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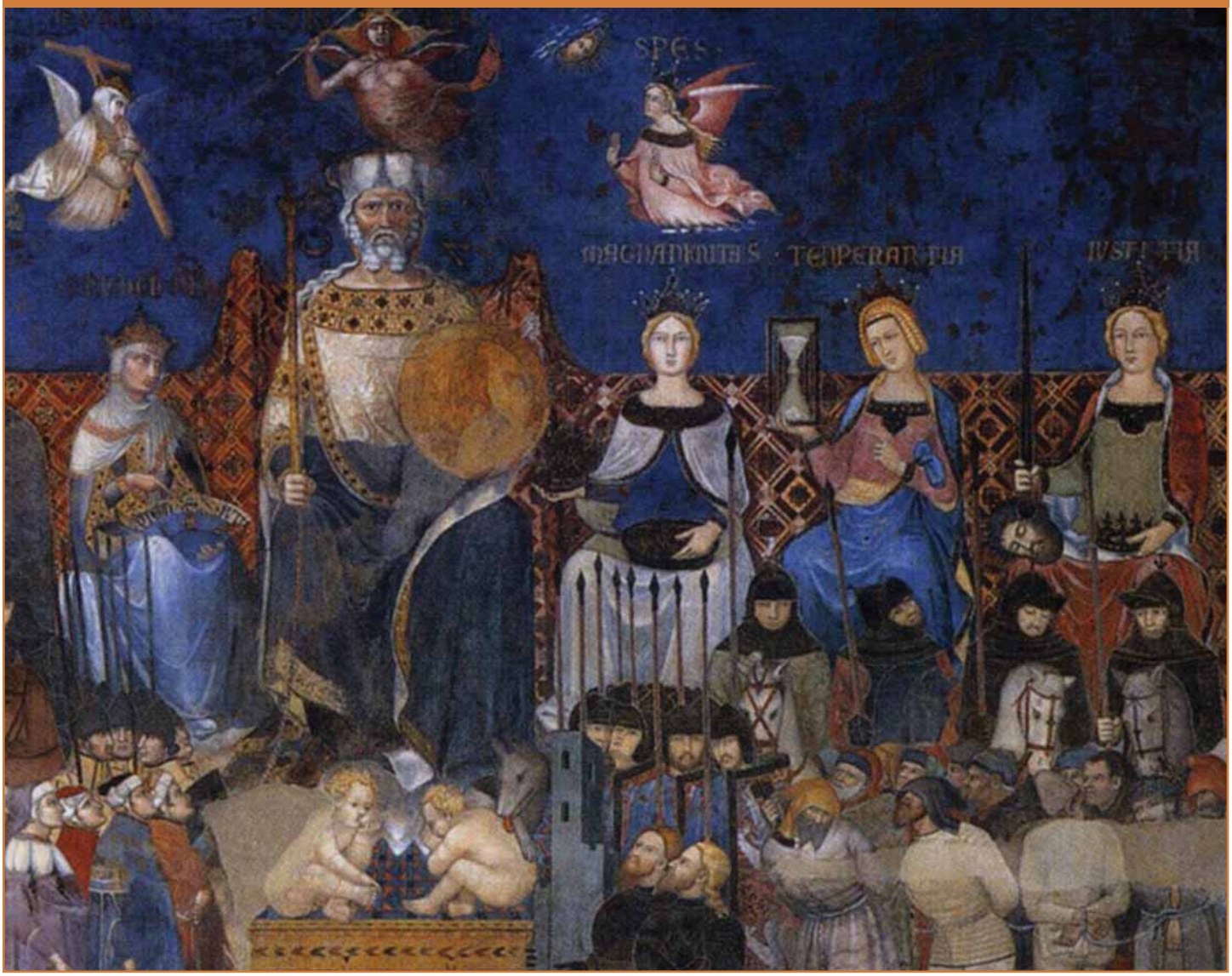

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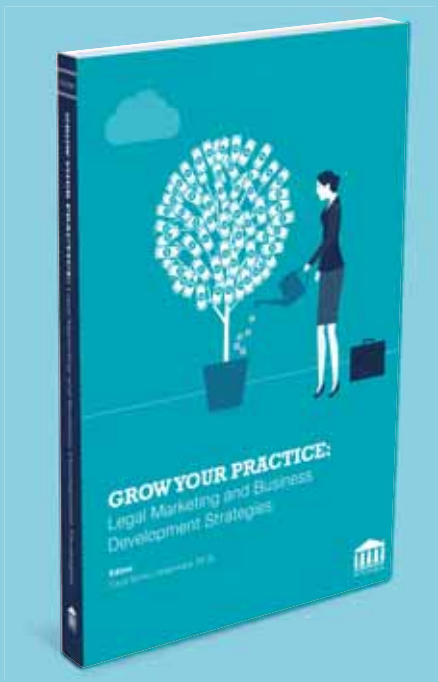

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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Cover artwork:
***Allegory of Good Government* by Ambrogio Lorenzetti**

Message from the Section Chair

I am pleased to serve as the Chair for the Health Law Section of the NYSBA. We believe that the committees in the Health Law Section are the heart of the Section. The committees allow our members the opportunity to meet with their colleagues and work on substantive issues in their respective fields. Recently, we have revised our committees that deal with health care providers and attempted to clarify the issues that each of the committees will be addressing.

The first of the revised committees, the Health Care Providers and In-House Counsel Committee, will address issues faced by hospitals, physicians and physician groups, home care agencies, and others in contractual corporate regulatory and related areas. This committee will also focus on issues that in-house counsel deal with on a daily basis, including patient care matters and changes to the law that can require changes to institutional policies and procedures. The co-chairs of this group are Margaret J. Davino, Esq., of Kaufman Borgeest & Ryan, Anoush Koroghlian Scott, Esq., of Ellis Medicine, and Caroline Levine of Memorial Sloan Kettering Cancer Center.

The second revised committee, entitled the Health Professionals Committee, will be chaired by Jay Silverman, Esq. of Ruskin Moscou Faltischek and Laurie Cohen, Esq., of Nixon Peabody. The mission of this committee is to focus on the legal issues, challenges, and laws and regulations that licensed individual health care professionals and their counsel face as a result of the rapid changes in the health care industry, such as licensed health care professionals accepting employment with large health systems or consolidating into larger single and multi-disciplinary groups.

If you are interested in any of the committees, please feel free to contact the committee chairs or co-chairs listed on p. 95 in this *Journal*, or staff liaisons.

The committee descriptions and work-plans for all of our committees are also listed with further information on the Health Law Section page of the NYSBA website at www.nysba.org/Health. We encourage all members to join a committee relative to your interests and remain an active participant.

On October 30, 2015, the Health Law Section Fall Meeting took place at the New York State Bar Association in Albany. The conference addressed population health issues in a changing legal landscape from a variety of perspectives. The program featured experts from diverse fields, including disaster preparedness, medical managed care and DSRIP, and discussed how these evolving areas impact the practice of health law. Representatives from governmental agencies, including the Department of Health, non-profits, and the private sector spoke on the rapidly changing landscape and the expanding integration taking place in the delivery of health care. This year's conference was a valuable forum for exchanging information and ideas about these topics.

We look forward to your continued involvement with the Section and encourage your involvement in the committees, upcoming meetings and Continuing Legal Education seminars.

Kenneth R. Larywon
Chair

In the New York State Courts

By Leonard M. Rosenberg

Court of Appeals Holds That Medical Examiner Has No Legal Obligation to Notify a Deceased's Next of Kin of Any Organs or Tissue Samples Removed and Retained During an Authorized Autopsy

Shipley v. City of New York, 2015 WL 3590553 (N.Y. June 10, 2015). Dr. Roux, a forensic pathologist and medical examiner, conducted an autopsy of the decedent, a seventeen year old killed in an automobile accident. The autopsy was conducted with the consent of the decedent's father. During the procedure, the medical examiner removed and stored in a jar the decedent's brain as well as tissue samples. The jar was placed in a cabinet in the autopsy room, pending review from a neuropathologist. The jar was labeled with decedent's name and the date of autopsy. Two months later, a student from decedent's high school, during a field trip to the mortuary, recognized decedent's name and informed the family.

Decedent's parents sued the City of New York, alleging negligent infliction of emotional distress. Defendant moved for summary judgment, arguing that the complaint failed to state a claim because it essentially asserted interference with Plaintiffs' right of sepulcher, a common law right to immediate possession of a decedent's body for preservation and burial. The trial court denied the motion.

The Appellate Division held that the medical examiner had the legal authority to conduct the autopsy, but under Public Health Law § 4215(1) and the common law right of sepulcher, was obligated to turn over the removed organs and tissue samples for preservation and proper burial once the legitimate purposes of their retention had been fulfilled. The court found that this obligation could have been achieved by alerting Plaintiffs before the funeral that the brain and

tissue samples had been retained.

The case proceeded to trial on the sole issue of whether the medical examiner returned the decedent's body without notifying Plaintiffs of the organ and tissue sample retention. Plaintiffs moved for a directed verdict on the issue of liability, relying on evidence that Plaintiffs were never notified. The court granted the motion and the jury entered a verdict for Plaintiffs, which the Appellate Court affirmed.

The Court of Appeals ruled that the Appellate Division erred when it imposed a mandatory and ministerial duty on medical examiners to turn over removed organs once the legitimate purposes of the retention have been fulfilled.

The Court began its review by evaluating the extent of a medical examiner's statutory authority to conduct autopsies. It explained that only ministerial acts of a municipal employee may subject municipal employers to liability for negligence. The Court held that medical examiners possess broad discretionary authority to perform autopsies and to remove and retain organs, such as a brain, under Title II of Article 42 of the Public Health Law and under New York City Charter § 557(f).

The Court then turned to the common law right of sepulcher and Public Health Law § 4215, and discussed how each would mandate the return of the corpse. First, the Court evaluated the common law right of sepulcher, which it found to be premised on the next of kin's right to possession of a body for purposes of obtaining comfort from any burial or other disposition. Accordingly, the Court held that a violation of this right occurred only by withholding the actual body; it did not apply to a medical examiner's retaining the organs or tissue samples from within the body.

Then, the Court considered and rejected Plaintiffs' argument that Public Health Law § 4215(1) required a medical examiner to return not only a body, but also the organs and tissue samples removed during an autopsy. The Court noted that this issue boiled down to the meaning of the statutory language, the "remains of the body," used in Public Health Law § 4215(1). Although recognizing the ambiguity concerning this language, the Court determined that the Legislature did not intend to include organs and tissue samples in its meaning. The Court explained that the Legislature had specifically referred to organs and tissues in other sections of Article 42 of the Public Health Law, but such language was absent from Public Health Law § 4215(1). The Court held that there is no rule or statutory command imposing an obligation to return retained organs or tissue samples, and, absent such a legal obligation, there can be no duty to notify the next of kin that organs and tissue samples had been retained.

The dissent asserted that the majority misread Public Health Law § 4215(1) and erroneously determined that the right of sepulcher only includes the dissected corpse. It concluded that the common law and New York statutory law impose on medical examiners a ministerial duty to return the organs once the legitimate basis for their withholding has ended. However, it noted that, although there is no statutory basis to impose a notification requirement, the common law provides a sufficient legal basis for such obligation. In its conclusion, it further observed that the majority's reading of the Public Health Law leaves open questions concerning demands or obligations

concerning a decedent's organs based on religious grounds.

Second Circuit Allows Lawsuit to Proceed Against Administrator of Self-Insured Health Plan Under the Mental Health Parity and Addiction Equity Act and ERISA

New York State Psychiatric Ass'n v. UnitedHealth Group, No. 14-20-cv (2d Cir. Aug. 20, 2015). Plaintiffs are New York State Psychiatric Association, Inc. ("NYSPA"), a professional organization of psychiatrists practicing in New York State; Jonathan Denbo, a beneficiary of a self-insured health plan; and Shelly Menolascino, M.D., a psychiatrist. Plaintiffs each brought individual or associational claims against Defendants UnitedHealth Group, UHC Insurance Company, United HealthCare Insurance Company of New York, and United Behavioral Health (collectively, "United") alleging violation of the Mental Health Party and Addiction Equity Act of 2008 (the "Parity Act"), which prohibits health insurers from imposing more stringent financial requirements or treatment limitations on mental health benefits than imposed on covered medical and surgical benefits. Plaintiffs also asserted claims under ERISA § 502(a)(1)(B), which enables a plan participant or beneficiary to file suit to recover benefits under such plan, or to enforce or clarify his rights thereunder, and § 502(a)(3), which authorizes a civil action for injunctive or other equitable relief to redress a violation of the terms of a covered health plan.

On December 4, 2013, upon United's motion, the district court dismissed the action, finding that NYSPA lacked associational standing to sue on behalf of its members; that United, as a third-party plan administrator, was not an appropriate defendant under the Parity Act or ERISA § 502(a)(1)(B); and that equitable relief under § 502(a)(3) was unavailable to Plaintiffs because their alleged injuries could be fully redressed by monetary damages under § 502(a)(1)(B). Plaintiffs appealed.

The Second Circuit first found that NYSPA had appropriately pled its associational standing to sue on behalf of its members. The court held that there was "no serious dispute on this appeal" that NYSPA's members would individually have standing, due to their status as assignees of ERISA-covered health plan benefits and their interest in preventing any future limitation of their provision of mental health treatment. Likewise, the court held that the action was "germane to NYSPA's purposes." Although United argued that NYSPA's claims required individualized proof, the court held that because NYSPA sought only injunctive and declaratory relief, it was plausible that a limited number of its members would be able to "prove that United's practices violate the relevant statutes." However, the court noted that the district court may dismiss NYSPA's claims for lack of standing at summary judgment or trial should it become apparent that the "claims require significant individual participation of proof." The court then remanded NYSPA's claims to the district court to determine whether it stated a plausible claim for relief.

The court then addressed Denbo's claims under ERISA §§ 502(a)(1)(B) and 502(a)(3). Denbo, who received psychotherapy treatment, is a beneficiary of a self-insured health plan administered by United. Under the plan, United was granted "exclusive authority and sole and absolute discretion to interpret and apply the rules of the plan to determine claims" for both mental health and medical benefits. Denbo alleged that United violated the Parity Act and the terms of the plan by subjecting mental health treatment, but not medical treatment, to preauthorization or concurrent medical necessity review and by applying review standards to mental health claims that are more restrictive than both generally accepted mental health standards and the standards set forth in the plan for medical claims. At the conclusion of such review, Denbo's treatment was deemed not medically necessary, and he was denied benefits. Observing that ERISA imposes a duty upon plan fiduciaries to act in accordance with the plan as consistent with the statute, the court held that the viability of Denbo's claims turned on whether United could be sued in its capacity as claims administrator.

The Second Circuit held that United could be sued under ERISA § 502(a)(1)(B) to recover benefits under the health plan because it "exercise[d] total control over claims for benefits" in that it "ha[d] 'sole and absolute discretion' to deny benefits and ma[de] 'final and binding' decisions as to appeals of those denials." The court found that where a claims administrator exercises such total control over claims, "that administrator is a logical defendant in the type of suit contemplated by § 502(a)(1)(B)." The court noted that its decision follows the holdings of several other circuit courts. It also noted that its decision logically follows *Harris Trust & Savings Bank v. Salomon Smith Barney*, 520 U.S. 238 (2000), in which the Supreme Court held that a non-plan defendant could be sued under § 502(a)(3) because the statute similarly "makes no mention at all of which parties may be proper defendants," but rather focuses "on redressing the 'act or practice which violates [ERISA].'"

Turning to Denbo's claims under § 502(a)(3), the court rejected United's argument that it could not be sued under the Parity Act because of its status as administrator of a self-funded plan, rather than a group health plan. The court rested its holding on *Harris Trust*, in which the Supreme Court determined that § 502(a)(3) itself gave rise to certain duties that were not otherwise found in the substantive provisions of ERISA. The court reasoned that "in light of that interpretation, § 502(a)(3) may impose a fiduciary duty arising indirectly from the Parity Act even if the Parity Act does not directly impose such a duty."

The court further held that it was premature for the district court to dismiss Denbo's § 502(a)(3) claim based upon the availability of adequate relief under § 502(a)(1)(B), as Denbo had not yet succeeded on his § 502(a)(1)(B) claim and it was not clear at the pleading stage whether monetary damages alone would be a sufficient remedy. Instead, the court instructed that should Denbo succeed on both claims, the district court must determine whether equitable relief is appropriate. The court also noted that to the extent that Denbo seeks monetary redress for United's past breaches of fiduciary duty or to enjoin any future breaches, the remedy would be appropriately classified as "equitable relief" under § 502(a)(3).

Lastly, the court upheld the district court's dismissal of Dr. Menolascino's claims. Dr. Menolascino alleged that she was assigned United's plan benefits for her provision of psychopharmacological services and that United "denied or reduced" such benefits. However, she did not specify how United treated comparable medical and surgical benefits, identify the terms of her patients' United health plans, or allege sufficient facts to support her claim that United had no basis for withholding benefits under the terms of those plans. Accordingly, the court held that she had not alleged a plausible claim for relief.

Court of Appeals Rules That Criminal Defendant's Statement to Psychiatrist That Defendant Sexually Abused a Child Is Protected by Physician-Patient Privilege and Not Admissible in Criminal Trial

People v. Rivera, 25 N.Y.3d 256, 33 N.E.3d 465 (2015). On November 1, 2007, a child revealed to her pediatrician, in her mother's presence, that she had been sexually abused by Defendant David Rivera ("Defendant"). The pediatrician reported the abuse to the Administration for Children Services ("ACS"). When Defendant was informed of the accusation, prior to charges being pressed, Defendant was taken by an ambulance to the psychiatric emergency room at Columbia Presbyterian Hospital (the "Hospital") where he complained of depression and suicidal ideation. During his treatment at the Hospital, Defendant told his psychiatrist that he had sexually abused the child. Defendant was discharged four weeks later from the Hospital, arrested, and charged with predatory sexual assault against a child.

Prior to trial, the People sought *in camera* review of Defendant's psychiatric records from the Hospital. The People specifically sought any admissions by Defendant concerning the crimes charged, which they asserted, fell under an exception to, or waiver of, the physician-patient privilege. In relevant part, the privilege under CPLR 4505(a) provides that "[u]nless the patient waives the privilege, a person authorized to practice medicine…shall not be allowed to disclose any information which he [or she] acquired in attending a patient in a professional capacity, and which was necessary to enable him [or her] to act in that capacity."

Following *in camera* review of the records, the trial court held that Defendant's admission to his psychiatrist was privileged because it was made during the course of diagnosis and treatment of his condition. However, the Court ruled Defendant's admission of abuse was admissible at trial because the psychiatrist had disclosed the reported abuse to ACS. At trial, the People called Defendant's psychiatrist, who testified that Defendant admitted to having sexually abused the child. During summation, the People referred to the psychiatrist's testimony, and during deliberation, the jury's only request was for a read-back of that testimony. Defendant was convicted and sentenced to a term of 13 years to life in prison.

The Appellate Division unanimously reversed and remanded for a new trial, holding that the trial court erred in permitting the psychiatrist to testify concerning Defendant's admission of sexual abuse. On appeal, the Court of Appeals agreed with the Appellate Division and held that the trial court's ruling violated the physician-patient privilege.

The Court held that regardless of whether a physician is required or permitted by law to report instances of abuse or threatened future harm to authorities, which may involve the disclosure of confidential information, it does not follow that such disclosure necessarily constitutes an abrogation of the evidentiary privilege a criminal defendant enjoys under CPLR 4504(a). The Court noted that whereas confidentiality is an ethical requirement of physicians, the physician-patient privilege is a rule of evidence that protects communications and medical records. Significantly, whenever the legislature has decided to limit the privilege's scope, it has done so through the enactment of specific legislation to address the particular subject matter. However, no exception was created permitting a criminal defendant's mental health professional to testify against the defendant in a criminal proceeding, even if a patient was cognizant of his or her psychiatrist's reporting obligations under child protective statutes.

Second Circuit Holds That Patients' Assignment of Rights to Collect Payment Does Not Render Healthcare Providers ERISA Beneficiaries, Nor Does It Vest Providers with Standing to Bring Suit Under ERISA

Rojas v. Cigna Health and Life Ins. Co., 793 F.3d 253 (2d Cir. 2015). Appellants, two physicians and the medical practice they co-own ("Rojas"), appealed from the U.S. District Court for the Southern District of New York's dismissal of their action seeking to enjoin Cigna from removing Rojas from its coverage network.

Pursuant to Section 502 of the Employee Retirement Income Security Act (ERISA), which establishes a federal cause of action for the enforcement of rights under ERISA plans, Appellants claimed that Cigna had violated the Act's anti-retaliation provision. In pertinent part, the

anti-retaliation provision renders it unlawful for "any person to...discriminate against a participant or beneficiary for exercising any right to which he is entitled under the provision of an employee benefit plan."

Following routine investigations, Cigna suspected that Rojas was ordering blood tests inconsistent with its coverage requirements. Ultimately determining that it had overpaid Rojas over $800,000, Cigna requested that Appellants return the overpaid amount in full. When Rojas refused to reimburse Cigna and also refused to submit to arbitration pursuant to the parties' provider agreement, Cigna notified Rojas that it would be terminated as a network provider.

The Southern District denied Appellants' motion for a preliminary injunction, finding that Rojas lacked standing to bring an ERISA action, as Appellants were not participants, beneficiaries or fiduciaries under an ERISA plan. The Court held that healthcare providers do not "become plan beneficiaries solely by virtue of receiving reimbursement from a plan administrator." Additionally, the Court noted that, although Rojas took assignments of the rights of plan participants as their healthcare provider, such assignments were limited to the receipt of reimbursements and did not convey the right to assert ERISA claims.

Affirming the District Court's decision, the Court of Appeals rejected Rojas' alternative arguments in favor of its standing either as a plan-designated beneficiary or as a participant-designed beneficiary.

As to the former, the Court held that the term "beneficiary," as used within ERISA's general statutory scheme, does not encompass healthcare providers. Examining legislative intent, the Court held that Congress did not wish to include doctors within the "beneficiary" category and, likewise, did not wish to confer upon extraneous parties standing to sue. Instead, beneficiaries are individuals who enjoy rights equal to those of the plan participants (such as spouses and children) to receive coverage from the healthcare plan for medical, surgical and hospital care.

The Second Circuit's analysis also centered upon on the distinction between a benefit *provided by* a healthcare plan and a benefit *through the operation of* a healthcare plan. Holding that Rojas' "benefit" was of the latter type, the Court found that Rojas' claim to payment for services was merely "a function of how Cigna reimburses healthcare providers under the Benefit Plan."

As to Rojas' argument regarding its participant-designated beneficiary status, the Court held that the assignments executed by Rojas' patients expressly conveyed only the patients' right to pursue claims for payment, excluding other categories of ERISA claims. The Court further emphasized that Rojas' grievance against Cigna was uniquely its own rather than one it would bring on patients' behalf as, of course, no patient was removed from the Cigna network as a provider. Accordingly, the instant assignment could never have conveyed the necessary standing, as an assignee is vested with no greater rights than its assignor.

As the Court of Appeals concluded that Rojas lacked standing to bring the ERISA anti-retaliation claim to begin with, the Court did not address the issue of injunctive relief.

Second Department Holds That Physician Who Operated Pain Management Clinic and Prescribed Narcotics to a Drug Addict Who Killed Four People During a Pharmacy Robbery Did Not Owe a Duty of Care to the Victims

Malone v. Cnty. of Suffolk, 128 A.D.3d 651, 8 N.Y.S.3d 408 (2d Dep't 2015). On June 19, 2011, David Laffer ("Laffer"), a drug addict, shot and killed four people including Plaintiff Miranda Malone's mother (hereinafter the "decedent") while committing a pharmacy robbery in an attempt to procure narcotics. Laffer was a patient of Defendant Dr. Stan Xuhui Li ("Dr. Li"), a physician who operated a pain management clinic, and prescribed narcotics to Laffer.

Plaintiff sued to recover for the wrongful death of the decedent, asserting causes of action in negligence and public nuisance. The Complaint alleged that Dr. Li ran a pain management clinic which functioned as a "pill mill," and gave prescriptions for narcotics to people he knew were abusing drugs, including Laffer.

Dr. Li moved to dismiss the complaint under CPLR 3211(a)(7) arguing that he did not owe a duty to the decedent or to the general public. The trial court denied Dr. Li's motion, concluding that he owed a duty to the general public, including the decedent, to refrain from overprescribing addictive drugs in an "irresponsible and potentially criminal manner." The court explained that Plaintiff's complaint sufficiently alleged a breach of that duty with respect to the prescriptions Dr. Li wrote to Laffer.

The Second Department reversed. The Court ruled that Dr. Li did not owe a duty to the decedent because she was a stranger to Laffer, and was a member of the general public, not a member of a determinate and identified class. In so holding, the Court emphasized that Dr. Li did not have the authority or ability to control Laffer, to protect against the risk of harm. The Court specifically rejected Plaintiff's argument that Dr. Li owed a duty to the decedent and to the general public at large because there was a special relationship between Dr. Li and Laffer. In dismissing Plaintiff's negligence claim, the Court also dismissed Plaintiff's public nuisance claim, premised on the same negligence theory.

Second Circuit Rules That a Hospital's Severance Policy Is an Employee Welfare Benefits Plan Under ERISA

Okun v. Montefiore Medical Center, 793 F.3d 277, 2015 WL 4385294 (2d Cir. July 17, 2015), Plaintiff, a pediatrician and professor who worked for Montefiore Medical Center (the "Hospital") from 1988 through 2011,

alleged that the Hospital terminated him to interfere with his right to severance payments under its company policy, in violation of the Employee Retirement Income Security Act ("ERISA"). At issue in this matter was whether the Hospital's severance policy met the statutory definition of an employee welfare benefit plan. Under ERISA, such a plan is defined as

> any plan, fund, or program…established or maintained by an employer or by an employee organization, or by both, to the extent that such plan, fund or program was established or is maintained for the purpose of providing for its participants or other beneficiaries…benefits in the event of sickness, accident, disability, death or unemployment, or…any benefit described in section 186(c) of this title.

29 U.S.C. § 1002(1). The United States District Court for the Southern District of New York dismissed the complaint for lack of subject matter jurisdiction, holding that the severance policy did not constitute an employee welfare benefit plan under ERISA.

The Court of Appeals considered the following factors to determine whether the severance policy was a "plan" as defined by ERISA: (1) whether the employer's undertaking or obligation requires managerial discretion in its administration; (2) whether a reasonable employee would perceive an ongoing commitment by the employer to provide employee benefits; and (3) whether the employer was required to analyze the circumstances of each employee's termination separately in light of certain criteria.

The Hospital's severance policy provided that all full-time individuals employed before August 1, 1996, who are terminated for reasons other than "for cause," are entitled to either twelve months' notice or six months' severance pay. In addition, those eligible employees who have been employed for more than fifteen years are entitled to automatic review of the amount of severance pay by the Hospital's president. The Hospital has maintained a severance policy since 1987, and the aforementioned policy has been in place since 1996, without revision.

On May 1, 2011, Plaintiff informed his supervisor that he planned to leave the Hospital in September 2011 for a new job. Under these circumstances he would have qualified for the severance pay as his separation was not for cause. However, on May 11, 2011, Plaintiff attended a meeting with a guest speaker, after which he was reprimanded by his supervisor for certain comments he made at the meeting. Two days later Plaintiff was terminated for cause due to the comments he made. Given his "for cause" termination he was ineligible for any severance pay, and thus Plaintiff filed suit.

The Court vacated and remanded the District Court's decision, as it found that the severance policy represented an "ongoing administrative program or scheme," which in its opinion involves the kind of undertaking that falls within the meaning of the phrase "any plan, fund, or program" under ERISA. The Court noted that not all employer severance plans constitute an employee welfare benefit plan under ERISA. For example, the Court cited a United States Supreme Court case wherein a state statute provided for a one-time severance payment to employees in the event of a plant closing. Because the payment was a one-time payment required by statute, it did not constitute a "plan, fund or program" under ERISA.

Using the factors set forth above, the Court found that the severance policy required discretion and individualized evaluation by the administrator, as it must determine whether the termination was "for cause" or for another reason set forth in the policy. In addition, under the policy the Hospital's president is required to engage in a discretionary review of the amount of severance benefits employees with more than fifteen years of service receive. Second, because the Hospital maintained a severance policy for nearly twenty-four years prior to Plaintiff's termination and only made one revision to the policy, the Court held that such a longstanding policy would give employees the reasonable impression that the Hospital has undertaken an "ongoing commitment to provide severance benefits." The Court noted that despite the fact that the severance policy maintained a provision that allows the Hospital to modify the policy unilaterally, such a provision does not defeat an employee's reasonable perception of an ongoing commitment.

As for the third factor, the Court opined that despite there being less room for managerial discretion (or minimal analysis), as the policy only provides that an employee must be employed prior to August 1, 2016, termination cannot be for cause to earn a severance payment; and asthe president reviews severance amounts for employees employed for more than fifteen years, such factors were sufficient to establish that the severance policy was a "plan" under ERISA. Ultimately, the Court held that the severance policy was a "multi-decade commitment to provide severance benefits to a broad class of employees under a wide variety of circumstances and requires an individualized review whenever certain covered employees are terminated." Thus, the Court remanded the matter to the District Court to determine whether the Hospital interfered with Plaintiff's rights to severance payments guaranteed by the policy and ERISA.

No Fault Insurer Is Not Required to Pay for Facility Fees of Office-Based Surgery Practice Accredited Under Public Health Law § 230-d

Government Employees Ins. Co. v. Avanguard Medical Group, PLLC, 127 A.D.3d 60, 4 N.Y.S.3d 267 (2d Dep't 2015). Appellant, a no-fault insurer, brought an action against an office-based surgical medical

provider seeking a declaration that it was not required to reimburse the provider for facility fees (charges for the use of a medical facility and its staff and equipment) as payable first-party benefits under the no-fault insurance law. The Supreme Court, Nassau County, denied the insurer's summary judgment motion and the insurer appealed. In a matter of first impression, the Appellate Division, Second Department, held that an insurer is not required to pay a facility fee for "office-based surgery" performed in a facility accredited under Public Health Law Section 230-d as a component of first-party benefits for "basic economic loss."

The Court analyzed the language of the No-Fault Law (Insurance Law. Art. 51), and noted that although the statutory and regulatory framework specifically provide that the operator of a hospital or "ambulatory surgery center" (both governed under Public Health Law Art. 28) may properly bill a no-fault carrier for facility fees, the statute is silent as to whether a provider offering "office-based surgery" (governed under Public Health Law §230-d) may bill a no-fault carrier for such services. Rejecting the medical provider's argument that its facility fees may be reimbursed as a component of "basic economic loss" under the Insurance Law because they meet the definition of a "necessary expense incurred for…medical,…surgical [and] nursing…services," the Court held that the medical provider failed to take into account that the definition of "basic economic loss" under Insurance Law § 5102 expressly incorporates the limitations imposed by Insurance Law § 5108. That provision limits the charges for such fees to the amounts set forth in the Workers' Compensation schedules. The Court concluded that because there is no provision in the Workers' Compensation schedules expressly providing for payment of facility fees for office-based surgery performed in a facility accredited under Public Health Law § 230-d, the absence of such provision supports the insurer's argument that the medical provider's facility fees are not necessary expenses under the Insurance Law.

The Court also rejected the medical provider's reliance upon a default provision under 11 NYCRR 68.5, which provides a mechanism for setting a fee for necessary services when no fee schedule is specifically set forth in the Workers' Compensation fee schedules. In rejecting this argument, the Court held that the medical provider cannot accurately state that there is no existing fee schedule to determine the amount of a facility fee when it is undisputed that the medical provider had consistently billed the insurer for facility fees based on existing fee schedules applicable to Article 28 ambulatory surgical centers. That schedule, however, is not applicable to facilities accredited under Public Health Law § 230-d, which are subject to a lower level of oversight and regulation than Article 28 facilities. The Court also held that the default provision applies to particular procedures that do not appear on any existing fee schedule. A facility fee is not a fee for a particular medical procedure, but a blanket charge added to the billing for all procedures. Determining that the obvious intent of the default provision is to fill in discrete gaps in schedules, and "not to make an entirely new category of services compensable," the Court rejected the medical provider's broad interpretation of the default provision.

Finally, the Court rejected the medical provider's argument that the Legislature created a new class of medical facility—an "office based surgical facility"—when it enacted Public Health Law § 230-d in 2007, and that its accreditation under that regulation entitles it to a facility fee. In rejecting this argument, the Court held that: (i) only Article 28 facilities are entitled to a facility fee under the existing no fault laws and regulations; and (ii) it is for the Legislature and the Commissioner of Financial Services, not the Court, to determine whether the laws should be changed to entitle an accredited Public Health Law §230-d facility to a facility fee.

Court Dismisses Restrictive Covenant Action as Moot After Plaintiff Withdraws Claim

Tamai v. Suffolk Anesthesiology, 46 Misc.3d 1228(A), 2015 N.Y. Slip Op. 50885 (N.Y. Sup. Ct. June 8, 2015). Plaintiff, an anesthesiologist, was employed by Suffolk Anesthesiology Associates (the "Practice"). Plaintiff resigned from her position in January 2015. Her employment agreement with the Practice contained a restrictive covenant that prohibited her from holding medical staff privileges at four Suffolk County hospitals for a period of three years after her resignation. Her new position provided anesthesiology services at two of the prohibited hospitals. After learning of Plaintiff's new position, the Practice sent a letter to Plaintiff and her new employer, threatening legal action if she violated the restrictive covenant. In response to this letter, Plaintiff's new employer withdrew its offer of employment. Plaintiff then sued the Practice seeking declaratory and injunctive relief.

Three months after commencing the action, Plaintiff informed the court that she found a new job that did not require having privileges at any of the four prohibited hospitals, and sought leave to discontinue the suit without prejudice, as the dispute was now moot. The Practice objected to discontinuing the action without prejudice, arguing that if the matter is discontinued, it should be with prejudice, and that it was not moot because Plaintiff may, at some time prior to the expiration of the three-year period, seek employment in violation of the restrictive covenant.

The Court held that discontinuing the action without prejudice was proper because the litigation was still in its infancy (*i.e.*, discovery was stayed and there were still pending motions before the Court) and no substantial rights of either party had accrued. The Court opined that despite the Practice's contention, any

delay, frustration, or expense incurred by the Practice in preparation of its defense did not constitute prejudice.

The Practice also argued that the exception to the mootness doctrine applied in this matter as it deals with a novel issue—whether restrictive covenants should be enforced in the field of anesthesiology. The Court noted that for an exception to the mootness doctrine to apply there must be: (1) a likelihood of repetition, either between the parties or among other members of the public, (2) a phenomenon typically evading review, and (3) a showing of significant or important questions not previously passed on (*i.e.*, substantial and novel issues).

Although the Court agreed that the issues raised in the action were likely to be repeated, it did not find that the issues were novel or typically evading review. The Court reasoned that restricting physicians, including anesthesiologists, from competing against their former employees is common and generally enforceable, as long as the restrictions are reasonable to time and location, necessary to protect legitimate interests, not harmful to the public, and not unduly burdensome.

The Court noted that given the absence of any violation of the restrictive covenant by the Plaintiff, it appeared that the Practice was attempting to use the litigation to obtain a judicial determination that may not be used against other physicians who may leave its employ. The Court ruled that the Plaintiff could not be forced to litigate a moot claim for the Practice's benefit.

Fourth Department Rules That Public Health Law § 2801-d Does Not Apply to Group Homes Because They Are Not a "Residential Health Care Facility" Under Public Health Law Article 28

Burkhart v. People, Inc., 129 A.D.3d 1475, 10 N.Y.S.3d 767 (4th Dep't 2015). Plaintiff, on behalf of her developmentally disabled brother, commenced a negligence action against the owner and operator of a group home where Plaintiff's brother resides. Plaintiff asserted causes of action based on Public Health Law § 2801-d. Section 2801-d allows a patient of a "residential health care facility" to maintain a private action against the facility when the facility deprives him or her of "any right or benefit created or established for the well-being of the patient by the terms of any contract, by any state statute, code, rule or regulation or by any applicable federal statute, code, rule or regulation." Defendant moved for summary judgment dismissing the causes of action based on Section 2801-d, arguing that the statute does not apply to group homes. The trial court held that because the group home provides some "health-related service" to its residents, it qualifies as a "residential health care facility." The Fourth Department reversed.

The Court first analyzed the meaning of a "residential health care facility" under Public Health Law § 2801-d. Specifically, a "'[r]esidential health care facility' means a nursing home or a facility providing health-related service." The Court noted that the group home was not a nursing home. Therefore, the main issue was whether a group home is a "residential health care facility" because it provides "health-related services."

The Court noted that Public Health Law Article 28 applies to institutions "serving principally as facilities…for the rendering of health-related service," such as hospitals and nursing homes. The Court reasoned that although the group home does provide some "physical care" to its residents, it does not principally provide "health-related services."

The Court also reasoned that Department of Health Regulations 10 NYCRR §§ 415.11 and 415.12 relate to the minimum standards applicable to nursing homes, and deal specifically with assessment and care planning, and quality of care for nursing home residents. In fact, the regulations use the term "[n]ursing home" interchangeably with the term "residential health care facility." These regulations were noteworthy because plaintiff premised the alleged violation of Public Health Law § 2801-d on them.

The Court further noted that Section 2801-d was enacted "to redress the abuse of patients in nursing homes" and "the term 'residential health care facility' was intentionally used by the Legislature in an effort to curb abuses in the nursing home industry and provide a more flexible penalty system against nursing homes than was previously available."

Finally, the Court noted that the group home is governed by the Mental Hygiene Law and regulated by the Office for People with Developmental Disabilities.

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a shareholder in the firm of Garfunkel Wild, P.C., a full service health care firm representing hospitals, health care systems, physician group practices, individual practitioners, nursing homes and other health-related businesses and organizations. Mr. Rosenberg is Chair of the firm's litigation group, and his practice includes advising clients concerning general health care law issues and litigation, including medical staff and peer review issues, employment law, disability discrimination, defamation, contract, administrative and regulatory issues, professional discipline, and directors' and officers' liability claims.

In the New York State Legislature

By James W. Lytle

The Year That Was

The 2015 legislative session may be among the most unusual legislative sessions in New York's history. Assembly Speaker Sheldon Silver and State Senate Majority Leader Dean Skelos were both indicted on federal corruption charges and soon thereafter replaced by Assemblyman Carl Heastie of the Bronx and Senator John Flanagan of Suffolk County, respectively. In the face of these significant leadership changes, it is impressive that a grand total of 718 pieces of legislation actually passed both houses in 2015, about 60 more bills than passed in 2014.

The following summarizes some (but not all) of the health-related legislation that may be of particular interest to the Health Law Section. Note that, as of this writing, many of these bills have not yet been acted on by the Governor.

Hospital-related

CARE Act **(A.1323-B/S.676-B Hannon):** This bill would require a hospital to allow a patient to identify a caregiver with whom the hospital could discuss the patient's plan of care prior to discharge from the facility and would further require the hospital to educate the designated caregiver on the aftercare measures required for the patient. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Hospital Sepsis Data **(A.7465 Gottfried / S.4874 Hannon):** This bill would implement measures to ensure that reported hospital sepsis data are accurate, valid and reliable. This bill was sent to the Governor on September 15th. This bill would take effect immediately.

Public Health Initiatives

Consent to Make an Anatomical Gift **(A.7431-A Ortiz / S.5101-A Hannon):** This bill would require individuals filling out driver's license applications or renewals either in-person at the New York State Department of Motor Vehicles or online at MyDMV.com to fill out the section regarding organ donation. If the section is not filled out, the application would not be processed until an affirmative choice is made. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Respiratory Disease and Obesity Management **(A.6506-A Crespo / S.1528-A Klein):** This bill would create an inter-disciplinary effort to combat obesity. This bill would require the cooperation of multiple state agencies to develop new strategies to prevent obesity from infancy to adulthood and to safely increase physical activity among adults and children, especially for those who struggle with respiratory disease. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Meningococcal Immunizations **(A.791-C / S.4324-A Hannon):** This bill would require students in public schools to be vaccinated against meningococcal disease when they enter the seventh and twelfth grades. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Mutual Aid Agreements for Coroners and Medical Examiners **(A.1629 Magnarelli / S.3738A Marchione):** This bill would authorize two or more counties to enter into agreements that allow them to provide mutual aid by sharing the services of their coroners and medical examiners as needed. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Tests for Tuberculosis **(A.7034 Glick / S.103 Hoylman):** This bill would allow registered nurses to administer tests to detect tuberculosis infections. This bill has not yet been sent to the Governor. This bill would take effect ninety days after it becomes law.

Breastfeeding Bill of Rights **(A.7202-A Gunther / S.5183 Hannon):** This bill would establish that nursing mothers have the right to take unpaid breaks from work to pump breast milk for up to three years following childbirth, and that employers must make a reasonable effort to provide them with a private location to do so. This bill also states that employers may not discriminate based on an employee's choice to pump breast milk at work. This bill has not yet been sent to the Governor. This bill would take effect on the first January following enactment of this bill.

Pharmacy-related

Safe Disposal of Controlled Substances **(A.6062 Gunther / S.3687 Hannon):** This bill would amend the existing drug disposal program to allow pharmacies and other Drug Enforcement Administration-authorized collectors to function as collection sites provided they are authorized by the DEA and in compliance with federal laws and regulations. Currently, the only available sites are at law enforcement agencies and not all counties have law enforcement agencies that participate in the program. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Substitution of Analgesic Opioid Drugs (A.7427-A Cusick / S.5170-A Hannon): This bill would prevent the substitution by insurance plans of abuse-deterrent drugs for less effective alternatives. This bill has not yet

been sent to the Governor. This bill would take effect one hundred and twenty days after becoming a law.

Electronic Prescribing (Chapter 13 of the Laws of 2015; A.4274 McDonald / S.2486 Hannon): The law delays the mandate to use electronic prescriptions until March 27, 2016. This bill was signed by the Governor on March 13, 2015, and took effect on that date.

Contracts with Pharmacy Benefit Managers (A.676-C Rosenthal / S.3346-B Hannon): This bill would require pharmacy benefit managers to offer the pharmacies they contract with the right to appeal a reimbursement rate within thirty days following a claim submission. This bill has not yet been sent to the Governor, This bill would take effect ninety days after it becomes law.

Collaborative Drug Therapy Management (A.5805-A McDonald / S.4857-A LaValle): This bill would extend and modestly expand the existing collaborative drug therapy management program, which allows pharmacists to collaborate in the management of drug therapy with physicians, by allowing the practice to occur in all general hospitals and in skilled nursing facilities that operate their own pharmacies. This bill was signed by the Governor on September 14th. This bill would take effect immediately.

Coverage of Prescriptions in Managed Care (A.7208 Gottfried / S.4893 Hannon): This bill would allow prescriber determinations to prevail for enrollees in managed care plans. While this bill purports to codify existing protections in Medicaid fee-for-service, this bill would remove the requirement for prescribers to provide medical justifications in order to override the substitution of a prescription drug. This bill was vetoed on August 14, 2015.

Expedited Access to Medical Marijuana (A.7060 Gottfried / S.5086 Griffo): This bill would allow the Department of Health to pursue an expedited process for approving applications from registered organizations interested in growing, manufacturing, and distributing medical marijuana; with the intent of providing access to medical marijuana for critically ill individuals who need immediate access, This bill has not yet been sent to the Governor. This bill would take effect sixty days after it becomes law.

Telehealth

Delivery of Telehealth Services (Chapter 6 of the Laws of 2015; A.2552-A Russell / S.2405 Young): This bill provides chapter amendments to Chapter 550 of the Laws of 2014, which were requested in the Governor's approval memo. The amendments would provide greater clarity to the definition of telehealth and teleservices while making it clear that insurers are not required to cover services that are outside the scope of the policies they currently offer. The bill was signed on March 13, 2015. This bill would take effect immediately.

Dentist Offices and Telehealth Services (A.7369 Russell / S.4182 Young): This bill would add dentist offices to the lists of eligible originating sites under the provisions of the telehealth statute. This bill was signed on August 13, 2015. This bill takes effect on March 13, 2015, the same date as Chapter 6 of the Laws of 2015.

Telehealth Providers (A.7488 Gottfried / S.5733 Young): This bill would include physical therapists and occupational therapists under the definition of eligible provider for the purposes of the telehealth statute. This bill has not yet been sent to the Governor. This bill would be deemed in effect as of January 1, 2015, the date Chapter 550 of the Laws of 2014 took effect.

Long-Term Services

Licensure of Social Adult Day Care (A.5352 Cymbrowitz / S.3923 Savino): This bill would require all organizations holding themselves out as social adult day care centers to abide by the rules and regulations promulgated by the State Office for the Aging. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Services Offered by Continuing Care Retirement Communities (Chapter 7 of the Laws of 2015; A.4490 Schimminger / S.5313 Hannon): This law creates an application and oversight process for continuing care retirement communities that wish to offer home care services, and requires that CCRCs that provide in-home services must also offer traditional CCRC services. This law was signed by the Governor on March 13, 2015 and took effect on April 15, 2015.

