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In an Era of Healthcare Delivery Reforms, the Corporate Practice of Medicine Is a Matter That Requires Vigilance

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I. INTRODUCTION

Since the early 20th century, the corporate practice of medicine doctrine (CPMD), the contours and content of which are determined by state law, generally prohibits business corporations from practicing medicine or employing physicians to perform professional medical services. The doctrine's origin is rooted in public policy, championed by the American Medical Association in 1934, when it proclaimed ethical principles for the practice of medicine.[1]

The corporate practice prohibition is rooted in the perceived evils that corporations and laypeople motivated by profit will exert control over physicians, tainting the fiduciary role of the physician vis-a-vis patient, and compromising the medical judgments of physicians. There is a corollary to the corporate practice ban whereby states have imposed restrictions on fee-splitting involving physicians and their services as a way to mitigate financial influences on medical decision-making. States provide for sanctions for unauthorized fee-splitting arrangements.[2]

To this day, the CPMD implicates various interrelationships in the medical sector. Not all states embrace a strong sense of vitality for the doctrine, and in a few jurisdictions, the prohibition does not exist. For a majority of states, however, the prohibition's reach, and consequences arising from its breach, have import for the transactional lawyer, medical facilities, physicians, and payors.

The sources of state law on the corporate practice of medicine prohibition are varied. The corporate practice ban can arise as a matter of common law, state legislative enactments and regulations. Courts have ruled extensively on the prohibition, and State Attorneys General, as well as professional licensing boards, have opined on the doctrine.

State legislatures have considered bills to amend the prohibition, re-calibrating the public policy bases relied upon in the past to adapt to more integration and collaboration as the new norm in healthcare delivery. This is so, for example, in Texas, where in 2011 the legislature enacted new provisions enabling employment of physicians by certain county hospital districts.[3] In 2011 and 2012, legislation was also enacted in Colorado,[4]

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[1] *Medical Ethics and New Methods of Practice*, 103 JAMA 263, 263–64 (1934); *see also* Am. Med. Ass'n Principles of Med. Ethics, ch. 3, art. VI, Section 2 (1937). The AMA's 1934 Principles, as interpreted by the ABA's Judicial Council in 1971, were challenged by the Federal Trade Commission (FTC) as an unreasonable restraint of trade. The FTC issued an order requiring the AMA to end its corporate practice restraints. On appeal, the Second Circuit affirmed the FTC's decision. *See Am. Med. Ass'n v. Fed. Trade Comm'n*, 638 F.2d 443 (2d Cir. 1980). The Supreme Court affirmed the Second Circuit's decision in a per curiam opinion. 455 U.S. 676 (1982). The individual states, though, have pursued their own paths to impose the corporate practice ban under their Medical Practice Acts.

[2] For example, in New York State, the Education Law § 6531 provides for the revocation or suspension of a physician's license on grounds of professional misconduct if a physician participates in splitting of a fee in connection with professional care or services. *See also* California's Business and Professional Code, § 652 (imposing criminal sanctions).

[3] *See infra*.

[4] SB 11-084 (Colorado).

Tennessee[5] and Washington[6] lifting the corporate practice ban for the employment of physicians by nursing homes, and mandating protections to ensure a physician's independent decision-making.

The moorings for the corporate practice prohibition is in a state's inherent police powers to guard the fiduciary relationship between physician and patient from corrupted motives of the commercialization of medicine and allied professional disciplines. Barring a corporate entity, or layperson, from owning a medical practice, employing a physician, or influencing medical decisions safeguards the medical judgment on a patient's health and safety.[7] The corporate practice prohibition has withstood constitutional challenge.[8]

The corporate practice prohibition has attracted heightened interest. This is so because of trends in hospital-physician alignment and payment regimes for a more integrated health delivery system. For these reasons, healthcare attorneys are best advised to become knowledgeable on the corporate practice of medicine prohibition as it may apply, as a matter of state law, in various state jurisdictions.

Noncompliance with a state's corporate practice ban has ramifications. State laws provide for criminal sanctions, including for aiding and abetting.[9] Additionally, physicians and other medical professionals risk disciplinary action by a licensing board.[10] Separate from these punitive measures, a state attorney general may seek to dissolve, or enjoin, an illicitly formed entity.[11] There are other implications as well for contracting parties, between insurers and providers of care, and those employed by healthcare entities.

The CPMD, then, is one that should give pause to attorneys representing healthcare clients, including insurers, on any number of issues. The corporate practice ban can influence the structuring of a legal entity, define collaborations, or impact reimbursement decisions. This is particularly germane in contemporary discourse on healthcare reform.

The purpose of this article is to highlight some state laws, and how courts in various jurisdictions have addressed the corporate practice prohibition in the context of reimbursement and non-compete clauses in employment agreements. The article will also mention fee-splitting to raise a level of awareness of rules set by states that prohibit

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[5] SB 3263 (Tennessee).

[6] SHB 1315 (Washington).

[7] As observed in *Cal. Med. Ass'n. Inc. v. Regents of Univ. of Cal.*, 94 Cal. Rptr. 2d 194, 199 (Cal. App. 2000), the corporate practice of medicine doctrine was "adopted to protect the professional independence of physicians and to avoid the divided loyalty inherent in the relationship of a physician employee to a lay employer."

[8] *Miller v. State Bd. of Dental Exam'rs of Colo.*, 287 U.S. 563 (1932) (denying appeal for want of a federal question); *Semler v. Or. State Bd. of Dental Exam'rs*, 294 U.S. 608, 611 (1935).

[9] *E.g.,* N.J. Stat. Ann. § 45:1-21(n).

[10] *E.g.,* I.C.A. § 147.55 and I.C.A. § 148.6(1) (Iowa) (provides for revocation or suspension of license, civil penalties not in excess of $10,000); *see also William Steinsmith v. Medical Board of California*, 102 Cal. Rptr. 2d 115 (Cal. App. 4th Nov. 13, 2000).

[11] *See, e.g., Bill Schuette, Attorney General of the State of Michigan v. Health Care Clinic, Inc., Womens Choice Clinic, Inc., et al.,* Case No. 11-1507-AW (Mich. 56th Judicial Cir. Ct. Nov. 7, 2011) (Verified Complaint In *Quo Warranto* To Dissolve Health Care Clinic, Inc. and Womens Choice Clinic, Inc. And For Injunctive Relief and Consent Judgment, entered Nov. 21, 2011).

or limit this practice. The lesson to be learned is that state laws are not uniform, and each state has pursued its own path of public policy.

II. MEDICAL PRACTICE ACTS

Generally, the ban on the corporate practice of medicine is rooted in the notion that a corporate or business entity is not able to satisfy the licensure requirements mandated by state statutes to practice the learned professions.

The starting point for determining whether a state prohibits the corporate practice of medicine is the jurisdiction's Medical Practice Act and its definition of the "practice of medicine.". A state's Medical Practice Act imposes licensure requirements. For example, the Maryland Medical Practice Act mandates that "an individual shall be licensed" to practice medicine.[12] The "practice of medicine" is defined, "to engage, with or without compensation, in medical . . . diagnosis, healing, treatment [ ] or surgery," and the "preventing, prescribing for, or removing any physical, mental, or emotional ailment . . . of an individual."[13] Exemptions from licensure are noted by statute,[14] none of which apply to entities. Thus, by implication, the Maryland Practice Act prohibits corporations from practicing medicine.[15] Under Maryland law, certain entities whose formation is governed by specialized statutes do not fall within the ambit of the corporate practice ban. As discussed further below, these statutes are exceptions, allowing the corporate practice of medicine, provided enumerated conditions are met. Thus, an entity is not affected by the corporate practice ban in Maryland if formed as a professional service corporation[16] or a limited liability company.[17] Some states impose by statute an explicit ban on the corporate practice of medicine. In Colorado, the legislature enacted a provision that reads "corporations shall not practice medicine."[18]

III. APPLICATION OF THE CORPORATE PRACTICE OF MEDICINE DOCTRINE TO HOSPITALS

States are divided on the applicability of the corporate practice ban to hospitals. California prohibits outright hospital employment of physicians. The corporate practice ban is embodied in California's Business and Professions Code within the Medical Practice Act.[19] Section 2052 mandates the licensure of any person "who diagnoses, treats, operates for or prescribes for any ailment . . . [or] . . . disease." Performing these acts without a license is a criminal offense.[20] Those who assist or participate

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[12] Md. Code Ann. Health Occ. § 14-301.

[13] Md. Code Ann. Health Occ. § 14-101(l).

[14] *See* Md. Code Ann. Health Occ. § 14-302.

[15] Maryland is not alone in providing for a corporate practice ban by implication. New York, along with other jurisdictions, imposes a corporate practice ban by implication, rather than by explicit statutory language. *See* N.Y. Educ. L. §§ 6521, 6522 and 6524 (mandating a person to be licensed to practice medicine, and setting forth licensure requirements).

[16] Md Code Ann. Corps. & Ass'ns § 5-101, *et seq*.

[17] Md. Code Ann. Corp. & Ass'ns § 4A-203(10).

[18] C.R.S. § 12-36-134(7)(a).

[19] Medical Practice Act, Business & Professions Code § 2400, *et seq*.

[20] *See* Cal. Bus. & Prof. Code, § 2052(a).

in committing the offense can be implicated and charged for aiding and abetting.[21] California's corporate practice ban, as applied to hospitals, is in section 2400, which explicitly states that corporations have "no professional rights, privileges, or powers."[22] Exceptions to the corporate practice ban provided by the California legislature are in the State's Business and Professions Code. There, certain entities are permitted to employ physicians, provided the conditions specified by statute are met. Thus, within section 2400, the Division of Licensing is empowered, in the exercise of its discretion, to "grant approval of the employment of licensees on a salary basis" by certain specified licensed entities. These licensed entities are: charitable institutions, medical foundations, teaching hospitals,[23] and clinics.[24] For example, under section 2401(a), a clinic operated for medical education purposes by a non-profit university medical school may charge for professional services by licensees who are on the faculty of the university. Additionally, under section 2401(b), a non-profit clinic operating pursuant to specified criteria[25] for charitable purposes may employ licensees and may charge for those services. However, it is explicitly provided that the clinic is prohibited from interfering with or controlling the professional decision-making of the physician or surgeon. Under section 2401(d), a hospital owned and operated by a health care district may employ a licensee and may impose charges for services if the physician or surgeon approves of the charges. It is explicitly provided, though, that the hospital shall not interfere with or control the judgments of the licensees.

California's general ban on hospital employment of physicians is in stark contrast to the law in Illinois. In Illinois, duly licensed hospitals may, as a matter of law, employ physicians. This exception in Illinois was established by the seminal case of *Berlin v. Sarah Bush Lincoln Health Center*.[26] The exception carved out for hospitals in Illinois, arising from *Berlin* is a narrow one. In that case, the Supreme Court of Illinois explained that the CPMD is rooted in a state's Medical Practice Act, in which education and training are mandated to obtain a professional license to practice medicine. Since corporations do not have the ability to undergo the rigorous licensing requirements imposed under the Medical Practice Act, such entities cannot lawfully practice medicine. The Court further wrote that, generally, in theory, hospitals cannot employ physicians since the actions of physicians while under the employ of a hospital would be imputed to the hospital which is not eligible to obtain a license for the practice of medicine. The Supreme Court of Illinois in *Berlin* also emphasized that the corporate practice ban is based on public policy, which seeks to guard against the profit motive influences of lay entities over a physician's medical judgment and their fiduciary role vis-à-vis patients.[27] The Court in

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[21] *See id,* at § 2052(b).

