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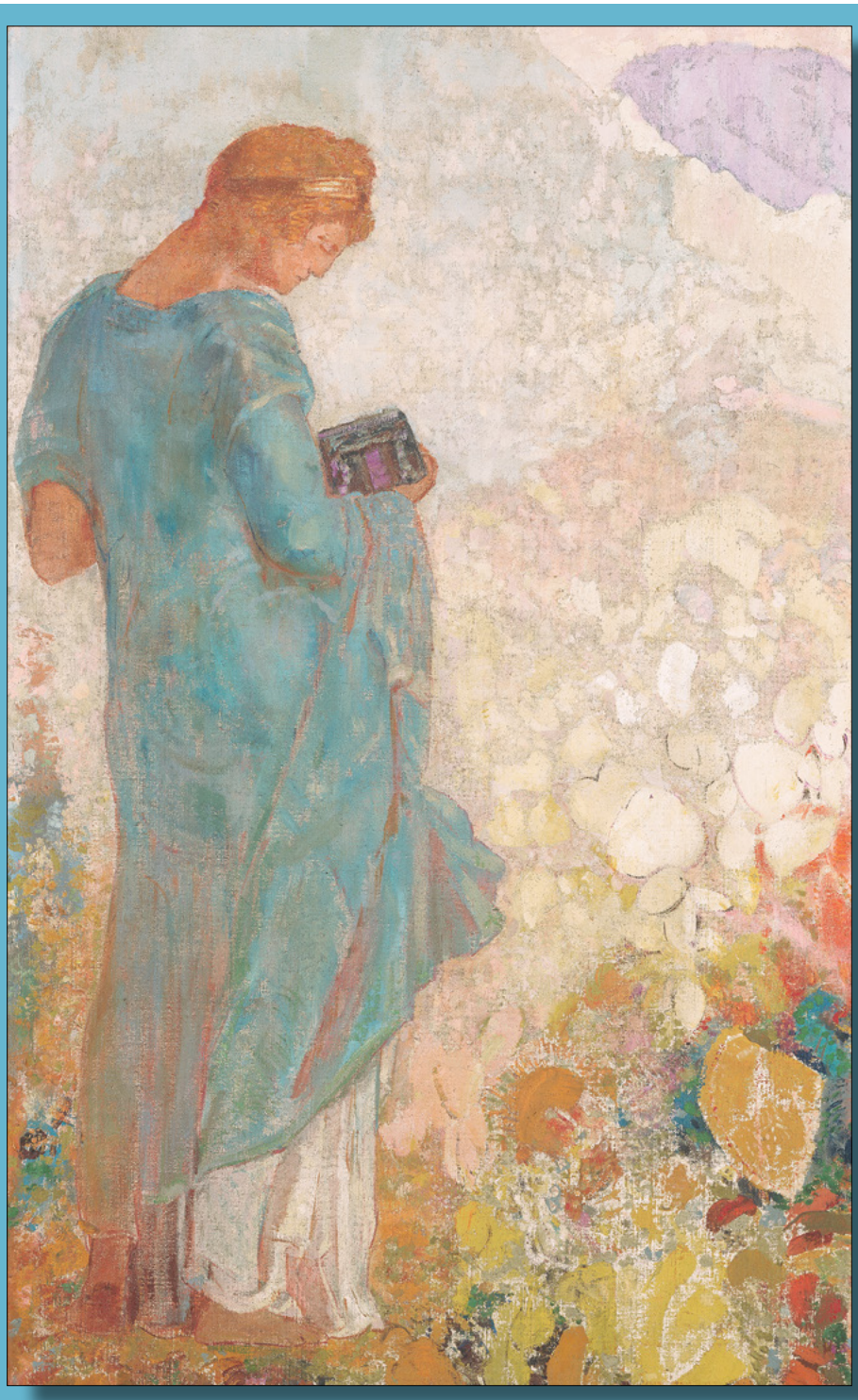
Health Law Journal

A publication of the Health Law Section
of the New York State Bar Association



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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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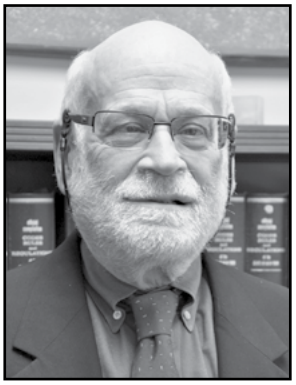
Cover artwork: Pandora, 1910/1912. Oil on canvas. Odilon Redon, French, 1840-1916. Chester Dale Collection. Courtesy National Gallery of Art, Washington.

Message from the Chair



It has been a busy fall for the members of the Health Law Section. Among the issues/topics and events undertaken by Section members are the following:

1. The presentation of a highly successful Fall Meeting with a reported attendance of 96. Our thanks to Anoush Koroghlian Scott for this successful program.
2. Ongoing planning for what looks like a very exciting program during the Annual Meeting of the Association in January. The program on hot topics in health care law is being organized by a Committee under the guidance of Margaret Davino.
3. The Special Committee, whose organization is being facilitated by Brendan Parent, Chair of the Committee on Ethical Issues in the Provision of Health Care, and newly appointed Editor of the *Health Law Journal*, is continuing its efforts to develop a proposal on needed reforms to guardianship under Article 17-A of the Surrogate's Court Procedure Act. Please see my comments below. The Committee has reached out to a variety of stakeholders, including other Sections of the Bar Association, in this effort. Recently, the Law Revision Commission has also taken an active role.
4. The Section is also facilitating discussions related to clarifying the relationship between the various New York healthcare decision-making statutes, including the Family Health Care Decisions Act and the Health Care Decisions Act for Individuals with Developmental Disabilities, and related statutes concerning health care, such as proxies, DNR orders, etc. Similar to the efforts regarding reform to guardianship, the Section has reached out to other Sections of the Bar Association and stakeholders encouraging participation.
5. The Section's Committee on Medical Research and Biotechnology has drafted correspondence, with supporting material and guidelines, on the sharing of information from research laboratories with clinical laboratories and primary care physicians in cases where research findings indicate possible healthcare anomalies. After a thorough review, communications addressed to the Department of Health in this area have been proposed by the Section to the Executive Committee of the Bar Association. The effort is being facilitated by Sam Servello, Chair of the Committee.
6. A Special Committee on the Committee Structure of the Section met and is proposing the combining of several existing committees and related changes to the section by-laws. These proposals will be presented to the members of the Section at the Annual Meeting in January.
7. The Executive Committee will also be presenting proposed changes in the Section's by-laws concerning the election of officers.
8. The Nominating Committee met and will be presenting the following slate of nominations for officers at the Annual Meeting of the members in January:

   Chair: Robert A. Hussar (elected last year)

   Chair-Elect: Hermes Fernandez

   Vice-Chair: Karen L.I. Gallinari

   Treasurer: Anoush Koroghlian Scott

   Secretary: Nathan G. Prystowsky

These are a few of the issues that have been addressed by this Section in the past few weeks. A complete list would be too long for this short column but I hope this encourages members of this Section who are not currently involved in a committee, or committees, to become involved.

I would like to take the remainder of this column to discuss how the current proposals for reform of guardianship under the Surrogate's Court Procedure Act Article 17-A reflect the evolution of thought concerning the rights of individuals with intellectual and developmental disabilities. The efforts to reform the statute currently before the legislature are not an anomaly or "radical" proposals. Rather they reflect the increasing recognition that individuals with intellectual and developmental disabilities are first persons under the law and entitled to enjoy the same rights and privileges of all other citizens. Any limitations of those rights and privileges should be based upon a clear showing of fact that the individual needs assistance in the exercise thereof.

Prior to 1965, New York State had a single statute concerning the appointment of a surrogate to make decisions for a person who was allegedly incompetent to make decisions. Mental Hygiene Law, Article 78, Committee of the Incompetent, was that statute. The appoint-

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ment of a Committee of the Incompetent, which could be, and usually was, a single individual, was based upon a judicial finding of "incompetence" and included appointment of a "Committee" to make all decisions for the person and property of the "incompetent" person. It is important to recollect that at that time individuals with intellectual and developmental disabilities were presumed to be unable to exercise the rights of citizenship. For those individuals residing in state-run "schools," such as the infamous Willowbrook, the state acted in its role as *parens patriae* to make all decisions on behalf of the individual, including medical. For those individuals who resided in the community there was no provision, short of a declaration of incompetency, to provide for any type of surrogate decision making. The families of individuals with intellectual and developmental disabilities educated and lobbied for a statute that would provide them with the authority to make decisions for such individuals after they reached the age of maturity.

The guardianship statute, Article 17-A of the Surrogate's Court Procedure Act, effective in 1969, was enacted as an amendment to Article 17 of the Surrogate's Court Procedure Act, guardianship of minors. The statute's placement reflected the attitude that individuals with intellectual and developmental disabilities were "children for life" and needed protection similar to that of minors and that parents or guardians of such individuals should be given the same rights as parents over a minor regardless of the age of said individual. Section 1750-B was added later codifying the authority of the guardian to make healthcare decisions for the individual. The statute is based on a medical diagnosis of intellectual or developmental disabilities, not a functional analysis. No declaration of incompetence is necessary, the appointments are generally plenary in nature providing near total authority over the individual and/or the individual's property, and the statute provides limited due process of law in that there is no requirement for the appointment for counsel, or for the holding of the hearing before a surrogate judge. In addition, while guardians of the property must file an annual report with the court, there is no such requirement for a guardian of the person.

The Committee of the Incompetent was joined by the Conservatorship Statute in 1972. Conservatorship did not require a declaration of incompetence. The court under the conservatorship statute was empowered to appoint conservators for persons who, because of advanced age, illness, mental weakness, drug abuse, alcohol abuse, or other causes, have suffered "substantial impairment" to their ability to care for their property or to provide for either themselves or their dependents. By 1991 the courts had limited coverage of conservatorship to property matters. In 1993 both the Committee of the Incompetent and the Conservatorship Statute were repealed and replaced by Guardianship under Mental Hygiene Law Article 81. Throughout the 1980s there had been efforts nationwide to provide more due process rights within guardianship statutes and a recognition that each individual had different strengths, weaknesses and needs. Mental Hygiene Law Article 81, Guardianship, reflects that approach. Guardianship under Article 81 is tailored to those specific areas where assistance is needed in decision making and a showing that such "limited" guardianship is the least restrictive type of relief, i.e., other types of relief are not adequate, and that the appointment must be necessary to provide for the personal or property needs of that person. The individual is entitled to an independent evaluation for the court by a court-appointed evaluator, it is not diagnosis based, the individual has the right to counsel and the right to a hearing and there is an annual report required of the guardian, both of property and person.

The differences between Article 81 and Article 17-A and the increasing recognition of the individual needs and rights of persons with intellectual and developmental disabilities have given rise to the current efforts for reform. Proposed reforms include recognition of the individual as an adult with civil rights similar to those of other adults, removal of the medical diagnosis and attached certifications and replacement thereof with the requirement that the petitioner must show specific impairments are present that make necessary the specific relief sought by the appointment of a surrogate decision maker. In most proposals for reform alternatives to guardianship must have been considered and found inappropriate for the circumstances. In addition, in some but not all of the proposed reforms, the guardian of the person, as well as the guardian of the property, is required to make annual reports.

These considerations are part of several bills recently introduced in the legislature. As reported earlier in this column, the Health Law Section has taken the lead in pulling together representatives of a several of Sections of the State Bar Association and other stakeholders in efforts to craft reform to Guardianship under 17-A of the Surrogate's Court Procedure Act.

Legislation forthcoming from these efforts must also recognize the important role played by families in the lives of individuals with intellectual and developmental disabilities. Any legislation, to be effective, must be crafted so that appropriate guardianship remains accessible to those families. If we keep in mind both the role played by families and the rights of citizenship and due process for individuals with intellectual and developmental disabilities, we can craft guardianship legislation that continues to provide an indispensable tool in the effort to avoid the unnecessary deprivation of citizenship rights and increases the ability of individuals with intellectual and developmental disabilities to live and work successfully in the community.

Lawrence Faulkner

In the New York State Courts

By Leonard M. Rosenberg

Two State Appellate Departments and a Federal District Court Disagree Over the Application of the "13-Hour Rule" Pertaining to Pay for Home Health Aides

In 2017, the Appellate Division's First and Second Departments issued similar opinions finding that employers potentially violated the Minimum Wage Order for Miscellaneous Industries and Occupations, specifically 12 NYCRR 142-2.1(b) (the "Wage Order"), and found that an "irrational and unreasonable" interpretation of the Wage Order by the New York State Department of Labor conflicted with the plain meaning of the regulation. A federal district court, however, disagreed and found that the Department of Labor's interpretation was correct. Those four cases are discussed chronologically below.

As a backdrop, 12 N.Y.C.R.R. 142-2.1(b) provides: "The minimum wage shall be paid for the time an employee is permitted to work, or is required to be available for work at a place prescribed by the employer, and shall include time spent in traveling to the extent that such traveling is part of the duties of the employee. However, a residential employee—one who lives on the premises of the employer—shall not be deemed to be permitted to work or required to be available for work: (1) during his or her normal sleeping hours solely because he is required to be on call during such hours; or (2) at any other time when he or she is free to leave the place of employment. Notwithstanding the above, this subdivision shall not be construed to require that the minimum wage be paid for meal periods and sleep times that are excluded from hours worked under the Fair Labor Standards Act of 1938, as amended, in accordance with sections 785.19 and 785.22 of 29 C.F.R. for a home care aide who works a shift of 24 hours or more."

Tokhtaman v. Human Care, LLC, 149 A.D. 3d 476, 52 N.Y.S.3d 89 (1st Dep't 2017). Plaintiff was a home health care attendant employed by Defendant. Defendant employed home health care attendants and scheduled these attendants to work in the homes of its clients. Plaintiff claimed that she was not paid in accordance with 12 NYCRR 142-2.1(b) (the "Wage Order") because she was not paid for all 24 hours of her shift. Plaintiff alleged in her Complaint that she maintained her own residence, and did not "live in" the homes of Defendant's clients, and that she generally worked 24 hours a day, seven days a week, but was only paid 13 hours of every 24-hour shift.

Defendant moved for dismissal of Plaintiff's claims based, in part, on a March 11, 2010 Department of Labor (DOL) opinion letter that advised that "'live-in employees,' whether or not they are 'residential employees,' 'must be paid not less than for thirteen hours per twenty-four hour period provided that they are afforded at least eight hours for sleep and actually receive five hours of uninterrupted sleep, and that they are afforded three hours for meals." Citing N.Y. St. Dept. of Labor, Op. No. RO-09-0169 at 4 (Mar. 11, 2010). The Supreme Court, New York County, denied Defendant's motion to dismiss and Defendant appealed. The Appellate Division, First Department affirmed the lower court's denial of Defendant's motion to dismiss.

The First Department found that the DOL's March 11, 2010 opinion letter conflicted with the plain language of the Wage Order and held that "if plaintiff can demonstrate that she is a nonresidential employee, she may recover unpaid wages for the hours worked in excess of 13 hours a day." The court held that Plaintiff's allegations that she maintained her own residence and did not "live in" the homes of her employers' clients were sufficient to state a claim under the Wage Order. The court also held that "Courts are not required to embrace a regulatory construction that conflicts with the plain meaning of the promulgated language" and that "the DOL opinion fails to distinguish between 'residential' and 'non-residential' employees, and should thus not be followed in this respect." On this record, it could not be determined that Plaintiff "lived on her employers' premises as a matter of law" and, therefore, Defendant was not entitled to dismissal of Plaintiff's claims.

Plaintiff also asserted a claim for breach of contract alleging that she was a third-party beneficiary of contracts requiring Defendants to pay Plaintiff certain wages pursuant to Public Health Law § 3614-c. The court held that Defendant was not entitled to dismissal of Plaintiff's breach of contract claim because Plaintiff had standing to sue as a third-party beneficiary of the alleged contracts requiring Defendant to pay Plaintiff

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certain wages. The court found that Plaintiff's reference to Public Health Law § 3614-c in her Complaint was a clear reference to contracts required for every company providing health care services that seek reimbursement from Medicaid and Medicare and was sufficient to survive a motion to dismiss.

Bonn-Wittingham v. Project O.H.R. (Office of Homecare Referral), Inc., 2017 WL 2178426 (E.D.N.Y. May 5, 2017). Plaintiffs were home health aides who brought a collective and class action against their former employer for unpaid wages and other labor law violations under the Fair Labor Standards Act (FLSA) and New York Labor Law (NYLL). By opinion and order dated December 12, 2016, the district court dismissed, *inter alia*, Plaintiffs' failure to pay minimum wage and failure to pay overtime claims related to Plaintiffs' claims that they worked 24-hour shifts without proper payment under New York law. Plaintiffs moved for reconsideration of the court's dismissal, arguing that the court did not take the complaint's pleaded facts as true, failed to draw all reasonable inferences in favor of Plaintiffs, and misapplied controlling precedent. The court denied that motion for reconsideration. Plaintiffs sought reconsideration again of the same portion of the court's December 12, 2016 order that dismissed Plaintiffs' minimum wage and overtime claims, arguing that a New York state intermediate court decision constituted "a change in controlling law" citing *Tokhtaman v. Human Care, LLC*, 149 A.D. 3d 476, 52 N.Y.S.3d 89 (1st Dep't 2017), and warranted reconsideration. The court denied Plaintiffs' second motion for reconsideration as untimely and without merit.

In denying Plaintiffs' second motion for reconsideration of the federal FLSA claims, the court held that Plaintiffs' reliance on a case from the Appellate Division, First Department did not constitute controlling law because "controlling decisions include decisions from the United States Court of Appeals for the Second Circuit; they do not include decisions from other circuits or district courts."

Regarding Plaintiffs' NYLL claims, the court held that "the court is not bound by rulings of intermediate or lower state courts on an issue on which the highest court of the state has not spoken." It was undisputed that New York's highest Court had not spoken on the "relevant issue." Therefore, *Tokhtaman* was not controlling on the district court. The court went on to find that the New York Court of Appeals is not likely to follow *Tokhtaman* because the First Department held that the DOL regulations only allow that residential employees "who live on the premises of the employer" not be paid during sleep and break hours. This finding, therefore, was a rejection of the DOL's March 10, 2010 opinion letter, which advised that the working hours of live-in employees should not include certain sleep and break hours. The court believed the First Department's rejection of the DOL's opinion letter was wrong because "an agency's interpretation of its own regulation generally is entitled to deference" by the courts. Citing *Visiting Nurse Srv. of N.Y. HomeCare v. N.Y. State Dep't of Health*, 840 N.E.2d 557, 506 (2005); and *Samiento v. World Yacht Inc.*, 883 N.E.2d 990, 995 (2008) ("The Labor Department's interpretation of a statute it is charged with enforcing is entitled to deference. The construction given statutes and regulations by the agency responsible for their administration, 'if not irrational or unreasonable,' should be upheld." (quoting *Matter of Chesterfield Assoc. v. N.Y. State Dep't of Labor*, 830 N.E. 287, 292 (2005))). The court found that the reasoning in the DOL's letter was not "irrational or unreasonable" because it explained that the NYLL makes a distinction between "on call" and "subject to call" time as employees must be paid only for time spent "on call." "Subject to call" time, however, is not compensable. Therefore, the court found that the DOL's opinion that a home health care attendant could be considered on "subject to call" time when he or she was sleeping or eating in a room separate from the client was not unreasonable or irrational under the meaning of the Wage Order.

The court held that the First Department's holding in *Tokhtaman* that the DOL letter conflicted with the plain language of 12 NYCRR 142-2.1 was incorrect because the relevant statute defines "residential employee" only as one "who live[s] on the premises of the employer"; it does not provide that such employees must live with the employer full time. Therefore, it would not be "unreasonable" to treat home health aides working "live in" shift as living part time with their clients, as the DOL letter does.

Andryeyeva v. New York Health Care, Inc., 153 A.D.3d 1216, 61 N.Y.S.3d 280 (2d Dep't 2017) and *Moreno v. Future Care Health Services, Inc.*, 153 A.D.3d 1254, 61 N.Y.S.3d 589 (2d Dep't 2017). These two appeals were consolidated for argument and heard on the same day, by the same panel. In both cases, home health care attendants brought a putative class action against their employers, alleging violation of the minimum wage requirements under Article 19 of the New York Labor Law (NYLL), including 12 NYCRR 142-2.1(b). The central issue in both cases was whether the home health care attendants were entitled to pay for 24 hours a day or were considered "residential employees" only entitled to 13 hours per days, assuming they were provided at least eight hours of uninterrupted sleep and meal time. The Second Department held in both *Andryeyeva* and *Moreno* that to the extent that the home health attendants were not "residential" employees who lived on the premises of their employer they were entitled to be paid the minimum wage for all 24 hours of their shifts.

The Plaintiffs in *Andryeyeva* were employed by the Defendant as home health care attendants. The Plaintiffs alleged that they worked 24-hour shifts, they did not "live in" the homes of their employer's clients, and that they were not "working in

the home of their employer." The Plaintiffs alleged that they were paid an hourly rate for the 12 daytime hours of their 24-hour shifts and a flat rate for the 12 nighttime hours. The Plaintiffs contended that this violated the NYLL because they were entitled to the minimum wage for each hour of their 24-hour shifts and that the Defendant's pay practice violated the NYLL and, specifically 12 N.Y.C.R.R. 142-2.1(b) (the "Wage Order"), because the pay practice resulted in a regular hourly wage that was below the minimum wage. The Defendant contended that it was not required to pay home attendants for each hour of a 24-hour shift, but was permitted to exclude eight hours of sleep time and three hours of meal time, so long as those breaks were actually provided. In support of this position, the Defendant relied on the New York State Department of Labor's (DOL) March 11, 2010 opinion letter that interpreted the Wage Order. The Plaintiffs in *Andryeyeva* sought class certification of their putative class. The Defendant opposed the class certification motion and contended that certification was improper because a fact-intensive inquiry was required under the Wage Order to determine if the attendants had each received the meal and sleep breaks. The Defendant's position was based on the DOL's interpretation of the Wage Order. The Supreme Court, Kings County granted the Plaintiff's motion for class certification and the Defendant appealed.

In *Moreno*, the Plaintiffs similarly alleged that they were paid flat rate for their 24-hour shifts resulting in wages that fell below the minimum wage in violation of NYLL. The Defendant contended that the Plaintiffs were not entitled to pay for each hour of a 24-hour shift because the Defendant provided uninterrupted meal and sleep time to the attendants. The Plaintiffs moved for class certification. The lower court denied the Plaintiffs' motion in reliance on the DOL's March 2010 opinion letter, finding that the Defendant was not required to pay the Plaintiffs for each hour of a 24-hour shift, but was permitted to exclude eight hours for sleep and three hours of meal time, so long as that time was actually afforded. Based on this interpretation, the class certification motion was denied because a fact-intensive individualized inquiry of each of the Plaintiffs' claims was required. The Plaintiffs appealed.

On the two appeals, the Second Department considered the Wage Order and the DOL's March 11, 2010 opinion letter interpreting the Wage Order. In particular, subsection (b) of the Wage Order (12 N.Y.C.R.R. 142-2.1 "Basic minimum hourly wage rate and allowances"), in relevant part, provides: "the minimum wage shall be paid for the time an employee is… required to be available for work at a place prescribed by the employer… However, a residential employee—one who lives on the premises of the employer—shall not be deemed to be…required to be available for work…during his or her normal sleeping hours solely because he or she is required to be on call during such hours; or…at any other time when he or she is free to leave the place of employment." The DOL 's March 11, 2010 opinion letter interpreting the Wage Order advised that "live-in employees," "must be paid not less than for 13 hours per 24-hour period provided that they are afforded at least eight hours for sleep and actually receive five hours of uninterrupted sleep, and that they are afforded three hours for meals."

In analyzing the DOL's opinion letter's interpretation of the Wage Order, the court recognized that "[t]he construction given statutes and regulations by the agency responsible for their administration, if not irrational or unreasonable, should be upheld." Citing *Samiento v. World Yacht Inc.*, 10 N.Y.3d 70, 79, 854 N.Y.S.2d 83 (2008). The court, however, agreed with the First Department's holding in *Tokhtaman v. Human Care, LLC*, 149 A.D.3d 476, 52 N.Y.S.3d 89 (1st Dep't 2017), and held that the DOL's interpretation of the Wage Order is neither rational nor reasonable, because it conflicts with the plain language of the Wage Order. In particular, the DOL's opinion of what it meant to be "available" under the Wage Order was contrary to the plain meaning of the Wage Order because the Wage Order provides that the attendants are entitled to minimum hourly wage for every hour they are available to work. The home health care attendants alleged that they were required to be at the clients' residences and were also required to perform services there if called upon to do so. Therefore, the home health care attendants were present and "available" to work and they were covered by the Wage Order. The DOL's opinion that attendants are not "available" to work "provided that they are afforded at least eight hours for sleep and actually receive five hours of uninterrupted sleep, and that they are afforded three hours for meals" was contrary to the plain meaning of the Wage Order. In *Moreno*, the Second Department also held that "to the extent that the DOL's opinion letter fails to distinguish between 'residential' and nonresidential employees, it conflicts with the plain meaning of 12 NYCRR 142-2.1(b), and should not be followed."

Based on the Second Department's rejection of the DOL's opinion letter, in both cases it held that: "to the extent that the members of the proposed class were not 'residential' employees who 'lived on the premises of the employer' they were entitled to be paid the minimum wage for all 24 hours of their shifts, regardless of whether they were afforded opportunities for sleep and meals." Based on this finding, the court affirmed the grant of class certification in *Andryeyeva* and reversed the denial of the Plaintiffs' class certification motion in *Moreno*.

Appellate Division Finds Private Right of Action Under Public Health Law § 4406-d

Ahmed Elkoulily, M.D., P.C. v. New York State Catholic Healthplan, Inc., 153 A.D.3d 768, 61 N.Y.S.3d 83 (2d Dep't 2017). Plaintiff (the "P.C.") is a medical clinic that entered into a par-

ticipating provider agreement with Defendant New York State Catholic Healthplan, Inc., doing business as Fidelis Care New York ("Fidelis"). Fidelis had the option to terminate the agreement upon the determination, at its sole discretion, that the P.C.'s provision of health care services would constitute an imminent harm to its enrollees.

Following its review of a random sample of the P.C.'s patient records, Fidelis advised the P.C. that it would be terminating its provider agreement on the ground that the P.C's principal physician, Ahmed Elkoulily, M.D., was providing services outside of his "credentialed expertise," and because the P.C. was employing staff without credentials. Fidelis asserted that such conduct constituted imminent harm to its enrollees.

The P.C. and Dr. Elkoulily sued Fidelis, seeking damages for breach of contract, violation of Public Health Law §§ 230(11)(b) and 4406-d, and intentional infliction of economic harm. The Plaintiffs alleged that Fidelis and its agents terminated the contract in bad faith and fabricated information to justify the termination, because Fidelis determined that they were "outliers with regard to the number and cost of those medical services provided" to its enrollees.

Defendants moved to dismiss the complaint in its entirety pursuant to CPLR 3211(a)(7). The lower court granted the motion to the extent that it sought dismissal of all claims asserted by Dr. Elkoulily individually and the P.C.'s claims for breach of contract, violation of Public Health Law § 230(11)(b), and intentional infliction of economic harm. The lower court denied the motion insofar as it sought dismissal of the P.C.'s claim for violation of Public Health Law § 4406-d.