Information on Aging Agency Programs (A.7791A Mayer / S.5892 Valesky): This bill would require the State Office for the Aging to create materials containing information on local aging agencies and NY Connects Programs. The State Office for the Aging would be required to make these materials available on its website and distribute copies to hospital discharge coordinators, who would then have to distribute those materials to individuals sixty years and older who are discharged from the hospital. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Dementia and Alzheimer's Disease Program Database (A.5318 Cymbrowitz / S.3968 Serino): This bill would authorize the State Office for the Aging to create a database of programs that have been shown to successfully support and treat individuals with Alzheimer's disease or other dementias. This bill has not yet been sent to the Governor. This bill would take effect one year after it becomes a law.

Consumer Directed Personal Assistance Programs (A.7532-A Morelle / S.5712-A Felder): This bill would permit a compensated personal assistant to include members of the family of the eligible individual with the exception of a person legally responsible for an eligible individual's care and support, an eligible individual's spouse or a designated representa-

tive. This bill has not yet been sent to the Governor. This bill would take effect on April 1, 2016.

Fiscal Intermediaries for CDPAP (A.7535-B Gottfried / S.5565 Hannon): This bill would define fiscal intermediary services in relation to the consumer directed personal assistance program (CDPAP) and require that fiscal intermediaries be licensed by the Commissioner of Health. This bill has not yet been sent to the Governor. This bill would take effect on July 1, 2016.

Decisions Regarding Hospice (A.2150 Gottfried / S.1153 Hannon): This bill would give a physician serving as a surrogate the right to elect hospice care for a hospice-eligible patient who is incapable of making decisions for themselves. This bill was signed on August 13, 2015. This bill would take effect immediately.

Hospice and Homecare Exemptions During Public Emergencies (A.5125-B Cusick / S.3482- B Lanza): This bill would require that municipalities that are developing comprehensive emergency management plans to develop procedures for allowing homecare workers or hospice staff into restricted areas during declared disasters. This would allow homecare and hospice staff to continue serving their homebound patients, who would otherwise need to be transferred to a hospital or other healthcare facility. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Insurance

Enrollment in Child Health Insurance Plan (A.7155-B Gottfried / S.4745-B Funke): This bill would allow families who sign up for Child Health Plus prior to or within sixty days of their child's birth to have coverage that takes effect the day of birth. This bill has not yet been sent to the Governor. This bill would take effect January 1, 2016.

Pregnancy and Health Insurance Coverage (A.6780-B Simotas / S.5972 Seward): This bill would allow pregnant women to enroll in a health plan on the State's Affordable Care Act-authorized health insurance exchange (the New York State of Health) at any time, rather than just during the otherwise applicable open enrollment period. This bill has not yet been sent to the Governor. This bill would take effect January 1, 2016.

Expedited Utilization Review of Court-ordered Services (A.1327-A Cahill / S.4922-A Hannon): This bill would require utilization review within seventy-two hours involving proposed mental health and/or substance use disorder treatment when the enrollee might be subject to court-ordered treatment. This bill is intended to avoid the prospect of court-ordered treatment conflicting with the utilization review determination by the health plan. This bill has not yet been sent to the Governor. This bill would take effect April 1, 2016 and shall apply to policies issued, renewed, or modified on and after such date.

Health Savings Account Pilot Program (A.7943 Cahill / S.5758 Seward): This bill would extend for two years the existing statute that allows HMOs to offer a group high deductible health plan in conjunction with a health reimbursement or savings account. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Developmental Disability-related

Transitional Care (A.866A Jaffee / S.1696 Bonacic): This bill would amend Chapter 478 of the Laws of 2014, which addressed the due process rights of persons with developmental disabilities who were aging out of residential facilities that provide services for children. This bill makes a series of changes to the prior law to ensure the efficient and expeditious transition of individuals to appropriate facilities, primarily modifying notice requirements, while preserving most of the due process protections contained in current law. This bill was signed by the Governor and will be deemed to have been in effect on November 21, 2014, the same date Chapter 478 became effective.

Oversight of DISCOS (A.7200 Gunther / S.3638-A Ortt): This bill would require that proposed managed care entities for the developmentally disabled that lack the experience in providing services to such persons must contract with a not-for-profit entity that has experience in providing residential, day and employment services for that population. A similar bill was vetoed last year by Governor Cuomo, which would have further limited the affiliated organization to New York State entities, which has not been included in this year's version of the legislation. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Continuity of Care and Developmental Disabilities (A.7332 Lupardo / S.4094 Libous): This bill would allow individuals with developmental disabilities who are currently receiving state-operated institutional services the choice of transitioning into community settings that are also state-operated and would allow them to remain in their state-operated institutional placement until a state-operated community placement was available. This bill has not yet been sent to the Governor. This bill would take effect immediately.

NY ABLE Savings Account Act (A.7767-B Gunther / S.4472-D Carlucci): This bill would allow individuals with disabilities to establish savings accounts for qualified health care and living expenses. This bill has not yet been sent to the Governor. This bill would take effect on April 1, 2016.

Federal Individuals with Disabilities Education Improvement Act of 2004 (Chapter 35 of the Laws of 2015; A.7677 Ryan / S.5150 Flanagan): This law extends the provisions of the Individuals with Disabilities Education Improvement Act, which was set to expire, until 2018. The

Governor signed this bill on June 30, 2015 and it took effect on that date.

***Reimbursement to Article 16 Facilities* (A.7327-A Gunther / S.4974-A Ortt):** This bill would restore the 2% across-the-board rate cut to Article 16 clinics. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Gifts for Autism Research and Awareness (A.3533 Titone / S.4517 Lanza): This bill would allow for contributions to be made to autism awareness and research on the personal income tax return. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Mental Health

Training of Staff in Residential Mental Health Treatment Units (A.836 Gunther / S.633 Carlucci): This bill would extend existing training requirements for correctional facility staff to require that a minimum of eight hours of mental health training annually be provided for all correctional officers, program services, mental health and medical staff with direct inmate contact, including training in suicide prevention. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Mental Illness Anti-Stigma Fund (A.833-A Gunther / S.632-A Carlucci): This bill would allow for contributions to a mental illness anti-stigma fund via the personal income tax return. The funds collected could be used by the State Office of Mental Health to support programs aimed at eliminating the stigma attached to mental illness. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Assault of Direct Care Workers (A.1034-A Gunther / S.3621-A Funke): This bill would classify an assault on a direct patient care worker in a health care setting as an assault in the second degree. This bill has not yet been sent to the Governor. This bill would take effect on the first November following the date of enactment.

Clinical Records and Confidentiality (A.2143 O'Donnell / S.5680 Ortt): This bill would provide the Justice Center for the Protection of People with Special Needs with the authority necessary to receive clinical medical records from the Office for People with Developmental Disabilities and Office for of Mental Health. This bill was sent to the Governor on September 15th. This bill would take effect immediately.

Professions

Professional Misconduct by **Healthcare Professionals (Chapter 11 of the Laws of 2015; A.2554 Barrett / S.1693 Hannon):** This law amends provisions enacted in 2014 to preclude charging physicians with professional misconduct for making recommendations or providing a treatment modality that is not universally accepted by the medical profession, including but not limited to, varying modalities used in the treatment of Lyme disease or other tick-borne diseases. This law was signed by the Governor on March 13, 2015 and took effect on that date and applies to any professional discipline matter or administrative or judicial review thereof pending on or after that date.

Occupational Therapy Licensure (A.1798-A Gunther / S.1567-A LaValle): This bill would establish a definition for occupational therapy and would establish a process and a series of requirements for the licensure of occupational therapy assistants and would permit occupational therapy assistants representation on the Board of Occupational Therapy. This bill has not yet been sent to the Governor. This bill would take effect one hundred and eighty days after becoming a law.

Licensure of Orientation and Mobility Specialists and Vision Rehabilitation Therapists (A.5451-C Lupardo / S.4467-C Griffo): This bill would establish the profession of vision impairment specialist and provide for the licensing of low vision therapists, orientation and mobility specialists and vision rehabilitation therapists. This bill has not yet been sent to the Governor. This bill would take effect 18 months after becoming a law.

Conforming Nurse Practitioner Amendments (A.4140 Gottfried / S.2300 Hannon): This bill would amend the public health, education, general business, and vehicle and traffic law to be consistent with Part D of Chapter 56 of the Laws of 2014, which eliminated the need for nurse practitioners with over 3,600 hours of experience to have a written collaboration or practice agreement with a physician. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Immunizations by Pharmacists (A.123-B Paulin / S.4739 Hannon): This bill would authorize pharmacists to administer vaccinations for acute herpes zoster, tetanus, diphtheria, and pertussis pursuant to a non-patient specific order, and extend the authorizations for administering influenza and pneumococcal meningitis vaccines for three years. This bill would also allow pharmacists to administer vaccines to the patients of healthcare practitioners who offer services in an adjoining county. This bill has not yet been sent to the Governor. This bill would take effect immediately.

Out of State Laboratory Practitioners (A.1202 Jaffee / S.14 LaValle): This bill would require out-of-state laboratory practitioners to meet the educational requirements set forth for clinical laboratory practitioners in New York State if the lab employing them accepts specimens from New York State. This bill was signed on June 30th. This bill would take effect one hundred and eighty days after it becomes law.

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In the New York State Agencies

By Francis J. Serbaroli

Emergency Medical Services

Notice of Adoption. The Department of Health amended Part 800 of Title 10 NYCRR to clarify terminology, eliminate vagueness, address legal statutes/crimes and incorporate modern professional, ethical and moral standards. Filing date: April 21, 2015. Effective date: May 6, 2015. *See* N.Y. Register May 6, 2015.

Opioid Overdose Programs

Notice of Adoption. The Department of Health amended Section 80.138 of Title 10 NYCRR to modify the rule consistent with new statutory language and with the emergency nature of opioid overdose response. Filing date: April 21, 2015. Effective date: May 6, 2015. *See* N.Y. Register May 6, 2015.

Computed Tomography (CT) Quality Assurance

Notice of Proposed Rulemaking. The Department of Health proposed amending section 16.25 and adding section 16.59 to Title 10 NYCRR to protect the public from the adverse effects of ionizing radiation. *See* N.Y. Register May 6, 2015.

Patients Committee to the Custody of the Commissioner Pursuant to CPL Article 730

Notice of Adoption. The Office of Mental Health amended Part 540 of Title 14 NYCRR to conform regulatory provisions to statute with respect to the performance of competency reports. Filing date: May 4, 2015. Effective date: May 20, 2015. *See* N.Y. Register May 20, 2015.

Consolidated Fiscal Report Penalty Amendments

Notice of Adoption. The Office of People with Developmental Disabilities amended section 635-4.4 of Title 14 NYCRR to change the requirements for imposing a penalty on providers that fail to meet filing deadlines for cost reports. Filing date: May 12, 2015. Effective date: June 1, 2015. *See* N.Y. Register May 27, 2015.

Independent Dispute Resolution for Emergency Services and Surprise Bills

Notice of Adoption. The Department of Financial Services added Part 400 to Title 23 NYCRR to establish a dispute resolution process and standards for that process. Filing date: May 19, 2015. Effective date: June 3, 2015. *See* N.Y. Register June 3, 2015.

Chronic Renal Dialysis Services (CRDS)

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 757 of Title 10 NYCRR to update the CRDS provisions concerning Medicare and Medicaid Programs for coverage for End State Renal Disease Facilities. *See* N.Y. Register June 3, 2015.

Medical Assistance Rates of Payment for Residential Treatment Facilities for Children and Youth

Notice of Adoption. The Office of Mental Health amended Part 578 of Title 14 NYCRR to amend date of trend factor elimination to December 31, 2014 instead of June 30, 2015. Filing date: May 15, 2015. Effective date: June 3, 2015. *See* N.Y. Register June 3, 2015.

Patient Access of Laboratory Test Results

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 34 and 58 of Title 10 NYCRR to give patients a right to access medical records directly from clinical laboratories, including completed laboratory test reports. *See* N.Y. Register June 17, 2015.

Personal Care Services Program (PCSP) and Consumer Directed Personal Assistance Program (CDPAP)

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPAP services. Filing date: June 4, 2015. Effective date: June 4, 2015. *See* N.Y. Register June 24, 2015.

PROS; Medical Assistance Payment Outpatient Programs; Medical Assistance Payment for Comprehensive Psychiatric Emergency Programs (CPEP)

Notice of Emergency/Proposed Rulemaking. The Office of Mental Health proposed amending Parts 512, 588 and 591 of Title 14 NYCRR to increase Medicaid fees paid to certain OMH-licensed programs consistent with enacted State Budgets and chapter 60 of Laws of 2014. Filing date: June 8, 2015. Effective date: June 8, 2015. *See* N.Y. Register June 24, 2015.

Incident Reporting in OASAS Certified, Licensed, Funded or Operated Programs

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 836 and added a new Part 836 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 12, 2015. Effective date: June 12, 2015. *See* N.Y. Register July 1, 2015.

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

Notice of Emergency/Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 810 and adding a new Part 810 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 12, 2015. Effective date: June 12, 2015. *See* N.Y. Register July 1, 2015.

Criminal History Information Reviews

Notice of Emergency/Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed adding Part 805 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 12, 2015. Effective date: June 12, 2015. *See* N.Y. Register July 1, 2015.

Patient Rights

Notice of Emergency/Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 815 and adding a new Part 815 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 12, 2015. Effective date: June 12, 2015. *See* N.Y. Register July 1, 2015.

Credentialing of Addictions Professionals

Notice of Emergency/Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 853 and adding a new Part 853 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 12, 2015. Effective date: June 12, 2015. *See* N.Y. Register July 1, 2015.

Children's Camps

Notice of Emergency Rulemaking. The Department of Health amended Subpart 7-2 of Title 10 NYCRR to include camps for children with developmental disabilities as a type of facility with in the oversight of the Justice Center. Filing date: June 11, 2015. Effective date: June 11, 2015. *See* N.Y. Register July 1, 2015.

Standards for Adult Homes and Adult Care Facilities Standards for Enriched Housing

Notice of Emergency Rulemaking. The Department of Health amended Parts 487 and 488 of Title 18 NYCRR in regards to the establishment of the Justice Center for Protection of People with Special Needs. Filing date: June 15, 2015. Effective date: June 15, 2015. *See* N.Y. Register July 1, 2015.

Implementation of the Protection of People with Special Needs Act and Reforms to Incident Management

Notice of Emergency Rulemaking. The Office for People with Developmental Disabilities amended Parts 624, 633 and 687 and added Part 625 to Title 14 NYCRR to enhance protections for people with developmental disabilities served in the OPWDD system. Filing date: June 11, 2015. Effective date: June 11, 2015. *See* N.Y. Register July 1, 2015.

Site-Based and Community Prevocational Services

Notice of Adoption. The Office for People with Developmental Disabilities amended Subparts 635-10 and 635-99 of Title 14 NYCRR to distinguish requirements for site-based prevocational services and community prevocational services. Filing date: June 16, 2015. Effective date: July 1, 2015. *See* N.Y. Register July 1, 2015.

Supported Employment Services (SEMP) Redesign

Notice of Adoption. The Office for People with Developmental Disabilities amended Subparts 635-10, 635-12 and 635-99 of Title 14 NYCRR to redesign SEMP by establishing requirements for the provision of funding of Intensive and Extended SEMP. Filing date: June 16, 2015. Effective date: July 1, 2015. *See* N.Y. Register July 1, 2015.

Implementation of the Protection of People with Special Needs Act and Reforms Incident to Management

Notice of Emergency Rulemaking. The Office of Mental Health amended Parts 501 and 550, repealed Part 524, and added a new Part 524 to Title 14 NYCRR to enhance protections for people with mental illness served in the OMH system. Filing date: June 24, 2015. Effective date: June 24, 2015. *See* N.Y. Register July 15, 2015.

Blood Banks

Notice of Adoption. The Department of Health amended Subpart 58-2 of Title 10 NYCRR to update practice standards, reflect changes and provide clarification of regulation provisions for blood banks and transfusion services. Filing date: July 14, 2015. Effective date: September 27, 2015. *See* N.Y. Register July 29, 2015.

Practice of Radiologic Technology

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 89 of Title 10 NYCRR to update regulations related to the practice of radiologic technology. *See* N.Y. Register July 29, 2015.

Medicaid Provider Enrollment

Notice of Proposed Rulemaking. The Department of Health proposed a consensus rulemaking amending section 504.5 of Title 18 NYCRR to make technical, conforming changes to regulations governing the enrollment of Medicaid providers of care, services and supplies. *See* N.Y. Register July 29, 2015.

Reciprocal Emergency Medical Technician Certification Requirements

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 800 of Title 10 NYCRR to replace the emergency medical technician-intermediate category with

the advanced emergency medical technician category. *See* N.Y. Register July 29, 2015.

Controlled Substances for EMS Agency Agent and Requirements for an Advanced Life Support System

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 80.136 and 800.5 of Title 10 NYCRR to amend the regulations regarding the EMS Agency and the Requirements for an Advanced Life Support System. *See* N.Y. Register July 29, 2015.

Requirements for Manufacturers and Distributors Regarding Controlled Substances

Notice of Proposed Rulemaking. The Department of Health proposed amending section 80.11 of Title 10 NYCRR to clarify and use language consistent with current terminology used by the State Board of Pharmacy. *See* N.Y. Register July 29, 2015.

Immediate Needs for Personal Care

Notice of Revised Rulemaking. The Department of Health proposed amending section 505.14 of Title 18 NYCRR to provide for meeting the immediate needs of Medicaid applicants and recipients for personal care services. *See* N.Y. Register August 5, 2015.

Outpatient Services Licensed Under the Mental Hygiene Law

Notice of Adoption. The Department of Health added Subpart 86-12 to Title 10 NYCRR to create a methodology for adjusting provider reimbursement in OPWDD, OHM, and OASAS-certified clinics based on annual patient visits. Filing date: July 22, 2015. Effective date: August 12, 2015. *See* N.Y. Register August 12, 2015.

Costs of Real Property

Notice of Adoption. The Office for People with Developmental Disabilities amended Subpart 635-6 of Title 14 NYCRR to allow OPWDD to pay lease costs or property costs not otherwise allowed in existing regulations. Filing date: July 28, 2015. Effective date: August 12, 2015. *See* N.Y. Register August 12, 2015.

Day and Residential Habilitation Changes

Notice of Emergency Rulemaking. The Office of People with Developmental Disabilities amended Subparts 635-9 and 635-10 and Part 671 of Title 14 NYCRR to discontinue Individual Day Habilitation and add allowable services under Residential Habilitation. Filing date: August 4, 2015. Effective date: October 1, 2015. *See* N.Y. Register August 19, 2015.

Person-Centered Planning

Notice of Proposed Rulemaking. The Office of People with Developmental Disabilities proposed amending Parts 633, 635, 671 and 686 of, and adding Part 636 to, Title 14 NYCRR to implement Federal requirements for a person-centered planning process and a person-centered plan. *See* N.Y. Register August 19, 2015.

Prohibit Additional Synthetic Cannabinoids

Notice of Emergency/Proposed Rulemaking. The Department of Health proposed amending section 9.1 of Title 10 NYCRR to add additional chemicals to the list of explicitly prohibited synthetic cannabinoids. Filing date: August 6, 2015. Effective date: August 6, 2015. *See* N.Y. Register August 26, 2015.

School Immunization Requirements

Notice of Adoption. The Department of Health amended Subpart 66-1 of Title 10 NYCRR to update regulations to ensure children entering grades kindergarten through 12 receive adequate number of required immunizations. Filing date: August 11, 2015. Effective date: September 1, 2015. *See* N.Y. Register August 26, 2015.

Personalized Recovery Oriented Services (PROS)

Notice of Adoption. The Office of Mental Health amended Part 512 of Title 14 NYCRR to add language back into regulation that had been erroneously eliminated in a previous rulemaking. Filing date: August 11, 2015. Effective date: August 26, 2015. *See* N.Y. Register August 26, 2015.

Public Access to Records of the Office of Mental Health

Notice of Adoption. The Office of Mental Health amended section 510.5 of Title 14 NYCRR to make a technical correction regarding the agency's records access officer. Filing date: August 11, 2015. Effective date: August 26, 2015. *See* N.Y. Register August 26, 2015.

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 a former Chair of the Health Law Section. The assistance of Caroline B. Brancatella and Edward Ohanian, both associates of Greenberg Traurig's Health and FDA Business Group, in compiling this summary is gratefully acknowledged.

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions
Compiled by Eugene M. Laks

Amida Care Inc., (DOH administrative hearing decision dated March 26, 2015, Denise Lepicier, Administrative Law Judge). The ALJ sustained recovery of capitation payments made to Amida Care Inc. under the Medicaid managed care program for 13 enrollees for months in which the individuals were incarcerated for the full month. The payment of pharmacy claims for three enrollees prior to disenrollment by the local social services district, at a time that Amida did not know they were incarcerated, does not relieve Amida of the responsibility to repay the capitation to the state.

New York State Attorney General Press Releases
Compiled by Joseph Murphy, Colm Ryan and Karen S. Southwick

Nurse Arrested for Allegedly Stealing $3,000 from Medicaid—Aug. 26, 2015—A registered nurse from Chazy was arrested on charges that she submitted more than $3,000 in false claims for in-home care to a Medicaid recipient on life support that the nurse did not actually provide. The nurse was charged with twelve counts of offering a false instrument in the first degree, a class E felony, and one count of grand larceny in the third degree, a class D felony. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-who-allegedly-stole-3k-medicaid.

Nurse Arrested for Allegedly Defrauding Medicaid of Over $1,000 in One Month—Aug. 26, 2015—A licensed practical nurse from Rochester was arrested on charges that she billed Medicaid over $1,000 for hours that she did not work while employed at a private facility to care for a special needs child. She was charged with grand larceny in the fourth degree, a class E felony, and eight counts of offering a false instrument for filing in the first degree, class E felonies. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-and-arraignment-rochester-nurse-allegedly-defrauding.

Former Director of Nursing at Health Center Pled Guilty to Covering Up Sexual Abuse and Neglect—Aug. 26, 2015—A registered nurse and former director of nursing at a senior health care center in Ilion, NY pled guilty to two felony counts of tampering with evidence. She admitted that she destroyed a witness statement that described a sexual assault between two residents of the facility and concealed patient records to cover up patient neglect. Sentencing is pending in Herkimer County Court. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-former-director-nursing-health-care-center.

Brooklyn Home Care Agency Settles Allegations of Improper Reporting of Hours and Administrative Costs on Cost Reports—Aug. 24, 2015—A Brooklyn home care agency agreed to pay $6 million to settle charges that it improperly reported its home health aide hours and administrative expenses on cost reports filed between 2002 and 2005, resulting in reimbursement rates that netted the agency over $3 million in reimbursements to which it was not entitled. The Brooklyn home care agency reported salaries and benefits of administrative personnel under direct care cost centers rather than administrative and general cost centers, yielding inflated Medicaid reimbursement rates. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-6-million-medicaid-settlement-brooklyn-home-care-agency.

Hospitals and Out-of-State Vendor Pay $8 Million to Settle Charges of Kickbacks for Referrals to Unlicensed Drug and Alcohol Treatment Programs—Aug. 24, 2015—Hospitals in Yonkers, Kingston and Hudson settled with the Attorney General and United States Attorney for the Eastern District over charges that they paid an out-of-state vendor monthly fees for referrals of patients to the unlicensed drug and alcohol treatment programs run by the hospitals. The vendor and its former CEO are barred from working with New York Medicaid or Medicare providers for five years. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-8-million-settlements-specialcare-hospital-management-corp.

Purdue Pharma Agrees to Marketing Limitations for OxyContin—Aug. 20, 2015—Purdue Pharma, L.P. entered into an agreement with the Attorney General to reform its marketing of the long-acting opioid OxyContin. Under the agreement, Purdue will strengthen and make permanent its internal Abuse and Diversion Detection program aimed at preventing its sales staff from promoting the painkiller to health care providers who may be involved in abuse and illegal diversion of opioids. The agreement also requires Purdue to disclose financial relationships with any individuals, including doctors and other health care professionals, who appear on the company's "unbranded" websites that endorse

the benefits of pain treatment, including the website www.inthefaceofpain.com. The company will pay $75,000 in penalties and costs. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent.

Registered Nurse Arrested for Diverting Narcotics from Residents at Irondequoit Nursing Home—Aug. 19, 2015—A registered nurse was charged with falsifying records and petit larceny for allegedly stealing Hydromorphone pills from elderly residents at a nursing home in Irondequoit and then altering records to cover up the theft. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-hamlin-nurse-diverting-narcotics-nursing-home.

Pharmaceutical Company Amgen Inc. to Pay $71 Million to Settle Multi-State Suit for Promoting Off-Label Use of Aranesp and Enbrel—Aug. 18, 2015—Amgen, Inc. agreed to a $71 million payment to New York and 46 other states and the District of Columbia to resolve allegations that it violated consumer protection laws by promoting anemia drug Aranesp and psoriasis drug Enbrel for uses beyond those approved by the FDA. Amgen will be required to reform its marketing and promotional practices and will be prohibited from overstating the drugs' efficacies or promoting them for off-label use. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-multistate-settlement-pharmaceutical-company-amgen-inc.

Brooklyn Nursing Home Aide Arrested for Allegedly Striking and Abusing Resident—Aug. 13, 2015—A certified nurse aide was arrested on charges she struck and mistreated an eighty-two-year-old resident suffering from dementia. The incident, captured on video, allegedly occurred during a bath and involved the aide striking the resident, throwing water in the resident's face and using the resident's fist to strike himself. The aide was charged with endangering the welfare of an incompetent or physically disabled person in the first degree, a class E felony, and willful violation of health laws, a misdemeanor. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-brooklyn-nursing-home-aide-allegedly-striking-and.

Capital Region Nurse Charged with Illegally Obtaining More Than 2,000 Narcotics Using Forged Prescriptions—Aug. 11, 2015—A licensed practical nurse was arrested on charges she illegally obtained narcotics by providing prescriptions with the forged signature of her employer to pharmacies. Over a thirteen-month period, the LPN presented eighteen prescriptions for hydrocodone and oxycodone, obtaining over 2,000 pills. She was charged with eighteen counts of criminal possession of a forged instrument in the second degree, class D felonies, and faces up to seven years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-capital-region-nurse-charged-illegally-obtaining-more.

Executive Director of Westchester Not-For-Profit Company Sentenced to Jail for Stealing Medicaid Funds—July 29, 2015—The Executive Director of a not-for-profit pled guilty to grand larceny in the fourth degree, a felony, for defrauding the Medicaid system of monies earmarked to allow the elderly and infirm to live in the community instead of an institutional setting. She was sentenced to ninety days in jail and five years' probation. The Poughkeepsie-based corporation was sentenced to pay a fine of $5,000, and both the Executive Director and corporation were ordered to pay $21,690 in restitution. The Executive Director admitted she falsified bids to agents of the New York State Department of Health Nursing Home Transition and Diversion program, which pays for renovations to the homes of the elderly and disabled. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-executive-director-westchester-not-profit-company.

Nurse Arrested for Allegedly Falsifying Patient Records to Cover Up His Neglect—July 27, 2015—A licensed practical nurse was arrested on charges that he falsified documentation concerning the medical records of several residents to cover up his failure to properly provide narcotics to residents of a Glens Falls nursing home where he worked. The LPN allegedly electronically signed medical records indicating he administered narcotics that he did not and signed records documenting he removed doses for residents when none had been provided. He was charged with falsifying business records, a class E felony, and five counts of willful violation of health laws, a misdemeanor. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-allegedly-falsifying-patient-records-cover-his.

Former Nursing Home Employee Charged with Stealing from Resident Trust Account—July 27, 2015—A finance associate allegedly stole $21,488 over a twenty-month period from a trust account established for residents' funds at a Syracuse nursing home. The associate made false entries in her employer's cash accounting sheet to hide the theft of $1,000 per month to pay for her personal expenses. She faces up to seven years in prison on charges of grand larceny in the third degree and falsifying business records in the first degree. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-former-nursing-home-employee-charged-stealing.

NYC Medical Supply Company Operator Sentenced to Up to 21 Years in Prison in Medicaid Fraud Scheme—July 20, 2015—The owner of a Brooklyn medical supply company was convicted at a jury trial of defrauding Medicaid of over $1 million by billing for over 3,000 units of an expensive liquid pediatric

nutritional formula when he actually dispensed a cheaper, over-the-counter nutritional formula. Humphrey Odeh was sentenced to serve 7 to 21 years in prison and pay a $1.7 million fine. An asset forfeiture and civil lawsuit brought by the Civil Enforcement Division of the Medicaid Fraud Control Unit is pending against Odeh and other defendants. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-prison-term-21-years-nyc-medical-supply-company-operator.

Nurse Pleads Guilty to Billing Medicaid $30k for Services She Did Not Provide—July 15, 2015—A licensed practical nurse pled guilty to stealing almost $30,000 from Medicaid by billing for hundreds of hours of care that she did not provide. The nurse claimed excessive hours for private nursing services to disabled and special needs children. Sentencing is pending in Monroe County Court. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-nurse-who-bilked-medicaid-out-30k.

NYC Pharmacy Agrees to $22.4 Million Settlement for Improper Medicaid Billings for Injectable Pediatric Drug Synagis—July 10, 2015—A Queens pharmacy will pay more than $22 million to settle charges that it submitted improper claims to Medicaid for the respiratory drug Synagis. As a result of a whistleblower report, the Attorney General investigated and alleged that the pharmacy improperly obtained baby names and patient information from a hospital's intensive care unit logbook and contacted the families to obtain prescriptions for their babies, regardless of clinical need. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-224-million-settlement-nyc-pharmacy-improper-medicaid.

Long Island Nursing Home Healthcare Workers Convicted by Jury in Resident Death—July 10, 2015—Five employees of a nursing home facility were convicted in the death of a 72-year-old nursing home resident who died when the employees failed to connect her to a ventilator overnight. A licensed respiratory therapist was convicted of criminally negligent homicide for ignoring alarms and messages to her pager for several hours. Two registered nurses were also convicted because of their failure to respond to visual and audio alarms for two hours. A licensed practical nurse was convicted after she claimed to investigators that the resident looked up at her several hours after the resident had died. The director of respiratory therapy concealed computer records documenting the alarms during the Department of Health's investigation. These five individuals face up to four years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-homicide-conviction-jury-long-island-nursing-home-healthcare.

Westchester Transportation Vendor Agrees to Pay Over $400,000 for Failing to Provide Proper Documentation for Medicaid Billings—July 6, 2015—A transportation vendor billed Medicaid $316,991 for services that were not supported by documentation. The transportation vendor agreed to repay the unsupported billings plus interest totaling over $400,000. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-400k-settlement-westchester-transportation-company-failing.

New York State Reaches $2.5 Million Settlement with NYC Pharmacy for Improper Medicaid Billings—June 29, 2015—New York State reached a settlement with Trinity Homecare LLC, a pharmacy owned by Walgreen Co., that resolves claims of undocumented delivery of infusion drugs by the pharmacy. The agreement began with a whistleblower claim of improper conduct and false Medicaid billings related to drugs mainly prescribed for hemophilia patients. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-25-million-settlement-nyc-pharmacy-improper-medicaid.

Three Nursing Home Caregivers Arrested for Alleged Neglect and Abuse of a Disabled Resident—June 24, 2015—Two nurses and one nurses' aide were arrested for allegedly dragging a disabled and bleeding patient across a hallway floor at a rehabilitation center, and for neglecting to treat the patient for over twenty minutes while he was bleeding from his head. The individuals are charged with endangering the welfare of an incompetent or physically disabled person in the first degree, a class E felony, and willful violation of health laws, a misdemeanor. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-three-nursing-home-caregivers-alleged-neglect-and.

Nursing Home Aide Arrested for Allegedly Neglecting Elderly Resident in Westchester County—June 22, 2015—A certified nurse aide was arrested for allegedly dropping an 85-year-old patient from a mechanical lift, causing injuries to the patient. The aide was trained in the use of mechanical lifts, including the necessity of two persons in performing any transfer, to ensure the safety of the resident. The aide is charged with endangering the welfare of an incompetent or physically disabled person in the first degree and endangering the welfare of a vulnerable elderly person, or an incompetent or physically disabled person in the second degree, both class E felonies, and two counts of willful violation of health laws, class A misdemeanors, and faces up to four years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nursing-home-aide-allegedly-neglecting-elderly.

A.G. Schneiderman Announces Settlement With Management Company That Bars Company from Making Decisions About Patient Care in New York Clinics—June

18, 2015—The Attorney General of New York reached a settlement with a company that provides business support and administrative services to independently owned dental practices. The settlement pertains to care provided by dentists and hygienists at dental practices among other matters. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-aspen-dental-management-bars-company-making.

Six Million Dollar Settlement Reached with Illinois-Based Inspire Pharmaceuticals for Illegal Off Label Marketing—June 18, 2015—New York State, along with 46 other states and the District of Columbia, reached a $6 million settlement with Inspire Pharmaceuticals ("Inspire"), an Illinois based company, to resolve allegations that Inspire violated state and federal False Claims Act laws by illegally marketing the drug Azasite, a topical antibiotic, for off-label use not approved by the U.S. Food and Drug Administration. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-6-million-settlement-illinois-based-inspire-pharmaceuticals.

Capital Region Personal Care Aides Arrested for Allegedly Defrauding Medicaid for Services Never Provided—June 16, 2015—Two personal care aides were arraigned in Albany City Court on multiple counts of falsifying business records in the first degree, and grand larceny in the fourth degree, both class E felonies, for allegedly causing more than 50 false entries in the business records of a Medicaid managed care contractor and stealing property in excess of one thousand dollars. The aides allegedly falsely documented that they provided care to a Medicaid recipient. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-capital-region-personal-care-aides-allegedly.

Nurse Arrested for Allegedly Using Forged Prescriptions to Illegally Obtain Narcotic Medication—June 15, 2015—A registered nurse from Germantown, Maryland, was charged with four counts of criminal possession of a controlled substance in the fourth degree, a class C felony, and four counts of criminal possession of a forged instrument in the second degree, a class D felony, for allegedly presenting four forged prescriptions to a pharmacy in Amherst in order to illegally obtain the narcotic medication Percocet. The prescriptions were written in the name of one of the nurse's daughters, both of whom reside in Maryland. Two of the prescriptions were signed with the name of a certified midwife and two were signed with the name of a physician, neither of whom authorized, issued, or signed the prescriptions nor had a physician-patient relationship with the daughters. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-who-allegedly-used-forged-prescriptions.

Four Nurses Charged with Failing to Properly Monitor Disabled Patient—June 10, 2015—Four nurses who worked at a rehabilitation and health care center in Woodmere were arrested for allegedly failing to monitor a disabled patient as ordered by the patient's physician. As a result, the patient fell and was injured. The individuals allegedly falsely documented or instructed others to falsely document that a disabled nursing home resident had been monitored every thirty minutes for his safety, as ordered by his physician after a series of falls. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-four-nurses-charged-failing-properly-monitor-disabled.

Licensed Practical Nurse Arrested for Allegedly Falsifying Medication Records to Conceal Neglect of Four Nursing Home Residents—June 10, 2015—A Buffalo licensed practical nurse was arrested for allegedly failing to administer medication to four residents of a skilled nursing facility and then falsifying the Medication Administration Record for each resident to reflect she had administered the medication. The nurse was charged with four counts of falsifying business records in the first degree, a class E felony, and four counts of willful violation of health laws, an unclassified misdemeanor. The E felony charge carries a maximum prison term of four years. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-lpn-allegedly-falsifying-medication-records-conceal.

Six NYC and Westchester Home Health Aides Charged with Defrauding Medicaid—June 10, 2015—Six home health care workers who worked in New York City and Westchester were arrested and charged with a variety of alleged Medicaid fraud schemes, including identity theft, grand larceny, faking home-health care credentials and submitting false billings for services which were never rendered. The defendants were charged with various felonies, including criminal possession of a forged instrument in the second degree for allegedly purchasing fake home-health aide credentials, identity theft in the first degree for allegedly stealing the identity of a certified home-health aide, grand larceny in the third degree for allegedly submitting documentation that falsely indicated that they had provided home health care services that were never rendered, and falsifying business records in the first degree for allegedly claiming on company records home-health aide services provided to a 14-year-old, severely developmentally disabled Medicaid recipient that were not actually provided. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-six-nyc-and-westchester-home-health-aides-charged.

Rochester Woman Arrested for Alleged Fraudulent Billing to Medicaid—June 9, 2015—A Rochester woman was charged with grand larceny, a felony, in Rochester City Court, for causing more than $13,000 in illegal billings to the New

York State Medicaid program. The woman allegedly falsely claimed to have a college degree to obtain a job at a service provider that then billed Medicaid for client services performed by the woman. State Medicaid regulations require that type of provider to have at least an associate's degree or be a Registered Nurse. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-rochester-woman-allegedly-involved-fraudulent-billing.

Nursing Home Aide Arrested for Causing Injury to Resident—June 3, 2015—A Certified Nurse Assistant was arrested for allegedly failing to provide appropriate care to a 74-year-old woman, resulting in a fall that caused significant injuries to the resident, which the aide failed to report. The defendant was arraigned on charges of endangering the welfare of an incompetent or physically disabled person in the first degree, a class E felony, and willful violation of health laws, a misdemeanor, for allegedly endangering the welfare of a nursing home resident. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nursing-home-aide-causing-injury-74-year-old-resident.

NYS Attorney General and Others Urged FDA to Reform Dietary Supplement Current Good Manufacturing Practices Regulations—June 2, 2015—Attorney General Eric T. Schneiderman and Indiana Attorney General Greg Zoeller sent a letter to the Food and Drug Administration, urging the agency to immediately enhance its oversight of the dietary supplement industry by reforming its Dietary Supplement Current Good Manufacturing Practices (CGMP) regulations. The letter outlines major flaws in the CGMPs pertaining to ingredient suppliers, testing of label claims, testing for allergens, and labeling ambiguity. http://www.ag.ny.gov/press-release/ag-schneiderman-and-ag-zoeller-urge-food-and-drug-administration-overhaul-regulation.

Rochester Man Sentenced for Posing as Doctor to Illegally Obtain Drugs Using Medicaid Benefits Card—May 29, 2015—A Rochester man, who pled guilty to pretending to be a doctor to unlawfully obtain narcotics from a pharmacy using his Medicaid benefits card, was sentenced to a prison term of 1½ years, 1½ years post-release supervision and restitution to the Medicaid program. The individual called a pharmacy, claiming he was a licensed physician working in a hospital emergency room and authorized the pharmacy to fill and dispense a prescription for Percocet for a patient. The individual then went to the pharmacy and obtained the drugs. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-rochester-man-who-posed-doctor-order-illegally.

Nurse Arrested for Falsifying Patient Records to Cover Up Neglect—May 28, 2015—A licensed practical nurse was arrested on charges that she falsely documented medical records of several diabetic residents at a nursing home to cover up neglect. The nurse allegedly wrongfully administered insulin to four nursing home residents by failing to check their blood glucose levels prior to the administration of insulin. The nurse allegedly documented a false blood glucose level in the residents' medical records to indicate that she checked the residents' levels prior to giving insulin when she did not. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-falsifying-patient-records-cover-her-neglect.

Woman Pleads Guilty to Submitting False Time Sheets to Medicaid for the Care of Her Daughter—May 26, 2015—The mother of a disabled Farmington woman pled guilty to petit larceny for $5,034.30 in home care services billed to Medicaid but not actually provided by the mother's two other daughters. The mother received a one-year conditional discharge and will pay restitution. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-rochester-woman-who-submitted-false-time-sheets.

Nursing Home LPN Charged With Stealing Percocet—May 20, 2015—A Licensed Practical Nurse was arrested on charges that she stole Percocet pills from a Medford nursing home for her own use and falsified medical records to state that she administered the drugs to a resident. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-medford-nurse-allegedly-stealing-prescription-drugs.

Southern Tier Nurse Arrested for Allegedly Diverting Narcotics from Nursing Home Patients—May 20, 2015—A licensed practical nurse was charged with felony counts of falsifying business records and misdemeanor charges of petit larceny and criminal possession of a controlled substance after allegedly diverting Percocet for her personal use from residents at the nursing and rehabilitation center where she worked in Horseheads. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-southern-tier-nurse-allegedly-diverting-narcotics.

Pharmacy Technician Pleads Guilty to Posing as Doctor to Obtain Narcotics—May 15, 2015—A Rochester man pled guilty to felony criminal possession of a controlled substance and is expected to be sentenced to one-and-a-half years in prison and restitution. William Martinez called a CVS pharmacy claiming to be an emergency room physician authorizing a prescription for Percocet and then picked up the drug himself. He previously admitted to similar conduct in a separate case. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-former-rochester-pharmacy-technician-who-posed.

Residential Health Care Facility Nurse Charged With Drug Theft—May 14, 2015—A Licensed Practical

Nurse was arrested on charges that she stole Percocet pills from a skilled nursing and rehabilitation facility for personal use and destroyed the narcotic record to try to cover up her theft. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-charged-stealing-percocet-pills-nursing-home.

Accredo Settles Kickback Claims for $60 Million—May 8, 2015—Accredo Health Group, Inc. agreed to pay $60 million to the Federal Government, New York, and several other states to settle allegations that it recommended the drug Exjade to Medicaid patients in exchange for kickbacks from Novartis Pharmaceuticals Corporation. Novartis allegedly gave more prescription referrals to one of three pharmacies that kept patients on Exjade the longest by employing nurses to downplay the drug's risks. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-60-million-national-settlement-accredo-pharmacy.

Nursing Home Owner and Officials Arrested for Covering Up Resident Abuse and Neglect—May 7, 2015—Two owners and top officials of a nursing home were arrested for allegedly suppressing evidence of a medication error that went unreported for two days and another incident in which a resident with dementia allegedly engaged in unlawful sexual conduct towards another resident in an unsupervised dining room. The nursing home, its owners, administrator and director of nursing were charged in Herkimer County for allegedly eavesdropping on investigators interviewing an employee about the incidents and destroying electronic evidence of the incidents. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-charges-against-owners-other-top-officials-mohawk-valley.

Westchester Transportation Company and Owner Plead Guilty to Fraud—May 6, 2015—A Yonkers-based ambulette company and its owner pled guilty to stealing more than $200,000 from the Medicaid program by altering taxi request forms to authorize more expensive ambulette services. The owner will receive six months in jail and five years of probation and will pay restitution, and the company will be fined $10,000. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-and-jail-sentence-owner-westchester.

New York State Office of the Medicaid Inspector General Update
Compiled by the Editor

New OMIG Audit Protocols—August 14, 2015—OMH Clinic Treatment Services; OMH Continuing Day Treatment; OMH Day Treatment Programs Serving Children; OMH Intensive Psychiatric Rehabilitation Treatment; OMH Partial Hospitalization; Traumatic Brain Injury. https://www.omig.ny.gov/audit/audit-protocols.

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For Your Information

By Claudia O Torrey

"Futuristic" healthcare is not just for the movies—it has arrived on the terra firma! It is predicted that the "Internet of Things" in healthcare could conceivably link ambulances, hospitals, and medical devices to/with integrated cloud-based services. According to *Entrepreneur* (entrepreneur.com[February 26, 2015]), in partnership with fortune.com, there are five remarkable facts about the future of health care:

1. Preventive medicine will soar (increased use of the cloud);
2. Health care will go from the general to being more personal (increased variations on concierge medicine);
3. Robots will be optimized for health tasks (the evolution of robotics);
4. Collaboration will destroy silos (collaborative team approaches for innovators; technology incubators); and
5. Physicians will have access to more data (the potential "dawn" of a handheld diagnostic tool/device).

Of course, one cannot forget about the possible use of drones in health care!

On Tuesday, September 1, 2015 it was announced that the Federal Aviation Administration had given a startup known as Measure the "green light" to fly 324 drones; these drones will be used to gather data for business purposes. It appears that FAA approval is easier for drone data collection than drone delivery of goods (medical or otherwise).

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Introduction to the Special Edition: Legal Issues in Biotechnology

By Sander Rabin, M.D., J.D., Special Edition Editor

The articles in this special edition of the *Health Law Journal* are intended to make the world of biotechnology and some of the legal and ethical issues it presents more understandable to attorneys and judges, and to introduce them to "human enhancement," a controversial new realm that biotechnology is creating, which raises unprecedented legal and ethical issues. Human enhancement occurs when medicine goes from healing to boosting, by which is meant, using biotechnology to augment all that's biological about us, and to radically extend our lifespan. While each of the feature articles has immediate relevance to law, ethics and present-day biotechnology, each also foreshadows legal and ethical issues in the application of biotechnology to human enhancement.

The article entitled "Ethics in the Age of Genomics and Bionics," by Ruth Scheuer, R.N., Dr. Ph., J.D., is a brief overview of the some of the vexing ethical issues presented by genomics and bionics, two key human enhancement technologies.

As a primer on stem cell technology for lawyers and a review of stem cell regulation, "Regulating Science: Genomic Editing, the Embryo and the Lives of Our Children" by Janet Cohn, J.D., Yu-fen Chou, Ph.D., Richard Dees, Ph.D. and Matthew Kohn, Ph.D., provides a summary of law and ethics in relation to stem cell technology, regenerative medicine, and genetic engineering. Regenerative medicine, perhaps the most promising application of genetic engineering and stem cell technology, has the human enhancement outcome of radical life extension as its tacit endpoint.

In discussing the shifting borders of bodily autonomy and property, the article entitled "Navigating the Control of the Body in the Age of Biotechnology," by Randall Hirsch, M.D., J.D., distinguishes various rights to the human body applicable to commerce in body parts and products. In so doing, it presents the legal foundation that the transhumanist claim to a right of "morphological freedom." It also asks us to consider the largely unseen process of "cyborgization" in which we are living, by posing the question of whether harm to a state-of-the-art prosthesis essential to the functioning of a human being should be deemed damage to property or a personal injury. This issue will soon impact insurance law, workers' compensation law, and the law of torts, as the sophistication, and in some cases superiority, of prostheses grows.