[22] Cal. Bus. & Prof. Code § 2400.

[23] *See Cal. Med. Ass'n v. Regents of the Univ. of Cal.,* 79 Cal. App. 4th 542 (2000).

[24] California, like many states, imposes fee splitting restrictions. *See* California Business and Professions Code § 650. California has also regulated beyond hospital-physician employment, to include alignments between physicians and management services organizations. *See* 83 Op. Atty. Gen. Cal. 170 (July 27, 2000).

[25] *See* Cal. Health and Safety Code § 1206(p).

[26] 688 N.E.2d 106 (Ill. 1997).

[27] *Id.* at 110.

Berlin examined whether the corporate practice ban would logically apply to hospitals in Illinois in view of the rationale for the doctrine. The Court concluded that it would not, and thus carved-out an exception for hospital employment of physicians. The Court's reasoning is based on the regulatory regime to which hospitals must adhere in Illinois. In that State, under the Hospital Licensing Act,[28] hospitals are authorized to practice medicine under a license to do so. The Court observed that In Illinois, the legislature enacted legislation allowing hospitals, duly licensed, to provide medical services. It thus concluded that to enable hospitals to perform this function, it was inferred that hospitals would need to employ licensed physicians. The Court in *Berlin* put to rest the public policy concerns that originally motivated the corporate practice ban. Specifically, the concern regarding corrupt influence of lay corporations over physicians would be mitigated since a separate medical staff in a hospital is responsible for the quality of medical services. The Court also noted that hospitals, as licensed facilities, had statutory duties to ensure the health of their patients.[29] In view of the statutory licensing authority for hospitals in Illinois, and the regulatory regime applicable to duly licensed hospitals more generally, the State Supreme Court in *Berlin* concluded there were grounds to exempt hospitals in Illinois from the corporate practice ban.

Illinois is not alone in its permissive stance on hospital employment of physicians. Other states allow this employment relationship, notwithstanding a corporate practice ban generally. Tennessee, for example, has provided by statute for hospital employment of physicians, with conditions. This provision authorizes a duly licensed hospital to employ physicians, except where noted, provided that the employing entity "shall not restrict or interfere with medically appropriate diagnostic or treatment decisions."[30] Tennessee, though, prohibits hospitals from employing radiologists, anesthesiologists, pathologist, or emergency physicians.[31] This jurisdiction, however, allows research hospitals to employ radiologists, anesthesiologists and pathologists.[32] In Florida, the Medical Practice Act imposes licensure for individuals to practice medicine,[33] but is silent on the authority of corporate entities to engage in the practice of medicine. The Florida Board of Medicine has opined on this point, concluding that the Medical Practice Act does not prohibit licensed physicians as employees of corporations.[34] Case law in Kansas similarly has established that there is no restriction to hospital employment of physicians. This was made clear in *St. Francis Reg'l Med. Ctr. v. Weiss*.[35]

It is noteworthy that those jurisdictions that do accommodate hospital-physician employment have done so in a way that ameliorates perceived evils underpinning the CPMD. Conditions on such affiliations, explicit in the statute, preclude influence by the

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[28] 210 ILCS 85/1, *et seq.*

[29] 688 N.E.2d 106, 110-114.

[30] Tenn. Code § 68-11-205(b)(1)(A).

[31] Tenn. Code § 68-11-205(b)(9).

[32] *Id.*

[33] Fla. Stat. § 458, *et seq.*

[34] *In re: Petition for Declaratory Statement of Conrad Goulet, M.D.,* Case No. 89-COM-01 (1989).

[35] 869 P.2d 606 (Kan. 1994).

employing hospital over the medical judgments of the physician, thereby ensuring a degree of professional independence.

Texas has historically been a state with a stringent corporate practice ban, precluding hospitals from employing physicians. In 2011, the Texas legislature inaugurated reforms in this area with the enactment of several laws. For example, SB 1661 was enacted to protect physicians employed by hospital-run, non-profit health care corporations known in Texas as 501(a) corporations. These types of entities are viewed as a viable avenue for hospital-physician alignment. The provisions protect the independence of physicians from lay influences in their treatment decisions.[36] SB 894 allowed critical access hospitals, sole community hospitals and hospitals in counties of 50,000 or less to employ physicians. Most of these hospitals are run by county governments. This new law contains provisions to protect physician independence. There were also a series of separate bills enacted that allow specific hospital districts in Texas to employ physicians, with explicit provisions to protect the autonomy of physicians.[37]

IV. APPLICATION OF THE CORPORATE PRACTICE OF MEDICINE DOCTRINE BEYOND PHYSICIANS

States have extended the corporate practice ban beyond physicians to other health professions, such as dentistry, podiatry, and chiropracty, and other learned professions. For example, in Maryland, the Dentistry Act prohibits the practice of dentistry by a corporate entity, except where otherwise noted.[38] Florida has similar restrictions for the practice of dentistry.[39] The New Jersey legislature has enacted an explicit ban for optometry, whereby it is unlawful "for any unlicensed person, or any association or corporation directly or indirectly to engage . . . in the practice of optometry by utilizing the services . . . of any person licensed to practice optometry."[40] Where states extend the practice ban to other health disciplines, there is a notable lack of uniformity,[41] and even

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[36] Tex. Occupations Code §§ 162.0021, 162.0023 and 162.0022.

[37] The bills enacted were: HB 1568 (Harris County Hospital District), HB 2351 (Bexar County Hospital District), HB 840 (El Paso County Hospital District), SB 303 (Tarrant County Hospital District). In 2005 and 2009, the Texas legislature also enacted bills that would allow Maverick County Hospital District and Dallas County Hospital District to employ physicians, dentists and other health care providers. SB 1027 (2005) and SB 1705 (2009), respectively.

[38] Md. Code Ann. Health Occ. § 4-603(a),(b), (c). Maryland law allows a licensed dentist to practice, under the name of the licensee, as an employee of a health maintenance organization that is properly certified. State law also permits a licensed dentist to practice, under the name of the licensee, as a member of a limited liability company. Additionally, Maryland provides for the practice of dentistry through a professional corporation. *See* Md. Code Ann. Corps. & Ass'ns § 5-101 *et seq*.

[39] Fla. Stat. § 466.0285. Section 466.0285 states that, except for a dentist duly licensed, a professional corporation or limited liability company composed of dentists, no person may employ a dentist or dental hygienist in the operation of a dental office, control use of dental equipment or interfere with a dentist's clinical judgment.

[40] N.J. Stat. Ann. § 45:12-19.1.

[41] *E.g., Isles Wellness, Inc. v. Progressive N. Ins. Co.,* 703 N.W.2d 513 (Minn. 2005) (Minnesota) (holding that the corporate practice ban does not apply to physical therapy); Iowa Op. Att'y Gen. No 74-9-4 (Sept. 4, 1974) (Iowa) (opining that the corporate practice ban applies to physical therapy).

by courts within the same state. This can be readily seen in Minnesota. In that state, the corporate practice ban applies to chiropractors, but not to optometrists.[42]

V. STATUTORY EXCEPTIONS

It is important to emphasize, as previously noted, that legal avenues exist under state statutory exceptions for the practice of medicine, and other professional disciplines, by entities that are formed under explicit statutory mandate for this purpose. By way of example, North Carolina allows the formation of a professional corporation under that state's Professional Corporation Act (applicable to, e.g., medicine, dentistry and chiropractic).[43] There is statutory authority, as well, in North Carolina for the formation of professional limited liability companies.[44] New Hampshire allows for the formation of this genre of entities, professional corporations,[45] and professional limited liability companies.[46] Arizona has legislated for not-for-profit medical service corporations whereby the provision of services is accomplished through contracts with physicians, podiatrists, dentists and optometrists.[47] California law authorizes the formation of dental corporations,[48] and optometric corporations,[49] for the practice of those disciplines, provided conditions specified by statute are met. Under California's Knox-Keene Act, a health service plan may contract with "any professional licensed . . . to deliver professional [medical] services."[50] Connecticut allows nonprofit medical foundations to be established for the provision of health care services by employees and agents.[51] New York allows for the formation of not-for-profit medical and dental expense indemnity corporations and hospital service corporations granting authority to employ licensed physicians and to enter into other contracts.[52] Thus, generally, states provide statutory exceptions, granting authority to organize entities for the practice of medicine and other medical professions where services rendered are by duly licensed professionals. State law usually mandates that all shareholders be duly licensed to render the same professional services as those for which the corporation was organized. Additionally, licensees must be designated as directors and officers. States also have legislated exceptions to the corporate ban for health maintenance organizations.[53]

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[42] *See Isles Wellness, Inc. v. Progressive N. Ins. Co.,* 703 N.W.2d 513 (Minn. 2005) (Minnesota) (holding that the corporate practice of medicine doctrine applies to chiropractic clinics); *Williams v. Mack,* 278 N.W. 585 (Minn. 1938) (Minnesota) (holding that there is a statutory exceptions to the corporate practice ban for optometry).

[43] N.C. Gen Stat. § 55B-2(5).

[44] N.C. Gen. Stat. §§ 57D-2-01, 02.

[45] N.H. Rev. Stat. § 294-A:2.

[46] N.H. Rev. Stat. § 304-D:2.

[47] ARS § 20-822(3).

[48] Cal. Corp. Code §§ 13401 and 13401.5

[49] Cal. Corp. Code §§ 13401 and 13401.5

[50] Cal. Health & Safety Code § 1395(b).

[51] Conn. Gen. Stat. § 33-182aa *et seq.*

[52] N.Y. Educ. L. § 6527(1).

[53] *See, e.g.,* S.C. Code Ann. § 38-33-50(A)(3) (South Carolina); N.Y. Pub. Health L. § 4410(1) (New York).

South Dakota is a jurisdiction that has an explicit statutory corporate practice ban. That State's Medical Practice Act states that "it is the public policy of this state that a corporation may not practice medicine or osteopathy."[54] The legislature provided an exception, however, by allowing a corporation to enter into an employment agreement with a duly licensed physician provided such agreement does not impinge on the physician's independent judgment. Additional restrictions are imposed on the corporation's ability to make charges associated with services rendered. The statute also limits the agreement to three years, and is renewable thereafter annually.[55]

It is noteworthy that in Ohio, the State Medical Board in 2012 opined on the state of the law on the corporate practice ban.[56] Traditionally, Ohio has been known to have had a robust CPMD. Essentially, in its 2012 opinion, the Medical Board declared an end to the CPMD in Ohio. In the Board's view, the State legislature had enacted various laws for the formation of entities, including a professional corporation under O.R.C. section 1701.03 for the practice of medicine and other learned professions, thus obviating the rationale for the CPMD. It is interesting to observe that under Ohio law, a corporation can be formed under section 1701.03 to provide a combination of professional services. It is provided that the entity formed shall not control the professional judgment of the medical professional in rendering treatment. The State Medical Board observed that although the Ohio Attorney General had previously opined that the CPMD was viable in the State, his views predated subsequent statutes enacted by the State legislature. In the Board's view, those statutes vitiate the vestiges of the corporate practice ban in Ohio.

VI. APPLICATION TO MANAGEMENT SERVICES

In an era that exemplifies collaboration between physician practices and entities engaged for the provision of management services, the corporate practice ban can impact the legality of such arrangements. North Carolina has recognized this, and, for the practice of dentistry, provides by regulation a structure that permits management services by non-licensed individuals and entities for dental practices. Specifically, the North Carolina State Board of Dental Examiners recognizes such management services agreements provided the arrangements do not entail the practice of dentistry by non-licensed persons or entities. The state's regulation of these management agreements imposes strict criteria, crafted to restrict the control of dental practices, including clinical and professional services.[57]

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[54] SDCL § 36-4-8.1.

