Health Law & Policy Summit

Unblurring the Lines in Healthcare: Understanding Key Legal Issues for Operations and Transactions and for the Delivery of Care

May 18, 2022
8:00 am – 12:00 pm

Join Haub Law professors as they clarify the practice of healthcare for lawyers and non-lawyer practitioners who seek to respond to everyday operations, transactional, and delivery of care challenges and emerging issues. Learn how healthcare organizations meet their current responsibilities, prepare for public health challenges, and seek more equitable health policies.

AGENDA

8:00 – 8:30 **Registration & Networking Breakfast**

8:30 – 9:00 **Opening Remarks**
Changing Times, Changing Practice: Navigating the Healthcare System

Steven J. Chananie, Esq., *Special Counsel, Sheppard Mullin*

9:00 – 10:20 **Transacting for Change: Understanding the Unique Issues in Today's Health Care Deals**
Panelists will discuss the lifecycle of a transaction and the legal implications for lawyers and professionals working in the field, including mergers and acquisitions, care delivery modes, compliance, and enforcement.

Steven J. Chananie, Esq., *Special Counsel, Sheppard Mullin*
Linda Martin, JD, *Chief Compliance Officer, CareOne Management, LLC & Affiliates*
Dale C. Van Demark, Esq., *Partner, McDermott Will & Emery LLP*

MODERATOR **James Toomey, Esq.**, *Climenko Fellow & Lecturer of Law, Harvard Law School*

10:30 – 11:50 **Delivery of Patient Care: Understanding Current Ethical and Legal Issues**
Panelists will discuss current issues in patient care, including lack of access to care, long-term care workforce issues, and end-of-life rules. Panelists will also address bioethical issues related to technological advancements in reproductive and genetic technologies.

Barbara L. Atwell, Esq., *Associate Professor of Law and Director of Diversity, Equity and Inclusion, Elisabeth Haub School of Law at Pace University*
Lauren H. Breslow, Esq., *Adjunct Professor, Elisabeth Haub School of Law at Pace University*
Margaret "Gretchen" M. Flint, Esq., *Professor of Law Emeritus, Elisabeth Haub School of Law at Pace University*

MODERATOR **James Toomey, Esq.**, *Climenko Fellow & Lecturer of Law, Harvard Law School*

11:50 – 12:00 **Closing Remarks**

Transacting for Change: Understanding the Unique Issues in Today's Health Care Deals

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Elisabeth Haub School of Law at Pace University

Health Law and Policy Summit

Wednesday, May 18, 2022
8:00 am – 12:00 pm

Elisabeth Haub School of Law
New York State Judicial Institute
78 N. Broadway, White Plains, NY

Unblurring the Lines in Healthcare: Understanding Key Legal Issues for Operations and Transactions and for the Delivery of Care

Health Law & Policy Summit

Part I: Overview

A. The Regulatory Due Diligence Process

B. Getting Oriented

Part II: The Legal / Regulatory Basics

A. The Stark Law

B. The Anti-Kickback Statute

C. The Civil Monetary Penalty Law

D. The False Claims Act Basics

Part III: The Basic Requirements for an Effective Compliance Program

Part IV: Risk Areas to be Reviewed

Part V: Advising Clients Generally

Part I:

Overview

OVERVIEW – The Regulatory Due Diligence Process for Physician Practice Deals

- Risk Assessment. Your focus is on identifying regulatory issues, both positive and negative, that will assist you in assessing both the value of the Target and the potential risks in proceeding with a transaction.

- Asset vs. Stock Purchase. A pure asset purchase generally has no successor liability issues (although some federal cases will allow for it under certain scenarios). In conducting the regulatory risk assessment, consider the scope of successor liability, along with the ability to otherwise manage identified risks by providing for strong representations and warranties, imposing special indemnifications, increasing escrow amounts, and obtaining Reps & Warranty Insurance.

OVERVIEW – The Regulatory Due Diligence Process for Physician Practice Deals

- Levels of Risk. Do not merely focus on whether there are instances of non-compliance or regulatory "gaps" in operations, but the materiality of such:
  - Material Red Flags. Is the identified issue a material "red flag" that could prevent the transaction from going forward, including, for example:
    - A substantive government investigation, audit or prosecution;
    - A Corporate Integrity Agreement with the OIG or other settlement agreement with the government;
    - Extensive patterns of identified non-compliant documentation, coding and billing;
    - Non-existent compliance or HIPAA programs;

OVERVIEW – The Regulatory Due Diligence Process for Physician Practice Deals

- Failure to quality as a Group Practice under the federal Stark physician anti-referral law or otherwise violate Stark in the manner in which internal referrals are made for Designated Health Service; and
- Questionable financial and referral relationships with third parties.

– Lower Risk Material Issues. Some identified instances of non-compliance, even if material, may present a lower risk profile and either be correctable pre or post-closing or client can be protected through post-closing covenants, special indemnifications, etc.

– Technical Issues. Other identified instances of non-compliance may be purely technical in nature. While such issues should be corrected, they may not impact the risk analysis in any material way.

OVERVIEW – The Regulatory Due Diligence Process for Physician Practice Deals

- Positive Factors. But don't overlook the positive, such as: a robust Compliance Program; a history of compliant documentation, coding and billing; positive engagement with population health and care coordination initiatives; etc.

OVERVIEW – Getting Oriented

- Initial Orientation.
  - Confidential Information Memorandum.
    If there is a CIM, review it first very carefully.
  - Size and Scope of the Practice Itself
    - Number of physicians
    - Number of mid-levels – NPs or PAs.
    - Number of other providers – PTs, chiropractors, radiologists, etc.
    - What in-office ancillaries service are provided – radiology, drugs (e.g., infusion), PT, clinical laboratory, pathology, radiation therapy, etc.

OVERVIEW – Getting Oriented

- Other Key Background Facts.
  - Is both a PC and an MSO being acquired?
  - What do state rules governing the Corporate Practice of Medicine dictate?
  - Does the Target have an ASC?
  - Is the Target involved in, or operate, an ACO?
  - Does the Target operate an IPA or Risk Based Entity?
  - Are there Joint Venture entities that we must consider?
  - Is the Target involved in gainsharing, bundled payment or other similar payment arrangements.
  - Does the Target bill on a risk adjustment basis (HCC-RAF), as well as fee for service?
  - Under MACRA, does the Target bill under MIPS or under an APM?

Part II:

The Legal / Regulatory Basics

The Legal / Regulatory Basics – The Stark Law

- The Stark Law prohibits making a referral or billing for a Medicare Designated Health Service (DHS) when:
  - a physician has a financial relationship, direct or indirect, with an entity that provides or bills for DHS;
  - unless a regulatory exception applies (no safe harbors).
- Stark is thus a search for an exception whenever a physician has *both* a referral relationship and a financial relationship with a DHS entity.

The Legal / Regulatory Basics – The Stark Law

- There are eleven DHS, including any Medicare inpatient or outpatient hospital service, as well as clinical lab, physical therapy, radiology and other imaging, radiation therapy, DME, parenteral and entend nutrients, equipment and supplies, prosthetics and orthotics, home health services, and outpatient prescription drugs.
- Applies only to Medicare (or Medicaid) DHS.
- State “Stark” laws can be all payor, have a different list of DHS, or have other material differences.

The Legal / Regulatory Basics – The Stark Law

- Stark is strict liability: there is no need for any intent to induce referrals or any quid pro quo. The existence of a referral relationship and a financial relationship triggers the statute.
- The financial relationship does not have to be related in any way to the referrals (e.g., a physician leases from a hospital a space to store supplies and otherwise admits patients at the hospital).

The Legal / Regulatory Basics – The Stark Law

- There are many, very broad exceptions, but to be applicable, and prevent a violation of the Law, every element of an exception must be satisfied for each financial relationship with a DHS entity, whether it is direct or indirect, or a compensation or an ownership relationship.

- Exceptions include:

  - In-Office Ancillary Services Exception (see slides 45-48 on Internal Group Practice);
  - Managed Care Exceptions which are very broad and useful, but do not protect all activities (e.g., marketing, pre-enrollment activities);
  - Indirect Compensation Arrangements (this is a potentially powerful exception that needs to be considered with any arrangement in which the referring physician does not have a direct financial relationship with the DHS entity);
  - Rental of Space and Equipment;
  - Employees;
  - Personal Services;
  - Value Based Enterprises;
  - Etc.

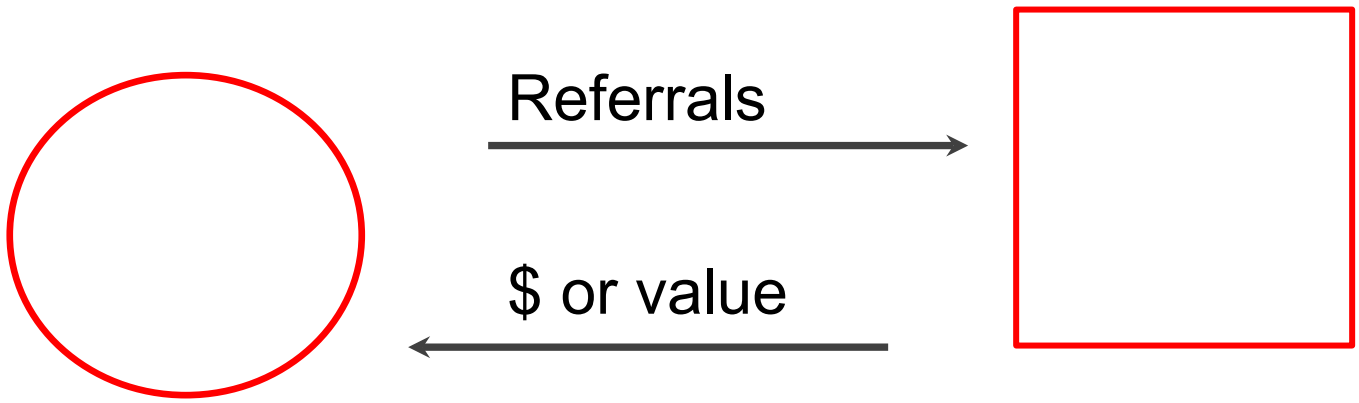
The Legal / Regulatory Basics – The Anti-Kickback Statute

- Unlike Stark, the AKS is a criminal statute, not civil.
- The AKS makes it a felony to:
  - Knowingly and willfully (intent required)
  - Offer, pay, solicit or receive (both parties are equally liable)
  - Remuneration
  - To induce or reward:
    - the referral of an individual or service; or
    - the purchasing, leasing, ordering or arranging for an item, or supply or service, or recommending such.
- Applies to services or items reimbursable under any federal health care program (Medicare, Medicaid, Medicare Advantage, Medicaid Managed Care, TriCare, etc.).