The Appellate Division first held that the lower court erred in dismissing the P.C.'s claim for breach of contract. The court asserted that while Fidelis had sole discretion under the agreement to determine whether the P.C.'s provision of services would be an imminent harm to its enrollees, it "had an implied obligation to exercise good faith in reaching its determination." The court thus held that the P.C.'s allegations were sufficient to state a cause of action predicated on the implied covenant of good faith and fair dealing.

Next, the Appellate Division found that the Supreme Court properly denied Fidelis' motion to dismiss the P.C.'s claim for violation of Public Health Law § 4406-d. Under that statute, a health care plan may not "terminate a contract with a health care professional" absent "a written explanation of the reasons for the proposed termination and an opportunity for review or hearing." The court observed that a statute creates a private right of action where (1) the Plaintiff is a member of the class for whose benefit the statute was enacted, (2) a private right of action would promote the legislative purpose, and (3) a private right of action would be consistent with the legislative scheme. Finding that Public Health Law § 4406-d is intended to provide enhanced protection for health care providers who enter into contracts with health plans, and that "the statute offers no other practical means of enforcement such that a private right of action is necessary to trigger the protections intended to be afforded to health care providers," the court held that the P.C. is entitled to bring a claim for damages thereunder.

The Appellate Division also ruled that the lower court properly dismissed the claim for violation of Public Health Law § 230(11)(b). The court found that the statute, which offers immunity from suits for civil damages or other relief to any person "who provides or reports information to the board in good faith, and without malice," creates a defense to an action, rather than a private right of action.

Finally, the Appellate Division found that the lower court properly dismissed the claim for intentional infliction of economic harm. The court noted that no such cause of action is recognized in New York, but that it is generally treated as a cause of action sounding in prima facie tort. The court ruled that the P.C. did not have a cause of action for prima facie tort, as the actions of Fidelis and its agents were not motivated solely by malice and disinterested malevolence, and because the P.C. failed to plead special damages.

Appellate Division Upholds $7.5 Million Judgment Directing Department of Health to Reimburse Provider For Improperly Denied Medicaid Claims

Community Related Servs., Inc. v. New York State Dep't of Health, 151 A.D.3d 429, 56 N.Y.S.3d 76 (1st Dep't 2017). Petitioner Community Related Services, Inc. (CRS) is an alcohol and substance abuse clinic. For years, CRS used "Code 10," a catchall code for administrative delay, as the reason for delayed Medicaid claims. Finding that CRS committed "unacceptable practices," the Office of the Medicaid Inspector General (OMIG) refused to pay CRS for 103,054 Medicaid claims totaling $7.5 million.

Following a hearing before an administrative law judge (ALJ), OMIG's determination was overturned. The ALJ found that OMIG was equitably estopped from seeking the alleged overpayments because it, or other state entities involved in the claims process, had for years accepted CRS's untimely Medicaid claims under Code 10. Accordingly, the ALJ found that CRS's use of Code 10 was not an unacceptable practice.

CRS brought an Article 78 proceeding against the New York State Department of Health (DOH) to enforce the ALJ's ruling. After a hearing before a Special Referee, the lower court found that it was "more likely than not" that CRS's use of Code 10

was the reason for the denial of its claims. Accordingly, the court granted the petition and directed entry of a money judgment in the total amount of the denied claims.

On appeal, DOH argued that the lower court did not have jurisdiction to enter a money judgment against a State entity, as only the Court of Claims has that authority. DOH also argued that entry of a money judgment was not incidental to the relief sought under Article 78.

The Appellate Division held that the lower court had exceeded its jurisdiction by granting a money judgment against State entities, but that requiring Respondents to reimburse CRS for improperly denied claims was incidental to the relief that CRS sought in its Article 78 petition. Accordingly, the Appellate Division vacated the Supreme Court's judgment and directed the Supreme Court to enter a new judgment with language requiring Respondents to "reimburse petitioner for improperly denied Medicaid claims in the amount of $7,458,017.98."

Following entry of the new judgment, DOH filed a second appeal, arguing that the first judgment was so deficient that they were unable to appeal it on substantive grounds. Because the new judgment was the first "valid" one, DOH asserted it was entitled to challenge the lower court's determination that they had improperly denied CRS' Medicaid claims. The Appellate Division held that while it technically modified the Supreme Court's order by "directing a different procedure" by which CRS would receive payment from Respondents, the "ultimate relief, a final judgment in petitioner's favor, was unaffected and affirmed." Thus, the Appellate Division held that the Supreme Court's entry of a new judgment at its direction was "purely ministerial and cannot be collaterally attacked" on appeal.

Appellate Division Holds That the NY Justice Center Has the Authority to Reject Recommendation Made by ALJ After a Hearing

Cauthen v. New York State Justice Ctr. for the Protection of People with Special Needs, 151 A.D.3d 1438, 58 N.Y.S.3d 682 (3d Dep't 2017). Petitioner, an employee of a residential facility operated by the Office of People With Developmental Disabilities (OPWDD), was reported to have intentionally and forcefully punched a facility resident in the chest.

Following witness interviews, an OPWDD investigator found the report of physical abuse to be substantiated. Petitioner then requested that the report be sealed and amended as unsubstantiated. The Justice Center for the Protection of People With Special Needs ("Justice Center") administrative appeals unit denied the request, and Petitioner requested an administrative hearing to challenge the findings. Following a hearing, the Administrative Law Judge recommended that Petitioner's request to seal and amend be granted. The Justice Center then rejected the ALJ's recommendation, and issued a final determination sustaining the report of physical abuse and denying Petitioner's request to seal and amend.

Petitioner brought a CPLR Article 78 proceeding challenging the Justice Center's final determination, which was transferred by the Supreme Court to the Appellate Division. Dismissing Petitioner's application, the Appellate Division held that the Justice Center's determination was supported by substantial evidence and that, as a result, the court could not substitute its own judgment even if a contrary result was viable. The court held that the Justice Center is not obliged to adhere to an ALJ's findings of fact or credibility, and is free to reach its own determination so long as the determination is supported by substantial evidence.

Under Social Services Law § 488(1)(a), physical abuse means conduct by a custodian that intentionally or recklessly causes, by physical contact, physical injury or serious or protracted impairment of the physical, mental or emotional condition of a service recipient, or causes the likelihood of such injury or impairment. A report of abuse is "substantiated" where a preponderance of the evidence suggests the alleged acts occurred following an investigation. (14 N.Y.C.R.R. 700.3(f)).

The record before the Justice Center included a hearing transcript, documentary evidence, and recordings of witness statements from Petitioner, the victim, an eyewitness, and other facility staff members. The eyewitness testified that he had seen Petitioner punch the resident so forcefully that he concluded it was deliberate, and had heard the victim shout in pain. Petitioner denied punching the victim, but admitted that the two had "engaged in horseplay." Also in evidence was that Petitioner had made statements on two other occasions that he did not recall whether he punched the victim. The victim, who suffers from a mild intellectual disability and is diagnosed with several severe psychiatric disorders, minimized the incident as "playing around" and exhibited anxiety about discussing it. The ALJ did not credit the eyewitness's statements in making his recommendation. The Justice Center, however, did credit the statements, finding that they were corroborated by other evidence.

The court held that Petitioner's statements presented credibility questions for the Justice Center's resolution and, accordingly, the Justice Center could interpret the corroborated description by the eyewitness as not seriously controverted and sufficiently reliable, constituting substantial evidence. The court also held that the eyewitness's corroborated statement was only controverted by Petitioner's denial that he punched the victim.

As to Petitioner's argument that hearsay statements in the record did not constitute substantial evidence, the court held that hearsay is admis-

sible in an administrative hearing and may support a finding of substantial evidence. The court also held that, in certain circumstances, hearsay evidence may form the sole basis of an agency's determination unless seriously controverted.

Hospital's Provision of Medical Record Copies to Patients After They Sued Under PHL § 18 Results in Dismissal of Claim

Smalls v. St. John's Episcopal Hospital, 152 A.D.3d 629, 58 N.Y.S.3d 536 (2d Dep't 2017). Plaintiffs, patients and parents of minor patients, requested copies of medical records from defendant St. John's Episcopal Hospital (the "Hospital"). Each request sought a waiver of the Hospital's copy charges based on a claim of indigence. The Hospital advised Plaintiffs that it would not waive the copy charges because it was a not-for-profit corporation.

Plaintiffs sought, *inter alia*, a declaratory judgment that the Hospital violated Public Health Law § 18, and damages based on an alleged violation of General Business Law § 349. The Hospital moved to dismiss based on CPLR 3211(a)(1) and (7). In support of its motion, the Hospital provided an affidavit indicating that after Plaintiffs sued, the Hospital provided them with copies of their medical records without charge. The court granted the motion and dismissed the complaint.

The Appellate Division affirmed. The court explained that dismissal of the claim was properly granted pursuant to CPLR 3211(a)(7) because the relief available under Public Health Law § 18 is limited to a judgment that would require a health care provider to make requested health information available to patients for inspection or copying. The court determined that because the Hospital had already provided the requested information at no cost, the complaint did not allege any facts upon which relief under Public Health Law § 18 could be granted.

The court also declined Plaintiffs' request that the issue be reviewed on appeal as an exception to the mootness doctrine. The court held that it was speculative that the issue would arise again, the issue was not novel, and it was not the type of matter that will typically evade appellate review.

The court also affirmed the dismissal of the alleged violation of General Business Law § 349 because the conduct alleged was not consumer oriented.

Appellate Division Holds That Deposition Testimony Sought From Risk Managers at Facility Operated By Office of Mental Health, Relating to an Investigation and Report Created Pursuant to Public Health Law § 2805-l, Is Privileged Under Education Law § 6527(3)

Bellamy v. State, 154 A.D.3d 1239 (3d Dep't 2017). Claimant Mary Bellamy ("Bellamy") and her husband (collectively "Claimants") commenced a negligence action against a facility operated by the Office of Mental Health (the "Facility"), after Bellamy, a patient at the Facility, was assaulted by another patient. During the course of fact discovery, Claimants deposed a risk manager who investigated and helped prepare a report on the assault. During that deposition, the risk manager identified a second risk manager who also assisted in the preparation of the investigation report. However, on advice of counsel, he refused to answer certain questions at the deposition relating to information he gained while investigating the assault as privileged, on the ground that such information was protected by the quality assurance privilege. Claimants thereafter sought the deposition of the second risk manager; the Facility moved for a protective order precluding the second deposition; and Claimants opposed that motion and cross-moved for an order compelling the first risk manager to answer the relevant questions at a renewed deposition. The Court of Claims granted the Facility's motion for a protective order precluding the deposition of the second risk manager, and denied Claimant's motion to compel information from the first risk manager. The Appellate Division affirmed.

The court explained that given the risk managers' involvement in the quality assurance investigation, questions related to the investigation and creation of a report, as required by Public Health Law § 2805-l, were properly held to be privileged under Education Law § 6527(3). The court also ruled that questions related to the examination of the assailant were privileged to the extent they sought protected health information of a nonparty patient under Mental Hygiene Law § 33.13. The court also affirmed the grant of the Facility's motion for a protective order precluding the deposition of the second risk manager as protected by Education Law § 6527(3). The court relied on an affidavit from that risk manager that he did not witness the assault and the relevant information he obtained was only by and through a limited investigation and preparation of the report. Accordingly, such testimony was also protected from disclosure as privileged because it related to the investigation of an incident reported pursuant to Education Law § 6527(3). In so holding, the Third Department rejected Claimant's attempt to rely on the party-statement exception provided for under Education Law § 6527(3), because neither risk manager was a party to the action, even though their employer, the Facility, was a named party.

A Physician's Credentials File Is Protected From Disclosure Under Education Law § 6527; Request for Physician's Entire Personnel File Is Overly Broad

Jousma v. Kolli, 149 A.D.3d 1520, 54 N.Y.S.3d 787 (4th Dep't 2017). In a medical malpractice action brought against a physician and medical center (collectively "Defendants"), the Court ruled that the named physician's credentialing file fell within the

scope of privilege protecting records related to the performance of quality assurance review, and that a request for the physician's entire personnel file was improper as overly broad. In reversing the lower court's decision, the court precluded the Plaintiff from taking a second deposition of the named physician in which he sought to question the physician about his credentialing or personnel files.

The court explained that the physician's credentials file fell squarely within the privilege provided by Education Law § 6527(3), which protects from disclosure the proceedings and records relating to the performance of a medical or quality assurance review function or participation in a medical malpractice prevention program. Although there is an exception to that privilege for statements made by a physician concerning the subject matter of a malpractice action, which statement is made pursuant to the hospital's quality-assurance inquiry into the incident underlying the action, the court found that the exception did not apply because the injury underlying the action was never the subject of the medical center's inquiry. The court noted that its holding may have been different if the Plaintiff merely sought to question the physician about his past malpractice history, and not sought his entire credentialing file.

The court also found that Plaintiff's request for the physician's entire personnel file was overly broad, and thus improper. The court, however, did not rule on what privileges, if any, may apply to the personnel file.

Nursing Home Waived Right to Arbitrate by Participating in Litigation

Hyde v. Jewish Home Lifecare. 149 A.D.3d 674, 53 N.Y.S.3d 57 (1st Dep't 2017). Plaintiff, the grandson of a nursing home resident, entered an agreement on behalf of his grandmother with Defendant nursing home in which the parties agreed to arbitrate any disputes under the Commercial Arbitration Rules of the American Arbitration Association (AAA). Plaintiff filed a demand for arbitration with the AAA after his grandmother fell and broke her hip. The AAA emailed the parties, notifying the nursing home of the demand and asking the parties to return a form indicating their agreement to have AAA administer the dispute under the Consumer Arbitration Rules. When the nursing home did not respond, the AAA notified the parties by letter that the matter was closed.

Plaintiff then commenced suit in the Supreme Court, Bronx County. Approximately four months into the lawsuit, after the nursing home had answered the complaint, appeared for and participated in a preliminary conference, and served a demand for authorizations, it moved to compel arbitration. The lower court granted the motion, and Plaintiff appealed.

The Appellate Division reversed, holding that the nursing home waived its right to arbitrate because it failed to participate in arbitration after it received notice of Plaintiff's demand. The court also held that the nursing home's active participation in the suit manifested a preference for litigation that was inconsistent with its claim that the parties were required to settle the dispute in arbitration.

The court also reviewed an affidavit filed by the nursing home's associate general counsel who asserted that he had overlooked the AAA's communications until the date to respond had lapsed. The court found that counsel had not provided a credible explanation for the failure to raise the issue of arbitration even after counsel learned of Plaintiff's demand for arbitration. The court further determined that it would be unfair to require Plaintiff to arbitrate at that juncture because the nursing home's actions caused unnecessary delay and expense.

Second Department Holds That a Capsule Camera Is Not a Foreign Object and Thus the Foreign Object Rule, Which Tolls the Statute of Limitations, Does Not Apply

Leace v. Kohlroser, 151 A.D.3d 707, 55 N.Y.S.3d 434 (2d Dep't 2017). Plaintiff commenced this medical malpractice action in August 2011. In January 2008, plaintiff's gastroenterologist had her swallow a capsule camera to assist in his performing an endoscopy. The camera inside the capsule transmitted pictures and was expected to pass through and exit plaintiff in the normal course. However, a CAT scan, which was taken in January 2009, revealed the presence of a metallic object lodged inside plaintiff's intestines. Plaintiff alleged that her radiologist never advised her of the results of the 2009 CAT scan. A 2011 CAT scan revealed the presence of the capsule camera inside plaintiff's intestines. Accordingly, the capsule camera had to be surgically removed.

The defendants—the radiologist who interpreted the 2009 CAT scan, plaintiff's primary care physician and his medical practice, and Good Samaritan Hospital—all moved pursuant to CPLR 3211(a)(5) to dismiss the complaint as time-barred. The lower court dismissed the action.

Pursuant to CPLR 241-a, a medical malpractice action must be commenced within two years and six months "of the act, omission or failure complained of." Here, the malpractice action was commenced two years and seven months after the 2009 CAT scan. However, "where the action is based upon the discovery of a foreign object in the body of the patient, the action may be commenced within one year of the date of such discovery or of the date of discovery of facts which would reasonably lead to such discovery, whichever is earlier." This is commonly known as the foreign object rule.

Plaintiff argued that the statute of limitations was tolled under the foreign object rule. The Appellate Division held that the lower court properly rejected this argument and dismissed the action as time-barred. The court reasoned that in order to determine whether objects are foreign objects pursuant to CPLR 214-a, the question is whether the object is "analogous to tangible items like… surgical paraphernalia likewise introduced into a patient's body solely to carry out or facilitate a surgical procedure." Here, the court held that the capsule camera was used diagnostically and not in the course of a surgical procedure. Thus, the foreign object rule did not apply.

No Violation of Right of Sepulcher Where Decedent's Family Was Not "Reasonably Available" to Dispose of Remains Under Public Health Law § 4201

Martin v. Ability Beyond Disability, 153 A.D.3d 695, 59 N.Y.S.3d 766 (2d Dep't 2017). Plaintiffs alleged that Defendants violated their right of sepulcher following the death of their son. Having suffered a traumatic brain injury, the decedent required the assistance of a legal guardian and lived in a nursing and rehabilitation facility, Ability Beyond Disability.

The decedent died on November 3, 2012 at the facility, where he had resided since 1996. Having had no contact with the decedent's family for many years, the facility made several attempts to locate the family between November 3 and November 9, including calling 411, leaving voicemail messages on two possible phone numbers, and contacting the Postal Service and local police department. After these efforts were unsuccessful, the guardian consented to hold a funeral for the decedent on November 9.

On November 11, the decedent's family learned of his death, the body was exhumed, and a family burial was held thereafter. The decedent's parents commenced an action against the facility and the guardian, alleging violation of their right of sepulcher. Defendants moved for summary judgment, arguing that they made proper arrangements for the decedent's burial because Plaintiffs were not available to do so. The lower court denied Defendants' motions.

The Appellate Division reversed. Under Public Health Law § 4201, a decedent's parents have priority with regard to disposing of the decedent's remains. However, if the parents are not "reasonably available," a court-appointed guardian has the right to control the disposition of the remains. Analyzing the legislative history of Public Health Law § 4201, the court held that the legislature had previously rejected a proposed requirement that defendants undertake "diligent efforts, to wit, persistent, assiduous, and careful steps" to contact the decedent's family and had, instead, determined that "reasonable availability" would be determined by the courts on a case-by-case basis. The court also noted that under Public Health Law § 4201, one who acts "reasonably and in good faith" is not subject to civil liability for disposing of a decedent's remains if done with the reasonable belief that such disposal is in compliance with the statute.

The Court held that Defendants had made a prima facie showing of entitlement to judgment as a matter of law, having submitted evidence that their actions concerning the burial were reasonable, made in good faith under the circumstances, and in compliance with Public Health Law § 4201. The court also held that Defendants had made a prima facie showing that Plaintiffs were not "reasonably available" to control the disposition of the decedent's remains.

Legislative Update
Single Payor for New York?

By James W. Lytle

For the past quarter of a century, a proposal to establish a single payor health care system in New York has been advanced by Assemblymember Richard Gottfried, longtime Chair of the Assembly Health Committee. Has the time for a New York State single payor plan finally arrived?

Political Background

The bill, known as New York Health, first passed the Assembly in 1992, its first year of introduction, when national debate over health care was heating up during the lead-up to the Clinton Presidency. After that attempt at national health care reform failed, the New York single payor bill languished in the Legislature until 2015, when it was passed again by the Assembly. The bill passed the overwhelmingly Democratic Assembly again in 2016 and 2017, during the time that Senator Bernie Sanders was advancing "Medicare for All" as a centerpiece of his Presidential campaign while the Republican Congressional leadership, along with the eventual nominee and President, were proposing to "repeal and replace" Obamacare.[1]

The bill has not progressed in the State Senate, which has been controlled by Republicans during most of the bill's existence. The current Senate version of the New York Health Act is sponsored by the Ranking Democrat on the Senate Health Committee, Senator Gustavo Rivera, and is exclusively co-sponsored by his fellow Senate Democrats. The 63-member Senate is currently governed by a coalition of 31 Republican members, eight members of a breakaway Independent Democratic Conference (IDC) and another Democrat who has conferenced with the Republicans since his election—leaving the 22 members of the mainline Democratic conference in a distinct minority.[2]

While its immediate prospects in the State Senate may be bleak, the bill would be highly likely to advance if the Democrats were able to secure a working State Senate majority, either by scoring substantial victories in the upcoming 2018 election or through a realignment of all Senate Democrats with the Senate Democratic Conference, which could occur either before or after the 2018 election.

Meanwhile, Governor Cuomo has recently expressed support for the single payor idea, at least as proposed by Bernie Sanders in Congress. While the Governor has indicated he is entirely focused on his re-election in 2018, he has been on the short list of potential candidates for President in 2020 and, in any case, he has recently emphasized issues that strengthen his support among the more progressive elements of his party. Were he to enthusiastically support the proposed legislation, its chances would improve dramatically.

Key Elements of New York Health

So how would it work?

Overview: In lieu of individual or employer-supported health insurance and instead of Medicare or Medicaid coverage, the proposal envisions a State-run insurance plan for all New Yorkers, financed by payroll taxes on New York employers, an income tax on certain income (other than on wages subject to the payroll tax) and the redirection of Medicaid and Medicare spending to support the coverage.

All New York residents would be entitled to enroll for coverage in New York Health. Benefits would be comprehensive, including everything currently covered by Medicaid, Medicare, Child Health Plus, and the New York State Employees health benefit plan, along with all mandated benefits under the Insurance Law. Coverage of long-term care services would be subject to further study, as would the integration of workers compensation benefits. No co-pays, deductibles or other cost-sharing requirements would apply. Insurers would be prohibited from offering health insurance coverage that duplicates the benefits in New York Health. The health insurance business would essentially cease to exist in New York State.

Governance: The program would be administered by the New York State Department of Health (DOH), but would be overseen initially by a 15-member commission appointed by the Governor and the legislative leaders to design the implementation of the new program. New York Health would eventually be governed by a 40-member Board of Trustees (also appointed by the Governor and the Legislature), representing various stakeholders. There would also be six regional advisory councils, each with 27 members appointed by the legislative leaders and these councils would be encouraged to form sub-regional committees, including one for each borough in New York City.

Medicare/Medicaid Integration: As noted, Medicare and Medicaid beneficiaries would also be covered by New York Health. The bill envisions that CMS would make payments to DOH

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under a formula to be negotiated with New York that would constitute the federal payment of claims costs for Medicare and Medicaid beneficiaries enrolled in New York Health.

Enrollment and Eligibility: All New York residents would be eligible to enroll, regardless of immigration status. Colleges could purchase coverage for any students who are not otherwise residents of New York. Claims payments would be made both for members and for newly arrived residents and others who have not yet had a "reasonable opportunity" to enroll in New York Health.

Care Coordination: Care coordinators would provide advice and suggestions, but would not be "gatekeepers" that determine whether providers would be paid if the patient did not heed the care coordinator's advice. Care coordinators could be primary care physicians, OB/GYNs or specialty practitioners for chronic care, as well as hospitals, home care agencies, managed long term care plans, mental health facilities, state-approved Accountable Care Organizations (ACOs) or Taft-Hartley funds.

Provider participation: Health care providers would participate in a fashion similar to fee-for-service providers under Medicaid and Medicare and providers already participating in Medicaid or Medicare would be deemed to be qualified to participate in New York Health. Participation by providers cannot be limited by New York Health for "economic purposes," which would seem to allow any willing provider to participate as long as the provider accepts New York Health payment rates and otherwise meets credentialing requirements. Not-for-Profit state-approved ACOs and Taft-Hartley networks of providers would be able to participate as "health care organizations."

Provider payment: Reimbursement rates and fee schedules for reimbursing providers would be established by regulations issued by DOH. The rates for services (other than care coordination) would, at least initially, be on a fee-for-service basis, "until and unless another payment methodology is established." The rates must be "reasonable and reasonably related to the costs of efficiently providing the health care service and assuring an adequate and accessible supply of health care service"—a standard similar to the formerly applicable Boren Amendment for Medicaid payment purposes. Reimbursement rates would be payment in full with no balance billing permitted. Payments to hospitals must include payment for direct and indirect graduate medical education. The bill authorizes collective negotiations by otherwise unaffiliated physicians and other health professions with New York Health.

Out-of-state residents and providers: State residents employed out of state would be covered, either by applying the payroll tax to the employer if it is subject to New York law or to the employee, as if the employee were self-employed. Out of state residents employed in New York would not be covered but would be subject to the payroll premium taxes (and a credit would be applied in the amount of conventional health insurance premiums paid for that out of state resident.) The program would establish procedures and standards for access to and payment for out-of-state providers.

Fiscal analysis: The legislation's sponsors cite a study by Gerald Friedman, a University of Massachusetts economics professor, to support their analysis of the program's financing.[3] The 2015 study concluded that its overall cost would be just over $242 billion, a total that assumed nearly $71 billion in savings from the current system, including $20.6 billion in provider billing savings, a $28.5 billion savings in current insurance and other third party administrative costs, $5.4 billion in reduced fraud and $16.3 billion in savings from negotiating prices with the pharmaceutical industry. Medicare would contribute $64 billion to the program's overall expense, along with nearly $70 billion from Medicaid. Payroll taxes would account for $59 billion and taxes on dividends, interest and capital gains would provide $32.5 billion.

Conclusion: There are a host of issues that might be raised by the proposal, including the current prospects for the kind of collaborative partnership with the federal government that the bill envisions. The State's precarious fiscal condition may also make the bill less feasible, at least in the short run. In any case, the health care field—including health care lawyers—should begin seriously considering the possibility that a proposal like this one or some variation on its theme may be enacted someday in New York State.

Endnotes

1. The bill passed most recently on May 16, 2017 by a 94-46 vote, largely along party lines.
2. As of January 1, two of the Democratic Senate seats will become vacant.
3. Gerald Friedman, *Economic Analysis of the New York Health Act,* April, 2015.

In the New York State Agencies

By Francis J. Serbaroli

Early Intervention Program

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 69-4 of Title 10 NYCRR to conform existing program regulations to federal regulations and state statute. *See* N.Y. Register July 12, 2017.

Children's Behavioral Health and Health Services

Notice of Proposed Rulemaking. The Department of Health proposed adding section 503.38 to Title 18 NYCRR to authorize Medicaid coverage of new behavioral health and health services for children under 21 years of age. *See* N.Y. Register July 12, 2017.

Valuation of Individual and Group Accident and Health Insurance Reserves

Notice of Adoption. The Department of Financial Services amended Part 94 (Regulation 56) of Title 11 NYCRR to adopt the 2013 Individual Disability Income Valuation Table. Filing date: June 30, 2017. Effective date: July 19, 2017. See N.Y. Register July 19, 2017.

Early and Periodic Screening, Diagnostic and Treatment Services for Children

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Part 511 of Title 14 NYCRR to promote the expansion of behavioral health services for children and youth under 21 years of age. *See* N.Y. Register August 2, 2017.

