's estimation.⁵⁸

Judge Stein also argued that the rule was unworkable on a practical level. In order to make out a defense in these types of cases, courts will have to intrude into the privacy rights of patients, who are protected as non-parties to a claim.⁵⁹ He noted that the majority did not address the situation where a physician cannot prove or disprove whether he met his obligations to an uncooperative third party patient without somehow violating the physician-patient privilege.⁶⁰

Judge Stein noted that while he was sympathetic to the plaintiff's situation, reasonable limits must be placed on liability, and common law courts must look beyond the facts of a particular case to take into account larger principles.⁶¹ Judge Stein concluded with a hope that the legislature will overrule the majority's decision by statute.⁶²

This decision leaves open several important questions. Although the majority's language seems to imply the rule in this case should be limited to the effects of medication while driving, it does not state so explicitly. It can and almost certainly will be argued that the majority's holding could apply to any situation where the effects of medication on a patient placed any other third person at risk of some harm. As Judge Stein noted in his dissent, this decision could impose liability for any medical effect beyond medication:

Following the majority's holding to its logical conclusion, a physician can arguably now be held liable, not just where a medication impairs driving ability due to its impact on a patient's state of wakefulness, but also where a medication causes any other physical malady, for example, a severe stomach ache that distracts a driver or a rash of itchiness that causes a driver to release the steering wheel and lose control.⁶³

As with any new rule that extends liability, practitioners should expect a series of appeals in the next several years seeking to test and

57. *Davis*, 26 N.Y.3d at 591, 46 N.E.3d at 632, 26 N.Y.S.3d at 249.

58. *Id.* at 593, 46 N.E.3d at 634, 26 N.Y.S.3d at 251

59. *Id.* at 592, 46 N.E.3d at 633, 26 N.Y.S.3d at 251.

60. *Id.* at 593, 46 N.E.3d at 634, 26 N.Y.S.3d at 251.

61. *Id.* at 594–95, 46 N.E.3d at 635, 26 N.Y.S.3d at 252 (citing *McNulty v. City of New York*, 100 N.Y.2d 227, 235, 792 N.E.2d 162, 167, 762 N.Y.S.2d 12, 17 (Kaye, J., concurring)).

62. *Davis*, 26 N.Y.3d at 596, 46 N.E.3d at 636, 26 N.Y.S.3d at 253.

63. *Id.* at 594, 46 N.E.3d at 634, 26 N.Y.S.3d at 251.

define the scope of the Court's holding in this case.

II. NEW YORK STATE LEGISLATION AND REGULATIONS

A. Telehealth Legislation

In March of 2015, Governor Cuomo signed into law A. 2552-a.⁶⁴ This bill, introduced by Assemblywoman Addie Russell, with Senator Cathy Young carrying the equivalent bill in the Senate, made several changes to the Public Health Law, the Insurance Law, and the Social Services Law in relation to the “telehealth delivery of services.”⁶⁵ As defined in the bill, “telehealth” means “the use of electronic information and communication technologies by telehealth providers to deliver health care services, which shall include the assessment, diagnosis, consultation, treatment, education, care management and/or self-management of a patient.”⁶⁶ According to the sponsor's memorandum, the purpose of the bill was to provide clarification to telehealth-related definitions and to provide insurance and Medicaid coverage for the provision of telehealth and other telemedicine services.⁶⁷ This bill enacts a chapter amendment previously negotiated by the governor and the legislature as part of Chapter 550 of 2014.⁶⁸

The bill added a new Article 29-G to the Public Health Law that defines telehealth and numerous related terms and authorizes reimbursement for telehealth services under New York's Medicaid program.⁶⁹ The bill also amended the Insurance Law and the Public Health Law by prohibiting health insurers and health maintenance organizations regulated by New York State from excluding telehealth services from their coverages, except where the underlying medical services are not otherwise covered by the insurance policy.⁷⁰

64. See Act of March 13, 2015, ch. 6, 2015 Sess. Laws of N.Y. 8 (McKinney) (codified at N.Y. PUB. HEALTH LAW § 2999 (McKinney Supp. 2016); N.Y. INS. LAW § 3217-h (McKinney Supp. 2016); N.Y. SOC. SERV. LAW §367-u(2) (McKinney Supp. 2016)).