The ethical and legal divide between genetic therapy and genetic enhancement is implicit in the article by Sam Servello, J.D., LL.M., entitled "Genomics and the Law: An Overview of Privacy, Data Sharing, Ethical Issues and a Shifting FDA Paradigm," which provides a primer on genetic engineering and a review of the law of genetic privacy. This article also reminds us that genetic discrimination is not limited to denying people insurance products and health care services on the basis of genetic information. If "designer babies" become a reality, genetic discrimination may also arise between children who are genetically enhanced and those that are not.

"While each of the feature articles [in this special edition] has immediate relevance to law, ethics and present-day biotechnology, each also foreshadows legal and ethical issues in the application of biotechnology to human enhancement."

The article entitled "Biobanks: Goals, Challenges, Ethics and the Law," by Karen L. Illuzzi Gallinari, J.D., describes the law and ethics attendant to the process of inviting people to participate in genetic research and the issues of informed consent for including their biological specimens in a biobank. Coming to grips with the social implications of human genomic knowledge, the precautionary note that forms part of the conclusion of this article has resonance in the human enhancement space.

Finally, the article I wrote, "At the Biotechnological Frontier: Law, Human Enhancement, and Transhumanism," explains how human enhancement raises fundamental questions regarding legal personhood, capacity, competence, the locus of liability, and free agency; and notes that even if these issues are resolved, the adequacy of prevailing legal systems to enact and enforce laws to govern human enhancement is far from assured.

Sander Rabin, M.D., J.D. is the executive director of the Center for Transhuman Jurisprudence, an NPO dealing with legal, medical, and public policy challenges arising from human enhancement.

An Introduction to Ethics in the Age of Genomics and Bionics

By Ruth Scheuer, RN, DrPH, JD

In April 1994 "The Lawful Uses of Knowledge from the Human Genome Project" was published (Grad Report).[1]

The impetus for its publication was the Human Genome Project, the enterprise that would unravel the human genetic code. An integral part of the Human Genome Project, the Grad Report was a milestone that sought to identify the unprecedented ethical, legal, and social issues that would arise once the human genetic code was broken.

"[T]he United States must deal with how to ethically and legally prevent, if possible, private individuals from using and abusing information they obtain from their own DNA samples and DNA samples of others."

The bioethical and legal priorities the Grad Report identified were:

- fairness (freedom from discrimination on the basis of one's genetic information);
- privacy (the extent to which an individual controls their genetic information):
- delivery of health care (the practices of health care providers and researchers in generating genetic information); and,
- education (informing health care providers, researchers and the public of the nature of genetic information, its use and misuse).[2]

Since the Grad Report there have been regulatory advances in meeting its priorities, especially in the area of privacy of health-related information.[3] However, many of the legal considerations needed to protect the privacy of genetic information in the 21st Century have yet to be enacted. This is because individuals will soon be able to access not only their own genetic information, but that of family members, friends, and even enemies—an eventuality not anticipated by the Grad Report.

1. An Overview of Genomics

The inability to guarantee patients that their de-identified, that is, anonymous, genetic information could be kept confidential became more apparent when researchers at the Whitehead Institute were able to show it was possible to discover the identities of subjects who participated in genetic research studies by cross-referencing their genetic data with publicly available information.[4]

It also became apparent that a Pandora's Box had been opened when consumers could discover critical information about their own genetic make-up simply by providing a sample of their DNA to private companies, such as 23andMe.[5] Thus, as discussed in the accompanying article "An Overview of Genomics and the Law," the United States must deal with how to ethically and legally prevent, if possible, private individuals from using and abusing information they obtain from their own DNA samples and DNA samples of others.

2. Biobanks: Goals, Challenges, Ethics and the Law

Biobanking also presents issues of genetic privacy. Of critical importance is what information must be disclosed to a donor of a tissue sample when a medical problem is discovered that may or may not be treatable. When does the duty to warn begin, and who bears that duty?[6] As noted in the accompanying article "Biobanks: Goals, Challenges, Ethics and the Law," this is also a critical issue when research subjects are asked to provide tissue for further study. While the use of community focus groups engaging with the public goes to the issue of education, that education must provide an honest assessment of whether and under what conditions a person's genetic privacy can reliably be protected.

3. Navigating the Control of the Body in the Age of Biotechnology

The article "Navigating the Control of the Body in the Age of Biotechnology" poses some very interesting questions. First, what is the right of a citizen to decide how to dispose of his or her tissue and organs?[7] In the U.S., blood is considered a service and not a product, and for ethical, medical and legal reasons, the sale of blood by an individual is not permitted.[8] Until recently, the sale of bone marrow was banned, but under a narrow ruling, the prohibition was overturned by the 9th Circuit.[9] That prohibition does not apply to plasma. While some countries may compensate an organ donor for medical expenses and time off from work, the sale of organs is not permitted in this country nor any other country except for Iran.[10] There remains a desperate need for more organ donations.[11]

The right to control one's body is very limited under some circumstances. The right to an abortion has come under increased scrutiny in the U.S. and efforts to limit that right are increasing. According to the Guttmacher Institute, "An unprecedented wave of state-level abortion restrictions swept the country over the past three years,[12] where there is no exception for the life or health of the mother during pregnancy.[13]

In years past, a Jehovah's Witness who was a mother would not be permitted to refuse blood, because her death might make the state locus parentis. This argument apparently does not seem to apply in the case of a forced pregnancy that threatens a woman's life. This again points to the fact that frequently ethical issues cannot be fully evaluated without looking at the religious, ethnic and political beliefs of the people involved.[14]

While surrogate contracts are permitted in some states, in New York a woman may not enter into a contract to become a surrogate.[15] Yet she may do so in some other states.[16]

Surrogacy raises ethical concerns, such as the possibility of coercing poor women into surrogacy, and legal issues, such as breaches of surrogacy contracts, the rights of the gestational woman versus the donor, and the best interest of the child.

4. Regulating Science: Genomic Editing, the Embryo and the Lives of Our Children

The ethical issues involving the new CRISPR-Cas9 gene editing technology were well laid out in the accompanying article "Regulating Science: Genomic Editing, the Embryo and the Lives of Our Children." This article asks us to be mindful of the eugenics movement, born in the United States in the 1920s, as a social movement to improve the genetic features of humans through selective breeding and sterilization. It was, unfortunately, a forerunner of Hitler's movement to create a perfect race, which resulted in the extermination of undesirables, including the mentally defective, the disabled, and the Jews.

Transhumanists argue that parents have a moral responsibility (creative beneficence) to use all effective methods to conceive the healthiest child possible.[17] In light of the soaring cost of health care is this a basis for a legal obligation to eliminate genetic variants before conception?

Is it ethical for parents to abort a fetus with a known genetic variant that may result in mental retardation or a disabled child?

On the other hand, who determines what constitutes a disability? For example, many who are deaf reject the notion that they have a disability and may ask that only embryos which have the gene for deafness be implanted. This is the issue raised by Dena Davis in her article "Genetic Dilemmas and the Child's Right to an Open Future."[18]

Additional bioethical issues abound. For example, Ohio has passed legislation that would make it illegal for a doctor to perform an abortion if a woman is terminating her pregnancy to avoid having a baby with Downs Syndrome.[19] Is it appropriate for a government to prevent a parent from making such a decision? Is it ethical to assist a couple to produce a child in order to provide hematopoietic stem cells, or serve as an organ or tissue donor for another child?[20]

The arguments for and against research on embryos were discussed in the accompanying article as noted above. However, there is virtual agreement that embryonic research must be scientifically valid, subject to strict oversight and approved by the donor. Some argue that even where de-identified frozen embryos are used, the donor's consent is required. The same need for informed consent has been suggested for research using gamete donors.[21]

There are fears that researchers may one day be at a point when it is used for human reproduction or cloning. If we allow humans to be cloned what would be the effect on the cloned child, the family and future generations?

Cytoplasmic hybrid embryos (using nonhuman oocytes to derive cell lines using human nuclear DNA has been suggested as a means of grappling with a shortage of human oocytes for Somatic Cell Nuclear Transfer (SCNT) research. Would such research result in a new form of life, a chimera part animal part human and thus change our view of the natural order of man?[22]

5. Ethical Perspectives in Cybernetic Medicine

As we become increasingly dependent on robotics or other artificial means of controlling our bodies, to what extent will we lose control of our physical and mental faculties if they become programmable by others? Will there come a day when Alzheimer's disease is cured, not by pharmacological means, but by memory chips inserted into the brain? It is not too far-fetched to think that in 20 years or less, instead of portable of wearable computers, we may have implanted computers that provide us with instant information. The more information the chip holds the higher the cost. Will the more detailed chip be only available to the wealthiest? Bertolt Meyer, who has a prosthetic arm, questions whether we are moving from the science of repair to the era of a post-human future. At issue is the concern that advances in robotics, nanotechnology, biotechnology and information technology are

blurring the lines between healthy function and enhanced performance. Will there come a time when healthy people would chose amputation of a healthy limb in favor of a prosthetic limb that would allow them to be faster, stronger or more dexterous?[23] How does the passage of time affect our ethical perspectives?[24]

The issue of autonomy and informed consent is debated in the use of Deep Brain Stimulation. This debate is the focus of an article by Koivuniemi, et al., "When Altering Brain Function Becomes Mind Control."[25] Scientists are now inserting chips or electrodes into a paralyzed patient's brain. The patient's brain conveys information to a computer to execute a task that the patient wants performed using an otherwise paralyzed limb. This method is also being used to allow the patient to control a robotic limb to perform tasks such as using a spoon, or walking.[26] Who is responsible ethically and legally if the computer malfunctions causing harm to the patient or others—the patient, the computer programmer, the developer of the computer, the person monitoring the transaction?

The *New York Times* is launching a series on extending life through medicine, technology, and lifestyle. The first article in this series is entitled, "Hoping to Transcend Death via Cryonics."[27] It tells the story of a 23-year-old woman, Kim Suozzi, with terminal brain cancer, who chose to cryopreserve her brain upon her death. She hoped that in the future, there would be a digital way to preserve connections to her brain and generate a replica of her mind. The concept may have been comically introduced to the public in the movie "Sleeper" in which Woody Allen plays a cryogenically preserved man who awakens 200 years in the future. However, Kim's decision comes at a time when President Obama has announced his " BRAIN" Initiative—"a bold new research effort to revolutionize our understanding of the human mind and uncover new ways to treat, prevent, and cure brain disorders like Alzheimer's, schizophrenia, autism, epilepsy, and traumatic brain injury."[28] Decoding the brain will raise enormous ethical issues. Who has the right to make decisions about changes in brain function (where the patient does not have capacity)? To what extent will those changes change the person and who is to decide whether, when or if such changes should be made?

Since much of Kim Suozzi's brain was damaged by the tumor, it is not known how much of her damaged brain, if any, could be repaired in the event that it is thawed years from now. Nor is it known whether her brain could be replicated digitally rather than physically. How much Kim would remain Kim? Would Kim's brain be attached to a robot or to a human being? The issues this presents for ethicists in the future, including who controls the brain function, are beginning to be asked in the present.

What seems science fiction today may be a reality tomorrow. When Louise Brown, the first baby conceived in a test tube, was born in 1978, it created a shift in how humans control or manipulate reproduction (this was on the heels of the *Roe v. Wade* decision permitting abortion in the first trimester of life).[29] While this was heralded as a major scientific breakthrough, it also increased fears about the misuse of technology. While in vitro fertilization is now an accepted technology, the impact of Louise Brown's conception continues today.[30]

"How we frame the ethics of biotechnology in the 21st Century will be a factor in how we view our own humanity."

Tremendous strides are being made in genetic engineering, improving our physical and mental abilities, and advancing our knowledge of human behavior. The ethical concepts of autonomy, beneficence non-malfiescience and justice will continue to confront us, as they have for centuries.

The articles in this edition delineate the myriad ways constraints have been imposed on new technology. Some of these constraints rely on state laws, others rely on federal laws, and yet others are country-dependent. Constraints are also imposed by institutions, commissions, or interested professional organizations. These constraints define the limits of biotechnology advances which will be tolerated. The limits we can or should go to control biotechnology will always be weighed in light of politics, religious beliefs and the law. However, history teaches us that constraints, whether implied or actual, have always been circumvented.

This teaching is likely to remain valid as we continue to usurp the role of natural selection in evolution, change the nature of human nature, and chart a destiny for all of humanity.

Knowing that ethics and law may be circumvented in no way relieves us of the responsibility of providing ethical and legal guideposts along the way. How we frame the ethics of biotechnology in the 21st Century will be a factor in how we view our own humanity.

Endnotes

1. Frank Grad, Principal Investigator: Legislative Drafting Research Fund, Columbia University Law School, New York (Ilise Feitshans, Associate Director, Legislative Drafting Research Fund). Pursuant to U.S. Department of Energy, Contract No. DE-FG02-92ER61394, April 15, 1994.
2. *Id*. Grad, page 8.
3. Patient Protection and Affordable Care Act ("PPACA"; Public Law 111–148) consolidating the amendments made by title X of the Act and the Health Care and Education Reconciliation Act of 2010 ("HCERA"; Public Law 111–152). The PPACA or ACA prohibits insurance companies from excluding patients with pre-existing conditions from coverage effective in January 2014. Children under 19 with pre-existing conditions could not be discriminated against by insurance companies, effective September 23, 2010.
4. Previous studies had shown that people whose anonymous genetic data was stored could be de-identified by matching their data to a sample of their DNA. Erlich went further by showing that all it required is an Internet connection. Gymrek, M., McGuire, A. L., Golan, D., Halperin, E. & Erlich, Y., Science 339, 321–324 (2013).
5. In November 2013, the Food and Drug Administration ordered 23andMe.com to halt sales of its DNA analysis product, claiming that it was being marketed "without marketing clearance or approval" from regulators. The company sold a kit to consumers who provided a sample of saliva for genetic sequencing. Consumers would then be alerted by the company about any diseases they carried or for which they were at risk. 23andMe claimed it could identify up to 254 diseases and other medical conditions.

   In February 2015, the FDA authorized marketing of the first direct-to-consumer genetic carrier test for Bloom Syndrome, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm435003.htm.

   Not all states permit direct-to-consumer genetic testing. For instance, in New York, direct-to-consumer genetic testing is illegal if it is performed on a New York State resident by a laboratory not approved by the New York State Department of Public Health. NY Pub. Health Law § 574, Article 5, Title V. See also "Clinical Laboratory Evaluation Program," New York State Department of Health (http://www.wadsworth.org, accessed 22 Dec 2012).
6. Osmond, K., *Medical Ethics For the Genome World*, The Journal of Molecular Diagnostics, vol. 10(5) September 2008 (377-382).
7. See Kasperkevic, Jana, *How much can you get for selling your body (parts)?,* The Guardian.com.
8. Peter Mondello, &C., Respondent, v. New York Blood Center—Greater New York Blood Program, The New York Hospital, Appellants, et al., Defendants, 80 N.Y. 2d 219, 604 N.E. 2d 81, 590 N.Y.S. 2d 19 (1992) October, 22, 1992, 1 No. 173. Decided October 22, 1992. Cite to Public Health Law § 580(4).
9. "In *Flynn v. Holder* (2011), the U.S. Court of Appeals for the Ninth Circuit (142 U.S.C. § 274e, 2, Fed. R. Civ. P. 12(b)(6) 20556) held that a common method of bone marrow donation—'peripheral blood stem cell apheresis'—did not fall under the ban on compensated organ donation under the National Organ Transplant Act (NOTA) of 1984. Pub. L 980-507, as amended by Pub. L. 100-607 and Pub. L. 101-616."

   In May 2012, the court denied the government's petition for a rehearing. However, in November 2013, the Department of Health and Human Services proposed a new regulation that would redefine bone marrow as an "organ," thereby nullifying the *Flynn* decision. The proposal never made it past the open comment period." Zhang, *Dan Compensated Altruism, Flynn v. Holder and the Market for Bone Marrow Donors,* U. Penn Law Review, 4/14/2014, www.pulj.org.
10. Aleccia, J., *A Kidney for $10,000: Paying Donors Actually Pays Off, New Study Finds*, Health News, October 21, 2013.
11. The need for human organ donations may be a thing of the past, as scientists use 3D printing. Medscape has published examples of 3D printing and how it is affecting medical science and care. Scientists are now using 3D printing to make skin, nails and hair, a prosthetic ear, nose, finger, hands, and skull and hope one day to create a human heart. It also has helped in developing prosthetic legs. Merrecca Fiore, *3D Printing: 10 Examples of How it Has Changed the World,* MedScape, March 23, 2015.
12. See Heather D. Boonstra and Elizabeth Nash, *A Surge of State Abortion Restrictions Puts Providers—and the Women They Serve—in the Crosshairs*, Guttmacher Policy Review, Winter 2014, Volume 17, Number 1, available at http://www.guttmacher.org/pubs/gpr/17/1/gpr170109.html.
13. See Gonzales v. Planned Parenthood Federation of America (Planned Parenthood Federation of America, Inc. v. Gonzales, 435 F.3d 1163, 1166 (9th Cir. 2006) and *Gonzales v. Carhart*, 550 U.S. 124 (2007). The Supreme Court upheld the Federal Abortion Ban, a measure that outlaws certain second-trimester abortions and has no exception for cases when a woman's health is in danger.
14. See No. 267 In the Matter of Francis J. Fosmire & C., Appellant v. Denise J. Nicoleau et al., Respondents, January 18, 1990. In that case the plaintiff did receive blood over her objection and the New York Court of Appeals overturned the lower Court, finding that the Appellete Division erred in adopting the "one-parent rule." Also see Lagay, F., *When a Parent's Religious Belief Endangers Her Unborn Child*, AMA J., Ethics, May 2005, Vol. 7, No. 5. In April 2015, a pregnant Jehovah's Witness' decision to refuse treatment was honored, resulting in her death and that of her unborn fetus.
15. NY CLS Dom. Rel. §§ 121-124 (2007).
16. See Guide to State Surrogacy Laws, Center for American Progress December 17, 2007. The laws run from an outright ban, to allow but regulate surrogacy.
17. Tucker, A., "You Robot," Smithsonian 43:1 (2012: 28) (it is also argued that those who do not believe in human enhancement are "Bio-Luddites").
18. Hastings Center Reports, Vol. 27, No. 2, March-April 1997. Also see Tucker, B., *Deaf Culture, Cochlear Implants and Elective Disability,* Hastings Center Report, Vol. 28, No. 4, July-August 1998, pgs. 6-14.
19. See HB 135 abortion ban (2015-2016). This is awaiting the Governor's decision whether or not to sign the legislation, https://www.legislature.ohio.gov/legislation/legislation-summary?id=GA131-HB-135.
20. Robertson, J., et al., *Conception to Obtain Hematopoietic Stem Cells*, Hastings Center Report, Vol. 32, No. 3, May-June 2002, pgs. 34-45.
21. Lo, B. and Parham, L.,"Ethical Issues in Stem Cell Research," Endocrine Rev. 2009, May 30(3) 205-213, published online 2009 Apr. 14 doi 10.1210/er2008-0031.
22. While human cells are injected into animals for research purposes, the converse is seen through a different lens. Nevertheless, tissue from pigs (Porcine) or cows (Bovine) are used in heart valve replacement. Tissue or Mechanical Heart Valve?-on–x life Technologies, Inc., http://www.onxlti.com/message-to-patients/tissue-or-mechanical-heart-valve/. In 1984, a baboon heart was transplanted into an infant who lived 20 days. Since then there have been no animal to human heart transplants.

There have been at least two attempts to implant a baboon's liver into a patient. Thirty three, and possibly more, animal to human organ transplants (xenotransplants) have been tried since 1905. However, failure to control the body's rejection of such transplants has hampered their success. *Man Dying from Hepatitis is Given a Baboon's Liver*, The New York Times, Lawrence Altman, January 11, 1993.

23. *Ethics: The questions posed by our bionic bodies*, Observer Editorial, The Guardian, Saturday June 15, 2013.

24. An interesting example of this is in the field of human enhancement enabling technology. Ten years ago, when human face transplants were proposed, the Bioethicist, Athur Caplan, was strongly opposed, believing the procedure to be unethical. The reasons given were not just on the issue of safety (if the transplant failed, there was thought to be no second chances and the person would die). He also opined on the effect of the transplant on the family of the donor and that of the recipient, who would look in the mirror and see the face of another. However, after meeting people with catastrophic facial disfigurement whose suffering was so great that they were willing to risk death rather than continue on, Dr. Caplan has changed his mind about the ethics of a face transplant. *Are face transplants ethical?,* The Skeptical OB, Dr. Amy Tuteur, January 6, 2009.

25. Koivuniemi, A. and Otto, K., *When Altering Brain Function Becomes "Mind Control,"* Front. Syst. Neuro. Science, 14 Oct. 2014.

26. Regalado, A., *The Thought Experiment*, MIT Technology Review, June 11, 2014.

27. Harmon, A., *Hoping to Transcend Death via Cryonics*, The New York Times, Sunday, September 13, 2015, page 1.

28. Brain Initiative, Tues., Sept. 30, 2014, https://www.whitehouse.gov/share/brain-initiative.

29. Roe v. Wade, 410 U.S. 113 (1973). The Court held that the decision to have an abortion in the first trimester should be left to the woman and her doctor. In regard to second trimester pregnancies, states may promote their interests in the mother's health by regulating abortion procedures related to the health of the mother in the second trimester. As to the third trimester, states may promote their interests in the potentiality of human life by regulating or prohibiting abortions except when necessary to preserve the life or health of the mother.

30. See *Test Tube Babies Interview: Ethical Questions,* American Experience, pbs.org.

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Regulating Science: Genomic Editing, the Embryo, and the Lives of Our Children*

By Janet Cohn, J.D.; Yu-fen Chou, Ph.D.; Richard Dees, Ph.D.; and Matthew Kohn, Ph.D.

In April 2015, Chinese scientists announced that they had used a new gene editing technique, CRISPR-Cas9, to alter the genome of defective human embryos,[1, 2] moving the prospect of genetic engineering from the world of science fiction to the realm of the possible. If perfected, this technique could allow parents to alter the genes of their potential children, either to eliminate disease or to make selections from a menu of attributes. Like many other biomedical breakthroughs, this one brings with it new ethical, legal, and regulatory challenges. In this article, we draw on lessons learned from our work at NYSTEM, New York State's stem cell science funding program, first, to recount the technical background and regulatory challenges of stem cell research generally; second, to describe the scientific breakthroughs that led to the use of CRISPR-Cas9 on human embryos; and finally, to assess the choices that society must make as research using this powerful technology continues.

"If perfected, [CRISPR-Cas9] could allow parents to alter the genes of their potential children, either to eliminate disease or to make selections from a menu of attributes. Like many other biomedical breakthroughs, this one brings with it new ethical, legal, and regulatory challenges."

I. The Stem Cell Revolution

When James Thompson first isolated embryonic stem cells in 1998,[3] it generated excitement and controversy: excitement because the cells offered hope for treating a wide variety of devastating diseases; controversy because they could not be obtained without destroying a human embryo.[4]

Stem cells have two properties that together make them powerful tools: they can renew themselves, and they can differentiate into other types of cells. Self-renewal means a stem cell can replenish its population. When a stem cell divides, each "daughter" cell can either remain a stem cell or can differentiate and become more specialized. The ability to self-renew means scientists can grow large numbers of stem cells, and the ability to differentiate—their "potency"—means scientists can use them to create any cell type in the body. There are different kinds of stem cells, however, and their potency and capacity for self-renewal are not equal. Embryonic stem cells (ESCs) are the only naturally occurring stem cells with virtually complete potency and immortality.

In contrast to much of Europe,[5] Latin America, Africa, Canada and a number of states, there is little federal law specifically applicable to the use of human embryos in medical research. While some other jurisdictions have banned or criminalized certain procedures, the United States has taken a different approach. Rather than prohibit procedures that result in the destruction of an embryo, for example, it prohibits the use of federal funds for such activities. So far, however, individual states and private philanthropies are free to fund this research. As a result, the Food and Drug Administration (FDA), which oversees clinical trials in this country no matter who is paying, may find itself supervising work that its sister federal agencies could not legally support. States with funding programs create their own regulatory structures, while nonbinding guidance has come from the National Academy of Sciences (NAS) and the International Society for Stem Cell Research (ISSCR). Overall, within the United States, New York has been the most progressive.

A. Somatic Stem Cells

Somatic stem cells—often called "adult" stem cells—occur in humans and animals of every age, and they are normally responsible for tissue maintenance and repair. The potential of somatic stem cells is limited, however, because they can only produce cells of their source tissue, have restricted capacity for self-renewal, and can be difficult to isolate from the body. Nevertheless, therapies using somatic stem cells have a long history. We now know that the "active ingredient" in bone marrow transplants is hematopoietic stem cells, which give rise to blood and immune cells. Many successful therapies have followed since the first bone marrow transplant in 1959, including treatments for certain cancers, sickle cell disease, and severe combined immunodeficiency.[6]

Bone marrow also contains another type of stem cell, mesenchymal stem cells (MSCs), that primarily give rise to bone, cartilage, fat, and connective tissue. To date, a single MSC-based therapeutic has been clinically approved—Prochymal, for the treatment of graft-versus-

host disease[7]—but only in Canada and New Zealand. MSCs have been tested for a number of other applications with mixed results. Several therapies based on other kinds of somatic stem cells are in early phase clinical trials. A notable example is neural stem cells, which are being tested to treat neurodegenerative diseases, spinal cord injury, and stroke. Retinal progenitor cells are being tested for eye diseases. And recently the European Medicines Agency approved Holoclar, which uses stem cells originating from the limbus of the eye, for the treatment of corneal damage.

In the United States, the "practice of medicine" is regulated at the state level by state licensing requirements. Whether the therapeutic use of somatic stem cells in a given situation is the practice of medicine, or whether it is a clinical use subject to FDA regulation, is a somewhat gray area. While treatments marketed here and abroad—so-called "stem cell tourism"—raise safety and efficacy concerns, the use of somatic stem cells in research, because they are generally harvested from adults, has not been controversial. Federal law requires that human subjects research be approved and overseen by an Institutional Review Board (IRB) to ensure that it is conducted with informed consent and proper oversight, and clinical trials must be approved and supervised by the FDA. However, some somatic stem cells—most notably neural stem cells—are harvested from aborted fetuses. These cells can only be obtained with the informed consent of the donor, who must have made the decision to undergo an abortion before the topic of donation can be broached.[8]

B. Human Embryonic Stem Cells

Still the gold standard, ESCs self-renew indefinitely. Because they are effectively immortal, scientists can easily generate vast numbers. ESCs are also pluripotent—theoretically, they are capable of generating any cell in the human body. ESCs are now being used to develop treatments for many conditions, particularly degenerative diseases like Parkinson's, multiple sclerosis, age-related macular degeneration (AMD), spinal cord injury, amyotropic lateral sclerosis (ALS, Lou Gehrig's disease), liver failure, diabetes, and Alzheimer's. Scientists think that these therapies will not only stop the progression of these diseases, but will also reverse them by replacing the missing or dysfunctional cells responsible for symptoms. Several trials using ESCs are in progress. The first to receive the green light from the FDA was Geron Corporation's trial to treat spinal cord injury. Ocata Therapeutics, Inc. (formerly Advanced Cell Technologies or ACT), is testing ESC-derived retinal pigment epithelium (RPE) for the treatment of dry AMD and Stargardt's macular dystrophy, another degenerative eye disease.

Critics maintain that because embryos contain all the genetic material needed to create a person, they should be accorded the same moral status as fully developed humans. Proponents counter that the embryos from which ESCs are derived—which are usually less than a week old, never more than two, and cannot develop into humans unless implanted in a uterus—have a lesser moral status, and that given their enormous therapeutic potential, research using them is warranted. In 2001, President George W. Bush responded to this controversy by limiting federal funding to research using only those human ESC lines that were already in existence at that time. Nonetheless, some research proceeded. A handful of states, notably California, Connecticut, Maryland and New York, responded to the restrictions by creating their own programs to fund ESC research. Private philanthropic groups also provided support.

In 2005, the NAS addressed the void in federal regulation by issuing recommendations for the oversight of ESC research. It concluded that any research involving ESCs must be essential to an important scientific goal. In addition to the protections required for any human subjects research,[9] institutions conducting ESC research were advised to form Stem Cell Research Oversight committees (SCROs or ESCROs), which should include at least one ethicist, to insure that proposed research merited the use of human ESCs (hESCs).[10] In 2006 the ISSCR promulgated its own guidelines on hESC research. These too emphasized the need for a strong scientific rationale and enhanced oversight and concluded that when these conditions were met, research involving embryos no older than fourteen days was permissible.[11]

The New York State Stem Cell Science program (NYSTEM)—the second largest state program, at about one fifth the size of the largest, California's—was created in 2007. It is advised by the Empire State Stem Cell Board (ESSCB), which makes recommendations for research standards, funding mechanisms, and awards. To date, over $350 million has been committed to funding basic stem cell research, disease modeling using stem cells, preliminary studies to develop therapies, infrastructure, training, and general education. In addition, it has made awards of up to $15 million each to six consortia to ready stem cell therapies for clinical testing for Parkinson's disease, AMD, multiple sclerosis, ovarian cancer, sickle cell disease, and other blood malignancies.

In 2009, President Barack Obama lifted the Bush era restrictions on federal funding for hESC research.[12] But because of the Dickey-Wicker amendment, which has been attached to every Health and Humans Services (HHS) appropriations bill since 1996, federal funding of research involving human embryos remains significantly limited. The amendment provides:

> SEC. 509. (a) None of the funds made available in this Act may be used for—
>
> (1) the creation of a human embryo or embryos for research purposes; or
>
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero….

It goes on to define "human embryo or embryos" to include

> any organism, not protected as a human subject under [the Human Subject Protection regulations]…, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes (sperm or egg) or human diploid cells (cells that have two sets of chromosomes, such as somatic cells).

After Obama issued his executive order, the National Institutes of Health (NIH) promulgated new guidelines on funding of hESC research, restricting it to research using leftover embryos that had been created for reproductive purposes. The guidelines explicitly noted that federal funding to derive stem cells from human embryos was prohibited by the Dickey-Wicker Amendment. James Sherley, a somatic stem cell researcher, filed a lawsuit challenging the regulations so far as they permitted the funding of hESC research. Ultimately a panel of the D.C. Court of Appeals upheld the NIH regulations, finding that Dickey-Wicker did not prohibit the funding of *research* on hESCs, just their *derivation* by means that could injure or destroy an embryo.[13] The Supreme Court denied certiorari. In compliance with the decision, NIH now maintains a registry of cell lines, derived from leftover IVF embryos obtained with documented consent, which are eligible for federal funding. As the table that accompanies this article demonstrates, however, the effect of the Dickey-Wicker Amendment remains extensive.

C. SCNT

Since the first isolation of hESCs, two new techniques have been developed to create ESC-like cells: somatic cell nuclear transfer (SCNT) and induced pluripotent stem cell (iPSC) technology. In SCNT, the nucleus of a somatic (non-embryonic) cell, which contains the cell's genetic material, is transferred into an egg from which the genetic material has been removed. Embryonic stem cells can then be derived from the new "embryo." This process constitutes the first step of "reproductive cloning," in which the resulting embryo is implanted into the womb of a surrogate mother; it was used to create Dolly the sheep in 1996[14] and other non-primate mammalian species since then. Many countries, and individual states in this country, have banned reproductive cloning. New York has not, but NYSTEM funds cannot be used for this purpose.[15]

In a process called "therapeutic cloning," however, SCNT has the potential to create effective therapies for disease. Instead of transferring the embryo created by SCNT into a uterus, as would occur in reproductive cloning, scientists can extract ESCs from the embryo. These cells would be an immunological match to the somatic cell's donor. If they were transplanted back into the donor as part of a therapy, the chance of rejection would be greatly reduced. In 2013, a group from Oregon Health Sciences University first succeeded in creating ESCs by SCNT, using fetal cells as a donor source. [16] The result was soon replicated in a lab at the New York Stem Cell Foundation, funded by NYSTEM, which went on to create the first disease-specific SCNT-ESCs from an adult diabetes patient.[17] Disease-specific ESCs, which contain the genetic defect that causes the disease, offer many advantages to researchers. Importantly, disease-specific cells allow researchers both to examine the mechanisms by which a disease arises and to test drugs to identify possible cures.

SCNT has brought with it its own share of ethical and legal challenges. SCNT requires a ready supply of scarce human eggs. Most jurisdictions prohibit the financial compensation of egg donors, beyond their medical expenses, except when donated for *in vitro* fertilization (IVF). Indeed, Governor Jerry Brown of California recently vetoed a bill that would permit compensating donors for the time, burden and discomfort associated with donation in amounts commensurate with IVF donation. The model for the failed bill came from New York State, the only jurisdiction in the country that permits the use of its funds for this purpose.[18] An unsuccessful lawsuit challenging the practice both as coercive and as advancing human cloning made its way through the New York courts and was ultimately rejected by the Appellate Division.[19]

A new controversy has followed the development of a procedure that is based on SCNT: the generation of embryos through mitochondrial DNA replacement therapy (sometimes and perhaps misleadingly called "three-parent embryos"). Mitochondrial DNA replacement therapy, also called mitochondrial donation, may allow women with mitochondrial diseases to have children that are genetically related to them, yet free of the diseases. One method involves removing the nuclear material from the egg of a healthy donor (the "third parent"), leaving her mitochondria intact, and inserting the nuclear material from the future mother's egg. The resulting egg is fertilized with sperm from the intended father and then

transferred to the womb of the mother-to-be. Less than 1% of the DNA in the modified embryo—all contained within the mitochondria, which have their own separate genome—would come from the mitochondrial donor. The United Kingdom approved allowing clinical trials using mitochondrial transfer in 2015, and U.S. agencies are holding discussions to determine their position on the procedure. Like other debates on procedures that create or modify human embryos, a divergence of strongly held views is expected.

D. iPSCs

Despite potential advantages, SCNT is not currently widely pursued. In 2006 and 2007, Shinya Yamanaka discovered a quicker, easier, and less controversial method to generate patient-specific pluripotent cells. He (and James Thomson in his own lab) created "induced pluripotent stem cells" (iPSCs) by inserting four pieces of DNA, or factors, into adult skin cells—first from mice and then from humans—to reprogram them into ES-like cells.[20] Like ESCs, iPSCs are immortal and pluripotent, but they can be generated from the cells of any living person and do not involve the use of embryos. This discovery rapidly changed the stem cell research landscape and in 2012 Yamanaka received the Nobel Prize. The technology is still new, however, and much work remains to determine its full potential and limitations. To date there is only one clinical trial testing an iPSC-based therapeutic: in 2014 a single patient in Japan was transplanted with iPSC-derived RPE generated from her own cells.

II. Genomic Editing

The latest controversy swirling around the stem cell field concerns the use of genomic editing on human embryos. This technique not only requires research on the embryo but, if it can be performed safely and effectively, poses new questions that are at least as hard to resolve. If modified embryos are implanted in a uterus, the edited genes will be transmitted to the resulting child and its descendants. Is it ever ethical to make changes that will affect future generations, changes to which they cannot consent? Is it ethical if the goal is the elimination of potential disease? The elimination of *certain* disease? What about genomic editing to make the children genetically "superior"—smarter, taller, stronger? Thinner? Blonder?

A. Gene Therapy and Recombinant DNA

Gene editing that does not affect the germline (is not passed down to future generations) is already being used by researchers around the world. Efforts to treat disease by genetic intervention began as early as the 1960s, when the American physician Stanfield Rogers and colleagues at Oak Ridge National Laboratory explored the use of viruses to carry and transmit genetic information to patients. In 1975, the group collaborated with German physician H.G. Terheggen in a study to treat two children suffering from hyperargininemia, a severe metabolic disorder.[21] They administered the Shope papillomavirus into the patients, believing it contained the gene needed to treat them. The study failed. It would take the sequencing of the papillomavirus in the mid-1980s to realize that the needed gene had been absent all along. But the concept of transferring therapeutic genetic information using viral gene therapy was established.

At about the same time, scientists began to manipulate DNA from bacteria, viruses, and mammals into new combinations. In 1972, Paul Berg at Stanford University created the first recombinant (hybrid) DNA molecule, combining a virus that infects monkeys with another virus that infects bacteria, in this case *E. Coli*. Concerns arose that recombinant DNA research could trigger a biodisaster: bacteria carrying a viral cancer gene might escape the lab and cause a pandemic, or recombinant DNA derived from infectious pathogens could cause unforeseen outbreaks or be used in bioterrorism. In 1974, the NIH responded by creating the Recombinant DNA Advisory Committee (RAC), a regulatory oversight committee, to supervise NIH-funded recombinant DNA research projects. In 1975, a group of scientists led by Berg agreed to a voluntary moratorium and gathered in California, at the so-called Asilomar Conference, to debate the dangers of recombinant DNA and the appropriate response. They decided that the research should continue, but only under stringent restrictions.[22] Their recommendations formed the basis of the official NIH guidelines on research involving recombinant DNA, first issued in 1976. Despite early reservations, the first patent on a recombinant DNA technology was granted in 1980 and the FDA approved the use of recombinant human insulin to treat diabetes in 1982. Berg shared the 1980 Nobel Prize in chemistry for his work in this field.

As work on gene therapies developed in the 1990s, the role of the RAC was expanded to work with the FDA to review protocols for human gene therapy trials. Gene therapy entails treating diseases by modifying, deleting, replacing or inserting genes into target cells.[23] In the 1990s, early gene therapy trials produced disappointing results.[24] Then, in 1999, another early trial led to the tragic death of an 18-year-old patient. Jesse Gelsinger had volunteered to participate in a clinical trial that used a virus carrying a specific gene to correct ornithine transcarbamylase (OTC) deficiency, a metabolic disorder of the liver. After receiving a single dose of the virus, Gelsinger suffered a massive inflammatory reaction and died as a result of multi-organ failure.[25] An FDA investigation questioned whether there had been appropriate patient screening and adequate disclosures. Gelsinger's death rocked the research community and resulted in height-

ened scrutiny for gene therapy oversight by both the RAC and the FDA. Despite these setbacks, a variety of gene therapy approaches are now in early clinical trials testing their safety and efficacy in humans; most target various forms of cancer.[26] Gene therapy is also being tested to treat blood disorders through viral delivery of functional genes into the genome of hematopoietic stem cells.

B. New Technologies for Gene Editing

An ongoing concern of viral gene therapy, however, is that the virus can insert randomly into the genome, disrupting necessary genes or inadvertently activating genes that cause cancer.[27]

To edit the genome more precisely, scientists have developed new technologies, building on earlier work involving recombinant DNA. These technologies act like DNA scissors, cutting the double helix at specific locations for gene addition, correction, and disruption. Sangamo BioSciences received FDA approval in early 2015 to conduct a safety and feasibility clinical trial of one such method, Zinc Finger Nucleases, in patients with HIV-1.[28]

CRISPR-Cas9, the newest technology to be used in this way, is the most efficient and accurate yet and the least expensive by far. The Cas9 enzyme, which acts as the scissors, is accompanied by a *guide RNA*—a small, synthetic RNA strand that directs the Cas9 to cut at a specific genomic site. Cells then repair the cut using a synthetic DNA template with the correct sequence. Theoretically, modifying the sequences in the guide RNAs will cause the system to target any site of interest, allowing it to correct the genetic causes behind many diseases. Major questions remain, however, concerning the specificity and safety of these gene-editing tools, including CRISPR-Cas9, for therapeutic applications.

Into this context came the paper from Liang, *et al.*, in *Protein & Cell*.[29] The researchers reported that they had used CRISPR-Cas9 to modify the genome of human embryos (albeit embryos that were defective and not viable) to target the gene that causes beta-thalassemia, an inherited blood disorder affecting the ability of red blood cells to transport oxygen. The team reported relatively poor results. The genetic modifications were successful in 4 of 54 tested embryos; in those, the gene repair was only partial, and many of the edits were at unintended sites (off-target). The research team concluded that the clinical use of CRISPR-Cas9 was premature.

C. The Community Response

Nevertheless, the study unleashed a firestorm. It put two contentious issues under the spotlight on the same stage: conducting research on human embryos and manipulating a gene that could be passed on to future generations. Groups of prominent scientists convened meetings to discuss the appropriate response. They issued papers and statements. Website and blogs posted interviews and debates. Most have urged restraint and called for a self-imposed moratorium.[30] Some have questioned whether such experiments should ever be conducted, now or in the future. A few have responded by stressing the importance of eliminating human suffering over yielding to fear. Others have argued that the ability to perform genetic engineering safely is years away and that research toward that goal should proceed. Eric Lander, the lead author of the paper that published the results of the Human Genome Project, commented: "It has been only about a decade since we first read the human genome. We should exercise great caution before we begin to rewrite it."[31]

In light of the widespread and easy access to CRISPR-Cas9 technology, and in response to both the technical challenges and the newly pressing concerns about future genetic modifications affecting the germline, the National Academy of Sciences will hold an Asilomar-like conference—by invitation only—to discuss whether limitations should be placed on the research.[32] Francis Collins, Director of the NIH, promptly issued a statement declaring that already existing regulations blocked federal funding of work that had the goal of modifying the germline and that no applications for such funding would be considered at this time.[33]

D. Current Legal Framework

As the table that accompanies this article shows, the existing legal framework should ease some fears of imminent applications of genomic editing with the intent to create a baby. Federal law blocks such funding on two fronts. First, as the recent research by the Chinese group showed, CRISPR-Cas9 currently poses risks to the embryos it seeks to modify and thus violates the Dickey-Wicker Amendment. Second, because the CRISPR-Cas9 system involves recombinant DNA, its use is regulated by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)[34] and therefore comes under the authority of the Recombinant DNA Advisory Committee (RAC) at the federal level and the Institutional Biosafety Committees (IBCs) at the institutional level. In Appendix M, the Guidelines provide that:

> RAC will not at present entertain proposals for germ line alterations but will consider proposals involving somatic cell gene transfer. The purpose of somatic cell gene transfer is to treat an individual patient, e.g., by inserting a properly functioning gene into the subject's somatic cells. Germ line alteration involves a specific attempt to introduce genetic changes

> into the germ (reproductive) cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring.

The Guidelines would also restrict New York research involving genomic editing. Not only are they explicitly applicable to any institution that receives any federal funding for the kind of work the Guidelines regulate (and all but a few of the 35 institutions that NYSTEM has funded receive such funding), but New York State immediately acted independently to require all New York based researchers to adhere to the Guidelines.[35] NYSTEM contracts also require compliance with the Guidelines. But NYSTEM funds, which are not subject to the Dickey-Wicker Amendment, can be used for research involving *in vitro* modification of embryos, so long as approval is obtained from the institution's IRB, SCRO and IBC.

As with reproductive cloning, however, nothing in federal law prevents researchers or clinicians with private funds in private clinics from attempting to edit the genome of an embryo and with it to create a child. A House Appropriations subcommittee responsible for FDA funding released a bill in June 2015 to ban the FDA from using public funds to evaluate applications for clinical trials involving genetically modified human embryos.[36] Other efforts to rein in the perceived risk of this research may follow. The question, then, is whether the new technology requires as strong or even a stronger legal response than research using human ESCs, or human cloning, or any other technique or biotechnology that has come along. Even if it does, could it succeed in stopping such experiments or is germline engineering inevitable?[37]

E. Ethical Considerations

The current use of CRISPR-Cas9 to create a child is unsafe and, at a minimum, a voluntary and temporary moratorium is appropriate. But the technical obstacles may with time be overcome,[38] and it is not too soon to consider whether genomic editing should ever be permissible. Genomic editing poses unique ethical challenges that fall roughly into two categories. The first, which concerns the use of embryos that could be injured in the process, raises the same or similar issues as hESC research and will not be the focus of this discussion. The second stems from the fact that any germline changes will affect future generations that will not be given an opportunity to consent to the modifications, which may be irreversible.

Proponents of genomic editing to create a child fall into two overlapping camps. The first points to the many genetic diseases that could be prevented, like Huntington's and sickle cell disease,[39] curing not only the child, but also the child's descendants. The second camp points to the possibility of improving the human species, and by extension the world we live in, by engineering children with genes for traits such as superior intelligence, greater creativity, and heightened empathy.[40]

Critics contend that neither of these benefits outweighs the moral costs. First, they argue that the medical case for genomic editing is not strong. Promising research that does not include genomic editing is underway to cure many genetic diseases, although without genomic intervention the cure cannot be passed down to future generations. Many heritable diseases can already be prevented by preimplantation genetic diagnosis (PGD),[41] which uses IVF to create embryos, from which cells are removed and analyzed for genetic defects. But PGD, like IVF, requires the creation of more embryos than are needed and, as with all assisted reproductive technologies, there is evidence from animal models that *in vitro* manipulations can affect the offspring. Those who object to genomic editing because of the use of embryos will not view PGD as an ethical substitute, and it too is outlawed in some jurisdictions and highly regulated in others. Nonetheless, thousands of couples have benefited from PGD, although there will still be some couples who cannot produce an embryo free of disease.[42] For these couples there is currently no known way to give birth to a genetically related disease-free baby. Those who object to genomic editing argue that these benefits are too small and that such couples have other options not including medical intervention, which better serve society as a whole.

