HEALTH LAW

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INTRODUCTION

In this *Survey* year, the Court of Appeals delivered two major evidentiary decisions in the health law field, one clarifying the parameters of disclosure of confidential patient information and one limiting the admissibility of propensity evidence permitted in a medical malpractice trial.[1] The Appellate Division, First Department has also indicated that it is the responsibility of the New York State Legislature to legalize aid-in-dying.[2]

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1. *See generally* Chanko v. American Broad. Cos. 27 N.Y.3d 46, 49 N.E.3d 1171, 29 N.Y.S.3d 879 (2016) (discussing the limitations of disclosure of confidential patient information); Mazella v. Beals, 27 N.Y.3d 694, 57 N.E.3d 1083, 37 N.Y.S.3d 46 (2016) (discussing the admissibility of evidence of the defendant's negligent treatment of other patients).

2. Myers v. Schneiderman (*Myers II*), 140 A.D.3d 51, 65, 31 N.Y.S.3d 45, 55 (1st

At the federal level, the Supreme Court refrained from issuing a decision regarding coverage for contraception as mandated by the Affordable Care Act (ACA).[3] The Second Circuit opined on the permissibility of prescribing FDA approved medications for off-label use and reinforced its position limiting the rights of third parties to bring statutory causes of action for patients.[4]

In the New York State Legislature, the tax code was modified in response to a class-action lawsuit to exempt feminine hygiene products from sales tax.[5] Furthermore, the New York State Department of Health yet again expanded Medicaid coverage for the treatment of gender dysphoria.[6]

The State Legislature has also been busy drafting and revising legislation related to the aid-in-dying initiative and the State Assembly has engaged in revising legislation that would provide for a public health plan for all New Yorkers.[7]

I. NEW YORK STATE CASE LAW

A. Chanko v. American Broadcasting Cos.

In *Chanko v. American Broadcasting Cos.*, the Court of Appeals clarified the extent of confidential medical information that is privileged under Civil Practice Law and Rules (CPLR) 4504.[8] The patient in this case was brought into the emergency room of the defendant hospital after being hit by a vehicle and was being treated by the defendant resident.[9] During his treatment, employees of the defendant broadcasting company were filming with the permission of the defendant hospital, but without the knowledge or permission of the patient or his family.[10] The employees were collecting footage for a

Dep't 2016).

3. Zubik v. Burwell (*Zubik II*), 136 S. Ct. 1557, 1560 (2016).

4. *See* United States *ex rel.* Polansky v. Pfizer, Inc. (*Polansky III*), 822 F.3d 613, 619–20 (2d Cir. 2016) (citing United States *ex rel.* Polansky v. Pfizer, Inc., 914 F. Supp. 2d 259, 265 (E.D.N.Y. 2012)).

5. Act of July 21, 2016, 2016 McKinney's Sess. Law News no. 4, ch. 99, at 489 (codified at N.Y. TAX LAW § 1115(a)(3-a) (McKinney Supp. 2017)).

6. 18 N.Y.C.R.R. § 505.2(*l*) (2016).

7. N.Y. Assembly Bill No. 5261-C, 238th Sess. (2015); N.Y. Assembly Bill No. 5062-A, 238th Sess. (2015); N.Y. Senate Bill No. 3685, 238th Sess. (2015).

8. 27 N.Y.3d 46, 55, 49 N.E.3d 1171, 1177–78, 29 N.Y.S.3d 879, 885–86 (2016); *see also* N.Y. C.P.L.R. 4504(a) (McKinney 2007).

9. *Chanko*, 27 N.Y.3d at 50, 49 N.E.3d at 1174, 39 N.Y.S.3d at 882.

10. *Id.* at 50–51, 49 N.E.3d at 1174, 39 N.Y.S.3d at 882.

documentary series about medical trauma.[11]

Shortly after being admitted to the hospital, the defendant resident declared the patient dead, which was also filmed by the employees.[12] The employees filmed the defendant resident informing the patient's family of his death as well.[13] The family was unaware that this was filmed until they saw the patient dying on television over a year later.[14] The family brought suit against the defendant hospital and the defendant resident for breach of physician-patient confidentiality, among other causes of action.[15]

The defendants each moved to dismiss.[16] The supreme court denied the motions for the plaintiffs' breach of physician-patient confidentiality claim against the defendant hospital and the defendant resident.[17] The defendant hospital and resident appealed.[18] After the Appellate Division, First Department reversed and granted the motions, the plaintiffs subsequently appealed.[19]

CPLR 4504 prohibits a person authorized to practice medicine from disclosing "any information which he acquired in attending a patient in a professional capacity, and which was necessary to enable him to act in that capacity."[20] The Court of Appeals has previously held that the statute extends to information obtained in a professional capacity despite not being necessary to enable the physician to fulfill his or her medical role.[21] However, subsequent cases seemed to implicate that "the disclosed medical information must be embarrassing or something that patients would naturally wish to keep secret."[22] This

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11. *Id.* at 50, 49 N.E.3d at 1174, 39 N.Y.S.3d at 882.

12. *Id.* at 51, 49 N.E.3d at 1174, 39 N.Y.S.3d at 882.

13. *Id.*

14. *Chanko*, 27 N.Y.3d at 51, 49 N.E.3d at 1174, 39 N.Y.S.3d at 882.

15. The family also brought a cause of action for intentional infliction of emotional distress against the defendant broadcasting company, the defendant hospital, and the defendant resident. All other claims were dismissed by the supreme court. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. *Chanko*, 27 N.Y.3d at 51, 49 N.E.3d at 1174, 39 N.Y.S.3d at 882 (citing Chanko v. Am. Broad. Cos., 122 A.D.3d 487, 488, 997 N.Y.S.2d 44, 45 (1st Dep't 2014)).

20. N.Y. C.P.L.R. 4504(a) (McKinney 2007).

21. *See, e.g.*, Lightman v. Flaum, 97 N.Y.2d 128, 136, 761 N.E.2d 1027, 1032, 736 N.Y.S.2d 300, 305 (2001) (first citing N.Y. EDUC. LAW § 6530(23) (McKinney 2016); and then citing 8 N.Y.C.R.R. § 29.1(b)(8) (2016)).

22. *Chanko*, 27 N.Y.3d at 54, 49 N.E.3d at 1177, 29 N.Y.S.3d at 885. *See* Doe v. Guthrie Clinic, Ltd., 22 N.Y.3d 480, 482–83, 485, 5 N.E.3d 578, 579, 581, 982 N.Y.S.2d 431, 432, 434 (2014) (holding physician-patient confidentiality violated where nurse revealed to patient's girlfriend that patient had a sexually transmitted disease); *see also*

limitation apparently stemmed from the public policy the Court used to justify the exception that a physician's disclosure of a secret acquired in treating a patient "naturally shocks our sense of decency and propriety" and discourages patients from disclosing all pertinent information to obtain proper medical care.[23]

The *Chanko* court rejected this limitation and instead held that CPLR 4504 protects all types of medical information: "[W]hether the confidentiality inherent in the fiduciary physician-patient relationship is breached does not depend on the nature of the medical treatment or diagnosis about which information is revealed."[24] The First Department incorrectly focused on the aired television episode, that the patient's image was blurred, and that his name was not used in the episode to find that the patient's confidential information was not disclosed.[25] The Court of Appeals disagreed and instead found that even if the patient was not recognized, the plaintiffs' claim is that the breach is in the disclosure of the information itself *to the defendant broadcasting company*.[26]

The Court thus found that the plaintiffs stated a viable cause of action against the defendant hospital and the defendant resident for violating physician-patient confidentiality in allowing the defendant broadcasting company to film, and subsequently air, the patient's final minutes of life and the defendant resident's declaration of his death without the consent of the plaintiff wife or the decedent.[27] The order granting the motion to dismiss was thus reversed.[28]

Randi A.J. v. Long Is. Surgi-Ctr., 46 A.D.3d 74, 76–77, 842 N.Y.S.2d 558, 560–61 (2d Dep't 2007) (finding confidentiality breached when clinic revealed to patient's mother that patient had had an abortion).

23. Dillenbeck v. Hess, 73 N.Y.2d 278, 285, 536 N.E.2d 1126, 1131, 539 N.Y.S.2d 707, 712 (1989) (quoting Davis v. Supreme Lodge, K. of H., 165 N.Y. 159, 163, 58 N.E. 891, 892 (1900)). The New York State Legislature has echoed this notion in stating that it is the public policy of New York State to protect the "privacy and confidentiality of sensitive medical information." *Chanko*, 27 N.Y.3d at 53, 49 N.E.3d at 1176, 29 N.Y.S.3d at 884 (quoting *Randi A.J.*, 46 A.D.3d at 82, 842 N.Y.S.2d at 565) (first citing N.Y. PUB. HEALTH LAW § 2803-c(3)(f) (McKinney 2012); and then citing N.Y. PUB. HEALTH LAW § 4410(2) (McKinney 2002)).

24. *Chanko*, 27 N.Y.3d at 54, 49 N.E.3d at 1177, 29 N.Y.S.3d at 885.

25. *Id.* at 55, 49 N.E.3d at 1177, 29 N.Y.S.3d at 885.

26. *Id.*

27. *Id.* at 56, 49 N.E.3d at 1178, 29 N.Y.S.3d at 886.

28. *Id.* at 58, 49 N.E.3d at 1180, 29 N.Y.S.3d at 888. The Court also assessed the denial of the plaintiffs' cause of action for intentional infliction of emotional distress, but upheld its dismissal in failing to find that the conduct failed to satisfy the high standard for extreme and outrageous. *Chanko*, 27 N.Y.3d at 57–58, 49 N.E.3d at 1179–80, 29 N.Y.S.3d at 887–88 (first citing Marmelstein v. Kehillat, 11 N.Y.3d 15, 22–23, 892 N.E.2d 375, 379, 862 N.Y.S.2d 311, 315 (2008); and then citing Freihofer v. Hearst Corp., 65 N.Y.2d 135, 143–

This case is significant in defining what constitutes confidential information that a physician is prohibited from revealing. As stated above, the Court decided the case on the grounds that medical information was improperly disclosed to the defendant broadcasting company's employees.[29] Most importantly, it did not explicitly overturn the First Department's holding that since the decedent was not identifiable, his confidential information was not disclosed.[30] Instead, the Court held the following:

> [E]ven if no one who actually viewed the televised program recognized decedent, *thereby rendering plaintiffs unable to state a cause of action based solely on the broadcast of the program*, the complaint expressly alleges an improper disclosure of medical information to the ABC employees who filmed and edited the recording, in addition to the broadcast, itself.[31]

In a recent Appellate Division, Second Department case, the court denied the plaintiff's request to view consent forms of other patients from the defendant plastic surgeon's practice.[32] In *Whitnum v. Plastic & Reconstructive Surgery*, the court found that even if the names had been redacted, the records were privileged so that the defendant was not obligated to comply with the discovery request.[33] This notion seems contrary to the Court of Appeals' implication that as long as the viewer of the medical information cannot identify the person receiving treatment, CPLR 4504 is not violated. While demands to review another person's medical records raises questionable relevancy issues, if other patients' medical records are determined to be relevant, the *Chanko* court's suggestion that this information may not be privileged could have significant implications.

B. Estate of Mazella v. Beals

One of the most significant Court of Appeals decisions in the last *Survey* year involving health law was, in our opinion, *Estate of Mazella*

44, 480 N.E.2d 349, 355, 490 N.Y.S.2d 735, 737 (1985)).