[55] *Id.*

[56] Statement of the State Medical Board of Ohio on the Corporate Practice of Medicine (March 15, 2012).

[57] 21 NCAC 16X.0101 (Management Arrangements). The regulation mandates that the management agreement be in writing, signed by all parties, and describe the services to be performed by the management company as well as the aggregate compensation to be paid, or the method of deriving compensation. 21 NCAC 16X.0101(b). The regulation also prohibits ownership or control of the dental practice, its operations, clinical decisions or distribution of revenues. No ownership or control may be exerted by a management company over patient records, or control over the transfer of ownership interests of the professional practice. Compensation to the management company may not be determined by the profitability of the dental practice, its gross revenues or net revenues. 21 NCAC 16X.0101(c). The regulation does not preclude setting payments

Other states have opined on the role of a management services organization (MSO), vis-à-vis payors and providers. The Attorney General for the State of California issued an opinion on July 27, 2000,[58] expressing concern about the difficulty of separating business and medical decision-making by the MSO. Where those two functions merge, there is the prospect that the MSO could be viewed as engaging in the unlawful practice of medicine. The State Attorney General was asked to opine on an arrangement whereby an MSO, unlicensed to practice medicine, was paid a fee by a labor union for the MSO to arrange for radiology diagnostic services that were prescribed by a physician for members of the union. The State Attorney General wrote that such an arrangement would result in the MSO practicing medicine without a license. He took issue with the involvement of the MSO in the details of arranging for the diagnostic services. Specifically, he explained that the MSO was tasked with duties that were an integral part of the practice of medicine. The MSO selected the venue and scheduled for the radiology procedure, ensuring that there would be the necessary equipment and personnel in view of the patient's physical ailment. The MSO also selected a radiologist to view and interpret the films. The State Attorney General viewed these tasks as requiring professional judgment, and thus the practice of medicine by the MSO. Additionally, the opinion noted that the MSO paid for the radiology services and added a separate management fee for profit. The Attorney General objected to this aspect as well, making clear that this would be a "further intrusion" into the physician-patient relationship.

The decision in *Flynn Brothers, Inc. et al. v. First Medical Associates, et al.*[59] provides further instruction. There, the court considered an arrangement between a professional corporation organized under Texas law and a management services company. The professional corporation, First Medical Associates (FMA), was organized by a physician, and it was under contract with a hospital to staff its emergency department. FMA entered into a contract with a management services company, Flynn Brothers, Inc. (FBI) to assist FMA in administering the contract with the hospital. It was agreed that FBI was the exclusive agent of FMA, with restrictions on the ability of the physician owner of FMA to sell his stock in the professional corporation. The contract precluded FMA from engaging another entity for management services. Additionally, the contract between FMA and FBI provided for a share of net profits of FMA for the services of FBI. The court in *Flynn Brothers* also noted that FBI was the recipient of revenues which were, in turn, deposited into the FMA checking account maintained by FBI. It was not unusual for there to be a commingling of funds between the accounts of FMA and FBI. It was further noted that, to secure a pre-existing FBI debt, FBI pledged assets of FMA. A dispute arose regarding the contract between FMA and FBI, resulting in a lawsuit. The court determined that the contract was not enforceable since it contravened the Texas Medical Practice Act. Explaining that the heightened concern for the physician-patient relationship, untainted by abuses from lay control of professional corporations employing physicians, the court concluded that the terms of the contract between FMA

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to the management company that takes into account cost increases and decreases of the professional practice. 21 NCAC 16X.0101(d). All management agreements are subject to advance review by the North Carolina State Board of Dental Examiners.

[58] Op. Atty. Gen. Cal. 00-206 (July 27, 2000).

[59] 715 S.W.2d 782 (Tex. Ct. App. 1986).

and FBI, in practical effect, allowed FBI to practice medicine without a license, contrary to law. The court emphasized several key points. The FBI management contract specified that FBI was to receive 66.6 percent of the profits derived from the FMA practice. FBI had the right to use the medical license of FMA's owner to conduct business. FBI also retained the right to select medical staff to work in hospitals under contract with FMA. All of these things led the court to conclude that the management company was indirectly practicing medicine.

VII. ENFORCEABILITY OF CONTRACTUAL OBLIGATIONS BETWEEN MEDICAL PROVIDERS AND PAYORS

The corporate practice ban can have implications in the contractual relations between medical providers and insurers for the payment for medical services. The ban can also arise in the context of non-compete agreements for physicians.

A. Payment for Services

Case law has developed in disputes between medical providers and insurers, where the insurer either sues for the return of payments made to the provider, or refuses to make payment for medical services, arguing that the contract between the parties is not enforceable on grounds that the provider has run afoul of the state's corporate practice ban. In either one of these scenarios, the insurer contends that the contractual obligation to make payment is void. The courts have not always ruled in favor of the insurer.

Some courts, as a threshold matter, have determined that the insurer lacks standing to bring suit. Here, the courts decline to recognize a private right of action for the insurer, concluding that the authority to enforce a state's corporate practice ban resides solely with the state's attorney general under state law. Thus, in *State Farm Mutual Automobile Insurance Company and State Farm Fire and Casualty Company v. Andrew Jacobs, et al.,*[60] State Farm brought an action to recover payments made to Tacoma Therapy and Tacoma Rehabilitation for medical services rendered to policyholders. The two entities provided massage and physical therapy services. State Farm contended it was entitled to refunds because the two entities were never properly formed under Washington state law professional service corporations, and thus they were in violation of the state's ban on the corporate practice of medicine. The district court for the Western District of Washington granted a motion to dismiss under Fed. R. Civ. P. 12(b)(6). The court concluded that there was no express or implied private right of action to bring the suit. The district court observed that state law prohibits corporations from employing medical professionals to practice their profession. There is, though, an exception to this rule, allowing for the formation of an entity under Washington State's Professional Service Corporation Act (PSCA). That statute allows medical professionals to form, and to be employed by, a professional service corporation, provided that the shareholders are licensed to provide the medical services that are offered.[61] It was conceded by the plaintiff insurer that there was no express private right of action under the PSCA. The issue was whether the insurer had an implied private right to sue for recovery of monies paid. The district court

[60] 2014 U.S. Dist. LEXIS 152564, No. C14-5512 (W.D. Wash. Oct. 28, 2014).

[61] Wash. RCW § 18.100.010.

declined to find such an implied right. To reach that conclusion, the court explained that the purpose of the legislature in enacting the PSCA was to preclude layperson influences on the doctor-patient relationship. Thus, insurers were not within the class for whose benefit the PSCA was enacted. The court wrote that the PSCA expressly provides that enforcement of the PSCA resides with the state.

In *State Farm Mutual Automobile Insurance Company v. Mobile Diagnostic Imaging, Inc.*,[62] the District Court for the District of Minnesota ruled against State Farm in an action brought by the insurer to relieve it of payment obligations to Mobile Diagnostic Imaging (MDI) for magnetic resonance imaging (MRI) scans performed for State Farm's insureds. In that case, MDI was in the business of doing MRI scans, and hired technicians for this purpose. Once the scans were done, MDI forwarded the results of the scans to physicians and radiologists with whom MDI independently contracted to interpret the results and write a report on the findings from the scan. These physicians and radiologists were employed separately by ProScan Reading Service (ProScan). In *Mobile Diagnostic Imaging*, State Farm contended that it was relieved of making further payments, on behalf of its insureds, to MDI for MRI scans since, in State Farm's view, MDI was in violation of Minnesota's ban on the corporate practice of medicine. The district court disagreed, and rejected the insurer's attempts to be relieved of payments to MDI on behalf of its insureds. First, State Farm argued that the technical component of the MRI scan was indivisible with the professional component of interpreting the scan, which was done by licensed medical professionals. According to State Farm, the MRI scanning procedure, as a whole, required the involvement of a licensed medical professional. Thus, the corporate practice ban was implicated, and MDI was in violation of it. The district court declined to reach this result. The court took note that under Minnesota law, a diagnostic imaging facility can be organized by laypeople,[63] suggesting that the MRI service itself can be performed by an unlicensed professional. The court's reading of the state statute thus provided for divisibility between the performance of the MRI scan and the interpretation of the test results. The court rejected State Farm's assertion that MDI technologists exercise independent professional judgment as unsupported by the evidence. State Farm pressed other points. It asserted that the actual performance of the scans by MDI, a lay organized entity, was itself a violation of the corporate practice ban. The court rejected this argument, explaining that the

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[62] 7 F.Supp.3d 934 (D. Minn. 2014). There are divergent views among states on the issue presented in *Mobile Diagnostic Imaging*. For example, New Jersey addresses ownership interests in diagnostic imaging facilities. Under N.J. Admin. Code § 13:35-2.6, "[a]ny diagnostic or screening office offering diagnostic or screening tests for a fee shall [b]e solely owned and under the responsibility of one or more physicians." In a Florida case, the court rejected the global billing used in *Mobile Diagnostic Imaging*. In *Regional MRI of Orlando, Inc. v. Nationwide Mut. Fire Ins. Co.*, 884 So.2d 1102 (Fl. Dist. Ct. App. 2004), the court reached its decision based on Florida Statute § 627.736(5)(a) that mandated a provider to "lawfully render" a medical service to be entitled to payment for the service. The court read "render" as not allowing the hiring of another company, or independent contractor, to perform the professional component on the MRI provider's behalf. In *Regional MRI of Orlando*, the MRI provider did not "render" the professional component of the MRI service, but rather used physicians under independent contract. The Florida court concluded that, in view of the global billing used by the MRI provider, it was not entitled to payment for the professional component.

[63] *Quoting from* Minn. Stat. § 144.565, subdiv. 1(2).

technicians employed by MDI were not state-licensed professionals. Finally, State Farm also argued that MDI relationship with the physicians and radiologists, as independent contractors, ran afoul of the corporate practice ban. This was so since, in State Farm's view, MDI used these professionals to interpret the scans and write a report on the findings. Thus, MDI was indirectly practicing medicine. The district court disagreed. It observed that MDI communicates directly with the patient's physician by transmitting the scans and the reports done by ProScan that interpret the scans. Thus, MDI has no direct communication with the patient's physician that would suggest the unlicensed practice of medicine.

Courts have declined to adopt a *per se* rule that would vitiate contractual duties for the payment of services rendered to an insured's enrollees where the medical provider is organized in violation of a state's corporate practice ban. The Supreme Court of Minnesota took this position in *Isles Wellness, Inc. v. Progressive Northern Insurance Co*.[64] There, the Court ruled that an insured's duty to pay must be honored where there is no determination that the owners exhibited a "knowing and intentional failure"[65] to adhere to a state's corporate practice ban. In *Isles Wellness*, three clinics, with a sole shareholder, were organized under Minnesota's Business Corporation Act,[66] and they provided chiropractic, massage, and physician therapy services. The owner was not licensed as a chiropractor; rather, the clinics hired chiropractors to provide services to the clinic's patients. Services were covered by the state's No-Fault Insurance Act, with patients assigning their insurance claims to the clinics. Two insurers had been paying under this insurance program for services rendered by the clinics; however, the insurers ceased payments, contending that there was no contractual duty to pay for the clinic's services. The insurers insisted that, since the clinics employed chiropractors, the clinics were in violation of the CPMD, and thus, as a matter of public policy, the contracts were void.[67] The Minnesota Supreme Court disagreed. The court wrote that the inquiry is whether the illegality has " tainted the transaction."[68] It ruled that, as a matter of law, a contract is not void as against public policy "unless it is injurious to the interests of the public."[69] The court emphasized that the corporate practice ban is aimed to protect the fiduciary role of physicians in making medical judgments, and to guard against conflicts that arise from profit motives. In *Isles Wellness*, the clinics, in seeking payment from the insureds, argued that the hired licensed chiropractors rendered services, thus allowing contracts with the insurers to be upheld on fairness grounds. The Minnesota Supreme Court rejected a bright-line rule that would have necessitated vitiating the contracts. It emphasized that the clinics hired licensed professionals. While state law allows for the voiding of contracts in violation of public policy, that need not always be the result. Voiding the contracts would do little to vindicate the policy for the corporate practice ban, to protect the public from lay control over the judgments of physician. On the other

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64 725 N.W.2d 90 (Minn. 2006).