65. *Id.*

66. *Id.* at 9 (codified at N.Y. PUB. HEALTH LAW § 2999-cc(4) (McKinney Supp. 2016)).

67. See Memorandum in Support of Legislation, A2552A.

68. *Id.*

69. See N.Y. PUB. HEALTH LAW §§ 2999-cc, 2999-dd (McKinney Supp. 2016).

70. See N.Y. INS. LAW § 3217-h(a) (McKinney Supp. 2016).

B. OMIG Compliance Guidance on Mandatory Compliance Program

The OMIG issued a compliance guidance to organizations where multiple corporate Medicaid providers, each with a mandatory compliance program obligation, are organized either into a holding company system or as a joint venture.⁷¹ Element number two of the mandatory compliance program obligations, as set out in Medicaid regulations, requires that the compliance program designate an employee of the Medicaid program who is vested with the responsibility of the day-to-day operation of the compliance program.⁷² This compliance guidance makes clear that OMIG only considers an employee to be “anyone who qualifies as an employee for New York State or federal employment tax purposes.”⁷³ Thus, independent contractors, consultants, volunteers, and other similar positions are not considered employees for the purposes of the second element.⁷⁴

However, this can become complicated when there is a complex organizational structure. According to OMIG, an employee of a wholly owned subsidiary can be the compliance officer of the holding company, if that employee:

- a. is vested by the holding company with responsibility for the day-to-day operations of the holding company’s compliance program;
- b. satisfactorily carries out all of the compliance responsibilities;
- c. reports directly to the holding company’s chief executive officer or other senior administrator; and
- d. periodically reports directly to the holding company’s governing body on the activities of the holding company’s compliance program.⁷⁵

However, an employee of a subsidiary that is not a wholly owned subsidiary cannot qualify as a compliance officer for the holding company under these regulations because there is no unity of ownership and control, so therefore, the compliance officer cannot also be said to be an employee of the holding company.⁷⁶ A joint venture, in turn, is considered to be in the same category as a not wholly-owned

71. COMPLIANCE GUIDANCE, *supra* note 3, at 3.

72. *Id.*

73. *Id.* at 4.

74. OMIG states that the tests for employees may include, but are not limited to: “W-2” employees, whether the employee is covered under unemployment or worker’s compensation insurance, or whether the employee has payroll tax deductions from his or her earnings. *Id.*

75. *Id.*

76. *See* COMPLIANCE GUIDANCE, *supra* note 3, at 4.

subsidiary.⁷⁷ Thus, an employee of one company in a joint venture cannot be the compliance officer for any other company within that joint venture.⁷⁸

C. Insurance Guidance on Treatment of Gender Dysphoria

On December 11, 2014, the New York State Department of Financial Services (“Department of Finance” or “Department”) took a bold step into the larger social debate on transgender rights.⁷⁹ In an insurance circular letter to all insurers who issue accident and health insurance in the state, the Department of Finance clarified insurer obligations in the treatment of health issues connected to gender dysphoria.⁸⁰ The Department relied on state and federal statutes and regulations to find that “[a]n issuer may not deny medically necessary treatment otherwise covered by a health insurance policy . . . solely on the basis that the treatment is for gender dysphoria.”⁸¹

With respect to New York statutes and regulations, the Department of Finance relied primarily on “Timothy’s Law,” a set of several individual statutes in the Insurance Law requiring insurers to provide coverage for the “diagnosis and treatment of mental, nervous, or emotional disorders or ailments.”⁸² As the fifth edition of the *Diagnostic and Statistical Manual* classifies gender dysphoria as a mental disorder, “Timothy’s Law requires an issuer . . . to provide coverage for the diagnosis and treatment of gender dysphoria.”⁸³ The Department also pointed to a much broader state regulation prohibiting insurers from limiting coverage by type of illness, treatment, or medical condition.⁸⁴

The Department of Finance went even further than pointing to the state regulations and New York’s “Timothy’s Law.” Specifically, the Department cited a federal regulation interpreting the Mental Health Parity and Addiction Equity Act of 2008.⁸⁵ That regulation prohibits any insurer providing mental health coverage from placing treatment

77. *Id.*

78. *Id.* at 4–5.