29. *Id.* at 50, 55, 49 N.E.3d at 1174, 1178, 29 N.Y.S.3d at 882, 886.

30. The Court did state that the plaintiffs put forward affidavits stating at least one person recognized the decedent. *Id.* at 54–55, 49 N.E.3d at 1176–77, 29 N.Y.S.3d at 884–85.

31. *Id.* at 55, 49 N.E.3d at 1177, 29 N.Y.S.3d at 885 (emphasis added).

32. Whitnum v. Plastic & Reconstructive Surgery, P.C., 142 A.D.3d 495, 496, 36 N.Y.S.3d 470, 473 (2d Dep't 2016).

33. *Id.* at 496–97, 36 N.Y.S.3d at 473 (first citing Quinones v. E. 69th St., LLC, 132 A.D.3d 750, 751, 18 N.Y.S.3d 106, 108 (2d Dep't 2015); and then citing Gilman & Ciocia, Inc. v. Walsh, 45 A.D.3d 531, 531, 845 N.Y.S.2d 124, 125 (2d Dep't 2007)).

v. Beals.[34] In *Mazella*, the Court of Appeals provided some much needed protection for the defendants on a critical evidentiary issue in medical malpractice cases—the admissibility of a Consent Agreement and Order ("Consent Order") from the New York State Office of Professional Medical Conduct (OPMC), which concerned a claim involving the instant matter as well as unrelated allegations of misconduct against the defendant physician.[35]

To provide some context for the evidentiary issue, the defendant, Dr. William Beals, treated the plaintiff's decedent beginning in October 1993 for major depression, obsessive-compulsive disorder, and generalized anxiety disorder.[36] The defendant initially prescribed twenty milligrams of Paxil and eventually discontinued the decedent's anti-anxiety medication, which had been prescribed by his primary care physician.[37] After reducing the decedent's dosage of Paxil in April 1994, the defendant's next contact with the decedent was in April 1998 after the decedent suffered from an episode of depression.[38]After a few weeks, the defendant, among other things, reduced the decedent's dosage of the Paxil to twenty milligrams.[39]

For more than ten years that followed, the defendant refilled the decedent's prescriptions for Paxil either over the phone or via facsimile, without having seen or examined the decedent since April 1998.[40] In August 2009, the decedent called the defendant and complained of anxiety, increased obsessive thoughts, and difficulty sleeping.[41] The defendant was on vacation at the time, but instructed the decedent to double his dosage of Paxil to forty milligrams and prescribed Zyprexa for anxiety and sleep issues.[42] The following day, the plaintiff and the decedent called the defendant complaining of nausea and lightheadedness, among other things.[43] The defendant, without seeing the decedent, doubled the decedent's Zyprexa dosage and told the

34. *See generally* Mazella v. Beals, 27 N.Y.3d 694, 57 N.E.3d 1083, 37 N.Y.S.3d 46 (2016) (finding that in a matter of medical malpractice the evidence proffered was sufficient to show that the doctor was negligent and that the negligence was the proximate cause of the decedent's death).

35. *Id.* at 701, 57 N.E.3d at 1087, 37 N.Y.S.3d at 50.

36. *Id.* at 698, 57 N.E.3d at 1085, 37 N.Y.S.3d at 48.

37. *Id.*

38. *Id.*

39. *Mazella*, 27 N.Y.3d at 698, 57 N.E.3d at 1085, 37 N.Y.S.3d at 48.

40. *See id.*

41. *Id.*

42. *Id.*

43. *Id.* at 698–99, 57 N.E.3d at 1085, 37 N.Y.S.3d at 48.

decedent he would call him the following afternoon to check in.[44] The plaintiff took the decedent to the emergency room the following day because his condition worsened and he was transferred to the hospital's Community Psychiatric Emergency Program (CPEP).[45] After several inpatient and outpatient psychiatric treatments, including another trip to the CPEP, the decedent committed suicide in his garage on September 12, 2009 by stabbing himself with a knife.[46]

The plaintiff commenced the instant medical malpractice and wrongful death action against the defendant and codefendant Dr. Mashinic.[47] The defendant admitted at trial that he deviated from accepted medical practice by prescribing Paxil to the decedent for ten years without monitoring him.[48] However, the defendant maintained that "superseding acts severed the causal connection between his conduct and the suicide, including medical care provided by [codefendant] Dr. Mashinic."[49] A jury found the defendant solely liable.[50]

In light of that context, the defendant filed a motion in limine prior to the trial to preclude, as relevant here, "the admittance of a [Consent Order] between [the] defendant and the Office of Professional Medical Conduct (OPMC)."[51] In January 2012, the OPMC brought charges against the defendant for deviation from the standard of care as to thirteen patients for prescribing medications without adequate monitoring.[52] The decedent was one of the thirteen patients.[53] The defendant agreed not to contest the allegations with respect to twelve of the patients in the Consent Order, but explicitly excluded the decedent.[54] Therefore, in his motion in limine, the defendant argued that the Consent Order was not relevant to the instant matter and would be "unduly prejudicial" because it did not concern the decedent.[55] The defendant also argued that the Consent Order did not address proper treatment for someone with anxiety, depression, and obsessive-

44. *Mazella*, 27 N.Y.3dat 699, 57 N.E.3d at 1085, 37 N.Y.S.3d at 48.
45. *See id.*at 699, 57 N.E.3d at 1086, 37 N.Y.S.3d at 49.
46. *See id.* at 699–01, 57 N.E.3d at 1086–87, 37 N.Y.S.3d at 49–50.
47. *See id.* at 701, 57 N.E.3d at 1087, 37 N.Y.S.3d at 50.
48. *See id.*at 702, 57 N.E.3d at 1088, 37 N.Y.S.3d at 51.
49. *See Mazella*, 27 N.Y.3d at 698, 57 N.E.3d at 1085, 37 N.Y.S.3d at 48.
50. *See id.*
51. *See id.* at 701–02, 57 N.E.3d at 1087, 37 N.Y.S.3d at 50.
52. *See id.* at 702, 57 N.E.3d at 1088, 37 N.Y.S.3d at 51.
53. *See id.*
54. *See Mazella*, 27 N.Y.3dat 702, 57 N.E.3d at 1088, 37 N.Y.S.3d at 51.
55. *See id.*

compulsive disorder.[56] The trial court denied the defendant's motion and admitted the entire Consent Order, including the other twelve patients' cases, to provide evidence of the defendant's "habit and credibility."[57] The defendant renewed his motion in limine to preclude the admission of the Consent Order immediately prior to trial, and the trial court denied the motion again.[58]

Accordingly, the Consent Order was admitted into evidence at trial and the plaintiff's counsel was permitted to question the defendant about the entire Consent Order, including details surrounding the unrelated twelve patients, the fact that the OPMC charged the defendant with "gross negligence" with respect to all thirteen patients, and that the defendant agreed to a Consent Order in satisfaction of the charges receiving a censure and reprimand for his conduct.[59]

Upon conclusion of the trial, the defendant appealed the trial court's decision on the motion in limine.[60] The appellate division affirmed the trial court's decision on the motion in limine with one justice dissenting.[61] The Court of Appeals granted the defendant's leave to appeal and unanimously reversed,[62]with Judge Fahey taking no part in the decision.[63] Although the court considered additional issues on appeal, including the legal sufficiency of the evidence and the admission of a photograph depicting the manner in which the suicide was committed,[64] the remainder of the discussion for the purposes of this *Survey* is limited to the Court of Appeals' decision with respect to the admissibility of the OPMC Consent Order.

Judge Rivera, who authored the opinion, began her discussion with the general principle that a trial court's evidentiary rulings are overturned only where it is determined that the trial court abused its discretion in making the ruling.[65] Although Judge Rivera recognized

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56. *See id.*

57. *See id.*

58. *See id.*

59. *See Mazella*, 27 N.Y.3d at 702–03, 57 N.E.3d at 1088, 37 N.Y.S.3d at 51.

60. *See id.*at 701−02, 57 N.E.3d at 1087−88, 37 N.Y.S.3d at 50−51.

61. *Id.* at 705, 57 N.E.3d at 1090, 37 N.Y.S.3d at 53 (citing Mazella v. Beals, 122 A.D.3d 1358, 1359, 997 N.Y.S.2d 849, 851 (4th Dep't 2014)).

62. *Id.* (citing Mazella v. Beals, 25 N.Y.3d 901, 30 N.E.3d 164, 7 N.Y.S.3d 273 (2015)).

63. *Id.* at 696, 57 N.E.3d at 1084, 37 N.Y.S.3d at 47. Judge Fahey took no part in light of his involvement in the case at the Appellate Division, Fourth Department, where he was a member of the panel that affirmed the decision of the trial court to deny the defendant's motion in limine. *See Mazella*, 122 A.D.3d at 1359, 997 N.Y.S.2d at 851.

64. *Mazella*, 27 N.Y.3d at 705, 57 N.E.3d at 1090, 37 N.Y.S.3d at 53.

65. *See id.*at 709, 57 N.E.3d at 1093, 37 N.Y.S.3d at 56 (quoting People v. Carroll, 95

that the OPMC Consent Order might be "admissible as 'presumptive evidence of the facts stated'" in the Consent Order as a public document, she agreed with the defendant that the OPMC "Consent Order was probative of neither [the] defendant's negligence or the question of proximate cause."[66] Indeed, because the defendant did not consent to the charges with respect to the decedent, Judge Rivera concluded that the defendant had appropriately "preserved his objections to [the] factual allegations" in the Consent Order as they concerned the decedent.[67] Additionally, Judge Rivera determined that the prejudice in admitting the Consent Order outweighed any probative value of the Consent Order because it was evidence of nothing more than unrelated prior bad acts (i.e., "[T]he type of propensity evidence that lacks probative value concerning any material factual issue, and has the potential to induce the jury to decide the case based on evidence of [the] defendant's character.").[68] Judge Rivera further rejected the plaintiff's claim that the Consent Order should be admitted "to impeach [the] defendant's credibility."[69]Collateral matters that bear only on the issue of credibility must be excluded, and admitting them is an abuse of a court's discretion, because such evidence lacks any probative value and "bears only marginal relevance."[70]

Finally, Judge Rivera concluded that admission of the OPMC Consent Order was not harmless error under CPLR 2002[71]:

> Given the multiple allegations of defendant's negligent monitoring of prescription drug treatment, and the numerous patients referenced in the Consent Order, we cannot say that the verdict was not influenced by this powerful evidence of defendant's professional misconduct. Indeed, it is difficult to imagine how a jury could simply ignore that defendant negligently treated 12 other patients for years in a similar manner as decedent, namely failing to monitor them, and that this conduct resulted in OPMC charges leading to its oversight of his

N.Y.2d 375, 385, 740 N.E.2d 1084, 1089, 718 N.Y.S.2d 10, 15 (2013)).

66. *Id.* at 710, 57 N.E.3d at 1093, 37 N.Y.S.3d at 56 (citing N.Y. PUB. HEALTH LAW § 10(2) (McKinney 2012)).

67. *Id.*

68. *Id.* at 710, 57 N.E.3d at 1094, 37 N.Y.S.3d at 57 (citing People v. Arafet, 13 N.Y.3d 460, 464–65, 920 N.E.2d 919, 921, 892 N.Y.S.2d 812, 814 (2009); and then citing Hosmer v. Distler, 150 A.D.2d 974, 975, 541 N.Y.S.2d 650, 652 (3d Dep't 2009)).