Financial Statement Filings and Accounting Practices and Procedures

Notice of Adoption. The Department of Financial Services amended Part 83 (Regulation 172) of Title 11 NYCRR to update citations in Part 83 to the Accounting Practices and Procedures Manual as of March 2017 instead of 2016. Filing date: July 21, 2017. Effective date: August 9, 2017. *See* N.Y. Register August 9, 2017.

Holding Companies

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Subpart 80-1 (Regulation 52) of Title 11 NYCRR to make technical correction to and clarification of 11 NYCRR Section 80-1.6(3). *See* N.Y. Register August 9, 2017.

Physician and Pharmacies; Prescribing; Administering and Dispensing for the Treatment of Narcotic Addiction

Notice of Emergency Rulemaking. The Department of Health amended section 80.84 of Title 10 NYCRR to allow any authorized practitioners to prescribe, administer and dispense buprenorphine for the treatment of narcotic addiction. Filing date: August 1, 2017. Effective date: August 1, 2017. *See* N.Y. Register August 16, 2017.

Medical Conditions for which an Exemption from Restrictions on Tinted Glass May Be Issued

Notice of Proposed Rulemaking. The Department of Health proposed amending section 69-7.1 of Title 10 NYCRR to amend the existing list of medical conditions for a NYS registered driver or habitual passenger for an exemption to tinted glass. *See* N.Y. Register August 16, 2017.

Medical Use of Marihuana

Notice of Revised Rulemaking. The Department of Health proposed amending Subpart 55-2 and Part 1004 of Title 10 NYCRR to comprehensively regulate the manufacture, sale and use of medical marihuana. *See* N.Y. Register August 23, 2017.

Residential Health Care Facility Quality Pool

Notice of Emergency and Revised Proposed Rulemaking. The Department of Health proposed the addition of section 86-2.42 to Title 10 NYCRR to reward NYS facilities with the highest quality outcomes as determined by methodology developed by regulation. Filing date: August 15, 2017. Effective date: August 15, 2017. *See* N.Y. Register August 30, 2017.

Privacy of Consumer Financial and Health Information, General Provisions

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Part 420 (Regulation 169) of Title 11 NYCRR to incorporate recent changes to federal privacy laws regarding information maintained by financial institutions. *See* N.Y. Register August 30, 2017.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a shareholder in the Health & FDA Business Group of Greenberg Traurig's New York office. He is the former Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal,* and is the former Chair of the Health Law Section. The assistance of Caroline B. Brancatella and Katharine J. Neer, respectively of counsel and associate of Greenberg Traurig's Health and FDA Business Group, in compiling this summary is gratefully acknowledged.

Updating Certificate of Need Thresholds

Notice of Adoption. The Department of Health amended section 710.1 of Title 10 NYCRR to updated Certificate of Need review thresholds. Filing date: August 22, 2017. Effective date: September 6, 2017. *See* N.Y. Register September 6, 2017.

Reportable Incidents and Notable Occurrences

Notice of Adoption. The Office for People with Developmental Disabilities amended Section 624.5(d) of Title 14 NYCRR to amend existing regulations for mandated reporters of reportable incidents to the Justice Center. Filing date: August 22, 2017. Effective date: September 6, 2017. *See* N.Y. Register September 6, 2017.

Agency Name Change Update

Notice of Proposed Rulemaking. The Office for People with Developmental Disabilities proposed to amend Parts 630 and 671 of title 14 NYCRR to update the agency name. *See* N.Y. Register September 6, 2017.

All Payer Database

Notice of Adoption. The Department of Health added Part 350 to Title 10 NYCRR to define the parameters for operation the APD regarding mandatory data submission by healthcare payers as well as data release. Filing date: August 23, 2017. Effective date: September 13, 2017. *See* N.Y. Register September 13, 2017.

Minimum Standards for Form, Content and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 NYCRR to ensure coverage for essential health benefits in all individual, small group, and student accident and health policies. Filing date: September 1, 2017. Effective date: September 1, 2017. *See* N.Y. Register September 20, 2017.

Trauma Centers

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 405 and 708 of Title 10 NYCRR to require hospitals to be verified by the American College of Surgeons Committee to be designated trauma centers by the Department. *See* N.Y. Register September 20, 2017.

Minimum Standards for Form, Content and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Proposed Rulemaking. The Department of Financial Services proposed adding Section 52.73 to Title 11 NYCRR to provide a formulary exception process for medication for the detoxification or maintenance treatment of a substance use disorder. *See* N.Y. Register September 27, 2017.

Managed Care Organizations

Notice of Adoption. The Department of Health amended section 98-1.11 of Title 10 NYCRR to amend prior approval requirements pertaining to asset transfers for managed care organizations. Filing date: September 12, 2017. Effective date: September 27, 2017. *See* N.Y. Register September 27, 2017.

Home and Community Based Services (HCBS) Waiver and Non-Waiver Enrolled Respite Services

Notice of Adoption. The Office for People with Developmental Disabilities amended Parts 633, 635 and 686 of Title 14 NYCRR to amend the existing regulations for HCBS Waiver Respite and create five separate categories of Respite. Filing date: September 12, 2017. Effective date: September 27, 2017. *See* N.Y. Register September 27, 2017.

General Service Standards for Chemical Dependence Outpatient (CD-OP) and Opioid Treatment Programs (OTP)

Notice of Revised Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 822 of Title 14 NYCRR to conform HIV and Hepatitis testing in accordance with the Public Health Law and clarify the services a peer may provide. *See* N.Y. Register October 4, 2017.

Residential Services

Notice of Revised Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 820 of Title 14 NYCRR to conform HIV and Hepatitis testing requirements in residential settings with the Public Health Law. *See* N.Y. Register October 4, 2017.

Establishment, Incorporation and Certification of Providers of Substance Use Disorder Services

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 810 of Title 14 NYCRR to clarify the obligation to recognize alcohol/substance abuse programs operated by Indian Health Services facilities. *See* N.Y. Register October 11, 2017.

Hospital Indigent Care Pool Payment Methodology

Notice of Adoption. The Department of Health amended section 86-1.47 of Title 10 NYCRR to extend the methodology for indigent care pool payments to general hospitals for another 3 year period- January 1, 2016 through December 31, 2018. Filing date: September 25, 2017. Effective date: October 11, 2017. *See* N.Y. Register October 11, 2017.

Representative Payee

Notice of Adoption. The Office for People with Developmental Disabilities added section 633.9 and amended section 633.15 of Title 14 NYCRR to regulate the management of benefit funds received by facility directors acting as representative payees. Filing date: September 26, 2017. Effective date: October 11, 2017. *See* N.Y. Register October 11, 2017.

Administration of the Long Term Ombudsman Program

Notice of Proposed Rulemaking. The Office for the Aging proposed repealing Part 6660 and adding new Part 6660 to Title 9 NYCRR to bring NYSOFA's rules and regulations governing LTCOP into conformance with the Federal Statute and regulations. *See* N.Y. Register October 18, 2017.

Establishment and Operation of Market Stabilization Mechanisms for Certain Health Insurance Markets

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 361 of Title 11 NYCRR to allow for the implementation of a market stabilization pool for the small group health insurance market. Filing date: September 28, 2017. Effective date: September 28, 2017. *See* N.Y. Register October 18, 2017.

Lead Testing in School Drinking Water

Notice of Emergency Rulemaking. The Department of Health added Subpart 77-4 to Title 10 NYCRR to require lead testing and remediation of potable drinking water in schools. Filing date: September 28, 2017. Effective date: September 28, 2017. *See* N.Y. Register October 18, 2017.

Physician and Pharmacies; Prescribing, Administering and Dispensing for the Treatment of Narcotic Addiction

Notice of Emergency Rulemaking. The Department of Health amended Section 80.84 of Title 10 NYCRR to allow any authorized practitioner to prescribe, administer and dispense buprenorphine for treatment of narcotic addiction. Filing date: September 28, 2017. Effective date: September 28, 2017. *See* N.Y. Register October 18, 2017.

Certification of Facilities and Home and Community Based Services (HCBS)

Notice of Adoption. The Office for People with Developmental Disabilities amended Parts 633, 635, 671, 679, 681, 686 and 690, and adding Part 619 to Title 14 NYCRR to update, reorganize and relocate existing requirements for certification of programs and services in OPWDD's system. Filing date: October 3, 2018. Effective date: October 18, 2017. *See* N.Y. Register October 18, 2017.

Charges for Professional Health Services

Notice of Adoption. The Department of Financial Services amended section 68.6 (Regulation 83) of Title 11 NYCRR to limit reimbursement of no-fault health care services provided outside NYS to highest fees in fee schedule for services in NYS. Filing date: October 25, 2017. Effective date: January 9, 2018. *See* N.Y. Register October 25, 2017.

Medical Use of Marihuana

Notice of Emergency Rulemaking. The Department of Health amended Section 1004.3, 1004.4, 1004.22 and 1004.23 of Title 10 NYCRR to allow certain defined facilities to become a designated caregiver for a certified patient in NYS's Medical Marihuana Program. Filing date: October 5, 2017. Effective date: October 5, 2017. *See* N.Y. Register October 25, 2017.

Repeal Part 14 NYCRR Part 830 (Acupuncture) and Add New Part 830 (Designated Services; Acupuncture and Telepractice)

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 830 and adding a new Part 830 to Title 14 of NYCRR to repeal obsolete regulations and incorporate provisions into a new Part with additional provisions. *See* N.Y. Register November 1, 2017.

Children's Behavioral Health Services

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed adding Part 823 to Title 14 NYCRR to define and implement children's behavioral health services pursuant to the EPSDT program in New York. *See* N.Y. Register November 1, 2017.

Residential Health Care Facility Quality Pool

Notice of Emergency Rulemaking. The Department of Health added section 86-2.42 to Title 10 NYCRR to reward NYS facilities with the highest quality outcomes as determined by methodology developed by regulation. Filing date: October 13, 2017. Effective date: October 13, 2017. *See* N.Y. Register November 1, 2017.

Developmental Disability Definition Update

Notice of Adoption. The Office for People with Developmental Disabilities amended Parts 624, 633, 635, 671, 676, 679, 680, 681, 686, 687, and 690 of Title 14 NYCRR to conform OPWDD's definition of developmental disability in existing regulations with Mental Hygiene Law. Filing date: October 24, 2017. Effective date: November 8, 2017. *See* N.Y. Register November 8, 2017.

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health Medicaid Decisions

Compiled by Margaret Surowka Rossi

There are no updates since the last edition.

New York State Attorney General and New York State Comptroller's Press Releases

Compiled by Bridget Steele, Jamie Dughi Hogenkamp, Eric Dyer, and Dena DeFazio

NYS Attorney General Announces a Lawsuit to Defend Health Care Subsidies—October 13, 2017—The Attorney General responded to the President's decision to cut off cost-sharing reduction payments under the Affordable Care Act by filing a lawsuit with a host of other States to defend health care subsidies. https://ag.ny.gov/press-release/ag-schneiderman-announces-multistate-lawsuit-defend-health-care-subsidies-0.

NYS Attorney General Issues a Statement on the President's Health Care Executive Order—October 12, 2017—In response to the President's Executive Order on Health Care, the Attorney General's Office announced that it will defend Affordable Care Act subsidies. https://ag.ny.gov/press-release/ag-schneiderman-statement-pres-trumps-health-care-executive-order.

Individual Sentenced for Stealing the Identities of Nursing Home Residents—October 11, 2017—A Rosedale, New York resident was sentenced to 2 to 4 years in prison after pleading guilty to multiple counts of Identity Theft in the First Degree, a Class D felony, and Scheme to Defraud in the First Degree, a Class E felony. The Rosedale resident fraudulently obtained the personal information of three nursing home residents through an employee at the nursing home and then used this information to purchase items, such as iPads, computers, televisions and designer handbags. https://ag.ny.gov/press-release/ag-schneiderman-announces-prison-sentence-queens-woman-convicted-stealing-identities.

NYS Attorney General Makes Statement Against the Federal Rule on the ACA Contraceptive Mandate—October 6, 2017—After an interim final rule was issued by the Federal Government, expanding the exemptions for contraceptive coverage under the Affordable Care Act, the NYS Attorney General responded by opposing the new rule and encouraging the New York Senate to pass the proposed Comprehensive Contraception Coverage Act. https://ag.ny.gov/press-release/statement-ag-schneiderman-federal-rule-weakening-aca-contraceptive-mandate.

Home Health Care Agency Owner Sentenced to Jail for Wage Theft—September 27, 2017—The owner of a Peekskill, New York home health care agency was sentenced to one year in jail after pleading guilty to multiple felonies, including Scheme to Defraud, Falsifying Business Records in the First Degree, Offering a False Instrument for Filing in the First Degree, and the following misdemeanors: Failure to Pay Wages and Willful Failure to Pay a Contribution to the Unemployment Insurance Fund. The guilty plea stems from the owner defrauding 67 employees out of $135,161.79 in wages. The owner is also required to dissolve the home care agency, pay full restitution of the back wages to employees and pay $66,000 to the state unemployment insurance fund. https://ag.ny.gov/press-release/ag-schneiderman-announces-jail-time-peekskill-home-health-care-agency-owner-convicted.

NYS Attorney General Calls on Insurance Companies to Review Policies That Drive Opioid Epidemic—September 18, 2017—New York joined a coalition of 37 bipartisan Attorneys General to urge health insurance companies to examine both financial incentives for payment, and coverage policies contributing to the United States opioid epidemic. The letter, sent nationwide to major

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The Editor would like to thank Barclay Damon's Law Clerk Dena DeFazio for her assistance with this edition.

insurance providers and industry trade groups, called for insurers to identify coverage and payment policies to assess the positive and negative impacts incentive structures have had on the opioid epidemic, and to encourage reforms increasing accessibility of non-opioid alternatives for treatment of chronic pain. https://ag.ny.gov/press-release/attorney-general-schneiderman-calls-insurance-companies-review-policies-drive-opioid.

NYS Attorney General Announces Civil Suit and Criminal Charges Against Pharmacy Owner for Allegedly Defrauding Medicaid of Millions—August 24, 2017—A civil lawsuit and criminal charges have been filed against a New York county pharmacy and pharmacist for alleged fraud, stemming from allegations of kickbacks paid to Medicaid recipients for HIV prescriptions and for referring other Medicaid recipients to the pharmacy, as well as $60,000 in allegedly fraudulent payments for prescription refills that were not dispensed between July 2014 and August 2017. The civil suit—filed in New York State Supreme Court, New York County—seeks over $11 million in damages from the pharmacist, pharmacy, and two closed pharmacies previously owned by the pharmacist. The pharmacist also faces criminal charges in New York City Criminal Court, New York County, including Grand Larceny in the Third Degree, a Class D felony, and Medical Assistance Provider: Prohibited Practices (Kickbacks), a Class E felony, with the possibility of additional criminal charges following investigation. A court order freezing the defendants' bank accounts to preserve funds obtained from Medicaid is in place, and if convicted of the top count, the pharmacist could face up to seven years in state prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-civil-suit-and-criminal-charges-against-pharmacy-owner.

NYS Attorney General Announces $465 Million Joint State-Federal Settlement with Mylan, Maker of Epipens—August 17, 2017—New York State agreed to join a state-federal $465 million settlement with Mylan Inc. and its wholly owned subsidiary, Mylan Specialty L.P., and will receive $38.5 million under the settlement agreement. The agreement resolves allegations that from July 29, 2010 to March 31, 2017, in violation of the Medicaid Drug Rebate Statute, Mylan knowingly underpaid rebates owed to Medicaid for EpiPens and EpiPen Jrs. dispensed to Medicaid beneficiaries, and allegedly submitted false statements to the Centers for Medicare and Medicaid Services, as well as several states that rely on EpiPen rebates, incorrectly classifying the drug and failing to report a Best Price. The settlement stemmed from whistleblower—*qui tam*—actions in Massachusetts District Court, and resolved allegations of overcharging certain entities participating in the 340B Drug Pricing Program. https://ag.ny.gov/press-release/ag-schneiderman-announces-465-million-joint-state-federal-settlement-mylan-maker.

NYS Attorney General Announces Indictment of State Detention Center's Private Medical Provider Staff for Alleged Theft From State—August 17, 2017—Two staff members of a private medical services provider for a State juvenile detention center were indicted by a Brooklyn Grand jury. The parties were arraigned in New York State Supreme Court, Kings County, and were released on their own recognizance, pending a return to court in October 2017. Both parties were charged with Grand Larceny in the Second Degree, a felony, for allegedly stealing and assisting in the theft of more than $50,000 each in state funds. In addition, the nursing supervisor also faces eight counts of Falsifying Business Records in the First Degree, a felony. The charges stem from allegations that between January 2011 and December 2015 the employees submitted time sheets containing false information to the State for payment, based on a contract between the New York State Office for Children and Family Services and the medical service provider. If convicted, the parties face up to fifteen years in prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-indictment-state-detention-centers-private-medical-provider.

NYS Attorney General Announces 5-Month Jail Sentence for Unlicensed Dentist Following "Operation Toothache"—August 15, 2017—A Kings County Supreme Court jury found an unlicensed dentist guilty of Unauthorized Practice of a Profession (Dentistry), a Class E felony. The charges stemmed from an undercover investigation finding that the party was practicing dentistry, despite having lost his license due to a 2000 conviction for felonies related to Medicaid fraud, including Grand Larceny in the Third Degree and Perjury in the First Degree. The current conviction resulted in a five-month jail sentence, an additional five years of probation, a $10,000 fine, and a bar from receiving direct or indirect Medicaid funds while on probation. https://ag.ny.gov/press-release/ag-schneiderman-announces-5-month-jail-sentence-unlicensed-dentist-following-operation.

NYS Attorney General Announces Sentencing of Former Head Nurse for Covering Up Neglect of Nursing Home Resident—August 15, 2017—A registered nurse was found guilty of Offering a False Instrument for Filing in the First Degree, a felony, by a Nassau County jury following a six day trial. The charges stemmed from false documents provided to a New York State Department of Health investigator, following a resident's repeated falls, resulting in injuries and hospitalization. The nurse was sentenced to a conditional discharge and was barred from future work in government-funded health care programs, and may have her nursing license revoked by the New York State Office of Professional Discipline. Three former employees of the subject nursing home, including two registered nurses and one licensed practical nurse, previously pled guilty to charges in connection with the incident. https://ag.ny.gov/press-release/ag-

schneiderman-announces-sentencing-former-head-nurse-covering-neglect-nursing-home.

NYS Attorney General Statement on DC Circuit Decision to Grant AGs' Motion to Intervene in Critical Affordable Care Act Case—August 1, 2017—The D.C. Circuit Court granted a motion by the New York State and California Attorneys General, and a coalition of 18 Attorneys General, to intervene in *House v. Price*, to defend the Affordable Care Act's cost-sharing reduction subsidies. Following the decision, the NYS Attorney General released a statement that the decision was "good news for the hundreds of thousands of New York families that rely on these subsidies for their health care." https://ag.ny.gov/press-release/ag-schneiderman-statement-dc-circuit-decision-grant-ags-motion-intervene-critical.

NYS Attorney General Announces 46-Year Prison Sentence for Former Traumatic Brain Injury Center Counselor Who Sexually Abused Disabled Residents—July 28, 2017—Following a one-week jury trial, a former counselor was found guilty of sexually abusing six traumatic brain injury center residents between July 2014 and February 2015. The defendant was convicted of 24 counts related to the sexual abuse, including one count of Criminal Sexual Act in the First Degree, a Class B violent felony, seven counts of Sexual Abuse in the First Degree, a Class D violent felony, and was sentenced by an Ulster County Court Judge to 46 years in prison and 20 years post-release supervision. https://ag.ny.gov/press-release/ag-schneiderman-announces-46-year-prison-sentence-former-traumatic-brain-injury-center.

NYS Attorney General Announces Joint State and Federal $4.4 Million Settlement with Visiting Nurse Service Managed Long-Term Care Plan—July 17, 2017—A settlement totaling $4,392,150 resolved allegations that Visiting Nurse Service of New York and VNS Choice knowingly retained over $1.6 million in Medicaid payments, in violation of both the state and federal False Claims Act. Following a whistleblower lawsuit under the *qui tam* provisions of the state and federal False Claims Act, the defendants admitted—as part of the settlement—that between January 1, 2011 and March 31, 2015, the entities failed to identify and disenroll members in a timely manner, continued receiving payments for unprovided care, and failed to return the corresponding payments. An additional settlement was reached in the matter in November 2014, resolving allegations surrounding the improper use of a social adult day center to enroll members in VNS Choice insurance. New York State will receive $2.63 million as a result of the settlement agreement. https://ag.ny.gov/press-release/ag-schneiderman-announces-joint-state-and-federal-44-million-settlement-visiting-nurse.

NYS Attorney General: "If This Health Care Bill Ever Becomes Law, I Will Challenge It in Court"—July 17, 2017—The NYS Attorney General addressed the pending federal health care bill to health care labor-related groups, including the New York State Nurses Association, SEIU, Greater New York Hospital Association, and Hospital Association of New York, highlighting concerns including the affordability and reduction of health care, reduced funding for hospitals and the Medicaid program, and a carve-out in the bill directly affecting federal funding for New York's Medicaid program. The NYS Attorney General stated, "Let me be clear: If this inhumane bill ever becomes law, I will go to court to challenge it—I will sue the Trump Administration and their congressional allies—to protect New Yorkers." https://ag.ny.gov/press-release/mount-sinai-event-attorney-general-schneiderman-announces-if-health-care-bill-ever.

NYS Attorney General Announces Guilty Plea, $500K Settlement with Binghamton-Area Transport Company Owners for Stealing from Medicaid by Failing to Secure Proper Insurance—July 13, 2017—The owners of a Binghamton-area transportation company were convicted of Medicaid fraud and related charges, following the company's knowing operation without Worker's Compensation insurance from June 2, 2012 until January 30, 2014, in violation of Broome County transportation regulations and the New York State Workers' Compensation Act. The owners individually plead guilty to charges including Grand Larceny in the Second Degree, a violation, Offering a False Instrument for Filing in the Second Degree, a violation, and Effect of Failure to Secure Compensation, a violation of the Workers' Compensation Act. The transportation company entered a guilty plea to Effect of Failure to Secure Compensation. A settlement agreement of $50,000 and forfeiture of the funds received from Medicaid during the time period, amounting to $455,604.39, was also reached. Sentencing of the parties was adjourned until a September 29, 2017 court date. https://ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-500k-settlement-binghamtom-area-transport.

NYS Attorney General Announces Guilty Plea of Queens Woman for Stealing Three Nursing Home Residents' Identities—July 10, 2017—A Queens resident plead guilty to three counts of Identity Theft in the First Degree, a Class D Felony, and two counts of Scheme to Defraud in the First Degree, a Class E Felony, after making $11,738 in purchases with the fraudulently obtained credit cards of three nursing home residents. After reports of suspicious activity on the credit cards, an investigation determined that the defendant received the credit card information from an unidentified friend working at the nursing home. The defendant will serve two to four years in jail. https://ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-queens-woman-stealing-identities-three-nursing.

NYS Attorney General Announces Sentence of Suffolk County Doctor for Criminal Sale of Opioid Prescriptions—June 27, 2017—A Long Island Doctor of Osteopathic Medicine was sentenced to one year in jail for selling prescriptions for opioid medications; aiding, abetting and authorizing a non-physician employee to issue prescriptions; and falsifying electronic medical records relating to the patients to conceal crimes. The doctor directed his receptionist to print and sign his name to prescriptions for controlled substances when he was not in the office and give the prescriptions to individuals after paying a cash "office visit" fee, while electronic medical records falsely showed physician examinations and observations. The doctor was found guilty by a jury of Criminal Sale of a Prescription for a Controlled Substance, Unauthorized Practice of Medicine, and Falsifying Business Records in the First Degree. The doctor lost his DEA license and will no longer be able to write prescriptions for controlled substances. https://ag.ny.gov/press-release/ag-schneiderman-announces-sentence-suffolk-county-doctor-criminal-sale-opioid.

NYS Attorney General Announces Arrest of Registered Nurse for Allegedly Defrauding Medicaid—June 26, 2017—The Attorney General announced the indictment, arrest and arraignment of a private duty nurse who allegedly submitted claims for Medicaid reimbursement for private-duty nursing services to two Medicaid recipients who never received services. The private duty nurse allegedly submitted false claims totaling over $390,000 between August 2010 and January 2015 for services that were not provided because the Medicaid recipients were in the hospital, another nurse had provided care, the defendant was on vacation abroad, the defendant was providing care to another patient, or an unlicensed individual was sent to the patient's home to provide care. The defendant was charged with Grand Larceny in the Second Degree, and Offering a False Instrument for Filing in the First Degree. If convicted, the nurse could face up to 15 years in prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-arrest-registered-nurse-allegedly-defrauding-medicaid.

NYS Attorney General Files Lawsuit to End Persistent Harassment of Women Entering Women's Health Clinic in Queens—June 20, 2017—The Attorney General filed a lawsuit and preliminary injunction motion in the United States District Court for the Eastern District of New York against a group of protesters alleging that every Saturday morning for at least five years a network of anti-choice protestors have attempted to block access to the Choices Women's Medical Center ("Choices") in Jamaica, Queens. The lawsuit alleges this group has subjected patients entering Choices to unwanted physical contact, verbal abuse, violent threats, and lies about Choices' hours and services. The lawsuit and preliminary injunction motion brought under the federal Freedom of Access to Clinic Entrances Act (FACE), the New York State Clinic Access Act, and the New York City Access to Reproductive Health Care Facilities Act, seeks damages, penalties, costs, and attorney's fees. Further the lawsuit seeks to prevent defendants from engaging in unlawful conduct and create a sixteen-foot buffer zone around Choices for patient safety. https://ag.ny.gov/press-release/ag-schneiderman-files-lawsuit-end-persistent-harassment-women-entering-womens-health.

NYS Attorney General Announces Settlement with Health Care Services Company That Illegally Deferred Notice of Breach of More Than 220,000 Patient Records—June 15, 2017—The Attorney General announced a settlement with CoPilot Provider Support Services, Inc. ("CoPilot") for delaying notice of a breach of patient records. CoPilot is a New York corporation that has a website to help physicians determine whether insurance coverage is available for certain medications. In October 2014, an unauthorized person gained access to confidential patient reimbursement data through CoPilot's website and downloaded records of 221,178 patients. The FBI opened an investigation at CoPilot's request in February 2016. In January 2017, more than a year after the breach, CoPilot provided notice to those affected in New York. CoPilot claimed the delay was due to an investigation by the FBI, but the FBI never stated that a consumer notification would compromise its investigation. Pursuant to the settlement agreement, CoPilot will pay $130,000 in penalties and agree to update its policies and comply with New York's consumer protection and data security laws. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-healthcare-services-company-illegally-deferred.