79. N.Y. State Department of Financial Services, *supra* note 3.

80. *Id.*, at 1.

81. *Id.* The letter defines “gender dysphoria” as “the term currently used for the condition of people whose gender at birth is contrary to the one with which they identify. *Id.* at 3 n.1.

82. *Id.* at 3. The specific statutory provisions cited in the letter are N.Y. INS. LAW § 3221(1)(5) (McKinney 2015), and N.Y. INS. LAW § 4303(g)–(h) (McKinney 2015).

83. N.Y. State Department of Financial Services, *supra* note 3, at 2.

84. *Id.* at 1 (citing N.Y. COMP. CODES. R. & REGS. tit. 11, § 52.16(c) (2015)).

85. *Id.* (citing 45 C.F.R. § 146.136 (2015)).

limitations on particular mental health conditions that it does not place on substantially all other mental health conditions.⁸⁶ The Department's reliance on this federal regulation is perhaps the most interesting aspect of its decision with respect to gender dysphoria. It is currently unclear how other states will interpret this regulation, but New York's application of it to gender dysphoria sets the stage for potential conflicts as to its meaning. If other states take a contrary view of this federal regulation, it is foreseeable that significant federal litigation will ensue defining the contours of anti-discrimination protections for the transgender community.

D. New Rules for Experienced Nurse Practitioners

On January 1, 2015, New York's Nurse Practitioner Modernization Act came into effect, giving the state's experienced nurse practitioners increased flexibility and autonomy in their practice areas.⁸⁷ Under prior state law, all nurse practitioners were required to practice pursuant to a written practice agreement with a practicing physician.⁸⁸

Under the Nurse Practitioner Modernization Act, nurse practitioners with more than 3600 hours of qualifying experience can opt to practice, pursuant to a collaborative relationship, with a licensed physician.⁸⁹ This new option allows more flexibility to experienced nurse practitioners than what was allowed under prior state law. The new law defines a "collaborative relationship" as a situation in which a nurse practitioner communicates with a physician for the purpose of exchanging information in order to provide comprehensive care or to make referrals.⁹⁰ This new option allows experienced nurse practitioners to operate without a signed agreement with a physician and does not require regular supervision by a physician.⁹¹

86. *Id.*

87. See N.Y. EDUC. LAW. § 6902 (McKinney 2015); see also Bobbie Berkowitz, *New Era Begins for Nurse Practitioners in New York*, COLUM. U. SCH. NURSING, <http://nursing.columbia.edu/new-era-begins-nurse-practitioners-new-york> (last visited May 22, 2016).

88. N.Y. EDUC. § 6902(3)(a)(i). That section also defines "nurse practitioner" as one who diagnoses illnesses and physical conditions and performs therapeutic and corrective measures within the specialty that he or she is certified for. *Id.*

89. *Id.* § 6902(3)(b).

90. *Id.*

91. *Id.*

III. FEDERAL CASE LAW

A. *United States Court of Appeals for the Second Circuit*1. *Phillips v. City of New York*

In *Phillips v. City of New York*, the Court of Appeals for the Second Circuit weighed in on the controversial political and social issue of mandatory childhood immunizations.⁹² Childhood immunizations, once widely accepted as beneficial to public health, are receiving increased media scrutiny as celebrities and political activists have alleged a link between immunizations and various health conditions. While the social aspects of this debate will likely linger, *Phillips* emphatically settles the issue's legal status in the Second Circuit. Simply put, the states of our circuit have the right to mandate immunizations for any child attending public schools.