69. *See Mazella*, 27 N.Y.3d at 711, 57 N.E.3d at 1094, 37 N.Y.S.3d at 57.

70. *Id.* (first citing Badr v. Hogan, 75 N.Y.2d 629, 635, 554 N.E.2d 890, 893, 555 N.Y.S.2d 249, 252 (1990); and then citing RICHARD FARRELL, PRINCE-RICHARDSON ON EVIDENCE §§ 4-410, 4-501 (11th ed. 1995)).

71. *See id.* (citing N.Y. C.P.L.R. 2002 (McKinney 2012)).

medical practice.[72]

With respect to the aforementioned analysis, Judge Rivera more specifically concluded that the nature and severity of the defendant's alleged misconduct was "not lost" on the plaintiff, inasmuch as counsel for the plaintiff referred to the defendant's numerous acts of negligence during summation to the jury.[73] Therefore, the admission of the OPMC Consent Order was so egregious and prejudicial to the defendant that a new trial was warranted.[74]

The Court of Appeals' decision is a major win for physicians and the medical community. The Court's guidance on the above evidentiary issue reminds trial courts to be judicious in exercising their discretion with respect to admitting evidence of unrelated negligence in medical malpractice cases, even if it is probative of a physician's credibility.[75] Furthermore, if *Mazella* was a case concerning the credentialing of a physician, then evidence of prior instances of medical malpractice and/or professional discipline might be relevant. However, the Court of Appeals has sent a clear message that, in traditional medical malpractice cases, a physician's liability cannot be determined by any prior instances of professional misconduct or medical malpractice.[76] Rather, in light of the Court of Appeals' decision in *Mazella* the determination of a physician's liability must rest solely on the conduct at issue in the particular case, absent unusual circumstances.[77]

C. Myers v. Schneiderman

Although often referred to as physician-assisted suicide, we use the term "aid-in-dying" in this issue of the *Survey* because the current legislation and case law use that new terminology in an attempt to

72. *Id.* at 711, 57 N.E.3d at 1094−95, 37 N.Y.S.3d at 57−58.

73. *Id.* at 712, 57 N.E.3d at 1095, 37 N.Y.S.3d at 58.

74. *See Mazella*, 27 N.Y.3dat 712, 57 N.E.3d at 1095, 37 N.Y.S.3d at 58 (first citing *Badr*, 75 N.Y.2d at 637, 554 N.E.2d at 894, 555 N.Y.S.2d at 253; and then citing Geary v. Church of Saint Thomas Aquinas, 98 A.D.3d 646, 647, 950 N.Y.S.2d 163, 165 (2d Dep't 2012)).

75. *See id.* at 697, 705, 711, 57 N.E.3d at 1085, 1090, 1094, 37 N.Y.S.3d at 48, 53, 57 (first citing *Badr*, 75 N.Y.2d at 635, 554 N.E.2d at 893, 555 N.Y.S.2d at 252; then citing People v. Schwartzman, 24 N.Y.2d 241, 245, 247 N.E.2d 642, 644, 299 N.Y.S.2d 817, 821 (1969); and then citing FARRELL, *supra* note 70, at § 4-410).

76. *See id.* at 697–98, 709, 57 N.E.3d at 1085, 1093, 37 N.Y.S.3d at 48, 56 (first citing Estate of Brandon, 55 N.Y.2d 206, 210–11, 433 N.E.2d 501, 503, 448 N.Y.S.2d 436, 438 (1982); then citing JEROME PRINCE, RICHARDSON ON EVIDENCE §§ 170, 184 (10th ed. 1973); and then citing Coopersmith v. Gold, 89 N.Y.2d 957, 959, 678 N.E.2d 469, 470, 655 N.Y.S.2d 857, 858 (1997)).

77. *See id.*at 705–06, 710, 57 N.E.3d at 1090, 1093, 37 N.Y.S.3d at 53, 56.

create a distinction between physician-assisted suicide and aid-in-dying, which is argued to be similar to a patient refusing life-saving treatment.[78] In the seminal physician-assisted suicide decision from the U.S. Supreme Court, *Vacco v. Quill*, the Supreme Court held that New York's prohibition on physician-assisted suicide (as referred to in the case) through the prescription of a lethal medication to "a mentally competent, terminally-ill" patient did not violate the Equal Protection Clause of the Fourteenth Amendment of the United States.[79]

Here, we review New York's most recent decision on aid-in-dying. On May 3, 2016, the Appellate Division, First Department decided *Myers v. Schneiderman*.[80] The plaintiffs included a terminally ill individual, an individual with an illness that could become terminal, five medical professionals who regularly treated patients with terminal illnesses, and End of Life Choices New York, a nonprofit organization providing "clients with information and counseling on informed choices in end-of-life decision-making."[81] The crux of the plaintiffs' arguments in *Myers* was that physicians who assisted patients in hastening their deaths through the use of lethal doses of prescription medications should not be criminally prosecuted under New York State Penal Law.[82] In fact, in their complaint before the trial court, the plaintiffs asserted that the physician plaintiffs were deterred from assisting terminally ill patients in dying when the patients, who were mentally competent, had no chance of recovering from the illness.[83]

Although somewhat unclear, the plaintiffs have assumed that a physician would be prosecuted under Penal Law § 120.30, Promoting a Suicide Attempt; and Penal Law § 125.15, Manslaughter in the Second Degree.[84] At present, section 120.30 states that "[a] person is guilty of promoting a suicide attempt when he intentionally causes or aids another person to attempt suicide."[85] Promoting a suicide attempt is a class E felony.[86] Section 125.15(3) states that "[a] person is guilty of manslaughter in the second degree when . . . [h]e intentionally causes or

78. *See* Vacco v. Quill, 521 U.S. 793, 798 (1997) (citing Quill v. Koppell, 870 F. Supp. 78, 84–85 (S.D.N.Y. 1994)).

79. *Id.* at 798–99, 808.

80. 140 A.D.3d 51, 54, 56, 31 N.Y.S.3d 45, 48, 65 (1st Dep't 2016).

81. *Id.* at 54, 31 N.Y.S.3d at 47.

82. *See id.*at 54, 31 N.Y.S.3d at 47–48.

83. Myers v. Schneiderman (*Myers I*), No. 151162/15, 2015 Slip Op. 31931(U), at 3 (Sup. Ct. N.Y. Cty. Oct. 16, 2015).

84. *Myers II*, 140 AD3d at 54; *Myers I*, 2015 NY Slip Op 31931(U), at 2.

85. N.Y. PENAL LAW §120.30 (McKinney 2009).

86. *Id.*

aids another person to commit suicide."[87] Manslaughter in the second degree is a class C felony.[88]

The New York State Attorney General moved to dismiss the plaintiffs' complaint under CPLR 3211(a)(2) and (7), and the trial court granted the Attorney General's motion.[89] Although the trial court disagreed with the Attorney General that the plaintiffs' claims were not justiciable and that the plaintiffs lacked the standing to sue, "it rejected [the] plaintiffs' claim that the Penal Law should be interpreted not to apply to aid-in-dying, stating that the Penal Law as written is clear and concise, rendering unnecessary any resort to an analysis of its legislative history."[90] The trial court concluded that *Vacco*, in which the U.S. Supreme Court recognized New York's distinction between the right to refuse life-saving medical treatment and the right to receive assistance to commit suicide, controlled the plaintiffs' constitutional claims.[91]

On appeal, the plaintiffs argued that the trial court erred in dismissing their complaint because the trial court lacked the authority

> to disregard factual statements pronouncing, for example, that professional organizations such as the American Public Health Association do not consider aid-in-dying to be equivalent to suicide, and that death certificates in Oregon and Washington, where aid-in-dying has been deemed lawful, list the cause of death as the underlying disease causing the patient's suffering, not the lethal medication administered to him or her.[92]

In fact, the plaintiffs argued that aid-in-dying is akin to a patient's right to refuse life-saving medical treatment, such as terminal sedation.[93] Furthermore, the plaintiffs asserted on appeal that aid-in-dying, as opposed to physician-assisted suicide, relates to an individual's "fundamental" right to self-determination over his or her own body and therefore, to the extent that the Penal Law would apply to aid-in-dying, the laws must be "strictly scrutinized" and may be enforced with respect to aid-in-dying only where there is a "compelling

87. N.Y. PENAL LAW §125.15(3) (McKinney 2009).

88. *Id.* at § 125.15.

89. *Myers II*, 140 A.D.3d 51, 55, 31 N.Y.S.3d 45, 48 (1st Dep't 2016).

90. *Id.*

91. *Myers I*, No. 151162/15, 2015 Slip Op. 31931(U), at 10–11 (Sup. Ct. N.Y. Cty. Oct. 16, 2015) (first citing *In re* Bezio v. Dorsey, 21 N.Y.3d 93, 101, 989 N.E.2d 942, 947–48, 967 N.Y.S.2d 660, 665–66 (2013); and then citing Vacco v. Quill, 521 U.S. 793, 808 (1997)).

92. *Myers II*, 140 A.D.3d at 55, 62, 31 N.Y.S.3d at 48, 53.

93. *Id.* at 55, 31 N.Y.S.3d at 48–49; Ben Bedell, *Panel Refuses to Legalize 'Aid in Dying' Procedures*, N.Y.L.J. (May 4, 2016), http://www.newyorklawjournal.com/id=1202756687361/Panel-Refuses-to-Legalize-Aid-in-Dying-Procedures.

state interest" to do so.[94] Finally, the plaintiffs asserted that the trial court erred in distinguishing between equal protection and substantive due process and considered aid-in-dying under only the United States Constitution rather than the New York State Constitution, which affords greater protections.[95]

In deciding the appeal, the First Department construed the plain meaning of "suicide" and determined that there is no difference between knowingly and voluntarily preferring death over life and aid-in-dying to prevent an unbearably painful, but certain, death.[96] The First Department provided a nice overview of the Court of Appeals' jurisprudence in the area of physician-assisted suicide and aid-in-dying. In *People v. Duffy*, the Court of Appeals determined that it was considered assisting suicide when the defendant "recklessly encourag[ed] a 17-year-old youth to shoot himself to death after the youth became distraught by a failed romance."[97] Although the defendant had argued that Penal Law § 125.15(3) (manslaughter in the second degree) did not apply to allegedly reckless conduct, the Court of Appeals in *Duffy* determined that a person is still guilty of second-degree manslaughter even where the defendant was motivated by humanitarian or "'sympathetic' concerns, such as the desire to relieve a terminally ill person from the agony of a painful disease."[98]

Therefore, the First Department determined that there was nothing permitting the court to ignore the plain language of Penal Law §§ 120.30 and 125.15 just because the plaintiffs believed that the State Legislature would have made an exception for aid-in-dying if given a chance. However, the court determined that, to the extent that there are omissions to the state statutes, those are questions of construction for the State Legislature and not the courts.[99] Based on that principle and an understanding "of the plain meaning of the term suicide," the court determined that, "as a matter of statutory construction, . . . Penal Law

94. *Myers II*, 140 A.D.3d at 56, 31 N.Y.S.3d at 49.