65 *Id.* at 95.

66 Minn. Stat. ch. 302A.

67 In *Isles Wellness, Inc. v. Progressive N. Ins. Co.*, 703 N.W.2d 513 (Minn. 2005), the Minnesota Supreme Court ruled that the corporate practice of medicine doctrine applies to chiropractic clinics.

68 725 N.W.2d 90, 93.

69 *Id.*

hand, the court emphasized that voiding the contracts would unjustly enrich the insurers since their insureds reaped the benefits of medical treatment. The court concluded that since there was no evidence that the clinics intended to organize in violation of state law, fairness dictated that the contracts be enforced.

Similarly, in *California Physicians' Service v. Aoki Diabetes Research Institute*[70] Blue Shield, a health care service plan organized under California's Knox-Keene Act,[71] entered into a contract with Aoki Diabetes Research Institute (ADRI) whereby Blue Shield would reimburse ADRI for services rendered to Blue Shield subscribers. A dispute arose over Blue Shield's duty to continue payments to ADRI for services being rendered to Blue Shield's subscribers. Blue Shield brought suit for declaratory judgment seeking to establish that it was not obligated to reimburse ADRI. One of the arguments pressed by Blue Shield was that ADRI was in violation of California's corporate practice ban since, as a non-profit corporation, it contracted with licensed physicians to render services. That relationship was not permitted under state law. The Court of Appeal of California agreed that ADRI was doing business contrary to the state's corporate ban. It nonetheless declined to declare the contract between Blue Cross and ADRI unenforceable. The court emphasized that the contract between Blue Shield and ADRI was not *malum in se*, but rather was *malum prohibitum*. Moreover, citing *Isles Wellness v. Progressive*,[72] the court explained that to declare the contract void would raise the specter of unjustly enriching Blue Shield for services rendered to its subscribers without reimbursing ADRI. The court wrote that allowing Blue Shield to avoid payment would not vindicate the policy behind the corporate practice ban, that of protecting patients from the lay influence over medical judgments. Thus, although ADRI had not adhered to the CPMD, the court ruled that ADRI was entitled to receive payments from Blue Shield for services that had been rendered under its contract.

Spine Imaging MRI, L.L.C. v. Country Casualty Insurance Company, et al.[73] is an interesting case where the court allowed discovery on the issue of the independent contractor status of licensed radiologists. In that case, filed in the District Court for the District of Minnesota, the plaintiff, Spine Imaging MRI , was a provider of magnetic resonance imaging services to patients who assigned their claim for benefits under their insurance policies to Spine Imaging. The insurers had informed Spine Imaging that in their view, Spine Imaging was in violation of the corporate practice ban, and thus, the insurers were seeking recoupment of monies paid to Spine Imaging as assignee under the insureds' policies. Spine Imaging then brought suit seeking a declaratory judgment against the insurers to establish that it was not in violation of the state's CPMD. Spine Imaging admitted that its owner was an unlicensed layperson. The business did not employ licensed physicians or chiropractors. The MRI services provided by Spine Imaging was comprised of two separate steps, a technical component and a professional component. Spine Imaging contracted with independent licensed contractors to analyze

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[70] 2008 Cal. App. LEXIS 922 (Cal. Ct. App. June 17, 2008), *review denied* 2008 Cal. LEXIS 11250 (Cal. Sept. 17, 2008).

[71] Cal. Health & Saf. Code § 1340, *et seq.*

[72] 725 N.W.2d 90 (2006).

[73] 2011 U.S. Dist. LEXIS 9681 (D. Minn. Feb. 1, 2011).

the scans. The district court declined to grant the insurers' motion to dismiss. Of import to the court was the involvement Spine Imaging maintained after the scans had been done, when radiologists, as independent licensed contractors, analyzed the scans. Spine Imaging insisted that its independent contractors exercised their own judgment when analyzing the scans. Thus, according to Spine Imaging, there could be no unlawful practice of medicine by laypeople. It was on this basis that the district court denied the insurers' motion to dismiss, allowing discovery on the independence of the radiologists, and implications for the corporate practice ban.

Some courts have ruled against the provider of medical services, in favor of the insurer, in disputes over entitlement to reimbursement. The decisions in those cases are fact-specific, and governed by the state regulatory regime. For example, in *Prudential Property & Cas. Ins. Co. v. Midlantic Motion X-Ray*,[74] the insurer sought a declaratory judgment to establish that it need not reimburse the defendant, a facility for medical diagnostic testing. Diagnostic testing was provided to Prudential's subscribers, and the insurer offered personal injury automobile coverage for such services under New Jersey's Personal Injury Protection law. The court determined that the facility was a "medical diagnostic testing service," and as such, was subject to state statutory rules for the formation and operation of such facilities. The court ruled in favor of Prudential, explaining that the defendant was organized and operated contrary to New Jersey law.[75] Under state statute, the facility was required to be owned and controlled by a licensed physician. Additionally, the test results were to be interpreted by a licensed physician. However, the court determined that the facility was organized and operated by a chiropractor, not a licensed medical doctor. Moreover, tests were interpreted by the lesser licensed individual. Since the defendant was not organized and operated as required by New Jersey law, the court concluded that it was not eligible for reimbursement. A similar result followed in *Andrew Carothers, M.D., P.C. v. Progressive Insurance Company,*[76] a case arising under New York State's no-fault insurance regime. There, the court concluded that an MRI provider was not eligible for reimbursement as an assignee of benefits under New York's no- fault insurance statute since it failed to comply with the State's regulation, 11 NYCRR 65-3.16(a)(12). That regulation, promulgated to implement the State's no-fault insurance regime, deemed a provider of health care services ineligible for reimbursement under the no-fault law where the provider "fails to meet any applicable New York State or local licensing requirement." In that case, the provider of MRI services had organized as a professional service corporation, but the entity ran afoul of New York State's licensing laws that required the entity to be owned and controlled only by licensed professionals. Thus, the court ruled in favor of the defendant insurers.

Where there is an element of fraud in the formation of a corporation that renders medical services, resulting in a violation of the corporate practice ban, courts are more inclined to hold the incorporators accountable, and rule in favor of an insurer that seeks to recoup or to withhold payments for medical services rendered. For example, in a seminal New

[74] 737 A.2d 711 (N.J. Super. Ct. 1999).

[75] *Citing* N.J.C. 13:35-2.5(b).

[76] 979 N.Y.S.2d 439 (2013).

York case, *State Farm Insurance v. Mallela*,[77] State Farm participated in New York State's no-fault insurance regime[78] as assignee of claims for medical services rendered to patients covered by that program. State Farm had brought suit in federal district court seeking relief, alleging that the corporation billing for medical services was fraudulently incorporated to evade the state's corporate practice ban. State Farm sought a declaratory judgment that it need not pay for medical claims, and, separately, that it was entitled to equitable relief for payments made for past claims. The district court dismissed the insurer's complaint. The Court of Appeals of the State of New York accepted certification to address whether, as a matter of law, a fraudulently incorporated company that rendered medical services was entitle to reimbursement under the state's insurance law. In this case, it was alleged that medical service corporations were established with bogus applications filed with the state. The unlicensed defendants had paid licensed physicians to use their names on papers to establish the physicians as nominal owners of the entities. The physicians played no role in the medical service corporations. Rather, the non-physician defendants controlled the business. To further the scheme, the defendants had the corporations enter into separate contracts with management companies (owned by the defendants) which billed the medical corporations for services at inflated rates. This allowed profits to be siphoned from the medical service corporations to the non-physician owners of the management companies. In rendering its opinion, the Court of Appeals assumed that the allegations made by State Farm were correct, that the medical provider was fraudulently incorporated. The Court of Appeals applied implementing regulation 11 NYCRR 65-3.16(a)(12), a rule that precluded payment for medical services where "the provider fails to meet any applicable New York State or local licensing requirement."[79] The Court of Appeals found that the rule was valid, precluding payment where a provider was fraudulently licensed. It thus ruled, as a matter of law, in favor of State Farm on its request for declaratory judgment.[80]

B. Non-Compete Clauses in Physician Employment Contracts

There is a lack of uniformity nationally with regard to the enforceability of non-compete provisions governing physician employment contracts. Some states have legislated that such restrictions are against public policy, and thus restrictive covenants in such contracts are not enforceable. State courts, moreover, differ in their views regarding non-compete provisions. Case law indicates that some courts have taken a dim view of these clauses, applying a *per se* rule of illegality and refusing to enforce them. Other state courts prefer to consider the terms of a non-compete clause in a physician's contract, especially the durational and geographic limitations, and render a judgment based on a rule of reasonableness. In litigation over these restrictive covenants, physicians have either sought a declaration of invalidity of the non-compete clause, or have asserted a

[77] 827 N.E.2d 758 (NY 2005).

[78] N.Y. Insurance Law § 5101, *et seq.*

[79] Rule effective April 4, 2002.

[80] The Court of Appeals ruled that no cause of action was allowed for any payments made by the insurer before April 4, 2002, the effective date of the regulation. *See also Liberty Mutual Insurance Company, et al. v. Excel Imaging, P.C. et al.,* 879 F. Supp. 2d. 243 (E.D. N.Y. 2012).

defense in an action for breach of contract, arguing that the non-compete provisions in the employment agreement are not enforceable.

In litigation where the enforceability of a non-compete agreement is at issue, physicians have separately raised the ban on the corporate practice of medicine, arguing that the employment contract between the hospital, or other medical facility, and the physician is itself void. There has been mixed success with this argument. In *Dr. Allison, Dentist, Inc. v. Allison*,[81] the Supreme Court of Illinois declined to enforce the non-compete provision on grounds that the employment agreement between the physician and a dental corporation ran afoul of the corporate practice ban, and thus, under state law, was illegal. A similar result was reached in a case considered by the Supreme Court of Kansas, in *Early Detection Center, Inc. v. Wilson*,[82] where the Court addressed a restrictive covenant in an employment contract between a physician and a general corporation. In that case, two physicians licensed to practice medicine and surgery in Kansas formed a partnership, and later established their practice as a professional corporation. The articles of incorporation restricted the directors and ownership of the corporation to persons licensed to practice medicine. The physician owners later took steps to re-organize into a general corporation, and the articles of incorporation permitted non-licensed individuals to be owners of the general corporation. Following the re-organization, the two physician owners sold a percentage of their ownership interests in the general corporation to individuals who were not licensed to practice medicine. The general corporation was in the business of offering medical services, and thus ran afoul of the State's CPMD. A dispute over management issues arose involving one of the licensed physicians, who resigned and then began to steer the corporation's patients to another medical provider. The corporation filed suit against the physician, claiming a breach of the non-compete provision in his contract. The district court declined to enforce the restrictive covenant, ruling that there could be no contract between a general corporation and a physician to perform medical services. The court of appeals affirmed, citing the Kansas Healing Arts Act,[83] which imposed licensure requirements and precluded entities from practicing medicine or offering such services through licensed practitioners. The court thus reasoned that the contract between the general corporation and its physicians was not enforceable.