New York state law requires that children seeking admission to public school undergo a series of immunizations prior to attending school.⁹³ Public Health Law provides that “[n]o principal, teacher, owner or person in charge of a school shall permit any child to be admitted to such school, or to attend such school, in excess of fourteen days.”⁹⁴ State law provides two express exceptions to this pro-immunization mandate.⁹⁵ The first exception requires the input of a licensed physician and focuses on the health of an individual child.⁹⁶ That portion of the statute allows for an immunization exception “[i]f any physician licensed to practice medicine in this state certifies that such immunization may be detrimental to a child’s health.”⁹⁷ The second exception focuses on the student’s parents rather than the child herself, and is tailored to comport with federal Free Exercise Clause jurisprudence.⁹⁸ Specifically, an exemption is afforded to “children whose parent, parents, or guardian hold genuine and sincere religious beliefs which are contrary to the [immunization mandate].”⁹⁹ There are several levels of state review available to parents who seek to exercise these exemptions but are denied.¹⁰⁰

92. 775 F.3d 538, 540 (2d Cir. 2015).

93. N.Y. PUB. HEALTH LAW § 2164(7)(a) (McKinney 2012).

94. *Id.*

95. *Id.* § 2164(8), (9) (McKinney 2012).

96. *Id.* § 2164(8).

97. *Id.*

98. N.Y. PUB. HEALTH LAW § 2164(9).

99. *Id.*

100. *Phillips v. City of New York*, 775 F.3d 538, 540 (2d Cir. 2015) (“The State

State regulations provide discretion to public school administrators where there is an outbreak of a contagious disease in their schools.¹⁰¹ That regulation allows administrators to exclude unimmunized students from school “in the event of an outbreak . . . of a vaccine-preventable disease in a school.”¹⁰² The *Phillips* plaintiff was the mother of a student excluded from school under this regulation.¹⁰³ The plaintiff’s child was not immunized against chickenpox and was prevented from attending her school after another student tested positive for that disease.¹⁰⁴ The plaintiff mother, a practicing Catholic, applied for an exemption from New York’s immunization requirement on religious grounds.¹⁰⁵ A Department of Education official reviewed that request and found that her objections to immunizing the child “were not based on genuine and sincere religious beliefs.”¹⁰⁶

The mother then filed suit in the United States District Court for the Southern District of New York alleging New York’s immunization mandate violated a host of federal constitutional provisions.¹⁰⁷ The plaintiff alleged causes of action under the First Amendment’s Free Exercise Clause, the Fourteenth Amendment’s substantive due process doctrine, the Ninth Amendment, and the Equal Protection Clause.¹⁰⁸ The federal magistrate judge held a hearing to determine the basis for the plaintiff-mother’s objections to vaccinating her daughter and the sincerity of the plaintiff’s religious objections.¹⁰⁹ During that hearing, the mother’s testimony appeared to cover both the religious-based and

provides multiple layers of review if either of these exemptions are denied.”). It should be noted that the Court did not clarify what procedural safeguards are available to a parent who is denied the ability to exercise one or both immunization exemptions. It seems safe to assume that such a parent has access to procedures outlined in state Education Law and its implementing regulations. *See, e.g.*, N.Y. EDUC. LAW § 310 (McKinney 2009) (providing that individuals aggrieved by a local school decision may appeal that decision to the New York State Commissioner of Education for review). Further, a parent in such situation would likely also have access to an Article 78 proceeding, the state’s version of seeking a writ of mandamus, to compel a local school district to admit a student who qualified for one or both of the immunization exemptions. There is scant case law on these procedural issues.

101. N.Y. COMP. CODES R. & REGS. tit. 10, § 66-1.10 (2015).

102. *Id.* (“[I]n the event of an outbreak . . . of a vaccine-preventable disease in a school, the commissioner, or his or her designee . . . may order the appropriate school officials to exclude from attendance [students who have received exemptions from mandatory childhood immunizations].”).

103. *Phillips*, 775 F.3d at 540–41.

104. *Id.*

105. *Id.* at 541.

106. *Id.*

107. *Id.*

108. *Phillips*, 775 F.3d at 542.