95. *See id.*at 56, 60, 31 N.Y.S.3d at 49, 52 (first citing *Vacco*, 521 U.S. at 797; then citing Hernandez v. Robles, 7 N.Y.3d 338, 361–62, 855 N.E.2d 1, 10, 821 N.Y.S.2d 770, 778 (2006); and then citing Obergefell v. Hodges, 135 S. Ct. 2584 (2015)).

96. See *id.* at 57, 31 N.Y.S.3d at 50.

97. *Id.* (citing People v. Duffy, 79 N.Y.2d 611, 613, 595 N.E.2d 814, 815, 584 N.Y.S.2d 739, 740 (1992)).

98. *Duffy*, 79 N.Y.2d at 614–15, 595 N.E.2d at 815–16, 584 N.Y.S.2d at 740–41 (quoting N.Y. State Comm'n on Revision of Penal Law & Crim. Code, *Commission Staff Notes on the Proposed New York Penal Law*, in PROPOSED N.Y. PENAL LAW §130.25, at 339 (McKinney's spec. pamphlet 1964)) (citing N.Y. PENAL LAW §125.15(3) (McKinney 2009)).

99. *See Myers II*, 140 A.D.3d at 58, 31 N.Y.S.3d at 50.

sections120.30 and 125.15 prohibit aid-in-dying."[100] With respect to the plaintiffs' constitutional claims (i.e., that prohibiting aid-in-dying violates an individual's equal protection and due process rights), the U.S. Supreme Court, in *Vacco*, already held that a ban on aid-in-dying did not violate such constitutional rights.[101]

In any event, the First Department also determined that New York's Equal Protection Clause is "no broader in coverage" than federal equal protection.[102] Although New York has long held that an individual's right to freedom of choice with respect to his or her body is paramount to the State's prerogatives except in compelling circumstances, the First Department held that the plaintiffs failed to meet their burden in demonstrating how the principles at the root of one's informed consent, or choice, to undergo a medical procedure or to refuse life-saving medical treatment apply to the affirmative decision to take one's own life.[103]

The First Department appears to have sidestepped the issue concerning the constitutionality of aid-in-dying under the New York Constitution when it stated that the plaintiffs' arguments are conclusory and they deliberately decided not to engage in the aid-in-dying discussion.[104] Even if, as the plaintiffs contended, the right to aid-in-dying is not a fundamental one, New York need only demonstrate that its ban on the practice "is rationally related to a legitimate government interest," which the U.S. Supreme Court already did in *Vacco*.[105] The Court also noted that the position against legalizing aid-in-dying had not changed for the American Medical Association, which has been that "'physician-assisted suicide is fundamentally incompatible with the physician's role as healer.'"[106]

In light of the foregoing, the First Department held that it was not convinced that a legitimate consensus had been reached on the subject of aid-in-dying/physician-assisted suicide and that, in any event, it was not for the court to rewrite the law or to say that a law violates a fundamental human right when neither the U.S. Supreme Court nor the

100. *Id.* at 58, 31 N.Y.S.3d at 51.

101. *Id.* at 59, 31 N.Y.S.3d at 51 (citing Vacco v. Quill, 521 U.S. 793, 797 (1997)).

102. *Id.* at 60, 31 N.Y.S.3d at 52 (quoting Hernandez v. Robles, 7 N.Y.3d 338, 362, 855 N.E.2d 1, 9, 821 N.Y.S.2d 770, 778 (2006)).

103. *See id.*at 60–61, 31 N.Y.S.3d at 52.

104. *See Myers II*, 140 A.D.3d at 61, 31 N.Y.S.3d at 52–53 (citing *In re* Bezio v. Dorsey, 21 N.Y.3d 93, 103, 989 N.E.2d 942, 949, 967 N.Y.S.2d 660, 667 (2013)).

105. *Id.* at 61, 31 N.Y.S.3d at 53 (citing *Vacco*, 521 U.S. at 808–09).

106. *Id.* at 62–63, 31 N.Y.S.3d at 53–54 (quoting Washington v. Glucksberg, 521 U.S. 702, 731 (1997)).

New York Court of Appeals has stated otherwise.[107] The court expressly indicated that it would "defer to the political branches of government on the question of whether aid-in-dying should be considered a prosecutable offense."[108]

The First Department's decision needs little interpretation—it has sent an unequivocal message regarding aid-in-dying. Courts do not legislate and, without express legislation distinguishing aid-in-dying from physician-assisted suicide, the courts can only enforce the law as it stands, however unequal and unjust that law is perceived to be.[109] Aid-in-dying is no exception.[110] There have been numerous challenges as to the constitutionality of the prohibition on aid-in-dying, as cited by the First Department in *Myers*.[111] Although New York has been working on new legislation to permit physicians to aid a patient in dying under certain circumstances, passing the legislation has proved difficult as indicated below.

II. FEDERAL CASE LAW

A. Zubik v. Burwell

Following the death of Justice Scalia, on March 23, 2016, the U.S. Supreme Court revisited the issue of insurance coverage for contraceptives under the ACA.[112] Under 45 C.F.R. § 147.130, women enrolled in group or student health insurance plans are guaranteed coverage for FDA approved contraception prescribed by a health care provider.[113] An exemption from this provision exists for religious employers, who are not obligated to provide coverage for contraception.[114]

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107. *Id.* at 65, 31 N.Y.S.3d at 55.

108. *Id.*

109. *Myers II*, 140 A.D.3d at 53, 58, 65, 31 N.Y.S.3d at 47, 50–51 (first citing MCKINNEY'S CONSOLIDATED LAWS OF N.Y., BOOK 1, STATUTES, § 363 (1971); and then citing People v. Boothe, 16 N.Y.3d 195, 198, 944 N.E.2d 1137, 1139, 919 N.Y.S.2d 498, 500 (2011)).

110. *Id.* at 58, 31 N.Y.S.3d at 50–51 (first citing MCKINNEY'S CONSOLIDATED LAWS OF N.Y., BOOK 1, STATUTES, § 363; and then citing *Boothe*, 16 N.Y.3d at 198, 944 N.E.2d at 1139, 919 N.Y.S.2d at 500).

111. *Id.* at 61, 31 N.Y.S.3d at 53 (first citing Vacco v. Quill, 521 U.S. 793, 797 (1997); and then citing *Glucksberg*, 521 U.S. at 708).

112. *See generally* Zubik v. Burwell (*Zubik I*), 194 L. Ed. 2d 599 (2016) (directing parties to file briefs addressing how employees of the petitioners may acquire contraceptive coverage).

113. 45 C.F.R. § 147.130(a)(1)(iv) (2016).

114. *See* 45 C.F.R. § 147.131(a) (2016) ("[A] 'religious employer' is an organization that is organized and operates as a nonprofit entity and is referred to in section

Similarly, an "accommodation" exists for other "eligible organizations" that oppose contraceptive coverage on religious grounds.[115] Originally, eligible organizations consisted solely of nonprofit entities holding themselves out as religious organizations.[116] After *Burwell v. Hobby Lobby*, the final rule was modified and the definition of "eligible organizations" was expanded to include closely held for-profit corporations objecting to the mandate on religious grounds.[117]

Under the accommodation, an eligible organization can notify either its insurer or the Secretary of Health and Human Services (HHS) in writing of its objection on religious grounds to providing coverage.[118] If the insurer is directly notified, the insurer then has "sole responsibility" for providing coverage for contraceptive services in compliance with 45 C.F.R. § 147.30.[119] If the Secretary of HHS is notified, then the Department of HHS will send notification to the insurer describing its obligations to provide coverage.[120] Rather than have coverage provided through the eligible organization's plan, instead, the insurer provides separate coverage at no extra cost.[121] The eligible organization is thus relieved of its obligation to contract, arrange, pay, or refer for contraceptive coverage as mandated by 45 C.F.R. § 147.130.

In *Zubik v. Burwell*, a consolidation of a series of cases decided by the intermediate appellate courts,[122] the petitioner nonprofit organizations challenged the accommodation.[123] The petitioners alleged

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6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.").

115. *See id.* § 147.131(b).

116. *See* Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2763 (2014) (citing 45 C.F.R. § 147.131(b)).

117. *Id.* at 2779 (finding that a substantial burden was imposed on the religious exercise of for-profit corporations, which were required to either provide health insurance coverage for contraception in violation of their religious beliefs or pay a fine); 45 C.F.R. § 147.131(b)(2)(ii).

118. 45 C.F.R. § 147.131(b)(3).

119. *Id.* § 147.131(c)(1)(i).

120. *Id.* § 147.131(c)(1)(ii).

121. *Id.* § 147.131(c)(2)(i).

122. Geneva Coll. v. Burwell, 136 S. Ct. 445 (2015); Little Sisters of the Poor Home for the Aged v. Burwell, 794 F.3d 1151 (10th Cir. 2015), *vacated and remanded by* 136 S. Ct. 1557 (2016); E. Tex. Baptist Univ. v. Burwell, 793 F.3d 449 (5th Cir. 2015), *vacated and remanded by* Univ. of Dall. v. Burwell, 136 S. Ct. 2008 (2016); Geneva Coll. v. Sec'y U.S. Health & Human Servs., 778 F.3d 422 (3d Cir. 2015), *vacated and remanded by* 136 S. Ct. 1557 (2016); Priests for Life v. U.S. Health & Human Servs., 772 F.3d 229 (D.C. Cir. 2014), *vacated and remanded by* 136 S. Ct. 1557 (2016).

123. 136 S. Ct. 1557, 1559 (2016).

that it burdened the exercise of their religion in violation of the Religious Freedom Restoration Act of 1993 (RFRA).[124] Under RFRA, the federal government cannot "substantially burden" the exercise of religion, even if the government action is of general applicability, unless it is the least restrictive means of achieving a compelling government interest.[125] Because the petitioners were required to notify either their insurer or the HHS so that female employees would still have access to insurance coverage for contraceptives, the petitioners argued that this notification is akin to substitute coverage since they are still required to ensure that their female employees have access to contraception.[126]

At the intermediate courts, the Third Circuit held that the accommodation did not place a substantial burden on the plaintiffs.[127] The Fifth Circuit found that the plaintiffs failed to show, "and are not likely to show" that the accommodation substantially burdens their religious exercise.[128] The Tenth Circuit held that the accommodation did not substantially burden the plaintiffs' religious exercise.[129] The D.C. Circuit found that the accommodation did not substantially burden the plaintiffs' religious exercise and that it survived strict scrutiny.[130]

At the U.S. Supreme Court, on March 29, 2016, after oral arguments, the Court ordered supplemental briefing to determine whether contraceptive coverage could be provided without notice from the petitioners to the insurer or Secretary of HHS.[131] As the Court instructed,

> [T]he parties should consider a situation in which petitioners would contract to provide health insurance for their employees, and in the course of obtaining such insurance, inform their insurance company that they do not want their health plan to include contraceptive coverage of the type to which they object on religious grounds. Petitioners would have no legal obligation to provide such contraceptive coverage, would not pay for such coverage, and would not be required to submit any separate notice to their insurer, to the Federal Government, or to their employees. At the same time, petitioners' insurance company—aware that petitioners are not

124. *Id.*

125. Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1 (2012).

126. *Little Sisters*, 794 F.3d at 1168–69; *E. Tex. Baptist Univ.*, 793 F.3d at 455; *Geneva Coll.*, 778 F.3d at 432, 437; *Priests for Life*, 772 F.3d at 237.

127. *Geneva Coll.*, 778 F.3d at 427.

128. *E. Tex. Baptist Univ.*, 793 F.3d at 452.