Other courts have similarly ruled in favor of physicians, declining to enforce non-compete clauses in contracts that run afoul of the CPMD. For example, in *Nipun Parikh, M.D. v. Family Care Center, Inc.*,[84] a corporation sought judgment against a physician for alleged violation of a non-compete clause in an employment contract. The Supreme Court of Virginia denied relief sought by the plaintiff after concluding that the corporation did not have a protected interest in enforcing the covenant not to compete. The plaintiff was originally organized as a professional corporation, the Family Care Center, with a physician as its owner and director. At that time, the corporation entered into an employment agreement with a physician. Whenhe entity's physician owner died,

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81 196 N.E. 799 (Ill. 1935).

82 811 P.2d 860 (Kan. 1991).

83 K.S.A. § 65-2803.

84 641 S.E.2d 98 (Va. 2007).

by operation of law it became a non-professional corporation. At the time the employment agreement was signed by the parties, it stated that the entity "is presently engaged in the practice of medicine . . .."[85] Upon becoming a non-professional corporation, the entity was no longer permitted to practice medicine. The physician terminated his employment with Family Care Center, leaving to work for another medical center nearby. The corporation brought suit to enforce the restrictive covenant. The Supreme Court of Virginia focused on whether the non-professional corporation had a legitimate business interest in enforcing the non-compete clause. The court concluded there was no such interest,noting that the employment agreement containing the restrictive covenant stated that, at the time it was executed, the corporation was "presently engaged" in the practice of medicine. At that time, the corporation had a protected business interest in the non-compete clause. The Court wrote that when the entity reverted to a non-professional corporation, itlost its legal authority to practice medicine. Thus, the Court reasoned that the corporation no longer had a legitimate business interest in enforcement of the covenant not to compete.

An often cited case, *Carter-Shields v. Alton Health Institute*,[86] provides instruction on the mode of reasoning used in Illinois by courts when faced with disputes involving non-compete agreements involving physicians where the CPMD is implicated. In that case, a board-certified family practice physician entered into an employment agreement with Alton Health Institute (AHI), a non-licensed general not-for-profit corporation. AHI was owned by two separate entities, each holding a 50 percent interest.[87] The contract between the physician and AHI contained a restrictive covenant. Disputes arose between the physician and AHI. The physician filed suit for declaratory judgment, contending that her employment agreement violated the corporate practice ban, and asked the court to find her employment agreement containing a restrictive covenant unenforceable. Defendant AHI filed a counterclaim, and moved for injunctive relief, seeking to enforce the non-competition clause in the employment agreement. The trial court ruled in favor of the defendant, in part citing the decision rendered by the Supreme Court of Illinois in *Berlin v. Sarah Bush Lincoln Health Center*. The trail court read that decision as carving out an exception to the Illinois corporate practice ban for entities, like AHI, that are non-profit charitable organizations. The court also held that the non-compete clause was reasonable on its face, and thus enforceable. The trial court further concluded that plaintiff had breached the employment agreement. On appeal, the court of appeals reversed the lower court's decision. It determined that the trial court's reliance on *Berlin* was misplaced. Specifically, the court of appeals explained that in *Berlin*, the Supreme Court of Illinois carved out an exception from the corporate practice ban for hospitals only. Thus, the trial court had wrongly applied the exception announced in *Berlin* to the defendant, a non-licensed charitable not-for-profit corporation. The court of appeals

[85] *Id.* at 99.

[86] 777 N.E.2d 948 (Ill. 2002).

[87] The first entity that owned a 50 percent interest in AHI was a health system, a tax exempt not-for-profit corporation, and was not licensed as a hospital or medical services corporation. The second entity owning a 50 percent share of AHI was a partnership, composed primarily of physician groups, and had one non-physician member.

wrote that "from its inception, the agreement between AHI and plaintiff was void . . .."[88] The Supreme Court of Illinois affirmed, in part, the appellate court's decision, finding that its earlier ruling in *Berlin* did not provide an exception to what was otherwise the unlawful practice of medicine by AHI in view of its nature as anentity that was not licensed to provide medical services to the public. Thus, the employment agreement between the physician and AHI, and thus the non-compete clause, were unenforceable.

Where an Illinois professional corporation fails to obtain a certificate of registration, as required by the Illinois Professional Service Corporation Act,[89] that fact, standing alone, will not provide grounds for declaring a contract between a medical group and a physician void. That was the holding in *Mary T. Riggs v. Woman To Woman, Obstetrics and Gynecology, P.C.* (*Riggs*),[90] where the court declined to void a contract in a challenge to a covenant not to compete. In that case, the plaintiff, a physician employed by a medical practice brought suit, alleged fraudulent accounting practices by the medical practice. The physician also averred that prior to employment with the medical practice, she was misinformed by the medical group in that assurances were given to her that the medical practice, a corporation, was registered to practice medicine in Illinois. It was alleged that at the time the employment contract was signed, the medical practice failed to register for a certificate with the Illinois Department of Professional Regulation (IDPR), as required under the Professional Service Corporation Act. In the lawsuit, the plaintiff sought a declaratory judgment that the contract with the medical group was void *ab initio*, and thus the restrictive covenant was not enforceable. The district court granted the relief sought and certified the matter for interlocutory appeal. On appeal, the court declined to rule in the plaintiff's favor. The court of appeals noted that the defendant was originally formed as a medical corporation, and it filed an application with the IDPR for a certificate of registration. The IDPR misdirected its written request that "minor, technical changes"[91] be made to the application. The application filed by the medical corporation expired. The IDPR was ultimately successful in communicating with the medical corporation, and it requested that a new application be filed, with the needed changes to the application. This was done, and a certificate was issued to the medical corporation, after the plaintiff brought her lawsuit. The court of appeals emphasized that no fine was imposed against the medical corporation, and no investigation was undertaken as a result of the "inadvertent expiration"[92] of the initial application for a certificate. The court then reviewed the purposes of the Professional Service Corporation Act. It interpreted the text of the Act, and observed that the Act was not enacted for the protection of the public health. Rather, the statute was "primarily permissive," affording medical professionals an avenue, and benefits, under state law to incorporate. In reaching this conclusion, the court of appeals contrasted the Act with the State's Medical Practice Act of 1987.[93] The Medical Practice Act, in the court's view, was a public health statute, enacted to impose licensure requirements to ensure adequate

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88 *Id.* at 954.

89 805 ILCS 10/12.

90 812 N.E.2d 1027 (Ill. Ct. App. 2004).

91 *Id.* at 1029.

92 *Id.* at 1030.

93 225 ILCS 60/1 *et seq.*

training, and thereby protect the public. The Professional Service Corporation Act, on the other hand, had a different purpose. That statute was to ensure that the owners, directors and officers, licensed to practice in their profession, are organized solely to render a type of service. The court wrote that "[c]learly, the intent of the legislation . . . was not to advance the public welfare but to allow professionals to incorporate . . . to enjoy certain . . . benefits" arising therefrom. Thus, the court rejected attempts by the plaintiff to analogize the lack of a certificate of registration by the defendant to practice as a medical corporation with the lack of a license to practice medicine. Since the Act lacked a public health purpose, the court ruled that the lack of a certificate of registration by the defendant would not result in voiding the contract between the plaintiff and the defendant, where there was no showing of prejudice against the plaintiff. The court of appeals in *Riggs* distinguished its ruling to the holding in *Carter-Shields v. Alton Health Institute*, reasoning that in *Carter-Shields*, a general corporation incorporated under Illinois law by non-licensed owners employed licensed physicians to practice medicine, directly contrary to licensure laws and the corporate practice ban. In *Riggs*, the professional corporation was owned by licensed physicians, and thus there was no implication of a lay entity employing the physicians.

It is reasonable to construe the decision in *Riggs* as predicated not only on the interpretation of the State's registration law, but on the facts as well. The court of appeals noted technical issues with the certificate of registration for the professional corporation, and through inadvertent mishaps, a delay occurred in the issuance of a certificate. There was no suggestion of fraud or attempts to evade state law, and the medical corporation, as required, was owned by licensed physicians. The analysis and reasoning of the *Riggs* court was embraced by the Supreme Court of Illinois in *Chatham Foot Specialists, P.C. v. Health Care Service Corporation,*[94] on a different set of facts. The issue in *Chatham* concerned the registration requirements under Illinois' Professional Service Corporation Act (the Act),[95] and a podiatric practice organized under that statute. The practice had as a sole shareholder, officer, and director who was a duly licensed podiatrist under the Podiatric Medical Practice Act of 1987.[96] The Court in *Chatham* wrote that the requirement under the Act to obtain a certificate of registration was not a regulatory measure to protect the public health. Thus, failure to have had a certificate would not lead to the conclusion that the professional service corporation was practicing podiatry without a license.

VIII. FEE-SPLITTING ARRANGEMENTS

As a corollary to the corporate practice prohibition, many states have fee-splitting rules that impact relationships between medical professionals and other parties. These rules differ among jurisdictions, and are an important consideration in crafting collaborations. The fee-splitting rules are codified in statutes, and some courts have rendered decisions on their applicability and scope. Additionally, state attorneys general have opined on the subject. Several opinions from various jurisdictions illustrate the issues that can arise in this area.

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[94] 837 N.E.2d 48 (Ill. 2005).

[95] 805 ILCS 10/12.

[96] 225 ILCS 100/1, *et seq.*

A decision rendered by the Supreme Court of Illinois on fee splitting is instructive. In *Vine Street Clinic et al. v. Healthlink, Inc.,* [97] the Court addressed the payment arrangement between Healthlink and its network of physicians. Healthlink engaged physicians to join it network of providers, and marketed the services of its network to members of health plans. The network physicians agreed to provide medical services to health plan members, and charge the plans a discounted rate. Healthlink would process the claims of the network physicians, and send them to the health plans for benefit determination and payment. Plaintiff Vine Street (a partnership of physicians) and an individual physician plaintiff were part of Healthlink's network, and they paid Vine Street an administrative fee for its services. Healthlink initially used a percentage-based fee, and later switched to a fixed flat-fee arrangement. The percentage-based fee was 5 percent of the amount in HealthLink's rate schedule for physician services provided to plan members. The fixed flat fee was derived by considering the physician specialty, and volume of claims submitted by the physician. In *Vine Street Clinic*, plaintiffs challenged these fee arrangements, alleging that both types of fees violated the Illinois Medical Practice Act.[98] In construing section 22(A) (14) of the Act, the court in *Vine Street Clinic* determined that the percentage fee was void, and deemed the fixed flat fee lawful. The court explained that a goal of section 22(A)(14) was to guard against referrals by a non-physician for medical services out of personal gain, and to safeguard the physician's independence. The court reasoned that the flat fee "fairly compensates" Healthlink and avoids "a prohibited diversion of the physician's remuneration."[99]

The Illinois legislature in 2009 amended the Illinois Medical Practice Act of 1987 regarding fee-splitting rules.[100] There, the State legislature relaxed restrictions on fee-splitting by physicians and optometrists. The newly enacted amendments permit a percentage fee for billing and collection services, and allow only a fixed fee for management and administrative services. Specifically, a fair market value, percentage fee or flat fee is permitted for billing, administrative preparation and collection services, provided the licensee maintains control over the amount of fees charged and collected, and the charges collected are deposited in an account of, and controlled by, the licensee. Additionally, the amendment precludes payment of a percentage fee by a licensee, but allows a flat fee paid to a third party for marketing or management of the licensee's practice, allowing the licensee to be included in a network of providers and negotiating fees on behalf of the licensee.