Some opponents of the technology for the purpose of improving human beings think that genetic enhancements come at too high a moral cost; others believe that even attempting to genetically engineer future generations is unethical. Some of the first group's objections are based on principles of distributive justice, that permitting the wealthy to make genetic selections for their children will give them even greater advantages over those who cannot, creating an unalterable two-class society that will finally lay to rest the American Dream. Supporters of genetic engineering answer that societal inequalities existed before the availability of these new technologies, are not a product of these technologies, and should be addressed directly.[43] Some have even suggested government subsidies for those who cannot pay for the technology themselves.

The concerns of the second group, which believes that genetic engineering is itself immoral, are harder to express and harder to answer. The argument is that choosing children's traits without their consent undermines their dignity and autonomy by commodifying them. Planning a child would become more like ordering up a

new car. Would society put limits on acceptable modifications? Would there be a limit on the extent to which a parent could impose their preferences and biases on another human being? Should we allow the prejudices of today to mold the genomes of future generations? Those who oppose genetic engineering also argue that designing the genome of children endows a degree of power over those children that may forever alter the human family. Michael Sandel argues that children would be a product of our will rather than a gift we receive, beings we control rather than cherish.[44] Supporters argue that parents have always tried to mold their children—with math tutors and piano lessons, compulsory church attendance and private schools. What makes genetic modification different?

Finally, the critics claim, genomic editing faces an insuperable problem: the people affected can never consent to the use being made of them; they face the risks of genetic engineering, but have no say about whether they want to participate.[45] On reflection, however, this worry too may be misplaced. Louise Brown did not consent to be the first "test tube baby," nor was there consent from any child created by IVF. But while IVF has its detractors, few think that IVF should be banned for that reason. No child consents to being created, yet many will face great hardships. What matters morally is whether they are subjected to undue risk. If genomic editing can be done safely, then the fact that its subjects cannot consent may not be determinative.[46]

These are difficult ethical questions. At this time it is almost impossible to separate them from the safety concerns. In the continuing conversations, and as the technology advances, they must be reassessed regularly.[47]

III. Going Forward

The central question is no longer whether there should be a voluntary moratorium on genomic editing to create a child. Even though the NAS has not yet held its meeting, the majority of scientists and bioethicists who have spoken out have already declared a moratorium, although one limited to germline modification. It is important to remember that the proposed moratorium would not preclude the work done by the Liang team in China, which never intended to implant the altered embryos. While there have been calls for a moratorium on all gene editing of embryos, whether to produce a child or for *in vitro* experiments in the lab, the consensus seems to be that *in vitro* research should continue. The ISSCR, the largest and most recognized international association of stem cell scientists, has called only "for a moratorium on attempts to apply nuclear genome editing of the human germ line in clinical practice."[48]

The fact of the self-imposed moratorium does not mean that all the issues have been resolved. Credible arguments have been made on both sides. Commentators have pointed out that a moratorium, in addition to giving needed time to debate the ethics, would also generate good will. It would demonstrate to the public that the scientific community is proceeding responsibly, and it may forestall congressional involvement. To fully achieve these potential benefits, however, more time is needed to hear from dissenters—both those who favor a broader moratorium and those who favor none.

The central question now is whether there is a need for a more restrictive response than a self-imposed moratorium. Is there a way to create a more effective deterrent? A moratorium will already deter those who view themselves as members of the scientific community and hope to have their work recognized by it someday. Are there others who do not care about community approbation, but who have the necessary skills and means to carry out such work? Should society's prohibitions be geared to the most egregious and unpredictable offenders?

George Daley, one of the researchers who sounded the alarm on genomic editing, told the *New York Times* that a deranged desire for world acclaim sometimes prompts people to attempt forbidden acts, acts like human reproductive cloning or implanting a modified embryo in a uterus.[49] Henry Greely, a professor at Stanford Law School, commented that only the criminally insane would attempt such an act at this time in light of the obvious dangers. If they are right, can society deter such actors?

Clearly, no law will deter everyone. It is unlikely that a renegade scientist will be more effectively deterred by the laws of general society than by the laws of the relevant professional community. Furthermore, does it make sense for Congress to legislate the practice of scientific investigation? In our highly politicized and ideologically driven system, can Congress be relied on to get it right?

The strength of our current regulatory system, cumbersome and sometimes random as it is, is that it should allow the flexibility needed to respond to scientific advancement. American laws, however, are notoriously difficult to change. If open discussion and debate is the best way to resolve the ethical challenges of an evolving field, nothing will stop that faster than a legislative prohibition. Despite the alarm generated by the first report of an *in vitro* attempt to modify the genome of embryos, and given the potential dangers of *in vivo* experiments, the response so far has been rational, appropriate and considered. We should allow it to continue.

Creating Human Embryos and Using Embryonic Stem Cells for Research				
TECHNOLOGY	FUNDING SOURCE	PERMISSIBILITY PER LAW/ REGULATIONS/ CONTRACT	OVERSIGHT REQUIRED	VOLUNTARY GUIDELINES (regardless of $ source)
Research using embryonic stem cells	Federal	Ok, if listed in NIH human ESC registry	IRB FDA*	NAS and ISSCR—limited oversight by [E]SCRO and IRB
	NYSTEM	Ok	IRB / SCRO FDA* & OP	
Derivation of new embryonic stem cell lines for use in research	Federal	No per D-W		NAS and ISSCR—Full [E]SCRO review
	NYSTEM	Ok, by whatever means derived	IRB / SCRO FDA* & OP	
Creating embryos by IVF for use in research** ±	Federal	No per D-W		NAS and ISSCR: OK up to lesser of 14 days or primitive streak (earliest development of nervous system)
	NYSTEM	Ok	IRB / SCRO FDA* & OP	
Creating embryos by SCNT for use in research (therapeutic cloning)	Federal	No per D-W—no creating embryos		NAS and ISSCR: Ok up to lesser of 14 days or primitive streak
	NYSTEM	Ok	IRB / SCRO	
Donation of oocytes to research for embryo creation (IVF or SCNT)	Federal	No per D-W—no creating embryos		NAS: compensation only for direct expenses incurred as result of procedure ISSCR: With SCRO, additional comp ok but NOT for number or quality of eggs; should not constitute undue inducement ASRM: comp for time and burden, regardless of successful retrieval or number of eggs
	NYSTEM	Ok, and ok to compensate donors with state funds for costs plus for associated time and burden	IRB / SCRO	
SCNT for reproduction (reproductive cloning)	Federal	No per D-W but no across-the-board ban		NAS: should not be conducted at this time. ISSCR: given current scientific and medical safety concerns, reproductive cloning should be prohibited
	NYSTEM	No— Use of NYSTEM funds prohibited. PHL § 265-a (2). Willful violation of any provision of PHL is misdemeanor PHL § 12-b. Penalties up to 1 year imprisonment and $2,000		

Modifying Human Embryos				
TECHNOLOGY	FUNDING SOURCE	PERMISSIBILITY PER LAW/ REGULATIONS/ CONTRACT	OVERSIGHT REQUIRED	VOLUNTARY GUIDELINES
Mitochondrial donation / transfer ≠	Federal	Under study by IOM and FDA ≠≠ D-W prohibits—risk to embryo		ISSCR—YES, with SCRO NAS—under review
	NYSTEM	Ok	IRB / SCRO FDA	
Editing genome of embryos in vitro (solely for research)	Federal	No per D-W		ISSCR—June 2015 draft Guidelines for Stem Cell Science and Clinical Translation support such research, with proper oversight
	NYSTEM	Ok	IRB / SCRO / IBC	
Editing genome of embryos for implantation	Federal	No per D-W and NIH Guidelines on Recombinant DNA	These entities would have oversight if such work planned or attempted: IRB / SCRO / IBC / RAC FDA* & OP	June 2015 draft Guidelines prohibit and call for broad public and international dialogue on genome-editing technologies and rigorous deliberation on ethical, legal and societal implications of modifying human germ line NAS—supports moratorium and organized discussions
	NYSTEM this applies to any work conducted in NYS, however funded, including privately	Probably not at this time NIH guidelines apply to any institution receiving federal funds for research using recombinant DNA NYS PHL § 3222 requires certification and adherence to NIH guidelines for recombinant DNA work. Willful violation of PHL § 3222 would constitute misdemeanor		

* for use in clinical trials.

± Canada—criminal penalties apply.

** IVF for individual reproductive purposes is legal both federally and in NYS and is regulated as a medical procedure.

≠ UK—approved February 24 2015. The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015; www.legislation.gov.uk/uksi/2015/572/contents/made (effective 29 October 2015).

≠≠ U.S. Food and Drug Administration, Cellular, Tissue and Gene Therapies Advisory Committee Meeting: Announcement, www.fda.gov/AdvisoryCommittees/Calendar/ucm380042.htm; www.iom.edu/activities/research/mitoethics.aspx.

Abbreviations

ASRM	American Society for Reproductive Medicine
D-W	Dickey Wicker Amendment
ESC	Embryonic Stem Cell
ESCRO	Embryonic Stem Cell Research Oversight
FDA	Food and Drug Administration
IBC	Institutional Biosafety Committee
IOM	Institute of Medicine
IRB	Institutional Review Board
ISSCR	International Society for Stem Cell Research
IVF	in vitro fertilization
NAS	National Academy of Sciences
NIH	National Institutes of Health
OP	NYSTEM's Independent Oversight Panels, applicable to NYSTEM Consortia awardees
PHL	New York State Public Health Law
RAC	Recombinant DNA Advisory Committee (NIH)
SCNT	Somatic Cell Nuclear Transfer
SCRO	Stem Cell Research Oversight

Endnotes

1. Puping Liang, et al., *CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes*, PROTEIN & CELL 6 (May 2015): 363-72.
2. We use the term genomic editing to mean editing the genome that affects the germline.
3. James Thomson, et al., *Embryonic stem cell lines derived from human blastocysts*, SCIENCE 282 (1998): 1145-7.
4. Typically, embryos used for derivation of embryonic stem cells are created by *in vitro* fertilization and are in excess of clinical need, i.e., the patients no longer need or want them for reproductive purposes.
5. See http://www.eurostemcell.org/stem-cell-regulations.
6. Severe combined immunodeficiency (SCID), or "bubble boy disease," is a disorder that renders the immune system unable to fight off infection. The term "bubble boy disease" refers to David Vetter, a boy with SCID who lived for over a decade in a plastic bubble that protected him from germs.
7. Graft-versus-host disease (GVHD) occurs after bone marrow or stem cell transplants when the newly reconstituted immune cells mount an attack on the patient's body.
8. 42 U.S.C. § 298g-1(b)(2)(A)(i).
9. Public Health Services Act, Title 42 United States Code, Chapter 6A.
10. National Academy of Sciences, *Guidelines for Human Embryonic Stem Cell Research* (NAS Press, 2005), chapter 2.
11. ISSCR, *Guidelines for the Conduct of Human Embryonic Stem Cell Research*, http://www.isscr.org/docs/default-source/hesc-guidelines/isscrhescguidelines2006.pdf.
12. Executive Order 13505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, http://www.gpo.gov/fdsys/pkg/FR-2009-03-11/pdf/E9-5441.pdf.
13. *Sherley v. Sebelius*, ("*Sherley VI*"), 689 F.3d 776, 785 (D.C. Cir. 2012), aff'g 776 F. Supp. 2d 1 (D.D.C. 2011).
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16. Masahito Tachibana, et al., *Human embryonic stem cells derived by somatic cell nuclear transfer*, CELL 153 (2013): 1228-38.
17. Mitsutoshi Yamada, et al., *Human oocytes reprogram adult somatic nuclei of a type 1 diabetic to diploid pluripotent stem cells,* NATURE 510 (2014): 533-36.
18. Empire State Stem Cell Board, Resolution of the Funding Committee Regarding Recommended Standards For the Compensation of Women Donating Oocytes Solely for Research Purposes, June 11, 2009, http://stemcell.ny.gov/node/226. See also Beth Roxland, *New York State's landmark policies on oversight and compensation for egg donation to stem cell research*, Regen. Med. (2012) 7(3) 397-408.
19. *Feminists Choosing Life of New York, Inc. v. Empire State Stem Cell Board*, 87 A.D.3d 47, 926 N.Y.S.2d 671 (3d Dept.), leave denied, 18 N.Y.3d 801, 938 N.Y.S.2d 858 (2011).
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21. Theodore Friedmann, *Stanfield Rogers: insights into virus vectors and failure of an early gene therapy model*, MOLECULAR THERAPY 4 (2001): 285-8; Cormac Sheridan, *Gene therapy finds its niche*, NATURE BIOTECHNOLOGY 29 (2011): 121-8; Gerhard Bauer and Joseph S. Anderson, Gene Therapy for HIV (Springer-Verlag New York, 2014), chapter 2: *History of Gene Therapy*.
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23. Magid H. Amer, *Gene therapy for cancer: present status and future perspective*, MOLECULAR AND CELLULAR THERAPIES 2 (2014): 27.
24. Revolution in Progress: Human Genetics and Medical Research, http://history.nih.gov/exhibits/genetics/sect4.htm, Gene Therapy.
25. Sheryl Gay Stolberg, *The Biotech Death of Jesse Gelsinger*, NEW YORK TIMES, Nov. 28, 1999.
26. Of current trials in gene therapy most are in phase I clinical trials (60%), followed by phase II clinical trials (35%), and only a very small fraction are in phase III clinical trials (5%). About 65% concern cancer. Brendan Lee and Beverly L. Davidson, *Gene therapy grows into young adulthood: special review issue*, HUMAN MOLECULAR GENETICS, 20(2011): R1.
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31. Eric Lander, *Brave new genome*, NEW ENGLAND JOURNAL OF MEDICINE B 373 (2015): 7.
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34. http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf.
35. New York PHL Article 32-A, NYCRR part 61.
36. House Fiscal Year 2016 FDA Appropriations Bill (H.R. 3049) & Report (H. Rept. 114-205), https://www.congress.gov/bill/114th-congress/house-bill/3049 and https://www.congress.gov/114/crpt/hrpt205/CRPT-114hrpt205.pdf.
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42. A couple cannot produce a disease-free embryo if one parent has two copies of an autosomal dominant disease gene or if both parents have an autosomal recessive disease.

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47. See note 30, *supra*.
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Navigating the Control of the Body in the Age of Biotechnology

By Randall Hirsch, M.D., J.D.

Synthetic organs, specific alteration of DNA targets, neurologically responsive mechanical limbs—these represent just a small selection of the advancements in medical technology and biologic science that we hear about every day. Technology that was only just science fiction a decade ago is now becoming more readily available to the public. This rapid growth in the state of biotechnology, and its associated profits, has created a demand for not only its products, but also its raw materials—human tissue.

An individual's rights in one's own body has been the subject of legal theory and philosophy ever since those concepts were developed, and touches upon almost all aspects of the law, including constitutional, property, torts, and criminal law, rights to autonomy and issues regarding personhood. Courts have used the rights to autonomy and liberty to determine cases such as abortion, marriage and slavery.

While the jurisprudence of bodily rights extends back for centuries, organ donation and transplantation are mere decades old while biotechnology is even younger. Consequently, the jurisprudence regarding bodily tissues, something less than the whole individual, is relatively new and has not yet been consistently defined. This article will propose a legal framework that not only comports to current law, but will also be adaptable to future cases even as medical science and biotechnology continue apace and issues become more complex.

I. Rights Analysis and Legal Framework

Medical technology and biological science have only recently advanced enough to make considerations about the rights individuals have in their own body parts and tissues while they are living, matter. While the potential issues involved encompass many aspects of the law, much of the case law in this area has been limited to the determination of an individual's property rights in one's own organs or tissues. Property rights analysis has been used as the legal analysis because "ownership is a precondition for (the standard forms of) economic transactions,"[1] and the cases under review usually deal with an individual's assertion of rights to profits or other economic interest in one's own tissues or organs.[2] However, while courts continue to mostly use (and state that they are using) a "property rights" analysis, property rights are not the only rights that they are analyzing.

A "right" can be defined as the legal recognition of the relative authority differential between an individual over oneself or objects versus the authority of all other individuals in that individual or object.[3] A right, therefore, encompasses the "bundle" of authority, control, ownership, etc. that an individual has in relation to any other individual.

An individual's "property" can therefore be described as the bundle of authority, control, or ownership an individual has in regard to a specific object versus those present in all other individuals.[4] This bundle includes the abilities to possess, manage, exclude, and sell the "owned" object.[5] In order for something to be considered property, it therefore needs to be external to the individual exercising rights over it.

On the other hand, the right of autonomy and/or individual liberty can be defined as the bundle of authority, control or ownership one has over himself or herself versus the bundle of authority, control or ownership all other individuals have over him or her. The bundle of authority and control in autonomy includes, for example, the ability to choose whether to take birth control, the prohibition against slavery, the choice not continue with a pregnancy, and enter into contracts or marriage. This right is essentially the ability to "dispose" of yourself free from any outside influence.

The difference between what is considered a right to "property" and what is considered the right to "autonomy," therefore, is that property is the bundle of authority an individual has over an object external to the body, while autonomy is the bundle of authority an individual has over himself or herself.[6] Whether a court should use property versus autonomy language, therefore, should be determined by the object being analyzed, not as an *a priori* determination of what "rights" will be involved.[7]

What rights an individual has in his own tissues (rather than the whole person/body), should therefore follow the same legal analysis. Tissues, organs, cells, etc. that are attached to the whole body, and in a way that is more than just a physical attachment (i.e., integrated so that they affect physiology), should be analyzed under the right to autonomy/individual liberty. For example, legal issues regarding an organ either before removal or after transplantation obviously deal with the individual's autonomy. A donated organ cannot be made to be "returned" to the

donor if contractual provisions are not met, like other property could, as someone's bodily integrity would have to be violated.

However, when removed from the body, tissues, organs, and cells should be analyzed as property as they are no longer part of the individual and have become an object outside of his or her own body. An individual does retain the complete bundle of authority in the tissues, organs, cells, etc. until his control is transferred to another, just like any other property would. For example, suppose you severed your finger. You have the right to have your finger reattached, which supersedes anyone else's right to dispose of your finger for other uses, such as for research, because it is "your" finger, your "property." You have the ultimate right to determine what happens to "your" finger unless you decide you do not want it reattached or dispose of it in another way.[8] This legal rights analysis not only is common sense, but also underlies, though not explicitly stated, the legal framework that has developed regarding body rights law.

II. Current Legal Framework and Application

A. Historical Common Law

English common law has never recognized a property right in a corpse or its parts.[9] This legal proposition was developed at a time when the body was valuable only after death, mostly for medical anatomy use, and the laws developed in order to protect against grave robbery, corpse desecration and unauthorized autopsies.[10] The use of organs for transplantation and harvesting of body tissues from living donors for use in medical science was not even dreamed of yet. The United States, in adopting the English common law, also has held that there are no property rights in a corpse or its parts, and courts commonly use this statement when analyzing cases regarding ownership of tissues and rights to profits.[11]

This holding does comport with the legal framework above. As with any autonomy rights consideration, third parties do not have any bundle of authority or control over another individual's body (or at the least, the individual's rights supersede those of all others). Third parties do not "gain" any additional rights over another's body just because they have died.

The only individual who would have possessed the bundle of authority over the corpse's tissues is the decedent, and he or she is not around to assert such rights against other individuals.[12]

B. Statutory

Whether it was from a reluctance to "violate the established normative view of the body as a sacred, inalienable object"[13] or to prevent "people [from becoming] slaves in a market for body parts or compromise the societal regard for bodily integrity,"[14] lawmakers prohibited the selling of organs for use in transplantation. This was codified in the National Organ Transplant Act (NOTA), which states, "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation…"[15] and New York Public Health Law Articles 43 and 43-a-, New York's Uniform Anatomical Gift Act (NYUAGA), which makes it unlawful for a person to "knowingly acquire, receive, or otherwise transfer for valuable consideration any human organs for use in human transplantation."[16]

These statutes are also consistent with the above legal analysis framework. Statutes like the NOTA are primarily public policy restrictions on selling of specific organs, such as the kidney, liver, heart, lung and pancreas;[17] organs, which, at the time of its drafting, required a deceased donor or were extremely hazardous to the donor to procure. As evidence of such, these statutes specifically do not prohibit the selling of sperm, ova, skin or blood, which can be considered renewable and more easily procured tissues. The statutory language is also written as a prohibition against the receipt or acquisition of the organs and tissues, not necessarily a prohibition upon the actions of the individual donor. These statutes, therefore, do not interfere with an individual's autonomy rights to *dispose* of his body as he sees fit, just the *receipt* of specific property, which can be and is regulated. The courts have upheld such property rights in sperm[18] and frozen embryos.[19] Furthermore, as medical science and biological technology advance, the selling of organs that are more easily procured and regenerate, like the liver or bone marrow, may be allowed.[20]

C. Recent Case Law

Two cases, *Moore v. Regents of Univ. of Cal.* and *Greenberg v. Miami Children's Hospital Research Institute, Inc*., are frequently cited for the proposition that an individual does not have "property rights" in his or her own tissues.

In *Moore v. Regents of Univ. of Cal.,* John Moore underwent treatment for hairy-cell leukemia at UCLA Medical Center.[21] Moore's doctors recommended the removal of his spleen and other tissues. However, before the surgery, Moore's doctor and an outside researcher made an arrangement to study and do research on Moore's removed tissues. No one told Moore of the proposed research before he signed his informed consent for the surgery. After the surgery, Moore was told to return to UCLA to have blood, serum, bone marrow and other tissues removed, based upon representations Moore's doctor made that they were necessary for his treatment. From these removed tissues, Moore's doctor established a cell line and

eventually applied for and received a patent. Moore's doctor then negotiated several commercial agreements for the development of the cell line and various products derived from them. Moore was not aware of the development of the cell line from his tissue until the patent was applied for. The cell-line derived from Moore's tissues had generated several billions of dollars of profit for the researchers.[22] He brought suit against his doctors and the medical center for conversion and other causes of action. The California Supreme Court dismissed Moore's conversion claim because, "[f]irst, no reported judicial decision supports Moore's claim [that he had a continued property interest in his excised cells]…[s]econd, California statutory law drastically limits any continuing interest of a patient in excised cells…and [t]hird, the subject matters of the [University's] patent…cannot be Moore's property."[23]

Conversion is a tort which requires possessory and ownership authority in the property.[24] Moore claimed he continued to retain authority over the use of his cells "following their removal from his body" (of which removal he had agreed to).[25] The *Moore* court held that a conversion action could not be maintained because, as "for purposes of determining whether the tort of conversion lies…only property can be converted,"[26] and Moore ceased to have a continued possessory interest in his tissues.[27] However, the court did not state that Moore did not have a possessory interest in his tissues at any point, as in no way "did [it] hold that excised cells [could] never be property for any purpose whatsoever…."[28] Far from a finding that there is no property right to tissues, the court only held that there is no continuing property right in tissues that have been transferred to a third party. This holding comports with any other property analysis. For example, a seller of a car to a buyer would have no interest in the profits from a future sale that the new buyer would receive once he sells it to a third party.

The *Moore* court did hold that the actions of Moore's physician, in having a conflict of interest, was a violation of Moore's informed consent. This informed consent violation is a recognition that Moore's right to autonomy was violated by interfering with his bundle of control and authority over the disposition of his own tissues through fraud.

The *Moore* case, therefore, follows the legal analysis framework above. Moore's rights to autonomy, his rights over his tissues when they were attached to his body, were violated in a fraudulent inducement in their removal. However, Moore's property rights to his tissues, once they were removed, were not violated—he had no right to the continued economic interest in them after he knowingly and willingly transferred them to a third party.

In *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, a parent of a child afflicted with Canavan disease approached a research physician to help in discovering the genes responsible for the fatal disease.[29] Other Canavan families were contacted and convinced to provide tissue samples and financial support. The researcher and his team made a breakthrough and successfully identified the causative genetic sequence. Unbeknownst to the families, the researcher applied for and received a patent on the genetic sequence. The patent holders then began restricting accessibility to the genetic testing by negotiating exclusive licensing agreements and royalty fees. The families brought suit against the researchers as it was their understanding that any discoveries "would be provided on an affordable and accessible basis, and that [the] research would remain in the public domain to promote the discovery of more effective… treatments and, eventually,…a cure…."[30] The court declined to find "a property interest for the body tissue and genetic information voluntarily given to Defendants,"[31] and plaintiff's claims for breach of informed consent and conversion were dismissed.[32]

However, the *Greenberg* court did uphold the plaintiffs' cause of action for unjust enrichment. Unjust enrichment requires that "the plaintiff confers a benefit on the defendant…."[33] The court did recognize a property right in the tissues in the plaintiffs as, in order to confer a benefit, something of value must have first been transferred to the defendants and the plaintiffs must have first had the right to control and dispose of the property.

The *Greenberg* holding also follows the legal analysis framework above. The plaintiffs and their families knowingly and intentionally underwent removal of their tissues, so there was no violation of their autonomy rights (informed consent). The plaintiffs also freely transferred the property to a third party, so they could not have any continued economic interest in their tissues (conversion). However, there was a question of fraud in the inducement of transferring the property to the researchers, which was a violation of their property rights (unjust enrichment).

III. Issues in the Age of Biotechnology

A. Profits

As medical science and biotechnology advance, application of the legal analysis framework above should be able to help attorneys and courts reevaluate issues and resolve issues that heretofore may not have been addressed.

It is well known that human tissues are a highly lucrative source for creating products such as cell lines, grafts and transplant organs.[34] Tissue samples from blood tests, biopsies, operations and other routine procedures are commonly retained, collected and stored.

These samples are then routinely sold to other hospitals, researchers, governments and universities for their own research, the products of which also may be commercialized.[35] The holdings of *Moore* and *Greenberg* partially were in response to the highly lucrative business of cell lines and tissue samples in medical research.[36] But why shouldn't the "producer" of these tissues be compensated accordingly? If tissues for research are valuable after they are removed from his body and can be sold by others, how can their intrinsic value and ability to be sold be any different before they are excised?[37] Consider the case of Henrietta Lacks, whose tissue samples were removed, without her consent, to create the first "immortal" cell line. Her cells have played a major role in the understanding and treatment of diseases like AIDS, cervical cancer, flu, herpes, Parkinson's, polio vaccine, radiation, and gene mapping,[38] and since Henrietta's death, "scientists have cultivated over twenty tons of her cells and obtained nearly 11,000 patents involving the HeLa line."[39] These breakthroughs derived from Henrietta's cells have enabled researchers to earn billions of dollars,[40] even though her family never saw any of the profits, and her descendants had often gone for years without health insurance.[41]

Under the legal framework above, an individual needs to contract for any potential economic interest that his tissues would generate before transferring them to a third party as you would with any other property. Unfortunately, if the physician has no plans to use the tissues for any research at the time of extraction and/or the informed consent is constructed "in the broadest possible terms, to any conceivable subsequent research use of excised cells,"[42] an individual does not have any legal recourse. It therefore would require an act of the legislature, under public policy reasons, to allow an individual to have a continued economic interest in his or her tissues. Furthermore, with the *Myriad*[43] decision and the limiting of patentability of body tissues, coupled with the increasing ability to create synthetic DNA/molecules, excised tissues may be becoming less and less valuable, making this issue moot.

B. Organ Donation

The prohibition against selling of organs will need to be reevaluated. Currently there are 122,425 people in need of a lifesaving organ transplant, and each day 22 people die waiting for an organ transplant.[44] Medical advancements now have made possible the donation of organs, like the liver, from living donors and the extraction of tissue, like bone marrow stem cells, in much less complicated and painful manners. As these techniques become more readily available, the laws and public policies prohibiting the selling of organs should be modified to better conform with individuals' rights to control of their own bodies.

C. Medical Technology

Advancements in medical science and biological technology could redefine what it means to be human. The difference line between what is external to "us" and what is "us" will become blurred as technology is increasingly being able to augment and replace human physiology. Limb replacements now are directly wired into the brain. Organs can be grown from stem cells outside the body. Legal issues regarding these new technologies will be the subject of court cases and laws in the near future.

If an individual's rights to autonomy are elicited in an analysis of rights regarding the removal of his tissues or organs that are part of his body, then the same autonomy analysis should be undertaken in regard to a transplanted (received) organ, synthetic tissue, or technology that affects his physiology (i.e., is now part of his body). If an individual's property rights are elicited in an analysis of rights regarding the transfer of tissues or organs that are already removed from his body (no effect on physiology), then the same property analysis should be undertaken in regard to a received mechanical addition, synthetic addition or augmentation that does not affect his physiology.

To illustrate, scientists say they will soon be able to transplant a head onto a new donor body.[45] What rights would the head have in the donor body? What should a court be able to decide if someone shot the body and the head died? Most people would consider it common sense that since the "head" died, it would be murder, not property damage. This holding follows the legal analysis above as the destruction of the body causing the death of the head implicates the same autonomy rights' violation as any other murder would.

However, in a more subtle situation, a quadriplegic had a mechanical augmentation that helps him walk, but also managed his blood pressure.[46] Destruction to this mechanical augmentation was held to be property damage only. Compensation for property damage only takes into account the value of the destroyed property. However, under the legal analysis above, as the augmentation affected his physiology, the damage should have been considered a personal injury, which would have allowed for damages for pain and suffering. As the use of such augmentations increases, with associated legal issues, courts will hopefully see the inconsistency in holding that such damage is to be analyzed under a property rights analysis only.

IV. Conclusion

Medical science and biological technology are advancing at an increasing pace. Legal issues regarding situations and technology that lawmakers have not yet even thought of will have to be addressed. Despite claims to the contrary, individuals do have rights to their own bodies and their own tissues. These rights are the result of the differential of authority between an individual versus others over the individual himself or herself or an individual's excised tissues. Applying the appropriate legal analysis when determining rights of the body and connected tissue will hopefully help guide courts and lawyers to make the proper decisions for whatever issues may arise.

Endnotes

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23. *Moore*, at 137.
24. *Id.* at. 134.
25. *Id.*
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28. *Id.* at 142; this was also reaffirmed in *Colavito* 8 N.Y.3d at 53 ("Considering, however, that the 'no property right' jurisprudence was developed long before the age of transplants and other medical advances, we need not identify or forecast the circumstances in which someone may conceivably have actionable rights in the body or organ...").
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Genomics and the Law: An Overview of Privacy, Data Sharing, Ethical Issues and a Shifting FDA Paradigm

By Samuel J. Servello, J.D., LL.M.

The study of genomics is becoming increasingly important in science, medicine and drug discovery. In order to advise their clients, many attorneys seek to understand the legal framework around genomic science in both its research and clinical applications. This article is meant to assist attorneys in understanding the basic terminology and biology of genomics as well as the importance of genomics in the legal context. The genomic terminology an attorney may encounter that is defined in this article has been written in ***bold type and italized***.

Part I **(Biology and Terminology)** of this article will begin by explaining the basics of genomic biology and terminology that will be helpful for attorneys to understand in advising clients in this area.

Part II **(Growing Importance)** explores the meteoric rise in genomics and its growing importance in science, medicine and drug development.

Part III **(Privacy Law)** discusses the application of privacy law to genomics. This discussion focuses on U.S. and New York State law.

Part IV **(Data Sharing)** discusses the barriers to sharing genomic data and some of the efforts to create an environment in which genomic data is more openly shared.

Part V **(Ethical Issues)** discusses some of the ethical issues that are presented by the emergence of genomic technology.

Part VI **(FDA and NGS Tests)** discusses the FDA's approach to the approval of tests utilizing next generation sequencing and the shifting paradigm necessitated by such new technology.

Part VII **(Criminal Justice; Patent Law)** touches on the use of DNA in the criminal justice system as well as the patentability of genetic information.

Through genomic information one can discover the diseases to which an individual and his or her close relatives are predisposed. On a larger scale, genomic information may unlock the mystery of diseases while finding novel treatments or assisting in new methods of diagnosis.

I. Basic Genomics Biology and Terminology for Attorneys

The following is a review of the basic biology and terminology an attorney may encounter when discussing genomic science. At the very foundation of this discussion is DNA. Each cell of the human body contains strands of deoxyribonucleic acid ("***DNA***"). The DNA strands in a cell, when taken together, is referred to as the human genome.

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DNA is made up of specific molecules made famous in popular culture by the Ethan Hawke, Uma Thurman movie *GATTACA*. The nucleotides (Guanine, Adenine, Thymine, and Cytosine) are the basic building blocks of DNA. A "***gene***" is a series of nucleotides along the length of a DNA strand. Within the double stranded DNA, each nucleotide on one strand is paired with a complementary nucleotide on the other. There are approximately 3 billion base pairs in the DNA of one human cell. The DNA is distributed across 23 pairs of the chromosomes, one set of 23 chromosomes from the individual's mother and one set of 23 from the individual's father. There are approximately 20,000–25,000 genes that code for a protein.[1]

Genomics has certain basic terminology with which an attorney working in this area should become familiar. "***Sequencing***" is a technology that allows scientists to determine the specific order of nucleotides in a region of the genome. An attorney working in this area will encounter the concept of "***whole exome sequencing***" versus "***whole genome sequencing***," described below. Through processes known as transcription and translation, the human body is able to "read the code" in the series of nucleotides in genes and convert what it reads into proteins that serve certain functions in the body.

DNA is transcribed to another molecule called ribonucleic acid ("RNA"). Genes are divided into "exons" and "introns." Transcription produces RNA from the exons, and skips the intronic regions in the genes.[2] Together the exons are called the "***exome***." The exome is approximately 1% of the entire genome. Importantly, it is the exome that contains the coding sections of the genome that are actu-

ally translated into a protein (i.e., approximately 99% of the genome does not code for any protein).

Therefore, when we talk about sequencing an exome (e.g., "whole exome sequencing"), we are talking about sequencing only those regions of DNA that code for and are expressed into proteins. Importantly, if the "code" found in DNA is faulty in some way and the protein that is produced by that code (e.g., the code for the production of an enzyme in a biological pathway, or a regulatory hormone, etc.) does not perform its normal function, the body as a whole may not function properly, causing illness. This causative link between faulty genetic coding and disease is the basis for the increasing importance of genomic data, and is important to our discussion of "precision medicine," discussed more fully below.

The distinction between whole genome sequencing and whole exome sequencing is effectively what it sounds like. In the former, only the "exome" is sequenced. In the latter, the entire genome is sequenced. Whole genome sequencing gives researchers information about non-coding regions and may lead to important discoveries, such as the reason why some genes are turned on while others are not, or other clues to gene activity and protein production that lead to genetic disorders. In legal application, these concepts are important when discussing data sharing, privacy and ethical concerns.

Sequencing a genome allows researchers to discover the specific variants in that person's DNA. The term "***variant***" implies an observation of a variation between two separate coding regions of a genome. In the case of genomic analysis, variants are observed in the comparison of the genome being analyzed and some other genome, called the "***reference genome***." Scientists first read the sequence of the nucleotides in the genome being analyzed by sequencing the DNA and then compare that sequence with the nucleotides in a reference genome. In most instances the "reference genome" is the genome built by the Genome Reference Consortium.[3]

On average whole genome sequencing can detect over 3 million variants in one human genome (i.e., out of the 3 billion base pairs).[4] This is the coding that makes each of us unique. When there is a change in a single nucleotide (e.g., the nucleotide on the DNA being sequenced and analyzed is, for example, guanine, but in the reference genome the nucleotide in that position should be an adenine) this is called a "***single nucleotide polymorphism***" or a "***SNP***" (often pronounced "snip"). In the privacy context, it is these variants or SNPs that may be used to identify an individual. Therefore, these variants will play a role in the discussion of privacy concerns below as well as clinical application of genomic science.

Another instance where variants play an important role is in the comparison of the DNA found in a tumor cell and the DNA found in a healthy cell in the same individual. The goal is the understanding of the genetic causes of the cancer in that individual by locating where the nucleotide sequence in the tumor cell DNA varies from that in a healthy cell.

The terms "***phenotype***" and "***genotype***" may also enter the negotiation of a contract involving genomic information. Importantly, "phenotype" does not always mean identifiable information. As described above, our DNA contains "code" that is used by our bodies to build the proteins that become our observable traits (e.g., hair color, eye color, skin color, etc.). The genotype may contain code for more than one trait but due to the dominance of one of the traits, it is that dominant trait that is expressed. The "code" in our DNA is the "genotype" and the observable traits are the "phenotype." While certain phenotypic information (e.g., a face, fingerprint or other biometrics) would be considered "identifiable health information" under HIPAA (discussed below), most phenotypic information would not be identifiable by itself (e.g., a disease state described by a red blood cell count, etc.).

A. Clinical vs. Research Uses of Genomic Data

It is helpful for an attorney to understand the difference between the use of genomic information in a research context and a clinical context. The main difference is whether the resulting genetic and bioinformatics analysis is specific to an individual versus to a cohort of individuals that share a particular common trait or disease. The reason for conducting the analysis in the clinical context is to deliver diagnostic and treatment information to a treating healthcare provider, while in the research context, the researcher is conducting a genetic analysis to explore a scientific hypothesis that is independent of diagnosis or treatment for any one individual. In the clinical context, the resulting analysis is ultimately shared with the patient by the healthcare provider. In the research context, however, the individual human subjects generally are not informed of the results of the analysis (see Part V regarding discussion of disclosure of incidental findings).

Where health results specific to an individual are given to such individual, the tests that create those results must be first shown to be accurate, being validated analytically or clinically. The U.S. Food and Drug Administration ("FDA") regulates ***in vitro diagnostic products*** or ***IVDs*** (i.e., tests that can detect diseases, conditions, or infections).[5] Some tests are used in laboratories or other health professional settings and other tests are for consumers to use at home. The FDA has recently indicated its intent to extend its oversight to test developed by single laboratories referred to as laboratory developed tests

("***LDT***s").[6] Due to distribution of a kit to collect samples for genomic sequencing followed by its communication to the individual of health-related information derived from that sequencing by the web-based company 23andMe, the FDA issued a cease and desist letter, as the kit was not registered as a medical device and no information had been given to the FDA to ensure that the tests used to derive the health related information was validated analytically and clinically.[7] (See further discussion of FDA issues below in Part VI).

Significantly, under current law, only sequencing results from a Clinical Laboratory Improvement Amendments ("***CLIA***") compliant laboratory may be returned to physicians for diagnostic and treatment purposes.[8] In New York State, a lab that returns results must be a permitted lab under the New York State Clinical Laboratory Evaluation Program ("***CLEP***").[9]

II. The Rising Importance of Genomics

A. Short Timeline of Genomics

Gregor Mendel's experiments, between 1856 and 1863, revealed how traits are passed down from parents. He is considered the father of modern (Mendelian) genetics. Through the pioneering efforts of scientists such as Rosalind Franklin, James Watson, Francis Crick, Marshall Nirenberg, Frederick Sanger and other groundbreaking scientists, we have been able to gain a more thorough understanding of the structure and function of the fundamental building blocks of life. From 1990 to 2003 the National Institutes of Health and Department of Energy were involved in an international effort to map and sequence the whole human genome.[10] In April 2003, it was announced that the Human Genome Project had successfully mapped and sequenced the entire human genome.

Genomic research has grown rapidly since then, with a move toward translational research. "***Translational research***" has become a popular buzzword in the world of biomedical research. Basically the goal of translational research is to "translate" existing knowledge about biology into techniques and tools for treating human disease. Another phrase often used to describe translational research is "from bench to bedside." An example of translational research occurs where scientists discover that a certain variation in the DNA "code" is common in individuals with a specific disease. (See discussion of "genome wide association studies" or "GWAS" below in Part IV of this Article.) Where that occurs, it may be possible to determine the protein for which such variation codes. For example, the variation may code for a misshaped enzyme that cannot perform its function in the body. As a result, the patient may present with an illness correctable by finding a drug therapy to perform the function of that misshapen enzyme in the body.

"***Next Generation Sequencing***" (or "***NGS***") has had a tremendous impact on genomic sciences (n.b., this technology is sometimes referred to as "high throughput sequencing." For purposes of this article, the terms NGS or Next Generation Sequencing will be used.) Technology has become much faster in a very short time. The technology used by the Human Genome Project to sequence the human genome was Sanger sequencing (named after Frederick Sanger, the scientist who developed it), a very slow process that cost millions of dollars to sequence one whole genome. To sequence the first human genome cost $3 billion and took 13 years. In 2003 the cost was approximately $100 million to sequence each further human genome.[11] By 2007 the cost was reduced to the bargain price of $10 million per genome but obviously still cost-prohibitive to move toward creating a large genomic database. Moreover, to sequence an individual's entire DNA using Sanger sequencing could take years. In 2007 a new technology was implemented called "Next Generation Sequencing." NGS has sped up the sequencing process, taking only days to weeks to sequence a human genome, while reducing the cost. In 2015, the cost of sequencing a whole human genome can be as low as $1,000-$3,000, depending on certain factors such as, the desired quality of resulting data, reagents used, the coverage of the genome, the instruments and other tools. Regardless of this variation in price, it is the dramatic reduction in cost in a very short period of time that is pushing genomics to the forefront, as data is gathered.

With the reduction in both cost and time to sequence a human genome, there is an ever-increasing amount of genomic data being produced globally. The size of these data is very large.[12] One researcher has stated that within the next decade, genomics is looking at generating somewhere between 2 and 40 exabytes a year. An exabyte is 10^{18} bytes of information.[13] With such a large pool of genomic data available, researchers are excited about the possibility of more in-depth scientific and medical research that may diagnose currently un-diagnosable diseases as well as create new drug therapy for diseases with no current course of therapy. President Obama's Precision Medicine initiative, described more fully below, aims to utilize this ever-growing pool of data.

Due to the large size of genomic data, individual laboratories at single institutions might not have the storage capacity to store the data or allow their researchers to manipulate that stored data. Therefore, there are vendors who are allowing researchers to upload that information onto the "cloud" (i.e., the vendor's servers) at a cost. This structure also allows the aggregation of data from multiple institutions for analysis by the researchers from such consortia, leading to faster discoveries.

B. Drug Development and Precision Medicine

Another example of "translational research" that has been in the news lately involves discoveries of variants in individuals with certain rare characteristics. If scientists determine the genetic basis for those desirable characteristics, such genetic understanding can also be developed into drug therapy. For example, on July 24, 2015, the U.S. Food and Drug Administration approved a cholesterol-lowering drug, Praluent, from Sanofi and Regeneron Pharmaceuticals.[14] Praluent is an antibody that blocks a particular protein that has been found to interfere with the body's ability to clear artery-damaging cholesterol from the blood. It is based on the rare gene mutation of an aerobics instructor with the "phenotype" of extremely low cholesterol levels. While statins, such as the blockbuster drug Lipitor, have contributed to a decline in heart attacks and death from cardiovascular disease, for a significant number of patients, statins are not enough to control cholesterol levels.[15] The companies are pricing Praluent at $14,600 a year. Credit Suisse, for instance, in a recent report that assumed an average $10,000 price for the drug, predicted total peak sales of Praluent and two expected rivals to eventually reach about $10 billion per year.[16]

Scientists are also exploring the DNA of other individuals with irregular, rare phenotypes. For example, they are currently researching pain reduction medicine based on the DNA of an individual who has the "phenotype" of insensitivity to pain.[17] By one estimate the painkiller market alone is worth $18 billion a year.[18] They are also researching the DNA of individuals with extremely high bone density in the hopes of further drug discoveries in osteoporosis and other bone disease.[19]

While advances in genomic science are good for patients, they are also good for business. With such potential blockbuster discoveries there is a lot of excitement and interest in the area of genomics. All of this has been made possible due to advancements in sequencing technology over the span of only a few years.

As discussed above, a tremendous amount of genomic data is being produced. This can lead to potential large-scale research initiatives such as the Precision Medicine Initiative created by President Obama's administration in 2015.

So what is "precision medicine"? The National Academy of Sciences and the President's Council of Advisors on Science and Technology ("PCAST") define precision medicine as the following:

> "***Precision medicine***" refers to the tailoring of medical treatment to the individual characteristics of each patient. It does not literally mean the creation of drugs or medical devices that are unique to a patient, but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease, in the biology and/or prognosis of those diseases they may develop, or in their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not. Although the term "Personalized Medicine" is also used to convey this meaning, that term is sometimes misinterpreted as implying that unique treatments can be designed for each individual. For this reason, the Committee thinks that the term "Precision Medicine" is preferable to "Personalized Medicine" to convey the meaning intended in this report.[20]

In the genomic context, the hope is to tailor therapies based on characteristics of specific patient subpopulations, taking into account the genomic code of such individuals to determine to which treatments a patient may better respond given the variants found in that patient's genome.