NYS Attorney General Announces Indictment Of Three-Quarter House Director Charged With Defrauding Medicaid Through the Use of a Kickback Scheme—June 13, 2017—The Attorney General announced the indictment, arrest and arraignment of an Executive Director, and the Executive Director's daughter for engaging in an illegal kickback scheme. The entity is an outpatient substance abuse treatment program, which owns several three-quarter houses in Queens and Brooklyn. The indictment alleged that Interline received Medicaid payments for claims based on a kickback arrangement where Interline provided housing at below market rent to homeless clients on the condition that they only receive treatment at Interline. The Executive Director's daughter managed the three quarter homes and evicted residents who did not comply with the mandatory treatment requirements. Prosecutors alleged Interline's Executive Director and his daughter acted in concert to execute the kickback scheme, resulting in the submission of $2,327,524 in fraudulent claims for Medicaid reimbursement. https://ag.ny.gov/press-release/ag-schneiderman-announces-indictment-three-quarter-house-director-charged-defrauding.

New York State Office of the Medicaid Inspector General Update

Compiled by Eric Dyer

UPDATE: Owner of Brooklyn-based Medical Clinics Sentenced in Federal Court—September 18, 2017—https://omig.ny.gov/latest-news/1070-update-owner-of-brooklyn-based-medical-clinics-sentenced-in-federal-court.

OMIG Issues Compliance Alert 2017-01—August 18, 2017—https://omig.ny.gov/latest-news/1068-compliance-alert-2017-01.

OMIG Participates in 2017 National Healthcare Fraud Takedown, Efforts Help to Uncover $125 Million in Alleged Fraud Schemes—July 13, 2017— https://www.omig.ny.gov/latest-news/1060-omig-participates-in-2017-national-healthcare-fraud-takedown-helps-to-uncover-125-million-in-fraud-schemes.

In the Journals

Edited by Cassandra Rivais

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A Right to Refuse? The Legalities of a Pregnant Patient's Refusal of Medical Treatment, R. Rhett Owen, 78 Ala. Law. 263 (2017).

A Woman's Private Choice, Erwin Chemerinsky and Michele Goodwin, 95 Tex. L. Rev. 1189 (2017).

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Big Data and the Americans with Disabilities Act, Sharona Hoffman, 68 Hastings L.J. 777 (2017).

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For Your Information

By Claudia O. Torrey

Before I list a couple of items that you may find of interest, I wish to take a personal moment in order to update you as "extended family" on a prior situation. You may recall two years ago one of my parents had a severe stroke, but was managing to do well despite the challenges. Unfortunately, that parent died on October 26th. We are all aware of the "seasons" of life, but I would just as soon not be going through this particular season; however, one perseveres in taking the bitter with the sweet! At this writing, the holiday season from Thanksgiving through Epiphany is upon us. Blessings and good wishes to each of you throughout 2018!

- On November 1, 2017, the Centers for Medicare and Medicaid Services of the Health & Human Services Department ("Department") issued a Final Rule[1] designed to cut payments to hospitals in the 340B program by 30 percent. This program allows facilities that serve low-income patients to buy drugs/medicines at a discount and seek reimbursement at a higher rate. While hospitals tend to see the 340B program as a critical subsidy to fund indigent care, some pharmaceutical companies claim the program has been abused by hospitals. The reductions are slated to go into effect at the beginning of 2018 for all hospitals participating in the program.

  According to the American Hospital Association, the Department's decision to make such a cut potentially threatens access to health care for many patients, including the uninsured and other vulnerable populations.[2]

- On October 2, 2017, the Department of Veterans Affairs (VA) issued a Proposed Rule[3] that permits VA health care providers licensed in any state to provide telehealth services to VA beneficiaries, regardless of where the health care provider or beneficiary is physically located. This action by the VA is a "clarion call" that the VA intends to exercise its federal preemption rights with respect to any conflicting state licensure laws; ironically, the U.S. House of Representatives unanimously passed legislation that tackles the same issue.[4]

  The VA has been a leader in telehealth services to rural areas and is one of the largest providers of telehealth services in the country.[5] Currently, the VA preempts state licensure regarding in-person care provided to beneficiaries at a VA facility, so long as the provider is licensed in at least one state; the proposed rule by the VA is limited to VA-employed physicians and would *not* apply to contracted health care providers such as community-based physicians who provide services under the Veterans Choice program.

Endnotes

1. 82 Fed. Reg. 52,356; 52,493-52,511; 52,622-52,625 (Nov. 1, 2017).
2. *See American Hospital Association v. Hargan*, U.S. District Court, District of Columbia (Case 1:17-cv-02447, filed Nov. 13, 2017).
3. 82 Fed.Reg.45, 756 (Oct. 2, 2017).
4. H.R.2123/S.925(2017,115 Cong.).
5. *See* 82 Fed. Reg. at 45,758.

Claudia Torrey is a Charter Member of the Health Law Section.

The Clinical, Ethical and Legislative Case for Medical Aid in Dying in New York

By David C. Leven and Timothy E. Quill

Introduction

Palliative care and hospice should be standards of care for seriously ill and dying patients.[1] Most, but not all, suffering can be adequately addressed with the skillful addition of palliative measures to a patient's treatment plan. Therefore, the first place to go if a patient makes a request for medical aid in dying is to ensure that his or her suffering is thoroughly understood and addressed with state of the art and science palliative care.[2] To be clear, medical aid in dying is not part of usual palliative care or hospice practice. It is the process by which an adult, mentally competent, terminally ill patient, who doctors determine is likely to die within six months, self-consumes prescribed medicines to end suffering and achieve a peaceful death.

Some patients making requests for medical aid in dying have witnessed bad deaths in their life experience, and are worried about going through a similar process in their own future. Such patients can benefit from a thorough exploration of what they have seen and are afraid of from their own lives, followed by a frank discussion about how one's doctor proposes to address such circumstances should they occur to the patient him or herself. In the vast majority of cases (but not 100 percent) such suffering can be addressed with the skillful provision of palliative treatments without resorting to treatments that intentionally hasten death. Experienced palliative care experts are increasingly available to help address the most challenging problems, making the need for direct assistance in dying because of immediate, intractable suffering relatively rare. However, if you happen to be one of those infrequent cases with intractable, unrelievable, severe suffering, you have a real problem that requires a direct medical response.

Of course, not all patients who request medical aid in dying do so because of severe immediate physical suffering that is refractory to treatment. The majority of patients making these requests do so because the dying process is going on too long for them to tolerate, and they are "tired of dying" or intolerant of the debility, which is so often a central part of the late stages of the experience.[3] Such patients may be used to being in control of their own lives and of their own bodies, so becoming extremely dependent upon others is not something they want to accept or to which they can adjust. As a society we tend to admire similarly situated patients who choose to stop life supports to maintain their independence, but should there be no life support to stop in the presence of a similarly debilitating illness, we sometimes accuse patients of having an excessive "need to control" their future.

Every dying person should have a right to excellent palliative care and hospice no matter what other choices they make—be it requesting long shot, aggressive, disease-directed treatment, or treatment devoted entirely to palliation delivered with the help of a hospice program, or, if they are mentally competent and fully informed, treatments that might hasten death. As much as possible, given constraints imposed by one's disease process as well as limitations imposed by the law, patients should be able to die in a way that is consistent with their values and beliefs. Clinicians who care for seriously ill patients should facilitate palliative care for the dying, and they should also become aware of the full range of legally available "last resort" options to help address severe and intractable suffering.[4] Ideally, in our opinion, medical aid in dying should be one of those legally available options of last resort.

Hastening death by medical aid in dying is ethically similar to other legal means of hastening death, including the withholding or withdrawal of life-sustaining treatment, voluntarily stopping eating and drinking, or palliative sedation to unconsciousness.[4] Each of these options will result in death, and each requires some form of physician participation. Health care professionals are arguably more actively involved in the resulting deaths of their patients when withdrawing life-sustaining treatment such as a ventilator than when providing a potentially lethal medication that a patient can take at a time of his or her own choosing. If a clinician took someone off a life support without the permission of the patient or her surrogate decision maker and the patient died, the clinician would potentially be subject to murder charges. Similarly, providing palliative sedation to unconsciousness while not simultaneously providing life-sustaining treatment without permission from the patient or his surrogate decision maker would be both unethical and illegal. The intent and consent of terminally ill patients matter much more than the intent and willingness of health care professionals.

Medical Aid in Dying Should Not Be Considered "Assisted Suicide"

Patients who choose medical aid in dying determine the manner of their deaths just as do many patients who choose other last resort options. They should be carefully evaluated for their decision-making capacity, but they are

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not by definition "suicidal" unless their decision is distorted by associated mental illness. Stark differences exist between dying patients who are making a life-ending decision in the context of a severe, irreversible terminal illness, and those with primarily mental illnesses who die by suicide.[5] Mental illness-related suicide is committed by those who usually do not have a terminal illness and could continue to live but choose not to, usually because of some distortion in their thinking based on potentially treatable mental illness. Such suicides are usually done in isolation, often impulsively and violently, and are tragic. We should do everything in our power, including potentially involuntary hospitalization, to prevent them. To the contrary, in the U.S. states where medical aid in dying has been legalized, it is available only to terminally ill patients who will soon die; it is the result of a carefully thought out process that usually takes several weeks; and it requires consultation from two physicians who must document their findings and almost always includes support of immediate family. The term "assisted suicide" is rejected by the American Public Health Association, American Academy of Hospice and Palliative Medicine, American Medical Women's Association, among others, and in state laws which permit aid in dying. Most recently, the American Association of Suicidology issued a comprehensive statement, "SUICIDE" IS NOT THE SAME AS "PHYSICIAN AID IN DYING" (http://www.suicidology.org/Portals/14/docs/Press%20Release/AAS%20PAD%20Statement%20Approved%20 10.30.17%20ed%2010-30-17.pdf)

Medical Aid in Dying Laws Have Worked as Intended as an Ethical Practice in U.S. States Where It Has Been Legalized

There is a growing body of evidence, compiled over two decades from Oregon and Washington, which demonstrates that aid in dying is beneficial to some terminally ill patients by allowing them to escape unwanted suffering, and that it causes no significant harm to patients, families, or the medical profession. It has not undermined efforts to improve hospice and palliative care within these jurisdictions, and in some cases may even improve delivery of palliative care and hospice services.[6] No major problems have emerged as expected by opponents.

Medical aid in dying is thought about frequently but rarely used. In Oregon, one out of six terminally ill patients talk to their family members about the option, and one out of 50 talk to their doctors about it, but it accounts for only about one in 300 deaths.[7] Furthermore, one-third of patients who obtain the medications do not take them, but such dying patients are probably comforted knowing that this option is available.

In U.S. states where the practice is legal, there is no evidence of disproportionate impact on vulnerable populations, nor is there evidence of related coercion or abuse.[8]

There is evidence that family members of those who request aid in dying may feel better prepared and accepting of their loved one's death.[9] There is also evidence that patients who access aid in dying have at least as good, and in some cases better, deaths than others.[10] About 90 percent of those who end their lives by using aid in dying in Oregon are receiving hospice care, so the issue of more palliative care resolving the issue is irrelevant (https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Documents/year19.pdf). Almost all patients who choose aid in dying have health insurance and most are college educated, as indicated in the above report.

There is no evidence of any slippery slope in the US. Medical aid in dying is only for the terminally ill, mentally competent adults. There is no serious or concerted movement to extend medical aid in dying to those who are not terminally ill. And, there is no evidence that where medical aid in dying is permitted the reputation of the medical profession has suffered in any way.

Seventy-seven percent of New Yorkers support aid in dying, according to a 2015 poll, including large majorities of Democrats, Republicans, Conservatives, and Catholics. Physicians support aid in dying by an almost 2 to 1 margin, 57 percent to 29 percent per a 2016 Medscape poll, though some of those physicians who support the practice in general terms would not want to provide medical aid in dying themselves. Where legal, physicians who do not want to participate are not required to do so.

Medical Aid in Dying Legislation in New York

Legislative efforts to establish medical aid in dying as a right began in New York in 2015. The current bills, A. 2383 (Paulin) and S. 3151 (Savino), also called the Medical Aid in Dying Act, are comprehensive and patterned after laws in other states which permit aid in dying and which have worked as intended.

Although there are no statutory safeguards and protections pertaining to other decisions by patients (or their agents or surrogates) where death results, such as withdrawing life-sustaining treatments, or voluntarily stopping eating and drinking, or palliative sedation, there are numerous safeguards and protections in the Medical Aid in Dying Act. Some of the key provisions are summarized below.

1. To legally request medical aid in dying (MAID), a patient must be at least 18 years of age and have a terminal illness as defined, confirmed by an attending physician and a consulting physician.

2. A patient must make an oral and a written request (on a form provided in the law) for MAID. The written request must be witnessed by 2 adults who attest that the patient: 1) has capacity; 2) is acting voluntarily; and 3) is not being coerced.

3. One witness shall NOT be: 1) a relative; 2) a person entitled to a portion of the patient's estate; 3) an owner, operator or employee of a health care facility where the patient resides or is being treated; or 4) the patient's attending physician, consulting physician or mental health professional, if applicable, who determines capacity.

4. If either the attending or consulting physician believes the patient lacks capacity, the physician must refer the patient for evaluation by a mental health professional. Only patients subsequently found to have capacity may proceed.

5. A patient may rescind his or her request for medication at any time without regard to capacity.

6. Patients must be able to self-administer the medication.

7. An attending physician must have primary responsibility for the care of the patient requesting MAID and the treatment of the patient's terminal illness.

8. Attending physician responsibilities: 1) determine that the patient has a terminal illness; 2) determine that the patient has capacity, made an informed decision, and made the request for aid in dying voluntarily and without coercion; 3) inform the patient of the need for a consulting physician's confirmation, and refer if requested; 4) refer the patient to a mental health professional for evaluation if the physician believes the patient lacks capacity; 5) provide information and counseling regarding palliative care; 6) ensure the patient is making an informed decision by discussing with the patient the patient's diagnosis and prognosis, the potential risks associated with taking the medication, the probable result of taking the medication, the possibility that the patient may choose to obtain the medication but not take it, the feasible alternatives or additional treatment options including hospice and palliative care; 7) discuss with the patient the importance of taking the medication with someone else present and not taking the medication in public; 8) inform the patient that he/she can rescind the request for medication at any time; 9) document in the patient's medical records all MAID actions as specified; 10) ensure that all appropriate steps have been carried out in accordance with the MAID act; 11) offer the patient an opportunity to rescind the patient's request prior to writing the MAID prescription.

9. The consulting physician must: 1) examine the patient and medical records; and 2) confirm in writing that the patient i) has a terminal illness, ii) has capacity, iii) is making an informed decision, and iv) is acting voluntarily and without coercion.

10. A mental health professional asked to determine the capacity of a patient must, in writing, report to the attending and consulting physicians his/her conclusions whether the patient has capacity. If the mental health professional determines that the patient lacks capacity, the patient may not receive MAID.

11. A patient requesting MAID shall not be considered "suicidal," and a patient who self-administers aid in dying medication shall not be deemed to have committed suicide.

Conclusion

The lessons from Oregon or Washington where medical aid in dying has now been legal for a combined total of almost 30 years are that their laws have functioned as intended, there have been no abuses, there is no evidence that such laws in any way undermine progress in promoting palliative care and hospice care as standards of care for seriously ill and dying patients, and there are currently no concerted efforts in those states to repeal or amend those laws. We are confident that the provisions, safeguards, protections and restrictions outlined above ensure that, if enacted, the Medical Aid in Dying Act will work well in New York and provide another needed, albeit infrequently used, last resort option for terminally ill New Yorkers.

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Hooked on Drugs: The Impact of Pharmaceutical Advertising on Rising Health Care Costs in the U.S.

By Mike Castiglione

America spends vastly more public dollars on health care than almost all other countries of similar economic development, including those that have publicly financed universal health care systems. [1] In 2013, for example, the U.S. spent 17.1 percent of its GDP on health care, as compared to 10.7 percent in Canada, 8.8 percent in the United Kingdom, and 9.4 percent in Australia.[2] This remains true even though Americans have comparatively few hospital admissions and physician visits.[3]

By many measures, we are not getting value for our health care dollars. According to the Bloomberg Health Care Efficiency Index, which rates efficiency based on life expectancy, health care spending per capita, and relative spending as a share of gross domestic product, America ranked 50th out of 55 countries in 2014.[4] And in a report released by the Commonwealth Fund in 2014, the U.S. ranked last among 11 industrialized nations[5] on measures of health system quality, efficiency, access to care, equity and health lives.[6] The report noted that "the U.S. stands out for having the highest costs and lowest performance."[7]

There have been many studies and articles analyzing the reasons behind America's escalating health care costs, but one factor they all seem to point to is the exaggerated growth of pharmaceutical spending.[8] This article describes how one unique aspect of the American pharmaceutical industry in particular, direct-to-patient consumerism, has played a significant role in the rising costs of health care.

A. History

Direct-to-consumer pharmaceutical advertising (DTCPA) refers to the pharmaceutical industry's ability to market its drugs and products directly to patients through advertisements, instead of exclusively to doctors. This practice has been legal in the U.S. since 1985 and is regulated by the Food and Drug Administration (FDA).[9] Prior to 1997, the FDA's rules required a level of detail in pharmaceutical advertising that made broadcast ads impractical and very expensive. For instance, the FDA required that the ads present a "balance" of information, describing both the risks and the benefits, and required a "brief summary" that mentioned *every* risk in the product's labeling.[10] The bulk of pharmaceutical advertising, therefore, was directed at physicians, because they had the power to recommend and prescribe drugs to their patients. Pharmaceutical companies spent enormous amounts of time and money trying to get their attention. Indeed, the average doctor received around 3,000 pieces of mail a year from the drug industry.[11] For big pharma, however, this system of advertising was just too slow.[12]

In 1986, in one of the first national direct-to-consumer television ad campaigns, a medical marketing firm found a way around the FDA's regulations. The drug was called Seldane, an allergy drug, and the loophole they used to avoid violating the FDA's regulations was to not identify the drug directly in the ads.[13] Instead, the ad simply said, "Your doctor now has treatment which won't make you drowsy. See your doctor."[14] The results of this ad campaign were phenomenal: sales of Seldane exploded over the next few years from about $34 million a year to $800 million a year.[15] In the mid-1990s, Schering-Plough employed a similar technique to launch a massive television ad campaign for Claritin; namely, it never mentioned the drug, but implored people to see their doctors to get relief.[16]

These successful drug advertising campaigns, together with political and cultural changes in the U.S. that both favored the pharmaceutical industry and encouraged patients to become more actively involved in their health care decisions,[17] put pressure on the FDA, which eventually relaxed its regulations in 1997.[18] Now, broadcast ads need only include a "major statement," which includes the major risks, and direct the viewer to other sources (such as a toll-free number, a health care provider, a website, or a print ad) for further information, instead of providing the lengthier "brief summary" listing *all* of the product's risks.[19] As a result, drug makers were able to make more detailed ads that include specific medical claims for specific drugs, the kind of ads that dominate the airwaves today.[20]

Not surprisingly, since 1997 DTCPA, and more particularly, broadcast TV advertising, have grown rapidly and are now the most prominent type of health communication the public encounters.[21] In 2011, the Nielsen Company determined that there are on average 80 drug commercials every hour of every day on television,[22] with the result that the average American television viewer watches as many as nine drug ads a day, totaling 16 hours per year, which far exceeds the amount of time the average individual spends with a primary care physician.[23] And since it is estimated that every dollar spent on DTCPA increases sales of the advertised drug by an estimated $2.20 to $4.20,[24] pharmaceutical marketing costs have also

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ballooned from $360 million in 1995, to $1.3 billion in 1998, to $5 billion by 2006.[25]

B. The Pros and Cons of DTCPA

In defense of DTCPA, the pharmaceutical industry argues that it has positive effects on health care by informing, educating, and empowering patients to take charge of their health.[26] Prior to the growth of DTCPA, the doctor-patient relationship was a "one-way street."[27] Patients took pills prescribed by their doctors without knowing what they were for and without asking any questions.[28] As patients become aware of treatments that are available, however, they are encouraged to seek medical advice, thereby opening a dialogue with their health care providers and, arguably, reducing the under-diagnosis and under-treatment of conditions.[29]

In addition, proponents of DTCPA argue that drug advertising reduces the stigma associated with certain conditions by raising awareness, such as with erectile dysfunction or depression.[30] For example, a poll of people who called a toll-free number in response to a 1997 DTCPA campaign for a genital herpes treatment revealed that 45 percent of the callers made an appointment to see their doctor to discuss the problem within three months of seeing the ad.[31]

The medical community, however, is strongly opposed to DTCPA, at least in its current form under the relaxed FDA regulations. In November 2015, the American Medical Association (AMA) went so far as to call for an outright ban on pharmaceutical advertising on the grounds that it was "prompting consumers to demand expensive medications that they might not need."[32] This concern by the AMA is bolstered by the fact that consumers have been found to place unwarranted trust in DTCPA ads.[33] In one survey, 50 percent of respondents thought the ads were approved by the government, 43 percent believed a medication had to be completely safe for it to be advertised, and 22 percent thought that a drug known to have serious side effects could not be advertised.[34]

Opponents of DTCPA also argue that it misinforms patients by overemphasizing drug benefits. [35] For example, from 1997 through 2006, nearly 84 percent of the FDA's regulatory letters sent out for DTCPA "cited ads for either minimizing risks (*e.g.*, omitting information about side effects) or exaggerating a drug's effectiveness (*e.g.*, portraying the indication too broadly or making unsubstantiated claims of superiority over other drugs), or both.[36]

Additionally, opponents of DTCPA argue that it leads to drug over-utilization because consumers are not diagnosticians. After seeing an ad, consumers may falsely believe that their symptoms are from a disease rather than the result of other factors such as aging or environment:

> One often-cited example is [DTCPA] ads for ED [erectile dysfunction] drugs, which seem to target men who may be experiencing normal variations in sexual performance. Studies show that only 10% of American men experience a total inability to achieve an erection. Therefore, many requests for ED drugs seem to be for occasional problems, which may actually be "normal." Similarly, DTC drug ads have also been criticized for redefining menopause as a hormone-deficiency disease rather than a normal midlife experience.[37]

In short, many believe that DTCPA creates what some have referred to as the "Modern Patient": a person who enters a doctor's office with specific requests for medications and procedures.[38] The Modern Patient is keen on self-diagnosis and pushes doctors to get what he/she wants.[39] And, for a variety of reasons, it's difficult for doctors to refuse these patient requests, even when those requests are "unreasonable, wrongheaded and potentially harmful."[40] In a bulletin published by the World Health Organization (WHO) concerning DTCPA, the WHO state: "Surveys carried out in New Zealand and in the USA [the only two nations where DTCPA is legally permissible] show that when a patient asks for a specific drug by name, they receive it more often than not."[41] This removes the power to diagnose from doctors, who have expertise and years of training and experience, and gives power to patients, who are easily swayed by the advertisements for brand-name medication they've seen on TV, even though other drugs might be more effective or less expensive, or both.[42] In effect, DTCPA has transformed people from passive "patients" who follow the doctor's orders into active and aggressive "consumers" of pharmaceutical products.[43]

C. DTCPA's Effect on Health Care Costs

Evidence demonstrates that since the change in DTCPA regulation in 1997, consumer demand for pharmaceutical drugs has increased dramatically, resulting in increased health care costs overall.[44] For instance, in 2008, the average American received twelve prescriptions a year, whereas in 1992, the average was only seven.[45] In other words, in a decade and a half, the use of prescription medication increased by 71 percent. Another study also found that advertising has raised the prescription rate of direct-to-consumer advertised drugs by over 30 percent.[46] This overall increase has added about $180 billion to our medical spending,[47] with prescription drugs accounting for nearly 17 percent of total health care spending in 2015, as compared to only 7 percent in the 1990s.[48] Moreover, researchers estimate that nearly 20 percent of the $180 billion has absolutely nothing to do with the increased number of medications available, or even

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A Note from Robert Swidler

NYSBA Health Law Journal Editor from 2005–2017

After 12 years as editor of the *NYSBA Health Law Journal*, I am stepping down. We are now very fortunate to have Brendan Parent as editor, and I leave confident that the *Journal* will thrive under his leadership.

The Health Law Section was formed in 1995, largely through the efforts of Albany health law attorney Barry Gold. Those of us involved in the new Section quickly recognized the need for a statewide, state law focused health law journal, given the growing volume, complexity and importance of New York health law. The formation of the Section provided that opportunity, and Vol. 1, No. 1 of the "Health Law Newsletter" was issued in Fall 1996. I've been involved with the *Journal* in one way or another since that first edition, then starting in 2002 as co-editor with Albany Law School Professor Dale Moore, and since 2005 as editor.


HEALTH LAW
Newsletter

A Message from the Section Chair

INSIDE THIS ISSUE

Over the years the *Journal* has grown and matured, just as the Section has. One can see that visually through the evolution of *Journal* covers from word processed-looking covers, to plain glossy red covers, to glossy red covers with stock photos (often featuring something legalish paired with something medicalish), to multicolored seasonal art, to our current practice of choosing fine art of any genre that readers might enjoy.


NYSBA
Health Law Journal
HEALTH CARE SYSTEMS IN N.Y.—THEIR UNIQUE LEGAL ISSUES

But of course the value of the *Journal* is its content. I am enormously proud that edition after edition, year after year, the *Journal* has offered well-written articles on health law topics of interest and value to New York State health lawyers. Many readers are not aware that an index and archive of all *Journal* articles is available on the NYSBA website, at http://www.nysba.org/HealthLawJournal. It is an impressive collection.

Equally important, the *Journal* has offered regular columns on developments in the courts, the legislature, the agencies, fraud and abuse enforcement, law reviews, Claudia Torrey's eclectic column *FYI*, and news from the Section.

I leave the *Journal* in good hands; Brendan Parent is uniquely qualified to be its editor. He is Director of Applied Health at NYU School of Professional Studies, a faculty affiliate of the Division of Medical Ethics at NYU School of Medicine, and director of NYU Sports and Society. He also serves as Chair of the Ethical Issues in Health Care Committee of the Health Law Section of the New York State Bar Association. Previously, he was the first Rudin Postdoctoral Fellow in the Division of Medical Ethics at NYU School of Medicine, then Special Legal Adviser for the New York Task Force on Life and the Law, a government agency that assists the state with policy in medicine, law, and ethics.

He designed his undergraduate major in Bioethics at University of California, Santa Cruz and received his JD from Georgetown University Law Center, where he was presented with the ABA Award for Excellence in Health Law.

Before I exit, there are colleagues to whom I am very grateful and whom I want to thank.

First, thank you to the *Journal's* stalwart columnists, most of whom have been on board as long as I have: Leonard Rosenberg of Garfunkel Wild (*In the NYS Courts*); Jim Lytle of Manatt Phelps (*In the NYS Legislature*); Frank Serbaroli of Greenberg Traurig (*In the NYS Agencies*); Melissa Zambri of Barclay Damon (*Fraud, Abuse and Compliance*); the several people who helped compile the *In the Journals* column including most recently Cassandra Rivais and before her Mishka Woodley; and Claudia Torrey, in solo practice (*FYI*). Your work is enormously valuable. Thank you.

Thank you to the many health lawyers who were special editors over the years, including most recently Nathan Prystowky (Young Lawyers Committee: Provocative Topics in Health Law). They have produced editions of great and enduring value.

I speak for the entire Section in thanking the hundreds of authors who contributed to the *Journal* over the years. You have made us better health lawyers.

Of course I am very grateful to the NYSBA Publications staff, notably Wendy Harbour and Lyn Curtis who put the *Journal* together for many years, and Kate Mostaccio who took over a year ago and who is terrific.