109. *Id.* at 541.

health-based exemptions to the immunization mandate.¹¹⁰ For instance, the plaintiff-mother testified that her objection to mandatory vaccinations stemmed from a belief that “[h]ow I treat my daughter’s health and her well-being is strictly by the word of God.”¹¹¹ Alternatively, the mother evidenced concern that vaccinations could cause her daughter serious health issues, including “anaphylactic shock,” and stated that the daughter had previously suffered adverse reactions to prior vaccinations.¹¹² Cross-examination did little to advance the plaintiff’s arguments, as she was forced to admit that she was unaware of “any tenants of Catholicism that prohibited vaccinations.”¹¹³

Following this testimony, the magistrate judge found that the mother’s objections were primarily based on health considerations rather than genuinely-held religious beliefs.¹¹⁴ The magistrate then denied an application for preliminary injunction.¹¹⁵ Shortly thereafter, the plaintiff-mother’s case was consolidated with two similar cases pending in the United States District Court for the Eastern District of New York.¹¹⁶ The defendant, the City of New York, was then granted summary judgment on the plaintiffs’ substantive constitutional claims, namely that New York’s mandatory vaccination statute violated the Free Exercise Clause of the First Amendment, the Ninth Amendment, the substantive due process requirements of the Fourteenth Amendment, and the Equal Protection Clause of the Fourteenth Amendment.¹¹⁷ The plaintiffs then appealed.¹¹⁸

The Second Circuit addressed each constitutional claim in turn.¹¹⁹ As should be expected, the court offered little analysis in upholding the district court’s grant of summary judgment on the Ninth Amendment claims as the circuit has continuously held that “the Ninth Amendment

110. *Id.*

111. *Id.*

112. *Id.* The court did not elaborate on the nature of these alleged adverse reactions to prior vaccinations.

113. *Phillips*, 775 F.3d at 541.

114. *Id.*

115. *Id.*

116. *Id.* at 542. The facts discussed in this Article, and the Second Circuit’s decision, are from the claims of the plaintiff, Check. Her case was subsequently consolidated with two other cases and re-captioned as *Phillips v. City of New York*.

117. *Id.*

118. *Phillips*, 775 F.3d at 542. The appeal came after the plaintiffs filed a motion for reconsideration at the district court level. That application was denied as they had already filed a notice of appeal and the court found that filing deprived it of jurisdiction to reconsider.

119. *Id.* at 542–44. The court, of course, reviewed the district court’s grant of summary judgment de novo.

is not an independent source of individual rights.”¹²⁰ The court offered a similarly curt analysis of the plaintiffs’ equal protection claims. That claim was on behalf of the plaintiff who argued that other similarly-situated Catholics had been granted religious-based exemptions to the mandatory vaccination statute whereas she had been denied such an exemption.¹²¹ The court rejected this argument, holding that the plaintiff had failed to present adequate evidence that her religious beliefs were substantially similar to those of other Catholics.¹²²

With respect to the plaintiff’s substantive due process claims, the court analyzed her argument that a “growing body of scientific evidence demonstrates that vaccines cause more harm to society than good.”¹²³ The court soundly rejected this argument. Pointing to the 1905 Supreme Court decision in *Jacobson v. Massachusetts*, the court found that long-settled federal law “rejected the claim that the individual liberty guaranteed by the Constitution overcame the State’s judgment that mandatory vaccination was in the interest of the population as a whole.”¹²⁴ In other words, requiring vaccinations for children attending public schools is an appropriate exercise of the state’s police powers.¹²⁵ The court did not analyze the merits of the plaintiff’s claims that vaccines cause more societal harm than good. Rather, the Second Circuit held that such a determination is a matter for the legislature, not the judiciary.¹²⁶

The bulk of the circuit court’s decision addressed the plaintiff’s claims under the Free Exercise Clause of the First Amendment.¹²⁷ Predictably, the plaintiff’s argument with regard to the exercise of religion was that “the temporary exclusion from school of the [plaintiff’s] children unconstitutionally burdens their free exercise of religion.”¹²⁸ Noting that the Supreme Court’s decision in *Jacobson* did

120. *Id.* at 544 (quoting *Jenkins v. Comm’r*, 483 F.3d 90, 92 (2d Cir. 2007)).