C. President Obama's Precision Medicine Initiative

During the State of the Union speech on January 20, 2015, President Barack Obama announced the launch of the new Precision Medicine Initiative, with an investment of $215 million in its first year to support the efforts of the National Institutes of Health ("NIH"), together with the Food and Drug Administration, and the Office of the National Coordinator for Health Information Technology ("ONC"). One of the goals of the President's Precision Medicine Initiative is to sequence 1 million or more individuals while setting the foundation for a new way of doing research through engaging participants in open, responsible data sharing. Another goal of this initiative is for the National Cancer Institute (part of the NIH) to scale up its efforts in identifying genomic drivers of cancer, as well as improve FDA technical capabilities and the creation of interoperability standards for sharing of genetic information and records.[21]

Another large federal initiative, when combined with the data from the Precision Medicine Initiative, will be a powerful tool in the genomics space. The Patient-Centered Outcomes Research Institute ("PCORI") is an independent nonprofit entity established by Congress. It has the mandate to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, policy makers, and insurers, to make informed health decisions. PCORI funds comparative

clinical effectiveness research and supports work that will improve the methods used to conduct such studies.[22] PCORI has granted millions of dollars to create a clinical data research network ("CDRN") across the country. As of July 2015, PCORI has invested $100 million in developing PCORnet, "a large 'network of networks' designed to link researchers, patient communities, clinicians, and health systems. The goal is to allow the nation to conduct patient-centered comparative clinical effectiveness research ("CER") more efficiently and less expensively than is possible now."[23] Another $142 million has been approved to be granted to the 34 clinical research data networks participating in PCORI.[24] The combination of the millions of patient records in the PCORI database and the President's Precision Medicine initiative is creating a strong foundation for large-scale translational research as such combination will include both genomic and clinical data.

D. New York State Genomic Medicine and Big Data Center

On July 17, 2014, Governor Andrew Cuomo announced an investment of $105 million to establish the NYS Genomic Medicine and Big Data Center ("GMBDC"). GMBDC connects the New York Genome Center in New York City and the Genomic Medicine Center in Buffalo in order to capture the economic and medical gains in the emerging field of genomic medicine and to make New York a center for genomic research and jobs.[25]

III. Privacy of Genomic Data

A. Federal Law and HIPAA

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA")[26] as amended under the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH")[27] and regulations promulgated under HIPAA, specifically the Privacy Rule[28] and the Security Rule,[29] protect certain health information. Importantly, HIPAA is not meant to protect all information regarding a particular individual; rather, only that information that falls under the definition of "protected health information" and that is held by a "covered entity"[30] or "business associate."[31]

Under HIPAA, "protected health information" means *individually identifiable* health information.[32] Within the definition of protected health information are two other terms that are relevant to our discussion of the privacy of genomic information under HIPAA: "health information" and "individually identifiable health information."

Health information is defined to include "genetic information."[33] Therefore, "genetic information that is "individually identifiable" would be considered protected health information and HIPAA would apply.[34] Importantly, the Privacy Rule defines "genetic information" very broadly.[35] The Privacy Rule does not explicitly state that genomic information itself is individually identifiable information. Therefore, the inquiry is whether genomic information, by itself, is deemed to fall under the definition of protected health information by some other means.

Under the definition of "identifiable health information" is the catch-all category of health information "with respect to which there is a reasonable basis to believe the information can be used to identify the individual."[36] It is in these few words where the current debate lies. When the Privacy Rule was finalized in December 2000, the Human Genome Project had not yet sequenced the first human genome and the cost of the sequencing that was occurring was astronomical. It is likely that the authors of the Privacy Rule would not have considered the identifiability of genomic information.

In the 15 years since the Privacy Rule was finalized scientists have made large advances in both genomic and re-identification sciences. In January 2013, a genetics lab out of the Whitehead Institute for Biomedical Research in Cambridge, Massachusetts published a paper in *Science*.[37] The authors were able to identify DNA donors by cross-referencing their genetic data with publicly available information from genealogy databases. Researchers were able to match variants on "anonymous" DNA from an area of the genome inherited from the anonymous person's father (i.e., on the Y chromosome, which is passed down only by the father, as the mother has no Y chromosome) with variants found on that region of the DNA of a different individual in a genealogical database that was publicly available with which surnames are associated. Using this surname information and other data, such as age and state, the researchers were able to triangulate the identity of the "anonymous" individual. This is different from the previously existing methodology of DNA profiling used in the identification of crime victims, criminal perpetrators or parentage. That methodology involves comparing "short tandem repeats" ("STR") loci found in the DNA of the sample being analyzed with the STR loci of samples in a database maintained by law enforcement.[38] (For more information on the use of DNA in the criminal justice system see Part VII. A., below.)

Researchers of the 2013 paper utilized next generation sequencing technology to identify SNPs (i.e., nucleotide level analysis) and, importantly, the data against which the sequence of the anonymous subject was compared to lead to identification of such subject was data available to the public and not held in a restricted governmental database. Another important difference between the use of STRs and nucleotide level analysis (e.g., whole genome

or whole exome sequencing) is that is STRs do not reveal predisposition to disease while nucleotide level analysis does. Privacy professionals should note that the "magic" is in the variants and SNPs.

When discussing whether genomic data is "identifiable," however, it is very important to take note of the fact that, with current technology, a genomic sequence alone is not identifiable. A researcher must have a source to compare the variants being observed in the "anonymous" DNA, and such source must be associated with other information sufficient enough to identify the individual.

Until the 2013 paper there was an assumption that the identification of an individual from any genomic sequence was a remote possibility. That paper changed our perception of the potential identifiable nature of genomic data, setting off a global recalibration of privacy in the genomic context. It was even cited by HHS and FDA in the September 8, 2015 notice of proposed rulemaking, discussed more fully below.

The question that has not been fully answered is whether all genomic information is to be considered *identifiable* health information, making it protected health information under the rules of HIPAA. In this context, it should be noted that a 2011 study showed that the risk of re-identification from a system intrusion of databases was only 0.22%.[39] This has led many to assert that the concern over re-identification may be overemphasized.

In July 2011 the United States Department of Health and Human Services ("HHS") (along with FDA) issued an Advanced Notice of Proposed Rulemaking (the "ANPRM") proposing changes to the Common Rule, which, if enacted, could have significantly impacted the application of privacy law to genomic information, as that ANPRM stated that genomic data would be treated as identifiable information.[40, 41] In that ANPRM HHS stated:

> Regardless of what information is removed, it is possible to extract DNA from a biospecimen itself and potentially link it to otherwise available data to identify individuals. Consequently, we are considering categorizing all research involving the primary collection of biospecimens as well as storage and secondary analysis of existing biospecimens *as research involving identifiable information*.…[42] (Emphasis added).

While the ANPRM was addressing the Common Rule and not the Privacy Rule, HHS is also the executive agency that has jurisdiction over the Privacy Rule. Therefore, there was concern that an articulation by HHS that genomic information is "identifiable information" could be interpreted to apply to the identifiability of genomic data for purposes of the Privacy Rule. In other words, if genomic information is deemed to be identifiable per se, this would mean that genomic information, included in the definition of "health information" under the Privacy Rule (discussed above), might be considered "individually identifiable health information," making it "protected health information" under the Privacy Rule and HIPAA. This could have had significant impact on the regulatory compliance and risk management of many entities holding genomic information.[43]

After a four-year wait, on September 8, 2015, HHS issued a notice of proposed rulemaking ("NPRM").[44] HHS stated, "This proposal would not modify the Common Rule standard of identifiability (in contrast to what was discussed in the 2011 ANPRM)."[45] Moreover, HHS also stated, "HHS does not currently consider whole genome sequencing data to meet the definition of [identifiable private information] for purposes of the Common Rule."[46] That said, however, in the NPRM HHS proposes three alternative ways to expand the definition of a "human subject" (i.e., the category of research that would require application of the Common Rule requirements) to include any research on a whole genome sequence.[47]

Also in the NPRM, HHS proposed, alternatively, to expand the definition of human subjects to include the research use of "information that was produced using a technology applied to a biospecimen that generates information unique to an individual such that it is foreseeable that, when used in combination with publicly available information, the individual could be identified."[48] Therefore, a whole exome sequence combined with other publicly available information (or even a series of SNPs or variants from a genome combined with other such information) that could identify an individual would trigger the application of the Common Rule, under this alternative.

Because HHS has explicitly stated that genomic information is not identifiable private information for purposes of the Common Rule, and researchers need source genomic data associated with identifiable information to identify an individual from genomic data, as of the time of writing this article, September 2015, it does not appear that genomic information itself is "identifiable health information," and, therefore, genomic information is not "protected health information" under the Privacy Rule. That said, this issue has not been finally or explicitly articulated by HHS and has left an open debate on the application of the Privacy Rule in this context. HHS may clarify this point upon the issuance of the final regulations. When advising a client on this topic, it would be wise to take into account that technology is rapidly

advancing, and that in the not-too-distant future, HHS might officially articulate that genomic information is identifiable per se, or, alternatively, that genomic information is deemed impossible to de-identify for purposes of the Privacy Rule.

B. Federal Protections Regarding the Use of Genomic Information by Employers and Health Insurers

The possibility of using genetic information to discriminate against a healthy person based on non-manifested diseases for which that person is genetically predisposed prompted Congress to enact the Genetic Information Nondiscrimination Act of 2008 ("***GINA***").[49] GINA prohibits the use of genetic information in health insurance and employment. Group health plans and health insurers cannot deny coverage to a healthy individual or charge a healthy person higher premiums based solely on a genetic predisposition to a disease that may develop in the future. GINA also prohibits employers from using an individual's genetic information in decisions around hiring, firing, job placement, or promotion decisions. Importantly, the protections of GINA do not extend to the decisions of other entities such as providers of life, disability or long-term care insurance.

C. New York State Civil Rights Law Section 79-l, "Confidentiality of records of genetic tests"

With certain exceptions listed in the statute, New York State Civil Rights Law Section 79-l requires that consent be obtained from an individual if a "genetic test" is to be performed on his or her biospecimen. The statute specifies elements that must be present in the consent before a clinical laboratory governed by CLEP may conduct a "genetic test."[50]

It is important to understand the meaning of the term "genetic testing" in Section 79-l. As the statute is part of the Civil Rights Law and not the Public Health Law, the agency that enforces this section is not the New York State Department of Health, but rather the Office of the Attorney General. While it has not issued any regulations or guidance under Section 79-l, in a press statement the Office of Attorney General did state:

> Genetic testing, as defined by the New York State Civil Rights Law, is a medical procedure by which human DNA, RNA or proteins are analyzed to determine whether an apparently healthy person is at increased risk for a specific future disease, or to determine whether the child of a healthy individual or couple is at risk of having a recessive disorder. *Although genetic tests can be performed to confirm a suspected diagnosis in symptomatic persons, diagnostic genetic tests are not covered by the state law.* The Civil Rights Law does not apply to those genetic tests that are performed as part of New York State's mandatory newborn screening program.[51] (Emphasis added).

The penultimate sentence (italicized above) is a clear articulation that 79-l applies to pre-dispositional (i.e., testing for diseases that have not yet expressed in the patient) and not diagnostic genetic testing (i.e., testing for diseases in a symptomatic patient). This is helpful, as the language of 79-l defining "genetic test" was adopted by the New York legislature in 1996. As outlined in this article, much has changed in the area of genomics since that time. Therefore, the current definition of "genetic test" in the statute may be difficult to interpret given our current framework for understanding genomics is very different from that of 1996.

Section 79-l also addresses the secondary use of a biospecimen collected for genetic testing for general research, specifying the elements that must be included in an informed consent to allow for such use.[52]

IV. Data Sharing Issues

A. Regulatory Restrictions on Sharing of Genomic Data: Balancing Advancement of Research and Privacy Concerns

There are two very well-meaning but countervailing perspectives that are evident in the discussion around sharing genomic data outside of the treatment context: On one hand, there is the desire to pursue rapid advancements of science. This desire favors greater freedom regarding the flow of genomic information among researchers in both academic and commercial settings, including the pharmaceutical and biotech industries, with a reduction of regulatory restrictions. On the other is the protection of the individual's right to privacy and protection against discrimination based on an individual's predisposition to disease that is revealed by genomic data.

B. Movement to Reduce Regulatory Restrictions

The Center for Data Innovation and Health IT recently published a white paper, "From Evolution To Revolution: Building 21st-century Genomic Infrastructure," in which the Center argues for less regulatory restriction on the sharing of genomic data to encourage scientific and medical discovery. In that white paper the Center stated:

> While these rules are intended to protect patient privacy, the same rules prevent drug companies from identifying or contacting those patients most likely to

> benefit from clinical trials. *The effect has been to discourage collaborative, multidisciplinary research, divert scarce research dollars toward lawyers and cybersecurity, and drive up the cost of drug development. Arguably, lives are being lost in the bargain.* The president's million-genome project will need to address these issues head on. Discovering the phenomic manifestations of genetic variation will require the correlation of all data donors' genomes with their health records and other personal information. Unless provisions are made for the active involvement of hundreds of institutions and many thousands of researchers, discoveries will follow too slowly to benefit U.S. competitiveness—or to help the millions who suffer from untreatable illnesses today.[53] (Emphasis added)

C. Proponents of Continued Privacy Protections

It is worth noting that the enforcement authority for HIPAA is placed in the Office of Civil Rights of the U.S. Department of Health and Human Services. Therefore, at the time of its enactment, the privacy protection afforded by HIPAA of an individual's health information was considered the civil right of a U.S. citizen. What is the origin of the concern with such privacy? The Ethical Policy Statement of the American College of Healthcare Executives on the privacy of health information reiterates that the basis for the protection of such information is one of patients' trust in the privacy of their health information: "Healthcare is among the most personal services rendered in our society; yet to deliver this care, scores of personnel must have access to intimate patient information. In order to receive appropriate care, *patients must feel free to reveal personal information*. *In return, the healthcare provider must treat patient information confidentially and protect its security*."[54] (Emphasis added).

D. Genomic Exceptionalism

The roots of such privacy concerns also give rise to the debate as to whether genomic data should be treated differently from other health information.

Laws such as New York Civil Rights Law § 79-l put genomic testing and the data derived from such testing into a special category. It has been argued that the results of genetic tests may have significant medical, psychological, and social implications for the individual and his or her family. Therefore, it has been argued that genetic information is different from other health information as it also contains information about family members and other blood relatives, even those who currently show no symptoms. In addition to the medical implications, genetic disorders present emotional challenges and special reproductive implications. Families may be concerned about prenatal and newborn testing decisions, difficult treatment options, and the risk that additional offspring will inherit a genetic condition.

In a white paper from the Genetics Alliance, a leading Washington, D.C.-based nonprofit healthcare advocacy organization in genomics, the psychological and social implications are discussed:

> A genetic diagnosis generally provides great benefit to patients. It helps patients understand their disorder, especially when the condition is rare and the patient has struggled to find a diagnosis. Oftentimes, patients spend years living with a condition without knowing its name or cause. Diagnoses usually lead to improved treatment options and access to support services. They can also help other family members make decisions about their own lives.
>
> A genetic diagnosis may lead to negative reactions, too. The science of genetics can be confusing, and patients are often frustrated until they understand the nature of their condition. Patients identified with a mutation may consider themselves at fault or "broken" or interpret their diagnoses as leading to something they cannot fight. A genetic diagnosis can lead to fears about insurance and employment discrimination.[55]

That report goes on to point out that a genetic test can also reveal mistaken understandings of parentage or ancestry. The psychological and social impact of realizing that your parentage or ancestry is other than that on which your social or communal relationships is based may have a very deep and lasting impact.

It is important to keep these psychological and social implications of genomic information in mind when considering the regulatory landscape that protects such data and balance such concerns with the countervailing, worthy cause of advancing scientific and medical research to help find cures for diseases for which there are no current treatments.

In 2012, the Presidential Commission for the Study of Bioethical Issues issued a white paper entitled, *Privacy and Progress in Whole Genome Sequencing*.[56] While the white paper is not the law, it is helpful to understand the landscape and challenges presented in the balancing

privacy in genomic data with a push toward scientific and medical progress. The Commission's recommendations are broken down into general categories: (i) creating strong baseline privacy protections while promoting data access and sharing; (ii) creating data security and access to databases; (iii) creating a consent that specifically addresses the risks and benefits of whole genome sequencing as well as how incidental findings may be communicated to the individual from whom the sample is derived; (iv) facilitating progress in whole genome sequencing by facilitating explicit exchange of information between genomic researchers and clinicians and engaging research participants in the research to promote collaborative relationships; and (v) ensuring the broadest population can benefit from the developments in whole genome sequencing.

E. First to Publish and First to Market: Other Factors Impeding Data Sharing in the Context of Genomic Data

> The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true.
>
> —Albert Einstein[57]

Sharing of data in research is important for many reasons, the primary of which is to disseminate the research data to other scientists who can either carry the exploration further, in a different direction, or simply not repeat the research unnecessarily. Slowing down or inhibiting the sharing of research data slows down and impedes scientific discovery that could lead to breakthroughs in medicine or novel treatments. Generally, where research is funded by a federal grant or a non-profit entity, the data is owned by the institution that created the data under the research. Where the research is funded by an industry sponsor, the ownership of the data will depend on the terms of the sponsorship agreement.

Why would research data not be shared? In a 2002 paper published in the *Journal of the American Medical Association*, the authors reported that "[a]mong geneticists who said they had intentionally withheld data regarding their published work, 80% reported that it required too much effort to produce the materials or information; 64%, that they were protecting the ability of a graduate student, postdoctoral fellow, or junior faculty member to publish; and 53%, that they were protecting their own ability to publish. Thirty-five percent of geneticists said that sharing had decreased during the last decade, 14%, that sharing had increased. Geneticists were as likely as other life scientists to deny others' requests…and to have their own requests denied…. However, other life scientists were less likely to report that withholding had a negative impact on their own research as well as their field of research."[58]

Therefore, within academia, where researchers' publications are extremely important to their careers, data may not be shared for fear of being "scooped" by another researcher using the data. Where an industry sponsor pays for research, the sponsor may inhibit the distribution of the data for fear of a competitor making a drug discovery and bringing it to market before the sponsor. Moreover, where research involves a sponsor's drug and results in findings unfavorable to the marketing of that drug, the sponsor may wish to inhibit the distribution of such results.

F. NIH Efforts to Create Data Sharing of Genomic Information

In the public sector, the NIH has been active in promoting data sharing and in 2003 it issued a general policy for sharing research data.[59, 60] In 2007, the NIH issued a specific policy to promote sharing of data generated through ***genome wide association studies (GWAS)***.[61, 62] A GWAS is any study of genetic variation examining thousands of single nucleotide polymorphisms across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition and identify genetic variants that contribute to such human diseases, conditions, and traits.

The guiding principle underlying the GWAS Policy as articulated by the NIH is:

> The greatest public benefit will be realized if data from GWAS are made available, under terms and conditions consistent with the informed consent provided by individual participants, in a timely manner to the largest possible number of investigators.[63]

All researchers funded by NIH for GWAS must share the genomic and phenotypic data in an NIH-created Database of Genotypes and Phenotypes (dbGaP). Researchers may query the dbGaP and access such genomic and phenotypic data.[64] The sharing of genomic data has an even greater impact when genome wide association studies are being conducted, as the more genomes analyzed the more certain the association of specific variants will be with a specific disease.

Since the issuance of the NIH GWAS policy in 2007, the implementation of next generation sequencing (described above in Part II of this article) has allowed for less expensive, faster sequencing, creating a lot more genomic data. The increase in such data has led the NIH to issue a specific policy on the sharing of genomic data, with a broader scope than the GWAS policy. On August 28, 2014

the NIH Genomic Data Sharing Policy ("GDS Policy") was published in the Federal Register.[65]

Per the NIH, the GDS Policy applies to all NIH-funded research (e.g., grants, contracts, intramural research) that generates large-scale[66] human or non-human genomic data, regardless of the funding level, as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic,[67] epigenomic,[68] and gene expression data.

The GDS Policy requires data sharing of all data, the creation of which is funded in part or in whole by NIH. It requires investigators to register all studies with human genomic data that fall within the scope of the GDS Policy with the Database of the Genotypes and Phenotypes (dbGaP) and submit the data to the relevant NIH-designated data repository (e.g., dbGaP, Gene Expression Omnibus (GEO), Sequence Read Archive (SRA), or the Cancer Genomics Hub). Moreover, the GDS Policy states that the NIH expects investigators to obtain participants' consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. The consent must include an explanation about whether participants' individual-level data will be shared through unrestricted or controlled-access repositories.

To understand NIH's data sharing plan expectations as well as a clearer picture of the type of research to which the GDA Policy applies, the GDA Policy must be read in conjunction with both the *Supplemental Information to the National Institutes of Health Genomic Data Sharing Policy*[69] and the *National Institutes of Health Guidance for Investigators in Developing Genomic Data Sharing Plans*.[70, 71]

G. Other Efforts to Encourage the Creation and Sharing of Genomic Data

In addition to the efforts of the NIH, others in the international scientific community have come together in various efforts to encourage the creation and sharing of genomic data. The prime example of this is the 1000 Genomes Project. Begun in 2008, the goal of the 1000 Genomes Project was to utilize the then-new technology of next generation sequencing to sequence at least one thousand participants across a number of varied ethnic groups, developing a database of genomic data to research the links between genotype and phenotype.[72] In 2010, the 1000 Genome Consortium published a paper in *Nature* presenting the results of their pilot project.[73] One of the fundamental principles of the 1000 Genome Project is the open sharing of the genomic data created so that scientists from around the world may utilize that data in further genomic discovery.[74]

In the private sector there have been "pre-competitive" consortia created in which entities that would otherwise be competitors agree to fund genomic research to create a larger pool of data for research purposes.[75] Such consortia may have terms in their founding documents that would allow open access to the data after a period of time has elapsed that allows the members to research such data. This may be a requirement of non-profit members of the consortia whose status as an exempt organization requires such sharing in order to avoid unrelated taxable business income implications or loss of exempt status.

Finally, many journals have begun to require that the data an author uses to support his or her findings be made fully available.[76] This is important, as publication in such journals is a key impetus for a researcher to conduct the research in the first place; as such publication assists the advancement of a researcher in his or her career.

V. The Indominus Rex, Incidental Findings and Other Ethical Issues Arising in the Context of Genomic Research

A. Incidental Findings

Incidental and secondary findings play a major role in the ethical concerns raised in the context of genomic research. For example, if a healthy individual volunteers to participate in research that includes brain scans using functional magnetic resonance imaging to look at brain activity, and the researcher notices a mass, this is a finding that is unanticipated and incidental to the research activity, but has significant clinical value for the individual. In genomic research the possibility of finding an unanticipated incidental finding is increased due to the amount of data produced by sequencing. Genomic analysis of a whole exome or whole genome sequence can reveal clinically relevant health information about an individual. Therefore, even if a researcher were studying a specific disease, such genomic analysis may reveal hereditary conditions that are beyond the original scope of the study.

An incidental finding can arise from a genomic test ordered by a doctor in a clinical setting, in analysis of genomic information in a research setting, or even in the analysis of genomic information submitted in a direct-to-consumer (DTC) context. In December 2013 the Presidential Commission for the Study of Bioethical Issues published *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts,* in which the Commission offered recommendations as to how to anticipate and communicate incidental findings.[77]

It is helpful in our discussion to have a clear understanding of what is considered an "incidental finding," as

well as how that is different from a "secondary finding." The Commission defined both incidental and secondary findings for purposes of its guidance as follows:

> The Bioethics Commission divides the term "incidental finding" into two categories: incidental findings that are "anticipatable" and those that are "unanticipatable." An *anticipatable incidental finding* is a finding that is known to be associated with a test or procedure. An *unanticipatable incidental finding* includes a finding that could not have been anticipated given the current state of scientific knowledge. A *secondary finding* refers to a finding that is actively sought by a practitioner that is not the primary target…. For simplicity, the generic term "incidental finding" is used in reference to both anticipatable and unanticipatable incidental findings; distinctions are made as necessary and relevant.[78]

These "incidental findings" present an ethical issue as they may indicate a condition that could be avoidable if there were clinical intervention. On the other hand, they could also indicate a predisposition to a disease for which there is not a current cure and a clinical intervention would not be useful. As discussed above, the understanding of one's own genomic predisposition may be beneficial in a clinical setting but may also have psychological and social implications. These concerns have given rise to a debate as to whether such findings should be returned to the individual, taking into consideration the potential psychological and emotional impact of learning one's genomic information, the individual's right to know that information, as well as informed consent issues, and the impact on privacy and professional duties.

In *Anticipate and Communicate*, the Commission made five overarching recommendations that apply to the clinical, research and DTC contexts:

(i) the Commission recommended that prior to testing, providers should describe to potential recipients incidental and secondary findings likely to arise and any plan for disclosing and managing those findings;

(ii) the Commission recommended that professional groups develop guidelines to categorize the findings likely to arise from each diagnostic modality and develop best practices for managing these findings;

(iii) the Commission recommended research about the types and frequency of incidental and secondary findings including costs, benefits and harms associated with these findings, as well as recipient and practitioner preferences with regard to these findings;

(iv) the Commission recommended that both public and private entities educate stakeholders about the ethical, practical, and legal considerations raised by incidental and secondary findings; and,

(v) the Commission recognized the principle of justice and fairness with respect to individual access to adequate information, guidance and support to make informed choices, noting that individuals should have affordable access to quality information about incidental and secondary findings, before and after testing.

The Commission also had specific recommendations in each clinical, research and DTC contexts.

In its *Privacy and Progress in Whole Genome Sequencing* (discussed above), the Commission specifically addressed incidental findings in the context of whole genome sequencing stating:

> While some individuals wish to share their data broadly for the advancement of science, others want control over their data to maintain their privacy, control information shared with intimate relations, or protect their right not to know results that might be discovered during whole genome sequencing.[79]

The Commission recommended that researchers, clinicians, and commercial whole genome sequencing entities make individuals aware that incidental findings are likely to be discovered in the course of whole genome sequencing. The consent process should convey whether these findings will be communicated, the scope of communicated findings, and to whom the findings will be communicated. The Commission also encouraged research to investigate the related preferences and expectations of individuals contributing samples and data to genomic research and undergoing whole genome sequencing in the clinical care, research, and commercial contexts. The Commission also encouraged studies to evaluate proposed frameworks for offering return of incidental findings and other research results derived from whole genome sequencing.[80]

B. Gene Editing and Ethical Concerns

In the 2015 movie, *Jurassic World*, the fictional scientists engineered a hybrid dinosaur from the DNA of different animals that coded for desirable traits, creating

the Indominus Rex. While we are safe from Indominus Rex, ethical concerns are raised by the non-fictional CRISPR/Cas9 genome editing technology[81] that has been used successfully by Chinese researchers to genetically engineer monkeys with targeted mutations.[82] These are the first reported primates to be so genetically modified, constituting a step toward leveraging such technologies in research regarding human health. In March 2015, different researchers out of China reported that they had utilized the CRISPR technology to edit human embryos.[83] While the editing occurred, it was not successful in that the embryos either did not survive or only a fraction contained the replacement genetic material when tested.

In the future, the use of CRISPR/Cas9 genome editing technology may assist researchers in finding a treatment of many human diseases such as HIV/AIDS, hemophilia, sickle-cell anemia, and several forms of cancer. Ethical concerns are raised, however, when the technology is used to edit genetic information that may be passed down in one's lineage by editing the "***germline cells***" (e.g., editing of sperm or egg cells). Non-germ line cells, which are all cells the DNA of which is not passed down to future generations, called "***somatic cells***," such as liver or heart cells, may be genetically edited without raising the same ethical concerns.

In April 2015, leading scientists, including a co-discoverer of CRISPR/Cas9, and experts in law, ethics and medicine, published an editorial in *Science*, advocating for a moratorium on the use of the technology in germline cells, as well as encouraging wide-ranging discussions and transparency in the scientific community and beyond.[84] Others have stated their concerns about the possible negative eugenic[85] uses of this technology.

Currently there is no ban in the United States against the editing of either germline or somatic cells. There are some safeguards, however. In the *NIH Guidelines For Research Involving Recombinant Or Synthetic Nucleic Acid Molecules*,[86] the NIH states that it "will not at present entertain proposals for germ line alterations but will consider proposals involving somatic cell gene transfer."[87] In April 2015, NIH issued a statement declaring that it would not fund such research.[88] The "Dickey-Wicker amendment" prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed.[89] Also, the U.S. Food and Drug Administration (FDA) has the authority to regulate cell and gene therapy products, as biological products and/or drugs. This would include FDA oversight of modifications to the human germline. Pursuant to 21 CFR Part 312, biological products may only be tested in humans if an investigational new drug application has been approved by the FDA. Finally, in the United States, researchers who want to investigate the clinical uses of genetically engineered germline cells must secure informed consents pursuant to the Common Rule described above. It would be difficult, however, to clearly explain or give sufficient information to obtain a consent that is truly informed regarding the potential risks, including risks to future generations.

C. Other Ethical Concerns

There are, of course, other ethical concerns presented by the new frontier of genomics, including "designer babies," through which parents may select from the fertilized eggs they have produced to determine which might have the most desirable characteristics; participatory genomics, through which individuals are directly involved with many, if not all, aspects of genomic information relating to their own genome; or, the question of compensation to individuals with rare variants from which blockbuster drugs are derived. Those topics are not addressed in this article but are mentioned to give the reader an understanding of the breadth of ethical issues emerging from genomic technology.

VI. FDA Approval of NGS Tests and the Shifting Paradigm

As discussed above, the FDA regulates ***in vitro diagnostic products* (*IVDs*)** which are defined as those "reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body."[90] IVDs are medical devices as defined in section 210(h) of the Federal Food, Drug, and Cosmetic Act, and may also be biological products subject to section 351 of the Public Health Service Act. Like other medical devices, IVDs are subject to premarket and postmarket controls. IVDs are also subject to CLIA.

IVDs are classified based on risk. Low risk IVDs are "Class I"; moderate risk IVDs are "Class II"; and high risk IVDs are "Class III." As the IVD is deemed to have more risk (and moves up in classification) more evidence is needed to show safety and effectiveness of the IVD before it will be approved by the FDA for marketing to the public. A significant factor in the evaluation of risk by the FDA is the impact of a false result in the clinical context. The FDA looks at analytical performance of the test, including whether the test measures what it is supposed to measure and if such measurement is done accurately and reproducibly. The FDA also looks at the clinical performance of the test in terms of making a diagnosis and, in some cases, recommending treatment. The FDA also looks at labeling to ensure that the materials created about the test are truthful and accurate.

Tests created utilizing next-generation sequencing present a unique challenge for the FDA in its approval process. Traditionally there has been a "one test, one disease" model. On February 20, 2015 the FDA held a public workshop entitled: "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests." (the "NGS Workshop"). At the NGS Workshop Dr. Margaret Hamburg, the then-Commissioner of the FDA, summarized the current FDA regulatory landscape regarding NGS tests:

> …we all recognize that our current premarket review approaches for evaluating a test analytical and clinical validity, performance are designed around the more traditional one test, one disease paradigm but that the massive amount of data that's produced in next-generation sequencing and the multitude of possible diseases and conditions which a single genomic sequence might identify present very new challenges for the FDA and frankly for all of us and it clearly requires us to think through new approaches that will really enable us to fulfill our critical mission of protecting and promoting the health of the public but ensure that the technologies that are serving as the foundation for important work that extends so far beyond the work of the FDA is grounded in the best possible science and the most creative and innovative thinking about how to proceed.[91]

On December 29, 2014 the FDA released a discussion paper entitled, "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests-Preliminary Discussion Paper" (the "Discussion Paper").[92] As discussed above, the sequencing of a human whole genome may detect over 3 million variants. These variants may have clinical significance with respect to more than one disease. This is very different from the traditional clinical test in which a laboratory identified a single or a defined number of substances to determine the clinical significance with respect to a single disease. The use of next-generation sequencing tests can result in the diagnosis or understanding of predisposition to many different diseases or conditions.

In its Discussion Paper the FDA defined an "NGS test" for FDA approval purposes as:

> …a human DNA sequencing assay performed on a particular NGS instrument (e.g., MiSeqDx) with a workflow defined by standard operating procedures that specify all materials and procedures. This includes all steps from defining the patient sample type and method of DNA extraction to computational processing of sequencing data, and, if offered, any portion of interpretation of the clinical meaning of individual variants identified in that patient that is performed within the test system (including software) rather than by a healthcare professional. The intended use of the NGS test may be specific for certain types of specimens, patient populations, etc., but does not necessarily include any claims about the clinical relevance of specific variants.[93]

Therefore, **all** steps in a genomic sequencing pipeline including the library preparation, sequencing and any bioinformatics analysis done by computer (i.e., as opposed to a healthcare professional) would be considered an "NGS test" and would be subject to the FDA's regulatory framework.

The FDA has authorized the marketing of one NGS instrument (Illumina MiSeqDxTM) and its universal sequencing reagents, and two accompanying assays for the diagnosis of cystic fibrosis (Illumina MiSeqDxTM Cystic Fibrosis 139 Variant and Clinical Sequencing Assays).[94] To do so FDA utilized a new method of determining clinical validity of the instrument:

> …because it was impractical to provide data on the ability of the instrument to accurately and reliably detect every possible variant that might exist in a genomic sequence, analytical test performance for the MiSeqDx system was demonstrated for a representative subset of types of variants in various sequence contexts. Demonstrating adequate analytical performance for this subset provided reasonable assurance that the test would be able to successfully identify relevant variants in the genome without requiring the company to submit data for every possible variant the test could identify. FDA plans to continue to use this subset-based approach when evaluating the analytical performance of NGS platforms, but is considering novel and efficient approaches for establishing analytical performance for specific NGS tests developed using FDA cleared or approved components in clinical diagnostic laboratories.[95]

In her comments at the NGS Workshop, Dr. Hamburg cited the fact that Illumina was able to leverage existing information by referring to a well-curated, shared database for cystic fibrosis mutation to demonstrate the test's clinical validity. She mentioned that there was patient engagement through the Cystic Fibrosis Foundation in creating the database. In its discussion paper, the FDA requested comments on this approach. In the Discussion Paper and the NGS Workshop, the FDA suggested utilizing high-quality external genetic databases, such as those curated by the NIH ClinGen[96] program and deposited in its ClinVar[97] database and other FDA-recognized external databases, in its determination of the clinical validity of a proposed NGS test.

In a special report of the *New England Journal of Medicine* the proposed approach of the FDA was questioned.[98] The authors state, among other conclusions, that the "notion that the FDA can harness pre-existing data resources is unduly optimistic." The authors cite the fact that there are over 3 million variants in a typical person, 500,000 of which are rare or novel. At least 90 to 125 variants merit further evaluation for clinical significance on the basis of current knowledge, but for most variants, the clinical implications, if any, remain unknown. They go on to state that ClinVar has only 76,606 unique variants with clinical interpretations (including variants of unknown significance). The authors go on to say that this leaves millions of variants for which the FDA seemingly would require premarket studies to demonstrate clinical validity.[99] The authors recommend a system of post-market surveillance. That approach would involve collecting data from commercial laboratories that administer genomic tests as well as the research settings from which the ClinVar system was originally designed to collect. "Establishing the clinical validity of genomic tests is largely a post marketing pursuit. It requires the accrual and review of evidence throughout the entire commercial life of a test and, indeed, requires access to post marketing data not just from the test but from all other tests that are trolling the same region or regions of the human genome. Premarket review is the wrong tool, and the traditional product byproduct regulatory focus of the FDA is myopic."[100]

At the writing of this article, the FDA has not issued any further guidance on how it intends to proceed with the approval of NGS tests, but has collected responses to the questions it posed in the Discussion Paper.

VII. Other Issues in Genomics and the Law

Genomic technology may be used for identification of individuals as well as the creation of novel therapies. While not the focus of this article, a few of these uses are mentioned to give the reader a general understanding of these other topics.

A. Use of Genomics in the Criminal Justice System

Effective August 1, 2012, under New York State law, with a few exceptions, any person convicted and sentenced for any felony under any state law or Penal Law misdemeanor is required to provide a DNA sample for inclusion in the New York DNA Databank.[101, 102] Also, any offender convicted in a New York State court who is required to register as a sex offender must provide a DNA sample for inclusion in the New York Databank.[103] The NYS DNA Databank is part of a national system called CODIS (Combined DNA Index System) operated by the FBI.[104] Since 1997 there have been 13 core Short Tandem Repeats (STR) loci (defined above, See Part III) that have been used to identify individuals through the use of CODIS and the National DNA Index System.[105]

In 2015 the FBI announced that the CODIS Core Loci Working Group selected an additional seven STR loci; and, following an implementation phase concluding on January 1, 2017, such seven additional STR loci will be required for upload and searching of DNA profiles at the National DNA Index System (NDIS).[106] (Use of STRs can be used for identification but does not yield further information that a whole genome or whole exome sequence can, such as predisposition to disease.)

The use of DNA in the criminal justice system has the obvious benefit of protecting (or releasing from wrongful imprisonment) the innocent. One issue that has been litigated is the collection of DNA samples from individuals who have not yet been convicted of a crime. In the 2013 decision, *Maryland v. King*, the U.S. Supreme Court ruled that the collection of DNA , through a buccal (cheek) swab, under the Maryland DNA Collection Act from an arrestee did not violate the Fourth Amendment.[107] The Court stated: "By comparison to the substantial government interest and the unique effectiveness of DNA identification, the intrusion of a cheek swab to obtain a DNA sample is minimal. Reasonableness must be considered in the context of an individual's legitimate privacy expectations, which necessarily diminish when he is taken into police custody."[108] In an unlikely combination of voices, Justices Ginsburg, Sotomayor and Kagan joined with Justice Scalia in issuing a very strong dissent to the Court opinion.

There have been bills introduced in both the New York Senate and Assembly in the 2015-2016 regular session to allow for the collection of DNA samples upon an individual's arrest for certain felony crimes.[109]

B. Patentability of Genes and the *Myriad* Case

In *Association of Molecular Pathology v. Myriad Genetics*, the U.S. Supreme Court found that naturally occur-

ring DNA sequence is a product of nature and therefore is not eligible to be patented merely because it has been isolated.[110]

The Court stated, however, that this does not hold true for "complimentary DNA"[111] or "cDNA" which is DNA created in a laboratory that contains only the exon portion of the naturally occurring DNA (i.e., only the nucleotide sequence that codes for proteins) and does not include any of the intron portion of the naturally occurring DNA (i.e., the non-coding regions). As the cDNA does not occur in nature the Court stated that cDNA is patent eligible.

> …the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under §101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.[112]

Prior to the decision in *Myriad*, nearly 20% of human genes were explicitly claimed under 4270 patents.[113] Some gene ownership was fragmented over more than one owner. This meant that a researcher would have to enter into a complex licensing structure to access and use those genes, reducing innovation. One study found that such patent ownership structure generated economically and statistically significant reductions in subsequent scientific research and product development, on the order of 20%-30%.[114]

The impact of this decision has allowed for competition to grow in the area of testing for genetic predisposition as well as use of genetic information in the creation of therapeutic proteins ("biologics") derived from genetic information. (See above, Part II, for example of the description of the use of a rare cholesterol lowering mutation to produce Praluent, a cholesterol lowing treatment). Moreover, the increased competitive space has led many laboratories to develop tests using genomic information. This increase in laboratory developed tests is one of the reasons the FDA has turned its attention to addressing the clinical validity and accuracy of such laboratory developed tests (See discussion above at Part I) and FDA's decision to look at how NGS should modify the approval process for tests using such technology (see discussion above at Part VI).

VIII. Conclusion

The emergence of Next Generation Sequencing technology has allowed scientists to explore new areas of genomics in the research and clinical contexts, as well as allowing for the expanding use of genomics in drug development and precision medicine. We have entered into a new frontier of science and medical discovery with the use of genomic technologies. In such a new world, we are faced with decisions on how to balance an individual's privacy and autonomy regarding his or her genomic data with the worthy goal of free flow of data to advance science and medicine. Along with these new breakthroughs come legal challenges in privacy, data sharing and ethics. It is indeed an exciting time, as we witness together the breathtaking expansion of this new technology and science that will change medicine forever.

Endnotes

1. International Human Genome Sequencing Consortium (Oct 2004). "Finishing the euchromatic sequence of the human genome," Nature 431 (7011): 931–45. Bibcode:2004Natur.431..931H. doi:10.1038/nature03001. PMID 15496913.
2. The term exon was derived from "EXpressed regiON," and refers to the regions that get read by the cell and ultimately expressed into proteins, as opposed to the intron, or "INTRagenic regiON" which is not expressed into a protein.
3. A link to the Genome Reference Consortium can be found at http://www.ncbi.nlm.nih.gov/projects/genome/assembly/grc/human/; "The reference genome provides a template by which sequencing reads can be mapped to their chromosomal locations. It is an indispensable resource for geneticists worldwide, who use it to piece together sequences, understand the context of reads, and find areas of genetic variation by comparing genomes against a 'standard' sequence," available at http://www.bio-itworld.com/2014/1/27/getting-know-new-reference-genome-assembly.html.
4. Shen H, Li J, Zhang J, Xu C, Jiang Y, Wu Z, et al. (2013), Comprehensive Characterization of Human Genome Variation by High Coverage Whole-Genome Sequencing of Forty Four Caucasians, PLoS ONE 8(4): e59494. doi:10.1371/journal.pone.0059494.
5. "In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." 21 CFR 809.3.
6. On October 3, 2014 the FDA issued its draft guidance, "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," which proposes to introduce a higher level of scrutiny on laboratory tests. http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm416685.pdf; in January 2015, the New York State Bar Association Health Law Section Committee on Medical Research and Biotechnology, and Food, Drug and Cosmetic Law Section, submitted comments to the U.S. Food and Drug Administration (FDA) Guidance, available at https://

www.nysba.org/Sections/Food_Drug_Cosmetic/FDC_Health_Comments_No_1_2015.html.

7. November 22, 2013 warning letter from the FDA to 23andMe, Inc. regarding 23andMe's Personal Genome Service is available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm.

8. Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a.

9. The requirements for the NYS Clinical Laboratory Evaluation Program are found at Article 5, Title V of the New York State Public Health Law, Parts 19, 58, 63 and 70 of Title 10, New York Code of Rules and Regulations (10 NYCRR), and in the New York State Department of Health's Laboratory Standards of Practice.

10. The National Human Genome Research Institute's description of the Human Genome Project is available at http://www.genome.gov/10001772.

11. Erika Check Hayden, Technology: The $1,000 genome, Nature, 507, 294–295 (20 March 2014) doi:10.1038/507294a (March 19, 2014), available at http://www.nature.com/news/technology-the-1-000-genome-1.14901#/falling.

12. One whole genomic sequence requires approximately 150-200 gigabytes of storage (nb. A gigabyte is 1 billion (10^9) bytes of storage (coverage equals 30 X). (See for example, http://www.strand-ngs.com/support/ngs-data-storage-requirements). In oncology the amount of storage is even greater due to the fact that the sequence of the DNA derived from both the tumor cell as well as the normal cell must be stored and the depth of coverage for such sequencing is greater. For one tumor/normal pair the amount of storage required could be 800 Gb–1 Tb (i.e., a terabyte is 1 million million (10^{12}) bytes).

13. Robert Gebelhoff, Washington Post, *Sequencing the genome creates so much data we don't know what to do with it* (July 7, 2015), available at http://www.washingtonpost.com/news/speaking-of-science/wp/2015/07/07/sequencing-the-genome-creates-so-much-data-we-dont-know-what-to-do-with-it/.

14. FDA News Release: FDA approves Praluent to treat certain patients with high cholesterol (July 24, 2015), available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455883.htm.

15. Caroline Chen, *These Superhumans Are Real and Their DNA Could Be Worth Billions*, Bloomberg Businessweek (July 22, 2015), available at http://www.bloomberg.com/news/articles/2015-07-22/these-superhumans-are-real-and-their-dna-could-be-worth-billions.

16. Ron Winslow, *FDA Approves Cholesterol Drug From Regeneron, Sanofi Praluent is among a powerful new class of cholesterol-lowering medicines*, Wall Street Journal (July 24, 2015), http://www.wsj.com/articles/fda-approves-cholesterol-drug-from-regeneron-sanofi-1437762374. See also Jill Arce, *FDA Approves Cholesterol-Lowering Drug Praluent By Regeneron And Sanofi: $15,000 A Year, Anyone*? Tech Times (July 25, 2015), available at http://www.techtimes.com/articles/71813/20150725/fda-approves-cholesterol-lowering-drug-praluent-by-regeneron-and-sanofi-15-000-a-year-anyone.htm.

17. Caroline Chen, *These Superhumans Are Real and Their DNA Could Be Worth Billions*, Bloomberg Businessweek (July 22, 2015), available at http://www.bloomberg.com/news/articles/2015-07-22/these-superhumans-are-real-and-their-dna-could-be-worth-billions.

18. *Id.*

19. *Id.*

20. *Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease*, The National Academy of Sciences (2011), p. 105 (see https://www.ucsf.edu/sites/default/files/legacy_files/documents/new-taxonomy.pdf).

21. *FACT SHEET: President Obama's Precision Medicine Initiative*, https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative. Also, in a February 2015 article in the New England Journal of Medicine by the Director of NIH, Dr. Francis Collins, and the then Director of NCI and Nobel laureate, Dr. Harold Varmus, described the President's initiative by stating that

> [t]he concept of precision medicine—prevention and treatment strategies that take individual variability into account—is not new; blood typing, for instance, has been used to guide blood transfusions for more than a century. But the prospect of applying this concept broadly has been dramatically improved by the recent development of large-scale biologic databases (such as the human genome sequence), powerful methods for characterizing patients (such as proteomics, metabolomics, genomics, diverse cellular assays, and even mobile health technology), and computational tools for analyzing large sets of data. What is needed now is a broad research program to encourage creative approaches to precision medicine, test them rigorously, and ultimately use them to build the evidence base needed to guide clinical practice.
>
> The proposed initiative has two main components: a near-term focus on cancers and a longer-term aim to generate knowledge applicable to the whole range of health and disease. Both components are now within our reach because of advances in basic research, including molecular biology, genomics, and bioinformatics. Furthermore, the initiative taps into converging trends of increased connectivity, through social media and mobile devices, and Americans' growing desire to be active partners in medical research. Available at http://www.nejm.org/doi/full/10.1056/NEJMp1500523?query=featured_home.