I owe a special thanks to Jim Reed, M.D., CEO of St. Peter's Health Partners. I am VP Legal Services for St. Peter's Health Partners, and I report to Jim (and to the board of St. Peter's Health Partners). I could not have engaged in this demanding extracurricular activity without his support.

Above all, I want to thank my wife Kim, for many many things of course. But among them is for letting me steal many evenings and weekend hours from her to work on the *Journal*. Fortunately Kim can relate—she is an attorney and has been a contributor to the *NYSBA Entertainment Law Journal* and more recently to the *Newsletter of the NYSBA Committee on Courts of Appellate Jurisdiction*.

Whenever a new edition of the *NYSBA Health Law Journal* shows up in my incoming mail, I am excited and delighted. Although I'm stepping down as editor, I know that will not change.

Robert Swidler

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increases in the cost of medication,[49] but rather can more likely be tied to increased demand created by DTCPA.

While it may be difficult to draw a straight line of causation between increased advertising and increased costs, one study on pharmaceutical pricing policy notes that pricing of pharmaceutical products "can be distorted … by pharmaceutical promotions," and further concluded:

> The total costs of medicines depend not only on selling prices but also on volumes of use. Unnecessary medicine use contributes to both costs and adverse clinical outcomes. The demand side of the pharmaceutical market is just as important as the supply side.[50]

And, in fact, at least one study conducted does draw that direct line correlation. Specifically, in 2010, economists Dhaval Dave and Henry Saffer conducted a study of four classes of pharmaceuticals, both advertised and non-advertised, from 1994 through 2005—the period of time which coincided with the change in FDA regulations and the subsequent dramatic increase in DTCPA.[51] They found that advertising could affect the pricing of pharmaceuticals through two mechanisms: 1) by increasing demand and decreasing the price sensitivity of purchasers (*i.e.*, advertising of brand name drugs increased consumer demand for newer, more expensive drugs and reduced consumer sensitivity to price that would otherwise drive consumers to purchase older, less expensive drugs or generics); and 2) by increasing the pharmaceutical industry's operating costs because of increased marketing which may then be shifted to consumers in the form of higher prices.[52] Based on their study, Dave and Saffer concluded that the increase in broadcast DTCPA "appears to have been responsible … for about 18% of the overall increase in prescription drug expenditures between 1994 and 2005 in the U.S., with about 12% due to greater sales and 6% attributed to higher prices."[53]

D. DTCPA and the First Amendment

From the foregoing discussion, it is clear that the loosening of FDA regulations relating to pharmaceutical advertising in 1997 has led to an increase in consumer demand for drugs, which in turn has created both public health concerns, in that the public is now demanding, and receiving, medications that might not be necessary or appropriate, as well as cost inflation. Efforts to rein in DTCPA, however, have largely failed, for the most part because of the First Amendment.[54]

Specifically, in a 1980 landmark decision, *Central Hudson Gas,* the Supreme Court held that commercial speech, including advertising, was protected under the First Amendment.[55] Subsequently, in 1993 the Court laid out the basis for the protection of commercial speech under that Amendment:

> The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. *But the general rule is that the speaker and the audience, not the government, assess the value of the information presented*. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.[56]

The Supreme Court, however, has recognized the "'common sense' distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech."[57] These distinctions have led the Court to conclude that "the Constitution . . . affords a lesser protection to commercial speech than to other constitutionally guaranteed expression."[58]

In *Central Hudson*, the Court laid out a four-prong test which must be met in order to permit government regulation of commercial speech: 1) whether the advertising relates to lawful activity; 2) whether the advertising is misleading; 3) whether banning it directly advances a substantial government interest (such as preserving public health); and 4) whether the government's interest could be achieved through a less restrictive route, such as by adding a special label.[59] The Court has relied on the *Central Hudson* test repeatedly in overruling prohibitions on the advertising of alcohol, tobacco—and prescriptions.[60] As a result, legal scholars believe that the courts would overturn a complete legislative or regulatory ban on DTCPA as being unconstitutional.[61]

Instead of an outright ban, however, some experts suggest that increased regulation of DTCPA could satisfy the *Central Hudson* test and survive constitutional scrutiny.[62] Indeed, both proponents and opponents of DTCPA seem to agree that "measures should at least be undertaken to maximize the benefits and minimize the risks of consumer drug advertisements."[63] The following is a summary of some of those proposals:

1. **Delay advertising for new products:** This is the proposal that arguably has received the most support, both by proponents and opponents of DTCPA, because of the Vioxx disaster.[64] Specifically, in May 1999, the FDA approved Vioxx as a pain killer and Merck marketed it aggressively directly to the public, touting its benefits as having fewer gastrointestinal problems than naproxen, for example, an older painkiller.[65] Merck, however, had only recent-

ly launched its own study of Vioxx in January 1999, and while early results in October of that year appeared promising, by December 1999 there was evidence that the risk of serious heart problems and death among Vioxx patients was twice as high as in the naproxen group.[66] Nevertheless, and with studies ongoing, Merck continued to market the drug until they pulled it in September 2004. By that time, an estimated 20 million Americans had taken the drug,[67] and it had been linked to over 140,000 cardiac events and more than 60,000 deaths.[68] Since that time, there have been many proposals to delay DTCPA for new drugs for at least two years—including a bill proposed by Senator Bill Frist, a former physician, in 2005, and a recommendation by the Institute of Medicine in 2007[69]—but none of these proposals has gone anywhere.[70]

2. **Ban product-specific ads:[71]** This proposal would revert back to pre-1997 conditions and hopefully induce patients to once again rely on their doctor's advice regarding specific medications instead of demanding brand name drugs that may be inappropriate and/or more expensive than other effective alternatives.

3. **Include quantitative information about the potential benefits and risks of a drug instead of the current qualitative—and often emotionally driven—ads:[72]** Studies have shown that including a table with quantitative data to DTCPA "led to a more realistic appraisal of a drug's benefits relative to a standard print ad that lacked this information, even for participants with little formal education."[73]

4. **Include drug cost information** so that consumers can do a cost/benefit analysis of the cost of the new drug versus the cost for other drugs, namely older drugs and/or generics that may be just as effective but much less expensive.[74]

E. Conclusion

America's health care system is clearly sick—we are spending more, and getting less for our money. But our sickness isn't fatal. Regulating DTCPA is one way in which we can substantially reduce unnecessary pharmaceutical costs that are driving up health care costs overall.

Regulation of DTCPA could take the form of an outright ban on broadcast advertising, which is receiving growing support from both the medical community[75] and the public.[76] While an outright ban might face a constitutional challenge, there is substantial data to suggest that DTCPA grossly misleads consumers, thereby providing the government with a compelling interest that could override First Amendment concerns.[77]

Even if the courts find a complete ban unconstitutional, however, there are incremental regulatory changes that could be implemented, such as removing the name of prescription drugs in advertisements or restricting advertising for new drugs for at least two years, that could achieve the same purpose.[78] These changes could recalibrate the current system, wherein Americans have become "Modern Patients" and aggressive consumers of drugs, into a system where once again the onus is on trained physicians to make pharmaceutical decisions in their patients' best interests. The result would be a reduction in the number of unnecessary prescriptions, thereby reducing overall health care costs.[79]

Any DTCPA regulation, however, will require overwhelming public pressure to counter the money interest that pharmaceutical companies wield so effectively in government, both through lobbying and the financing of public campaigns.[80] What's more, regulation of any industry is a starkly political issue, and with the bitter partisanship that marks our political system today, both in Congress and the general public, it seems doubtful that the kind of political will necessary to effect change can be mustered any time soon.

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What Should We Do About Artificial Intelligence in Health Care?

By Jason Chung

Artificial intelligence (AI) in health care has gone from a futuristic proposition to a burgeoning business proposition. Recent reports show that 86 percent of health care provider organizations, life science companies and technology vendors currently use some form of AI with the current average spend being $38 million per company.[1] This investment in AI is spurred by the wide variety of industries leveraging AI, including companies engaging in apps and wearables, big data, imaging, genetic research, pharmaceutical and telemedicine applications.

However, the most compelling potential application of AI is having it provide personalized treatment advice. Such a system promises to disrupt the medical industry by reducing diagnosis times so that doctors may treat far more patients than is possible today.

IBM has been the technology giant most aggressively developing and marketing such an AI product to health care systems and providers, most notably in the cancer space via IBM's Watson for Oncology (hereinafter "Watson") product. IBM claims that Watson uses cognitive computing to "interpret cancer patients' clinical information and identify individualized, evidence-based treatment options."[2]

The seemingly rapid recent development of technologies such as Watson has led to public concerns about AI. Questions abound regarding the present capabilities of such technologies, their capacity for disrupting multiple industries and their potential impact on human employment.

At its heart, however, there is one key question of interest to the legal community—how should AI be treated by the courts and regulation? To tackle this question, this article will focus on AI's application in the health care sector and on Watson in particular.

How Advanced Are AI and Watson Anyway?

Not all AI is created the same. While the term evokes interactive computers and androids popular in science fiction, there is quite a disparity between the future promised by AI systems and their current capabilities.

For instance, Siri and Google Assistant are often referred to as AI but they can be classified as "weak" or "narrow" as they are largely dedicated to organizing information and answering queries in a relatively restricted manner. These assistants use a combination of speech recognition, natural language processing and AI to perform a diverse array of tasks such as using voice activation to bring up maps, search through calendars and identify songs that have been played.[3] However, they cannot do much more than recognize question archetypes and search for answers either locally or on the internet.

By contrast, some forms of AI are simply beyond current capabilities and likely will be for the foreseeable future. To match human levels of reasoning, AI systems would have to be capable of recursive self-improvement and identifying and solving complex problems on their own without the need for human intervention. While media and technology leaders like Elon Musk hype the coming of self-aware AI capable of usurping humanity, the truth is that such "strong" AI or Artificial *General* Intelligence (AGI) is at least decades away.[4]

So what is Watson? Watson represents a point between weak and strong systems. Commonly referred to as an "expert system," Watson uses AI to solve defined problems in a specialized subject area. These expert systems can leverage "fuzzy logic" to go beyond binary "yes/no" and "true/false" questions to tackle tasks such as logic games, financial investing, legal research, and medical research.[5]

IBM has repurposed the DeepQA software it developed—and used on *Jeopardy*!—to answer diagnostic and treatment questions about cancer. DeepQA has a software architecture that "analyzes, reasons about, and answers the content fed into Watson."[6] This means that Watson can be fed reams of information on oncological matters—namely 300 medical journals, 200 textbooks and nearly 15 million pages of text—and scour them to present doctors with treatment options, and recommended drugs and instructions for administration.[7] This raw capability of parsing through data is combined with "training" by doctors at institutions such as Memorial Sloan Kettering who regularly monitor Watson's conclusions and validate or correct them. Unlike AGI, Watson does not seek answers to problems on its own but can draw upon disparate data sources to synthesize potential solutions.

The success of Watson is currently debatable. In certain jurisdictions rising concordance rates demonstrate the viability of Watson as a reliable option for diagnosis of treatment of cancer. With doctors and Watson agreeing in 96.4 percent of 112 lung cancer cases and between 81 percent to 92.7 percent in other cancer cases, Watson has emerged as a potentially important tool in supporting

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overstretched oncologists in India.[8] However, in South Korea, concordance rates for gastric cancer have been markedly worse—to the tune of 49 percent in 185 cases. This disparity can be chalked up to different treatment philosophies between South Korean doctors and those at Memorial Sloan Kettering where Watson is "trained." [9] Furthermore, after a much publicized launch at MD Anderson at the University of Texas, the partnership between UT and Watson is on indefinite hold with an audit finding irregularities in the focus and training of the AI.[10]

Watson, then, is far from perfect. It is inherently limited by the current technology of expert systems. It might sometimes suffer from the fallibility of the people both tasked with initially programing Watson and the doctors training Watson. And some errors may simply occur randomly due to the unpredictable nature of how machines process and organize unfamiliar data. Whatever the reason, the fallibility of Watson opens it up to potential lawsuits and calls for regulation.

IBM, Watson and Regulation

Regarding regulation, IBM claims that excessive regulation would stifle innovation and has called for a "more modern regulatory framework" to facilitate its work in health care. It has also spent an impressive amount of money to convince lawmakers of the need to be unencumbered by regulation. Recent reports have highlighted IBM's successful $26.4 million lobbying blitz of Congress, the White House, and federal agencies to avoid FDA regulation[11] through the favorable application of Section 3060 of the 21st Century Cures Act, which exempts "clinical decision support software" or CDSS—a definition which presumably includes Watson—from regulation as a "device" to be covered by the Food, Drug, and Cosmetic Act.

However, IBM's efforts at avoiding regulation is undercut by its zealousness in marketing Watson. Even as Watson suffers setbacks by sometimes "struggling to master the various forms of cancer" which limits its propagation to "a few dozen hospitals worldwide"[12] and has been criticized by some for being "artificially intelligent only in the most rudimentary sense of the term," sales representatives have continued to pitch Watson as a revolution in cancer treatment and as capable of generating "new approaches" to cancer care.[13]

With such bold marketing claims, IBM has opened itself up to the scrutiny of regulators and courts who are naturally curious about what insights Watson may generate and, most importantly, how it reaches such conclusions. With such increased interest, it is unlikely that IBM will avoid regulation, or lawsuits, for long. For that reason, it may be wise of IBM to embrace a regulatory scheme that it can tolerate.

Can AI Be Liable for Its Faults?

Watson generates fees of between $200 to $1,000 per patient.[14] It examines patient history and medical literature to provide personalized treatment advice. In many ways, it could be regarded as a member of the team. But what happens when Watson is wrong?

Currently, there is no clear legal or regulatory regime concerning liability for AI such as Watson. Contemporary theories of recovery under tort law are usually divided by personhood. For instance, negligence-based tort law, such as medical malpractice or vicarious liability, generally apply to the actions of **persons** owing a duty of care. On the other hand, the regime of products liability attach to **things** and generally hold the manufacturer strictly liable for defective products.

AI defies such neat categorization both by capability and responsibility. While a machine, experts such as Dr. Meaghan Dierks of Harvard Medical School note that Watson may foster dependency on the part of some practitioners and "[i]f how Watson got from input to output is not obvious to the end user, it's a harder case to be made that the practitioner is independently making the choice."[15] This ability to offer, and rank, solutions distinguishes Watson from mere "robots" who, according to U.S. courts, "cannot be sued."[16]

A look to regulation also provides no easy answers. The FDA is meant to regulate medical devices and drugs. But the ambiguous nature of Watson and its capabilities appear to be tripping up regulators. Watson is more than a mere device that monitors biometric signals or analyzes samples, it is marketed and viewed as a first step in democratizing medical research and treatment via technology.[17] While the legislators have punted the issue by classifying Watson as a CDSS, regulators are clear that the situation could change as the gulf between man and machine shrinks in terms of Watson's capabilities and responsibilities.

This struggle with what Watson *is* will likely go from abstract to practical in the foreseeable future. With Watson already providing "advice" to oncology practitioners in the U.S. and abroad, it is probable that a speculative suit against Watson and its advice will be filed in the coming years. IBM would be naïve to believe otherwise.

In fact, some legal observers have already identified the difficulties of adapting the current legal and regulatory system to the new realities posed by AI and proposed that a new legal regime be created in anticipation of such an event.[18] However, given the difficulties in educating lawmakers about issues in technology and the unknown variables in the development of AI, it is likely that such a wholesale change will create more problems and legal questions than it answers.

As such, it is more likely that courts will look to the existing theories of recovery in torts to analogize situa-

tions to determine damages. Contrary to IBM's expectations, this may work out in its favor.

What Should Courts Do and What Does This Mean for Watson?

In an upcoming article for the *Asia-Pacific Journal of Health Law and Ethics*, a colleague and I will argue that it is advisable for the courts to assign legal personhood to AI, make it liable under a medical malpractice regime and analogize Watson's level of responsibility and duties with those of medical students. We argue that while this is admittedly an imperfect analogy, that there is enough overlap between the two in terms of level of authority, tasks and level of oversight for the courts to make such a determination.

Such an outcome would be a coup for IBM even if it may not agree. This is for three main reasons:

1. *It opens the door to a predictable liability regime as well as insurance.* If Watson is analogized to a medical student, it can be argued that Watson's degree of liability regarding medical malpractice should be capped at that of medical student—a relatively trivial amount. This would also allow for negotiations to begin with insurance companies regarding malpractice coverage on this basis.

2. *It makes recovery under products liability more difficult.* Given that products liability entails strict liability for the manufacturer and given the unpredictable nature of the results that AI can generate algorithmically, it would be wise for IBM to concentrate its efforts on ensuring that a products liability regime is put in place. Additionally, reducing the likelihood of success of products liability arguments would disincentivize such claims in future lawsuits, thereby reducing Watson-related legal costs for the company.

3. *It provides a predictable template for future advances in technology.* As Watson matures, it is conceivable that IBM and health care providers will feel more comfortable giving it more autonomy and decision-making power. In that case, this system of analogy will allow Watson's degree of liability and insurance coverage to scale up in a logical manner based on a functional view of Watson's current capabilities (e.g., to that of a resident or physician).

There are also benefits for the courts and claimants. Courts would be unencumbered from having to continuously opine on the nature of AI and its duties. Claimants would benefit from additional information during the discovery process. By giving Watson legal personhood, it will allow Watson to be a party to lawsuits and claimants will be able to gain greater access to its logs and see who was involved in the patient's care. As noted by injury lawyer Max Kennerly, adding students or residents to lawsuits often helps pull back the curtain on attribution for faults. He notes that many physicians and even hospitals will deny being involved in the patient's care.[19] Seeing who accessed Watson or input information into it should help alleviate this issue.

Balancing the need for necessary innovation in the health care sector and stakeholder rights is an admittedly tricky task. But as Watson matures, all sides would benefit from greater predictability—something that the current AI legal and regulatory landscape lacks. To do so, it would be wise to lean on existing legal frameworks to avoid overcomplicating the issue. While issues posed by AI may be novel, the humans seeking to litigate and regulate AI are not.

Conclusion

Watson is no longer merely a "thing." Taking a functional view of what Watson can already do—as well as what IBM claims Watson will be able to do in the near future—the level of analysis and research performed by Watson far outstrips past devices.

In truth, Watson represents an intermediate step between man and machine. It excels in tasks such as aggregation and search far beyond human capabilities. But it cannot reason, it cannot self-direct and it does not have the requisite agency to be considered a decision-maker in any current context. IBM is being accurate when it says that all Watson is currently meant to do is provide information and analyze data to advise the human in charge.

However, advisors also have power and, as it may be argued, a degree of duty of care. The exact degree may be in question but through analogy and an examination of the facts, it can often be found. As the U.S. is seeing in other contexts, it is natural to seek to define and regulate the role of advisors like Watson. Ultimately, if IBM persists on fighting for self-regulation, a more restrictive regime might be implemented when the winds change.

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Artificial Intelligence: Realizing the Promise of Big Data in Health Care

By Wahida Bhuyan

Forty years ago, the concept of artificial intelligence (AI) was prominent, but only in science fiction, as C-3PO in *Star Wars* or the Cyborg Steve Austin, a.k.a. the Six Million Dollar Man. Today, artificial intelligence is a mainstream reality and, with over 100 AI startups in the health care space in the past four years, health care shows great promise for positive outcomes with practical AI utilization.[1] The application of AI in health care is in its infancy and the emerging opportunities that use our health data bring forth associated legal and ethical risks that call for an adaptive regulatory and legal environment.

The definition of AI has shifted over time and will continue to do so as it becomes more familiar. It has been used synonymously with machine learning, cognitive learning, neural networks, augmented intelligence, and many other terms that are actually components of AI rather than AI itself.

A simplistic way to describe AI: massive amounts of information, provided by humans and other data sources (e.g., for health care—electronic medical records (EMR), pharmaceutical and administrative records, fitness trackers, medical devices), that run through algorithms and solve problems by way of pattern detection that a human would either be unable to recognize or take a prolonged period to process. In essence, AI is a transformative tool that expedites problem solving, allows for efficiency, and creates new information. One recognizable example is the Google search application. Historically, we are familiar with Google's search result capabilities, but, with the addition of AI, the search engine is able to provide answers to questions.[2]

According to a recent McKinsey Global Institute report, "If US health care were to use big data creatively and effectively to drive efficiency and quality, the sector could create more than $300 billion in value every year."[3] AI pilot projects have shown effective, revolutionary results in the field of behavioral health and life science that allow for early clinical intervention.

Last year, University of Buffalo undergraduate students developed a mobile application that tracks eye movements and uses AI to detect potential autism spectrum disorder—a disorder that affects 1 in 68 U.S. children.[4] The application delivered 94 percent accurate diagnoses.[5]

Use of AI is planned for medical matchmaking services to connect patients who have medically complex cases to specialist doctors, no matter the physical or time zone difference.[6] Additionally, mining through both structured (organized, codified data) and unstructured patient data (such as handwritten clinical notes) using AI will allow for disease intervention at earlier stages and the ability to connect with clinical trials.[7]

Applying artificial intelligence in health care uncovers unlimited possibilities in pursuit of addressing the triple aim of population health: improve outcomes, improve patient experiences, and reduce costs.[8] Yet, with such possibilities come many challenges.

Incorporating technology that allows for big data efficiency has not been an easy culture fit in the medical profession. After the past few years of burdensome EMR implementations and related workflow adjustments, the provider community has hesitations when it comes to adding more technology. For AI to be incorporated into health care delivery settings, its application must be transparent and gain the trust of clinicians, technicians, and patients.

As technology continues to outpace the law, we should expect regulatory bodies to maintain discretion in their enforcement.[9] For AI to expand in health care, overlapping oversight amongst the Department of Health and Human Services, Federal Trade Commission, Department of Justice, Office of the Inspector General and various state regulators, such as the New York State Department of Health, is to be expected. Plus, as the United States has a health care business ecosystem that exists across international borders, it is difficult to separate data into country-specific silos. One person's data can be sourced, controlled, and processed by vendors scattered around the globe, so it is foreseeable that the information used in the AI process could be subject to international jurisdictions.

Developing laws and policies for emerging health care technologies has been complex; the slow pace of regulatory agencies or professional associations in developing standards or frameworks makes it likely that much of it will come from the courts. Tort liability and medical malpractice claims could be tested as AI systems are used in clinical decision-making. If there is a malfunctioning algorithm in the AI and the AI's recommendations are used to administer treatment to a patient, who or what is liable—the end-user physician, the system's custodian, or the algorithm developer/data scientist? Thus, collateral tort claims could include defective software, incorrect algorithms, and or program developer/data scientist negligence.

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In May of this year, an unprecedented ransomware attack impacted global hospitals and some medical devices (X-ray, MRI machines) that ran on Windows operating systems.[10] The "WannaCry" ransomware not only prevented surgeries, but patients were turned away due to scrambled and inaccessible data on computers. Payments of 300 to 600 bitcoins (a digital currency where one bitcoin is currently equal to $16,744.05) were demanded to have data released or decrypted and restore access.[11] In light of this global cybersecurity attack that impacted the health care setting, it is anticipated that malicious intent scenarios or other emergency situations could arise from the use of AI in health care.

As health data information is gathered from nonclinical sources and access is provided to large repositories, privacy and cybersecurity concerns are plentiful. Unlike credit card or social security numbers, health care data has permanence—a person's medical diagnosis or drug allergies cannot be cancelled or voided. In the wrong hands, this information could lead to grim events.

Data privacy in health care is governed by the Healthcare Information Portability and Accountability Act (HIPAA),[12] Health Information Technology for Economic and Clinical Health (HITECH) Act[13] and also FTC regulations. Violations of these acts can lead to civil monetary penalties and potential jail sentences.

Covered entities or their business associate developers who create software applications ("apps") for patient monitoring or disease management will be covered under HIPAA and HITECH laws. Even if a digital health company does not provide medical services, but creates, stores, or transmits PHI, it is likely subject to HIPAA and HITECH, along with stringent state laws. However, most health hardware and software developers are not considered business associates and health data is increasingly being generated outside of the HIPAA protected zone.

In circumstances where apps or robotic health care devices fall outside of the HIPAA domain, Section 5(a) of the Federal Trade Commission Act (FTCA), which prohibits "unfair or deceptive acts or practices in or affecting commerce"[14] may be applied. It has been used to punish app and service developers that have put forth inaccurate or misleading privacy policies.

AI is contained in software and the algorithms that run AI are part of the software service. Software and other digital products fall under the purview of the federal copyright laws.[15] Connected to these are license agreements—most software is provided to health care organizations through licenses to use from the organization that holds the copyright.

Based on current and expected AI use in health care, additional laws that could be triggered include: state licensure requirements (e.g., telemedicine), fee sharing laws, third party and vendor compliance, and even criminal liabilities (e.g., *mens rea* behind the AI).[16]

To overcome some of these legal challenges, it will fall on legal and compliance professionals to perform deep due diligence in the development, use, and application of AI in health care. In doing so, a global view of the potential issues must be applied. Often, technology developers and businesses that are building the information technology or digital products do not seek legal assistance to review the process until *after* the build or launch phase—or after a patient/user complaint arises. In-house counsel should instead be brought into the product design stage so that appropriate questions could be asked to enable controls to be put into place *before* problems occur, thereby eliminating the financial and resource costs to correct and rebuild.

"Health care organizations, policy makers and technologists must come together to develop and implement quality assurance programs to mitigate the likelihood of harm in using AI technologies."

Proactive collaboration among engineering, medical, and legal teams is critical when putting forth innovative technologies that are in the gray, not-yet-defined areas of health care. Lack of this collaboration has been evident in the ongoing collapse of the medical device company Theranos in 2016. Theranos, which sought to improve blood-testing technology, received a valuation of over $9 billion, and multiple partnerships were forged on the promise of their technology—yet the organization was unable to explain how the technology worked or prove its claims.[17] Theranos currently faces several government probes from the Centers for Medicare and Medicaid Services, the Food and Drug Administration, the Securities Exchange Commission, and is currently involved in multiple civil lawsuits, including a class action accusing it of consumer fraud.[18]

Should patients start to expect "robotic reveals" from physicians at their next annual checkup? Will it come down to humans battling robots in the health care arena? Contrary to the warnings of Elon Musk that AI will be the end of the human race,[19] the evidence shows that with proper application and collaboration with existing stakeholders in health care, it's more conceivable that AI could extend the human race. Health care organizations, policy

makers and technologists must come together to develop and implement quality assurance programs to mitigate the likelihood of harm in using AI technologies. "We have the technology" to make health care "better, stronger, faster."[20]

Endnotes

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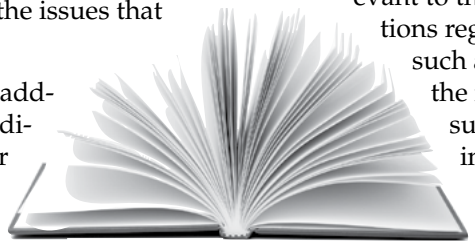
Book Review

Commercial Litigation in New York State Courts (Fourth Edition)

By Edward S. Kornreich

Bob Haig and scores of his colleagues have revised and improved the well-regarded treatise, *Commercial Litigation in New York State Courts*, with a new expanded Fourth Edition (the "Treatise"). For health care lawyers who seek a primer in New York litigation procedure and substantive law, there is no better, single comprehensive source of information on litigating, and the issues that tend to be litigated, in New York.