121. *Id.* at 543–44. This is an area in which the procedural history of the case, namely the consolidation of Check’s claims with those of the plaintiffs Phillips and Mendoza-Vaca, causes some confusion. Plaintiff Check essentially argued that the two plaintiffs with which her claims had been consolidated were: (1) also Catholic; and (2) had been granted religious exemptions while she had been denied.

122. *Id.*

123. *Phillips*, 775 F.3d at 542. The court did not cite any studies to substantiate the plaintiffs’ claims with respect to the alleged social harms caused by vaccines. It is unclear whether they were able to point to any specific credible scientific evidence on that point.

124. *Id.* (citing *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905)).

125. *Id.* (citing *Jacobson*, 197 U.S. at 25–27; *Zucht v. King*, 260 U.S. 174, 176 (1922)).

126. *Id.* (citing *Jacobson*, 197 U.S. at 37–38).

127. *Id.* at 543.

128. *Phillips*, 775 F.3d at 542.

not control, the circuit court pointed to dicta in *Prince v. Massachusetts* stating that “[t]he right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.”¹²⁹ The circuit court’s decision with respect to free-exercise issues rested on one of the most fundamental tenants of First Amendment jurisprudence, namely that a law of neutral and general applicability does not interfere with the First Amendment even if it just so happens to have an incidental impact on religious expression.¹³⁰

The *Phillips* decision likely puts to rest any lingering issues of New York’s ability to mandate vaccinations for children attending public school in the state. Although mandatory vaccinations have become increasingly controversial, Supreme Court jurisprudence dating to the early twentieth century has already decided the issue. The only door that the Second Circuit left open to vaccine opponents is in the area of substantive due process, placing the burden on anti-vaccine activists to address the issue with the assembly.

B. United States Supreme Court

1. Affordable Care Act Update: King v. Burwell

Undoubtedly the highest-profile decision impacting health law was the Supreme Court’s decision in *King v. Burwell*.¹³¹ This case was a matter of statutory interpretation, deciding whether language included in the Affordable Care Act (ACA) provides tax credits to residents of states that chose to not establish health care exchanges for the purchase of health insurance.¹³²

By way of background, the ACA requires the establishment of health care exchanges in each state where the state’s residents can shop for insurance.¹³³ If the state itself does not establish a health care exchange, the federal government may do so through the Department of Health and Human Services.¹³⁴ Further, the ACA provides a series of tax credits to individuals with household incomes between 100% and 400% of the federal poverty line to assist with purchasing health

129. *Id.* (quoting *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944)).

130. *Id.* (quoting *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 531 (1993)).

131. 135 S. Ct. 2480 (2015).

132. *Id.* at 2487–88.

133. *Id.* at 2487 (citing 42 U.S.C. § 18041(b)(1) (2012)).

134. 42 U.S.C. § 18041(c)(1) (2012).

insurance.¹³⁵ At issue in *King* was whether those tax credits are available to individuals residing in states that did not establish their own exchanges.¹³⁶ Significantly, the ACA's tax provisions state that the tax credit amounts are determined based on whether a given taxpayer is a part of a health plan he "enrolled in through an Exchange established by the State under . . . the [ACA]."¹³⁷ The IRS's implementing statutes treated this "established by the state" language as pertaining to exchanges established both by the states and by the Secretary of Health and Human Services.¹³⁸

The plaintiffs in *King* opposed the ACA and brought suit alleging that the tax credits at issue were unavailable in states that had not established their own exchanges.¹³⁹ The Fourth Circuit had decided the case at the appellate level by relying on the *Chevron* doctrine, finding that the statute was ambiguous and the IRS regulation recognizing both state and federal exchanges was reasonable.¹⁴⁰ The plaintiffs then appealed.¹⁴¹

Chief Justice Roberts wrote for a six-to-three majority holding that the tax credits at issue were available regardless of whether an exchange was established by a state or the federal government.¹⁴² At the outset, Chief Justice Roberts determined that the tax credits were too central to the overall scheme to make this case appropriate for the *Chevron* test.¹⁴³ With that preliminary administrative law question out of the way, the Court's "task [was] to determine the correct reading of Section 36B."¹⁴⁴ In other words, to determine whether the statute was ambiguous and, if so, what the proper interpretation should be with respect to the availability of tax credits.