129. *Little Sisters*, 794 F.3d at 1160.

130. *Priests for Life*, 772 F.3d at 237.

131. *Zubik II*, 136 S. Ct. 1557, 1559–60 (2016) (citing *Zubik I*, 194 L. Ed. 2d 599, 599 (2016)).

> providing certain contraceptive coverage on religious grounds—would separately notify petitioners' employees that the insurance company will provide cost-free contraceptive coverage, and that such coverage is not paid for by petitioners and is not provided through petitioners' health plan.[132]

In their supplemental brief, the petitioners admitted that their religious exercise is not infringed where they merely contract for a plan that does not provide contraceptive coverage, even if their employees received contraceptive coverage from the same insurance company.[133] The Court, however, refrained from making a decision on the merits.[134] Instead, in a decision dated May 16, 2016, the Court merely vacated the judgments below and remanded to the intermediate appellate courts in each respective case with the direction that the parties must be afforded the "opportunity to arrive at an approach going forward that accommodates [the] petitioners' religious exercise while at the same time ensuring that women covered by [the] petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'"[135]

Justice Sotomayor, joined by Justice Ginsburg, concurred to further emphasize that the Court's opinion expresses no view on the merits of the case.[136] In this sense, neither the opinion, nor the order dated March 29, 2016, should be construed as instructive of the Court's position on the issue.[137] Justice Sotomayor reiterated that the lower courts were only to consider whether existing or modified regulations could provide contraceptive coverage to the petitioners' employees without any notice from the petitioners.[138] In this sense, the Court's decision was not to be construed to mean that the notice requirement burdens the petitioners' religious exercise or that coverage for contraceptives must be a separate policy.[139]

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132. *Zubik I*, 194 L. Ed. 2d at 599.

133. *Zubik II*, 136 S. Ct. at 1560 (citing Supp. Brief for Petitioner at 4, *Zubik II*, 136 S. Ct. 1557 (Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, 15-191), 2016 U.S. S. Ct. Briefs LEXIS 1631, at *6).

134. *Id.* ("In particular, the Court does not decide whether petitioners' religious exercise has been substantially burdened, whether the Government has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest.").

135. *Id.* (citing Supp. Brief for Respondents at 1, *Zubik II*, 136 S. Ct. 1557 (Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, 15-191), 2016 U.S. S. Ct. Briefs LEXIS 1632, at *4).

136. *Id.* at 1561 (Sotomayor, J., concurring).

137. *Id.*

138. *Zubik II*, 136 S. Ct. at 1561 (Sotomayor, J., concurring) (citing *Zubik II*, 136 S. Ct. at 1559–60 (majority opinion)).

139. *Id.* (first citing Supp. Brief for Petitioner, *supra* note 133, at 1; and then citing

In light of the Court's refusal to decide this case on the merits as well as the election of Donald Trump in 2016, who subsequently appointed Neil Gorsuch to the Supreme Court,[140] the future of the accommodation as applicable to nonprofit organizations as well as closely-held for-profit corporations, not to mention the ACA as a whole, is uncertain.

B. United States ex rel. Polansky v. Pfizer, Inc.

The Second Circuit recently examined whether a pharmaceutical company violated the False Claims Act in marketing Lipitor, a statin used to treat high cholesterol, beyond guidelines referenced in the drug's label, thus causing the submission of false claims for reimbursement.[141]Pursuant to the Federal Food, Drug and Cosmetic Act, a pharmaceutical company cannot market or sell a drug until it obtains approval from the Food and Drug Administration (FDA) that the drug is safe for its intended use.[142] Any use not explicitly outlined in the label is considered an off-label use.[143]

In *United States ex rel. Polansky v. Pfizer, Inc.*, the defendant pharmaceutical company previously used a label that cited the National Cholesterol Education Program Guidelines ("Guidelines").[144] The plaintiff former employee argued that while the Guidelines were not cited in full in the label, they were nonetheless incorporated into and made mandatory by the drug's label.[145] The Guidelines outlined the ranges of cholesterol levels within which consumers should ingest the drug.[146]

A pharmaceutical company is generally prohibited from promoting an off-label use if the off-label marketing is false or misleading or if it shows that the drug is intended for such off-label use and is thus

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Supp. Reply Brief for Petitioner at 5, *Zubik II*, 136 S. Ct. 1557 (Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, 15-191), 2016 U.S. S. Ct. Briefs LEXIS 1714, at *7).

140. *See* Ariane de Vogue, *President Trump Nominates Neil Gorsuch for Supreme Court*, CNN, http://www.cnn.com/2017/01/31/politics/donald-trump-supreme-court-nominee/ (last updated Feb. 1, 2017, 5:05 AM).

141. *Polansky III*, 822 F.3d 613, 614 (2d Cir. 2016).

142. *Id.* at 615 (first citing 21 U.S.C. § 355(a), (d) (2012); then citing United States v. Caronia, 703 F.3d 149, 152–53 (2d Cir. 2012); and then citing 21 U.S.C. § 393(b)(2)(B) (2012)).

143. *Id.*

144. *Id.* at 614. It later changed its label in 2009, removing reference to the Guidelines. *Id.* at 617 (citing 21 C.F.R. § 201.57(a)(5) (2016)).

145. *Polansky III*, 822 F.3d at 618.

146. *Id.* at 616–17.

misbranded.[147] In general, Medicaid does not cover off-label uses.[148] According to the plaintiff, the defendant pharmaceutical company was advertising Lipitor beyond the framework outlined in the Guidelines.[149] This marketing caused the medical providers to submit the prescription for reimbursement in instances outside the Guidelines' framework, thus falsely implying that the prescription was for an on-label use.[150] This, the plaintiff alleged, constituted a false claim under the False Claims Act, which imposes liability on any person that knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval to the United States government.[151] The plaintiff's argument thus rested on two contentions: that the Guidelines were incorporated into the label and that requests for reimbursement of Lipitor prescriptions impliedly certified that the prescription was for an on-label use so that the defendant pharmaceutical company was causing the submission of false claims.[152]

The Eastern District of New York initially dismissed the complaint because, as a fraud claim, it was not pled with the requisite particularity.[153] The Eastern District then dismissed the plaintiff's amended complaint, finding that the label did not incorporate the Guidelines and thus did not require compliance with the Guidelines.[154] The plaintiff appealed to the Second Circuit on this question.[155]

The Second Circuit affirmed.[156] The court found that the Guidelines were not incorporated into the label and were thus not mandatory requirements: We "cannot accept plaintiff's theory that what the scientists at the National Cholesterol Education Program clearly

147. *Id.* at 615.

148. *Id.* (first citing 42 U.S.C. § 1396r-8(k)(2), (3), (6) (2012); then citing 42 U.S.C. § 1395w-102(e)(1), (4) (2012); and then citing 42 U.S.C. §1396r-8(d)(1)(B)(i)).

149. *Id.* at 616.

150. *Polansky III*, 822 F.3d at 616.Pursuant to *United States ex rel. Mikes v. Straus*, claims submitted to the government are "legally false" where the "party certifies compliance with a statute or regulation as a condition to governmental payment."274 F.3d 687, 697 (2d Cir. 2001) (citing United States *ex rel.* Siewick v. Jamieson Sci. & Eng'g, Inc.,214 F.3d 1372, 1376 (D.C. Cir. 2000)). Certification can be implied where it is expressly mandated that a provider comply with the statute or regulation in order to be paid. *Id.* at 700 (citing *Siewick*, 214 F.3d at 1376).

151. *Polansky III*, 822 F.3d at 616; *see also* 31 U.S.C. § 3729(a)(1)(A) (2012).

152. *Polansky III*, 822 F.3d at 618.

153. United States *ex rel.* Polansky v. Pfizer, Inc. (*Polansky I*), No. 04-cv-0704 (ERK), 2009 U.S. Dist. LEXIS 43438, at *5–10 (E.D.N.Y. May 22, 2009).

154. United States *ex rel.* Polansky v. Pfizer, Inc. (*Polansky II*), 914 F. Supp. 2d 259, 266 (E.D.N.Y. 2012).

155. *Polansky III*, 822 F.3d at 614.

156. *Id.* at 618.

intended to be advisory guidance is transformed into a legal restriction simply because the FDA has determined to pass along that advice through the label."[157] The court found that the Guidelines were merely guidance not to surpass the judgment of a physician.[158] Furthermore, the court noted that while the label explicitly restricted use for pediatric patients, the same restriction was wholly absent for adult patients.[159] The Second Circuit found that since the defendant pharmaceutical company could have just as easily placed a restriction for adults, its absence is all the more "conspicuous."[160] Thus, because the Guidelines were not incorporated into the label and merely served as additional guidance, marketing Lipitor outside of the Guidelines did not constitute the promotion of off-label use.[161]

The Second Circuit refrained from addressing whether submitting a drug for reimbursement was an implied certification that it was prescribed for an on-label use.[162] The court commented that it was skeptical of this claim since it was unclear whom the defendant pharmaceutical company caused to submit a false claim: "The physician is permitted to issue off-label prescriptions; the patient follows the physician's advice, and likely does not know whether the use is off-label; and the script does not inform the pharmacy at which the prescription will be filled whether the use is on-label or off."[163] Nonetheless, the court was explicit that this case was not decided on this ground.[164] The Second Circuit suggested, however, that this argument may be successful in a case where the drug is marketed for something "obviously not contemplated by the label," such as Lipitor being used for hair growth or to cure cancer.[165] It cannot work, though, in instances where the drug is marketed for its FDA-approved purpose to a group

157. *Id.* at 614, 618–19 (citing Polansky II, 914 F. Supp. 2d at 265).

158. *Id.* at 618.

159. *Id.* at 619.

160. *Polansky III*, 822 F.3d at 619 (citing Polansky II, 914 F. Supp. 2d at 263).

161. *Id.* (quoting *Polansky II*, 914 F. Supp. 2d at 263, 265).

162. *Id.*

163. *Id.* at 619–20 ("[B]ecause the FDA has expressly advised physicians that, 'unlabeled uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature,' and because physicians 'commonly exercise professional medical judgment and prescribe drugs for uses not within the indications articulated by the FDA,' the entities to which reimbursement claims are made could hardly be understood to have operated on the assumption that the physician writing the prescription was certifying implicitly that he was prescribing Lipitor in a manner consistent with the Guidelines.").

164. *Id.*

165. *Polansky III*, 822 F.3dat 620 (quoting *Polansky II*, 914 F. Supp. 2d at 265).

neither specified nor excluded in the label.[166]

While the Second Circuit did not decide this case on the off-label use question, its opinion on this issue has significant implications going forward. This case was decided following a similar question presented in *United States v. Caronia*.[167] In that case, the defendant pharmaceutical sales representative promoted off-label uses of a certain drug.[168] He was charged with both conspiring to introduce and introducing a misbranded drug into interstate commerce in violation of the Food, Drug, and Cosmetic Act (FDCA).[169] The Second Circuit found that while the FDCA criminalizes misbranding or conspiring to misbrand the drug, it does not criminalize off-label promotion.[170] The Second Circuit emphasized that criminalizing off-label promotion raises First Amendment concerns.[171]The court also noted how physicians are permitted to prescribe the drug for off-label uses.[172] In this sense, while the "outcome" of off-label uses is permissible through a physician, it seems contradictory to prohibit the "free flow of information" behind such an outcome.[173]

The *Polansky* court cited the *Caronia* court's justification of physicians prescribing off-label uses in support of its opinion on the implied certification question.[174] While the *Polansky* court provided some boundaries in prohibiting off-label uses "obviously not contemplated by the label,"[175] both opinions seemingly provide leeway for pharmaceutical companies in regard to off-label uses of its drugs.[176]

166. *Id.* (citing *Polansky II*, 914 F. Supp. 2d at 265).