22. PCORI Patient-Centered Outcomes Research Institute. Available at http://www.pcori.org/about-us.

23. Rachael Fleurence, PhD and Joe V. Selby, MD, MPH, *PCORnet: Progress, Challenges, and Opportunities Ahead* (July 21, 2015), available at http://www.pcori.org/blog/pcornet-progress-challenges-and-opportunities-ahead.

24. *Id.*

25. See press release from the Office of the Governor, "Governor Cuomo Announce $105 Million in Funding Approved for New York State Genomic Medicine and Big Data Center" (July 17, 2014), available at www.governor.ny.gov/news/governor-cuomo-announces-105-million-funding-approved-new-york-state-genomic-medicine-and-big.

26. Pub. L. No. 104-191, 110 Stat. 1936 (1996).

27. HITECH is included in the provision of The American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111-5, 123 Stat. 115 (February 17, 2009).

28. 45 CFR part 160 and Subparts A and E of Part 164.

29. 45 CFR Part 160 and Subparts A and C of Part 164.

30. "Covered entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter." 45 CFR section 160.103.

31. A business associate acts on behalf of a covered entity and uses protected health information to the accomplishment of those services. For the full definition see 45 CFR section 160.103.

32. 45 CFR section 160.103

33. "Health information means any information, including **genetic information**, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual." (Emphasis added). 45 CFR section 160.103.

34. "Individually identifiable health information" is information that is a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual and (i)That identifies the individual; or (ii) **With respect to which there is a reasonable basis to believe the information can be used to identify the individual.**" (Emphasis added). 45 CFR section 160.103.

35. "*Genetic information* means: (1) Subject to paragraphs (2) and (3) of this definition, with respect to an individual, information about: (i) The individual's **genetic tests**; (ii) The genetic tests of family members of the individual; (iii) The manifestation of a disease or disorder in family members of such individual; or (iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual." (Emphasis added). 45 CFR section 160.103; "Genetic Tests" means "**an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes**. Genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition." (Emphasis added). 45 CFR section 160.103.

36. 45 CFR Section 160.103; Also, see 45 CFR Section 164.514(b)(2)(R) which lists as one of the factors to be stripped from health information to fit into the category of "de-identified" health information: "Any other unique identifying number, characteristic or code…"

37. Melissa Gymrek, Amy L. McGuire, David Golan, Eran Halperin, and Yaniv Erlich, *Identifying Personal Genomes by Surname Inference*, Science 339, no. 6117 (January 18, 2013): 321–24. doi:10.1126/science.1229566.

38. Within the human genome there are sections of repeating nucleotide sequences. These repeating sections come in various sizes. DNA regions with short repeat units (usually 2-6 base pairs in length) are called "Short Tandem Repeats" or "STR." Such STRs are variable among individuals and therefore are useful for identification purposes. The STR methodology does not reveal nucleotide sequence information but rather works based on size of the DNA fragments analyzed and their respective charges moving through a gel.

39. Kwok P et al., Harder Than You Think: A Case Study of Re-Identification Risk of HIPAA Compliant Records. NORC at The University of Chicago and Office of the National Coordinator for Health Information Technology, 2011, available at http://www.amstat.org/meetings/jsm/2011/onlineprogram/AbstractDetails.cfm?abstractid=302255.

40. The "Common Rule" refers to the set of regulations adopted by 15 separate federal agencies; the purpose of such regulations is to protect human subjects of research funded by federal dollars. The HHS regulations that contain the Common Rule are found at 45 CFR Part 46.

41. 76 Fed. Reg. 44512 (July 26, 2011).

42. 76 Fed. Reg. 44512, at 44525.

43. The inclusion of genomic data in the category of "protected health information" would have had a significant impact on the regulatory compliance of entities holding such data. The penalties for violating HIPAA can be significant. The civil money penalties under 45 CFR 160.404(b) can be millions of dollars. For example, in 2014 a major hospital system entered into a $4.8 million settlement with the Office of Civil Rights for an alleged HIPAA violation. Available at http://www.hhs.gov/news/press/2014pres/05/20140507b.html. It should also be noted that New York Civil Rights Law contains penalties for disclosure of genetic test results to persons or organizations not named on the applicable informed consent. New York Civil Rights Law Section 79-l(2)(d); see also the Assurance of Discontinuance from the New York State Attorney General's office regarding an alleged violation of 79-l. Available at http://www.ag.ny.gov/sites/default/files/pdfs/bureaus/civil_rights/New%20York%20and%20Presbyterian%20Hospital%20Agreement%20%28AOD%29.pdf.

44. 80 Fed. Reg. 53931 (Sept. 8, 2015); The Notice of Proposed Rulemaking is available at http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf.

45. *Id.* at 53945.

46. *Id.*

47. *Id.* at 53945. (See "Alternative Proposal A: Expand the Definition of "Human Subject" To Include Whole Genome Sequencing (WGS)").

48. *Id.* at 53945 -53946. (See "Alternative Proposal B: Alternative Proposal B: Classifying Certain Biospecimens Used in Particular Technologies as Meeting the Criteria for "Human Subject").

49. Pub.L. 110–233, 122 Stat. 881, enacted May 21, 2008; see also http://ginahelp.org/ for an informative guide to GINA created by Genetic Alliance, the Genetics and Public Policy Center at the Johns Hopkins University, and the National Coalition for Health Professional Education in Genetics through funding by The Pew Charitable Trusts.

50. NYS Civil Rights Law Section 79-l(2)(b).

51. *Attorney General Andrew Cuomo Reaches Agreement On Genetic Testing Disclosures With Columbia University And N.Y.—Presbyterian Hospitals*, available at http://www.ag.ny.gov/press-release/attorney-general-andrew-cuomo-reaches-agreement-genetic-testing-disclosures-columbia.

52. See NYS Civil Rights Law Section 79-l(9).

53. Center for Data Innovation and Health IT now, *From Evolution to Revolution: Building the 21st Century Genomic Infrastructure* (July 2015), available at http://www.healthitnow.org/wp-content/uploads/2015/07/Genomics-White-Paper-FINAL-Formatted.pdf.

54. American College of Healthcare Executives, Health Information Confidentiality policy statement (November 2012), https://www.ache.org/policy/hiconf.cfm.

55. Genetic Alliance; The New England Public Health Genetics Education Collaborative. Washington (DC), Chapter 7: Genetic Alliance; 2010 Feb 17. Available at http://www.ncbi.nlm.nih.gov/books/NBK132186/; The Genetics Alliance paper goes on to articulate other impacts of genetic diagnosis could have on families, couples, parents and communities. For example,

"[f]or adult-onset diseases, unaffected spouses may view their partners differently, and the diagnosis can lead to a breakdown in communication." The paper also states that "[g]enetics has been used in the past to stigmatize and discriminate along ethnic or racial lines, and underserved or underrepresented communities often view genetic research and services with distrust. They may feel that the results of a genetic test or newborn screening will be used to segregate their communities."

56. Presidential Commission for the Study of Bioethical Issues (2013, October). *Privacy and Progress in Whole Genome Sequencing*. Washington, DC: PCSBI, available at http://bioethics.gov/sites/default/files/PrivacyProgress508_1.pdf.

57. Einstein quotation inscribed on his statue on the grounds of the National Academy of Sciences, Washington, D.C.

58. Campbell EG, Clarridge BR, Gokhale M, et al., *Data Withholding in Academic Genetics: Evidence From a National Survey*. JAMA, 2002;287(4):473-480. doi:10.1001/jama.287.4.473.

59. *Final NIH Statement on Sharing Research Data,* February 26, 2003. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html; starting October 1, 2003, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year were expected to include a plan for data sharing or state why data sharing is not possible.

60. *NIH Intramural Policy on Large Database Sharing*, April 5, 2002. See http://sourcebook.od.nih.gov/ethic-conduct/large-db-sharing.htm.

61. *Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)*, August 28, 2007. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html.

62. Previous to the issuance of GWAS policy, data sharing was required for funding over a threshold of $500,000. Importantly, the GWAS policy had no threshold, and was required for any amount of NIH funding.

63. See *Genomic Data Sharing at NIH: The GWAS Policy Example*, Laura Lyman Rodriguez, Ph.D., National Human Genome Research Institute, National Institutes of Health from the SACGHS Genomic Data Sharing Session February 4, 2010, available at http://osp.od.nih.gov/sites/default/files/Rodriguez_NIHGDSPolicies_GWAS.pdf.

64. *Id.*; also see the Database of Genotypes and Phenotypes (dbGap), available at http://www.ncbi.nlm.nih.gov/gap.

65. 79 FR 51345. Available at https://gds.nih.gov/PDF/NIH_GDS_Policy.pdf.

66. See *Supplemental Information to the National Institutes of Health Genomic Data Sharing Policy* for an explanation of what is considered "large scale" for these purposes.

67. As discussed above, DNA is "transcribed" into RNA before it is "translated" into a protein. Not all of the DNA of a given cell is "transcribed" in that cell and therefore looking at the "transcripts" (i.e., the RNA that was transcribed from the DNA) can give researchers clues as to the amount of gene activity, also called gene expression, in a certain cell or tissue type. It is the differences in gene expression that are responsible for the different properties and behaviors of various cells and tissues, both in health and disease. For example, since the function of most genes is not known, if the study of these transcripts shows that an unknown gene's expression levels are dramatically higher in cancer cells than in healthy cells, the unknown gene may play a role in cell growth. On the other hand, however, if an unknown gene is expressed in fat tissue but not in bone or muscle tissue, the unknown gene may be involved in fat storage or metabolism. In both instances, it is the study of these transcripts that give researchers a good place to start searching for a newly found gene's function (see the NIH Transcriptome Fact Sheet, available at http://www.genome.gov/13014330).

68. The epigenome is made up of chemical compounds and proteins that can attach to/tag DNA and direct such actions as turning genes on or off, controlling the production of proteins in particular cells. These tags do not change the sequence of the DNA. Rather, they change the way cells use the DNA's instructions. A human being has trillions of cells, specialized for different functions in muscles, bones and the brain, and each of these cells carries essentially the same genome in its nucleus. The differences among cells are determined by how and when different sets of genes are turned on or off in various kinds of cells. Specialized cells in the eye turn on genes that make proteins that can detect light, while specialized cells in red blood cells make proteins that carry oxygen from the air to the rest of the body. The epigenome controls many of these changes to the genome.

    Until recently, scientists thought that human diseases were caused mainly by changes in DNA sequence, infectious agents such as bacteria and viruses, or environmental agents. Now, however, researchers have demonstrated that changes in the epigenome also can cause, or result from, disease. Epigenomics, thus, has become a vital part of efforts to better understand the human body and to improve human health. Epigenomic maps may someday enable doctors to determine an individual's health status and tailor a patient's response to therapies (excerpts taken from the NIH Epigenomics Fact Sheet available at http://www.genome.gov/27532724).

69. *Supplemental Information to the National Institutes of Health Genomic Data Sharing Policy* (August 27, 2014), available at https://gds.nih.gov/pdf/supplemental_info_GDS_Policy.pdf.

70. The *National Institutes of Health Guidance for Investigators in Developing Genomic Data Sharing Plans* (July 15, 2015), available at https://gds.nih.gov/pdf/NIH_guidance_developing_GDS_plans.pdf.

71. See also NIH's Genomic Data Sharing overview presentation, available at https://gds.nih.gov/pdf/NIH_GDS_Policy_Overview.pdf.

72. http://www.1000genomes.org/about.

73. The 1000 Genomes Project Consortium. A map of human genome variation from population scale sequencing, Nature, 2010;467(7319):1061-1073. doi:10.1038/nature09534, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3042601/.

74. See the 1000 Genome Data Release Policy, available at http://www.1000genomes.org/data#DataReleasePolicy.

75. See the Center for Global Health R&D Policy Assessment explanation of pre-competitive collaborations/consortia, http://healthresearchpolicy.org/primer/rules/selective-rules/organizational-models.

76. See for example, *Data Access for the Open Access Literature: PLOS's Data Policy* found at https://www.plos.org/data-access-for-the-open-access-literature-ploss-data-policy/: "PLOS journals require authors to make all data underlying the findings described in their manuscript fully available without restriction, with rare exception"; or the data availability policy of Nature which states, "A condition of publication in a Nature journal is that authors are required to make materials, data, code, and associated protocols promptly available to readers without undue qualifications," available at http://www.nature.com/authors/policies/availability.html.

77. Presidential Commission for the Study of Bioethical Issues published *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, Presidential Commission for the Study of Bioethical Issues (2013), available at http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf.

78. *Id.* at p. 3.

79. Page 95 of *Privacy and Progress in Whole Genome Sequencing.*

80. Page 98 of *Privacy and Progress in Whole Genome Sequencing.*

81. This technology allows a scientist to cut and insert small pieces of DNA along a DNA strand at a precise location targeted by the scientist.

82. Niu, Y., et al., Cell, http://dx.doi.org/10.1016/j.cell.2014.01.027 (2014).

83. Liang, P. et al., Protein, Cell, http://dx.doi.org/10.1007/s13238-015-0153-5 (2015).

84. Baltimore, D. et al., *A prudent path forward for genomic engineering and germline gene modification*, Science 3 April 2015: Vol. 348 no. 6230 pp. 36-38 DOI: 10.1126/science.aab1028; Among the authors' recommendations was to "[s]trongly discourage, even in those countries with lax jurisdictions where it might be permitted, any attempts at germline genome modification for clinical application in humans, while societal, environmental, and ethical implications of such activity are discussed among scientific and governmental organizations." p. 37.

85. Pollack, R., *Eugenics lurk in the shadow of CRISPR*, Science 22 May 2015: Vol. 348 no. 6237 p. 871 DOI: 10.1126/science.348.6237.871-a.

86. *NIH Guidelines For Research Involving Recombinant Or Synthetic Nucleic Acid Molecules* (November 2013). (Available at http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf).

87. *Id.* at p. 100.

88. *Statement on NIH funding of research using gene-editing technologies in human embryos*, April 29, 2015. Available at www.nih.gov/about/director/04292015_statement_gene_editing_technologies.htm.

89. The "Dickey-Wicker amendment" has been attached to federal appropriation bills of the Departments of Health and Human Services, Labor and Education each year since 1996. The language of that amendment prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. The original language can be found at H.R. 2880, Sec. 128 and had remained generally the same:

    None of the funds made available in this Act may be used for—

    > the creation of a human embryo or embryos for research purposes; or
    > (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
    > (b) For purposes of this section, the term `human embryo or embryos' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

90. 21 CFR 809.3.

91. A full transcript of the FDA Workshop "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests." Available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM439974.pdf.

92. Food and Drug Administration, Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests -Preliminary Discussion, Silver Spring, MD, December 29, 2014. Available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM427869.pdf.

93. See the FDA Discussion Paper Section IV, "Exploring New Regulatory Approaches for NGS Tests."

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101. L.2012, ch.19, eff. Oct.1, 2012, amended L. 2012, ch. 55, eff. August 1, 2012.

102. "The New York State DNA Databank is a computerized collection of DNA descriptions or 'profiles' derived from DNA samples of convicted offenders required by law to provide a sample; from crime scenes; from missing persons or the relatives of missing persons, and from offenders who voluntarily provide a sample in connection with a plea bargain, participation in a Department of Correctional Services temporary release program, or release on parole or probation. These profiles are maintained in the convicted offender index, the forensic index, the missing persons index, and the subject index, respectively. The DNA Databank is maintained at the New York State Police Forensic Investigation Center in Albany." NYS Division of Criminal Justice Services, DNA Frequently Asked Questions; see http://criminaljustice.ny.gov/forensic/dnafaqs.htm.

103. The New York State DNA Databank was created pursuant to Chapter 737 of the Laws of 1994. The statutory provisions establishing the Databank are found in Executive Law §995-c.

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Biobanks: Goals, Challenges, Ethics and the Law

By Karen L. Illuzzi Gallinari

Introduction

The wonders and woes of modern medicine create fascinating and frustrating conflicts between patient rights and public health. These days, everyone is aware and usually involved in the annual example of influenza vaccination. Given the population's experience with the flu, most people understand the issues and the import. Fewer folks, however, know much about how our knowledge of and ability to control contagious diseases came about. Now, given the tremendous opportunities presented by advances in genetics, the general population is learning about medical research and how they can personally participate in the discoveries that will improve our lives tomorrow.

This article will describe the process of inviting people to participate in genetic research by consenting to the inclusion of their specimens in a biobank. It will also discuss the law which regulates the process and the ethical issues involved.

"[G]iven the tremendous opportunities presented by advances in genetics, the general population is learning about medical research and how they can personally participate in the discoveries that will improve our lives tomorrow."

A biobank is a collection of blood, urine, saliva or tissue specimens for use in medical research. Participation is being encouraged throughout the country to permit us to enjoy the promise of personalized medicine as soon as possible. Personalized or precision medicine involves the use of diagnostic tools, treatments, medications and preventive advice tailored to a person's individual genetic characteristics.[1] Examples include the use of Herceptin for patients who have HER2 positive breast cancer[2] and selection of medication for asthma based on a patient's genetic characteristics.[3] Research studies revealed specific treatments to be most effective in patients with those characteristics. Additional research on large groups of biospecimens is expected to identify improved treatment for many illnesses.[4] Despite the promise of genetic research, legal regulations and ethical principles require that researchers proceed with responsible attention to the rights of those who donate their specimens.

Much has been written on the ethical issues involved in biobanking. Rogelio Lasso presented a list of biobanking issues in his review of the 2009 tome on the Ethics of Research Biobanking.[5]

> Biobanking raises a host of legal and ethical concerns that extend well beyond issues of privacy protection and the confidentiality of medical information, including
>
> (1) what information biobank donors should be given;
>
> (2) when is the commercialization of biobanked tissue and information appropriate;
>
> (3) who should reap the benefits of commercialized biobanking;
>
> (4) whether individuals can protect themselves from unauthorized use of their tissue samples; and
>
> (5) what new ethical policies and legal regulations are necessary to govern the emerging biobanking economy.[6]

Since that time, hundreds of articles have addressed these issues, as well as others which have become apparent such as the management, governance and stewardship of biobanks.[7] Even the under-utilization of donated specimens has become a concern.[8] Nonetheless, given the clear promise of genetic research and the diligent attention being devoted to facilitate and maximize ethical and legally compliant research practices, progress must and is being made.

The Goals of a Biobank

All medical centers have tissue and blood specimens stored as required by law for patients who underwent diagnostic procedures. Excess tissue and blood specimens are generally discarded after diagnostic testing. One of several goals of most biobanks is to obtain patient permission for the medical center to store leftover specimens in order to conduct medical research. The value of doing so is especially important in multi-cultural communities with highly culturally diverse and minority populations.

Significant numbers of minorities often have not been included in medical research from which drugs and other treatments have been developed. As a result, researchers are often unable to identify cultural differences in the effectiveness of most treatments.[9] Similar issues exist with respect to the opportunity to include children in research studies. A biobank designed to invite parents to consider consenting to the inclusion of their child's blood and tissue specimens facilitates the development of information on how drugs and other treatments impact the pediatric population.

In addition to expanding the number and diversity of human specimens available for general research to include a larger representation of minorities and children, patients can also be offered the opportunity to be contacted for specific research studies for which they may qualify. Increasing the pool of potentially qualified study participants provides researchers with better data, and communities with greater representation, as improved and new medical treatments are developed.

The Process

While medical researchers are free to prepare a legally compliant consent form to expand their biobanks, a number of academic medical centers decided to use this opportunity to further engage with their communities in their planning stages. Community focus groups have been convened to react to and help researchers improve educational materials and the consent approach. The following outlines the goals of some consent forms and community focus groups:

1. Obtain permission to store and use patients' leftover blood and tissue for general genetic research.
2. Obtain permission to contact patients for clinical trials, potentially including trials involving HIV, mental health, substance abuse and genetic markers.
3. De-identify data, but link back through an honest broker[10] when more information is needed or a clinical trial opens warranting outreach to qualified patients. An example of additional information that may be needed are risk factors that were not previously known to be relevant.

Goals for Community Focus Groups

1. Educate the patient population on community based research and biobanks.
2. Elicit community input on a proposed consent form.
3. Assess patient understanding and comfort with the consent form.

Community Engagement

Biobanks have provided a rich opportunity for community outreach and education. Many academic medical centers have taken this opportunity to expand their patient population's knowledge and interest in research efforts.[11] Equally important is the value of addressing the ethical issues presented with those most affected and showing the community the commitment that researchers have to protect their privacy and deserve their trust. A fair amount of literature has been published on the results of these efforts.[12]

Cardozo Law student Jaclyn D'Arminio reviewed the interesting results of one of these efforts, in her law journal article regarding *State Storage and Usage of Baby's Blood Samples*.[13]

> A recent study examined the American public's view on the possibility of a large scale biobank and how various changes in the biobanking process would encourage greater contributions.[14] Interestingly, the study showed that when asked about the types of entities people were concerned about having their samples and information, seventy-five percent of respondents indicated that they were concerned over government control, whereas only fifty-six percent were concerned over private researchers having control.[15] Further, ninety-two percent of the study participants agreed to allow academic and medical researchers to submit research projects using biobank samples, twelve percent higher than those who would agree to allow government researchers to use the same samples.[16]
>
> The study also examined participant's preferences for consent. Research participants overwhelmingly[17] responded that being asked for consent made them feel "respected and involved," and nearly three-quarters of the participants suggested it would make them feel that they "had control" over the samples.[18] When asked about types of consent,[19] forty-eight percent felt comfortable with a blanket consent form for all research approved by an oversight panel, in comparison to forty-two percent of those who wanted to be asked prior to every research project.[20]

In fact, many studies reveal that when participant rights are responsibly addressed, the majority of individuals support the development of biobanks.[21]

Existing Biobanks

Hundreds, perhaps thousands, of biobanks exist worldwide. The most comprehensive listing is available through Specimen Central, a global resource to aid biomedical research.[22] Even Specimen Central's directory is not complete, as it only lists biobanks which have been registered with it.

List of New York biobanks registered with Specimen Central, as of July 2015:

NY	Syracuse	Central New York Eye & Tissue Bank
NY	New York	Creative Bioarray
NY	New York	Columbia U. Brain Bank
NY	New York	Mantle Cell Lymphoma Cell Bank
NY	New York	Manhattan HIV Brain Bank
NY	New York	Mount Sinai Biobank
NY	New York	New York University Specialty Tissue Banks
NY	New York	StemSave
NY	Manhasset	North Shore LIJ Biorepository
NY	Buffalo	Roswell Park Biorepository
NY	Vestal	Cardio-Facio-Cutaneous Syndrome International Biobank

There are also numerous industry organizations which support biobanks and address biobanking issues.[23] The following are among the issues currently being addressed.

Patient Specific Results

Medical research moves deliberately and slowly to ensure that participant safety remains paramount. Further, in most cases, vast amounts of information must be analyzed before informative patterns emerge. As a result, samples from many people must be studied over many years before research results have meaning. It has, therefore, been unlikely that any meaningful patient specific result would surface during a single research study. Nonetheless, given the increased ability to process large amounts of data quickly and the increased numbers of genetic markers of disease risk, there is a possibility of discovering a patient specific result with potential health or reproductive importance. Such an actionable patient specific result is called an "incidental finding" because the discovery is outside the aims of the study.[24]

The possibility of the discovery of an actionable patient specific result presents a number of challenges. Specifically, it is impossible to predict whether attempting to contact an individual who contributes a sample to the biobank will make sense in the future. Further, if contact may be valuable, the ability to locate the participant in the future cannot be guaranteed. It is also very important to avoid a "therapeutic misconception." Accordingly, participants must be advised not to confuse participation in a biobank with medical treatment. Consent form language, along the following lines, is recommended to inform participates about these possibilities and challenges.

> ***Will I receive my genetic results or information about my health?***
>
> *You should not expect to receive genetic or other test results. We will not be conducting standard tests to evaluate your health. Researchers must study samples from many people over many years before they know if the results have meaning. In the rare event that we discover information which may help you prevent or treat a serious illness, we may try to locate you and offer you the information.*

The nature of incidental findings and the ethical obligations they raise was the subject of dialog and analysis by the Presidential Commission on Bioethics in 2013. The Commission's deliberations culminated in the Incidental Findings Report it published.[25] The Commission's acknowledgements and recommendations include:

- Researchers are not under any duty to look for specific incidental findings.[26]
- Researchers should develop a specific plan, as part of their Institutional Review Board (IRB) submission, articulating how predictable and unpredictable individual results will be managed.[27]
- Research participants should be informed about the scope of incidental findings, whether they will be disclosed and the process of disclosure.[28]

Risks of Participation

The risks of participation in biobanks are typically quite minimal, especially for those which use only residual samples from diagnostic testing or treatment a patient is already receiving. Research studies which involve taking a blood sample, which is not otherwise necessary for the individual's medical treatment, present the small risk of infection or bruising. There is also an unavoidable, albeit small privacy risk.

Many patient samples are used without researchers knowing the identity of the participant. Further, when identified samples are used, access should be strictly limited to authorized researchers. State and federal privacy, information security and data sharing[29] obligations also mandate that research institutions implement required electronic and other security measures. Nonetheless, the possibility of a security or data breach can never be completely eliminated.

In addition, given the rare possibility that meaningful individual results become available, receipt of actionable health or reproductive information may cause the individual anxiety. Private life, long term care, or disability insurance may also be affected. Genetic counseling can and should be offered to help address risks of learning individual genetic results.

Laws limiting genetic discrimination provide some protection. The Genetic Information Nondiscrimination Act (called "GINA")[30] prevents group *health* insurers from denying insurance, increasing costs or otherwise discriminating against anyone based on genetic information. GINA also prevents *employers* from using genetic information for hiring, firing, promotion or salary decisions. Additional federal and state laws also provide some protection.[31]

GINA does not, however, apply to life, disability, or long term care insurance companies. If an individual applies for *private* life, disability, or long term care insurance, some life, disability and long term care insurance companies may ask for personal genetic information, and may deny or increase the cost of that coverage based on the information provided. Life or disability coverage provided by an employer, however, should not be affected, as individual employees usually do not have to fill out applications for group life or disability coverage.

Keep in mind, as well, that genetic information is already used by the insurance industry for deciding how much to charge for life, disability, and long term care insurance. Most insurance companies already ask anyone interested in buying private insurance about people in their immediate family who died young of cancer, diabetes, heart or kidney disease.

Pediatric Samples

Including children to participate in biobanks is important and controversial.[32] Pediatric samples are needed for most studies designed to address childhood illness. The medical and ethical issues include whether children whose parents provide consent on their behalf can and should be contacted once they are old enough to consent on their own behalf,[33] and whether genetic carrier testing or testing for childhood or adult onset conditions will be conducted.[34] Nonetheless, researchers will not be able to speak confidently to effectiveness in the pediatric population without including children. Therefore, many academic medical centers include children when they seek consent for participation.

While the parents of children under the age of 18 will be approached for consent on behalf of their children, literature is prepared to explain the issue to children old enough to read, and their assent is generally elicited.

Given the difficulty in locating a child for further consent once the child turns 18, some institutions elect to remove unused pediatric samples at that time, unless the individual consents to the continued use of the samples. Other institutions inform parents or legal guardians that the samples will remain in the biobank as long as they may be useful, and rely upon the adult to remind the participant about his/her right to have unused samples removed once the child turns 18.

Adults Who Lack Capacity

The nature of research conducted on specimens contributed to a biobank prevents any significant possibility of benefit to a participant. Therefore, despite the very minimal risk involved in participating, including adults who lack capacity, has been controversial and generally avoided. Nonetheless, including such adults is valuable for certain research, especially research on illnesses which involve decreased mental capacity.

In January 2014, the New York State Task Force on Life and the Law issued a *Report and Recommendations For Research With Human Subjects Who Lack Capacity.*[35] It was the first detailed treatment of the issue since the 2009 recommendations proposed by U.S. Secretary of Health and Human Services Advisory Committee on Human Research Protections' Subcommittee on the Inclusion of Individuals with Impaired Decision Making in Research.[36] The NYS Task Force's thorough and thoughtful analysis of existing law and the ethics involved provides much needed guidance to permit IRBs to approve worthy research involving mentally incapacitated participants when certain criteria and procedures are met, even when there is no prospect of benefit to the participant.

> For research with minimal risk and *no prospect of direct benefit* to the participant, IRBs may approve such studies if the risks are reasonable in relation to the prospective benefits.[37]

The Law

A number of federal and state statutes and judicial decisions apply to the legality of using an individual's DNA[38] in medical research. It has been noted that the current regulatory system may need "to be revised"[39] to better secure patients' privacy without "unduly burdening research."[40] Nonetheless, compliance with existing law ensures a fair amount of attention to the importance of making every feasible effort to inform individuals, protect their privacy and provide them an opportunity to agree or object to the use of their specimens and information.

Some judicial decisions have addressed the right of researchers to use patients' blood and tissue specimens.[41] There has also been groundbreaking federal agency activity to increase participant involvement in research development. Specifically, in the first action of its kind, the National Institute of Health (NIH) reached an agreement with the family of Henrietta Lacks, an African-American woman who was the unwitting source of cells which, when cultured, became the first known human immortal cell line, now known as the HeLa cell line.[42] The agreement invites the Lacks family's participation in reviewing requests to use their matriarch's cells which have become invaluable to the research community.[43] Nonetheless, the most important developing law is legislative.

Federal and state statutes impose specific obligations on researchers to protect patients' privacy and their right to informed consent. The broadest federal privacy protections enacted along with other protections in the Health Insurance Portability and Accountability Act (HIPAA)[44] applies to identifiable patient information. Patient information which excludes seventeen (17) data elements and any other unique identifier[45] is deemed de-identified and is exempted from the patient authorization requirement of HIPAA, even when the samples are coded in a manner that permits future re-identification of the patient.[46] Patients are informed that their information may be used in certain circumstances for research by the HIPAA Privacy Notice that must be provided on each patient's first visit.[47] Nonetheless, patient consent for use of DNA data, collected for research, which may be linked to a patient, is required by some state genetic information confidentiality laws.[48] The inconsistencies among state laws present challenges for researchers who collaborate across the country.

To encourage the discovery of valuable information that comes from broad data sharing among researchers, without compromising participant privacy, the NIH recently issued the Genomic Data Sharing Policy.[49] The federal statute for the Protection of Human Subjects is also under revision.[50]

HHS' Revisions to the Common Rule

On July 26th, 2011, the Office of the Secretary of Health and Human Services (HHS) and the federal Office of Science and Technology (OSTP) published proposed reforms to the federal human subject regulation codified thirty years ago at 45 CFR Part 46.[51] Twenty years ago these regulations were adopted by 15 U.S. Federal departments and agencies and have since been known as the "Common Rule." Federal Drug Administration regulations which apply primarily to drug and device research are separate but similar.[52]

Advances in human subject research and health information technology, especially involving genetic research, have raised issues and opportunities not clearly addressed by the current regulations. Therefore, the Agencies' (HHS and OSTP) purposes in revising the Common Rule are to:

(1) enhance the protection of research subjects and

(2) improve the efficiency of the process of reviewing research proposals.

HHS' Advanced Notice of Proposed Rule Making (ANPRM)[53] presented the first of two opportunities to comment before the proposals are finalized. On September 8, 2015, HHS published a Notice of Proposed Rule Making (NPRM) in the Federal Register.[54] Any additional comments are due by December 7, 2015.

Significant proposed reforms in the ANPRM included:

1. Requiring consent for research use of any biospecimens collected, after the effective date of the proposed revisions.

   Currently, under federal law, researchers may use existing biospecimens, not collected for research, without a patient's consent, provided the specimen is stripped of identifying information.[55] New York State already requires consent for the use of even de-identified biospecimens for genetic research.[56]

2. Establishing mandatory data security and information protection standards to eliminate the need for IRBs to review informational risks of research.

   These standards are being designed to mirror those in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) and would include breach notification. They may also, however, mandate encryption of data, which is now only a voluntary "reasonable safeguard" under HIPAA/HITECH. Nonetheless, in practice, most institutions are

already striving to encrypt data to avoid patient notification regulations imposed when non-encrypted data is lost or stolen.

3. Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk.

   These proposed revisions are designed to reduce detailed IRB review of minimal risk research.

4. Using a single IRB for all domestic sites of multi-site studies.

5. Updating the forms and processes used for informed consent.[57]

6. Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient.

7. Extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from any of the agencies which require compliance with the Common Rule.

8. Providing uniform clarification and guidance on federal regulations.

In addition to requesting comments on the proposed revisions, the Agencies (HHS and OSTP) invited input on 74 specific related questions.[58] The Association of Academic Medical Centers is one of the industry organizations which submitted comments on behalf of its members.[59]

The revisions to the Common Rule, once completed, will attend to a number of concerns about participant protections and research procedures.[60] Nonetheless, challenges such as incidental findings, commercialization and pediatric participants will require additional attention from all stakeholders.

Conclusion

Continued commitment to legal compliance with genetic testing and research regulations is necessary to protect participants' rights and to educate and fully inform them. Further, continued dialog on the ethical issues which are not always fully addressed by existing regulations is also warranted. Deliberate attention to these issues is necessary to avoid scientific progress from advancing faster than our ability to ensure sufficient human subject protections. Otherwise, Hans Jonas's 1969 warning may prove warranted.

> Let us…remember that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having.[61]

Endnotes

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6. Lasso, *supra* note 5.
7. *See e.g.* Gail E. Henderson, et al., *Stewardship practices of US biobanks*, 5 Science translational medicine 215 (2013); Teresa Edwards, et al., *Biobanks containing clinical specimens: defining characteristics, policies, and practices*, 47.4 Clinical biochemistry 245-251 (2014); Gail E. Henderson, et al., *Characterizing biobank organizations in the U.S: results from a national survey*, 5(1) Genome Medicine 3 (2013); Jean R. Cadigan, et al., *Neglected Ethical Issues in Biobank Management: Results from a US Study*, 9 Life Sciences, Society, and Policy, 1-13 (2013).
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11. *See e.g.* D. M. Roden, et al., *Development of a Large-Scale De-Identified DNA Biobank to Enable Personalized Medicine*, 84(3) Clinical Phamacology & Therapeutics 362-369 (2008) (Regarding Vanderbuilt University's DNA Biobank, Nashville Tenn.). *See also Engage Project, Deliberative Community Engagement collaboration among researchers, health care providers, University of California leaders, and community members*. Supported by the National Center

for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), http://ctsi.ucsf.edu/sites/ctsi.ucsf.edu/files/attachments/EngageUC_BriefingBook_English.pdf.

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15. *Id.*
16. "75% of participants stated they would allow pharmaceutical company researchers to use their samples and surprisingly 49% said that, so long as their samples were de-identified, the information and research could be made available "'on the internet to anyone.'" *Id.* at 647.
17. *Id.* at 636.
18. *Id.* at 647.
19. "This research question examined the extent to which the subjects felt they should be involved in deciding which research studies should have access to their tissues and/or information. An action of blanket consent happens once, at the time in which the tissue is deposited, and covers any and all research the review board allows. Varying from blanket consent is a situation where a biobank donor consents to all areas of research but declines to allow participation in specific areas of research. Finally, the extreme form of consent would be a requirement that the biobank re-contact the donor for consent with every research study." *Id.* at 647.
20. "The remaining 10% selected the option to opt out of those categories of research for which they would not like to participate." *Id.* at 647.
21. *See e.g.* Jamie Bryant, et al., *Oncology patients overwhelmingly support tissue banking*, 15(1) BMC Cancer 413 (2015).
22. http://www.specimencentral.com/biobank-directory.aspx.
23. *E.g.* International Society for Biological and Environmental Repositories (ISBER is a global organization which creates opportunities for sharing ideas in biobanking and harmonizes approaches to evolving challenges for biological and environmental repositories, http://www.isber.org/); The Public Population Project in Genomics and Society (P^3G is a not-for-profit consortium that provides the international research community with access to the expertise and tools for research and encourages collaboration between biobanks, http://www.p3g.org/about-p3g). *See also* Public Responsibility in Medicine and Research (PRIM&R advances ethical standards in the conduct of research through education, membership services, professional certification, public policy initiatives, and community building, http://www.primr.org/); The American Society for Bioethics and Humanities (ASBH promotes the exchange of ideas and fosters interdisciplinary scholarship among people engaged in bioethics, http://www.asbh.org).
24. S.M.Wolf, et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36(2) The Journal of Law, Medicine & Ethics: A Journal of the American Society of Law, Medicine & Ethics, 219-211 (2008).
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26. *Id.* at 16.
27. *Id.* at 15-16.
28. *Id*. at 14.
29. NIH Genomic Data Sharing Policy (GDS Policy), NIH Guide Grants and Contracts (available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html), and in the Federal Register (available at https://federalregister.gov/a/2014-20385) (August 28, 2014).
30. Genetic Information Nondiscrimination Act of 2008, 42 USC Sec. 2000ff-10 (2008) (GINA, pronounced Gee-na).
31. In New York State, Article 26 of the Insurance Laws (ISC § 2615) and Article 79-l of the Civil Rights Laws (CVR § 79-l) address the need for written informed consent relating to genetic testing. These laws also address the confidentiality of genetic test results and prohibit the misuse of genetic information by health insurers. You can locate the full content of these laws at public.leginfo.state.ny.us/menugetf.cgi.

    In 1996 the Health Insurance Portability and Accountability Act (HIPAA) was created which prevents employers from denying health insurance based on genetic information. The Americans with Disabilities Act of 1990, and the Equal Employment Opportunity Commission of 1995, also provide some protection. Additionally, in 2000, Executive Order 13145 was issued to prohibit agencies of the federal government from obtaining genetic information about their employees or job applicants and from using genetic information in hiring and promoting decisions." New York State Department of Health Web Site, https://www.health.ny.gov/diseases/cancer/genetics/genetic_discrimination.htm.
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35. Report and Recommendations for Research With Human Subjects Who Lack Capacity, New York State Task Force on Life and the Law, https://www.health.ny.gov/regulations/task_force/docs/report_human_subjects_research.pdf.
36. *Id*. at 4.
37. *Id.* at 24.
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39. M. A. Rothstein, *Is Deidentification Sufficient to Protect Health Privacy in Research?*, 10(9) The American Journal of Bioethics, 3 (2010).
40. *Id.*
41. *E.g.* Moore v. the Regents of the University of California et al., 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990) (Plaintiff did not state a cause of action for conversion against physician who developed cell line from his cells without his permission. He did, however, state a cause of action for lack of informed consent and

breach of fiduciary duty.); Greenberg v. Miami Children's Hospital Research Institute, Inc., 264 F.Supp.2d 1064 (USDC, S.D. Fla. 2003) (Physician did not owe persons from whom he was receiving body tissue and fluid samples, for use in research on Canavan disease, duty to obtain their informed consent to commercial use of materials before he could obtain patent on gene discovered to be source of disease, as result of research using materials); N. Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research,* 23(1) Harvard Journal of Law & Technology, 119-177 (2009); Marshall Kapp, *Legal Approach to the Use of Human Biological Materials for Research Purposes*, 10 Rutgers JL & Pub. Policy 1 (2013).

42. https://en.wikipedia.org/wiki/Henrietta_Lacks.

43. http://www.nih.gov/news/health/aug2013/nih-07.htm (Describing NIH agreement with Lacks family).

44. Health Insurance Portability and Accountability Act ("HIPAA") Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule"), 45 CFR 164 (1996). Final Omnibus Rule Jan 2013.

45. "(A) Names (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000. (C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older; (D) Telephone numbers; (E) Fax numbers; (F) Electronic mail addresses; (G) Social security numbers; (H) Medical record numbers; (I) Health plan beneficiary numbers; (J) Account numbers; (K) Certificate/license numbers; (L) Vehicle identifiers and serial numbers, including license plate numbers; (M) Device identifiers and serial numbers; (N) Web Universal Resource Locators (URLs); (O) Internet Protocol (IP) address numbers; (P) Biometric identifiers, including finger and voice prints; (Q) Full face photographic images and any comparable images; and(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section." HIPAA, 45 CFR Part 164.514 (b)(2).

46. HIPAA, 45 CFR 164.514(c); *see also,* Guidance on Research Involving Coded Private Information or Biological Specimens, Office for Human Research Protections, http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm (providing guidance on HIPAA and 45 CFR Part 46.102) (OHRP Guidance).

47. *For example, Montefiore Medical Centers' Privacy Notice states:* "Notice of Privacy Practices…. How we may use and disclose health information about you…. Research under certain circumstances, we may use and disclose Health Information for research purposes. For example, a research project may involve comparing the health and recovery of all patients who received one medication to those who received another, for the same condition. Before we use or disclose Health Information for research, however, the project will go through a special approval process, which balances the benefits of research with the patient's need for privacy. Even without special approval, we may permit researchers to look at records to help them identify patients who may be included in their research projects or for similar purposes, so long as they do not remove or take a copy of any Health Information," http://www.montefiore.org/privacy-policy.

48. *See* National Conference of State Legislatures, http://www.ncsl.org/research/health/genetic-privacy-laws.aspx.

49. 79 Fed. Reg. 51345 (August 28, 2014, available at https://federalregister.gov/a/2014-20385). Note: "Research that was initiated prior to the effective date of the [Genomic Data Sharing] Policy will continue to operate under the terms of the policies that were in effect when the research began, such as the 2008 *NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies* (the GWAS Policy), the 2004 *NIH Policy on Sharing of Model Organisms for Biomedical Research*, or the 2003 *NIH Data Sharing Policy*," https://gds.nih.gov/03policy2.html.

50. NPRM, 80(173) Fed. Reg. 53933 (Sept.8, 2015), http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf; *see also* http://primr.blogspot.com/2015/06/prim-meets-with-omb-to-offer-input-on.html (Professional Responsibility in Medicine and Research Association Meets with Office of Management and Budget on Proposed Changes to the Common Rule).

51. Protection of Human Subjects, 45 CFR 46 (Revised 2009).

52. Food and Drug Administration, 21CFR 50.25 Elements of Informed Consent.

53. ANPRM 76 (143) Fed. Reg. 44512-44531 (Tuesday, July 26, 2011), http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm.

54. NPRM 80(173) Fed. Reg. 53933 (Sept.8, 2015), http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf.

55. OHRP Guidance, *supra* note 46.

56. New York State Civil Rights Law Section 79-L (2)(f). Note that New York State's Statute for the Protection of Human Subjects, NYS Public Health Law Article 24-A, is not applicable to use of specimens left over from medical treatment given definition of Human Subject and given applicability of federal Common Rule. *See* 24-A Pub. Hlth. Law Sections 2441 and 2445.

57. For recent research regarding the benefits of multimedia approaches to improve participant comprehensive of consent forms *see* Christian Simon, et al., *Interactive multimedia consent for biobanking: a randomized trial,* Genetics in Medicine, (advance publication online April 2015), http://www.nature.com/gim/journal/vaop/ncurrent/pdf/gim201533a.pdf.

58. Full text of the ANPRM, including the related questions, is available at: http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm.

59. Comments submitted to HHS to date can be viewed at: http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html.

60. For an example of recent legislation abroad see García-Merino, Isabel Ma, et al., "Specific Legislation on Biobanks in Spain."*Biopreservation and biobanking* 13.3 (2015): 207-211.

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At the Biotechnological Frontier: Law, Human Enhancement, and Transhumanism

By Sander Rabin, M.D., J.D.

Prologue

Much sooner than you think, a new client will arrive at your office. She'll be wearing augmented reality glasses with a heads-up display, and will tell you that she's had a chip implanted in her brain that's raised her IQ to 200. Although petite, she dopes herself regularly and demurely claims to have the strength and agility of Serena Williams. Your client claims that her civil rights were violated and wants your counsel. She tells you that her right to cognitive liberty was violated in the course of an MRI scan of her head, during which the National Security Agency hacked the neural correlates of her political affiliations. She tells you that her rights to procreative liberty and participant evolution were violated when her health insurer declined to cover a three-parent in vitro fertilization procedure to prevent passing defective genes to her offspring. She adds that a bill pending in the New York State legislature will restrict her right to morphological freedom. Puzzled yet fascinated, you ask for more details and permission to activate a voice recorder. She tells you it's unnecessary because her videocam is already recording your encounter, adding that she'll upload a copy to her Dropbox account for your access. As she speaks, an artificial intelligence app in her augmented reality glasses is interpreting your facial expressions, correlating them with a databank of emotional states. It informs her that you've got a lot to learn about transhumanism and human enhancement enabling technology.

A. Introduction

Human enhancement enabling technology ("HEET"),[1] will generate fundamental legal issues regarding personhood, intention, responsibility, liability, competence, and capacity that will impact all areas of legal practice. To prepare the legal profession for this challenge, this article is an introduction to HEET, it's allied philosophy and political ideology transhumanism, and the role that the legal profession can play as HEET is deployed in the U.S.

HEET is designed to boost human physical and mental capabilities beyond their biological limits, and to radically extend the human lifespan. HEET can also create human-animal hybrids, and perhaps eclipse the bounds of human intelligence. Because of these impacts, HEET calls on us to revisit fundamental questions about our human nature and nature itself. Our answers to these questions are unchallenged and old. And, because they underlie bedrock legal concepts such as personhood, property, competence, liability, rights and duties, these too will need to be revisited in light of what HEET will make possible.

"HEET will generate fundamental legal issues regarding personhood, intention, responsibility, liability, competence, and capacity that will impact all areas of legal practice."