The Legal / Regulatory Basics – The Anti-Kickback Statute

- Remuneration includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind (not just actual kickbacks)
    - e.g., anything of value qualifies, including payments that are not at Fair Market Value (e.g., a physician pays rent to a hospital below FMV; a hospital rents space from a referring physician above FMV; rebates from a manufacturer).

The Legal / Regulatory Basics – The Anti-Kickback Statute



The Legal / Regulatory Basics – The Anti-Kickback Statute

- The AKS applies not just to physicians but to anyone who is inducing or recommending referrals.
- Any kind of marketing or advertising thus potentially implicates the AKS. It is crucial to analyze the scope and extent of marketing to assess the AKS risk:
  - Mere print or other advertisements, brochures, etc.;
  - Direct marketing to providers or patients; or
  - “white coat” marketing.

The Legal / Regulatory Basics – The Anti-Kickback Statute

- Is the marketing within a Safe Harbor?
  - Written contracts for at least one year;
  - Fixed, aggregate amount for the year;
  - Percentage arrangements, per patient or commission payments are outside of safe harbor, unless the arrangement is with a non-physician employee;
  - Bona fide employees.
- If the arrangement is outside of Safe Harbor, then you must carefully analyze the AKS risk based on the scope and nature of the marketing activities and the potential for abuse.

The Legal / Regulatory Basics – The Anti-Kickback Statute

- Because of the broad reach of the AKS (i.e., it potentially criminalizes innocuous or beneficial arrangements), the OIG has promulgated Safe Harbors (per authorization from Congress) that, if followed, provide assurances that a business practice will not be subject to liability under the AKS or related administrative authorities.
- Compliance with a Safe Harbor is voluntary; being outside of a Safe Harbor does not necessarily make an arrangement illegal (as does being outside of a Stark exception).
- Arrangements outside of Safe Harbor must be carefully analyzed:
  - What safeguards against abuse are in place? Be creative and design workable safeguards – look to favorable OIG Advisory Opinions for ideas;
  - Under the OIG's Advisory Opinions, the OIG analyzes whether arrangements outside of Safe Harbors pose more than a minimal risk of fraud and abuse (e.g., over-utilization, overriding patient choice; compromising medical judgment; influencing referrals, etc.).

The Legal / Regulatory Basics – The Anti-Kickback Statute

- Safe Harbors include, for example:
  - Managed Care Safe Harbors;
  - Employees (no FMV requirement as opposed to the Stark employee exception, which does);
  - Rental of space or equipment;
  - Management and Personal Services arrangements
  - Small Investments (Joint Venture Safe Harbor);
  - ASCs;
  - Value Based Arrangements
  - Etc.

The Legal / Regulatory Basics – The CPML

- The CMPL prohibits various activities and empowers the OIG to administrate civil monetary penalties and exclude non-compliant persons, providers or entities from federal health care programs (federal and state).
- Patient Inducements. As relevant here, the CPML prohibits any person from offering or transferring remuneration to a patient that the person knows or should know is likely to influence the patient's selection of a particular provider, practitioner or supplier of any item or service reimbursement by Medicare or a state health care program.

The Legal / Regulatory Basics – The CPML

- Exceptions to the CMPL include:
  - The provision of items of "nominal" value, including the provision of complimentary local transportation which the OIG has valued in commentary at $10 per item/trip, $50 per year (not a regulatory exception yet);
  - Remuneration that "promotes access to care and poses a low risk of harm to patients and federal health care programs" (new exception);
  - Incentives that promote the Delivery of Preventive Care (new exception);
  - Providing remuneration when there is demonstrated financial need (new exception);
  - Gainsharing (new provision).
- If provision of remuneration is not likely to induce a patient to self-refer, then there is no need for an exception.
- The term "should know" means, as under the FCA, acting with reckless disregard or deliberate ignorance of the truth or falsity of information.

False Claims Act Basics

- Enacted in 1863 during the Civil War
- Expanded steadily over the years and is now “the weapon of choice” in health care governmental enforcement actions
- Severe penalties and low *mens rea* (knowledge, reckless disregard, deliberate ignorance – not intentional)
- Can be used to prosecute Anti-Kickback Statute and Stark Law violations (i.e., every prohibited referral becomes a false claim)
- Applies only to governmental programs (including Medicare and Medicaid management plans)
- Most states now have their own FCAs, and we often see federal and state authorities working jointly on Medicare and Medicaid cases

False Claims Act Basics

- Elements – Knowingly submitting a false or fraudulent claim to a federal health care program will result in penalties being imposed. 31 U.S.C. §3729.
- Knowing – "Knowing" includes not only actual knowledge, but also:
  - Submitting a claim that is false or inaccurate with "reckless disregard" or "deliberate ignorance" of the truth or falsity
  - No proof of a specific intent to defraud is required
- Documentation → Coding → Billing – FCA covers all three and many investigations focus on the adequacy of documentation in the medical record to support the codes selected to justify the bill submitted. **"If it is not documented, it did not happen."**
- Clerical Support – DOT is now pursuing cases in the Medicare Advantage space asserting first diagnoses are not supported *clinically* by the documentation.

False Claims Act Basics

- Patterns and Innocent Mistakes – While there is a defense for innocent mistakes, the government may infer reckless disregard or deliberate ignorance if there is a pattern of deficient documentation, coding or billing.
  - Adequacy of compliance program is directly relevant to determining recklessness
- Penalties – Potential penalties can be draconian and are used by the government to force settlements:
  - Treble damages
  - Per claim penalties
  - Debt Collection Improvement Act of 1996 mandates increases to account for inflation since 1986
  - Exclusion
  - Corporate Integrity Agreements with the OIG

False Claims Act Basics

- Downstream Contractors – The Fraud Enforcement Act ("FERA") of 2009 redefined the term "claim" in the FCA in response to the U.S. Supreme Court's Opinion in Allison Engine Co. v. U.S. ex rel. Sanders, 553 U.S. 662 (2008), to ensure that downstream contractors could be liable for false claims under the FCA. 31 U.S.C. §3729(b)(2)(expanding the definition of the term "claim")

- Anti-Kickback Statute – The Affordable Care Act clarified that claims submitted in violation of the Anti-Kickback Statute (the "AKS") constitute false claims for purposes of the False Claims Act. 42 U.S.C. §1320d-7b(g).
  - Thus, if claims were properly submitted by a hospital, but the claims were for services improperly referred under the AKS, all such referrals, for whatever period of time, are all potentially false claims – i.e., the entire stream of referrals.
  - Federal government often prosecutes AKS claims under the FCA.

Part III:

The Basic Requirements for an Effective Compliance Program

Basic Requirements for an Effective Compliance Program

- **The Federal Sentencing Guidelines**.
  - Designed to provide mitigation credit in sentencing an organization, if seven required compliance program elements are in effect.
  - Used by federal and state agencies as guidance in civil enforcement actions as well.
  - HHS OIG follows the seven elements.

Basic Requirements for an Effective Compliance Program

- **The Seven Elements**.

1. Written Standards. A Code of Conduct and Policies and Procedures that addresses risk and potential fraud and abuse areas.
2. Appropriate Compliance Program Structure. Designated, high level Chief Compliance Officer, and Compliance Committee, directly reporting to the governing body.
3. Effective Training and Education.
4. Open Communication Line, including a Compliance hotline.
5. Response to Allegations, including enforcement of appropriate disciplinary actions.
6. Use of Auditing and Monitoring Procedures.
7. Process to Investigate and Correct Issues, including not only appropriate investigatory and corrective action protocols but also not employing or retaining excluded individuals.
    - Monthly exclusion checks?

Basic Requirements for an Effective Compliance Program

- **Key Concerns.**
  - In a Qui Tam, SDNY examined a physician practice's compliance program and conducted a detailed and comprehensive review.
  - Many office depositions.
  - Beyond the Compliance Program's documents, SDNY focused especially on how the practice: (1) followed up on identified issues; (2) the scope of auditing program; (3) when it expanded audits; and (4) when it did voluntary disclosures/refunds and with what frequency.

Basic Requirements for an Effective Compliance Program

- **Is the Program Actually Operating Effectively in Practice?**
  - Not just a binder on the shelf.
  - Are policies and procedures actually being followed? If not , they can be used against the entity in a governmental enforcement action.
  - Actually doing audits, monitoring and training?
  - Is there follow-up and implementation of corrective actions when issues are identified (e.g., broader audits; feedback to providers; broader remedial training; voluntary refunds; change or modification of procedures, etc.)?
  - Is there an active compliance structure?

    (1) a Compliance Officer;
    (2) a Compliance Committee with minutes;
    (3) a Compliance Issues Log;
    (4) reporting to the Governing Body; and
    (5) annual risk assessments and annual work plans.

Basics - CMS's Pronouncements

- In the February 12, 2016 Federal Regulations, in commenting on the new regulations as to addressing Part A or Part B overpayment, CMS stressed:
  - **"Clear Duty" – Ongoing Compliance**. CMS stressed that "proactive compliance activities are necessary to monitor for receipt of overpayments." As a result, providers/ suppliers "have a clear duty to undertake proactive activities to determine if they have received an overpayment or risk potential liability for retaining such overpayment."
  - **Potential Liability**. If there is "no or minimal compliance activities," the provider will face potential liability under the overpayment regulations, because the provider will not have been acting with reasonable diligence, even if the provider has not received credible information of an overpayment.

Basics - The Deficient Reduction Act

- If $5 million or more of straight Medicaid revenues in a state, the entity must:
  - Have an effective fraud and abuse compliance program
  - Have a policy on FCA and whistleblowing laws, both federal and state
  - Distribute the policy
  - Have the policy in the entities' Employment Mail
  - Very technical requirement with no practical benefit, but:
    - Non-compliance can result in forfeiture of all Medicaid payments.