167. *See* 703 F.3d 149, 152 (2d Cir. 2012).

168. *Id.* at 152, 156.

169. *Id.* at 157 (first citing 21 U.S.C. § 331(a) (2012); and then citing 21 U.S.C. § 333(a)(2) (2012)).

170. *Id.* at 160.

171. *Id.*; *see* Sorrell v. IMS Health, Inc., 564 U.S. 552, 557 (2011) ("Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment."). Here, he was prosecuted for his constitutionally protected speech, the restriction of which could not survive heightened scrutiny. *Caronia*, 703 F.3d at 164.

172. *Caronia*, 703 F.3d at 166.

173. *Id.* at 167. ("[T]he government's construction of the FDCA's misbranding provisions does not directly advance its interest in reducing patient exposure to off-label drugs or in preserving the efficacy of the FDA drug approval process because the off-label use of such drugs continues to be generally lawful.").

174. *Polansky III*, 822 F.3d 613, 615 (2d Cir. 2016) (first citing *Caronia*, 703 F.3d at 153; and then citing 21 U.S.C. § 396 (2012)).

175. *Id.* at 615, 620.

176. *See id.*at 614–15; *Caronia*, 703 F.3d at 152.

C. American Psychiatric Ass'n v. Anthem Health Plans, Inc.

The Second Circuit recently fortified *Lexmark International, Inc. v. Static Control Components, Inc.*[177] and its proposition that whether a cause of action exists under a statute is a separate consideration from determining whether a party has standing to sue such that prudential standing principles cannot apply to the former consideration.[178] In *American Psychiatric Ass'n v. Anthem Health Plans, Inc.*, psychiatrists and professional associations of psychiatrists brought suit against the defendant health insurance companies alleging that the insurance companies' reimbursement practices discriminate against patients with mental health and substance abuse disorders in violation of the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)[179] and breach the insurers' fiduciary duties under section 502(a)(3) of the Employee Retirement Income Security Act of 1974 (ERISA).[180] The plaintiffs alleged that mental health providers are reimbursed at lower rates than other providers for other services, which causes mental health providers to refuse to accept insurance benefits.[181] Since patients are limited in their access to necessary services, they are forced to change providers frequently so that the disparity inhibits their treatment.[182]

The psychiatrists brought suit pursuant to ERISA on behalf of their patients with one psychiatrist, Dr. Savulak, claiming to be an assignee of two of her patients.[183] The professional associations brought suit on behalf of the members and the members' patients as well.[184] The District Court of Connecticut dismissed the case, holding that the psychiatrists failed to assert a constitutional claim on behalf of their patients to confer constitutional standing [185]and that they lacked a cause

177. 134 S. Ct. 1377, 1383 (2014) (citing 15 U.S.C. § 1125(a) (2012)).

178. Am. Psychiatric Ass'n v. Anthem Health Plans, Inc., 821 F.3d 352, 360 (2d Cir. 2016) (citing *Lexmark*, 134 S. Ct. at 1387–88).

179. In general, the MHPAEA prohibits treating coverage for mental health services different from coverage for other medical and surgical services. *Id.* at 355 (citing 29 U.S.C. § 1185(a) (2012)).

180. *Id.* at 355–56, 360 (citing 29 U.S.C. § 1132(a)(1) (2012) ("A civil action may be brought (1) by a participant, beneficiary, or fiduciary (A) to enjoin any act or practice which violates any provision of this title or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this title or the terms of the plan . . . .")).

181. *Id.* at 356.

182. *Id.*

183. *Anthem Health Plans*, 821 F.3d at 355–56.

184. *Id.* (first citing 29 U.S.C. § 1132(a)(1); and then citing 29 U.S.C. § 1185(a) (2012)).

185. To have constitutional standing, a party must show that it suffered an injury in fact, that there is a causal connection between the injury and conduct, and that it is likely that the

of action under ERISA such that the court did not have jurisdiction to hear their claims.[186] Furthermore, because the associations' members lacked standing, the associations similarly did not have standing.[187] Plaintiffs appealed to the Second Circuit, which limited its analysis to determining whether the plaintiffs had standing and whether they had a cause of action under ERISA, two separate considerations pursuant to *Lexmark*.[188]

The Second Circuit agreed and found that while the psychiatrists could have constitutional standing in asserting a claim for themselves due to having a financial stake in the reimbursement amount, which they failed to assert, they could not assert a cause of action under ERISA because they were not among the enumerated groups identified in the statute.[189] Congress explicitly codified in ERISA that only participants, beneficiaries, or fiduciaries could enforce the statute.[190] The plaintiffs in this case were none of these eligible classes and were claiming a cause of action on behalf of their members and patients, which were encompassed in the statute.[191] The Second Circuit explained that while prudential standing principles[192] may have allowed a third party action had the physicians asserted a constitutional claim on behalf of their patients, those principles are inapplicable for stating a cause of action pursuant to a statute: under *Lexmark*, courts "cannot expand the congressionally-created statutory list of those who may bring a cause of action by importing third-party prudential considerations" since standing is a separate consideration from whether the party has a cause of action.[193] Thus, the Second Circuit held, "The psychiatrists here lack a cause of action under ERISA's § 502(a)(3), irrespective of whether they may stand in the shoes of their patients in other matters."[194]

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injury would be redressed by a favorable decision. *Id.* at 358 (citing Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992)).

186. *Id.* at 356–57.

187. *Id.* at 357.

188. *Anthem Health Plans,* 821 F.3d at 357.

189. *Id.*at 359 (citing Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992)).

190. *Id.* at 360 (citing 29 U.S.C. § 1132(a)(3) (2012)).

191. *Id.*at 360.

192. Prudential standing concerns judicially self-imposed limits to help define constitutional standing. Generally, individuals cannot assert the legal rights of another; however, in instances where a close relationship exists between a third party and an injured party that bars the injured party from asserting its own interest, then the third party may be able to assert that party's claim pursuant to prudential standing principles. This includes physicians, who can assert the constitutional rights of their patients. *Id.* at 358–60.

193. *Anthem Health Plans*, 821 F.3d at 360(citing Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1388 (2014)).

194. *Id.* at 360 (first citing 29 U.S.C. § 1132(a)(3); and then citing Connecticut v.

Turning to Dr. Savulak, the court found that since there was no consideration, the assignment was not valid.[195] Typically, assignment cases are acceptable where the beneficiary assigns a claim in exchange for healthcare benefits.[196] However, because there was no such consideration here, Dr. Savulak similarly had no cause of action.[197]

Finally, since the members of the professional psychiatric associations lacked standing for failing to assert their own Article III injuries, the associations similarly lacked standing.[198] The Second Circuit notes that while the members could have sued for the restrictions imposed on their ability to provide care, this claim was not alleged and no plaintiffs were members.[199] Therefore, the Second Circuit affirmed the District Court of Connecticut dismissing the lawsuit in its entirety.[200]

This case raises important considerations regarding what claims a provider may assert on behalf of his or her patients. Notably, physicians paved the way for changes in abortion law.[201] However, the Second Circuit is clear that while the class of individuals that may bring constitutional claims can be expanded through prudential standing principles, claims pursuant to statutes are limited to the class of individuals identified in the statute.[202] When a statute controls a claim that a patient could bring, he or she must either bring the claim or properly assign the claim to his or her provider.[203] In clarifying that prudential standing principles cannot apply to determine whether a party has a cause of action pursuant to *Lexmark*, *American Psychiatric Ass'n* fortifies that the claims providers may bring on behalf of their patients are limited.

Physicians Health Servs. of Conn., Inc., 287 F.3d 110, 120 (2d Cir. 2002)).

195. *Id.* at 361.

196. *Id.*

197. *Anthem Health Plans*, 821 F.3d at 361–62.

198. *Id.* at 362 (citing Hunt v. Wash. State Apple Advert. Comm'n, 432 U.S. 333, 343 (1977) (holding an association may bring a claim on behalf of its members where its members would have standing if they brought the claim, the interests at issue in the suit are germane to the purpose of the association, and "neither the claim asserted nor the relief requested requires" that the members are involved)).

199. *Id.* at 362 (citing 29 U.S.C. § 1132(a)(3)).

200. *Id.*

201. See Singleton v. Wulff, 428 U.S. 106, 118 (1976).

202. *Am. Psychiatric Ass'n*, 821 F.3d at 358, 360.

203. *Id.* at 361.

III. NEW YORK STATE LEGISLATION AND REGULATIONS

A. Significant Legislation and Regulations

1. Sales Tax Exemption: Feminine Hygiene Products

On July 21, 2016, Governor Cuomo signed legislation exempting feminine hygiene products from local and state sales tax.[204] The legislation was passed following the commencement of a class action lawsuit earlier in 2016 against the New York State Department of Taxation and Finance in which the women claimed that the sales tax violated the Equal Protection Clause of both the United States and New York Constitution.[205] The women alleged that while certain medical items such as Rogaine, adult diapers, chapstick, and dandruff shampoo are exempt from sales tax, feminine hygiene products are not.[206]

The sales tax was previously upheld, according to the Department of Taxation and Finance, as a product used to control a normal bodily function and to maintain personal cleanliness.[207] This is separate from something to treat a specific medical condition, which would be tax exempt.[208] This stands in stark contrast to the FDA's characterization of feminine hygiene products as "medical devices."[209] The women argued that in absence of using certain hygiene products, they could be at a greater risk for diseases such as cervical cancer.[210] As such, feminine hygiene products are not for personal cleanliness but rather are a medical necessity.[211] The women estimated that New York State collects approximately fourteen million dollars per year by taxing women for such purchases.[212]

In light of these considerations, the New York State Legislature passed a bill exempting the products from the state sales tax and, as stated above, the bill was signed into law on July 21, 2016.[213] As of

204. Act of July 21, 2016, 2016 McKinney's Sess. Law News no. 4, ch. 99, at 489 (codified at N.Y. TAX LAW § 1115(a)(3-a) (McKinney Supp. 2017)).

205. Verified Class Action Complaint at 1, Seibert v. N.Y. State Dep't of Taxation & Fin., No. 151800 (N.Y. Sup. Ct. Mar. 3, 2016), 2016 WL 822532, at *5 [hereinafter Seibert Class Action Complaint].

206. *Id.* at 6.

207. N.Y. STATE DEP'T OF TAXATION & FIN., PUB. 840, A GUIDE TO SALES TAX FOR DRUGSTORES AND PHARMACIES9 (1998).

208. *Id.*

209. *See* 21 C.F.R. § 801.430 (2016).

210. Seibert Class Action Complaint, *supra* note 205, at 7.

211. *Id.* at 6–7.

212. *Id.* at 9.