Outside of the legal profession, the permissible impacts of HEET on our views of nature and human nature form opposing views in a fierce ethical and political debate. On one side of this debate are bioconservatives, defending us from any human enhancement, and, on the other side are transhumanists, standing for our right to become more than human. The political aspect of this debate suggests that heretofore philosophical questions about our human nature and nature itself will soon take on a practical, day-to-day relevance, as we wrest control of evolution from either natural selection or a divine creator.

With bioconservatives and transhumanists endorsing opposing moral imperatives over outcomes reminiscent of the myth of Prometheus and the bargain of Faust, the time has come for the legal profession to take part in the controversy over the human governance of its own evolution.[2]

B. What Is Human Enhancement?

We're all familiar with medical technology that's used to manage or cure disease and replace or repair damaged body parts. Human enhancement[3] refers to the use of HEET to radically extend the human lifespan and to boost human physical and mental capabilities beyond their inherent biological limitations. With its additional capabilities of creating human-animal hybrids or inorganic sentient beings with artificial intelligence that exceeds our own, it is possible that human enhancement will transform, not merely change, the nature of human nature and the human condition.

C. What Is HEET?

HEET refers to a set of emerging technologies designed to extend the human lifespan or augment human physical and mental capabilities, and includes:

- biotechnology (including genetic engineering);
- nanotechnology;
- information technology (including robotics and artificial intelligence); and,
- neurotechnology.

Exemplary products of HEET include, drugs, bionic implants, smart prostheses, and brain-machine interfaces.

Present-day pharmaceutical examples of HEET include the use of Prodigal (modafinil)[4] to enhance learning and concentration, or the use of erythropoietins (Epogen or Procrit)[5] to increase aerobic capacity and endurance in athletes.

Present-day bionic precursors of HEET include retinal implants to treat blindness,[6] and thought-controlled prosthetic limbs to restore lost function in amputees.[7] The U.S. Defense Advanced Research Projects Agency (DARPA) is developing HEET to augment learning ability and the recall of information, expand battlefield situational awareness, boost endurance, sharpen focus, and overcome combat fatigue.[8] HEET also encompasses the creation of a variety of 'humanoid' beings, such as, chimeric humans,[9] transgenic humans,[10] cybernetic humans,[11] and inorganic humanoids.[12]

D. What Is Transhumanism?

Transhumanism[13] is an ideology that advocates the use of HEET to redefine human nature by enhancing human physical and cognitive abilities and replacing natural selection as the driver of evolution. Transhumanists believe that human nature is an evolutionary work in progress, which has finally arrived at a stage where it's capable of modification by human beings, with extraordinary benefits for the entire human race.

Transhumanism originated as a philosophy built around freedom of choice and freedom from coercion in the use of HEET consistently with the maintenance of a stable democratic society. Transhumanism has formulated a supportive ethical stance, and has evolved into a hoped-for future that is mobilizing a loosely knit and growing worldwide movement. Transhumanism is also becoming a political ideology[14] as evidenced by the first U.S. presidential contender running on a transhumanist platform.[15]

E. What Is Bioconservatism?

With a philosophy, political ideology, and ethical stance in opposition to transhumanism, bioconservatives[16] believe that human nature is sacred and fragile, being either the final product of a divine creator or millions of years of evolution. As such, it should never be modified. Moreover, because the long-term consequences of human enhancement are unpredictable, the risk of altering anything "intrinsic" to the human nature is unacceptable to bioconservatives.

F. What Are Human Nature and the Human Condition?

Given the transhumanist view of human nature as dynamic and malleable and the opposing bioconservative view of human nature as sacrosanct and inviolable, it's useful to review what is meant by human nature.

While human nature[17] refers to those distinctive characteristics that human beings are endowed with independently of the influence of culture, such as inherent ways of thinking, feeling, and behaving. The questions of what these characteristics are, how many of them must be present for a being to be a human being, how fixed they are, and where they originate, are among the oldest of questions. The problem with all theories about human nature is that none are amenable to objective testing for verification. The most that can be said for theories of human nature is that they have adherents who advocate moral conclusions that their theory of human nature implies.[18]

For some, the definition of human nature may be religious. For those without a religious basis for their definition, actual human behavior and activity in the prevailing state of nature might be a plausible indicator of human nature. Both ways of defining human nature face the problem that little about today's human beings and the present state of nature resembles human beings and the state of nature at the time religious or other definitions were created.

Our history of continuous progress, which can be viewed as an uninterrupted process of human enhancement, changes how we live and what we do with our lives. In many respects, HEET extrapolates from earlier technologies that have long been used and accepted. When taken with the observation that human nature is dynamically adaptive, the lack of consensus over human nature's definition and its disputed relationship to human behavior weaken the argument that human enhancement threatens human nature.

The controversy over proceeding with human technological enhancement because of the concern that it may alter human nature has no conclusive logical or moral resolution. This is not to say that human enhancement should happen in a laissez faire manner. Rather, each kind of enhancement will likely need to be assessed on its own, weighing its personal and societal benefits against its personal and societal costs. The "answers" about human enhancement will vary from technology to technology, from culture to culture, and from time to time.[19]

The human condition may defined as the known and presumed characteristics, key events, and situations which define the limits and features of human existence, such as birth, growth, emotionality, aspiration, conflict, and mortality. This topic continues to be pondered from many perspectives.[20] If realized, transhumanist goals will profoundly impact the human condition.

G. What Drives Human Enhancement?

The 5 Ps of our human nature:

- Permanency (self-preservation, immortality);
- Power;
- Profit;
- Pleasure; and
- Pride (vanity),

strongly pull for human enhancement.[21] Global competitiveness is driven by profit and economic power. National security is driven by self-preservation, profit, and military power. A multi-billion dollar fashion and beauty industry is driven by vanity. High standards of living are driven to comfort, convenience, and pleasure.

With its increasing reliance on bionic implants, such as cardiac pacemakers, cochlear implants,[22] and neuroprostheses,[23] medicine is another major driver of human enhancement. Regenerative medicine, stem cell technology and feats of genetic engineering are blurring the line that divides healing and restoration from enhancement.

H. Haven't We Been Enhancing All Along?

A major characteristic of human nature is inventing tools and HEET may be regarded as an irresistible extension of our tool-making genius. On this interpretation, we have always been enhancing ourselves, although much of the resulting control has been external to our bodies. However, the objection to human enhancement because it makes supernormal changes in the body, whereas tools do not, weakens when we realize that memories and mental skills are embodied in physical changes in our brains. The location of any line drawn to distinguish tool making from human enhancement is arbitrary.[24]

I. Why Is Human Enhancement Problematical?

Objections to human enhancement typically arise from strongly held beliefs, religious convictions, adherence to traditions, or subscriptions to taboos.

Examples of such beliefs, convictions, traditions, or taboos are captured in such phrases as:

- "Human enhancement reduces human beings to 'machines'."
- "Human enhancement tampers with our 'human essence'."
- "Human enhancement is 'playing God'."
- "Human enhancement is 'tampering with' human nature."

While rigorous analysis reveals these objections to be scientifically untenable, it does not diminish their import, because questions about human nature and our relationship to human nature can't be answered by scientific inquiry alone.[25] Similarly, the question of whether human nature is an evolutionary work in progress ready for modification or the precious product of a divine creator or millions of years of natural selection is unlikely to be answered on the basis of evidence. One way of understanding this is to see people as divided between two different epistemologies. One model is procedural, evidence-based, and reflects scientific thinking. The other model focuses on outcomes, accepts beliefs based on their compatibility with other commitments, and rejects evidence if it does not support these commitments.[26]

J. What Is Transhuman Jurisprudence?

American constitutional principles provide the framework for the deliberation of bioethical issues important to the law. However, in many cases it will be unlikely that legal issues in human enhancement and transhumanism can, even in principle, be resolved by reference to constitution principles. That is because human enhancement and transhumanism challenge the validity of the very norms and assumptions implicit in human nature that inform the text, logic, and interpretation of the Constitution. For example, the legal standards by which to assign or deny legal personhood to a cybernetic human being, a transgenic human being, or an artificial intelligence entity can't be inferred or extrapolated from the Constitution because the existence of such beings was impossible in the state of nature that has prevailed from it's drafting until now. The assignment of legal capacity to artificial intelligence entities is becoming a pressing transactional necessity in a digital economy, and legal competence for artificial intelligence entities will necessarily follow.[27] Legal capacity and competence follow the attainment of majority, an age-related norm, and have no relevance to artificial intelligence entities. Legal capacity and competence will have to become more rigorously defined, perhaps as an attained measure along an intelligence scale, provided we can legally define intelligence.

Issues of personhood, intention, responsibility, liability, competence, and capacity will impact all areas of legal practice. Adding to these impacts, transhumanists, in support of HEET, will likely assert four new rights that are not recognized in law.

- "Morphological Freedom"—is a right to maintain, modify, or refuse to modify one's body, on one's own terms.[28]
- "Cognitive Liberty"—is a right of privacy for thoughts and feelings where they arise within the nervous system and a right to maintain or modify one's nervous system, on one's own terms.[29]
- "Procreative Liberty"—is the right against interference by the state or others with reproduction and reproductive decisions.[30]
- "Right to Participant Evolution"—encompassing the foregoing three rights, the right to participant evolution is the right to the deliberate redesign of the human body and brain using technology. The right of participant evolution is effectively a right to individual evolutionary self-determination.[31]

K. Why Should We Care and What Can We Do?

Presently, there are no laws dealing with human enhancement. Transhumanism has not yet given rise to any justiciable controversies. HEET's limited reduction to practice and hypothetical impacts have not yet focused the attention of legislatures on its regulation. But even if laws on human enhancement were in existence, the difficulty, for example, that international law encounters on the high seas foreshadows the difficulty that law will have in the realm of human enhancement. This is because HEET will have global impacts that will not respect national sovereignty. The impacts of HEET cannot be controlled by the legal system of any individual nation. In restrictive nations, people of means will avail themselves of contraband or foreign-sourced HEET.

The global dissemination of HEET raises the question of whether law can make any difference in its applications. Still, given what's at stake, the case for a legal response, even if only as an ideal, is compelling. If we do nothing, human enhancement's emergence may give way to disruption. We will be unprepared to manage the risks and we will lose the opportunity to fairly distribute the benefits. If we prepare, we can design a legal framework that serves a technologically enhanced world, as we preempt or minimize the potential for harm. But what are our options?

Presently, we have three options: the imposition of a moratorium; no laws or regulations; and, some laws and regulations.

A moratorium would have to be worldwide to be effective and no worldwide moratorium on anything has proven to work. Given the possibility that HEET could overcome the effects of trauma and certain diseases, there are humanitarian disadvantages to frank prohibition. Moreover, achieving agreement on what constitutes a prohibited use of HEET will be formidable. As with any dual-use technology, compliance with and enforcement of a multilateral moratorium on human enhancement will be challenging. Evasion of a multilateral moratorium on human enhancement will be relatively easy.

Another way the future of HEET may unfold is with little or no legal regulation. A laissez faire legal regime would be reckless given the risks to human safety. It's unlikely that complete market freedom will be acceptable, either because of market failures or unacceptable ethical failures.

Given the appeal of enhancements and radical life extension, regulation is likely to be appropriate, if imperfect. There is a shared conviction that law should least try to moderate social ills, even if it cannot eliminate them. In the U.S., a likely scenario is one in which law lags behind the impacts of HEET and creates an ad hoc regulatory infrastructure involving the Justice Department, HHS, FDA, EPA, etc. The fact that the U.S. is a nation with 51 legal jurisdictions will not simplify matters. In any event, in the U.S., the most critical legal issue will, in my opinion, not be how to regulate HEET, but whether or not the creations of HEET are endowed with legal personhood and its constitutional protections.

Internationally, the U.S. has a strategic interest in developing a shared normative framework for how HEET must be used to be lawful. The U.S. could take the lead in publicly articulating the legal principles it applies and the policies and processes it establishes, encouraging others to do likewise. The development of norms and best practices worked out in the U.S. can be exported to discussions around the world.[32]

Epilogue

The impact of technology on human nature requires reflection on who we are and on what we want to become. Human enhancement exemplifies the most revolutionary and ironic turn in the development of humanity—the usurpation by human beings of the role of natural selection in evolution; and, once it takes hold, homo sapiens will become something else. This article extends an invitation to pay attention to the human-machine interaction, its increasing in-distinction, and its impact on human nature and the human condition. Thinking about regulating these developments should entail thinking in terms of possibilities, rather than limitations, provided such thinking encompasses the question of what it is that we want to become. This is a normative question par excellence. Given that humanity itself is now subject to engineering, reflecting the question of what we want to become has acquired a particular urgency.[33]

Endnotes

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26. Dale Jamieson, *Reason in a Dark Time: Why the Struggle Against Climate Change Failed—and What It Means for Our Future* (Kindle Locations 302-304), Oxford University Press. Kindle Edition.
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28. Wikipedia, *Morphological freedom*, available at: http://en.wikipedia.org/wiki/Morphological_freedom (accessed September 14, 2015).
29. Cognitive liberty is defined as "the right of each individual to think independently and autonomously, to use the full spectrum of his or her mind, and to engage in multiple modes of thought." Cognitive liberty is a response to (i) the increasing ability of technology to monitor and manipulate cognitive function, and, (ii) the corresponding increase in the need to ensure individual cognitive autonomy and privacy. Rather than just protecting the content of an individual's thoughts, cognitive liberty seeks to protect an individual's right to determine his or her own state of mind and be free of external control over his or her state of mind.

    The principle of cognitive liberty received a limited level of recognition in the United States in a decision of the U.S. Supreme Court in *Sell v. United States*, 29 U.S. 166 (2003). In *Sell*, the Supreme Court examined whether a lower court had the power to make an order to forcibly administer antipsychotic medication to an individual who had refused such treatment, for the sole purpose of making him competent to stand trial. The Supreme Court held that while the lower court did retain the power to make such an order, it could do so only in rare circumstances, and where no less intrusive method is available. Though there is no explicit mention of cognitive liberty in the judgment, it tacitly upholds the right to keep one's mind free from direct outside interference except in the rarest of circumstances.
30. John A. Robertson, *Procreative Liberty in the Era of Genomics*, 440 American Journal of Law & Medicine, 29 (2003): 439-87.
31. Wikipedia, *Participant evolution*, available at: https://en.wikipedia.org/wiki/Participant_evolution (accessed September 14, 2015).
32. Kenneth Anderson and Matthew Waxman, *Law and Ethics for Autonomous Weapon Systems Why a Ban Won't Work and How the Laws of War Can*, available at: http://ssrn.com/abstract=2250126 (accessed on September 14, 2015).
33. Orna Ben-Naftali and Zvi Triger, *The Human Conditioning: International Law and Science Fiction*, available at: http://ssrn.com/abstract=2343601.

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Shrouded in Controversy: Evolution of the Right of Sepulcher and a Medical Examiner's Obligations Under the Right of Sepulcher and the Public Health Law

By Karen M. Richards and Brian M. Jacobson

I. Introduction

> Death is unique. It is unlike aught else in its certainty and its incidents. A corpse in some respects is the strangest thing on earth. A man who but yesterday breathed and thought, and walked among us has passed. Something has gone. The body is left still and cold, and is all that is visible to mortal eye of the man we knew.*** And the law—that rule of action which touches all human things—must touch also upon this thing of death.[1]

The Court of Appeals recently touched "upon this thing of death." In *Shipley v. City of New York*, the issue was whether a medical examiner has a mandated obligation, pursuant to the common-law right of sepulcher and the Public Health Law, to notify a decedent's next of kin that, although a decedent's body is available for burial, organs and/or tissues have been retained for further examination and testing as part of an authorized autopsy.[2] *Shipley* is reviewed later in this article, but first this article summarizes the right of sepulcher and provides a brief history of the evolution of this ancient right and of the ownership of the dead.

II. The Right of Sepulcher: "An Indignity to the Dead Is an Offense to the Living"[3]

It is well-settled that "[t]he common-law right of sepulcher gives the surviving next of kin an absolute right to the immediate possession of the decedent's body for preservation and burial."[4] Next of kin "are entitled to such right of possession as a solace and comfort in their time of distress."[5] Damages have been awarded for interfering with the surviving kin's immediate right to possession of the body and also for desecrating or mishandling the body, inappropriately dealing with the body, mistakenly identifying the remains, failing to notify the surviving kin of the decedent's death, or performing an unauthorized autopsy.[6]

The right of sepulcher compensates the next of kin for the emotional suffering, mental anguish, psychological injuries, and physical consequences they experience from the interference with their ability to properly bury their decedent.[7] The likelihood of mental anguish in right of sepulcher actions is considered inherently genuine and is therefore generally presumed.[8] Thus, violation of the right is one of the "narrow category of [negligence causes of action] that requires no physical harm, no fear of harm, and no zone of danger" in order for the plaintiff to recover for purely emotional damages.[9]

III. Evolution of the Ownership of the Dead and of the Right of Sepulcher

The ownership of the dead has held a unique, if not odd, status in New York law. Early New York courts adhered to the common-law doctrine, derived from the dictum of a 17th century Englishman, that there is no property right in a corpse, but societal changes in the late 18th and early 19th centuries led to a modification of the doctrine.

A. Ecclesiastical Law in England

Before the Norman Conquest, there were no separate ecclesiastical courts in England.[10] "[T]he power of the clergy over the dead was kept in check by uniting the lay with the clerical order in the ecclesiastical tribunals."[11] Around 1072, soon after the Norman Conquest, temporal courts and Courts Christian were separated by an ordinance of William the Conqueror.[12]

Ecclesiastical cognizance, the exclusive power of the ecclesiastics, over the remains of the dead was both executive and judicial.[13] It was executive in taking the body into its actual, corporeal possession, and "guarding its repose in consecrated ground," and it was judicial in deciding all controversies involving interment, including who should be allowed to lie in consecrated earth and who should be allowed to be interred at all.[14] The Courts Christian virtually monopolized judicial power over burials, while "[s]ecular courts, stripped of all authority over the dead, were left to confine themselves to matters involving the protection of monuments, and other external emblems of grief, erected by the living."[15]

"[D]uties with respect to corpses were excluded from actions at common law because burials were matters of ecclesiastical cognizance."[16] The heirs and next of kin "were not permitted to have any choice or to give directions as to the ceremonies attending the funeral, or the place of burial, or to have control in any manner over the bodies of their deceased relatives."[17] They were only permitted to erect monuments and embellish the graves of their deceased kin.[18]

In addition, the heirs and next of kin could not maintain a civil action "for indecently, or even impiously, disturbing the remains of his buried ancestor."[19] Yet, the

parson, who had the freehold of the soil, could maintain a trespass action against the person who disturbed the remains.[20]

In the 17th century, Sir Edward Coke, a prominent English barrister, judge, and politician, commented on the church's exclusive jurisdiction over the dead:

> It is to be observed, that in every sepulcher, that hath a monument, two things are to be considered, viz., the monument, and the sepulture or buriall of the dead. The buriall of the *cadaver* (that is *caro data vermibus*) is *nullius in bonis* [among the property of no man], and belongs to ecclesiasticall cognizance; but as to the monument, action is given (as hath been said) at the common law for the defacing thereof.[21]

The rejection by Lord Coke and his contemporaries of a property right in a dead body formulated the common-law doctrine in the ownership of the dead.[22] As the Court of Appeals stated, "Coke's classic edict is of more than historical interest; it has been a staple of the common law."[23]

B. Rejection of Ecclesiastical Law and Lord Coke's Dictum

The United States "adopted many of the laws and institutions of England in the formation of our government, [but it] persistently, constantly, and successfully…resisted all attempts on the part of ecclesiastical authorities or churches to usurp or control the powers and rights of the legislative or judicial departments of this country."[24]

> The English emigration to America—the most momentous event in political history—commenced in the very age when Chief-Justice Coke was proclaiming, as a legal dogma, the exclusive authority of the Church over the dead. The liberty-loving, God-fearing Englishmen who founded these American States, had seen enough of 'ecclesiastical cognizance,' and they crossed a broad and stormy ocean to a new and untrodden continent, to escape from it forever.[25]

However, Lord Coke's "classic edict" became part of Anglo-American law, but criticism of his dictum by the referee in *In re Widening of Beekman Street* changed the view courts held on the ownership of the dead.[26]

In *Beekman Street*, the subject of the right of burial and the protection of corpses arose when New York City condemned land in an 18th century church cemetery in order to widen a street. Considered "the premier American case on the right to burial of a dead body,"[27] it was referred to Samuel B. Ruggles to determine the rights respecting reburial of disinterred bodies.[28] In 1856, he issued a "learned and elaborate" report, which the court confirmed in all aspects.[29]

Ruggles questioned "both the wisdom and the etymology [of Coke's] verbal deceit...[that] "[t]he burial of a cadaver, this is, caro data vermibus (flesh given to worms) is nullius in bonis and belongs to ecclesiastical cognizance."[30] He contended that Coke's dictum did not preclude an individual's legal interest in a corpse, but rather:

> only that the burial was 'nullius in bonis'; and this assertion was legally true in England, where it was made, for the peculiar reason…that the temporal office of burial had been brought within the exclusive legal cognizance of the Church, who could and would enforce all necessary rules for the proper sepulture and custody of the body, thus rendering any individual action in that respect unnecessary.[31]

He asserted that the right to protect the dead was not eradicated by the Norman Conquest, although the ecclesiastics, "who poured into England with the Conqueror exerted themselves actively and indefatigably to monopolize for the Church the temporal authority over the dead."[32] Instead, the right to protect the dead "was a concentration in the ecclesiastical body, of every right which any individual had previously possessed to secure their repose. The individual right was not extinguished; it was only absorbed by the Church."[33]

Ruggles found that much of the difficulty regarding the subject of whether a body was entitled to protection arose from the "false and needless assumption…that nothing is property that has not a pecuniary value."[34] The real question was not "the disposable, market value of a corpse or its remains as an article of traffic [but rather it was] the sacred and inherent right to its custody in order decently to bury it and to secure its undisturbed repose."[35] Thus, he opined that adopting English ecclesiastical law "would be an eternal disgrace to American jurisprudence [because its dogma that] a child has no claim, no such exclusive power, no peculiar interest in the dead body of its parent [was] utterly inconsistent with every enlightened perception of personal right [and] inexpressibly repulsive to every proper moral sense."[36]

After a "quite full and interesting discussion" of the history of burial and the disposition of the body after death in the report,[37] Ruggles determined that "no ecclesiastical element exists in the jurisprudence of [New York] State, or in the framework of its government" and should have no influence on the rights inherent in, and related to, the dead and their resting place.[38] Accordingly, he submitted the following conclusions:

1. That neither the corpse, nor its burial, is legally subject, in any way, to ecclesiastical cognizance nor to sacerdotal power of any kind.
2. That the right to bury the corpse and to preserve its remains, is a legal right, which the courts of law will recognize and protect.
3. That such right, in the absence of any testamentary disposition, belongs to the next of kin.
4. That the right to protect the remains includes the right to preserve them by separate burial, to select the place of sepulture, and to change it at pleasure.
5. That if the place of burial be taken for public use, the next of kin may claim to be indemnified for the expense of removing and suitably reinterring their remains.[39]

Ruggles was aware that his answers to the questions of "Who is legally and primarily entitled to the custody of a dead body? and as a necessary result, Who is legally bound to bury it? and further, if a body be ejected from its place of burial, Who then is legally and primarily entitled to its custody, and who is bound to rebury it?" would be important, not just for the *Beekman Street* case, but also for furnishing a rule in other cases.[40] Indeed, Ruggles' report, cited with approval in nearly all subsequent cases involving rights in the dead, "has exerted more influence on American decisions in this field than any other piece of literature, judicial or otherwise."[41]

C. New York Courts Recognize a Quasi-Property Right to a Corpse and Recovery for "Mental Suffering and Injury to the Feelings" for Violation of the Right of Sepulcher

In the 19th century, the combination of conflict between family members over control of the deceased's body for burial, unauthorized autopsies, and body-snatching from graveyards by thieves and medical students,[42] and the growing use of cremation as an alternative to burial led to an "outpouring" of cases regarding the dead.[43] This flood of cases led to judicial recognition of the exclusive right of the next of kin to possess and control the disposition of the bodies of their loved ones, the violation of which was actionable at law.[44]

During this period, New York courts were guided by decisions in other jurisdictions. In particular, they looked to *Pierce v. Proprietors of Swan Point Cemetery* for precedent in recognizing a quasi-property right to a body, and to *Larson v. Chase* for precedent in allowing recovery for emotional injury in right of sepulcher actions.[45]

In *Pierce*, the Rhode Island court expressly stated that there is no property right in a corpse, "using the word in the ordinary sense…[, but it understood that] the burial of the dead is a subject which interests the feelings of mankind to a much greater degree than many matters of actual property."[46] The court considered the body "as a sort of *quasi* property, to which certain persons may have rights as they have duties to perform towards it arising out of our common humanity," such as the duties to bury the dead and to protect the corpse from violation.[47] Nevertheless, the person having charge of the body was not "the owner of it in any sense whatever [; rather, this person held it] only as a sacred trust for the benefit of all who may from family or friendship have an interest in it…"[48]

In the seminal case of *Larson*, which "appears to have been the first case in the United States recognizing a cause of action for unlawful autopsy,"[49] the Minnesota court that held the widow could recover for "mental suffering and injury to the feelings" for the unlawful mutilation and dissection of her husband's corpse, even though she could not claim pecuniary damages from the dissection itself.[50] *Larson* rejected the conclusion that trespass was the only action that could be brought for mutilating or disturbing remains, as common sense dictated that the real and substantial wrong was an indignity to the dead, not a trespass on the land.[51]

In 1896, in *Foley v. Phelps*, a case of first impression in New York, the issue was whether the defendant was civilly liable to Mrs. Foley for the unauthorized autopsy performed on her late husband's remains.[52] The court found "a sort of *quasi* property right" in the "duty imposed by the universal feelings of mankind to be discharged by some one [sic] toward the dead" and a duty and also a right "to protect [the dead] from violation, and a duty on the part of others to abstain from violation."[53]

Nonetheless, the court was not "disposed to put the right of the plaintiff to maintain this action on the ground of a property right in the remains of her husband."[54] Instead, "[i]rrespective of any claim of property," the court determined that Mrs. Foley, as the decedent's nearest relative, had a clear legal right to the possession of her husband's corpse for the purpose of burial.[55]

> That right of possession is a clear legal right, and to use the language of Mr. Ruggles in his valuable report, adopted by the court, in the Brick Church Case, 4 Bradf. (Sur.) 532, 'The right to bury a corpse, and to preserve its remains, is a legal right, which the courts of law will recognize and protect.' The right is to the possession of the corpse in the same condition it was in when death supervened.[56]

Violating Mrs. Foley's "right to what remains when the breath leaves the body [not] to a hacked, hewed, and mutilated corpse…" furnished a ground for a civil action for damages.[57] While the court considered *Larson's* opinion in allowing recovery for mental injury "well-considered and well-reasoned," it declined "to express any opinion with respect to the measure of damages in a case of this kind [but the court was] satisfied that the action [would] lie, and [would] lie in favor of the widow."[58]

Recovery for emotional injury in right of sepulcher actions was recognized in New York in 1911, when the Court of Appeals decided *Darcy v. Presbyterian Hospital in the City of New York*.[59] Jane Darcy sought to recover damages from the defendant for interfering with her right to possess her deceased son's body and for performing an autopsy on his body without her authorization.[60] The Court approved of the rule adopted in *Larson* and held that Mrs. Darcy, being the mother and the nearest surviving kin to the decedent, was entitled to "recover damages for her wounded feelings and mental distress" resulting from the unauthorized autopsy.[61]

Although New York courts accept the concept of a quasi-property right in a corpse,[62] they nonetheless carefully point out that a quasi-property right in a dead body is "clearly distinguishable from the right of ownership."[63] They have consistently stated that there is no property right in the ordinary, proprietary, commercial sense of the term in a dead body;[64] rather, the body was only "regarded as property so far as it is necessary to entitle the next of kin to legal protection from violation or invasion of its place of burial."[65]

However, the concept of a quasi-property right has been criticized as a "legal fiction" created by courts as a means of awarding damages to the deceased's next of kin.[66] As stated by Prosser in The Law of Torts, "[i]t seems reasonably obvious that such 'property' is something evolved out of thin air to meet the occasion, and that it is in reality the personal feelings of the survivors which are being protected, under a fiction likely to deceive no one but a lawyer."[67]

D. The Right of Sepulcher in the 21st Century

New York courts in the 21st Century have reviewed the rights inherent in, and relating to, a dead body or its parts, but they have not modified the common-law right of sepculcher. *Colavito v. New York Organ Donor Network, Inc*.[68] and *WTC Families for a Proper Burial, Inc. v. City of New York*[69] are two cases decided by modern courts.

In *Colavito*, when the Court of Appeals heard the issue of whether a specified donee of an anatomical gift could sustain a claim for conversion, it reviewed the right in a deceased human body and its parts.[70] After Robert Colavito's longtime friend died, his friend's widow directed a donation of both kidneys to Colavito, who was on a waiting list for a kidney transplant.[71] After Colavito had been fully prepped for surgery, an aneurysm was found in the kidney, rendering it unfit for transplant.[72] His surgeon contacted the New York Organ Donor Network and asked for the other kidney but was informed that it had been allocated to someone else, contrary to the wishes of the donor's widow.[73] Subsequent tests indicated that both kidneys were histo-incompatible with Colavito's antibodies, and therefore, even if the other kidney had been available, it would not have been of use to Colavito.[74]

Colavito argued that upon the widow's directed organ donation, the kidneys, unconditionally and irrevocably, became his property, and that the defendants' actions constituted conversion because they intentionally and wrongfully acquired the other kidney when they misdirected it to another transplant recipient.[75] He maintained that the incompatibility of the kidneys had no bearing on the fact that the defendants misappropriated the other kidney.[76]

The district court granted the defendants' motion for summary judgment, concluding "that it would be against public policy to engage in a valuation of Mr. Colavito's kidneys, which are not property" and "inappropriate to expand the limited right that courts recognize in a deceased's body, which only belongs to the next of kin to ensure proper burial."[77] Colavito appealed.

Determining that the case raised novel and important questions of New York law, the Second Circuit reserved judgment on the conversion claim and certified several questions to the New York Court of Appeals, including:

> Do the applicable provisions of the New York Public Health Law vest the intended recipient of a directed organ donation with rights that can be vindicated in a private party's lawsuit sounding in the common law tort of conversion or through a private right of action inferred from the New York Public Health Law?[78]

The Court of Appeals answered in the negative, basing its answer on the fact that the kidney was an incompatible match to Colavito: "as a specified donee of an incompatible kidney, [Colavito] had no common-law right to the organ. For that reason, his cause of action of conversion must fail, as it is necessarily based on his claimed right to possess the kidney in question."[79]

Colavito's private cause of action under the New York Public Health Law also failed because the statute is available only to those who fall within the statutory term "donee."[80] The Court construed "donee" as "someone who needs the donated organ" and because the kidney was medically incompatible with Colavito, he did not "need" the organ.[81]

In light of the Court of Appeals' answer to its certified question, the Second Circuit concluded that Colavito had no cause of action under either the common law of conversion or the Public Health Law.[82] The defendants, therefore, were entitled to summary judgment.[83]

WTC Families resulted from the September 11, 2001 terrorist attacks on the World Trade Center. In this case, the plaintiffs contended that commingling the remains of their deceased with other debris from the World Trade Center site, and permanently leaving those commingled remains at a landfill, violated their right to possess and bury the bodies of their next of kin.[84]

In addressing the plaintiffs' allegations, federal courts relied on the doctrine of a quasi-property right in a dead body, noting that:

> New York law recognizes a quasi-property right of the next of kin in the remains of a deceased person for the purposes of ensuring a proper disposal of the remains. The right is not a property right in the ordinary sense of the term; rather the right extends only as far as necessary to entitle the next of kin to protection from violation or invasion of the place of burial, and to protect the next of kin's right to ensure a proper burial.[85]

Although acknowledging that a "'quasi-property right' has been extended to identifiable, recoverable bodies of the next of kin," the court found that this right did not extend to "an undifferentiated mass of dirt that may or may not contain undetectable traces of human remains not identifiable to any particular human being."[86] "Without something tangible or identifiable, there is no property right."[87]

Thus, "a total and complete absence of identifiable remains of any identifiable person" was fatal to the plaintiffs' Constitutional claims.[88] It was also fatal to their claims under New York's conversion, burial, and/or public health laws "because without identified remains of an identifiable deceased, there is no person, or part of a person, and there can be no right, to bury."[89]

IV. *Shipley v. City of New York*

In *Shipley v. City of New York*, the Court of Appeals held that a medical examiner does not have a mandated obligation—pursuant to the New York Public Health Law and the common-law right of sepulcher—to notify a decedent's next of kin that, although a decedent's body is available for burial, organs and/or tissues have been retained for further examination and testing as part of an authorized autopsy.[90] Judge Pigott wrote the majority opinion, with Judges Read, Abdus-Salaam, Stein, and Fahey concurring. Judge Rivera dissented in an opinion in which Chief Judge Lippman concurred.

Jesse Shipley, a 17-year-old high school senior, died in an automobile accident on January 9, 2005.[91] The day following the accident, with the consent of Jesse's father,[92] Dr. Stephen de Roux, a forensic pathologist and a medical examiner employed by the Office of the New York City Medical Examiner, conducted an autopsy at the Richmond County Mortuary. Mr. Shipley asked the medical examiner to make his son's body "as presentable as possible" for the funeral.[93]

During the autopsy, the medical examiner removed the decedent's brain and took tissue samples from other organs for further examination.[94] The brain was placed in a jar "fixed in formalin for [subsequent] neuropathologic examination and reporting" and was placed in a cabinet in the autopsy room of the Richmond County Mortuary.[95]

The autopsy was completed within 24 hours of Jesse's death, and his body was released to a funeral home for burial.[96] A wake and funeral were held, and Jesse's remains were interred on January 13, 2005.[97]

In March 2005, forensic science students and a teacher from Jesse's high school participated in a field trip to the Richmond County Mortuary.[98] During a tour of the autopsy room, the students observed a jar containing a brain and labeled with Jesse's name.[99] This information was relayed to Jesse's sister, who informed her parents.[100]

The Shipley's priest informed them that, under Catholic dogma, their son's burial was not proper without the remaining body parts.[101] In response to the Shipleys' request, the Medical Examiner's Office returned the brain and the retained samples from other organs. They were placed in a "little casket"[102] and a second funeral and burial service was held.[103]

On March 31, 2006, Jesse's parents and sister commenced an action against the City of New York and the Medical Examiner's Office (collectively, the "City"), alleging negligent infliction of emotional distress resulting from the public display and alleged mishandling and withholding of their son's brain.[104] A lengthy court battle ensued.[105]

A bifurcated trial was held, and on the issue of liability, the trial court granted the Shipleys' motion for a directed verdict.[106] Following a trial on damages, the jury awarded $1 million for the Shipleys.[107] The City's motion to set aside the verdict, on the basis that the award exceeded reasonable compensation, was denied.[108] The Appellate Division affirmed the judgment entered upon the Shipleys stipulating to a reduced award of $300,000 to each individual plaintiff.[109]

The Court of Appeals granted the City leave to appeal. Oral arguments were held on January 5, 2015, but as two vacancies existed on the Court, only five judges heard the arguments. Realizing they were unlikely to reach a four-judge majority, the five judges decided to hold reargu-ments.[110] After Judges Stein and Fahey were appointed to the Court, oral arguments were heard again on May 7, 2015.

The pertinent issue on appeal was "whether, in the exercise of his statutory duties and obligations, the medical examiner nevertheless had a common-law and statutory duty to notify the Shipleys of his retention of certain organs and tissues, and therefore violated the Shipleys' common-law right of sepulcher and the Public Health Law when he failed to do so."[111] The Court dismissed the complaint in its entirety, finding:

> there is simply no legal directive that requires a medical examiner to return

> organs or tissue samples derived from a lawful autopsy and retained by the medical examiner after such autopsy. The medical examiner's obligations under both the common-law right of sepulcher and Public Health Law § 4215(1) are fulfilled upon returning the deceased's body to the next of kin after a lawful autopsy has been conducted.[112]

In reaching this conclusion, the Court first recognized that "the right of sepulcher is premised on the next of kin's right to possess the body for preservation and burial (or other proper disposition), and is geared toward affording the next of kin solace and comfort in the ritual of burying or otherwise properly disposing of the body."[113] Therefore, "it is the *act of depriving the next of kin of the body*, and not the deprivation of organ or tissue samples within the body, that constitutes a violation of the right of sepulcher."[114] The Shipleys were not deprived of their son's body; it was returned to them once the authorized autopsy had been conducted and was thus available for preservation and burial.[115]

The Shipleys' right of sepulcher could be violated only if the common law directed the medical director to return to the next of kin, once the authorized autopsy was conducted, their decedent's body and the organs and tissue samples as well.[116] However, New York's "right of sepulcher jurisprudence does not mandate that a medical examiner return [a] decedent's organs and tissue samples."[117]

The issue of whether the medical examiner had a ministerial duty pursuant to Public Health Law § 4215(1) boiled down to whether the statutory language "'remains of the body' refers to what is left of the body *after* an autopsy is conducted (as the City argue[d]) or whether it requires the medical examiner to turn over not only the body but also any organs or tissue samples that have been removed during the autopsy (as the Shipleys contend[ed])."[118] Section 4215(1) provides:

> [i]n all cases in which a dissection has been made, the provisions of this article [42, entitled 'Cadavers'], requiring the burial or other lawful disposition of a body of a deceased person, and the provisions of law providing for the punishment of interference with or injuries to it, *apply equally to the remains of the body after dissection as soon as the lawful purposes of such dissection have been accomplished*.[119]

After reviewing language in other sections of the Public Health Law, the Court interpreted the statute as excluding organs removed during an autopsy, reasoning that "[h]ad the Legislature so intended, rather than utilizing the phrase 'remains of the body,' it could have utilized the specific words 'tissue, organ or part thereof' as it has done in other sections of article 42 of the Public Health Law."[120] Since the Legislature did not do so, the Court found "there is no language that would cause a medical examiner to divine from section 4215(1) that he or she is required to return not only decedent's body, but the organs and tissue samples that the medical examiner is legally permitted to remove."[121]

> Thus, because there was no governing rule or statutory command requiring a medical examiner to turn over organs and tissue samples, it could not be said that he or she has a ministerial duty to do so. At most, a medical examiner's determination to return only the body without notice that organs and tissue samples are being retained is discretionary, and, therefore, no tort liability can be imposed for either the violation of the common-law right of sepulcher or Public Health Law § 4215(1).***Absent a duty to turn over organs and tissue samples, it cannot be said that the medical examiner has a legal duty to inform the next of kin that organs and tissue samples have been retained.[122]

V. Conclusion

Since the earliest pre-Christian civilizations, virtually every faith and society has provided the dead with a proper burial.[123] "The ancient concept that every person is entitled to a proper burial…provides the origins of American jurisprudence concerning the right of sepulcher."[124]

Neither the right of sepulcher nor the Public Health Law requires a medical examiner to notify the next of kin that organs, tissues, and other specimens were removed from the body or to return them to the next of kin prior to burial or other disposition of the body. Whether a medical examiner's obligations will be broadened depends on the state Legislature. As Judge Pigott, writing for the majority in *Shipley*, stated, "it is the Legislature that is in the best position to examine the issue and craft legislation that will consider the rights of families and the next of kin while concomitantly taking into account the medical examiner's statutory obligations to conduct autopsies."[125]

Endnotes

1. *Louisville & Nashville Railroad Co.*, 123 Ga. 62, 51 S.E. 24, 25 (1905).
2. *Shipley*, 25 N.Y.3d 645, 648, 37 N.E. 58 (2015).
3. *Finley v. Atlantic Transport Co.*, 220 N.Y. 249, 258, 115 N.E. 715, 718 (J. Pound, concurring).
4. *Shipley*, 25 N.Y.3d at 653, 37 N.E.3d at 58 (stating it "is less a quasi-property right and more the legal right of the surviving next of kin to find 'solace and comfort' in the ritual of burial") (citations omitted).
5. *Stahl v. William Necker, Inc.*, 184 A.D. 85, 90-90, 171 N.Y.S. 728, 732 (1st Dep't 1918); *see also Shipley*, 25 N.Y.3d at 653, 37 N.E.3d at 58 (stating it "is less a quasi-property right and more the legal right of

the surviving next of kin to find 'solace and comfort' in the ritual of burial") (citations omitted).

Even if interference with immediate possession of the decedent's body was only for a matter of minutes, liability may be triggered. *Gratton v. Baldwinsville Academy and Central School*, 49 Misc.2d 329, 330, 267 N.Y.S.2d 552, 553 (Sup. Ct., Onondaga Co. 1966). In *Gratton*, the court allowed recovery where the defendant deprived the mother for some three or four minutes of the right to view and take possession of her daughter's body after she drowned in the defendant's swimming pool. "[B]rief though the period of deprivation may have been [the court found] it still would be sufficient for a Court to grant damages for such denial. The cause of action for emotional upsetness and disturbance certainly does exist in this State." *Id*. at 330, 267 N.Y.S.2d at 553 (citations omitted).

6. *See, e.g*, *Shipley*, 25 N.Y.3d 645, 37 N.E.3d at 58 (noting that an unauthorized autopsy is deemed an unlawful mutilation by the courts in New York); *Lubin v. Sydenham Hosp*., 181 Misc. 870, 42 N.Y.S. 654 (Sup. Ct., N.Y. Co. 1943) (where the hospital refused to hand over to the mother for burial the body of her child, who had been born in a calcified condition, also known as a stone baby); *Drever v. State of New York*, 45 Misc.3d 224, 984 N.Y.S.2d 550 (Ct. Cl. N.Y. 2014) (where harvesting of the decedent's eyes, without the decedent's consent to being an organ donor, constituted an unauthorized interference with the claimant's immediate possession of her mother's intact body); *Emeagwali v. Brooklyn Hosp. Ctr*., 11 Misc.3d 1055(A), 815 N.Y.S.2d 494 (Sup. Ct., Kings Co. 2006) (where the hospital did not have permission to dispose of the plaintiffs' stillborn child's body, which was never recovered); *Correa v. Maimonides Med. Ctr.*, 165 Misc.2d 614, 629 N.Y.S.2d 673 (Sup. Ct., Kings Co. 1995) (where the hospital lost the corpse of the plaintiffs' stillborn child); *Lott v. State of New York*, 32 Misc.2d 296, 225 N.Y.S.2d 434 (Ct. Cl., N.Y. 1962) (where the hospital provided the undertaker with the wrong body, and the undertaker physically mishandled the body by means of unauthorized embalming and application of cosmetics, and consequently, the decedent was not prepared for burial according to the requirements of her faith); *Massaro v. Charles J. O'Shea Funeral Home, Inc*., 292 A.D.2d 349, 738 N.Y.S.2d 384 (2d Dep't 2002) (where the casket was cracked and leaked, causing a noxious odor to emanate from the mausoleum, there was an improper dealing with the body); *Wainwright v. N.Y.C. Health and Hosp. Corp.*, 61 A.D.3d 851, 877 N.Y.S.2d 201 (2d Dep't 2009) (where the decedent's body became badly decomposed after being placed in a malfunctioning refrigerated unit in the defendant's mortuary for five days); *Schwartz v. State of New York*, 162 Misc.2d 313, 616 N.Y.S.2d 921 (Ct. Cl., N.Y. 1994) (where there was an unauthorized autopsy performed on an inmate); *Rotondo v. Reeves*, 153 Misc.2d 769, 583 N.Y.S.2d 739 (Sup. Ct., Wayne Co. 1992), *rev'd in part on other grounds*, 192 A.D.2d 1086, 596 N.Y.S.2d 272 (4th Dep't 1993) (where the coroner misidentified the remains of the pet rabbit as those of the child, who died in a fire, and later, when the child's father was looking through the debris of the premises where the fire had occurred, he came upon the remains of his child, which had been mangled and disemboweled by animals); *Weingast v. State*, 44 Misc.2d 824, 254 N.Y.S.2d 952 (Ct. Cl., N.Y. 1964) (where the claimants were awarded damages for mental suffering as a result of a reversal of identity which occurred between two patients at a state hospital and their decedent was buried without notice to the claimants); *Coto v. Mary Immaculate Hosp.*, 26 Misc.3d 1205(A), 906 N.Y.S.2d 778 (Sup. Ct., Queens Co. 2006) (where the hospital did not make attempts to notify the decedent's next of kin for months following his death); *Melfi v. Mt. Sinai Hosp*., 64 A.D.3d 26, 877 N.Y.S.2d 300 (1st Dep't 2009) (where the morgue made no effort to identify or locate the next of kin).

7. *Shipley* 25 N.Y.3d at 653, 37 N.E.3d at 58 (*citing Melfi*, 64 A.D.3d at 32, 36-37, 877 N.Y.S.2d at 305).

Punitive damages have been awarded in a loss of sepulcher claim. *See, e.g., Melfi*, 64 A.D.3d at 41-42, 877 N.Y.S.2d at 310 (recognizing that punitive damages may be awarded if the conduct was willful and in conscious disregard of others); *Liberman v. Riverside Mem. Chapel*, 225 A.D.2d 283, 289-291, 650 N.Y.S.2d 19, 199-200 (1st Dep't 1996) (upholding the jury award for punitive damages against the defendant, although not the precise amount, based on evidence that the defendant "advertised itself as adhering to the highest standards of Jewish funerary practices with a special understanding of the needs of Jewish families" but acted "consciously and deliberately in complete disregard of both civil and religious law in its actions...").