Basics - Real World Impact

- Federal and State Investigations
- Imposition of OIG Corporate Integrity Agreements
- Outstanding federal investigations, actions and CIAs can materially impact transactions and M&A deals

Basics - OIG Compliance Program Guidance

- There are OIG "Compliance Program Guidance" in the Federal Register for a variety of provider types, including, for example:
  - Hospitals
  - Nursing home
  - Clinical laboratory
  - Home health agencies
  - Pharmaceutical companies; and
  - Physician practices

Basics - Various OIG White Papers

- Effective governance and oversight for Compliance Programs is a central concern of the OIG:

  (1) Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors

  (2) An Integrated Approach to Corporate Compliance: A Resource for Health Care Boards of Directors

  (3) The Health Care Director's Compliance Duties: A Continued Focus of Attention on Enforcement

  (4) Practice Guidance for Health Care Governing Boards in Compliance Oversight

Part IV:

Risk Areas to be Reviewed

Advising Clients – M&A

- Key → advising clients on potential red flags, troubling issues, program findings, and/or steps that will have to be taken post-closing
- Assisting the client in assessing the bona fide's of the entity and identified risks
- Must distinguish for the client material vs. non-material risks

Investigations, Audits and Actions

- Government Investigations – known or suspected; look for copies of Subpoenas, Civil Investigatory Demands, record requests.
- Government Audits – RAC, MAC, ZPIC, Integrity Safeguard Contractors, State Medicaid, federal OIG, etc. Analyze any findings for any apparent patterns of non-compliant documentation, billing or coding either as to a specific audit or across audits (also include commercial payor audits)
- Government Proceedings – civil, criminal, administrative.
- Government Settlements or Orders – Corporate Integrity Agreements; Non-Prosecution Agreements; Department of Health survey findings, with Corrective Action Plans; etc.
- Third-Party Payor Audits or Investigations – both routine billing and coding audits, as well as inquiries by payor Special Investigation Units.

Billing and Coding

- Hire an Outside Billing Consultant. At the outset, consider hiring an outside consultant to conduct a documentation, coding and billing review of a sample of records. Consider doing so under attorney-client privilege.
- Review Internal Billing Compliance.
  - Are there strong internal documentation, coding and billing protocols? Review their compliance program in this regard carefully.
  - Are providers trained in documentation and coding? Look for training schedules, and policies, and review all training materials
  - Are there regular internal audits? If so, do the following:
    - Review such audits for the past three years.
    - What do the findings look like? Any persistent patterns of errors?
    - What kind of corrective actions were put into place?

Billing and Coding

- Did the Target hire an outside consultant to do a review? Review all reports and findings.
- Does the Target use centralized coders? Are they certified coders?
- Try to evaluate overall if the Target is taking accurate coding and billing seriously. Review all Compliance Committee and Board minutes.

- Review all Voluntary Disclosures.
  - Review refunds and disclosures both to federal and state agencies
  - Review other disclosures
    (e.g., disclosure to OIG for employing an excluded individual, etc.)

Billing and Coding

- Outside Billing Audits. As per prior slide, review all outside governmental and commercial billing audits.
- Look for Patterns of Material Deficiencies. Compare the findings of all available third-party billing audits to those of any internal audits and that of your consultant. Suspect areas include such things as:
  - Upcoding Evaluation & Management (E&M) codes by 2 levels or more.
  - Being an outlier on utilization of E&M codes as compared to CMS benchmarks
  - High Risk Adjustment scores under HCC-RAF coding or overly aggressive mining for missed diagnosis codes.
  - Improper “Incident to” billing (for services provided by NPs or PAs)
  - Improper Teaching Physician coding (if they utilize residents)
  - Poor MACRA compliance under MIPS
  - Billing for radiologists or pathologists who work off-site. Is there compliance with the Medicare Anti-Mark-Up Rule?

Referral Relationships with Third Parties

- Review All Material Agreements. As part of the regulatory due diligence, focus on agreements with any third parties with whom the Target or any of its providers have a referral arrangement, including, for instance:
  - Medical Director Agreements (with hospitals, home health agencies, SNFs, etc.);
  - Lease agreements; and
  - Agreements with Pharm companies paying physician to consult, be on an advisory board, etc.
- Analyze the Agreements for Compliance with Law. Conduct your analysis under both federal anti-referral laws – the Stark Law and the Anti-Kickback Statute – as well as under applicable state law equivalents.

INTERNAL GROUP PRACTICE STARK LAW COMPLIANCE

- Conduct a Summary Stark Analysis. If the Target provides in-office ancillary services that qualify as Stark covered Designated Health Service ("DHS"), analyze whether the Target qualifies as a "Group Practice" and satisfies the Stark in-office ancillary services exception. Stark is strict liability, so non-compliance can quickly become a red flag issue.
- Legal Opinions. Request any legal opinions by the Target's counsel as to its compliance with the Stark Law. If not, look at the following factors under Stark.
- Location. Are the DHS provided in a "centralized location" owned or leased by Target on a 24/7 basis or in "the same building" where the Target provides non-DHS services?

INTERNAL GROUP PRACTICE STARK LAW COMPLIANCE

- Group Practice. Does the Practice qualify as a Stark unified "group practice." There are a number of requirements here:
  - The 75% Test. The Owners and Employees, in the aggregate and on average, must provide 75% or more of their total patient services through the Practice. This requires the following calculation:
    - Take each owner and employee and determine how much each one spends *providing patient services* at the Practice versus elsewhere. For example, if a physician is part-time at the Practice, but provides no patients services elsewhere, he will count as 100%. If another physician spends 60% of his time at the Practice and 40% of his time at another provider, then he counts as 60%. If these were the only physicians in the group, then the aggregate percentage would be 60% plus 100% divided by two or 80%. This is greater than 75%, so the Test is met.

INTERNAL GROUP PRACTICE STARK LAW COMPLIANCE

- Perform this calculation for ONLY owners and W2 employees are counted. Do NOT count independent contractors.
- Request information as to how many employed and owner physicians there are, whether they are full-time or part-time (and if part-time, what percentage)

- The 25% Independent Contractor *Patient "Encounter"* Test. There is a separate test for independent contractors. In the aggregate, they can provide no more than 25% of the total patient *encounters* being provided by the practice. Conversely, at least 75% of total patient encounters must be performed by owners and employees.
- Distribution of DHS Net Profits. The profits from any DHS must be distributed within the Practice to the physicians in a Stark compliant manner. This is a complex and very important requirement. For instance, one compliant methodology is under the so-called "Rule of 5" methodology, which requires the creation of a pod of at least 5 physicians to whom the profits are distributed in a manner that does not take into account their referrals for lab tests.

INTERNAL GROUP PRACTICE STARK LAW COMPLIANCE

- Other Miscellaneous Requirements. There are other miscellaneous requirements. These include, for instance, that:
  - The Target must be a single legal entity, practicing as a unified practice under centralized management (no confederations of affiliated practices – although "cost centers" within a unified practice are allowed, as long as final decision-making resides in a central governing body);
  - The Practice must bill through its own billing number;
  - All proceeds from billing must be considered practice proceeds; and
  - The distribution of expenses and income must be determined by a methodology set before the receipt of reimbursement.

COMPLIANCE PROGRAM

- The Importance of a Compliance Program.

  Without a robust compliance program,
  you “don’t know what you don’t know,” and
  there could be hidden material issues and risks
  that an effective program might have uncovered.

COMPLIANCE PROGRAM – M&A

- If there are potential regulatory issues as to the Compliance Program's structure or operations, look for evidence that:
  - Entity was aware of the issue, and
  - Has taken steps to address or resolve the issue
  - For example:
    - MSAs and marketing and percentage fee arrangements
    - Discharge Planning Services Agreements

COMPLIANCE PROGRAM

- Review the Documentation of the 7 Elements.
  Under federal OIG guidelines, an effective compliance program must satisfy 7 elements. Request documentation as to each element and review for compliance.
  The 7 elements include:
  - Compliance Officer and Compliance Committee
  - A Code of Conduct and Written Compliance Policies and Procedures
  - Conducting Training and Education
  - Open Lines of Communication (is there a hotline?)
  - Internal Monitoring and Auditing
  - Disciplinary Procedures
  - Responding to Identified Issues and Implementing Corrective Actions

COMPLIANCE PROGRAM

Other important elements to check include:

- Monthly exclusion checks
- Clear policies on non-retaliation and non-intimidation

COMPLIANCE PROGRAM

- Review Evidence That the Program is Operating. Documentation is not enough; the compliance program must be operating effectively in practice. To test this, request and review the following for the past three years for both actual compliance program operations, but also for any issues that the program may have identified:
  - Compliance Committee and Board minutes
  - Issue Log
  - All voluntary disclosures and refunds
  - Internal compliance training materials and schedules
  - Copies of all internal billing audits
  - Copies of Annual Compliance Work Plans for the past three years
  - Copies of any compliance reports to the Board.

HIPAA COMPLIANCE

Request and Review the following:

- Security Risk Assessments for the Past 3 Years. In Response to each Assessment, review the corresponding Corrective Action Plan and how it was implemented.
- All HIPAA Policies & Procedures.
- All Business Associate Agreements (or template[s]).
- The HIPAA Breach Log. Review all breaches, how they were resolved, whether appropriate corrective actions were taken, and whether there were any reports to the federal Office of Civil Rights.
- HIPAA Training. Request copies of HIPAA training materials and training schedules.

MANAGEMENT SERVICES AGREEMENT

Review any MSA for the following:

- Compliance with Corporate Practice of Medicine Rules ("CPOM"). Is the MSO exercising too much control over the Practice under that state's CPOM rules?
- Medicare Anti-Assignment Rule. Confirm that the cash flow from governmental payors to the Practice to the MSO is consistent with Medicare's Anti-Assignment Rule prohibitions.
- Management Fee. Is the fee a percentage? If so:
  - Do state rules allow for such (some do, some don't)

MANAGEMENT SERVICES AGREEMENT

- Marketing. Does the MSA provide substantive marketing services? That may likely present an issue under the federal Anti-Kickback Statute if there is a percentage fee. Questions to ask are:
  - Do state rules allow for such (some do, some don't)
  - Is marketing being done by the Practice of by the MSO?
  - How are sales staff being compensated?
  - What kinds of marketing/advertising being done and by whom – by the Practice or by the MSO?
  - Where are direct sales staff employed? Are there fraud and abuse training materials for the sales staff?
  - If they are doing marketing to other practices or entities, do they have marketing guidelines as to appropriate interactions, gifts, provision of benefits of nominal value in compliance with the Stark annual allowed ceiling?