213. Act of July 21, 2016, 2016 McKinney's Sess. Law News no. 4, ch. 99, at 489

September 1, 2016, women will no longer have to pay a sales tax on feminine hygiene products.[214]

2. Medicaid Coverage for Transgender-Related Care

Effective April 27, 2016, the New York State Department of Health amended 18 N.Y.C.R.R. § 505.2(*l*) to broaden Medicaid coverage for the treatment of gender dysphoria.[215] The regulation was first adopted on March 11, 2015.[216] The regulation provides for Medicaid coverage for medically-necessary hormone therapy as well as gender reassignment surgery.[217] Under the original rule, an individual was required to be eighteen years or older to receive coverage for hormone therapy and for gender reassignment surgery.[218] If the surgery would result in sterilization, however, the individual was required to be twenty-one years of age or older.[219] In order to undergo gender reassignment surgery, the individual was required to obtain approval letters from two qualified New York State licensed health professionals after being individually assessed.[220]The letters had to collectively show that the individual has a "well-documented case" of gender dysphoria; that the individual has received twelve months of hormone therapy; has lived in a gender role congruent with the individual's gender identity, and has received any medically necessary mental health counseling during such time; has no health conditions that would contraindicate surgery; and can make informed consent to surgery.[221]

Coverage did not extend to certain procedures, such as breast augmentation, various lifts and implants, anything relating to hair growth or loss, electrolysis, liposuction, and voice therapy.[222] Coverage also did not extend to preserving reproductive tissue, reversing genital or breast surgery, reversing surgery to revise secondary sex

(codified at N.Y. TAX LAW § 1115(a)(3-a) (McKinney Supp. 2017)).

214. *Id.*

215. 38 N.Y. REG. 5 (Apr. 27, 2016) (codified at 18 N.Y.C.R.R. § 505.2(*l*)).

216. 37 N.Y. REG. 19 (Mar. 11, 2015) (adopting final rule proposed in 36 N.Y. REG. 2 (Dec. 17, 2014)).

217. 18 N.Y.C.R.R. § 505.2(*l*)(1) (2016).

218. 36 N.Y. REG. at 2 (previously codified at 18 N.Y.C.R.R. § 505.2(*l*)(3)).

219. *Id.* (previously codified at 18 N.Y.C.R.R. § 505.2(*l*)(3)).

220. *Id.* (previously codified at 18 N.Y.C.R.R. § 505.2(*l*)(3)) ("One of these letters must be from a psychiatrist or psychologist with whom the individual has an established and ongoing relationship. The other letter may be from a licensed psychiatrist, psychologist, physician, psychiatric nurse practitioner or licensed clinical social worker acting within the scope of his or her practice, who has only had an evaluative role with the individual.").

221. *Id.* (previously codified at 18 N.Y.C.R.R. § 505.2(*l*)(3)(i)–(v)).

222. *Id.* (previously codified at 18 N.Y.C.R.R. § 505.2(*l*)(4)(v)(a)–(m)).

characteristics, and reversing procedures that resulted in sterilization.[223]

After the regulation's adoption, supporters argued that it did not go far enough. Comments suggested that the absence of coverage for certain procedures, labeled "cosmetic," should be stricken.[224] Comments also suggested that coverage should extend to those under the age of eighteen, that gender reassignment surgery resulting in sterilization should not be restricted to those aged twenty-one and older, and that the list of providers from whom an individual must obtain a referral letter should be expanded.[225]

In response, the Department of Health amended the regulation on April 27, 2016 to expand the list of providers to include nurse practitioners and established eighteen as the minimum age for gender reassignment surgery, even if sterilization would result.[226] Supporters argued again that the regulation did not go far enough.[227]

> [A]ll of the commenters urged that the list of individuals who can provide referral letters for [gender reassignment surgery] be further expanded. Suggestions included general nurse practitioners, licensed clinical social workers, licensed masters of social work under clinical supervision, mental health counselors, and individuals with a master's degree or its equivalent in a clinical behavioral science field.[228]

Commenters suggested this was a barrier to necessary services, for individuals would have to travel farther to find qualified professionals from whom to obtain referral letters.[229] The Department of Health rejected this argument and instead concluded that because Medicaid covers transportation to the offices of qualified clinicians to obtain necessary services, the limitation on providers would not serve as a barrier.[230]

On May 11, 2016, the Department of Health published a proposed amendment for comment in the New York State Register.[231] The amendment modified the language pertaining to cosmetic procedures: the new rule would state that the enumerated procedures are deemed cosmetic *unless* justification of medical necessity is provided and the

223. 36 N.Y. REG. at 2 (previously codified at 18 N.Y.C.R.R. § 505.2(*l*)(4)(i)–(iv)).
224. 37 N.Y. REG. 20 (Mar. 11, 2015).
225. *Id.* at 19–20.
226. 38 N.Y. REG. 5 (Apr. 27, 2016) (adopting final rule proposed in 44 N.Y. REG. 18 (Nov. 4, 2015) (codified at 18 N.Y.C.R.R. § 505.2(*l*)(3)).
227. *Id.*
228. *Id.*
229. *Id.*
230. *Id.*
231. 38 N.Y. REG. 28 (May 11, 2016) (codified at 18 N.Y.C.R.R. § 505.2(*l*)).

procedure is previously approved.[232] The proposed amendment also would extend coverage to breast augmentation in the event twenty-four months of hormone therapy results in negligible breast growth.[233] As the regulation continues to expand, it is probable that individuals with gender dysphoria can expect greater coverage and access to services.

B. Pending New York State Legislation

1. Aid-in-Dying Developments

Beyond *Myers*, there are currently two critical bills pending before the New York State Senate and Assembly on the issue of aid-in-dying: Senate Bill 3685, "New York End of Life Options Act"; and Assembly Bill 5261-C, "The Patient Self-Determination Act." The New York End of Life Options Act has been awaiting approval by the Senate Committee on Health since February 2015, while the Patient Self-Determination Act was amended and recommended to the committee on health in January 2016 by the New York State Assembly.[234] This is in keeping with the trend across the nation, where twenty-five state legislatures have considered bills to authorize aid-in-dying between January and September 2015.[235] Some highlights of this proposed legislation are provided below.

Briefly, by way of context, the New York End of Life Options Act (proposed Public Health Law article 29-CCCC) would permit a "qualified individual" (over eighteen years of age) with the appropriate mental capacity to make a request for aid-in-dying medication where the attending physician and consulting physician have determined that the individual is suffering from a terminal illness and the individual has

232. *Id.* (codified at 18 N.Y.C.R.R. § 505.2(*l*)(5)).

233. *Id.* (codified at 18 N.Y.C.R.R. § 505.2(*l*)(5)(ii)).The proposed rule was adopted on August 31, 2016. Commenters again challenged the amendment, arguing that it's more difficult to obtain approval for the procedures listed in section 505.2(*l*)(5) to treat gender dysphoria than it is to obtain approval for the same procedures to treat other conditions or diagnoses. This seems in part due to the difficulty in defining the line between medically necessary procedures to treat the condition and cosmetic procedures. 38 N.Y. REG. 26 (Aug. 31, 2016) (adopting final rule in 38 N.Y. REG. at 28).

234. *See* N.Y. Senate Bill No. 3685, 238th Sess. (2015); N.Y. Assembly Bill No. 5261-C, 239th Sess. (2016). We discuss only the Patient Self-Determination Act in any detail because the End of Life Options Act lies outside the time period covered by the *Survey*. The Assembly Bill for the New York Patient Self Determination Act is available at *N.Y. Assembly Bill No. 5261-C, 238th Sess.*, N.Y. ST. ASSEMBLY, http://assembly.state.ny.us/leg/ (from term field select "2015-16" dropdown; then search bill number field for "5261-C"; then follow "Search" hyperlink; then follow "A05261" hyperlink; then select "Actions"; "Committee Votes"; "Floor Votes"; "Memo"; and "Text") (last visited May 16, 2017).

235. *See* David Orentlicher, Thaddeus Mason Pope & Ben A. Rich, *Clinical Criteria for Physician Aid in Dying*, 19 J. PALLIATIVE MED. 259, 260 (2016).

expressed a desire for the medication.[236] The proposed End of Life Options Act is, of course, more complicated than that, but the discussion of the details is beyond the scope of this *Survey* year.

The Patient Self-Determination Act is consistent with aid-in-dying proposals from the medical-legal scholars in the field. The criteria include, among other things, that the patient has an incurable, terminal condition likely to result in the patient's death within six months, and must be a resident of the state in which he or she exercises his aid-in-dying option.[237] Additionally, the criteria suggest that patients understand alternatives to aid-in-dying (e.g., hospice or aggressive symptom management), that a physician should refer the patient to hospice, obtain a second opinion regarding the diagnosis, and encourage the patient to involve close family members and other loved ones in the decision.[238] The criteria further suggest that the physician document the patient's understanding of the diagnosis and prognosis, that the patient understands that he or she will be ingesting medication to hasten death, and that the patient retains the right to change his or her mind about proceeding with an aid-in-dying course of treatment.[239] It is also recommended that the physician alert the pharmacist once the aid-in-dying prescription is written and provide the pharmacist with an opportunity to decline participation.[240]

Although largely similar to the New York End of Life Options Act (proposed Public Health Law article 29-CCCC), the Patient Self-Determination Act further expands the New York End of Life Options Act and raised the age of qualification. In the Patient Self-Determination Act (proposed Public Health Law article 28-F), a patient who is twenty-one years old or older, upon a determination that he or she is terminally ill from his or her private attending physician and, if applicable, his or her consulting physician, will be able to file a written application and consent to administer medication for purposes of ending one's life.[241] However, the request to self-administer medication that will end one's life must be witnessed by two individuals, attesting that

236. S. 3685, at 2–3.

237. Orentlicher, Pope & Rich, *supra* note 235, at 260 (citing MONT. CODE. ANN. § 50-9-102(16) (2015)).

238. *Id.* (citing Sean Morrison et al., *Palliative Care*, 350 N. ENGL. J. MED. 2582, 2586, 2589 (2004)); Kathryn L. Tucker, *Aid in Dying: Guidance for an Emerging End-of-Life Practice*, 142 CHEST J. 218, 221–22 (2012).