In *Bernstein*, the plaintiff attempted to add "a new twist" to the right of sepulcher by claiming such a right in her own body. 2012 WL 3887228 at *7. She sought recovery for emotional damages from her inability to be buried next to her husband because other family members had been mistakenly buried in the plot next to her husband. The court disagreed as the plaintiff proffered "neither a convincing argument, nor authority for this Court to recognize the extraordinary right to possess a present solace and comfort on one's own future burial." *Id*.

To establish a cause of action and recover damages for emotional injury for violation of the right of sepulcher, the plaintiff must establish that: (1) the plaintiff is the decedent's next of kin; (2) the plaintiff had the right to possess the decedent's body; (3) the defendant interfered with the plaintiff's right of sepulcher; (4) the interference was unauthorized; (5) the plaintiff was aware of the interference; and (6) the interference caused the plaintiff mental anguish. *Shepherd v. Whitestar Dev. Corp*., 113 A.D.3d 1078, 1080, 977 N.Y.S.2d 844, 846 (4th Dep't 2014) (citation omitted). A cause of action does not accrue until interference causes mental anguish for the next of kin. *Melfi*, 64 A.D.3d at 32, 877 N.Y.S.2d at 304 (stating "Further, because the injury is emotional or mental, it is axiomatic that a plaintiff must be aware of the interference giving rise to his/her distress before he/she can actually experience distress."); *accord Tinney v. City of New York*, 94 A.D.3d 417,418, 941 N.Y.S.2d 571, 572 (1st Dep't 2012).

8. *Shipley*, 80 A.D.3d 171, 177, 908 N.Y.S.2d 425, 431(2d Dep't 2010), *lv. to appeal granted*, 22 N.Y.3d 857 (2013*), on remand to*, 24 N.Y.3d 1116 (2015), *rev'd by*, 25 N.Y.3d 645,37 N.E.3d 58 (2015) (recognizing the likelihood of emotional injury in right of sepulcher actions "is deemed so inherently genuine in such cases that neither proof of the plaintiffs' accompanying physical harm nor of a specific medical diagnosis and course of treatment is essential to a successful prosecution of the claim," and therefore, emotional injury is generally presumed); *Correa v. Maimonides Med. Ctr.*, 165 Misc.2d at 620, 629 N.Y.S.2d at 677 (where the hospital lost the corpse of the plaintiffs' stillborn child, there was "'an especial likelihood of genuine and serious mental distress, arising from the special circumstances, which serves as a guarantee that the claim is not spurious'") (citation omitted); *Plunkett v. NYU Downtown Hosp*., 21 A.D.3d 1022, 801 N.Y.S.2d 354 (2d Dep't 2005) (stating "While evidence of a specific medical diagnosis or course of treatment may be relevant to the issue of damages, it is not essential to the prosecution of such an inherently genuine claim.").

9. 14 N.Y. Practice, New York Law Of Torts, §§ 6:28, 21.23 (August 2014); *see also Johnson v. State of New York*, 37 N.Y.2d 378, 381-382, 372 N.Y.S.2d 638, 641 (1975) (stating "In the absence of contemporaneous or consequential physical injury, courts have been reluctant to permit recovery for negligently caused psychological trauma, with ensuing emotional harm alone… There have developed, however, two exceptions. The first is the minority rule permitting recovery for emotional harm resulting from negligent transmission by a telegraph company of a message announcing death. The second exception permits recovery for emotional harm to a close relative resulting from negligent mishandling of a corpse."); *Bernstein,* 2012 WL 3887228 at *6 (recognizing that the ancient right of sepulcher is one of the well-established exceptions recognized by New York courts where damages for emotional harm can be awarded even if not accompanied by physical injury); *Whack v. St. Mary's Hosp*., 2003 WL 230702 at *3 (Civ. Ct., N.Y.C. 2003) (stating "While New York courts have consistently held that negligent conduct causing injury is not actionable by those who witness it unless they are both immediate family and in the zone of danger, it can be understood

that the courts view matters involving the mishandling of corpses differently.").

"In New York, right of sepulcher cases are a subset of negligence causes of action." *Matter of Human Tissue Litigation*, 38 Misc.3d 184, 199, 955 N.Y.S.2d 721, 732 (Sup. Ct., Richmond Co. 2012) (noting American courts use tort law rather than property law to award damages and stating "the editors of the New York Practice Series-New York Law of Torts placed this cause of action in a section entitled 'Duty not to inflict emotional distress—Special circumstances and special duty cases.'"); *accord Drever*, 45 Misc.3d at 231, 984 N.Y.S.2d at 556.

10. *In re Widening of Beekman Street*, 4 Bradf. Sur. 503, 518 (N.Y. 1856).

11. *Id.*

12. *Id.* (stating the separation of the lay and clerical order had a "plainly discernible" effect upon the dead).

13. *Id.* at 518-519.

14. *Id.*

15. *Id.* at 519 (stating "But these they guarded with singular solicitude. The tombstone, the armorial escutcheons, even the coat and pennons, and ensigns of honor, whether attached to the church edifice or elsewhere, were raised as 'heirlooms' to the dignity of inheritable estates, and descended from heir to heir, who could hold even the parson liable for taking them down or defacing them.").

16. *Colavito v. New York Organ Donor Network, Inc*., 438 F.3d 214, 223 (2d Cir.2006) (citation omitted), *certified question answered by*, 8 N.Y.3d 43, 827 N.Y.S.2d 96 (2006), *answer to certified question conformed to and aff'd*, 486 F.3d 78 (2d Cir. 2007) (citation omitted); *see also Beekman Street*, 4 Bradf. Sur. at 521 (stating "that the temporal office of burial had been brought within the exclusive, legal cognizance of the Church, who could and would enforce all necessary rules for the proper sepulture and custody of the body, thus rendering any individual action in that respect unnecessary"); *Griffith v. Charlotte, Columbia & Augusta R. R. Co*., 23 S.C.25, 41, 55 Am.Rep.1 (S.C. 1885) (stating "We have looked diligently through the common law reports of England, and have found no case in which the civil courts have been appealed to in matters connected with the bodies of the dead. On the contrary, their burial, the graveyards and cemeteries in which they are interred, and the religious ceremonies observed, have been left exclusively to ecclesiastical cognizance, the civil courts universally holding, in the language of Lord Coke, that the burial of the cadaver is *nullius in bonis*.").

17. *In re Donn*, 14 N.Y.S. 189, 190 (Sup. Ct., Erie Co. 1891); *see also Cohen*, 85 A.D. at 67, 82 N.Y.S. at 919 (acknowledging the common law did not confer upon an heir a property right in the body of an ancestor, even though an heir possessed rights in monuments and escutcheons); *Melfi*, 64 A.D.3d at 34 (stating "The church enforced all the necessary rules for proper sepulture, that is, for the burial and the custody of the buried remains, rendering any individual action in that respect unnecessary.") (citation omitted).

18. *Donn*, 14 N.Y.S. at 190; *Cohen*, 85 A.D.at 67, 82 N.Y.S. at 919.

19. *Beekman Street*, 4 Bradf. Sur. at 519; *Kellogg*, 189 Misc.3d at 761, 735 N.Y.S.2d 350 (stating "The prevailing principle, as expressed in the ecclesiastical law of England, was that the law did not recognize a property right in a dead body, and thus a wrong to the body itself was not actionable.").

20. *Beekman Street*, 4 Bradf. Sur. at 519; *see also Johnston v. Marinus*, 18 Abb. N. Cas. 72, 80 (Sup. Ct., N.Y. Co. 1886) (stating "A suit for trespass could be maintained by the owner of the land or person having charge or custody of it, against any person disturbing a grave, and the party who had caused the burial, or next of kin, could bring an action for any injury done to the monuments, erected by them over the grave, or for carrying off the coffin and habiliments furnished by them, and could even maintain a bill in equity to prevent such injury or removal.") (citation omitted).

21. Edward Coke, The Third Part of The Institutes of the Law of England: Concerning High Treason and Other Pleas of the Crown and Criminal Causes, at 203 (1644)); *see also Beekman Street*, 4 Bradf. Sur. at 520.

22. *Melfi*, 64 A.D.3d at 35, 877 N.Y.S.2d at 306 (stating "Coke's statement was interpreted by many contemporaries as rejecting a property right in corpses. Unfortunately, this interpretation was imported into Anglo-American law and ultimately led to the conflation of the common-law right of sepulcher with the common-law right of interment or sepulture."); *In re Johnson's Estate*, 169 Misc. 215, 217-218, 7 N.Y.S. 81,83-84 (Sur. Ct., N.Y. Co. 1938) (stating "The body was the temple of the Holy Ghost from which man at his death was temporarily to be separated. That this sacred object should be property was unthinkable to Lord Coke and his contemporaries."); *Larson v. Chase*, 47 Minn. 307, 310 50 N.W. 238, 239 (Minn. 1891) (stating "The doctrine that a corpse is not property seems to have had its origin in the dictum of Lord Coke, 3 Inst. 203, where, in asserting the authority of the church, he [stated his classic edict].").

Sir William Blackstone, an English jurist and judge, reiterated the common law doctrine that there is no property right in a corpse: "But though the heir has a property in the monuments and escutcheons of his ancestors, yet he has none in their bodies or ashes; nor can [an heir] bring any civil action against such as indecently at least, if not impiously, violate and disturb their remains, when dead and buried." 2 William Blackstone, Commentaries on the Law of England at 429 (1811); *see Newman*, 287 F.3d at 791 (stating "Many early American courts adopted Blackstone's description of the common law, holding that 'a dead body is not the subject of property right.'") (citation omitted).

23. *Colavito*, 8 N.Y.3d 43, 50, 827 N.Y.S.2d 96, 100 (2006).

24. *Donn*, 14 N.Y.S. at 190; *see also Darcy v. Presbyterian Hosp. in City of New York*, 202 N.Y. 259, 262, 95 N.E. 695 (1911) (stating "While we adopted the common law in organizing our state governments, we have never considered ourselves bound by the ecclesiastical decisions, many of which were inapplicable for our form of government."); *A.F. Hutchinson*, 127 Misc. at 562, 217 N.Y.S. at 418 (stating "The maxims, doctrines, and practices of the ecclesiastical law of England have never become a part of our system of jurisprudence.").

25. *Beekman Street*, 4 Bradf. Sur. at 526.

26. *Larson*, 47 Minn. at 309, 50 N.W. at 239; *see also Griffith*, 23 S.C. at 39, 55 Am.Rep.1 (stating "[T]o make such venerated remains the absolute property of any one, in the sense of objective appropriation, would be abhorrent to every impulse and feeling of our natures."); *Melfi*, 64 A.D.3d at 34-35, 877 N.Y.S.2d at 306 (where the court considered the importation of Coke's pronouncement into American jurisprudence as unfortunate because it "ultimately led to the conflation of the common law right of sepulcher with the common law right of interment or sepulture").

27. Walter F. Kyzenski, Property in Dead Bodies, Marquette Law Review, Vol. 9 Art. 3, Issue I, December 1924, at 17; *see also* R.P. Taylor, Right of Sepulture, 53 Am. L. Rev. 362 (1919) (stating Ruggles' report "has been said to be the most accurate and elaborate collection and statement upon the subject of burial yet").

28. The City made an award to the owners, proprietors, and parties interested in the land taken to widen the street. The court held the award until their respective interests in the award could be determined. The Brick Presbyterian Church claimed the whole amount awarded, subject to the rights of persons claiming rights to vaults and graves. Ruggles was directed by the court to investigate the facts and report the amount due from the fund.

Of the 80 or more graves within the strip of land taken by the City, only a small number were identified. The remains of Moses Sherwood were identified by his daughter, Maria Smith, who, acting for her brothers and sisters and their descendants, claimed that her father's remains should be reinterred in a separate grave, in a suitable locality selected by her; that the existing monument be erected over the separate grave; and that the necessary expenses be defrayed out of the fund in the court.

29. 2 The American Ruling Cases, National Law Book Company, at 1112 (1914); *Renihan v. Wright*, 125 Ind. 536, 542, 25 N.E. 822, 824 (1890) (stating "Mr. Ruggles filed his report and the case coming on for hearing at the special term of the Supreme Court, in April, 1856, the report, as the law of the case, was affirmed.").

30. *Beekman Street*, 4 Bradf. Sur. at 520 (stating "With all proper respect for the legal learning of this celebrated judge, we may possibly question both the wisdom and the etymology of this verbal deceit, this fantastic and imaginary gift, or outstanding grant to the worms. In the English jurisprudence, a corpse was not given or granted to the worms, but it was taken and appropriated by the Church***The learned lexicographers and philologists, Martinius and elder Vossius, both of them contemporaries of Coke, wholly dissent from his whimsical derivation.").

31. *Id.* at 521.

32. *Id*. at 525-526.

33. *Id*. at 526.

34. *Id.* at 529.

    One of the anomalies in England's body of law was that the secular tribunals protected the monument and the grave-clothes, but the Church guarded the skull and bones. 2 William Blackstone, Commentaries on the Law Of England, at 429 (1811) (noting that stealing the shroud or other apparel of a corpse was a felony, but stealing the body itself was a misdemeanor); 4 William Blackstone, Commentaries on the Law of England, at 236 (stating "Notwithstanding, however, that no larceny can be committed, unless there be some property in the thing taken, and an owner; yet, if the owner be unknown, provided there be a property, it is larceny to steal it; and an indictment will lie, for the goods of a person unknown. This is the case of stealing a shroud out of a grave; which is the property of those, whoever *** they were, that buried the deceased; but stealing the corpse itself, which has no owner (though a matter of great indecency) is no felony, unless some of the grave-clothes be stole with it."); *Pierce*, 10 R.I. at 238 n.1, 14 Am.Rep. 667 (stating "[U]nder the English law, the only protection of a grave, independent of ecclesiastical authority, was by indictment. It was an offense at common law to remove a body. And it was a felony to steal the shroud or apparel."). Ruggles questioned this oddity, "which of these relics best deserve the legal protection of the Supreme Court of law and equity of the State of New York? Does not every dictate of common sense and common decency demand a protection of the grave and all of its contents and appendages?" *Beekman Street*, 4 Bradf. Sur. at 522.

35. *Beekman Street*, 4 Bradf. Sur. at 529.

36. *Id.*; *see also Renihan*, 125 Ind. 536, 25 N.E. at 824 (referring to Ruggles as "the learned" referee and stating his report was "the most accurate and elaborate collection and statement of the law [of burial] yet published").

37. *Larson*, 47 Minn. at 308, 50 N.W. at 239 (stating "A quite full and interesting discussion" ["of the history of the law, civil, common, or ecclesiastical, of burial and the disposition of the body after death"] could be found in the report of referee Ruggles).

38. *Beekman Street*, 4 Bradf. Sur. at 532; *see also* 2 The American Ruling Cases, National Law Book Company, 1142 (1914) (noting "the English cases rest on a system of ecclesiastical law unknown in the United States and accordingly are said to be of slight authority"); *Larson*, 47 Minn. at 308, 50 N.W. at 239 (stating "Upon the questions who has the right to the custody of a dead body for the purpose of burial, and what remedies such person has to protect that right, the English common-law authorities are not very helpful or particularly in point for the reason that from a very early date in that country the ecclesiastical courts assumed exclusive jurisdiction of such matters.").

39. *Id.* at 532 (where the court directed the petitioner to re-inter separately such remains as were found in other graves, if any, when identified by the next of kin).

40. *Id*. at 515-516.

41. R.P. Taylor, Right of Sepulture, 53 Am.L.Rev. 362 (1919); *see also* 2 The American Ruling Cases at 1143; R.F. Martin, Removal And Reinterment of Remains, 21 A.L.R. 472, § 4[b] (originally published in 1852) (stating "The quick seizure of his report by the courts, who were not impressed by his learned critics emancipated them from inappropriate English strictures, and with a minimum of legislation made possible the development of an ingenious, useful, and workable body of American law, the internal contradictions and unsoundness of its theory notwithstanding.") (citation omitted); *Pettigrew v. Pettigrew*, 207 Pa.St. 313, 316, 56 A. 878 (Pa. 1904) (stating the report was "said to be the most accurate and elaborate collection and statement upon the subject of burial yet"); *Pierce v. Proprietors of Swan Point Cemetery*, 10 R.I. 227, 233 n. 1, 14 Am.Rep. 667 (R.I. 1872) (stating "[Ruggles' report] is a very learned and exhaustive treatise on the law of burial, and will prove of great value to members of the profession interested in this subject."); *Cohen*, 85 A.D. at 67, 82 N.Y.S. 918 (stating "In the report of RUGGLES, Referee, confirmed in all respects (citation omitted), the learned referee, *inter alia*, concluded that the right to protect the remains includes the right to preserve them by separate burial, to select the place of sepulture, and to change it at pleasure."); *Renihan*, 125 Ind. 536, 25 N.E. at 824 (referring to Ruggles as "the learned" referee and stating his report was "the most accurate and elaborate collection and statement of the law [of burial] yet published"); *Louisville & Nashville Railroad Co*., 123 Ga. 62, 63-64, 51 S.E. 24, 25 (1905) (stating "The subject of the right of burial, and the protection of the bodies of the dead arose in the matter of the widening of Beekman street (sic) in the city of New York, and was referred to Hon. Samuel B. Ruggles, as referee. He made a learned and elaborate report, which was confirmed by the court.").

42. *Johnson's Estate*, 169 Misc. at 220, 7 N.Y.S.2d at 85 (stating "The rise of medical schools, the increase in the number of doctors, and the recognition in medical circles of the need for knowledge of the human body based on the art of dissection resulted in unauthorized autopsies, and body-snatching from graveyards."); Dorothy Nelkin and Lori Andrews, "Do the Dead Have Interests? Policy Issues for Research After Life," 24 Am. J.L. & Med. 261, 263 (1998) (stating "Body snatching from black and almhouse graveyards was rampant in nineteenth century America.").

    Body snatching was so prevalent in Edinburgh, Scotland, that walls and watchtowers were erected around and in cemeteries to protect bodies from being taken from their graves. "William Burke & William Hare, 'The Resurrectionists'," http://scotshistoryonline.co.uk/burke.html. "[O]beying the law of supply and demand," William Burke and William Hare, provided Scottish doctors with corpses of people they had murdered. *Johnson's Estate*, 169 Misc. at 220, 7 N.Y.S.2d at 85 (stating these men provided doctors "what they greatly needed but could not legally obtain in sufficient quantity" by "the development of a business in homicide"). "It was thus that the verb 'to burke'—meaning to kill by suffocation—entered our language." *Id*.

43. *Johnson's Estate*, 169 Misc. at 220, 7 N.Y.S.2d at 85 (noting the use of cremation led to the next of kin contesting the decision of the decedent's testator to cremate the corpse); *see also Colavito*, 8 N.Y.3d at 50, 827 N.Y.S.2d at 100 (stating "A good deal of the [common] law [regarding property rights in the body of a deceased person] arose out of religious and cultural sensibilities involving grave robbery, desecration of corpses and, later on, unauthorized autopsies.").

44. *Id.*, 169 Misc. at 220, 7 N.Y.S.2d at 85; *Colavito*, 438 F.3d at 223 (citation omitted).

45. *Pierce*, 10 R.I. 227, 237-238, 14 Am.Rep. 667 (R.I. 1872); *Larson*, 47 Minn. 307, 50 N.W. 238 (Minn. 1891).

46. *Pierce*, 10 R.I. at 237-238, 14 Am.Rep. 667.

47. *Id.* at 242-243, 14 Am.Rep. 667 (stating a court of equity could "regulate it as such, and change the custody if improperly managed"); *see Louisville & Nashville Railroad Co*., 123 Ga. 62, 65, 51 S.E. 24, 26 (1905) (stating "Potter,J., delivered an able opinion in

that case [*Pierce*], reviewing the matter both from the standpoint of history and of authority.").

48. *Id.* at 243, 14 Am.Rep. 667.

49. *Kellogg v. Office of Chief Medical Examiner of City of New York*, 189 Misc.2d 756, 762, 735 N.Y.S.2d 350, 357 (Sup. Ct. Bronx Co. 2001) (stating "Surprisingly, despite the long cultural tradition pertaining to decent burial, a private cause of action for unlawful dissection was not recognized at common law. The prevailing principle, as expressed in ecclesiastical law of England, was that the law did not recognize a property right in a dead body, and thus a wrong to the body itself was not actionable.").

50. *Larson*, 47 Minn. at 308, 50 N.W. at 233, 239 (stating "Time will not permit, and the occasion does not require, us to enter into any extended discussion of the history of the law, civil, common, or ecclesiastical, of burial and the disposition of the body after death. A quite full and interesting discussion of the subject will be found in the report of the referee (Hon. S.B. RUGGLES) (citation omitted).").

    The *Larson* court also rejected Lord Coke's famous dictum because from a very early date in England, "the whole matter of sepulture and custody of the body after burial was within the exclusive cognizance of the church and the ecclesiastical courts." *Id*. at 309-310, 50 N.W. at 238-239. Instead, "all courts now concur in holding that the right to the possession of a dead body for the purposes of decent burial belongs to those most intimately and closely connected with the deceased by domestic ties, and that this is a right which the law will recognize and protect." *Id*. at 309, 50 N.W. at 238-239. "[T]he mere fact that a person has exclusive rights over a body for the purposes of burial leads necessarily to the conclusion that it is his property in the broadest and most general sense of that term, viz., something over which the law accords him exclusive control." *Id*. at 310, 50 N.W. at 239. Whether a corpse was property in the ordinary or commercial sense or whether it had any value as "an article of traffic" was unimportant to the *Larson* court. *Id*.

    "[T]he important fact is that the custodian of it has a legal right to its possession for the purposes of preservation and burial, and that any interference with that right by mutilating or otherwise disturbing the body is an actionable wrong." *Id*.

51. *Id*., 47 Minn. at 312, 50 N.W. at 240 (stating "[I]t would be a reproach to the law if a plaintiff's right to recover for mental anguish resulting from the mutilation or other disturbance of the remains should be made to depend upon whether in committing the act the defendant also committed a technical trespass upon plaintiff's premises."); *see also Melfi*, 64 A.D.3d at 34-35, 877 N.Y.S.2d at 306 (stating "Toward the end of the nineteenth century, when mutilation and theft of cadavers rose in proportion to the increasing needs of medical science, the courts purportedly constrained by Lord Coke's dictum, often fashioned remedies by, for example, finding a cause of action in trespass."); *Foley v. Phelps*, 1 A.D. 551, 554, 37 N.Y.S. 471, 473 (1st Dep't 1896) (stating "courts of equity have frequently interfered to protect the remains of the dead, and courts of law have also afforded remedies, through formal legal actions, wherever any element of trespass, real or personal, was associated with the molestation of the remains of the dead."); *Meagher v. Driscoll*, 99 Mass. 281, 284, 60 Am. Dec. 759 (Mass. 1868) (where the court announced that a dead body was not the subject of property and that after burial it became a part of the ground to which it had been committed and concluded that the only action that could be brought for disinterring a body was "trespass *quare clausum*").

52. *Foley*, 1 A.D. at 552, 37 N.Y.S. 471 at 471.

53. *Id*. at 555, 37 N.Y.S. at 473.

54. *Id*., 37 N.Y.S. at 473.

55. *Id*., 37 N.Y.S. at 473 (stating "In more recent times the obdurate common-law rule has been very much relaxed, and changed conditions of society, and the necessity for enforcing that protection which is due to the dead, have induced courts to re-examine the grounds upon which the common-law rule reposed, and have led to modifications of its stringency [and stating that old case law in England did not need to be followed because it was] decided when matters of burial and the care of the dead were within the jurisdiction of the ecclesiastical courts.").

56. *Id*., 37 N.Y.S. at 474.

    Since *Foley*, "[t]he law is clear that the next-of-kin have the right of possession of the corpse in the same condition as it was in when death occurred." *Whack v. St. Mary's Hosp*., 2003 WL 230702 (Civ. Ct., N.Y.C. 2003) (where the body decomposed due to lack of proper refrigeration while it was held in the defendant's morgue and due to the decomposition it could not be embalmed and a proper funeral could not be held).

57. *Foley*, 1 A.D. at 555, 37 N.Y.S. at 474 (acknowledging that *Larson* held, "[t]he right to the possession of a dead body for the purposes of preservation and burial" is a legal right—"one which the law recognizes and protects, and for any infraction of it,-—such as an unlawful mutilation of the remains—an action for damages will lie").

58. *Id*. at 556, 37 N.Y.S. at 474 (also considering *Larson's* opinion "that the right to the possession of a dead body for the purposes of preservation and burial is a legal right—one which the law recognizes and protects" was well-considered and well-reasoned).

59. *Darcy*, 202 N.Y. 259, 95 N.E. 695 (stating "But even in England, in more recent periods, the courts have recognized the right of possession of a dead body in those nearest in relation for the purpose of burial or other lawful disposition of it.") (citation omitted).

60. *Id.* at 261, 95 N.E. at 696.

61. *Id.* at 263, 95 N.E. at 696 (stating it did not need to further discuss whether a cause of action for damages existed from an unauthorized autopsy).

    After *Darcy*, the concept that emotional damages could be recovered for violating the right to sepulcher quickly gained acceptance in New York. *See, e.g., Hasselbach v. Mt. Sinai Hosp*., 173 A.D. 89, 159 N.Y.S. 376 (1st Dep't 1916) (where a widow sought damages for emotional distress from an unauthorized autopsy performed on her husband's body after he died in the defendant's hospital).

62. *Cohen*, 85 A.D. at 67, 82 N.Y.S. at 919 (stating "the more modern and the current judgment of many courts recognize a *quasi*-property right in the body of the dead in the nature of a sacred trust that a court of equity will sometimes recognize in order to afford control of the body to the next of kin") (emphasis in original).

63. *Gostkowski*, 237 A.D. at 642, 262 N.Y.S. at 105 (stating "[The] right of protecting the remains of the dead and saving them from desecration, which can be enforced by appropriate legal remedies,…is a right clearly distinguishable from the right of ownership."); *see also Danahy v. Kellogg*, 70 Misc. 25, 29, 126 N.Y.S. 444, 447-448 (Sup. Ct., Erie Co. 1910) (stating "[The right of protecting the remains of the dead] is a right clearly distinguishable from the right of ownership."); *Donn*, 14 N.Y.S at 191 (stating "[W] hile a dead body is not property, in the strict sense of the common law, it is a *quasi* property, over which the relatives of the deceased have rights which the court will protect; but the person having charge of it cannot be considered as the owner of it, in any sense whatever. He holds it only as a sacred trust, for the benefit of all who may, from family or friendship, have an interest in it, and a court of equity may regulate it as such, and change the custody, if improperly managed.") (emphasis in original); *Hasselbach*, 173 A.D. at 92, 159 N.Y.S. at 379 (stating "It is well settled, however, that there are no property rights, in the ordinary commercial sense, in a dead body, and the damages allowed to be recovered for its mutilation are never awarded as a recompense for the injury done to the body as a piece of property.").

64. *See, e.g*., *Louisville & Nashville Railroad Co*., 123 Ga. 62, 64, 51 S.E. 25 (1905) (stating "It is not surprising that the law relating to this

mystery of what death leaves behind cannot be precisely brought within the letter of all the rules regarding corn, lumber, and pig-iron."); *Danahy*, 70 Misc. at 29, 126 N.Y.S. at 447 (stating there was no property right in a dead body "strictly speaking"); *Donn*, 14 N.Y.S. at 190 (stating there was no property right in a dead body "in the sense that it is a subject of barter and sale"); *Hasselbach*, 173 A.D at 92, 159 N.Y.S. at 379 (stating there is no property right in a dead body in a "commercial sense"); *Finley v. Atlantic Transport Co.*, 220 N.Y. 249, 255, 115 N.E. 715, 717 (1st Dep't 1907) (stating "That there is no right of property in a dead body in the ordinary acceptation of the term is undoubtedly true when limited to a property right as understood in the commercial sense.").

65. *A.F. Hutchinson*, 127 Misc. at 562, 217 N.Y.S. at 418 (stating "While there is no right of property in a dead body in the ordinary sense of the term, it is regarded as property so far as it is necessary to entitle the next of kin to legal protection from violation or invasion of its place of burial.") (citation omitted).

66. *See, e.g., Johnson*, 37 N.Y.2d at 382, 372 N.Y.S.2d at 642 (stating "It has been noted […] that […] such a property right is little more than a fiction; in reality the personal feelings of the survivors are being protected."); *Melfi*, 64 A.D.3d at 38, 877 N.Y.S.2d at 309 (stating "Courts in other jurisdictions also recognized that a 'quasi-property' right was a legal fiction to enable recovery of damages for injury to the feelings of the next of kin."); *Colavito*, 8 N.Y.3d at 52 n.8, 827 N.Y.S.2d at 719 n.8 (noting Prosser referred to a property right in a body as a fiction).

67. Prosser, The Law of Torts, at 58-59 (4th ed. 1971) (stating "In most [cases involving the mishandling of dead bodies], the courts have talked of a somewhat dubious 'property right' to the body, usually in the next of kin, which did not exist while the decedent was living, cannot be conveyed, can be used only for the one purpose of burial, and not only has no pecuniary value but is a source of liability for funeral expenses.").

68. *Colavito v. New York Organ Donor Network, Inc.*, 356 F.Supp.2d 237 (E.D.N.Y.2005), *aff'd in part, question certified by*, 438 F.3d 214 (2d Cir. 2006), *certified question accepted by*, 6 N.Y.3d 820 (2006), *certified question answered by*, 8 N.Y.3d 43, 827 N.Y.S.2d 96 (2006), *answer to certified question conformed to and aff'd*, 486 F.3d 78 (2d Cir. 2007).

69. *WTC Families for a Proper Burial v. City of New York*, 567 F.Supp.2d 529 (S.D.N.Y.2008), *aff'd*, 359 Fed.Appx. 177, 179 (2d Cir. 2009), *cert. denied*, 562 U.S. 855 (2010).

70. *Colavito v. New York Organ Donor Network, Inc.*, 356 F.Supp.2d 237, 242 (E.D.N.Y.2005) (stating it "found no cases involving similar facts in either this or any other federal circuit or state court"), *aff'd in part, question certified by*, 438 F.3d 214 (2d Cir. 2006), *certified question accepted by*, 6 N.Y.3d 820 (2006), *certified question answered by*, 8 N.Y.3d 43, 827 N.Y.S.2d 96 (2006), *answer to certified question conformed to and aff'd*, 486 F.3d 78 (2d Cir. 2007).

71. *Id.*, 356 F.Supp.2d at 238-239.

72. *Id*. at 240.

73. *Id*.

74. *Id.*

75. *Id*. at 241-242.

    This article does not address Colavito's claims under New York Public Health Law Article 43, the state's codification of the Uniform Anatomical Gift Act, or Article 43-A, which delineates the duties of hospital administrators, organ procurement organizations, and eye and tissue banks.

76. *Id*. at 240-242; *Colavito*, 8 N.Y.3d at 48, 827 N.Y.S.2d at 99.

77. *Id*. at 244.

78. *Colavito*, 438 F.Supp.2d at 233.

    This article does not discuss the other questions certified to the Court of Appeals.

79. *Colavito*, 8 N.Y.3d at 53, 827 N.Y.S.2d at 102.

80. *Id.*, 8 N.Y.3d at 57, 827 N.Y.S.2d at 105.

81. *Id*., 827 N.Y.S.2d at 105.

82. *Id*.

83. *Id*.

84. *WTC Families for a Proper Burial v. City of New York*, 567 F.Supp.2d 529, 541 (where the plaintiffs also argued that the defendants' failure to re-search through the debris moved to the landfill violated their due process rights) (S.D.N.Y.2008), *aff'd*, 359 Fed. Appx. 177, 179 (2d Cir. 2009), *cert. denied*, 562 U.S. 855 (2010); *see Lewis v. Lloyd*, 40 Misc.3d 1223(A), 975 N.Y.S.2d 710 at *3 (Sup. Ct., Kings Co. 2013)) (stating "Prior to the passage of Public Health Law § 4201, which was prompted by the events of September 11, 2001 and its aftermath, the right to dispose of deceased persons' remains was established and governed—and to a great extent still is—by a complex of common law, statutes, and regulations, including the common law right of sepulcher.") (*citing* Public Health Law §§ 4200, 4210; 24 RCNY Public Health Code Reg. §§ 205.01, 205.19, 205.379 (case citations omitted)).

    The plaintiffs alleged that the defendants violated their Constitutional rights and New York State law when finely sifted material ("fines"), which may have contained undetectable particles of human remains, was left in a landfill with other debris from the World Trade Center site. *WTC*, 567 F.Supp.2d at 537-542 (also alleging violation of their right to free exercise of their religious beliefs guaranteed by the First and Fourteenth Amendments of the United States Constitution). An action was commenced to force the City to remove the fines to a more suitable location and to create a cemetery for the 1,100 victims who perished without identifiable remains. *WTC*, 359 Fed.Appx. at 179.

    Of the 2,749 people murdered that tragic day, full bodies were recovered for only 292 victims, partial remains were found for 1,357 people, and 1,100 people perished without leaving a trace. *WTC*, 567 F.Supp.2d at 531.

85. *WTC*, 567 F.Supp.2d at 537 (citations omitted).

86. *Id.* (citations omitted).

87. *Id.*; *see WTC*, 359 Fed.Appx. at 180 (finding no error in the district court's "thorough analysis of plaintiffs' constitutional and state law claims [and affirming the district court's holding], that, under New York law, plaintiffs do not have a cognizable property right in unidentifiable human remains").

    The district court held, and the Second Circuit affirmed, that the city's procedures relating to the recovery effort after September 11 "'did not target religious beliefs,' and that '[t]he governmental interest in clearing the debris of the World Trade Center efficiently and economically' was compelling." *WTC*, 359 Fed.Appx. at 181 (*citing* 567 F.Supp.2d at 540-541).

88. *WTC*, 567 F.Supp.2d at 541.

89. *Id.*

90. *Shipley*, 25 N.Y.3d at 648, 37 N.E.3d at 58.

    "To a great degree, [Article 42 of the Public Health Law] codifies the common law right of sepulcher." *Jackson v. Jackson*, 42 Misc.3d 931, 934 n.2, 979 N.Y.S.2d 477, 480 n.2 (Sup. Ct., Albany Co. 2013).

91. *Shipley*, 25 N.Y.3d at 648, 37 N.E.3d at 58.

    Jesse's sister was injured in the accident but survived. *Shipley*, 80 A.D.3d at 173, 908 N.Y.S.2d 425.

92. *Shipley*, 25 N.Y.3d at 648, 37 N.E.3d at 58 (where the majority noted that Mr. Shipley's consent to an autopsy was not needed).

93. *Id.*, 37 N.E.3d at 58; *see also Shipley*, 80 A.D.3d at 173, 908 N.Y.S.2d 425(noting that according to Mr. Shipley, he asked Dr. de Roux to make the autopsy "nice and clean because I wanted the boy to look good for his funeral and stuff.").

94. *Id.* at 649, 37 N.E.3d at 58.

95. *Id.* at 648-649, 37 N.E.3d at 58.

96. *Id.* at 649, 37 N.E.3d at 58.

97. *Id.*, 37 N.E.3d at 58.

98. *Id.*, 37 N.E.3d at 58.

99. *Id.*, 37 N.E.3d at 58.

"The students had an emotional reaction to seeing the jar and its contents, and as a result the teacher immediately cancelled the trip and left with the students." *Id*. at 662 (in dissent).

100. *Id*. at 649, 37 N.E.3d at 58.

101. *Id*. at 662, 37 N.E.3d at 58.

102. Defendants-Appellants' Brief at 5, APL-2013-00345, Feb. 27, 2014 (*citing* R. B184, B228).

103. *Shipley*, 25 N.Y.3d at 662, 37 N.E.3d at 58.

104. *Id*. at 649, 37 N.E.3d at 58.

New York courts have made clear that each member of the family cannot maintain a separate action to recover for mental pain and anguish. Instead, they must join together in a single action. *See, e.g.*, *Bernstein v. Mt. Ararat Cemetery, Inc*., 2012 WL 3887228 at *8 (E.D.N.Y.), *reconsideration denied*, 2013 WL 1820911 (E.D.N.Y.) (citations omitted); *Gostkowski v. Roman Catholic Church*, 262 N.Y. 320, 326, 186 N.E. 798 (1933); *Weingast v. State*, 44 Misc.2d 824, 254 N.Y.S.2d 952 (Ct. Cl., N.Y. 1964). The complaint of Jesse's sister was dismissed on the ground that she lacked standing to sue because she did not qualify as "next of kin" as that term was defined in the New York City Health Code. *Shipley*, 80 A.D.3d at 174, 908 N.Y.S.2d at 428 (citation omitted).

105. *See Shipley*, 2009 WL 7401469 (Sup. Ct., Richmond Co. 2009); *Shipley*, 80 A.D.3d 171, 908 N.Y.S.2d 425 (2d Dep't 2010); *Shipley*, 2011 WL 8908185 (Sup. Ct., Richmond Co. Nov. 25, 2011); *Shipley*, 2011 WL 8908184 (Sup. Ct., Richmond Co. Dec. 16, 2011); *Shipley*, 3 Misc.3d 1239(A), 950 N.Y.S.2d 726 (Sup. Ct., Richmond Co. 2012); *Shipley*, 105 A.D.3d 936, 963 N.Y.S.2d 692 (2d Dep't 2013); *Shipley*, 22 N.Y.3d 857 (2013); *Shipley*, 24 N.Y.3d 1116 (2015).

106. *Shipley*, 105 A.D.3d at 936, 963 N.Y.S.2d at 693.

107. *Shipley*, 950 N.Y.S.3d at *4 (where the questions presented to the jury on the issue of damages "were whether the plaintiffs suffered an exacerbation of their emotional injuries as a result of defendants' actions and if so, what was the value of that injury").

108. *Id.* (where the court did not disturb the jury's verdict, stating that the jury's decision "was rational based on the facts at issue, and the amount was reasonable, if low").

109. *Shipley*, 105 A.D.3d 936, 908 N.Y.S.2d 425 (2d Dep't 2013).

110. *Shipley*, 24 N.Y.3d 1116, 26 N.E.3d 780 (2015).

111. *Shipley*, 25 N.Y.3d at 653, 37 N.E.3d at 58.

112. *Id*. at 660, 37 N.E.3d at 58.

113. *Id*. at 654, 37 N.E.3d at 58.

114. *Id.*, 37 N.E.3d at 58 (emphasis in the original).

115. *Id*. at 653, 37 N.E.3d at 58.

Mr. Shipley consented to the autopsy, but the medical examiner had the authority to conduct the autopsy without his permission pursuant to Public Health Law § 4215(1) and New York City Charter § 557(f)(1). *Id*. at 652, 37 N.E.3d at 58.

116. *Id*. at 654, 37 N.E.3d at 58.

117. *Id.*, 37 N.E.3d at 58.

118. *Id*. at 655, 37 N.E.3d at 58.

The majority found that the Appellate Division's determination that a medical examiner had a "mandatory obligation" and "ministerial" duty pursuant to both the common-law right of sepulcher and Public Health Law § 4215(1) to turn over the decedent's retained organs once the dissection had been completed and the legitimate purposes for retaining those remains had been fulfilled "was error that broadly expanded the medical examiner's obligations under common law and statute." *Id*. at 655, 37 N.E.3d at 58 (noting "section 4215(1) contains a 'governing rule' or 'statutory command' to the extent that the medical examiner, once he or she is finished with the unauthorized dissection, must turn the 'remains of the body after dissection' over for 'burial or other lawful disposition").

After the Appellate Division's decision, the Office of the Medical Examiner followed the court's "'notification rule'***(not out of its belief that it is appropriate but rather because it felt compelled by the Appellate Division to do so). *Id*. The Court found "the claimed ease of that rule's application is irrelevant in the context of these matters because practical and policy considerations exist beyond merely providing next of kin with notification." *Id*.

119. Public Health Law § 4215(1)(emphasis supplied by the Court).

120. *Shipley*, 25 N.Y.3d at 656, 37 N.E.3d at 58 (referring to Public Health Law §§ 4216, 4217, 4218, 1389-aa[1](b)).

121. *Id*. at 657-658, 37 N.E.3d at 58.

122. *Id*. at 658, 37 N.E.3d at 58 (stating "Once a medical examiner returns a decedent's body sans the organs and tissue samples, the medical examiner for all intents and purposes has complied with the ministerial duty under section 4215(1).").

123. *Melfi v. Mt. Sinai Hosp*., 64 A.D.3d 26, 32-34, 877 N.Y.S.2d 300, 305 (1st Dep't 2009) (stating "The right of sepulcher, evoking the mystery and sorrow of death and the hope for an afterlife, has been ritualized since the earliest pre-Christian civilizations."); *Liberman v. Riverside Mem. Chapel*, 225 A.D.2d 283, 284, 650 N.Y.S.2d 194, 196 (1st Dep't 1996) (stating "Many forms of honoring and respecting the mysteries of life and death are found among the religious and nonreligious alike" and "most persons, believers or nonbelievers, will not countenance disrespectful treatment of the body."); *Kellogg v. Office of the Chief Medical Examiner of the City of New York*, 189 Misc.2d 756, 761, 735 N.Y.S.2d 350 (Sup. Ct., Bronx Co. 2001) (stating "From the time of Sophocles' 'Antigone' in 442 B.C., there has existed a long cultural history concerning the treatment of the dead, which incorporates the concept that a wrong committed to the dead constitutes an affront to the living; and 'disrespectful treatment of the body' will not be countenanced (citations omitted). This concern for the treatment of the dead is reflected in Public Health Law § 4200(1), which provides, 'Except in the cases in which a right to dissect it is expressly conferred by law, every body of a deceased person, within this state, shall be decently buried or incinerated within a reasonable time after death.'") (citation omitted).

124. *Melfi*, 64 A.D.3d at 34, 877 N.Y.S.2d at 306; *see also Shipley v. City of New York*, 25 N.Y.3d 645, 37 N.E.3d 58 (2015) (Judge Rivera, dissenting, stated, "The concept of a family's right to burial, recognized by diverse cultures and religious faiths, is age-old and serves an important role in the complexity of human existence."); *Newman v. L. Sathyavaglswaran, M.D.*, 287 F.3d 786, 790 (9th Cir. 2002) (stating "Duties to protect the dignity of the human body after its death are deeply rooted in our national history."), *cert. denied*, 537 U.S. 1029 (2002).

125. *Shipley*, 25 N.Y.3d at 660, 37 N.E.3d at 58.

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NEWS flash

What's Happening in the Section

Upcoming Programs

- **Aid In Dying: A Terminal Patient's Right to Choose.** ***December 16, 2015****.* This is a full day MCLE program (6 1/2 credits) in New York City at the New York State Society of Security Analysts at 1540 Broadway.

  The program will be a comprehensive look at the topic that will include the history and context of "aid in dying," presentations of the NYS case of *Myers, et al. v. Schneiderman, et al.* and the legislative proposals now pending in the Assembly and Senate. The second half of the program will address the ethics of the right to die and present a panel comprised of two plaintiffs in the lawsuit, attorneys and advocates who will discuss the various issues and individual aspects of cases presented to them. The concluding portion of the program will be devoted to a summary of changes and amendments in existing health law. Among the presenters will be Dr. Timothy Quill, a plaintiff in the NYS case; Kathryn Turner, Executive Director of the Disability Legal Rights Center and counsel in the lawsuit; Arthur Caplan, preeminent bioethicist; and David Leven, Executive Director, End of Life Choices New York.

- **Annual Meeting Program.** ***January 27, 2016.*** This meeting is held along with the NYSBA Annual Meeting at the New York Hilton Midtown, 1335 Avenue of the Americas, NYC. Once again the program will survey key developments in health law, including compliance/fraud and abuse, affordable care act, managed care, hospitals, nursing homes, physicians, population health, DSRIP and more. Check the NYSBA website for the latest information regarding the program and speakers.

Recent Programs

- **Senior Housing in New York State.** This program was held at the office of Duane Morris in NYC on September 25, 2015. It covered standards and licensing requirements, regulatory trends; financing and policy issues. Speakers included Nancy Sciocchetti, Esq. from O'Connell and Aronowitz, PC (Albany NY); Rebecca Fuller-Gray from NYSDOH; Robert Borsody from Premier Senior Living; Mark Kissinger from NYSDOH; Assembly member Richard N. Gottfried and Meredith Savitt from O'Connell and Aronowitz.

- **Fall Meeting.** The topic of the Fall Meeting was Population Health—Systemwide Collaboration & Public/Private Partnership. The meeting was held on October 30, 2015 at the Bar Center in Albany. The Co-Chairs were Raul Tabora, Jr. of Bond, Schoeneck & King PLLC and Mary Beth Morrissey of the Global Healthcare Innovation Management Center, Fordham University. Among the prominent speakers were Thomas Merrill and Gregory S. Allen of the NYS Department of Health. The program was well attended.

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Articles should be submitted in electronic document format (pdfs are NOT acceptable), along with biographical information.

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NEW YORK STATE BAR ASSOCIATION

January 25th–30th, 2016
New York Hilton Midtown, NYC

ANNUAL MEETING 2016

HEALTH LAW SECTION PROGRAM

Wednesday, January 27, 2016