135. 26 U.S.C. § 36B (2012).

136. *King*, 134 S. Ct. at 2487 ("[T]he issue in this case is whether the Act's tax credits are available in States that have a Federal Exchange rather than a State Exchange.").

137. 26 U.S.C. § 36B.

138. Treas. Reg. § 1.36B-2(a)(1) (2015); 45 C.F.R. § 155.20 (2015) (defining exchange as including those established by the federal government).

139. *King*, 134 S. Ct. at 2487.

140. *Id.* at 2488 (citing *King v. Burwell*, 759 F.3d 358, 372 (4th Cir. 2014)).

141. *Id.*

142. *Id.* at 2489.

143. *Id.* at 2491 ("[t]he tax credits are among the Act's key reforms, involving billions of dollars in spending each year and affecting the price of health insurance for millions of people. Whether those credits are available on the Federal Exchanges is thus a question of deep 'economic and political significance' that is central to this statutory scheme; had Congress wished to assign that question to an agency, it surely would have done so expressly.") (citing *Util. Air Regulatory Grp. v. Env'tl. Prot. Agency*, 134 S. Ct. 2427, 2444 (2014)).

144. *King*, 134 S. Ct. at 2489.

Chief Justice Roberts found that section 36B's language referring to exchanges created by the states was ambiguous.¹⁴⁵ After that threshold determination, the Court turned to the question of the proper reading of section 36B, an inquiry that required analysis of the major goals Congress sought to advance through the ACA.¹⁴⁶ The Court determined that those goals were threefold, namely that,

Congress based the Affordable Care Act on three major reforms: first, the guaranteed issue and community rating requirements; second, a requirement that individuals maintain health insurance coverage or make a payment to the IRS; and third, the tax credits for individuals with household incomes between 100 percent and 400 percent of the federal poverty line.¹⁴⁷

After framing the purpose of the ACA in such terms, the Court's analysis became fairly straightforward. The plaintiffs' reading of section 36B would require that a large portion of the country would be ineligible for the tax credits that Congress created to help shape the insurance marketplace nationwide.¹⁴⁸ In other words, the "combination of no tax credits and an ineffective coverage requirement could well push a State's individual insurance market into a death spiral. . . . It is implausible that Congress meant the Act to operate in this manner."¹⁴⁹ As such, the proper reading of section 36B requires that the tax credits at issue be available to all eligible tax payers regardless of which entity established their local health care exchanges.¹⁵⁰

Of course, *King v. Burwell* is only the latest challenge to the ACA. Since its passage, the act has been assailed on Commerce Clause, Establishment Clause, and now fundamental statutory interpretation grounds.¹⁵¹ After years of high-profile litigation, it is now unlikely that the courts will do significant damage to the ACA and any major changes to its health care scheme will come from political, not legal, angles.

145. *Id.* at 2488. The conclusion that Section 36B was ambiguous came after a long and somewhat technical analysis of statutory ambiguity that is not entirely appropriate to rehash in an article addressing health law developments. *Id.* at 2490–92.

146. *Id.* at 2492–93.

147. *Id.* at 2493.

148. *King*, 134 S. Ct. at 2493.

149. *Id.*

150. *Id.* at 2496.

151. *See, e.g., id.* at 2489 (attacking the ACA using principles of statutory interpretation); *NFIB v. Sebelius*, 132 S. Ct. 2566, 2581 (2012) (attacking the ACA under the commerce clause); *Cutler v. U.S. Dep't of Health & Human Servs.*, 797 F.3d 1173, 1175 (D.C. Cir. 2015) (attacking the ACA under the establishment clause), *cert. denied*, 136 S. Ct. 877 (2016).

CONCLUSION

Looking ahead, the most interesting topic to monitor is easily the effects of the Court of Appeals' ruling in *Davis*, a case that represents a radical departure from decades of established case law on duty. In addition, the authors look forward to monitoring any practical impacts from the new laws regulating nurse practitioners with more than 3,600 hours of experience. There is potential for interesting liability decisions for physicians entering into the new collaborative agreements with such practitioners in the coming years.