239. Orentlicher, Pope & Rich, *supra* note 235, at 260; Tucker, *supra* note 238, at 218, 221.

240. Orentlicher, Pope & Rich, *supra* note 235, at 259–61.

241. N.Y. Senate Bill No. 5814-A, 239th Sess., at 2 (2015).

the patient has the mental capacity, and is acting voluntarily in signing the request.[242]

The attending physician must make the determination that the patient is terminally ill, is mentally competent, is a New York State resident, and is making the decision to self-administer the lethal medication voluntarily.[243] Additionally, the attending physician must refer the patient for counseling, if appropriate; must provide information and counseling under Public Health Law § 2997-C; and fulfill all medical records documentation requirements under proposed Public Health Law § 2899-I.[244] The following must be clearly documented in the patient's medical records: (1) all of the patient's oral requests for life-ending medication; (2) all of the patient's written requests for life-ending medication; (3) the attending physician's diagnosis and prognosis, to determine whether the plaintiff is mentally competent and is acting voluntarily in making the request for the life-ending medication; (4) report on outcomes from counseling, if applicable; and (5) note from the attending physician indicating whether all requirements have been met under the statute and indicating the steps taken to fulfill the patient's request.[245]

The proposed Patient Self-Determination Act also provides protection from civil and criminal liability for health care providers and facilities, including the physicians and pharmacists involved in the ordering, and facilitation of the administration, of life-ending medications.[246] Specifically, the health care provider will be protected for discussing the risks and benefits of end-of-life options with the patient, being present when the patient takes the medication, refraining from preventing the patient from administering the medication, and refraining from trying to resuscitate the patient after he or she takes the medication.[247] A health care facility is also protected from participating in providing access to such end-of-life treatment and medications as long as the facility informed the patient upon admission, but must transfer the patient, upon request, to a facility that will provide access to such medications.[248]

Furthermore, the proposed legislation expressly states that a patient who self-administers the medication to end his or her life will not be

242. *Id.*
243. *Id.* at 3–4.
244. *Id.* at 3.
245. *Id.* at 3-4.
246. *See* S. 5814-A, at 4.
247. *Id.*
248. *Id.*

considered suicidal and any action taken under the legislation by anyone "shall not be construed for any purpose to constitute suicide, assisted suicide, attempted suicide, promoting a suicide attempt, mercy killing, or homicide under the law, including as an accomplice or accessory or otherwise."[249] A patient may also not be denied life insurance benefits for any end-of-life actions the patient takes and a health care provider's medical malpractice policy may not be conditioned on whether the provider participates in any end-of-life care.[250]

When a patient dies as a result of taking the end-of-life medications, the cause of death will be listed as "the underlying terminal illness or condition of the patient," but where the patient has rescinded his or her consent to use the end-of-life medications and the patient dies from the self-administration of the medications, "the self-administration of the medication may be listed as the cause of death."[251]

Although these proposed legislative changes seem to address the concerns of the individuals in *Myers*, they have been slow to win approval in the political arena.[252] Nevertheless, we expect that the legislation will be met with minimal opposition from patient care facilities because no facility would be required to offer aid-in-dying to a patient.[253] Their only obligation would be to transfer the patient, upon request, to a facility that provided such assistance.[254] If the legislation does succeed, however, New York will join the growing list of states with "Death with Dignity" laws.[255] Even if the legislation passes, we do not foresee that there will be a sudden uptick in individuals with terminal illnesses seeking aid-in-dying. Rather, it seems that terminally ill individuals want only to have the freedom to choose aid-in-dying and to control their care, and would not necessarily end their lives.[256] The legislation would provide terminally ill individuals in New York State with that very freedom.

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249. *Id.* at 5.

250. *Id.*

251. S. 5814-A, at 5.

252. *Myers II*, 140 A.D.3d 51, 62, 64, 31 N.Y.S.3d 45, 53–54 (1st Dep't 2016) (first citing Obergefell v. Hodges, 135 S. Ct. 2584, 2602 (2015); and then citing Washington v. Glucksberg, 521 U.S. 702, 729 (1997)).

253. *See* S. 5814-A, at 4.

254. *Id.* at 4.

255. *Death with Dignity Acts*, DEATH WITH DIGNITY, https://www.deathwithdignity.org/learn/death-with-dignity-acts/ (last visited May 16, 2017).

256. *See*, *e.g.*, Orentlicher, Pope & Rich, *supra* note 235, at 260–61 (noting that, in Oregon, which has a Death with Dignity Act, more than one-third of the patients who have access to the medication do not use it and die from progression of their terminal illnesses).

2. Universal Health Care

New York is making great strides in the health care arena since the passage of the federal ACA in 2010. The New York State Assembly has decided that the ACA is not progressive enough and continues its efforts to implement a universal health care plan for New York State.[257] Initially, Assemblyman Richard Gottfried proposed New York's Universal Health Care Bill (the "Bill") Assembly Bill 5062-A in early 2015, which was passed by the New York State Assembly in May 2015.[258] However, the Bill failed in the Senate on January 6, 2016.[259] It was then returned to the Assembly, where it was revised and passed by the Assembly a second time on June 1, 2016.[260] The Bill was delivered to the Senate Committee on Health, where it awaits approval.[261] According to one news article, the Bill has the support of more than twenty state senators, but the Chair of the New York Metro Chapter of Physicians believes that the Bill will not receive enough votes to reach the Senate floor.[262]

Nevertheless, the goal of the Bill, known as New York Health Act, is to establish a statewide comprehensive system of access to health insurance for all New Yorkers, including the "administrative structure of the [program]; . . . powers and duties of the board of trustees, the scope of [health] benefits, payment method[s] and care coordination."[263] Assemblyman Gottfried, who is the lead sponsor for the Bill, commented that part of the reason for the Bill was to alleviate the burden on employers and the taxpayers from the ever increasing cost of health insurance coverage, which grows faster than both wages and inflation.[264]

The expectation is that the comprehensive health care plan will be funded through the New York Health Trust Fund, which will be

257. Simon Rosenbluth, *For Second Year in a Row, Assembly Passes Universal Health Care Bill*, LEGIS. GAZETTE (June 2, 2016), http://legislativegazette.com/archives/3373.

258. *N.Y. Assembly Bill No. 5062-A, 238th Sess.*, N.Y. ST. ASSEMBLY, http://assembly.state.ny.us/leg/ (from term field select "2015-16" dropdown; then search bill number field for "5062-A"; then follow "Search" hyperlink; then follow "A05262A" hyperlink; then select "Actions"; "Committee Votes"; "Floor Votes"; "Memo"; and "Text") (last visited May 16, 2017).

259. *Id.*

260. *Id.*

261. *Id.*

262. Andrea Sears, *Universal Health Care Bill Passes N.Y. Assembly*, PHYSICIANS FOR NAT'L HEALTH PROGRAM (June 3, 2016), http://www.pnhp.org/news/2016/june/universal-health-care-bill-passes-ny-assembly.

263. *N.Y. Assembly Bill No. 5062-A, 238th Sess.*, *supra*note258.

264. *See* Rosenbluth, *supra* note 257.

established solely for the purpose of the New York Health Plan.[265] The universal single-payer plan will be available to every New York resident "regardless of age, income, wealth, employment, or other status."[266] As compared to current private health plans, the universal health plan will have "no network restrictions, deductibles, or co-pays."[267] With respect to the coverage, the proposed universal health plan would "include comprehensive outpatient and inpatient medical care, primary and preventive care, prescription drugs, laboratory tests, rehabilitative [services], dental, vision, [and] hearing" coverage.[268] Although long-term care coverage is not included in the Bill for proposed universal health care from the start, the Bill would require the Board of Trustees to develop a statewide long-term care plan within five years of the Bill's passage.[269]

Eligibility is straightforward. Every resident of New York State qualifies for the program and will not be required to pay any premium or other fee to be a member in the program.[270] Once enrolled, "[n]o member shall be required to pay any premium, deductible, co-payment or co-insurance under the program."[271] The resident will also be entitled to "comprehensive health coverage," including, most commonly, benefits individuals receive as part of Child Health Plus, Medicaid, Medicare, and emergency/temporary health coverage.[272] A member would also be entitled to receive care and treatment from any participating provider, and to select a care coordinator to direct the patient's care, who is usually a primary care physician, a gynecologist for females, or a specialist who regularly provides treatment for a chronic condition.[273] Under the proposed revisions to the New York Health Act, a member may also choose to enroll in the New York Health Plan through a health care organization.[274]

Apart from regulating the care coordinators and the health care organizations, the Commissioner of Health will be required to establish comprehensive standards for the entire New York Health Plan,

265. N.Y. Assembly Bill No. 5062-A, 238th Sess., at 20 (2015).

266. N.Y. Assembly Bill No. 5062-A, 238th Sess., Legislative Memorandum of Assemb. Gottfried (2015).

267. *Id.*

268. *Id.*

269. *Id.*

270. A. 5062-A, at 7.

271. *Id.*

272. *Id.*

273. *Id.* at 7–8.

274. *Id.* at 10.

including the following:

> (a) the scope, quality and accessibility of health care services; (b) relations between health care organizations or health care providers and members; and (c) relations between health care organizations and health care providers, including (i) credentialing and participation in the health care organization; and (ii) terms, methods and rates of payment.[275]

The program regulations must be consistent with several goals of the New York Health Plan, such as simplifying the process of credentialing a health care provider and making it more transparent, ensuring that primary and preventive care are more efficient and effective, eliminating health care disparities, ensuring there is no discrimination in the New York Health Plan, and ensuring accessibility of health services including accessibility for people with disabilities.[276]

Ideally, the proposed legislation contemplates that the New York Health Plan will still allow individuals entitled to federal health benefits, such as Medicare (including Medicare part D coverage), to continue to receive those benefits while on the New York Health Plan.[277] The Commissioner is further required under the proposed legislation to promulgate regulations that increase the number of individuals eligible for federal health programs, such as Medicaid, by increasing income eligibility levels and increasing or eliminating the eligibility resource test, among other things.[278] Additionally, the Commissioner will be able to enroll each member in Medicare or a federally-matched public health program, such as Medicaid, as he or she becomes eligible for the programs, provided the member responds to requests for information prior to enrollment.[279] The New York Health Plan will also provide assistance with premiums for Medicare part D drug coverage, "limited to the low-income benchmark premium amount established by the federal centers for Medicare and Medicaid services."[280]

If this legislation passes, it will take effect immediately.[281] However, there are many economic and logistical questions that would have to be answered, such as how the infrastructure of the program

275. A. 5062-A, at 11.
276. *Id.* at 11–12.
277. *Id.* at 12–13.
278. *Id.* at 13.
279. *Id.* at 13–14.
280. A. 5062-A, at 14.
281. *Id.* at 22.

would be created, how the transition would work from private carriers to the New York Health Plan, whether the proposal for funding the New York Health Plan will be self-sustaining, and so on.[282]

Additionally, it has been suggested that passing this Bill will help boost the local economy by keeping health insurance costs down for employers and thus incentivize businesses to remain in New York instead of moving out-of-state and to other countries.[283] While, we are not so sure that lowering health care costs will single-handedly keep businesses in the state, we would agree that a reduction in health care costs would not hurt in incentivizing businesses to remain in New York.

CONCLUSION

Looking ahead, in light of significant political changes at the federal level, universal health care will be the most interesting topic to monitor, both at the state and federal level. With some federal elected officials having run on campaign promises of repealing the ACA, we anticipate significant changes to federal health care law.[284] Considering New York's response to the passage of the ACA was that the law did not go far enough, we question whether any challenges to the ACA at the federal level will result in an even more progressive state health care program.[285] Furthermore, in the event New York State's proposed legislation on aid-in-dying is signed into law, we anticipate additional challenges regarding the criminality of aid-in-dying, considering at least one appellate court has signaled that the law in its current state requires it to maintain that aid-in-dying is an impermissible practice.[286] We also expect further expansions in Medicaid coverage for the treatment of gender dysphoria.[287]

It is presently uncertain whether any future off-label use claims pursuant to the False Claims Act will clarify the line impliedly drawn by the Second Circuit. In addition, it will be interesting to follow the extent to which physicians may disclose medical information pertaining to their patients.

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282. *See* Dan Goldberg, *Assembly Passes Universal Health Care Bill*, POLITICO (May 27, 2015, 8:41 PM), http://www.politico.com/states/new-york/albany/story/2015/05/assembly-passes-universal-health-care-bill-022496.

283. *See* Rosenbluth, *supra* note 257.

284. *See* Caroline Humer, *Trump Promised to Repeal Obamacare. Now What?*, REUTERS (Nov. 10, 2016, 1:36 PM), http://www.reuters.com/article/us-usa-election-obamacare-analysis-idUSKBN135171.

285. Rosenbluth, *supra* note 257.

286. *Myers II*, 140 A.D.3d 51, 64–65, 31 N.Y.S.3d 45, 55 (1st Dep't 2016).

287. *See supra* Section III.A.2.