OTHER MISCELLANEOUS ISSUES

- Change of Ownership ("CHOW") Issues. If there any change of ownership of any entity? Change of ownership issues may be triggered as to:
  - Notice and Consent requirements in payor contracts.
  - Notice and Consent requirements in material vendor contracts.
  - Notice and Consent requirements as to leases.
  - State licensure approval (e.g., CHOW approval requirements for ASC, labs, licensed agencies or diagnostic and treatment centers).

OTHER MISCELLANEOUS ISSUES

- Credentialing and Closing.
  - If physicians are engaged by a group, they must be linked under Medicare (855R) to the group and credentialled by commercial plans.
  - If a new practice entity is being created, then all providers will likely have to be recredentialed with all payors. This can take time and must be carefully coordinated with Closing.
- Anti-Trust Concerns.
  - If the Buyer already employs physicians in the same area and specialty as the Seller, then a preliminary anti-trust analysis should be done to ensure that market concentration and other anti-trust concerns are not implicated.

OTHER MISCELLANEOUS ISSUES

- Licenses, Accreditations and Credentials. All must be confirmed to be in place, including, for instance:
  - Physician licenses
  - Lab licenses
  - ASC licensure (where required) and/or accreditation
  - Radiation licenses

OTHER MISCELLANEOUS ISSUES

- Unique Issues for Different Specialties. For some specialties, there may be unique issues that should be reviewed, such as:
  - With a pain practice, are there adequate controls as to opioid prescription, monitoring patient substance abuse (e.g., urine testing) or checking state prescription database?
  - With a dermatology practice, is the practice selling products (e.g., skin creams) to patients and, if so, is it doing so ethically and compliantly?

Part V

Advising Clients Generally

Advising Clients Generally

The Compliance Mindset

- Good documents and good legal analyses of terms are not enough.
- DOJ or OIG will blow through the documents, if there is an appearance of impropriety.
- Guide the client to not act with “reckless disregard” or “deliberate ignorance”

Advising Clients Generally

Be Operationally Minded

- Law is practical philosophy: analysis of legal rules, policy, etc., but all of that is applied in the real world and our advice must be practical, realistic and reasonable.
- True for compliance as well as transactional work.
- Understand/learn how the client operates:
  - What are their operational, clinical and business objectives?
  - How can we use their Compliance Program to help them achieve those objectives?

Advising Clients Generally

Be Operationally Minded *(continued)*

- Are adequate safeguards in place?
  - Are they reasonable?
  - Can the client implement them?
  - Will it?
  - Internal policies that are not implemented will be used against the client.
- Can or should existing compliance or quality procedures be used or modified to address and protect new arrangements or procedures?

Delivery of Patient Care: Understanding Current Ethical and Legal Issues

Barbara L. Atwell, Esq., *Associate Professor of Law and Director of Diversity, Equity and Inclusion*, *Elisabeth Haub School of Law at Pace University*
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MODERATOR **James Toomey, Esq.**, *Climenko Fellow & Lecturer of Law, Harvard Law School*

Medicaid and EMTALA Resources

NFIB v. Sebelius, 567 U.S. 519; 132 S. Ct. 2566 (2012)
https://www.supremecourt.gov/opinions/11pdf/11-393c3a2.pdf

The Affordable Care Act, 42 U.S.C. §18001 https://www.govinfo.gov/content/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf

Medicaid 42U. S. C. §1396 et seq. https://www.govinfo.gov/content/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXIX.htm

Medicaid expansion https://www.healthcare.gov/medicaid-chip/medicaid-expansion-and-you/

Expanded coverage under the ACA --
https://www.hhs.gov/about/news/2022/04/29/new-reports-show-record-35-million-people-enrolled-in-coverage-related-to-the-affordable-care-act.html

Emergency Medical Treatment and Active Labor Act -- 42 U.S.C. §1395dd
https://www.law.cornell.edu/uscode/text/42/1395dd

Baber v. Hospital Corporation of America, 977 F.2d 872 (4th Cir. 1992) (EMTALA)https://scholar.google.com/scholar_case?case=6845185189616749009&q=baber+v.+hospital+corporation+of+america&hl=en&as_sdt=6,33&as_vis=1

General national health information -- https://www.kff.org/

Census Poverty Thresholds -- https://www.census.gov/data/tables/time-series/demo/income-poverty/historical-poverty-thresholds.html

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 7. Social Security (Refs & Annos)
Subchapter XI. General Provisions, Peer Review, and Administrative Simplification (Refs & Annos)
Part C. Administrative Simplification

42 U.S.C.A. § 1320d-1

§ 1320d-1. General requirements for adoption of standards

Effective: August 21, 1996

Currentness

(a) Applicability

Any standard adopted under this part shall apply, in whole or in part, to the following persons:

(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 referred to in section 1320d-2(a)(1) of this title.

(b) Reduction of costs

Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

(c) Role of standard setting organizations

(1) In general

Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

(2) Special rules

(A) Different standards

The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if--

(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of Title 5.

(B) No standard by standard setting organization

If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part--

(i) paragraph (1) shall not apply; and

(ii) subsection (f) shall apply.

(3) Consultation requirement

(A) In general

A standard may not be adopted under this part unless--

(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f), consulted with each of the organizations described in subparagraph (B) before adopting the standard.

(B) Organizations described

The organizations referred to in subparagraph (A) are the following:

(i) The National Uniform Billing Committee.

(ii) The National Uniform Claim Committee.

(iii) The Workgroup for Electronic Data Interchange.

(iv) The American Dental Association.

(d) Implementation specifications

The Secretary shall establish specifications for implementing each of the standards adopted under this part.

(e) Protection of trade secrets

Except as otherwise required by law, a standard adopted under this part shall not require disclosure of trade secrets or confidential commercial information by a person required to comply with this part.

(f) Assistance to Secretary

In complying with the requirements of this part, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 242k(k) of this title, and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

(g) Application to modifications of standards

This section shall apply to a modification to a standard (including an addition to a standard) adopted under section 1320d-3(b) of this title in the same manner as it applies to an initial standard adopted under section 1320d-3(a) of this title.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XI, § 1172, as added Pub.L. 104-191, Title II, § 262(a), Aug. 21, 1996, 110 Stat. 2023.)

42 U.S.C.A. § 1320d-1, 42 USCA § 1320d-1
Current through P.L. 117-102. Some statute sections may be more current, see credits for details.

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

Remarks by Chair Lina M. Khan on the
Health Breach Notification Rule Policy Statement
Commission File No. P205405

September 15, 2021

The global pandemic has hastened the adoption of virtual health assistants, with Americans placing their trust in various technologies to track and manage their personal health. As we have seen, however, digital apps are routinely caught playing fast and loose with user data, leaving users' sensitive health information susceptible to hacks and breaches. Given the rising prevalence of these practices, it is critical that the FTC use its full set of tools to protect Americans.

In 2009, Congress instructed the FTC to issue a rule protecting the public from breaches of personal health data. This Health Breach Notification Rule is among a small set of privacy laws covering users' health information, and it requires vendors of unsecured identifying health information to notify users, the FTC, and, in some cases, the media if there is an unauthorized disclosure.[1] Although the Rule was first issued over a decade ago, the Commission has not brought any enforcement actions under it.

While users have been adopting health apps at a rapid rate,[2] the commercial owners of these apps too often fail to invest in adequate privacy and data security, leaving users exposed. For example, one recent peer-reviewed study found that these health apps suffer from "serious problems," ranging from insecure transmission of user data (including geolocation) to unauthorized dissemination of data to advertisers and other third parties in violation of the apps' own privacy policies.[3] In my view, these problems stem in part from a gap: health apps are

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[1] 85 Fed. Reg. 31,085, 31,087 (codified at 16 C.F.R. pt. 318) ("the Rule"). The Rule implements the requirements of the American Recovery & Reinvestment Act of 2009, 42 U.S.C. §§ 17937, 17953.

[2] See, e.g., Elad Natanson, *Healthcare Apps: A Boon, Today and Tomorrow*, FORBES (July 21, 2020), https://www.forbes.com/sites/eladnatanson/2020/07/21/healthcare-apps-a-boon-today-and-tomorrow/?sh=21df01ac1bb9; Emily Olsen, *Digital health apps balloon to more than 350,000 available on the market, according to IQVIA report*, MOBIHEALTHNEWS (Aug. 4, 2021), https://www.mobihealthnews.com/news/digital-health-apps-balloon-more-350000-available-market-according-iqvia-report; Lis Evenstad, *Covid-19 has led to a 25% increase in health app downloads, research shows*, COMPUTERWEEKLY (Jan. 12, 2021), https://www.computerweekly.com/news/252494669/Covid-19-has-led-to-a-25-increase-in-health-app-downloads-research-shows (finding that COVID-19 has led to a 25% increase in health app downloads and that of the 350,000 health apps available on the market, 90,000 of which were introduced in 2020 alone, an average of 250 per day); *Digital Health Habits in the UK: a Quin nationwide survey*, QUIN (Oct. 2, 2020), https://quintech.io/what-do-the-uk-public-think-about-health-apps/ (finding that usage of health apps has increased by 37% in the U.K. since the start of the pandemic).

[3] Gioacchino Tangari et al., *Mobile health and privacy: cross sectional study*, 373 BRITISH MED. J. 1, 11 (June 17, 2021), https://www.bmj.com/content/373/bmj.n1248.

generally not covered by HIPAA, and some may mistakenly believe that they are not covered by the Commission's Rule.

Today we are clarifying that the Health Breach Notification Rule applies to connected health apps and similar technologies. Notably, the Rule does not just apply to cybersecurity intrusions or other nefarious behavior; incidents of unauthorized access also trigger notification obligations under the Rule. It is particularly important to note that the Rule extends to evolving technologies, an interpretation that is a logical reading of its language. Contrary to my dissenting colleagues' suggestion, today's statement is entirely consistent with—and, in fact, serves to clarify—the FTC's earlier guidance.[4] Consistent with that guidance, health apps that are capable only of collecting data from users directly—in other words, apps that are *not* capable of drawing data from multiple sources—are not covered by the Rule. I will also note that there is no notice of proposed rulemaking pending on this Rule. We have solicited comments as part of our general periodic review and have reviewed those comments as part of our analysis here.