The already substantial Treatise has added 22 new chapters in this new Fourth Edition. The new chapters include a number that are of particular interest to the Health Law bar: medical malpractice, reinsurance, social media, worker's compensation, internal investigations, and mediation and arbitration. The authors are luminaries of the bench and bar in New York, led by Jonathan Lippman, and the late Judith Kaye, former Chief Judges of the Court of Appeals, and more than 25 other sitting and former members of the judiciary, and litigators from Cravath, Sullivan, Wachtell, Skadden, Simpson, Stroock, Davis Polk, Debevoise, Kelley Drye, Paul Weiss, and Proskauer, among others. Forms and checklists are included, and they provide practical guidance to the practitioner.

For example, the chapters on Governmental Entity Litigation and Article 78 Proceedings, which are critical to the health care lawyer, carefully review (over almost 140 pages), the applicable law, and the complex venue, standing and statute of limitations issues that challenge the most expert lawyers. Not-for-Profit Institution Litigation and Health Care Institution Litigation, which include traditional issues of fiduciary duty and liability and Federal and State False Claims Act litigation, with particular focus on State False Claims Act issues, will also be worth the health care lawyers' time.

Thus, while not a primer on health law, the Treatise does incorporate discussion of many issues directly relevant to the health care lawyer. Moreover, for questions regarding the nuts and bolts of litigation, such as subpoenas, service of process, venue, the requirements for a motion to dismiss or summary judgment, and discovery (including technology issues), the Treatise offers straightforward, accurate answers, and is an excellent desktop tool.

For the more advanced health care litigator, the Treatise's chapters on Trials, Settlements, Sanctions, Appeals, Damages, Experts, Discovery (and the significance of "litigation holds") and many others provide detailed information and knowledge gleaned from long experience.

Health care lawyers are generalists, and often regulatory specialists and transactional attorneys with a smattering of litigation exposure. As such, they frequently have procedural and substantive questions concerning ongoing New York State Court litigation in which their client is involved. The Treatise continues to be a welcome source of answers to those questions.

Royalties from the Treatise accrue to the New York County Lawyers Association.

Edward S. Kornreich is a partner in Proskauer Rose LLP. He is a past Chair of the Health Law Section.

Cybersecurity in the Health Care Sector

By Francis J. Serbaroli

As if it were not facing enough challenges, the health care industry is now becoming a more frequent target for hacking and ransomware by miscreants both domestic and foreign. Health care organizations have lagged behind other business sectors in protecting data, which is hard to understand given the extreme sensitivity of the data in their possession: personal and health information on individual patients; confidential information on internal quality assurance, risk management and utilization; results of clinical research on drugs, medical devices, and therapies; personal information on employees; sensitive internal financial information; confidential information on potential partnerships and deals with other organizations; and so on. Of even greater concern is the reality that hackers can interfere with web connected medical equipment and devices and physically harm patients.

The Health Care Industry Cybersecurity Task Force, which was established by Congress in 2015, is comprised of representatives from both the government and private sector, and is charged with analyzing and making recommendations regarding securing and protecting the health care sector against cybersecurity incidents. S.754— 114th Congress: Cybersecurity Information Sharing Act of 2015. The Task Force recently issued its "Report on Improving Cybersecurity in the Health Care Industry" (Report). The Report highlights the vulnerabilities to cyberattacks of organizations involved directly or indirectly in providing health care services and products, and makes recommendations to both the government and the industry to enhance awareness and improve protections.

Industry

The Report begins by describing the observes that the continuing evolution of electronic health records and the health care industry's extensive connectivity to the Internet have led to major improvements in both the quality and timeliness of patient care. The Report notes that the downside to these advances is that they have resulted in an increased attack surface for health care providers, medical device companies, and many other parts of the health care industry. The Report emphasizes that securing health care data as well as securing the operation of medical devices is essential to protecting patients and providing them with the highest level of medical care.

Turning to the reality of cybersecurity and preparedness in the industry, the Report found that many health care organizations lack the infrastructure to identify and track threats, the capacity to analyze and translate the threat data they receive into actionable information, and the capability to act on that information. Many see the industry as a "mosaic" of large health care systems, physician practices, public and private payors (e.g., Medicare, Medicaid, private insurers and plans), research institutions, medical device developers and manufacturers, software companies, as well as a large and diverse population of patients. Its organizations also have not crossed the digital divide in not having the technology resources and expertise to address current and emerging cybersecurity threats. These organizations may not know that they have experienced an attack until long after it has occurred.

As to regulatory oversight, the Report finds that multiple federal agencies play a role in establishing and policing how health care organizations secure the privacy of their health care information, which has the potential to create complications.

Some entities may be subject to regulation and oversight by multiple federal government entities, each with their own rules, which may be difficult to reconcile. Product and technology innovations for medical devices and health IT outpace the development and creation of regulations.

Then there is the cost of compliance: While many regulations that apply to cybersecurity in health care are well-meaning and individually effective, taken together, they can impose a substantial legal and technical burden on health care organizations. These organizations must continually review and interpret multiple regulations, some of which are vague, redundant, or both. In addition, organizations must dedicate resources to implement policy directives that may not have a material impact on reducing risks.

Recommendations

The Report includes six "high level" imperatives, for each of which the Task Force provides a number of recommendations.

Imperative 1: "Define and streamline leadership, governance, and expectations for health care industry cybersecurity." To bring this about the Task Force recommends:

- creating a cybersecurity leader role within the U.S. Department of Health and Human Services (HHS) to align industry efforts for health care cybersecurity;

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- establishing a consistent, consensus- based Cybersecurity Framework that is health-care specific, and includes standards, guidelines, and best practices;
- requiring federal regulatory agencies to harmonize existing and future laws and regulations that affect health care cybersecurity;
- identifying scalable best practices for governance of cybersecurity across the health care sector; and
- exploring potential changes to the Stark Anti-Referral Law (42 U.S.C. §1395nn), the Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)), and other fraud and abuse laws to allow large health care organizations to share cybersecurity resources and information with their partners (e.g., physician practices).

Imperative 2: "Increase the security and resilience of medical devices and health information technology." Specifically

- securing legacy systems through compensating controls, device update, device retirement, network segmentation, etc.;
- improving manufacturing and development transparency among software developers and users;
- increasing the adoption and rigor of the secure development lifecycle (from concept generation through end of life recycling or disposal) in the development of medical devices and electronic health records;
- requiring strong authentication to improve identity and access management for health care workers, patients, medical devices and electronic health records;
- employing strategic and architectural approaches to reduce the attack surface for medical devices, electronic health records, and their interfaces; and
- establishing a Medical Computer Emergency Readiness Team to coordinate medical device-specific responses to cybersecurity incidents and vulnerability disclosures.

Imperative 3: "Develop the health care workforce capacity necessary to prioritize and ensure cybersecurity awareness and technical capabilities." To that end, the Task Force recommends:

- requiring every health care organization to identify the cybersecurity leadership role (e.g., chief information security officer) for driving more robust cybersecurity policies, processes and functions, with involvement of senior executives;
- establishing a model for adequately resourcing the cybersecurity workforce with qualified individuals, and determining an acceptable ratio of health care cybersecurity expertise to the size of the organization, complexity of care, degree of interconnectedness with other organizations, etc.;
- creating managed security service providers (MSSP) models to support small and medium-sized health care providers so they can have state-of-the-art security monitoring, defensive and reporting capabilities; and evaluating options for small and medium-sized health care providers to migrate patient records and legacy systems to secure environments such as hosted, cloud, and shared computer environments.

Imperative 4: "Increase health care industry readiness through improved cybersecurity awareness and education." The Task Force believes this can be accomplished by:

- developing education programs targeting executives and boards of directors about the importance of cybersecurity education;
- ensuring existing and new products/ systems' risks are managed in a secure and sustainable fashion through "cybersecurity hygiene" (i.e., an evaluation of each individual's security practices and precautions when conducting activities online);
- establishing an assessment model for evaluating a health care organization's conformity with cybersecurity hygiene that regulatory agencies and industry can rely upon;
- customizing the Baldridge Cybersecurity Excellence Builder, a cybersecurity self-assessment tool created by the National Institute of Standards and Technology, for use by health care organizations;
- increasing outreach and engagement for cybersecurity across all levels of government and the private sector through a cybersecurity education campaign involving both HHS and the Department of Homeland Security; and
- providing patients with information on how to manage their health care data to enable them to make educated decisions when selecting services or products from non-regulated entities (e.g., fitness trackers, devices and other consumer health care/ lifestyle products).

Imperative 5: "Identify mechanisms to protect research and development efforts and intellectual property from attacks or exposure." The Task Force recommends:

- developing guidance for industry and academia on creating economic impact analysis and loss for cybersecurity risk for health care research and development; and

- pursuing research into protecting health care "big data" sets.

Imperative 6: "Improve information sharing about industry threats, risks, and mitigations." The Task Force outlined the following steps to accomplish this:

- make information-sharing on threats and risks easier among small and medium-size health care organizations that rely on limited or part-time cybersecurity staff;
- create more effective mechanisms for disseminating and utilizing data about threats, vulnerabilities and incidents; and
- encourage cybersecurity annual readiness exercises by the health care industry to prevent uncoordinated and ineffective responses to cyberattacks.

Conclusion

The Task Force's Report is a wake-up call to every organization in the health care sector, large or small. Cyberattacks are increasing and becoming even more dangerous. The inherent vulnerabilities in the health care sector, together with the fact that health care will soon account for 20 percent of this country's gross domestic product, make it all the more attractive to cyberattackers, and virtually guarantee that the problem will only get more serious and more complicated.

Health care organizations that do not recognize these dangers or take effective steps to mitigate them are not only doing a disservice to their patients or customers, they are risking their reputations and subjecting themselves to costly notification processes and remediation expenses, as well as regulatory crackdowns, class action lawsuits, significant penalties and legal liabilities, and the potential separation from employment of the senior executives on whose watch the problem occurred. Placed in that context, expenditures on appropriate cybersecurity protections look like a wise investment.

Myers v. Schneiderman 2017

N.Y. Slip Op. 06412, decided on September 7, 2017. Court of Appeals Per Curiam. Published by New York State Law Reporting Bureau pursuant to Judiciary Law § 431. This opinion is uncorrected and subject to revision before publication in the Official Reports.

Decided on September 7, 2017
No. 77

Sara Myers et al., Plaintiffs, Eric A. Seiff, et al., Appellants,
v.
Eric Schneiderman, & c., Respondent, et al., Defendants.

Edwin G. Schallert, for appellants.
Anisha S. Dasgupta, for respondent.

Michael R. Aiello, et al.; New York State Catholic Conference; Not Dead Yet, et al.; New York Civil Liberties Union; Alan A. Pfeffer et al.; Agudath Israel of America; New York Chapter of the National Academy of Elder Law Attorneys; American Medical Student Association, et al.; Richard N. Gottfried, et al.; Betty Rollin, et al.; National Association of Criminal Defense Lawyers; Vincent Bonventre, et al.; Unitarian Universalist Association, et al.; Compassion & Choices, amici curiae.

Per Curiam:

Plaintiffs ask us to declare a constitutional right to "aid-in-dying," which they define (and we refer to herein) as the right of a mentally competent and terminally ill person to obtain a prescription for a lethal dosage of drugs from a physician, to be taken at some point to cause death. Although New York has long recognized a competent adult's right to forgo life-saving medical care, we reject plaintiffs' argument that an individual has a fundamental constitutional right to aid-in-dying as they define it. We also reject plaintiffs' assertion that the State's prohibition on assisted suicide is not rationally related to legitimate state interests.

I. FACTUAL AND PROCEDURAL HISTORY

Plaintiffs filed the instant action against New York State's Attorney General and [*2]several District Attorneys,[FN1] requesting declaratory and injunctive relief to permit "aid-in-dying," whereby a mentally competent, terminally ill patient may obtain a prescription from a physician to cause death. Plaintiffs request a declaratory judgment that physicians who provide aid-in-dying in this manner are not criminally liable under the State's assisted suicide statutes — Penal Law § 120.30 and § 125.15 (3)[FN2]. They further request an injunction prohibiting the prosecution of physicians who issue such prescriptions to terminally ill, mentally competent patients.

When the complaint was filed, plaintiffs included three mentally competent, terminally ill patients. Two of those plaintiffs have died, and the third is in remission. Plaintiffs also include individual medical providers who assert that fear of prosecution has prevented them from exercising their best professional judgment when counseling and treating their patients. They are joined by organizational plaintiff End of Life Choices, which sued on its own behalf and on behalf of its clients, for whom it provides "information and counseling on informed choices in end of-of-life decisionmaking."

The Attorney General moved to dismiss the complaint on the grounds that plaintiffs failed to state a cause of action and did not present a justiciable controversy (see CPLR 3211 [a] [7], [2]). Supreme Court granted the motion, and plaintiffs appealed. The Appellate Division modified on the law, declaring that the assisted suicide statutes provide a valid statutory basis to prosecute physicians who provide aid-in-dying and that the statutes do not violate the State Constitution, and as so modified, affirmed (140 AD3d 51, 65 [1st Dept 2016]). Plaintiffs appealed to this Court as of right, pursuant to CPLR 5601 (b) (1).

On appeal, plaintiffs argue that the State's assisted suicide statutes do not prohibit aid-in-dying as a matter of law, and that the Appellate Division's "literal" interpretation of the statutes is flawed. Alternatively, plaintiffs contend that application of the assisted suicide statutes to aid-in-dying violates their equal protection and due process rights under the State Constitution.

[*3]II. REVIEWABILITY

"On a motion to dismiss pursuant to CPLR 3211, the pleading is to be afforded a liberal construction" (Leon v Martinez, 84 NY2d 83, 87—88 [1994], citing CPLR 3026). "We accept the facts as alleged in the complaint as true, accord plaintiffs the benefit of every possible favorable inference, and determine only whether the facts as alleged fit within any cognizable legal theory" (id.). "However, 'allegations consisting of bare legal conclusions, as well as factual claims inherently incredible or flatly contradicted by documentary evidence are not entitled to such consideration'" (Simkin v Blank, 19 NY3d 46, 52 [2012], quoting Maas v Cornell Univ., 94 NY2d 87, 91 [1999]; see Connaughton v Chipotle Mexican Grill, Inc., 29 NY3d 137, 142-143 [2017]).

We reject plaintiffs' argument that the lower courts improperly resolved numerous factual issues. This case involves questions of law, including: whether aid-in-dying constitutes assisted suicide within the meaning of the Penal Law; whether a competent terminally ill person has a fundamental right to physician-assisted suicide; and whether denying a competent, terminally ill patient aid-in-dying violates that patient's right to equal treatment

under the law. As there are no countervailing reasonable interpretations, these questions can be decided without any factual development.

III. PLAINTIFFS' STATUTORY CLAIM

Plaintiffs initially assert that we should interpret the assisted suicide statutes to exclude physicians who provide aid-in-dying. Such a reading would run counter to our fundamental tenets of statutory construction, and would require that we read into the statutes words and meaning wholly absent from their text (see Majewski v Broadalbin-Perth Cent. Sch. Dist., 91 NY2d 577, 583 [1998]).

"The governing rule of statutory construction is that courts are obliged to interpret a statute to effectuate the intent of the Legislature, and when the statutory language is clear and unambiguous, it should be construed so as to give effect to the plain meaning of the words used" (People v Finnegan, 85 NY2d 53, 58 [1995] [internal quotation omitted]). "[C]ourts may not reject a literal construction [of a statute] unless it is evident that a literal construction does not correctly reflect the legislative intent" (Matter of Schinasi, 277 NY 252, 259 [1938]).

"Suicide" is not defined in the Penal Law, and therefore "we must give the term its ordinary and commonly understood meaning" (People v Ocasio, 28 NY3d 178, 181 [2016] [internal quotations omitted]). Suicide has long been understood as "the act or an instance of taking one's own life voluntarily and intentionally" (Webster's Collegiate Dictionary [11th ed 2003]; see Webster's American Dictionary of the English Language [ed 1828]). Black's Law Dictionary defines "suicide" as "[t]he act of taking one's own life," and "assisted suicide" as "[t]he intentional act of providing a person with the medical means or the medical knowledge to [*4]commit suicide" (10th ed 2014). Aid-in-dying falls squarely within the ordinary meaning of the statutory prohibition on assisting a suicide.

The assisted suicide statutes apply to anyone who assists an attempted or completed suicide. There are no exceptions, and the statutes are unqualified in scope, creating an "irrefutable inference . . . that what is omitted or not included was intended to be omitted or excluded" (People v Jackson, 87 NY2d 782, 788 [1996] [internal quotation omitted]). Furthermore, this Court previously resolved any doubt as to the scope of the ban on assisted suicide. In People v Duffy, we explained that "section 125.15 (3)'s proscription against intentionally causing or aiding a suicide applies even where the defendant is motivated by 'sympathetic' concerns, such as the desire to relieve a terminally ill person from the agony of a painful disease" (79 NY2d 611, 615 [1992], citing Staff Notes of the Commission on Revision of the Penal Law, Proposed New York Penal Law, McKinney's Spec. Pamph. [1964], at 339).

As written, the assisted suicide statutes apply to a physician who intentionally prescribes a lethal dosage of a drug because such act constitutes "promoting a suicide attempt" (Penal Law § 120.30) or "aid[ing] another person to commit suicide" (Penal Law § 125.15 [3]). We therefore reject plaintiffs' statutory construction claim.

IV. PLAINTIFFS' CONSTITUTIONAL CLAIMS

Alternatively, plaintiffs claim that the assisted suicide statutes, if applied to aid-in-dying, would violate their rights under the Equal Protection and Due Process Clauses of our State Constitution. We reject those claims.

A. Equal Protection

Plaintiffs allege that the assisted suicide statutes violate the State Equal Protection Clause because some, but not all, patients may hasten death by directing the withdrawal or withholding of life-sustaining medical assistance. Plaintiffs therefore contend that the criminalization of aid-in-dying discriminates unlawfully between those terminally ill patients who can choose to die by declining life-sustaining medical assistance, and those who cannot.

Our State's equal protection guarantees are coextensive with the rights protected under the federal Equal Protection Clause (see People v Aviles, 28 NY3d 497, 502 [2016]; Esler v Walters, 56 NY2d 306, 313—314 [1982]). In Vacco v Quill, the United States Supreme Court held that New York State's laws banning assisted suicide do not unconstitutionally distinguish between individuals (521 US 793, 797 [1997]). As the Court explained, "[e]veryone, regardless of physical condition, is entitled, if competent, to refuse unwanted lifesaving medical treatment; no one is permitted to assist a suicide. Generally, laws that apply evenhandedly to all unquestionably comply with equal protection" (id. at 800 [emphasis in original]). The Supreme Court has not retreated from that conclusion, and we see no reason to hold otherwise.

B. Due Process

In support of their due process argument, plaintiffs assert that their fundamental right to self-determination and to control the course of their medical treatment encompasses the right to choose aid-in-dying. They further assert that the assisted suicide statutes unconstitutionally burden that fundamental right.

In Washington v Glucksberg, the United States Supreme Court "examin[ed] our Nation's history, legal traditions, and practices," and concluded that "the asserted 'right' to assistance in committing suicide is not a fundamental liberty interest protected by the Due Process Clause" of the Federal Constitution (521 US 702, 710, 728 [1997]). We have, at times, held that our State Due Process Clause provides greater protections than its federal counterpart (see Aviles, 28 NY3d at 505), and therefore Supreme Court precedent rejecting plaintiffs' claim as a matter of federal constitutional due process is not dispositive.

Accordingly, we turn to whether the right claimed here falls within the ambit of that broader State protection.

Contrary to plaintiffs' claim, we have never defined one's right to choose among medical treatments, or to refuse life-saving medical treatments, to include any broader "right to die" or still broader right to obtain assistance from another to end one's life. In Schloendorff v Society of New York Hospital, we held that a surgeon who performed an operation without the patient's consent committed an assault and, in that context, we noted that "[e]very human being of adult years and sound mind has a right to determine what shall be done with [such person's] own body" (211 NY 125, 129—130 [1914]). Matter of Storar likewise concerned the right to refuse life-sustaining medical treatment when the patients were not mentally competent (52 NY2d 363, 377 [1981]). In Rivers v Katz, holding that involuntarily committed mental patients have a fundamental right to refuse antipsychotic medication, we concluded that a patient's right "to refuse medical treatment must be honored, even though the recommended treatment may be beneficial or even necessary to preserve the patient's life" (67 NY2d 485, 492 [1986]).

We have consistently adopted the well-established distinction between refusing life-sustaining treatment and assisted suicide (see Matter of Bezio v Dorsey, 21 NY3d 93, 103 [2013]; Matter of Fosmire v Nicoleau, 75 NY2d 218, 227 [1990]; Storar, 52 NY2d at 377 n 6). The right to refuse medical intervention is at least partially rooted in notions of bodily integrity, as the right to refuse treatment is a consequence of a person's right to resist unwanted bodily invasions (see Cruzan v Director, Mo. Dept. of Health, 497 US 261, 269-270 [1990]; Schloendorff, 211 NY at 130). In the case of the terminally ill, refusing treatment involves declining life-sustaining techniques that intervene to delay death. Aid-in-dying, by contrast, involves a physician actively prescribing lethal drugs for the purpose of directly causing the patient's death. As the Court stated in Matter of Fosmire v Nicoleau, "[i]n many if not most instances the State stays its hand and permits fully competent adults to engage in conduct or make personal decisions which pose risks to their lives or health," however, "[t]he State will [*5]intervene to prevent suicide" (75 NY2d at 227).

"[M]erely declining medical care, even essential treatment, is not considered a suicidal act" (id.). Although we do not reach the issue addressed by Judge Rivera's concurrence on this appeal, the Supreme Court has noted that "the distinction between assisting suicide and withdrawing life-sustaining treatment, a distinction widely recognized and endorsed in the medical profession and in our legal traditions, is both important and logical; it is certainly rational," and it turns on "fundamental legal principles of causation and intent" (Vacco, 521 US at 801). As a general matter, the law has "long used actors' intent or purpose to distinguish between two acts that may have the same result" (id. at 802; see also Bezio, 21 NY3d at 103, quoting Von Holden v Chapman, 87 AD2d 66, 70 [4th Dept 1982]).

The right asserted by plaintiffs is not fundamental, and therefore the assisted suicide statutes need only be rationally related to a legitimate government interest (see People v Knox, 12 NY3d 60, 67 [2009]). "The rational basis test is not a demanding one" (id. at 69); rather, it is "the most relaxed and tolerant form of judicial scrutiny" (Dallas v Stanglin, 490 US 19, 26 [1989]). Rational basis involves a "strong presumption" that the challenged legislation is valid, and "a party contending otherwise bears the heavy burden of showing that a statute is so unrelated to the achievement of any combination of legitimate purposes as to be irrational" (id. at 69). A challenged statute will survive rational basis review so long as it is "rationally related to any conceivable legitimate State purpose" (People v Walker, 81 NY2d 661, 668 [1993] [citation omitted]). "Indeed, courts may even hypothesize the Legislature's motivation or possible legitimate purpose" (Affronti v Crosson, 95 NY2d 713, 719 [2001] [citation omitted]). At bottom, "[t]he rational basis standard is a paradigm of judicial restraint" (id. [citation omitted]).

As to the right asserted here, the State pursues a legitimate purpose in guarding against the risks of mistake and abuse. The State may rationally seek to prevent the distribution of prescriptions for lethal dosages of drugs that could, upon fulfillment, be deliberately or accidentally misused. The State also has a significant interest in preserving life and preventing suicide, a serious public health problem (see Bezio, 21 NY3d at 104; Storar, 52 NY2d at 377; see also Glucksberg, 521 US at 729). As summarized by the Supreme Court, the State's interests in prohibiting assisted suicide include: "prohibiting intentional killing and preserving life; preventing suicide; maintaining physicians' role as their patients' healers; protecting vulnerable people from indifference, prejudice, and psychological and financial pressure to end their lives; and avoiding a possible slide towards euthanasia" (Vacco, 521 US at 808-809). These legitimate and important State interests further "satisfy the constitutional requirement that a legislative classification bear a rational relation to some legitimate end" (id. at 809).

These interests are long-standing. As the Supreme Court observed, "[t]he earliest American statute explicitly to outlaw assisting suicide was enacted in New York in 1828" (Glucksberg, 521 US at 715 [citation omitted]). New York's Task Force on Life and the Law, [*6]which was first convened in 1984, carefully studied issues surrounding physician-assisted suicide and "unanimously concluded that [l]egalizing assisted suicide and euthanasia would pose profound risks to many individuals who are ill and vulnerable" and that the "potential danger[s] of this dramatic change in public policy would outweigh any benefit that might be achieved" (id. at 719 [citation omitted]). The Legislature has periodically examined that

ban — including in recent years — and has repeatedly rejected attempts to legalize physician-assisted suicide in New York.

The Legislature may conclude that those dangers can be effectively regulated and specify the conditions under which it will permit aid-in-dying. Indeed, the jurisdictions that have permitted the practice have done so only through considered legislative action (see Or Rev Stat Ann §§ 127.800 - 127.897 [enacted in 1997]; Wash Rev Code §§ 70.245.010 - 70.245.904 [enacted in 2008]; 18 Vt Stat Ann ch 113 [enacted in 2013]; California End of Life Option Act, Cal. Health & Safety Code pt 1.85 [enacted in 2015]; Colorado Rev Stat §§ 25-48-101 - 25-48-123 [enacted in 2016]; D.C. Act 21-577 [enacted in 2016]), and those courts to have considered this issue with respect to their own State Constitutions have rejected similar constitutional arguments (see Morris v Brandenburg, 2016-NMSC-027, 376 P3d 836, 843 [2016]; Sampson v State of Alaska, 31 P3d 88 [Alaska 2001]; Krischer v McIver, 697 So 2d 97, 104 [Fla 1997]; People v Kevorkian, 447 Mich 436, 446, 527 NW2d 714, 717 [1994]; see also Donaldson v Lungren, 2 Cal App 4th 1614, 1622, 4 Cal Rptr 2d 59, 63 [Cal Ct App 1992])[FN3]. At present, the Legislature of this State has permissibly concluded that an absolute ban on assisted suicide is the most reliable, effective, and administrable means of protecting against its dangers (see Glucksberg, 521 US at 731-733).

V. CONCLUSION

Our Legislature has a rational basis for criminalizing assisted suicide, and plaintiffs have no constitutional right to the relief they seek herein. Accordingly, the order of the Appellate Division should be affirmed, without costs.