In *Alpha Real Estate Company of Rochester v. Delta Dental Plan of Minnesota, et al.*[101] the court reviewed a five percent charge formula that was at the heart of a dispute in negotiations to purchase property being leased as a dental practice. The dispute was between a lessee of a dental clinic, Alpha Real Estate Company, and a company that owned the property, Delta Dental Plan. Delta owned a subsidiary, Sui Generis Development Company. Sui Generis constructed and equipped the dental clinic, and it

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97 856 N.E.2d 422 (Ill. 2006).

98 225 ILCS 60/22/(A)(14).

99 856 N.E.2d 422, 435.

100 Ill. Public Act 096-0608.

101 671 N.W. 2d 213 (Minn. Ct. App. 2003), *reviewed denied* 2004 Minn. LEXIS 27 (Minn. 2004).

leased the property to Alpha. Delta Dental was also a health service plan that sold and administered dental benefits to group plans. The clinic was, in turn, leased by Alpha to a separate dental center, Apollo Dental Center, PLC, which entered into a provider agreement with Delta Dental to provide services to plan members. A licensed dentist owned both Alpha and Apollo. The lease agreement between Sui Generis and Alpha contained a provision stating that if during a period of years, the adjusted cash receipts exceeded $1 million, Alpha would pay to Sui Generis an additional five percent of adjusted cash receipts. Alpha did not honor this provision under the lease. The owner of Alpha, the dentist, attempted to exercise the option to purchase the property Alpha had been leasing from Sui Generis. The owner of the leased property, Delta Dental, conditioned the sale on Alpha's agreement to pay, after the sale, a five-percent charge, similar to the five percent clause in the lease agreement, on a continuing basis after the sale. A dispute arose, and Alpha sued to enforce its option to purchase the property. The court in *Delta Dental Plan* considered the five percent charge that Delta Dental had sought as a condition of the sale. The court determined that the five percent charge violated Minnesota's anti-fee splitting law.[102] Under the state's statute, it was unlawful for a dentist to divide fees, or to pay a commission to a person who sends patients to the dentist for treatment. The court in *Delta Dental Plan* explained that public policy precludes the payment of referral fee, and fee-splitting agreements require a division of labor to be lawful. The court viewed the five percent charge as directly tied to the amount of receipts from patients. It viewed Delta Dental, the health service plan, and the owner of the property to be sold, as engaging in marketing efforts to refer patients to the dental clinic. In finding the five percent charge to be in violation of Minnesota's anti-fee-splitting statute, the court concluded that the law prohibited dentists from dividing fees with those who refer patients for treatment.

Other courts have addressed the splitting of fees in the context of management services arrangements. *Virgiliu Necula, M.D. v. Martin J. Conroy et al.,*[103] involved a physician and radiologist, as a provider under the New York Medicaid program. In that case, the federal court construed and applied New York's fee-splitting statute,[104] and ruled against the physician. The physician established a radiology practice. Under review were contracts at different times that the physician had with two MSOs for management services. Those agreements specified that the MSO would provide facilities, x-ray and other medical equipment as well as non-physician staff and management of the finances for the radiology practice. The physician agreed to pay the MSOs a fixed percentage of his receipts for billing services and a fixed dollar amount for each procedure performed. During the period of these management services agreements, the physician received payments from the New York's Medicaid program. The State audited Medicaid payments made to the physician, and a determination was made that the physician engaged in unlawful fee-splitting under the MSO arrangements. New York's fee-splitting statute prohibited sharing in fees by the physician with the MSO as payment based upon "a percentage of, or is otherwise dependent upon, . . . income or receipts of the licensee . .

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[102] Minn. Stat. § 150A.11.

[103] 2000 U.S. Dist. LEXIS 8928 (S.D. N.Y. June 30, 2000).; *aff'd* 2001 U.S. App. LEXIS 13729 (2nd Cir. 2001).

[104] N.Y. Education law § 6530(19).

. ."[105] The State determined that the physician violated the fee-splitting provision. It thus requested the physician to return Medicaid payments received and also excluded the physician from the State Medicaid program. The physician sought review of the State's actions at several administrative and judicial levels. The district court granted New York's motion for summary judgment. The court affirmed the State's determination that the physician violated the state's prohibition on fee-splitting, and upheld the remedies and sanction imposed by the state.

IX. OBSERVATIONS

The CPMD is a state law driven concept, and is thus one that varies widely from state to state. This variance, of necessity, requires a heightened inquiry in any given case to determine how state law applies to a particular set of facts. Practitioners need to also have an awareness of the fee-splitting rules adopted by many states.

The healthcare industry has looked for ways to adapt to the CPMD because of economic forces and the mounting pressures to collaborate and integrate among medical providers. This is no less so in the present day, with healthcare reform's emphasis on adopting models to promote and reward collaboration among medical providers of varied disciplines.

Through time, the restrictive impacts of the corporate practice ban, in its absolute form, have been reined in either by state enactment of statutory exceptions and amendments to state laws. Legal structures have also been crafted to accommodate, or work around, the reach of the prohibition. To be sure, the corporate practice ban is still a doctrine that retains relevance in many states, necessitating an awareness of the prohibition by those who are participants in healthcare delivery, and the collaborations that arise therefrom.

105 *Id.*

Conceiving a National Gamete Donor Registry: Policy Considerations, Privacy Concerns, and Legal Authority

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I. INTRODUCTION

> *"When my wife and I met in college, the attraction was immediate, and we quickly became inseparable. . . . We married soon after graduation . . . and had three children by the time we were 30. We were both born to lesbians, she . . . had sought out her biological father as soon as she turned 18, as the sperm bank her parents used allowed contact once the children were 18 if both parties consented. I decided to . . . see if my biological father was interested in contact as well. He was, and even though our parents had used different sperm banks, it appears so did our father, as he is the same person. . . . I can't help but think "This is my sister" every time I look at her now. . . . Please help me figure out where to go from here."*[1]

The scenario described in the advice column above, which Professor Naomi Cahn refers to as "accidental incest,"[2] is one of the three main justifications for establishing a nationwide registry to systematically track sperm, egg, and embryo (hereinafter referred to as "gamete") donors and the results of those donations.

Advocates argue that a donor gamete registry, in addition to preventing accidental incest, would facilitate increased access to donors' medical history and outcomes of their previous donations. This information would benefit intended parents and their resulting offspring by informing their reproductive and medical decisions.[3] Consider the case of Anne Morriss and Frances Frei. Their son, who was conceived with donor sperm purchased from a well-known sperm bank, has medium-chain acyl-CoA dehydrogenase deficiency (MCADD), a rare genetic disease that prevents the body from converting fats into sugar.[4] MCADD is a recessive trait, meaning that it develops if "a child inherits two flawed copies of a gene, one from each parent," which has a 25% chance of occurring if both parents are carriers.[5] Morriss was unaware that she was an MCADD carrier until her son was born, and the sperm donor is probably still unaware that he is an MCADD carrier.[6]

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[1] **Emily Yoffe**, Dear Prudence: My Wife Is My Sister, **Slate**, Feb. 19, 2013, 6:15AM, http://www.slate.com/articles/life/dear_prudence/2013/02/dear_prudence_my_wife_and_i_came_from_the_same_sperm_donor.html.

[2] *See generally* Naomi Cahn, *Accidental Incest: Drawing the Line—Or the Curtain?—For Reproductive Technology*, 32 Harv. J.L. & Gender 59, 59–60 (2009) (quoting Libby Purves, *Whose Body is it Anyway?*, **The Times**, Jan. 15, 2008, available at http://www.thetimes.co.uk/tto/opinion/columnists/libbypurves/article2043028.ece) [hereinafter Cahn, *Accidental Incest*].

[3] Michelle Dennison, *Revealing Your Sources: The Case for Non-Anonymous Gamete Donation*, 21 J.L. & Health 1, 14–15 (2007).

[4] **Carolyn Y. Johnson**, *Company Seeks to Make Sperm Banks Safer*, **Bos. Globe**, Oct. 14, 2013, http://www.bostonglobe.com/lifestyle/health-wellness/2013/10/13/company-seeks-make-sperm-banks-safer-but-raises-questions-about-preconception-dna-testing/rIV2rypd3NnRRYQdeszR1M/story.html; **Paul Rincon**, *Genepeeks Firm to Offer "Digital Baby" Screen for Sperm Donors*, **BBC News: Science & Environment**, Oct. 4, 2013, http://www.bbc.co.uk/news/science-environment-24398312.

[5] Johnson, *supra* note 4.

[6] *See, e.g.*, **Jennifer Bleyer**, *A Conception Conundrum*, **Psychol. Today**, Nov. 5, 2013, at 78, 85, *available at* http://www.psychologytoday.com/articles/201310/conception-conundrum)(noting "dozens of documented cases" where donated sperm is still on the market even though children

While sperm banks screen donors for the most common genetic diseases, they do not currently screen donors to see if they are recessive carriers for rare genetic conditions. Morriss has now cofounded GenePeeks, a company that simulates the reproductive process to determine the hypothetical offspring's risk for single-gene recessive conditions. This information will inform intended parents' choice of donor by signaling out donors whose genetic material, when combined with the donor's sperm or egg, could result in illness. A gamete donor registry would allow parents to view this information prior to purchasing donor gametes, and allow the donor and any resulting children to share relevant medical history or genetic information with each other and with any other donor offspring.

Finally, children born from gamete donations are increasingly borrowing from the adoption rights movement[7] in claiming a psychological benefit from knowing (perhaps even a right to know) their genetic origins, including the identifying information of their gamete donors,[8] and to establish relationships with their genetic half-siblings. Consider *Generation Cryo*, a new reality show on MTV that "follows Breeanna, daughter of a lesbian couple who was conceived through sperm donation—'Grandma signed for the sperm,' her parents tell her—on a search to connect with her genetic half siblings and, ultimately, her sperm donor."[9] Family law is not necessarily equipped to handle these demands.[10] The legal limitations of guaranteeing a "right to know" one's genetic origins do not diminish the psychological importance of genetic ties for identity formation.[11] A gamete donor registry would facilitate these connections for those who want to make them.

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conceived with that sperm suffer from genetic conditions); **Nathalia Holt**, *Weaving together the DNA of parenthood*, **SciLogs**, Oct. 31 2012, *available at http://www.scilogs.com/backstory/weaving-together-the-dna-of-parenthood/* (discussing how a parent may unknowingly carry a recessive trait such as MCADD).

7 Naomi Cahn, *Necessary Subjects: The Need for a Mandatory National Donor Gamete Databank*, 12 DePaul J. Health Care L. 203, 213–214 (2009) [hereinafter Cahn, *Necessary Subjects*].

8 Dennison, *supra* note 3, at 16–19.

9 Jon Caramanica, *Half Siblings Linked by a Mystery Father: MTV's "Generation Cryo" Links Families*, **N.Y. Times**, Nov. 24, 2013, http://www.nytimes.com/2013/11/25/arts/television/mtvs-generation-cyro-links-families.html?_r=0.