The Commission will enforce this Rule with vigor. Violations of the Rule carry civil penalties of $43,792 per violation per day, and the Commission should not hesitate to seek significant penalties against developers of health apps and other technologies that ignore its requirements.

Lastly, I believe our efforts to protect Americans from abusive data practices must extend beyond this Rule. While this Rule imposes some measure of accountability on tech firms that abuse our personal information, a more fundamental problem is the commodification of sensitive health information, where companies can use this data to feed behavioral ads or power user analytics. Given the growing prevalence of surveillance-based advertising, the Commission should be scrutinizing what data is being collected in the first place and whether particular types of business models create incentives that necessarily place users at risk.

In the meantime, it is vital that the Commission use the full suite of its authorities to protect Americans from abusive data practices. Today's action will be a step in the right direction.

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[4] The dissenters point to existing guidance about the term "Personal Health Record related entity," but the Policy Statement issued today addresses an entirely different set of entities covered by the Rule—vendors of personal health records.

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

STATEMENT OF THE COMMISSION
On Breaches by Health Apps and Other Connected Devices

September 15, 2021

In recognition of the proliferation of apps and connected devices that capture sensitive health data, the Federal Trade Commission is providing this Policy Statement to offer guidance on the scope of the FTC's Health Breach Notification Rule, 16 C.F.R. Part 318 ("the Rule").[1]

The FTC's Health Breach Notification Rule helps to ensure that entities who are not covered by the Health Insurance Portability and Accountability Act ("HIPAA") nevertheless face accountability when consumers' sensitive health information is compromised. Under the Rule's requirements, vendors of personal health records ("PHR") and PHR-related entities must notify U.S. consumers and the FTC, and, in some cases, the media, if there has been a breach of unsecured identifiable health information, or face civil penalties for violations. The Rule also covers service providers to these entities. In practical terms, this means that entities covered by the Rule who have experienced breaches cannot conceal this fact from those who have entrusted them with sensitive health information.

The Rule was issued more than a decade ago, but the explosion in health apps and connected devices makes its requirements with respect to them more important than ever. The FTC has advised mobile health apps to examine their obligations under the Rule,[2] including through the use of an interactive tool.[3] Yet the FTC has never enforced the Rule, and many appear to misunderstand its requirements. This Policy Statement serves to clarify the scope of the Rule, and place entities on notice of their ongoing obligation to come clean about breaches.

The Rule covers vendors of personal health records that contain individually identifiable health information created or received by health care providers. The Rule is triggered when such entities experience a "breach of security."[4] Under the definitions cross-referenced by the Rule, the developer of a health app or connected device is a "health care provider" because it "furnish[es] health care services or supplies."[5] When a health app, for example, discloses

[1] The Rule implements the requirements of the American Recovery & Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115, codified at 42 U.S.C. § 17937.
[2] *Mobile Health App Developers: FTC Best Practices*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices (last visited on Sept. 15, 2021).
[3] *Mobile Health Apps Interactive Tool*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool (last visited on Sept. 15, 2021).
[4] *See* 16 C.F.R. § 318.2(a)
[5] *See id.* § 318.2; 42 U.S.C. § 1320d(6), d(3).

sensitive health information without users' authorization, this is a "breach of security" under the Rule.[6]

The statute directing the FTC to promulgate the Rule requires that a "personal health record" be an electronic record that can be drawn from multiple sources. The Commission considers apps covered by the Rule if they are capable of drawing information from multiple sources, such as through a combination of consumer inputs and application programming interfaces ("APIs"). For example, an app is covered if it collects information directly from consumers and has the technical capacity to draw information through an API that enables syncing with a consumer's fitness tracker. Similarly, an app that draws information from multiple sources is covered, even if the health information comes from only one source. For example, if a blood sugar monitoring app draws health information only from one source (e.g., a consumer's inputted blood sugar levels), but also takes non-health information from another source (e.g., dates from your phone's calendar), it is covered under the Rule.

In addition, the Commission reminds entities offering services covered by the Rule that a "breach" is not limited to cybersecurity intrusions or nefarious behavior. Incidents of unauthorized access, including sharing of covered information without an individual's authorization, triggers notification obligations under the Rule.

As many Americans turn to apps and other technologies to track diseases, diagnoses, treatment, medications, fitness, fertility, sleep, mental health, diet, and other vital areas, this Rule is more important than ever. Firms offering these services should take appropriate care to secure and protect consumer data. The Commission intends to bring actions to enforce the Rule consistent with this Policy Statement. Violations of the Rule face civil penalties of $43,792 per violation per day.

[6] *Id*. § 318.2(a) (defining "breach of security" as "acquisition of [PHR identifiable health information] without the authorization of the individual.").

Code of Federal Regulations
Title 16. Commercial Practices
Chapter I. Federal Trade Commission
Subchapter C. Regulations Under Specific Acts of Congress
Part 318. Health Breach Notification Rule (Refs & Annos)

16 C.F.R. § 318.3

§ 318.3 Breach notification requirement.

Effective: September 24, 2009

Currentness

(a) In general. In accordance with §§ 318.4, 318.5, and 318.6, each vendor of personal health records, following the discovery of a breach of security of unsecured PHR identifiable health information that is in a personal health record maintained or offered by such vendor, and each PHR related entity, following the discovery of a breach of security of such information that is obtained through a product or service provided by such entity, shall:

(1) Notify each individual who is a citizen or resident of the United States whose unsecured PHR identifiable health information was acquired by an unauthorized person as a result of such breach of security; and

(2) Notify the Federal Trade Commission.

(b) Third party service providers. A third party service provider shall, following the discovery of a breach of security, provide notice of the breach to an official designated in a written contract by the vendor of personal health records or the PHR related entity to receive such notices or, if such a designation is not made, to a senior official at the vendor of personal health records or PHR related entity to which it provides services, and obtain acknowledgment from such official that such notice was received. Such notification shall include the identification of each customer of the vendor of personal health records or PHR related entity whose unsecured PHR identifiable health information has been, or is reasonably believed to have been, acquired during such breach. For purposes of ensuring implementation of this requirement, vendors of personal health records and PHR related entities shall notify third party service providers of their status as vendors of personal health records or PHR related entities subject to this Part.

(c) Breaches treated as discovered. A breach of security shall be treated as discovered as of the first day on which such breach is known or reasonably should have been known to the vendor of personal health records, PHR related entity, or third party service provider, respectively. Such vendor, entity, or third party service provider shall be deemed to have knowledge of a breach if such breach is known, or reasonably should have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of such vendor of personal health records, PHR related entity, or third party service provider.

SOURCE: 74 FR 42980, Aug. 25, 2009, unless otherwise noted.

AUTHORITY: Public Law 111–5, 123 Stat. 115 (2009).

Current through April 29, 2022, 87 FR 25430, except for Title 36, which is current through April 14, 2022; 87 FR 22428, and Title 40, which is current through April 21, 2022; 87 FR 23768.

THE HASTINGS CENTER

Hastings Center News

Polygenic Embryo Testing: Understated Ethics, Unclear Utility

Published On: March 24, 2022
Posted in Children and Families, Genetics

New technologies are expanding the reach and accessibility of preimplantation genetic testing of human embryos. But what these advances can deliver is still unclear, and a frank assessment of their profound ethical implications is urgently needed, concludes a commentary in *Nature Medicine*.

The authors are Josephine Johnston, director of research and a research scholar at The Hastings Center, and Lucas J. Matthews, an assistant professor at Columbia University who is a Hastings Center presidential scholar. They cite several ethical questions about the use of polygenic risk scores, or PRS, (which combine the effects of many genetic variants with individual small effects into a single risk estimate) during in vitro fertilization, including:

- PRS exhibit limited predictive accuracy in populations of non-European ancestry.
- Patients may not fully understand the risks and limitations of the tests, and fertility clinics may lack the time and resources to explain them. This problem would be exacerbated if "testing for common diseases [were] bundled into treatment packages or routinized in ways that gloss over details and implications for subsequent care, as appears to have been the case with some prenatal screening tests."
- Expanded genetic testing, like existing preimplantation genetic tests used to identify embryos with or without specific genes, could be labeled discriminatory because it

involves embryo selection on the basis of genetic risks for specific diseases, disabilities, or traits.

The commentary responds to an article in *Nature Genetics* that describes a method to enable polygenetic testing for 12 common diseases. This method could make preimplantation genetic testing far more common than it is today.

Until now, most of the debates around the preimplantation genetic testing "have been confined to specialist and academic circles and personal challenges for relatively small numbers of people," Johnston and Matthews write. "The rapid development of fast and affordable molecular genotyping and PRS construction for common conditions . . . could soon make these challenges a reality for countless clinicians and patients."

Should the new techniques be used to screen embryos for social outcomes, such as educational attainment, "the justice issues will be greatly compounded."

https://www.thehastingscenter.org/news/polygenic-embryo-testing-understated-ethics-unclear-utility/?utm_source=Master+List&utm_campaign=7f05a3a166-EMAIL_CAMPAIGN_2020_10_26_05_57_COPY_01&utm_medium=email&utm_term=0_5c9274ec4d-7f05a3a166-62170511

NewsRoom

4/1/22 Int'l N.Y. Times 1
2022 WLNR 10274040

International New York Times

April 1, 2022

Section: technology

The True Crime-Obsessed Philanthropists Paying to Catch Killers

Kashmir Hill

Last January, Carla Davis was on LinkedIn when she saw an intriguing post: "Identify the Victim of 1978 Tennessee Murder."

Ever since the man's burned remains were found on a campground outside Nashville, the authorities had been trying to figure out who he was and who had killed him. After 42 years with no leads, the local sheriff's office wanted to try a relatively new technique pioneered in the Golden State Killer case , combing through consumer genetic databases to find the man's relatives, however distant, to triangulate his identity. The local sheriff couldn't afford it, so a genetics lab called Othram was panhandling on the internet.