RIVERA, J. (concurring):

Our state and federal constitutions guarantee heightened due process protections against unjustified government interference with the liberty of all persons to make certain deeply personal choices (NY Const, art I, § 6; US Const, 14th Amend; see also Rivers v Katz, 67 NY2d [*7]485, 492-493 [1986]; Obergefell v Hodges, 135 S Ct 2584, 2597 [2015]). This conception of liberty is grounded in notions of individual freedom, personal autonomy, dignity, and self-determination (see Rivers, 67 NY2d at 493; Planned Parenthood of Southeastern Pa. v Casey, 505 US 833, 857 [1992]; Lawrence v Texas, 539 US 558, 562 [2003] ["Liberty presumes an autonomy of self that includes freedom of thought, belief, expression, and certain intimate conduct."]; John P. Safranek, M.D. & Stephen J. Safranek, Can the Right to Autonomy Be Resuscitated After Glucksberg?, 69 U Colo L Rev 731, 733-742 [1998]) [FN4]. "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life" (Casey, 505 US at 851).

On this appeal, the plaintiffs essentially seek a declaration that mentally competent, terminally-ill patients have an unrestricted State constitutional right to physician-prescribed medications that hasten death. I concur with the Court that this broad right as defined by plaintiffs is not guaranteed under the New York State Constitution, and that the State has compelling and legitimate interests in prohibiting unlimited and unconditional access to physician-assisted suicide [FN5]. These interests, however, are not absolute or unconditional. In particular, the State's interests in protecting and promoting life diminish when a mentally-competent, terminally-ill person approaches the final stage of the dying process that is agonizingly painful and debilitating. In such a situation, the State cannot prevent the inevitable, and its interests do not outweigh either the individual's right to self-determination or the freedom to choose a death that comports with the individual's values and sense of dignity. Given that the State already permits a physician to take affirmative steps to comply with a patient's request to hasten death, and that the State concedes that the Legislature could permit the practice sought by [*8]plaintiffs, the State's interests lack constitutional force for this specific sub-group of patients. Considering the State's sanctioning of terminal sedation in particular, the statute does not survive rational basis review. Therefore, in my view, the State may not unduly burden a terminally-ill patient's access to physician-prescribed medication that allows the patient in the last painful stage of life to achieve a peaceful death as the end draws near.[FN6]

I.

"Death will be different for each of us. For many, the last days will be spent in physical pain and perhaps the despair that accompanies physical deterioration and a loss of control of basic bodily and mental functions. Some will seek medication to alleviate that pain and other symptoms" (Washington v Glucksberg, 521 US 702, 736 [1997] [O'Connor, J. concurring]). Justice O'Connor's poignant description of the end of life is familiar to plaintiffs, who included, at the time the complaint was filed, three mentally competent, terminally-ill adults. These patient-plaintiffs expressed a desire for more than pain management; they sought to maintain a sense of dignity, autonomy, and personal integrity in the face of death, which they claimed had been compromised by both their respective illnesses and by the State's prohibition on assisted suicide. They requested judicial recognition of a right to decide how and when to die by accessing medication that would permit each of them to put an immediate end to their respective suffering.

Two of these patient-plaintiffs have since passed. When the complaint was filed, one plaintiff was 62 years old and suffered from Lou Gehrig's disease, a neurodegenerative condition without a cure. As the disease took hold, she was in constant pain and "fe[lt] trapped in a torture chamber of her own deteriorating body," fully aware

of all that was transpiring to her physically and, worse yet, that the agonizing pain would persist for the rest of her days. She sought relief in the form of prescription medications that she could ingest "to achieve a peaceful death."

The other deceased patient-plaintiff was 57 years old and terminally ill with acquired immune deficiency syndrome (AIDS). A regimen of several medications kept him alive. He suffered from a variety of ailments and, as a consequence, had part of his foot amputated. He developed laryngeal carcinoma, which necessitated a tracheotomy that made it difficult for him to speak. He took more than 24 medications either through his feeding tube or [*9]by injection, and required morphine for pain management. He slept 19 hours a day and spent most of his five waking hours cleaning and maintaining his feeding and oxygen tubes, and taking his daily medications and injections. According to the complaint, he "wishe[d] to have the comfort of knowing that, if and when his suffering [became] unbearable, he [could] ingest medications prescribed by his doctor to achieve a peaceful death."

The surviving patient-plaintiff is in his eighties. He developed cancer and, after surgery to remove his bladder, suffered a recurrence but is now in remission. The complaint states that he wants "to be sure that if the cancer progresses to a terminal state, and he finds himself in a dying process he determines to be unbearable, he has available to him the option of aid-in-dying."

These patient-plaintiffs, joined by a group of physicians practicing end-of-life care and the non-profit End of Life Choices New York, challenge the application of New York's Penal Law to physicians who are willing to provide mentally competent, terminally-ill patients, like the named patient-plaintiffs, with a prescription for medication that they could ingest to end their lives before they succumb to the ravages of their illnesses. These providers maintain that aid-in-dying is a medically and ethically appropriate treatment that should be legally available to patients. They are supported by several amici, including professional organizations such as the American Medical Student Association, American Medical Women's Association, American College of Legal Medicine, National Academy of Elder Law Attorneys, and amici representing several surviving family members who have witnessed the death of a loved one, and who describe the emotional impact and stress endured by the family caregivers.

The stories retold by patient-plaintiffs and amici family survivors describe the painful and harrowing experiences many terminally-ill patients endure in the final stage of life. The dying process, candidly recounted, illustrates the struggle of the terminally ill to live and die on their own terms, and is a vivid reminder of the fragility of human existence. It also provides necessary context for the legal analysis.

II.

Constitutional limits on governmental interference with individual liberty have long included protection of the fundamental right to bodily integrity (Rivers, 67 NY2d at 492; Matter of Bezio v Dorsey, 21 NY3d 93, 119 [2013]; Glucksberg, 521 US at 720; Vacco v Quill, 521 US 793, 807 [1997]). Courts have recognized that decisions about what may or may not be done to one's body are "central to personal dignity and autonomy" and so are subject to heightened scrutiny (Casey, 505 US at 851; Cruzan v Dir., Missouri Dep't of Health, 497 US 261, 278 [1990]). While we have not defined its outer limit, "[t]his Court has repeatedly construed the State Constitution's Due Process Clause to provide greater protection than its federal counterpart as construed by the Supreme Court" (People v LaValle, 3 NY3d 88, 127 [2004]; see [*10]also People v Scott, 79 NY2d 474, 496 [1992]).

Patients in New York State unquestionably have certain fundamental rights regarding medical treatment. In Rivers v Katz, this Court stated that "[i]t is a firmly established principle of the common law of New York that every individual of adult years and sound mind has a right to determine what shall be done with his own body" (67 NY2d at 492). The Court continued,

"[i]n our system of a free government, where notions of individual autonomy and free choice are cherished, it is the individual who must have the final say in respect to decisions regarding [his or her] medical treatment in order to insure that the greatest possible protection is accorded [his or her] autonomy and freedom from unwanted interference with the furtherance of [his or her] own desires" (id. at 493).

A few years later, this Court noted that "the State rarely acts to protect individuals from themselves, indicating that the State's interest is less substantial when there is little or no risk of direct injury to the public. This is consistent with the primary function of the State to preserve and promote liberty and the personal autonomy of the individual" (Matter of Fosmire v Nicoleau, 75 NY2d 218, 227 [1990]). As such, the "fundamental common-law right [of refusing medical treatment] is coextensive with the patient's liberty interest protected by the due process clause of our State Constitution" (Rivers, 67 NY2d at 493).

While this language may seem to countenance aid-in-dying, there are important caveats. First, the right to refuse medical treatment, while fundamental, "is not absolute and in some circumstances may have to yield to superior interests of the State" (Fosmire, 75 NY2d at 226). If a challenged statute infringes on a fundamental right, "it must withstand strict scrutiny and is void unless necessary to promote a compelling State interest and narrowly tailored to achieve that purpose" (Golden v Clark, 76 NY2d 618, 623 [1990]). It is for the courts "to weigh the interest of the individual against the interests asserted on behalf of the State to strike an appropriate balance"

(Fosmire, 75 NY2d at 226-227). Second, the Court has, as the per curiam makes clear, consistently distinguished between refusing life-sustaining or life-saving medical treatment and assisting suicide (see Bezio, 21 NY3d at 103; Fosmire, 75 NY2d at 227; Matter of Storar, 52 NY2d 363, 377 n 6 [1981]; per curiam at 9-11). Across these cases the Court has held that an individual has a fundamental right to refuse medical treatment but, implicitly, not to physician-assisted suicide.

Even though this Court's precedent establishes that the right to control medical treatment generally does not extend to assisted suicide, because the criminal statutes challenged on this appeal effect a curtailment of patients' liberty, the State's prohibition must still be rationally related to a legitimate government interest (People v Knox, 12 NY3d 60, 67 [2009]). The Court here highlights how the State's legitimate interest in protecting life has led it to make a [*11]rational distinction between permitting a patient to refuse life-sustaining medical treatment and a ban on assisted suicide (per curiam at 12-13; see e.g. Bezio, 21 NY3d at 103). This interest extends to protecting the lives of the terminally ill, as does the rational link between this interest and prohibiting assisted suicide. There are several bases on which the State may justify prohibiting physician-assisted suicide for the terminally ill in most cases: a terminal diagnosis may be incorrect, or at least underestimate the time a patient has left; palliative care can often reduce a patient's will to die, whether caused by physical pain or depression, and thus prolong life; vulnerable, terminally-ill patients could face external influences encouraging them to hasten their deaths, such as familial or financial pressure; the fear of opening the door to voluntary and involuntary euthanasia; and, finally, the possible negative impact on the integrity and ethics of the medical profession.

I agree, on constraint of this prior case law, that the right of a patient to determine the course of medical treatment does not, in general, encompass an unrestricted right to assisted suicide, and the State's prohibition of this practice in the vast majority of situations is rationally related to its legitimate interests. Nevertheless, this conclusion does not support the State's position that its interests are always superior to and outweigh the rights of the terminally ill. In particular, when these patients are facing an impending painful death, their own interest may predominate. For the reasons I discuss, in those limited circumstances in which a patient seeks access to medical treatment options that end pain and hasten death, with the consent of a treating physician acting on best professional judgment, the State's interest is diminished and outweighed by the patient's liberty interest in personal autonomy.

III.

The liberty interest protected by our State Constitution is broader than the right to decline medical treatment. At its core, liberty is the right to define oneself through deeply personal choices that form a lifetime of human experience (Casey, 505 US at 851; Rivers, 67 NY2d at 493). As we have stated "to preserve and promote liberty and the personal autonomy of the individual" is "the primary function of the State" (Fosmire, 75 NY2d at 227).

An individual's interests in autonomy and freedom are not less substantial when facing the choice of how to bear the suffering and physical pain of a terminal illness at the end of life. Self-determination includes the freedom to make decisions about how to die just as surely as it includes decision making about life's most private matters — e.g. sexuality, marriage, procreation, and child rearing — all choices that reflect personal beliefs and desires (see e.g. Lawrence, 539 US at 567; Brooke S.B. v Elizabeth A.C.C., 28 NY3d 1, 26 [2016]). As the United States Supreme Court has recognized, "[t]he choice between life and death is a deeply personal decision of obvious and overwhelming finality" Cruzan, 497 US at 281).

For the terminally ill patient who is experiencing intractable pain and suffering [*12]that cannot be adequately alleviated by palliative care, plaintiffs and amici affirm that the ability to control the end stage of the dying process and achieve a peaceful death may lead to a renewed sense of autonomy and freedom [FN7]. So while the State's interest in protecting life is paramount, the law requires that we balance that interest against those of an individual facing an imminent and unbearably painful death. Contrary to the State's argument, the government's interest in protecting life diminishes as death draws near, as that interest "does not have the same force for a terminally ill patient faced not with the choice of whether to live, only of how to die" (Glucksberg, 521 US at 746 [1997] [Stevens, J. concurring]; see also Wilkinson v Skinner, 34 NY2d 53, 58 [1974] ["The requirements of due process are not static; they vary with the elements of the ambience in which they arise."]). In such cases, patients have "a constitutionally cognizable interest in obtaining relief from the suffering that they may experience in the last days of their lives" that outweighs the State's interest in essentially prolonging the agony (Glucksberg, 521 US at 737).

Certainly, the State may "stay its hand" by doing nothing to assist a terminally ill patient, thus letting the dying process take its natural course (Fosmire, 75 NY2d at 227). However, this is not the approach chosen by the State of New York. The reality is that the State already permits a patient to choose medical measures that hasten death in ways that require active, deliberate assistance of a physician. These measures are not passive. For example, the State permits the turning off of ventilators, the removal of breathing tubes, and the removal of intravenous life-sustaining nourishment and medications, even when the physician and patient know this will lead rapidly to certain death. As such, the State currently allows a physician, with a patient or a guardian's informed consent, and in the exercise of the physician's professional judgment, to affirmatively assist in bringing about a terminally-ill

patient's death (see Pub Health Law §§ 2994-e [1]; 2994-f [1]).

These processes are widely considered appropriate and humane end-of-life [*13]treatments that recognize the dignity of the individual patient. The justifications for allowing a physician to take active steps to precipitate a patient's death were powerfully noted in 2010, in the context of changes to the Public Health Law that now allows guardians of mentally-incompetent patients to withdraw or withhold life-sustaining treatments. Supporters of the bill wrote that,

"[l]ost in the gaps of existing law, many families have witnessed what they knew to be the ardent desires of their incapacitated loved ones go unfulfilled for weeks and months, while every participant — from the patient, to family members, to the professionals providing care — has anguished. At the same time, families have been frozen by the lack of legal means to honor the deeply personal wishes of their loved ones" (Letter from Healthcare Association of New York State, Bill Jacket, 2010, AB 7729, ch 8).

The Assembly Memorandum in Support described the legislation as necessary because mentally-incompetent patients "may linger, through unnecessary medical intervention, in a state of irrevocable anguish," and "are, as a class, uniquely disqualified from health care rights essential to the humane and dignified treatment to which every other citizen is entitled" (2001 NY Assembly Bill A08466D).

Plaintiffs and amici Surviving Family Members similarly describe how terminally-ill patients, deprived of a legal path to bring about a death in line with their wishes, suffer excruciatingly through the final moments of their lives as their loved ones and caregivers watch helplessly. The complaint, plaintiffs' affidavits, and amici briefs are filled with accounts of patients who would have chosen aid-in-dying if the option were available. One account describes an elderly man whose bones were so riddled with cancer they would spontaneously break, even when he was lying in bed without bearing weight. Despite receiving opioids and other medications around the clock, he found his pain and suffering unbearable. He wanted to know his options for a peaceful death and the only option the physician was able to offer was for him to voluntarily stop eating and drinking. Another describes a man suffering from a degenerative motor neuron disease who, eight years after diagnosis, was wheelchair bound, had lost control of his bladder and bowels, as well as the ability to cough up food caught in his lungs, experienced his limbs atrophy, and "everything which he had previously identified as degrading about dying." Ultimately he too chose to stop eating and drinking. He remained conscious during the 12 days that followed until his death, at one point developing terminal agitation that caused "sudden uncontrollable fits of yelling and violent thrashing" that led to him being strapped to his bed.

The State argues a dichotomy between active and passive physician conduct differentiates aid-in-dying from other sanctioned end-of-life treatments. This binary is unpersuasive in this context. First, it does not conform with the experience of all physicians (TE [*14]Quill, et al., Palliative Options of Last Resort, 278(23) JAMA 2099, 2102 [Dec 17, 1997] ["[T]here is nothing psychologically or physically passive about taking someone off a mechanical ventilator who is incapable of breathing on his or her own."). Second, the withdrawal of nourishment is anything but passive, as patients without an underlying disease die if they are prevented from eating and drinking. Third, and in contrast, the physician's role in aid-in-dying is "passive" in a practical sense, for it is the patient who administers the lethal medication, often spatially and temporally distant from the moment the physician provided the prescription (id.). In some cases, the patient never ingests the dosage.[FN8]

Apart from the fact that the State permits these non-passive actions to hasten death for the terminally ill, the State's interest in prohibiting aid-in-dying for this particular sub-group of patients is further weakened by its sanctioning of terminal sedation. This end-of-life treatment consists of the intravenous administration of sedatives and pain medication, often coupled with the withholding of nutrition and hydration, to a terminally-ill patient (J M van Delden, Terminal Sedation: Source of a Restless Ethical Debate, 33(4) J Med Ethics 187, 187 [2007]). In 2003, the American Medical Association issued a policy statement supporting the practice, which it calls "palliative sedation to unconsciousness," as "an intervention of last resort to reduce severe, refractory pain or other distressing clinical symptoms that do not respond to aggressive symptom-specific palliation" (see The AMA Code of Medical Ethics' Opinions on [*15]Sedation at the End of Life, 15(5) Virtual Mentor 428-429 [May 2013]).[FN9]

For this sub-group of terminally ill patients, the State recognizes this as a lawful means to end life [FN10]. As in Glucksberg, the "parties and amici agree that . . . a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death" (Glucksberg, 521 US at 736-37 [O'Connor, J. concurring]). The difference between injecting a drug that sedates a patient while simultaneously quickening death and prescribing lethal medication is not meaningful in the constitutional sense. Regardless of the method, the purpose of the physician's act and the patient's goal in both situations is to expedite the dying process and avoid the severe pain, suffering, and indignity associated with the last stage of a terminal illness. In these cases, a patient's "interest in refusing medical care is incidental to [the patient's] more basic interest in controlling the manner and timing of her death" (Glucksberg, 521 US at 742 [1997] [Stevens, J. concurring]). Moreover, by sanctioning a patient's right to refuse medical treatment,

which leads to certain death, this Court has, like the United States Supreme Court, "in essence, authorized affirmative conduct that would hasten [a patient's] death" (id. at 743).

The State and my colleagues rely on an analysis of physician intent to differentiate aid-in-dying from terminal sedation and the withholding or withdrawal of life-saving treatment (per curiam at 10-11; J. Fahey concurring op at 4; J. Garcia concurring op at 6). The argument presumes that physicians who adopt aid-in-dying intend to cause the patient's death, while physicians who perform these other treatments intend solely to alleviate the patient's pain, and death is merely a potential unintended consequence. My colleagues quote Vacco v Quill for the proposition that the law "has long used actors' intent or purpose to distinguish between two acts [*16]that may have the same result" (521 US 793, 802 [1997]; per curiam at 11; J. Fahey concurring op at 4; J. Garcia concurring op at 5). This is irrelevant, because in every case involving individual liberty, the constitutional question turns on the nature and expanse of the patient's right to autonomy and bodily integrity as weighed against the State's interest, not the intent of a third party who assists the patient in receiving the proper medical treatment (Rivers, 67 NY2d at 498)[FN11]. Besides, we do not defer to federal analysis when we construe our broader state constitutional due process clause (LaValle, 3 NY3d at 127).

Moreover, this intent-based analysis fails even on its own terms. Simply put, it is impossible, as a practical matter, to distinguish between these various end-of-life practices based on a third party's state of mind. When a physician removes a patient from a life-sustaining apparatus, or declines to administer life-saving procedures, the physician's intent, in accord with the wishes of the patient, is to precipitate the death of the patient. A physician who complies with a patient's constitutionally protected choice to forego life-sustaining treatment knows that when a ventilator is withdrawn, for example, the patient will soon die [FN12]. To argue otherwise is to ignore the reality of the physician's actions and the patient's wishes.

Even the primary distinction cited by the State and my colleagues does not hold in all cases because, as the State concedes, the drugs involved in terminal sedation are known to cause a patient's death in certain cases. A physician providing this medical option knows very well about the potential immediate consequence and must forewarn the patient (see AMA Code of Medical Ethics' Opinions on Sedation at the End of Life at 428). Furthermore, while sedation may be necessary to alleviate a patient's pain, the withdrawal of nourishment, which forms part of the treatment, can only serve to bring about death (see David Orentlicher, The Supreme Court and Terminal Sedation: Rejecting Assisted Suicide, Embracing Euthanasia, 24 Hastings Const L [*17]Q 947, 957 [Summer 1997]). Resolution of the constitutional question requires consideration of the patient's rights; not a speculative exploration of the physician's intent.

Terminal sedation is intended to initiate what must be described for what it is: a slow-acting lethal process. While it may fall under the umbrella of palliative care (see Glucksberg, 521 US at 737-738 [O'Connor, J. concurring]), terminal sedation is not solely a method of pain management but is instead a procedure that hastens the inevitable death of the patient. It places the patient in a condition where choosing to struggle against death is no longer possible. It facilitates the patient's choice to end life.

If terminally-ill patients may exercise their liberty interest by choosing to be terminally sedated, the State has no compelling rationale, or even a rational interest, in refusing a mentally-competent, terminally-ill patient who is in the final stage of life the choice of a less intrusive option — access to aid-in-dying — which may better comport with the patient's autonomy and dignity. It is also an option which lessens the time patients and their families are forced to wait for the inevitable — often by no more than days and possibly much less.

IV.

Concerns about allowing aid-in-dying for the subgroup I have identified are misplaced. Consider, first, the State's interest in preserving life. Admittedly, the State has compelling interests that justify prohibiting assisted suicide as a general matter, but those interests are diminished and do not outweigh the individual's liberty interest in the case of a competent terminally-ill patient in the final stage of life, with no cure or recourse other than inadequate pain management, facing a death the patient feels is bereft of dignity. As the State's own policies regarding terminal sedation attest, it has accepted that its interest in preserving life should cede to the rights of a patient in this condition. Acknowledgment of the individual's right to decide when and how to end life in the limited situations I have discussed does not undermine the sacredness of life or devalue the patient any more than terminal sedation does. Instead, by honoring a patient's wishes, the State recognizes the individual's right to full autonomy and to make a choice that reflects deeply held beliefs about life and death.

Nor does the State's general interest in preventing suicide and avoiding misdiagnosis outweigh the liberty interests in aid-in dying for mentally-competent, terminally-ill patients facing imminent, agonizing death. The State's interests for this group of patients are not comparable to cases involving persons without terminal illnesses who are able to manage their illness and its debilitating effects, or those who for any number of personal reasons do not want to hasten death with a lethal prescription. There is no possibility of an erroneous terminal diagnosis for these patients as aid-in-dying would only be available in the last stage of life, when the end is imminent and certain. The fear that allowing aid-in-dying will result

in patient coercion or be the first step to government-sanctioned euthanasia is as misplaced as the notion [*18] that terminal sedation inevitably leads to government-sanctioned euthanasia [FN13]. Permitting these patients to choose whether to experience the short time that remains under conditions some may find unbearable is a recognition of the importance of individual autonomy and the limits of the State's ability to interfere with a patient's most intimate personal decisions (Rivers, 67 NY2d at 492-493; Obergefell, 135 S Ct at 2597).

The State's argument that aid-in-dying would make it more difficult to ensure adequate medical treatment for those with untreated pain and depression is a valid interest in support of the State's prohibition on physician-assisted suicide as a general matter. However, it does not outweigh the interests of the terminally ill for whom pain treatment is inadequate and whose choice is not motivated by depression and helplessness, but by the desire to exercise autonomy to achieve a peaceful death, one that honors individuality and dignity (see Glucksberg, 521 US at 746-74 [1997] [Stevens, J. concurring]). Nor can it be said to be rational when the State already permits terminal sedation.

The State's other argument, that aid-in-dying undermines the integrity and ethics [*19]of the medical profession as it is incompatible with the physician's role as a healer,[FN14] is not uniformly accepted and is contradicted by the experiences of some medical professionals [FN15]. The plaintiff-physicians who treat the terminally ill and amici representing the American Medical Student Association, American Medical Women's Association, and American College of Legal Medicine, describe how inhibiting a physician's exercise of best professional judgment when counseling a patient about end-of-life choices undermines the doctor-patient relationship. Indeed, aid-in-dying is openly practiced in various parts of the country without having [*20]compromised the profession [FN16] — the physician standard of care is governed by statutes and professional guidelines that have ensured the quality and careful application of this end of life treatment [FN18]. By all measures, the State fails to address that the [*21]"time-honored line between healing and harming" does not provide much guidance for practices like terminal sedation or aid-in-dying (Glucksberg, 521 US at 731 [citations and quotation marks omitted]). For this sub-group of patients, healing, as understood as a restoration of bodily health, is no longer a possibility.

In addition to the interests asserted by the State, my colleagues "hypothesize" an additional concern in avoiding misuse of a patient's dosage (per curiam at 11-12). Yet, the risk of the drugs involved in aid-in-dying being "deliberately or accidentally misused" is no more than with any other drug with the potential to cause severe injury or death that a physician may legally prescribe (see Office of the New York State Comptroller, Prescription Opioid Abuse and Heroin Addiction in New York State [June 2016], available at https://www.osc.state.ny.us/press/releases/june16/heroin_and_opioids.pdf [accessed August 29, 2017]). At most, this simply shows that the State may regulate this area, as other states have done.[FN19]

V.

"It is the province of the Judicial branch to define, and safeguard, rights provided [*22]by the New York State Constitution, and order redress for violation of them" (Campaign for Fiscal Equity, Inc. v State, 100 NY2d 893, 925 [2003]). Although a liberty interest is at stake here, the Court implies and Judge Garcia argues that this question is best addressed by the Legislature (per curiam at 13; J. Garcia concurring op at 17). "The Court, however, plays a crucial and necessary function in our system of checks and balances. It is the responsibility of the judiciary to safeguard the rights afforded under our State Constitution" (People v LaValle, 3 NY3d 88, 128 [2004]). We may not abdicate that role to any other branch of government (Campaign for Fiscal Equity, 100 NY2d at 925).

Mentally-competent, terminally-ill patients, with no cure or recourse other than inadequate pain management or palliative sedation to unconsciousness, and who face certain, imminent, excruciating death, are situated quantitatively and qualitatively differently from other individuals, even others living with terminal illnesses. State interests that animate the prohibition on physician aid-in-dying for these patients are diminished as death draws near and ultimately are outweighed by these patients' liberty interest and extant rights to self-determination and bodily integrity. The compelling state interests that bar physician assisted suicide in general are not, for this group, dispositive. When the State already permits physicians to instigate other processes that precipitate death, there is no compelling basis for depriving such patients of an option that can better comport with their sense of dignity, control, and independence. Our State Constitution protects the rights of these terminally-ill patients to make the deeply personal choice of how they define and experience their final moments.

Order affirmed, without costs. Opinion Per Curiam. Judges Rivera, Stein, Fahey, Garcia and Wilson concur, Judge Rivera in a concurring opinion, Judge Fahey in a separate concurring opinion, and Judge Garcia in a separate concurring opinion in which Judge Stein concurs. Chief Judge DiFiore and Judge Feinman took no part.

(The separate concurring opinions of Judge Fahey and Judge Garcia are omitted here, and can be accessed at *http://www.courts.state.ny.us/ctapps/Decisions/2017/Sep17/77opn17-Decision.pdf*

Footnotes

Footnote 1: In Montana, a terminally ill patient's consent to physician-assisted suicide constitutes a defense to a charge of homicide under a state criminal statute, as interpreted by the Montana

Supreme Court (see Baxter v State, 224 P3d 1211, 1222 [Mont 2009]).

Footnote 2: See generally Sullivan, Active and Passive Euthanasia: An Impertinent Distinction?, in Steinbock and Norcross at 136; R.G. Frey, Intention, Foresight, and Killing, in Tom L. Beauchamp, Intending Death: The Ethics of Suicide and Euthanasia 69-70 (1996); Greg Beabout, Morphine Use for Terminal Cancer Patients: An Application of the Principle of Double Effect, 19 Philosophy in Context 49 (1989), reprinted in P.A. Woodward, The Doctrine of Double Effect 298-311 (2001).