10 For example, the Supreme Court of Appeals of West Virginia recently dismissed a petition asserting a right to sibling visitation with the petitioner's half-sibling who was conceived with the same anonymously-donated sperm because the state's custody and visitation statute only confers parents, not siblings, with visitation rights. Bobbie Jo R. v. Traci W., No. 11-1753, 2013 WL 2462173 at *2 (W. Va. June 7, 2013)(unpublished opinion)(dismissing a petition asserting a right to sibling visitation with the petitioner's half-sibling who was conceived with the same anonymously-donated sperm because the state's custody and visitation statute only confers parents, not siblings, with visitation rights).

11 Jean Benward et al., *Maximizing Autonomy and the Changing View of Donor Conception: The Creation of a National Donor Registry*, 12 DePaul J. Health Care L. 225, 232–34 (2009). *But see* H.M.W. Bos & N.K. Gartrell, *Adolescents of the U.S. National Longitudinal Lesbian Family Study: The Impact of Having a Known or an Unknown Donor on the Stability of Psychological Adjustment*, 26 Hum. Reprod. 630, 636 (2011) ("Our findings indicate that donor type has no bearing on the development of the psychological well-being of the offspring of lesbian mothers over a 7-year period from childhood through adolescence.").

In the last few years, dozens of academics, practitioners, and students have written law review articles debating the merits and pitfalls of anonymous gamete donation. Those in favor of non-anonymous gamete donation often advocate two concomitant policy proposals: the creation of a national gamete donor registry,[12] and a requirement that all gamete donations be "open"—that the resulting children have access to their donors' information at the age of majority.[13] Those against mandatory open gamete donation argue that this policy would compromise the fundamental privacy rights of both the intended parents and the donors.[14] As scholars debate the merits of mandatory open gamete donation, the assisted reproductive technology (ART) industry is trending toward non-anonymous gamete donation. More clinics are providing an open donation option,[15] donor-conceived children and their parents are creating or joining private online donor registries to find their genetic relatives.[16] Donor-conceived children are using the Internet to track down their donors, regardless of whether the clinic guaranteed donor anonymity.[17] Despite the real consumer demand for more information about gamete donors, the current ad-hoc response to this demand is inadequate because participation in existing registries is voluntary and the donor medical history that clinics and banks require is not systematically tracked across different clinics or after donation occurs.[18]

Given these shortcomings, the United States needs a national donor gamete registry to standardize information across states and industry, provide equal access to donor information, and facilitate connections with genetic relatives while respecting the privacy rights of donors and parents. This paper proposes a national donor gamete

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[12] Cahn, *Necessary Subjects*, *supra* note 7, at 223.

[13] *Id*. *But see* Mary Patricia Byrn & Rebecca Ireland, *Anonymously Provided Sperm and the Constitution*, 23 Colum. J. Gender & L. 1 (2012) (arguing that while a donor registry is good policy, offspring do not have a right to know a donor's identity).

[14] Nicole J. Messing, Note, *Protecting a Man's Right to Choose: Why Mandatory Identity Release for Sperm Donors Is a Bad Idea*, 16 Mich. St. U. J. Med. & L. 429 (2012) (arguing against mandatory identity release legislation because it would violate individuals' constitutionally protected right to privacy with regard to reproduction); Julie L. Sauer, Comment, *Competing Interests and Gamete Donation: The Case for Anonymity*, 39 Seton Hall L. Rev. 919 (2009) (arguing that states should balance the privacy interests of parents, children, and donors by permitting, but not requiring, open donation).

[15] Andrea Mechanick Braverman, *How the Internet Is Reshaping Assisted Reproduction: From Donor Offspring Registries to Direct-to-Consumer Genetic Testing*, 11 Minn. J. L. Sci. & Tech. 477, 485 (2010).

[16] Donor Sibling Registry, https://www.donorsiblingregistry.com (last visited Jan. 3, 2014).

[17] Dawn R. Swink & J. Brad Reich, *Caveat Vendor: Potential Progeny, Paternity, and Product Liability Online*, 2007 BYU L. Rev. 857, 857–58 (2007) ("Recently a fifteen-year-old boy decided to track down his genetic father. He sent a swab of his own saliva to an online DNA lab. He waited nine months for initial results to return. He then gathered additional information from his mother about his sperm donor father (year of birth, hometown, and surname) and commissioned an online investigation service to determine the true match. Within ten days, the boy met his biological father. Is this an isolated case? No.").

[18] *See* **Rene Almeling**, *The Unregulated Sperm Industry*, **N.Y. Times**, Nov. 30, 2013, http://www.nytimes.com/2013/12/01/opinion/sunday/the-unregulated-sperm-industry.html [hereinafter Almeling, *The Unregulated Sperm Industry*] ("In the United States, we do not track how many sperm donors there are, how often they donate, or how many children are born from the donations.").

registry that mandates a basic level of donor participation, but does not require donors to disclose any identifying information or impose a post-donation obligation to update their medical histories unless they agree to do so. This approach, while modest, would be a huge step forward from the current laissez-faire state of gamete donation. It would respond to the three main consequences of donor anonymity—accidental incest, limited access to medical history, and the psychological desire to know one's genetic origins—without establishing undue state intrusion into the protected rights associated with individual health information and family privacy.

This paper will fill a gap in the literature by delving into the concrete details of what a national donor gamete registry would actually look like, the legal authority for establishing it, and how it would be implemented. A national gamete donor registry raises several legal and policy questions. Should all clinics and donors be required, or merely encouraged, to participate in the registry? What are the HIPAA implications of creating such a registry? Would only donors and offspring have access to the registry, or would it also be open to clinics, researchers, or commercial entities, or even the public at large? Does the federal government already have the authority to establish a registry pursuant to the U.S. Centers for Disease Control and Prevention's (CDC's) authority under the Fertility Clinic Success Rate & Certification Act (FCSRCA), or the Food and Drug Administration's (FDA's) regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), or would Congress have to pass a statute? This paper will analyze these questions by considering the U.S. Department of Health and Human Services' (HHS's) increased authority over and involvement with post-market patient and product registries and other electronically stored health information, as well as FDA's assertion of authority over novel ART procedures, to contextualize a national donor gamete registry within the current regulatory atmosphere.

With these legal and policy considerations in mind, this paper proposes that the FDA and the CDC, in collaboration with the American Society for Reproductive Medicine (ASRM), establish a national donor gamete registry that employs a tiered approach to the disclosure of donor information. Tier I would require all fertility clinics and donor gamete banks to disclose donors' health and screening information (that they already collect pursuant to FDA regulations) at the time of donation. In addition, Tier I would mandate that clinics and banks input how many times a donor's gametes had been used for conception, and whether that process had resulted in a successful pregnancy and birth. Finally, Tier I would set a national limit on the number of offspring born from any one donor's contributions.

At the time of donation, the donor would be able to select whether his or her data could be used for research purposes, and would have the option of "upgrading" to a higher tier by agreeing to disclose more information. Tier II would consist of further disclosure of non-medical personal history and physical characteristics, which many donors already disclose to sperm banks (e.g., race, height, weight, education, profession, baby picture, clinic's impressions of donor, etc.). Tier III would require a more complete medical history beyond what the FDA currently requires and would allow the donor to continually upgrade his or her health information and medical history after donation. Finally, Tier IV would retain the donor's identifying information and make that information available to any resulting children at the age of eighteen (if so requested). Regardless of tier, all

children born from donor gametes would be able to view their donor's profile, "link" to that profile to identify oneself as the progeny of that donor to connect to other children born from the same donor (and thus prevent accidental incest), and disclose any relevant genetic condition or medical history that they wish to share.

Part II of this paper summarizes the FDA's and the CDC's current authority over ART, provides background on the donor gamete industry, and introduces the privately-run Donor Sibling Registry. Part III discusses in further detail the policy justifications for a gamete donor registry. Part IV provides an overview of HHS's increasing involvement with post-market product and patient registries, as well as the health privacy concerns involved in this increased surveillance. Part V proposes a national gamete donor registry—a public-private partnership between the CDC, the FDA, and the Society for Assisted Reproductive Technology (SART). Part VI explains the legal authority for creating such a registry, as well as its health privacy implications. Ultimately, this paper contends that a national donor gamete registry would represent an incremental change to existing ART regulation that would complement HHS's existing reliance on post-market surveillance.

II. ASSISTED REPRODUCTIVE TECHNOLOGY: REGULATORY OVERSIGHT & INDUSTRY PRACTICE

A. Fertility Clinic Success Rate & Certification Act

Approximately 61,610 infants, or 1.56% of the total infants born in the United States in 2011,[19] were born as a result of assisted reproductive technology (ART).[20] Despite the exponential growth of ART, a $3 billion dollar industry in the United States,[21] Congress has passed only a single law governing the industry: the Fertility Clinic Success Rate Certification Act of 1992 (FCSRCA).[22] The Act's objective is to prevent fertility clinics from inflating their success rates to attract consumers.[23] FCSRCA serves two main purposes: (1) it instructs the CDC to develop a model embryo laboratory certification program for states to adopt on a voluntary basis,[24] and (2) it requires that all ART

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[19] Brady E. Hamilton et al., Ctrs. for Disease Control and Prevention, Dep't of Health & Human Servs., Births: Preliminary Data for 2011 (National Vital Statistics Report, Vol. 61, No. 5, Oct. 3, 2012), *available at* http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_05.pdf.

[20] *Assisted Reproductive Technology (ART)*, CDC, http://www.cdc.gov/art/ (last visited Nov. 3, 2013).

[21] *Issues: Assisted Reproductive Technologies*, **Pro-Choice Alliance for Responsible Research**, http://prochoicealliance.org.s66061.gridserver.com/Assisted-Reproductive-Technologies (last visited Nov. 5, 2013).

[22] Fertility Clinic Success Rate Certification Act of 1992 (FCSRCA), Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. §§ 201, 263a(1-7) (2012)).

[23] *See* Brenda Reddix-Smalls, *Assessing the Market for Human Reproductive Tissue Alienability: Why Can We Sell Our Eggs But Not Our Livers?*, 10 Vand. J. Ent. & Tech. L. 643, 659 (2008).

[24] FCSRCA § 3, 42 U.S.C. § 263a-2. No state has adopted the certification program. Yaniv Heled, *The Regulation of Genetic Aspects of Donated Reproductive Tissue: The Need for Federal Regulation*, 11 Colum. Sci. & Tech. L. Rev. 243, 251 n.38 (2010).

programs annually report their pregnancy success rates[25] to the CDC, which must publish this information in a publicly-available annual report.[26] The Act delegates authority to the CDC to establish procedures to approve outside accreditation organizations to inspect and certify embryo laboratories on its behalf.[27] FCSRCA explicitly prohibits the CDC from regulating the practice of ART medicine in developing its embryo laboratory certification program.[28] Although Congress defined ART for purposes of the statute,[29] it unequivocally delegated authority to HHS to amend the definition through notice-and-comment procedures.[30] In its final notice concerning pregnancy success reporting requirements, the CDC clarified that ART does not include artificial insemination;[31] therefore, ART clinics do not have to report pregnancy success rates for patients who only receive donor sperm (e.g., use their own eggs and do not undergo IVF).