Othram's founder and chief executive, David Mittelman, a metaphor-loving geneticist, compares the forensic money request to Kickstarter. "Instead of a product, you're getting justice for a family," he said. "We're crowdfunding for justice."

That phrase has traditionally meant funding bail or legal bills for the accused, but Othram was seeking $5,000 to sequence the victim's DNA. On a whim, Ms. Davis, a wellness coach who lives in Dubai, donated the remaining $3,897.52 needed.

She didn't stop there. Over the last year, Ms. Davis has given more than $100,000 to Othram, as if it were a charity rather than a venture-backed start-up, primarily for cold cases in Mississippi, her birth state.

"A friend told me I should just invest in the company," Ms. Davis said. "It didn't matter to me that it wasn't tax-deductible. These families have waited so long for answers."

Ms. Davis is part of a growing cohort of amateur DNA detectives, their hobby born of widespread consumer genetic testing paired with an unquenchable desire for true crime content. Why just listen to a

murder podcast when you can help police comb through genealogical databases for the second cousins of suspected killers and their unidentified victims?

So far donors around the country have given at least a million dollars to the cause. They could usher in a world where few crimes go unsolved — but only if society is willing to accept, and fund, DNA dragnets.

'It's Not Quite "Minority Report"'

It's hard to commit a crime, or do anything, without leaving some DNA behind. While crime scenes may include incriminating genetic evidence from perfectly innocent people, "probative" DNA — material that is clearly relevant to an investigation, such as a bloodstain — can be a powerful clue. But only if investigators can match it to the right person.

The case of the Golden State Killer, who committed 13 murders and dozens of rapes in California, went unsolved for decades, until the F.B.I. decided in 2018 to use DNA evidence from a sexual assault to build out the perpetrator's likely family tree. The resulting identification and prosecution of a 72-year-old former police officer proved the value of what's called "forensic genetic genealogy."

What made the investigation possible was GEDmatch , a low-frills, online gathering place for people to upload DNA test results from popular direct-to-consumer services such as Ancestry or 23andMe, in hopes of connecting with unknown relatives. The authorities' decision to mine the genealogical enthusiasts' data for investigative leads was shocking at the time, and led the site to warn users. But the practice has continued, and has since been used in hundreds of cases .

Because many local agencies lack the resources to participate, philanthropists have stepped in to help. A group of well-off friends calling themselves the Vegas Justice League has given Othram $45,000, resulting in the solving of three murder-rape cases in Las Vegas, including those of two teenage girls killed in 1979 and in 1989.

"We want to help the police and the community just knock these out," said Justin Woo, an online marketer who founded the Las Vegas group. "It's not quite 'Minority Report,' where you're predicting and stopping, but if you get these people off the street through the DNA stuff, it's really helpful."

In the publicized cases in Las Vegas, the perpetrators were dead.

Mr. Woo said people had contacted him to ask if they could donate money to prioritize the case of a loved one. "I don't have that ability," he said. "But I can pass this along to Las Vegas Metropolitan Police and they decide."

Natalie Ram, a law professor at the University of Maryland, expressed concern about "the public picking and choosing between cases," saying investigative priorities could be determined by who can donate the most. Ms. Ram said the "largest share" of cases solved so far with the method "tend to involve white female victims."

An existing bias toward prioritizing white victims, which has been documented in media coverage, could be compounded by the demographic makeup of the genealogy databases. Their composition

“skews heavily white,” according to a recent law review article , which contrasted these databases to state collections of DNA, such as the F.B.I.’s Codis, which overrepresent Black people, who are more likely to be arrested and have their DNA taken.

Ms. Ram is also concerned about the constitutional privacy issues raised by the searches, particularly for those people who haven’t taken DNA tests or uploaded their results to the public internet.

Even if you resolve never to put your DNA on a site accessible to law enforcement authorities, you share DNA with many other people so could still be discoverable. All it takes is your sibling, aunt or even a distant cousin deciding differently.

’The GoFundMe Generation’

As donations pour in for these searches, the fortunes of the services that make them possible are also on the rise. The two main consumer databases used for law enforcement searches — FamilyTreeDNA and GEDmatch — have both recently been acquired by larger companies, while the DNA testing behemoths Ancestry and 23andMe , which have largely resisted police access to their databases, have valuations in the billions of dollars.

Even a former F.B.I. lawyer who worked on the Golden State Killer case is getting in on the action. Steve Kramer, who said he helped the F.B.I. establish three forensic genetic genealogy units across the country, left the agency in November to help found a company seeking to automate genealogical research.

”I don’t consider genetic genealogy for just cold cases. We’ve solved active homicides within weeks,” said Mr. Kramer, who has already come up with a catchphrase. “We want to take the word serial out of serial killer.”

The philanthropy is also being fueled by true crime, an entertainment genre that has come to dominate podcast charts. Audiochuck, an Indiana company with a slate of popular true crime shows, has donated approximately $800,000 to organizations doing investigative genealogical research, including Othram, but the majority has gone to a nonprofit started by Ashley Flowers , host of the network’s “Crime Junkie” podcast.

”What keeps me sane is knowing we’re doing something to make it better,” said Ms. Flowers, whose show largely consists of discussing murders in detail.

The nonprofit, called Season of Justice, has raised another $250,000, some through crowdfunding, and so far, has made grants toward 53 unsolved murders.

”I was pretty stunned when we put our PayPal button up and raised that money almost without trying,” said Steve DuBois, the nonprofit’s executive director. “This is the GoFundMe generation, this is what they do.”

The processing of DNA evidence typically costs around $5,000. And then there’s the painstaking creation of the family tree by forensic genetic genealogists. This new breed of experts are often women,

like Ms. Davis, who honed their skills initially as amateurs piecing together their own family history.

A ‘Search Angel’

For most of her life, Carla Davis did not know who her father was. Her teenage mother, who had kept the man’s identity a secret, died in a motorcycle accident when Ms. Davis was 5 years old. Raised by her grandmother in a Mississippi town with just 2,000 people, a population that almost certainly included her father, Ms. Davis had no way to find out who he was.

That is, until four decades later, when relatively inexpensive consumer genetic tests became popular. Starting in 2013, Ms. Davis sent vials of her saliva to 23andMe, FamilyTreeDNA and Ancestry, which extracted and analyzed her DNA for about $100 each, and then provided lists of other customers to whom she was genetically related, unearthing third cousins.

From there, she tracked down census records, marriage licenses, death records, obituaries, and social media accounts to build out her unknown father’s family tree, much like putting together a puzzle, but one filled with relatives. After three years, she found the missing piece: Her father was a drag car racer who had lived mere miles from her childhood home. He had died of prostate cancer, but his brother took a DNA test to confirm the match.

”It felt like the weight of the world had lifted off me, like I had finally learned who I was,” Ms. Davis said. “I started learning everything I could about DNA and how to build trees.”

By then, Ms. Davis had moved from Mississippi to the United Arab Emirates, where her husband’s family-owned real estate company was based. Her daughter was grown and Ms. Davis was working as a nutrition and lifestyle consultant, advising people virtually. After absorbing books and YouTube tutorials about genetics, she joined a Facebook group called DNA Detectives , which led to a new calling: helping over 200 strangers identify their unknown parents.

”I’m a volunteer search angel,” she said.

Ms. Davis funded the Tennessee murder victim’s case because she believed in the power of her hobby to help solve crimes. She also knew the pain inflicted when a loved one is missing; years earlier, her daughter’s 11-year-old friend was abducted and killed. “For three horrible days, we didn’t know her fate,” Ms. Davis said.

Hours after Ms. Davis made the contribution, an Othram employee emailed, asking whether she’d really meant to donate almost $4,000.

”We don’t usually receive contributions of that size,” he wrote.

Donate Your Money … or Your DNA

Mr. Mittelman, Othram’s C.E.O., said his company had received more than $400,000 from philanthropic donors. According to Crunchbase , the start-up has also raised $28.5 million from institutional investors to corner the market around this new investigative technique. Founded in The Woodlands, Texas, in

2018, the company now has 30 employees, said Mr. Mittelman, including five full-time genealogical researchers, and will soon move to a new building, with a lab four times the size of its current one.

Othram's pitch is simple: Government labs lack the expensive equipment needed to process DNA evidence — cigarette butts, bloodstained fabric, bone — which may be decades old, degraded or mixed with nonhuman materials. For now, private labs must do the work of creating genetic profiles that are compatible with those generated, much more easily, from a consumer's saliva. Then forensic genetic genealogists must do the time-consuming labor of sorting through third cousins and population records. Finally, another DNA test is typically required to confirm a suspected match.

Othram wants to be the authorities' one-stop shop for the whole process. "Once they see it, they are never going back," Mr. Mittelman said.

The company created a site called DNASolves to tell the stories of horrific crimes and tragic John and Jane Does — with catchy names like "Christmas tree lady" and "angel baby" — to encourage people to fund budget-crunched police departments, so that they can hire Othram. A competitor, Parabon NanoLabs, had created a similar site called JusticeDrive , which has raised around $30,000.

In addition to money, Othram encouraged supporters to donate their DNA, a request that some critics called unseemly, saying donors should contribute to databases easily available to all investigators.

"Some people are too nervous to put their DNA in a general database," said Mr. Mittelman, who declined to say how large his database is. "Ours is purpose-built for law enforcement."

Carla Davis has donated her DNA, as well as that of her daughter and son-in-law. Her husband declined.

Volunteer Detective

After reassuring Othram that her large donation was intentional, Ms. Davis expressed interest in another DNASolves case: the "Talladega Superspeedway Jane Doe."

The decomposing remains of a white woman of average height had been found nine years earlier in the yard of an abandoned house near the famous racetrack. According to law enforcement officials, the deceased, who had lung cancer, had been wearing dentures inscribed with the word "Powders." The local police department in Lincoln, Ala., believed her body might have been dumped by someone who planned to steal her identity to access her finances.

Othram had come across the case while perusing the approximately 14,000 unidentified people cataloged in NamUs , a database maintained by the Justice Department, which describes when and where a body was found, its condition, and any clothing or accessories.

The case seemed likely to have usable DNA, so in 2020, Othram contacted Shannon Hallmark, the Lincoln police captain of investigations, describing what the company could do if it could raise enough money. "A lot of small agencies don't have the funding to do something like that," Captain Hallmark said.