Footnote 3: This figure includes 1,933 reported cases and 477 unreported cases. The study classified actions as euthanasia or physician-assisted suicide if the physician administered, supplied, or prescribed drugs with the explicit intention of hastening death, and at the explicit request of the patient, resulting in the patient's death. Not classified as instances of euthanasia or physician-assisted suicide were situations in which medical treatment was withheld or withdrawn, or measures to alleviate pain or other symptoms (such as palliative sedation) were intensified.

Footnote 4: In 1985, the New York State Task Force on Life and the Law was established by Governor Mario Cuomo, commissioned with "a broad mandate to recommend public policy on issues raised by medical advances" (https://www.health.ny.gov/regulations/task_force/reports_publications/when_death_is_sought/preface.htm [accessed August 21, 2017]).

Footnote 5: There is also evidence of an extension of the practice of physician-assisted suicide to non-physicians in the Nethelands. A Dutch "suicide counselor" was acquitted of helping a 54-year-old woman kill herself, despite advising her on the quantity of drugs to be taken to be certain of death (T. Sheldon, Dutch court acquits suicide counsellor of breaking the law, 334 BMJ 228 [2007], available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1790785 [accessed August 21, 2017]).

Footnote 6: Although the lower court's holding "was not limited to a particular set of plaintiffs before it" (id. at 709 n 6, quoting id. at 739 [Stevens, J., concurring]), the Court determined that it had nonetheless ruled on the statute's constitutionality "as applied to members of a group" — an approach that is "not uncommon" (id. at 709 n 6, citing Compassion in Dying v Washington, 79 F.3d 790, 798 n 9 [9th Cir 1996 en banc]).

Footnote 7: Judge Rivera's assertion that "the intent of a third party who assists the patient" is "irrelevant" to the legal analysis (J. Rivera concurring op at 18) ignores the factual foundation of plaintiffs' claim: plaintiffs seek a constitutional right not only to hasten death, but to the affirmative assistance of another in doing so. As the Supreme Court explained, "[t]he law has long used actors' intent or purpose to distinguish between two acts that may have the same result," and on this basis, "many courts, including New York courts, have carefully distinguished refusing life-sustaining treatment from suicide" (Vacco, 521 US at 803). Comporting with this fundamental legal principle, the State may rationally distinguish between various end-of-life practices.

Footnote 8: The analysis in Judge Rivera's concurring opinion — which concludes that the State's interests "do not outweigh" a patient's right as death draws near (J. Rivera concurring op at 2; see also id. at 10, 12, 21, 23, 27) — bears little resemblance to our well-established rational basis review. Rational basis is not a balancing test. Rather, under this relaxed standard, plaintiffs' claims must fail so long as any conceivable legitimate State interest supports the challenged legislation (Affronti, 95 NY2d at 719 [citation omitted]). As discussed below, the assisted suicide statutes "easily satisfy" this requirement (Vacco, 521 US at 809).

Footnote 9: Given the breadth and nature of plaintiffs' allegations, outlined briefly below, I agree with Judge Rivera's implicit determination that plaintiffs' claims encompass the "sub-group of patients" who have entered the "final stage of the dying process" (J. Rivera concurring op at 2-3). Our disagreement concerns the merits — rather than the scope — of these claims.

Footnote 1: Plaintiffs discontinued the action against the District Attorneys after entering into a stipulation that all parties would be bound by any result reached in the litigation between plaintiffs and the Attorney General.

Footnote 2: Penal Law § 120.30 provides that "[a] person is guilty of promoting a suicide attempt when [such individual] intentionally causes or aids another person to attempt suicide." Penal Law § 125.15 (3) provides that "[a] person is guilty of manslaughter in the second degree when . . . [such person] intentionally causes or aids another person to commit suicide."

Footnote 3: The Supreme Court of Montana has held that a statutory consent defense protects physicians from prosecution for physician-assisted suicide, but it did not reach the constitutional question (see Baxter v State, 2009 MT 449, ¶ 50, 354 Mont 234, 251, 224 P3d 1211, 1222 [2009]).

Footnote 4: There is a rich debate taking place over centuries discussing the meaning of the term "dignity," and the significance of the concept remains controversial today (see generally Richard E. Ashcroft, Making Sense of Dignity, 31 J Med Ethics 679 [2005]). As used here, the term is intended to evoke an individual's freedom to pursue autonomously chosen goals as well as an individual's need to be free from debasement and humiliation, broadly conceived (id. at 681).

Footnote 5: I agree with the Court's analysis that what plaintiffs call "aid-in-dying" is assisted-suicide within the meaning of our criminal law (per curiam at 5-7), and that the plaintiffs' equal protection claim is without merit (id. at 7-8). I address only the rights of the terminally ill under the State Due Process Clause.

Footnote 6: Lest my intention be misconstrued, I do not write to expound on plaintiffs' State due process rights as limited by their complaint, but rather to address the State's position that its interests outweigh the rights of all terminally-ill patients regardless of their condition.

Footnote 7: It is worth noting that in her Glucksberg concurrence, Justice O'Connor was operating on the assumption that all dying patients in Washington and New York could obtain palliative care that would relieve their suffering. As a result, she did not reach the narrower question of "whether a mentally competent person who is experiencing great suffering has a constitutionally cognizable interest in controlling the circumstances of his or her imminent death" (Glucksberg, 521 US at 737-738 [O'Connor, J. concurring]). As plaintiffs and amici allege, and as medical science indicates, palliative care is not always an option for a terminally ill patient in severe pain approaching death.

Footnote 8: Not all physicians who prescribe a patient a lethal dosage necessarily know for certain that the patient will die from taking the prescription, as many patients prescribed these drugs do not ultimately take them. Many patients simply want to regain a modicum of control over the dying process (see Glucksberg, 521 US at 751 n 15 [Stevens, J. concurring]). The ranges vary from state to state. In California, under the End of Life Option Act, 173 physicians prescribed 191 individuals lethal medication between June 9, 2016, and December 31, 2016. Of the 191 prescribed patients, 111 (58.1%) were reported by their physician to have died following ingestion of lethal medication and 21 (11.0%) died without ingestion of the prescribed drugs. The outcome of the remaining 59 (30.9%) individuals was undetermined at the time of the report (California Department of Public Health, California End of Life Option Act 2016 Data Report [2016] at 3, available at: https://www.cdph.ca.gov/Programs/CHSI/CDPH%20Document%20Library/CDPH%20End%20of%20Life%20Option%20Act%20Report.pdf [accessed August 29, 2017]).

Footnote 9: The statement recommends ethical guidelines for physicians using the practice, such as only using it for patients in the final stage of a terminal illness when their symptoms have been unresponsive to aggressive treatment, and stresses that it is not appropriate when the patient's suffering is primarily existential (AMA Code at 429). These guidelines are not dissimilar from those codified in aid-in-dying statutes across the country (see Or Rev

Stat Ann §§ 127.800 - 127.897 [enacted in 1997]), and in the bill currently before the legislature (Proposed Medical Aid in Dying Act, NY Assembly Bill A02383 [Jan 19, 2017]).

Footnote 10: Determining whether terminal sedation is appropriate is a decision for physicians and patients (see AMA Code of Medical Ethics' Opinions on Sedation at the End of Life at 428).

Footnote 11: Due to the conceptual murkiness of determining whether a physician's act is active or passive, and whether death is intended or merely foreseen by a physician, some experts on palliative care advise that considerations of "the patient's wishes and competent consent are more ethically important [than these concerns about the physicians's mindset]" (Quill, Palliative Options of Last Resort, at 2102).

Footnote 12: Arguably, at least as long as the patient remains conscious, it may be possible for a patient who has asked for a ventilator or nourishment to be withdrawn to change course and decide to resume life-sustaining treatment. Terminal sedation, however, initiates a process whereby the patient cannot object once sedated and inevitably ends in the patient's death.

Footnote 13: The prediction that sanctioning aid-in-dying would put New York State on a slippery slope toward legalizing non-voluntary euthanasia is far from certain. Studies of two decades of euthanasia in the Netherlands "show no evidence of a slippery slope [leading to non-voluntary euthanasia]. . . . Also, there is no evidence for a higher frequency of euthanasia among the elderly, people with low educational status, the poor, the physically disabled or chronically ill, minors, people with psychiatric illnesses including depression, or racial or ethnic minorities, compared with background populations" (JA Rietjens, et al., Two Decades of Research on Euthanasia from the Netherlands. What Have We Learnt and What Questions Remain?, 6(3) J Bioeth Inq 271 [2009], at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2733179/ [accessed August 29, 2017]; see also MP Battin, et al., Legal physician-assisted dying in Oregon and the Netherlands: evidence concerning the impact on patients in "vulnerable" groups, 33(10) J Med Ethics 591 [2007]). This finding is mirrored in the data from Oregon, which shows no evidence of heightened risk in any of the above categories (id.).

Footnote 14: The State does not adopt Judge Garcia's argument that the opinion of some medical professionals alone is enough for this statute to survive rational basis scrutiny as applied to this sub-group (J. Garcia concurring op at 15). And with good reason: such a low threshold risks rendering our rational basis test meaningless.

Footnote 15: For example, the New York State Academy of Family Physicians, representing over six thousand physicians and medical students, recently decided to support aid-in-dying ("Physician's group endorses medical aid-in-dying legislation," The Legislative Gazette [June 25, 2017], available at: http://legislativegazette.com/physicians-group-endorses-medical-aid-in-dying/ [accessed August 29, 2017]). Also, this year the Medical Society of the State of New York decided to conduct a survey of physicians in the State to determine their attitudes towards aid-in-dying, citing public support and changes in the law elsewhere (see "New York's medical society will survey doctors on attitudes towards physician assisted dying," WXXI News [April 24, 2017], available at: http://wxxinews.org/post/new-york-s-medical-society-will-survey-doctors-attitudes-toward-physician-assisted-dying [accessed August 29, 2017]). This included a survey commissioned by Compassion & Choices, a non-profit organization focusing on end-of-life care, which indicates that 77 percent of New Yorkers support access to aid-in-dying (Compassion & Choices, New York 2015-16 Research Report, available at: https://www.compassionandchoices.org/wp-content/uploads/2017/02/2NY-POLL-INFO.pdf [accessed August 29, 2017]).

Footnote 16: Notably, a 2003 survey of doctors and nurses published by the Journal of the American Medical Association indicated that aid-in-dying was being practiced clandestinely throughout the country (see Diane E. Meier, MD et al, Characteristics of Patients Requesting and Receiving Physician-Assisted Death, 163(13) Arch Intern Med 1537 [2003], available at: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/215798 [accessed August 29, 2017]). . Several amici point out that in those states where aid-in-dying is lawful — Oregon, Washington, Vermont and California [FN17] Colorado has recently adopted a ballot measure permitting aid-in-dying (Colo End of Life Options Act, Prop 106 [2016]).

Footnote 18: The decisions from other states cited by the Court to demonstrate that assisted suicide has nowhere yet been deemed a fundamental right by a high court in the United States do not affect the analysis, as plaintiffs rely on the guarantees afforded by the New York State Constitution and our Court's broad interpretation of the state Due Process Clause. To the extent some of the cases cited by the per curiam analyze their own state constitutions in a manner similar to that employed by the per curiam here (per curiam at 13-14), I note that not all are based on their respective state's due process clause (see People v Kevorkian, 447 Mich 436, 538, 527 NW2d 714, 758 [Mich 1994]). Further, the analysis is not uniform across these cases. For example, in Morris v Brandenburg (2016-NMSC-027, 376 P3d 836, 841 [NM 2016]), the most recent case cited by the per curiam, the Supreme Court of New Mexico reversed the trial court, which had found a statute that prohibited aid-in-dying violated the New Mexico State Constitution's guarantee to protect life, liberty, and happiness. However, in that case, the State conceded that it did not "have an interest in preserving a painful and debilitating life that will end imminently." The court found that the State had, instead, a legitimate interest in providing protections to ensure that decisions regarding aid-in-dying are informed, independent, and procedurally safe (id. at 855). The court ultimately determined that the right to aid-in-dying is best defined by the legislature, which is better equipped to develop appropriate safeguards than the judiciary (points also made by the courts in the Florida and Alaska cases [Krischer v McIver, 697 So 2d 97, 104 (Fla 1997); Sampson v State of Alaska, 31 P3d 88,98 (Alaska 2001)]). A dissenting judge in the Michigan case also argued that the State's interest in the preservation of life dwindles as a terminally-ill patient suffering great pain seeks to hasten death through physician-prescribed medications (Kevorkian, 447 Mich at 538 [Mallett, J., dissenting]). Thus, to the extent these cases may be instructive, they reveal that the constitutional analysis of aid-in-dying is specific to each state's constitutional jurisprudence and interests.

Footnote 19: Although the State's authority to regulate the exercise of a terminally-ill patient's access to aid-in-dying medications is not directly presented in this appeal, some regulation of this medical treatment option would fall within the State's power over public health matters (see Viemeister v White, 179 NY 235, 238 [1904]).

Telehealth Considerations

By Gary S. Sastow and Katherine Dandy

Overview

Telehealth encompasses a broad variety of technologies and tactics to deliver virtual medicine, health, and education services.[1] Currently, there are four distinct categories of telehealth applications:

1. Live video (also referred to as synchronous communication), which involves real-time interaction between patients and providers using audiovisual telecommunications technology;
2. Store-and-forward (also known as asynchronous communication), in which recorded health history is transmitted through a secure electronic communications system to a practitioner;
3. Mobile health, which involves healthcare and public health practice education supported by mobile communication devices (e.g., targeted text messages that promote healthy behavior, or wide-scale alerts about disease outbreaks); and
4. Remote patient monitoring (RPM), in which personal healthcare and medical data is collected from an individual in one location via electronic communication technologies and transmitted to a provider in a different location for use in care and related support.

Benefits of Telehealth

There are multiple benefits to telehealth, including increased patient access; enhanced reach of healthcare services; improved continuity of care and case management; higher patient satisfaction; and reduction of risk. Telehealth makes it possible to provide quality and timely specialty care in areas without specialized providers, so patients do not have to choose between convenience and quality.[2] RPM allows providers to continue to track healthcare data for patients once released to home or a care facility, thereby reducing readmission and complication rates.

Importantly, telemedicine has been shown to reduce the cost of healthcare and increase efficiency through better management of chronic diseases (which account for about 75 percent of healthcare costs),[3] shared health professional staffing, reduced travel times, and fewer or shorter hospital stays.

In the context of medical malpractice allegations, remote patient monitoring, which is being used in the many tele-ICUs coming online throughout the country, should strengthen the ability of healthcare providers to establish that the standard of care has been met. When a patient is being cared for and monitored by both a bedside ("local") physician and a remote monitoring physician who is supported by tele-ICU software, the risk of medical error decreases. Thus, in the event of an adverse outcome, the telemedicine support in place will serve as an additional hurdle potential malpractice plaintiffs will have to overcome to prove departures from the standard of care.

Resources for Telemedicine Development

To encourage and facilitate the spread of telemedicine, many regions in the U.S. are now served by Telehealth Resource Centers (TRCs), which offer sample documents and descriptions of successful programs.[4] In 1993, the American Telemedicine Association (ATA) was established to promote access to medical care for consumers and health professionals via telecommunications technology. The Center for Connected Health Policy (CCHP) was created in 2008 and became the federally designated National Telehealth Policy Resource Center. CCHP is a public interest organization that develops and advances telehealth policy solutions to promote improvements in health and healthcare systems.

TRCs, ATA, and CCHP are valuable resources, and they stand ready to assist providers in developing and implementing telehealth solutions.

Legal and Regulatory Landscape

Telemedicine is being encouraged and assisted by both state and federal governments, as well as multiple medical associations, including the American Medical Association (AMA). On the federal level, the Department of Health and Human Services, largely through its Health Resources Services Administration and Office for the Advancement of Telehealth, has become increasingly involved in telehealth, by, among other things, administering telehealth grant programs (which include a focus on licensure portability, discussed below), providing technical assistance, developing telehealth policy initiatives to improve access to quality health services, and promoting knowledge exchange about "best telehealth practices."

Hoping to help physicians understand how their fundamental responsibilities may play out differently when patient interactions occur through telemedicine, as

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opposed to more traditional methods, the AMA recently adopted new guidance for ethical practice in telemedicine. The AMA guidelines advise telemedicine physicians to "recognize the limitation of the relevant technologies and take appropriate steps to overcome those limitations" and to recognize that a coordinated effort across the profession is necessary to achieve the promise and avoid the pitfalls of telemedicine.

While the government has been helping in many ways to stimulate the growth of telemedicine,[5] there is currently no uniform legal approach to telehealth, which continues to be a major challenge to its progress. Telehealth implementation varies from state to state in terms of what service providers will be reimbursed for delivering, as well as what sort of parity (defined as "equivalent treatment of analogous services") is expected between in-person health services reimbursements and telehealth reimbursements.

A Look at Reimbursement Policies

States can govern private payer telehealth reimbursement policies, as well as which, if any, telehealth services are covered by Medicaid. Forty-nine states and the District of Columbia have some coverage for telehealth, and nearly all reimburse for live video telehealth.[6] Currently, at least 16 states provide some level of Medicaid reimbursement for RPM, while only nine reimburse for store-and-forward services.[7] Thirty-two states and the District of Columbia have parity laws that cover private insurers and reimbursement for telehealth services. Many variations exit in how states and private insurers pay out reimbursements and what they cover. Almost 50 percent of the current state telehealth coverage laws—including New York—lack parity language,[8] meaning that reimbursement by health plans for telehealth services is not required to be at the same rate as what is paid for in-person services. Without parity, the incentive to provide telehealth services decreases.

In 2015, New York enacted a telemedicine commercial reimbursement statute, requiring commercial insurers to cover services provided via telemedicine and telehealth.[9] Legislation was introduced in May of 2016 that would require insurers to reimburse telehealth providers "for covered services delivered via telehealth on the same basis and at the same rate as established for the same service when not delivered via telehealth."[10] The bill is currently in committee.

On the federal level, Medicare will only reimburse for synchronous communications and does not cover any store-and-forward services or remote patient monitoring for chronic diseases, except in Alaska and Hawaii.[11] The federal government places numerous limitations on Medicare reimbursement for telehealth services, based on the location of the patient and provider, as well as the type of distant site facility. As such, it provides a less-than-ideal example for states to follow.[12] In 2015, a nationwide telehealth parity act, the Medicare Telehealth Parity Act (H.R. 2948), was introduced in Congress with the intention of modernizing how Medicare reimburses telehealth services and expanding coverage for Medicare beneficiaries. Unfortunately, no action has been taken on the proposed legislation since it was referred to the congressional subcommittee on health in July of 2015.

The ongoing debate over whether telemedicine should be reimbursed at the same levels as in-patient care, and the lack of clarity on the issue, continues to hinder the development of telemedicine, even in the face of its proven cost savings, increased access and efficiency, and the rise in consumer demand for telehealth services such as mobile apps and health tracking devices.

Challenges of Telehealth

Professional licensing for telemedicine providers is often cited as a barrier to the expanded use of telehealth and telemedicine. Most states, including New York, require the physician to be licensed in the state in which the patient is located.[13] Currently, 18 states have enacted legislation to join the Interstate Medical Licensure Compact (IMLC), which is expected to help streamline the licensure process by offering a voluntary expedited pathway to licensure for qualified physicians who wish to practice in multiple states.[14] In addition, the Tele-Med Act (S. 1778 and H.R. 3081) was introduced to Congress in 2015 and would allow Medicare participating physicians to treat Medicare patients in all 50 states with a single license. Unfortunately, the bill was referred to the congressional subcommittee on health in July of 2015, and no action has been taken since.

Malpractice liability concerns have also been raised by the move toward more telehealth-based services.[15] For example, liability policies typically specify that coverage is only available for claims occurring in a specific jurisdiction. A telehealth physician sued in a state other than the jurisdiction in which he or she is covered might find that no coverage is available.

Future of telehealth

Telehealth can and should be applied to many other disciplines and specialties, including acute care, oncology, and stroke care. New York law defines the use of RPM to encompass "treatment and management of medical conditions that require frequent monitoring, including congestive heart failure, diabetes, chronic obstructive pulmonary disease, wound care, polypharmacy, mental or behavioral problems, and technology-dependent care such as continuous oxygen, ventilator care, total parenteral nutrition or enteral feeding."[16] Under such a broad definition, the possibilities for telemedicine solutions are seemingly endless.

Endnotes

1. The term "telemedicine" is used when referring to traditional clinical diagnosis and monitoring that is delivered by technology. The term "telehealth" is now more commonly used, as it more broadly describes the wide range of diagnosis and management, education, and other related fields of healthcare.
2. Twenty percent of Americans live in rural areas, but only 9 percent of physicians practice in these areas. T. Yang, Telehealth Parity Laws, Health Affairs Health Policy Brief (Aug. 15, 2016), www.rwjf.org/en/library/research/2016/08/telehealth-parity-laws.html. Health Affairs is a journal of health policy thought and research.
3. *Id*.
4. Currently, there are 12 regional and two national resource centers throughout the country. A list can be found at https://www.telehealthresourcecenter.org.
5. By shifting reimbursement structures to incentivize better patient care with more cost efficiency, and penalizing hospitals for high readmission rates, the Affordable Care Act is promoting telehealth solutions.
6. *See* note 4.
7. *Id*.
8. Twenty-three states and the District of Columbia have full parity, meaning coverage and reimbursement is comparable from in-person to telehealth servicers.
9. Public Health Law § 2999-dd (PHL).
10. Senate Bill 7953.
11. *See* note 4.
12. *Id*.
13. PHL § 2805-u.
14. www.licenseportability.org. Thirty state medical boards have endorsed the IMLC.
15. T. Yang, Telehealth Parity Laws, Health Affairs Health Policy Brief (Aug. 15, 2016), www.rwjf.org/en/library/research/2016/08/telehealth-parity-laws.html. Health Affairs is a journal of health policy thought and research.
16. PHL § 2999-cc.

NEWS flash

What's Happening in the Section

In the Health Law Section

Section Officer Nominations

The Nominating Committee of the Health Law Section proposed the following candidates for the following Section officers for election at the upcoming Annual Meeting:

Chair-Elect: Hermes Fernandez

Vice-Chair: Karen L. I. Gallinari

Treasurer: Anoush Koroghlian Scott

Secretary: Nathan G. Prystowsky

The current Chair-Elect, Robert A. Hussar of Barclay Damon in Albany, will begin his term as Chair in June 2018.

Upcoming Events

Annual Meeting

The Section's Annual Meeting will be held at the New York Hilton Midtown, New York City on Wednesday, January 25, 2018. The program, "Hot Topics in NY Health Law" will touch on the following topics:

- Legislative update, including the Affordable Care Act and other potential changes under the Trump Administration
- How developing areas in Medicare, e.g., MIPS and meaningful use, are being audited by the federal government and other regulators
- DSRIP update
- Cybersecurity, HIPAA, ransomware and NY's new cybersecurity regulations
- What's new in HIPAA enforcement
- Value based payment update
- The future of long term care, including assisted living and legal issues associated with other forms
- Updates in Health IT: Fraud, Waste and Abuse implications of misusing HIT/EHRs, and how HIPAA Business Associates' sharing data for research and other purposes impacts covered entities

To register, go to: www.nysba.org/am2018.

Recent Events

Section Fall Meeting New Frontiers in Health Law

This program, held in Albany on October 27, offered insight to regulatory changes, anticipated regulatory changes, and the corresponding legal, ethical, and political implications. Panelists described how these new regulatory programs work, recent changes, and how to help clients avoid pitfalls. Anoush Koroghlian Scott of served as Program Chair, with Section Chair Lawrence Faulkner of ARC Westchester, James Dering of Garfunkel Wild PC and Caitlin Monjeau of Community Care Physicians as members of the Program Committee. Topics explored included: Privacy Implications with the Use of Mobile Devices in the Health Care Industry, NYS Regulatory Updates, New York's Medical Marijuana Program, HIPAA Audits, ACA Repeal and Replace: Implications for New York State, Aid in Dying—Legislation, Litigation and Ethics.

Recorded Programs Now Available Online

The Section has three recordings available to purchase and view for CLE credit, any time that is convenient for you:

1. Legal Issues Surrounding Eye, Organ and Tissue Donation

CLE: *1.5 credits in professional practice, non-transitional and accredited for MCLE credit in New York State only.*

Cost: Free to Health Law Section Members.

Presented by the Health Law Section in partnership with the New York Alliance for Donation (NYAD), and co-sponsored by the Health Law Committee and Bioethical Issues Committee of the New York City Bar.

New York State is facing a health care crisis: the need for transplantable organs far exceeds the availability. While a single donor can help save the lives of up to eight people, potential donors are rare. It is crucial that all of the participants in the process, legal, clinical, administrative and governmental are knowledgeable about the law and the process surrounding organ and tissue donation.

2. Health Law Section Fall Meeting: Disrupting the System: Innovation and Collaboration in Health Care in New York

CLE: 7.0 MCLE credits, 6.5 Professional Practice, 0.5 Ethics. (*This program is for experienced attorneys only, is non-transitional, and accredited for MCLE credit in New York State only.)*

Cost: Health Law Section Members: $175

This program offers a look at innovative programs that are designed to facilitate access to comprehensive, coordinated care to improve patient satisfaction and clinical outcomes. These programs and the use of the technology necessary to support them do not come without legal

barriers and challenges. A diverse panel of speakers will describe initiatives that are disrupting the health care system, and the practical ways to overcome the real and perceived barriers to sustained implementation. This program is relevant for attorneys representing all provider types, health systems, in-house counsel, insurance/payor plans and governmental attorneys involved in health care regulation.

Topics:

- In-House General Counsel: Hot Topics
- Medical-Legal Partnerships in Health Care
- Collaborative Affiliations Among Large Systems and Physician Practices: Tales from the Trenches
- Medical-Legal Implications and Sustainability of SHIN-NY Regulations in Healthcare Delivery System
- Concierge Medicine/Telemedicine/Direct Primary Care
- Ethics of Health Information Technology Privacy

3. E-Health Clinical Records & Data Exchange II: Live and Webcast

CLE: *This program is accredited for 2.0 MCLE credits in the area of Professional Practice, and is non-transitional and accredited for MCLE credit in New York State only.*

Cost: Health Law Section Members: $50

The NYSBA's Health Law Section, in collaboration with Albany Law School and Fordham Law School, is holding the second program of a two-part series exploring the state of population health initiatives for improving the public's health and the law affecting: Electronic Health Records (EHRs) across provider types and payor systems; Health Information Exchanges (HIEs) and Regional Health Information Organizations (RHIOs), including the State Health Information Network of New York (SHIN-NY) and e-MOLST; data collection and integration; and research and ethics.

Topics:

- Expanding Public Policy Goals for EHR to Improve the Public's Health: Utilizing Integrated Medical and Social Data for Designing Care Systems and Population-Level Interventions—Issues in Law, Research and Ethics.
- E-Health Licensure Standards—Gaps in Law and Regulations at the State Level

Part I of this series is available for free, and does not offer CLE credit. Visit www.nysba.org/ehrs.

Section Committees and Chairs*

The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers or Committee Chairs for further information about these Committees.

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