The case jumped out to Ms. Davis because she had already researched families from the area while searching for someone's parent. "I'm not sure if Othram accepts the help of volunteers," Ms. Davis wrote in an email, "but if so, I would like to help solve this particular case."

She donated nearly $4,000 again, so that Othram could process a bloodstain card collected during the woman's autopsy, using a million-dollar DNA sequencing machine called the NovaSeq 6000. From there, Othram generated a data file containing her autosomal DNA, the genetic material that is shared among families. When uploaded to GEDmatch Pro, a special investigative version of the service, it revealed that the woman had over 1,000 distant relatives in the database.

Othram asked Captain Hallmark whether she was interested in a civilian volunteer and Ms. Davis became part of the cold case task force, a scenario that Captain Hallmark called "very rare." Then the sleuthing started.

'Where Is Jean?'

Ms. Davis works from a guest bedroom that she has converted into a his-and-her office decorated in the style of a high-end hotel room. She has the research abilities of a digital archaeologist, the can-do energy of a personal trainer and the fervor of a true believer. "This is what I know is my purpose," she said.

GEDmatch told her how many centimorgans, a measure of genetic linkage, each of the relatives shared with the victim. Ms. Davis fed the 25 closest relations into software called DNA Painter that predicted how they relate, to build a possible family tree: Is it a great-grandniece or a second cousin? She then used Ancestry.com to map the tree, keeping it private so only she could see it.

"The DNA unfolds and tells a specific story and you just have to follow the story and see where it leads," Ms. Davis said. It's not usually a story that unfolds easily. People on GEDmatch typically list anonymous email addresses. It's one thing to put your DNA publicly on the internet, it's another to explicitly say it's yours.

Ms. Davis tries not to contact matches directly, particularly in a forensic investigation, because it could tip off a suspect or send a family into despair. So instead, to figure out the person behind an email address, she will turn to data broker sites such as BeenVerified that specialize in linking phone numbers and email addresses to names, home addresses and housemates (who could be other relatives). "It's a tedious process," Ms. Davis said.

In this case, the closest match shared a great-great-grandparent with the victim. Starting from there, Ms. Davis learned the family's roots so intimately that she discovered an 1800s-era affair between an ancestor and a neighbor, another example of the surprising historical revelations encoded in our genes.

After five months of digging, Ms. Davis figured out where on the tree the victim had to be, a branch with two sisters. One was alive, but when Ms. Davis searched for the other on Facebook, she gasped at the post that came up: "Where is Jean?"

A retired biology teacher and grandmother who had lived in Georgia, Jean Ponders had been declared missing in July 2013. "I was very emotional," Ms. Davis said. "I finally had a face to look at."

Closure

Ms. Davis emailed her findings to Captain Hallmark, asking whether the “Powders” on the dentures could have been “Ponders.” Captain Hallmark got contact information for the Ponders family from local authorities, and a daughter, Jennifer Hazelwood, provided a DNA sample. It was a match.

For years, Ms. Hazelwood had longed to know her mother’s whereabouts, Googling her frequently. “My mind was tortured,” Ms. Hazelwood said. “It really touches my heart that someone cared enough to keep pushing to find her family.”

Captain Hallmark is now investigating how Ms. Ponders got to Alabama from Georgia and who dumped her body in the yard.

Carla Davis hopes that more family members like Ms. Hazelwood can get closure, but that is relatively rare so far. Beyond the funding issues, the genealogical databases have limited populations. Tens of millions of Americans have taken DNA tests, but only a small portion have made that DNA available to investigators.

Of the 24 cases Ms. Davis has funded, seven previously unknown individuals have been publicly named, including, most recently, Gary Simpson , a 20-year-old Black man from New Orleans, whose remains were found in a Mississippi river in 1982.

But some have stalled out, including the Tennessee murder victim. He is still unidentified.

Heather Murphy contributed reporting.

Heather Murphy contributed reporting.

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Company: BeenVerified; DNASolve; LINKEDIN CORPORATION; 23ANDME HOLDING CO.; Las Vegas Metropolitan Police Department; KICKSTARTER, PBC; UNIVERSITY OF MARYLAND MEDICAL SYSTEM CORPORATION; CRUNCHBASE, INC.; Federal Bureau of Investigation; PARABON NANOLABS, INC.; META PLATFORMS, INC.; Audiochuck LLC; OTHRAM, INC.; ANCESTRY.COM INC.; YOUTUBE, LLC; APPLIED DNA SCIENCES, INC.

News Subject: (Legal (1LE33); Police (1PO98))

Industry: (Biomedical Engineering (1BI75); Biopharmaceuticals (1BI13); Biotechnology (1BI78); Genetic Testing (1GE72); Genomics (1GE19); Molecular & Cellular Biology (1MO84); Pharmaceuticals & Biotechnology (1PH13))

Region: (Americas (1AM92); Arab States (1AR46); Gulf States (1GU47); Middle East (1MI23); Nevada (1NE81); North America (1NO39); Tennessee (1TE37); U.S. Southeast Region (1SO88); U.S. West Region (1WE46); USA (1US73); United Arab Emirates (1UA66))

Language: EN

Other Indexing: (GEDmatch; Vegas Justice League; GoFundMe Generation; Season of; PayPal; FamilyTreeDNA; JusticeDrive; Talladega; Justice Department; Lincoln police; BeenVerified; DNASolves; LinkedIn; 23andMe; Las Vegas Metropolitan Police; Kickstarter; University of Maryland; Crunchbase; F.B.I.; Parabon NanoLabs; Facebook; Audiochuck; Othram; Ancestry; Ancestry.com; YouTube; DNA Detectives) (Carla Davis; Othram; David Mittelman; David R Mittelman; Justin Woo; Natalie Ram; Steve Kramer; Ashley Flowers; Steve DuBois; John; Jane Does; Shannon Hallmark; Captain; Jean Ponders; Jennifer Hazelwood; Gary Simpson; Heather Murphy)

Keywords: Forensic Science; DNA (Deoxyribonucleic Acid); Genealogy; Genetics and Heredity; Crime and Criminals; Police; Crowdfunding (Internet); Philanthropy

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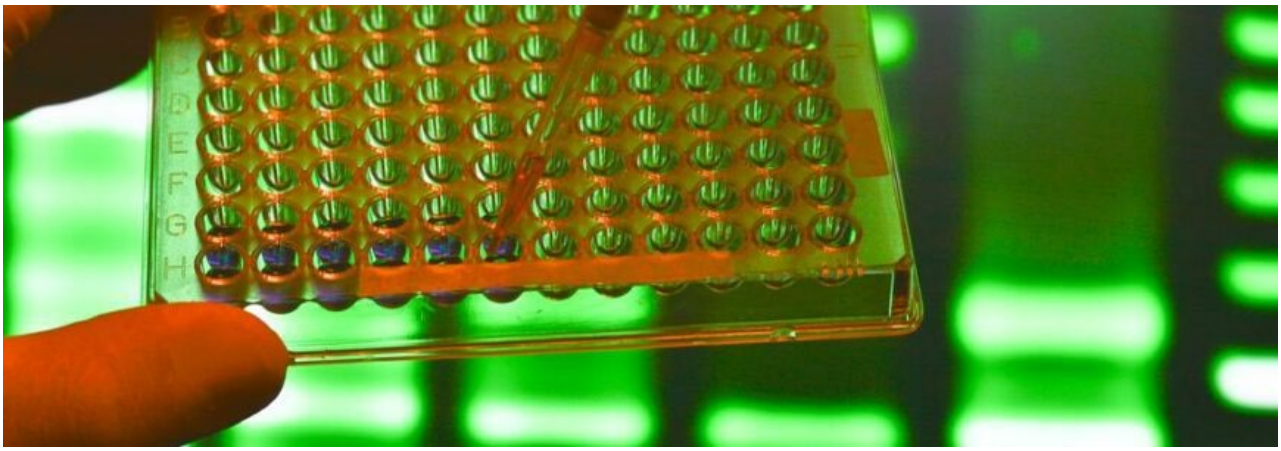

Hastings Center News

Bias and Inaccuracy in Marketing Noninvasive Prenatal Tests

Published On: March 8, 2022
Posted in Human Reproduction

Bias and inaccuracy are pervasive in the marketing of noninvasive prenatal tests (NIPTs), concludes an early-view study in the *Hastings Center Report.* The tests are marketed to consumers around the world without regulatory oversight.

NIPTs are screening tests that assess the chance that a fetus is affected by various chromosomal and other conditions by analyzing fetal DNA in a maternal blood sample. In the absence of regulation, the responsibility to ensure that NIPTs are represented accurately and ethically falls to manufacturers.

The study examined whether manufacturers live up to this responsibility by evaluating English-language consumer brochures for NIPTs marketed globally. For a benchmark, the study used a guidance document produced by the Nuffield Council on Bioethics in the United Kingdom. Among the major findings:

- None of the brochures complied with all of the Council's criteria.
- Fifty-two percent of the brochures misrepresented NIPTs as diagnostic rather than screening tests. Patients who do not understand that follow-up diagnostic testing is required to confirm a positive NIPT result may make decisions about their pregnancy, such as having an abortion, based solely on the NIPT result.
- Companies failed to offer evidence to support their claims about their tests' performance.

- The brochures invoked the patient's own health care provider as an authority on NIPT. This is concerning for two reasons. 1) Several studies indicate that physicians have limited understanding of NIPTs. 2) There is evidence that physician-researchers have been engaged by NIPT manufacturers to conduct studies validating the tests, raising the possibility of a conflict of interest in evidence supporting a test.

The authors conclude that their study raises questions about the ability to access material on NIPTs that is "accurate, trustworthy, and ethically responsible." They call for regulation of NIPTs and the claims made about them.

The authors of the study, "The Market in Noninvasive Prenatal Tests and the Message to Consumers: Exploring Responsibility," are at the Institute of Health Policy, Management and Evaluation at the University of Toronto: Kelly Holloway is an assistant professor, Nicole Simms is regional director for Central Canada for CASCADES (Creating a Sustainable Health System in a Climate Crisis) at the Institute, Robin Z. Hayeems is an associate professor, and Fiona A. Miller is a professor of health policy.

Health Law Summit
Materials Submitted by G. Flint

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Health Law & Policy Summit

Unblurring the Lines in Healthcare: Understanding Key Legal Issues for Operations and Transactions and for the Delivery of Care

May 18, 2022
8:00 am – 12:00 pm

POWERPOINT PRESENTATION

Elisabeth Haub School of Law at Pace University

Health Law and Policy Summit

Wednesday, May 18, 2022
8:00 am – 12:00 pm

Elisabeth Haub School of Law
New York State Judicial Institute
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AGENDA

8:00 – 8:30 **Registration & Networking Breakfast**

8:30 – 9:00 **Opening Remarks**
Changing Times, Changing Practice: Navigating the Healthcare System

Steven J. Chananie, Esq., *Special Counsel, Sheppard Mullin*

9:00 – 10:20 **Transacting for Change: Understanding the Unique Issues in Today's Health Care Deals**
Panelists will discuss the lifecycle of a transaction and the legal implications for lawyers and professionals working in the field, including mergers and acquisitions, care delivery modes, compliance, and enforcement.

Steven J. Chananie, Esq., *Special Counsel, Sheppard Mullin*
Linda Martin, JD, *Chief Compliance Officer, CareOne Management, LLC & Affiliates*
Dale C. Van Demark, Esq., *Partner, McDermott Will & Emery LLP*

MODERATOR **James Toomey, Esq.**, *Climenko Fellow & Lecturer of Law, Harvard Law School*

10:30 – 11:50 **Delivery of Patient Care: Understanding Current Ethical and Legal Issues**
Panelists will discuss current issues in patient care, including lack of access to care, long-term care workforce issues, and end-of-life rules. Panelists will also address bioethical issues related to technological advancements in reproductive and genetic technologies.

Barbara L. Atwell, Esq., *Associate Professor of Law and Director of Diversity, Equity and Inclusion, Elisabeth Haub School of Law at Pace University*
Lauren H. Breslow, Esq., *Adjunct Professor, Elisabeth Haub School of Law at Pace University*
Margaret "Gretchen" M. Flint, Esq., *Professor of Law Emeritus, Elisabeth Haub School of Law at Pace University*

MODERATOR **James Toomey, Esq.**, *Climenko Fellow & Lecturer of Law, Harvard Law School*

11:50 – 12:00 **Closing Remarks**

Transacting for Change: Understanding the Unique Issues in Today's Health Care Deals

PANELISTS

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Delivery of Patient Care: Understanding Current Ethical and Legal Issues

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Bioethics: Privacy and Genomics

Presented by Lauren Hammer Breslow, J.D., M.P.H.
May 18, 2022 @ Elisabeth Haub School of Law at Pace University

Mini agenda

- Traditional Bioethics Questions
- New Consumer Paradigm, with New Questions
- Privacy of Health Data
- Consumer Genomic Data

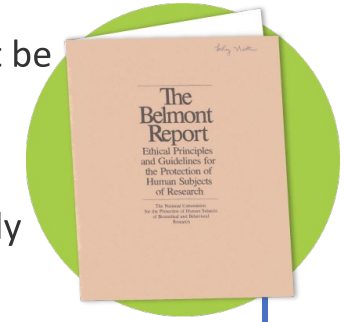
Bioethics – Patient Lens

Relationship between patient and healthcare provider

- When is there a duty to treat
- How should fully informed consent be obtained, especially if person is incompetent
- When is there a duty not to treat
- When does patient have the right to prevent treatment
- What is appropriate care as opposed to negligent care – how can that be measured
- How can providers offer culturally sensitive and inclusive care

Bioethics – Human Subjects Participant Lens

Relationship between research participant and research institution



- How can fully informed consent be obtained
- Who can give consent
- Which participants are especially vulnerable and deserve special protections
- How should research studies be overseen for integrity
- How can research studies better integrate and include underrepresented populations

Bioethics – Consumer/ User Lens

And what about public health?

NEW QUESTIONS

- Who owns consumer data
- What laws keep consumer health data safe
- How can companies use consumer health data
- What are unanticipated consequences of consumer access to health information
- Do all races have equitable access to consumer data

The HIPAA Misconception

Health Insurance Portability and Accuracy Act of 1996 (HIPAA)

- **Privacy Rule for Protected Health Information** (PHI) protects identifiable health information.
  - See 45 U.S.C. § 1320d(4); 45 C.F.R. § 164.500 – 164.534.
- **Covered entities include only**:
  - Health plans;
  - Health care clearinghouses;
  - Health care providers who transmit any health information in electronic form in connection with a transaction named within HIPAA; AND
  - Their business associates.
    - See 45 U.S.C. § 1320d-1; 45 U.S.C. § 1320d-2; 45 C.F.R §160.103.

Take Note: No mobile apps, wearable tech, at-home tests….

Federal Trade Commission & Health Information

- **February 2009**: Congress passes the American Recovery & Reinvestment Act (42 U.S.C. §§ 17937, 17953).
  - Directs Congress to protect public from breaches of personal health data
- **August 2009** : FTC issues Health Breach Notification Rule (16 C.F.R. pt. 318)
  - Requires **vendors** of unsecured identifying health information to notify users, the FTC, and, in some cases, the media if there is an unauthorized disclosure of personal health information.
- **September 2021**: FTC issues statement
  - Clarifies that Health Breach Notification rule applies to “health apps and similar technologies”
  - Refers to personal health information or personal health records (distinct from PHI)
  - Reminds vendors of civil penalties of $43,792 per violation per day

Why the Need for Restatement

" Since February 2010, when the rule took full effect requiring notification for unauthorized disclosures of covered information, the FTC and the public have been notified exactly four times about breaches. Four times. It is impossible that there have been only four covered incidents in our country during this time period."

- PREPARED REMARKS OF COMMISSIONER ROHIT CHOPRA Regarding the FTC Policy Statement on Privacy Breaches by Health Apps and Connected Devices September 15, 2021
  - https://www.ftc.gov/system/files/documents/public_statements/1596352/20210915_final_chopra_oral_remarks_health_breach_notification_rule.pdf

Genetic Information Nondiscrimination Act of 2008 (GINA)

GINA (generally) prohibits:

1) Health insurance companies from discriminating based on genetic information.
2) Employers (with 15+ employees) from discriminating based on genetic information.
   - Note: NY applies non-discrimination rules to all employers. N.Y. Exec. Law §§ 292(5) (McKinney 2019), N.Y. Exec. Law 296 (McKinney 2022)

What is left out:

- Life insurance, disability insurance, any other insurance
- **Law enforcement** (federal/state entities outside of employment context)
- **Individual users/consumers**

Consumers of Genomic Information

Spotlight on Individual, Parental, and Law Enforcement Use of Genomic Data

Genetics: Family-Member Identification

- Consumer driven, public databases
- Donor-conceived children triangulate to siblings and donor parents
- FDA does not regulate
- CDC has voluntary mechanism for reporting pregnancy rates. See 42 U.S.C. § 263(a)-1.

• NY State – regulations limited to public health measures/STD screens. 10 NYCRR § 263(a)-1.

Genomics: Testing for Traits

- **2005**: **First Genome Wide Association Studies** (GWAS) published: looks at millions
  - Looks a millions of genomes and see if any genes align with certain genetic traits from diseases to height. https://www.genome.gov/genetics-glossary/Genome-Wide-Association-Studies
- **2013**: Major study issues regarding multiple genetic markers (polygenic scores) and educational attainment
- **2013+:** Polygenic Scores and Social Outcomes:
  - Educational traits
  - Psychological and psychiatric behaviors
  - Social and environmental factors
  - Sexual behaviors
  - See https://www.thehastingscenter.org/genomic-findings-on-social-and-behavioral-outcomes-faqs/#Traits-&-Outcomes.

Genomics: Prenatal and Pre-implantation Genetic Testing

- Companies offering pre-implantation testing for polygenetic traits like height and intelligence as well as single-gene traits (diseases)
  - https://elifesciences.org/articles/64716
  - https://www.thehastingscenter.org/polygenic-embryo-screening-ethical-and-legal-considerations/ https://www.thehastingscenter.org/noninvasive-prenatal-genetic-testing-eugenic/ (by James Toomey)

Questions:

- Should these consumer tests be better regulated?
- Do we consider these private consumer tests?
- Does society allow parents discretion to select certain babies? What about selecting against others?

Genetics: Criminal Investigations

Golden State Killer case:

- First reported arrest using genetic genealogy data bases
- Golden State Killer/James D'Angelo – raped and killed dozens in the 1970s-1980s in CA.
- Great unsolved crime until in 2018 when law enforcement used information from publicly available genealogy database to connect killer's DNA with family DNA.
- GEDMatch – created fake profile and created family tree of hundreds of people
- Same technique used to solve this crime can identify ~60% (now perhaps 90%) of Americans with European ancestry.
    - https://www.pbs.org/newshour/science/dna-ancestry-searches-can-now-identify-most-white-americans-heres-why-thats-legally-questionable
- Hundreds of crimes solved this way now – recent NYTimes article profiling philanthropists making this a hobby.
    - https://www.nytimes.com/2022/03/27/technology/dna-tests-crime-solving.html

DNASolves Rape

CASES FAQ HOW IT WORKS LOGIN CONTRIBUTE DNA

LEARN MORE

Your DNA Could Solve a Cold Case

1 Terms of Use

2 Upload Data

3 Account Details

Sign up | Log in

Your DNA data could help solve a cold case. DNASolves data is used exclusively to aid human identification investigations in order to help law enforcement solve cold cases. Before you upload your DNA data and register your account, please read our Terms of Use and Privacy Policy.

☐ I have read and agree to the Terms of Use and Privacy Policy.

https://dnasolves.com/user/register/

Ethics: Genomics and Law Enforcement

- Did consumers who uploaded their DNA understand that law enforcement could use that information?
- Should consumers need to be notified that their data has been used?
- What happens if companies change their policies?
- Should users be given full opportunity for consent? Will they understand it?
- Should their information be protected from law enforcement now?
- Should value of solving crime outweigh privacy concerns?

Bioethics: Consumer Genomic Data

- Individual choices to use DNA for finding family or criminals
- Individual choices about children they wish to have
- Do we want government/state using that DNA to find parents or criminals
- Do we want government/state to regulate how individuals use DNA in parenting choices

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