To collect ART clinic data on pregnancy success rates, CDC chose to partner with the Society for Assisted Reproductive Technology (SART), a national ART professional organization that had started collecting similar cycle-specific data from its members in 1986.[32] Building on this practice, the CDC's original contract with SART mandated that SART perform random validation site visits to reporting clinics.[33] In response to commenters' concerns about the CDC "ceding its regulatory authority to a private entity," the CDC explained that its partnership with SART, and reliance on its existing data system, would be more efficient than duplicating clinics' reporting burdens by creating another reporting system; the CDC emphasized that it would "maintain[] ultimate control and authority" over the data collection and validation process.[34] In 2006, the CDC launched the National ART Surveillance System (NASS) to collect ART data, though SART member clinics may still report their data to SART, which in turn reports it to NASS.[35] The CDC still refers to SART, as well as the American Society for Reproductive Medicine (ASRM) (SART's parent organization), as partners

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[25] Basically, the number of live births per the number of ovarian stimulation procedures or oocyte retrieval procedures. FCSRCA § 2(b)(2), 42 U.S.C. § 263a-1(b)(2).

[26] FCSRCA § 6, 42 U.S.C. § 263a-5.

[27] FCSRCA § 4, 42 U.S.C. § 263a-3.

[28] *Id.* § 3(i), 42 U.S.C. § 263a-2(i).

[29] "The term 'assisted reproductive technology' means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer . . . ." FCSRCA § 8(1), 42 U.S.C. § 263a-7(1).

[30] FCSRCA § 8(1), 42 U.S.C. § 263a-7(1).

[31] Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,310, 53,313 (Sept. 1, 2000).

[32] *Id*. at 53,311.

[33] *Id.*

[34] *Id.*

[35] *National ART Surveillance*, Ctrs. for Disease Control and Prevention, http://www.cdc.gov/art/NASS.htm(last updated July 24, 2012).

> who are involved in framing the surveillance and research questions and in collecting and reporting data from member clinics. Other important partners who represent consumers of ART and infertility services include RESOLVE . . . , the American Fertility Association . . . , and most recently, Fertile Hope . . . . These organizations provide ongoing consultations about the ART Report and its use for public health communications and education.[36]

In addition to the pregnancy success rate data, the CDC also requires that ART clinics report data on whether they provide ART services to single women, their patients' ethnicities, and whether they are members of SART, as well as whether the ART clinics use laboratories that are accredited by three industry accreditation programs.[37] The FCSRCA itself does not mandate collection of any data beyond pregnancy success rates. In response to commenters' concerns that ART clinics were being required to report too much information, the CDC explained that its reporting requirements were developed "with consideration for the spirit" of the FCSRCA.[38] The CDC explained that it was mandating provision of the information "as a public service" because stakeholders had indicated that such information is useful and would assist consumers in a "thorough and complete analysis, which will help in their goal of making an informed decision about ART."[39] The CDC thus already has a policy of requiring ART clinics to report more information than the FCSRCA mandates.

B. FDA's Human Cells, Tissues, & Cellular & Tissue-Based Products Regulation

In 1997, the FDA asserted its authority over donor gametes, along with other human cells, tissues, and cellular and tissue-based products (HCT/Ps), when it published a proposed regulatory scheme for cellular and tissue-based products pursuant to its regulatory authority over biologics.[40] The FDA's first regulation established a mandatory registration and listing program for HCT/Ps.[41] The FDA employed a "tiered, risk-based approach . . . to exert only the type of government regulation necessary to protect the public health."[42] Some HCT/Ps—including donor gametes[43]—are regulated only to the extent that they pose a risk of communicable disease transmission under Section 361 of the Public Health Service Act (PHSA). The FDA regulates other HCT/Ps under a broader scope of authority as biological products under Section 351 of the PHSA or as

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[36] *Id*.

[37] Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. at 53,313.

[38] *Id*. at 53,312.

[39] *Id.*

[40] FDA, Proposed Approach to Regulation of Cellular and Tissue-Based Products 6 (1997).

[41] *See generally* Human Cells, Tissues and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001) (codified at 21 C.F.R. pt. 1271).

[42] *Id*. at 5448.

[43] FDA, Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Small Entity Compliance Guide 4 (2007) (including "reproductive cells and tissues (e.g., semen, oocytes, embryos)" in its list of HCT/Ps regulated solely under Section 361 of the Public Health Service Act (PHSA)).

drugs or devices under Section 510 of the Food, Drug, and Cosmetics Act (FDCA).[44] Various ART providers and clinics objected to the FDA's regulation of donor gametes given the Fertility Clinic Success Rate Certification Act's prohibition on regulating the practice of ART medicine.[45] In response, the FDA claimed that this regulation would not be "duplicative" because the FCSRCA does not focus on the prevention of communicable disease transmission.[46] The second HCT/P regulation established mandatory screening and testing procedures for tissue donors to prevent communicable disease transmission.[47] Donor gametes must be screened for HIV, Hepatitis B, Hepatitis C, syphilis, Chlamydia, and gonorrhea; donated sperm must also be screened for Human T-lymphotropic virus and cytomegalovirus.[48] In addition, HCT/P establishments must conduct a "donor medical history interview" to screen the gamete donor's medical records and relevant social behavior for communicable disease risk factors.[49] These testing and screening requirements do not apply to gametes donated for autologous (one's own) use, for use by a sexually intimate partner, or to embryos donated by individuals who did not undergo a donor-eligibility determination[50] when they donated the original sperm or eggs that resulted in the embryo(s).[51] If a gamete donor is donating to a specific person, the FDA does not prohibit that donor from doing so, even if he or she fails the

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[44] Human Cells, Tissues and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. at 5448–49; *see also* Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 Hous. J. Health L. & Pol'y 1, 12, 15 (2002) (noting the expansive statutory definitions of biological products and devices).

[45] *E.g.*, Comment on Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products from András Z. Széll, Alta Bates Med. Ctr., to Dockets Mgmt. Branch, FDA (Jan. 26, 1999), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-1997-N-0011-0041; Comment on Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products from Wayne S. Maxson, Nw. Ctr. for Infertility and Reprod. Endocrinology, to Dockets Mgmt. Branch, FDA (Jan. 13, 1999), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-1997-N-0011-0040. Another fertility doctor's comment asserted that the registration requirements should not apply to in vitro fertilization or egg retrieval or donation because those medical practices involve treating patients, not manufacturing products, and the FDA does not have the mandate to regulate the practice of medicine. Comment on Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products from Sherman J. Silber to Dockets Mgmt. Branch, FDA (Jan. 8, 1999) *available at*http://www.regulations.gov/#!documentDetail;D=FDA-1997-N-0011-0038.

[46] Human Cells, Tissues and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. at 5452–53.

[47] Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,786 (May 25, 2004) (codified at 21 C.F.R pt. 1271). The FDA's third HCT/P regulation established practices and methods for HCT/P manufacture, recordkeeping, labeling, and reporting. Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. 68,612 (Nov. 24, 2004) (codified at 21 C.F.R. pt. 1271, subpart D–E).

[48] FDA, Compliance Program Guidance Manual: Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Attachment C—Donor Testing (2012).

[49] FDA, Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) 11 (2007).

[50] "A conclusion that a donor is either eligible or ineligible to donate cells or tissues to be used in an HCT/P, based on the results of donor screening . . . and testing . . . ." *Id*. at 2.

[51] 21 C.F.R. §§ 1271.90(a)(2)–(3) (2012).

donor-eligibility determination, as long as the clinic ensures the recipient's informed consent.[52] In summary, the FDA established its intent to regulate donor gametes solely for the purpose of preventing communicable disease, not to assert authority over ART procedures themselves.

C. The Donor Gamete Industry

Donor gametes include sperm, eggs, and embryos. Donor sperm is by far the most common donor gamete because the "low-tech" artificial insemination procedure has been around for decades.[53] However, as medical and storing technology advances, the donor egg market is increasing.[54] Embryo donation for procreation is frequently offered as an option for unused embryos after an IVF cycle. As of 2003, there were approximately 400,000 embryos in storage in IVF clinics in the United States.[55] While that number has likely grown over the past decade, only about two percent, or 8,000 of those 400,000 embryos, were designated for donation for procreation.[56] My proposal for a donor gamete registry includes sperm, egg, and embryo donors because all three types raise the same policy concerns.[57] Before addressing these concerns, it is useful to understand the basics of the egg and sperm donor markets.

The egg and sperm donor markets are very selective. Sperm banks claim that they accept only one to two percent of men who apply,[58] while egg banks reject over eighty percent of applicants.[59] Most sperm banks, in addition to requiring that donors have high sperm counts to survive the cryogenic freezing process, require donors to "be between the ages of eighteen and thirty-eight, be a minimum height (usually around 5'8"), have a college degree or be a currently enrolled college student, not use tobacco or alcohol heavily, and be able to make weekly visits to the sperm bank to donate for some minimum period."[60] Most sperm and egg donors are young, single, and White.[61] Sperm donors are usually college-educated, while egg donors "have lower levels of education and socioeconomic status than do sperm donors, and are more likely to have children of their own."[62]

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[52] *Id.* §1271.65(b)(1)(ii).

[53] *Cf.* Susan L. Crockin & Howard W. Jones, Legal Conceptions: The Evolving Law and Policy of Assisted Reproductive Technologies 133 (2010) (noting that "both legislatures and courts have had decades of experience" dealing with the legal issues surrounding sperm donation.

[54] Almeling, *The Unregulated Sperm Industry*, *supra* note 18 ("Now that scientists have figured out how to successfully freeze eggs, egg banks are being established, and the scale of production may eventually lead to the same challenges sperm banks face.").

[55] David I. Hoffman et al. *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 Fertility & Sterility 1063, 1066 (2003).

[56] *Id.*

[57] *See infra* Part III.

[58] Bleyer, s*upra* note 6, at 82.

[59] Rene Elmeling, *Selling Genes, Selling Gender: Egg Agencies, Sperm Banks, and the Medical Market in Genetic Material*, 72 Am. Soc. Review 319, 328 (2007) [hereinafter Almeling, *Selling Genes, Selling Gender*].

[60] Kimberly D. Krawiec, *Sunny Samaritans and Egomaniacs: Price-Fixing in the Gamete Market*, 72 Law & Contemporary Problems 59, 69 (2009).

[61] *Id.*

[62] *Id*. at 64, 69.

Because the pool of eligible sperm donors is so small, sperm banks require men to donate sperm over a period of time, usually nine months to a year, "resulting in large caches of genetic material that can produce tens and perhaps even hundreds of offspring."[63] Receiving around $75 per donation, which they make one to two times per week, sperm donors can make over $7,000 over the course of a year.[64] Men cite financial motivations as their primary incentive to donate.[65] Women, on the other hand, cite altruism as their principal motivation.[66] Women are paid more than men per donation—typically $5,000 per donation—because the egg extraction process is much more intrusive and carries health risks.[67] Regardless of a donor's motivation, current FDA regulatory procedures prohibit gamete banks from sharing information about each other's donors,[68] creating a loophole that allows a man to donate to multiple sperm banks.[69]

D. The Donor Sibling Registry

The CDC's and FDA's regulatory authority over ART does not currently extend to after the birth of a child[70] or, in the case of gamete donors, to after that donation occurs.[71] Children conceived with donor gametes are limited in their ability to track down gamete donors or connect to other people born with the same donor gamete(s) because ART clinics may close down, lose records, or simply not provide post-birth services.[72] Wendy Kramer, the mother of a child conceived with donor sperm, founded the Donor Sibling Registry (DSR) in 2000 to fill this gap.

The DSR allows individuals conceived with donor gametes to "make mutually desired contact with others with whom they share genetic ties."[73] Donor-conceived children or gamete donors can, for a small fee, become members of the DSR, then affiliate with a gamete bank or fertility clinic and provide their "donor number" (the ID number

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[63] Almeling, *The Unregulated Sperm Industry*, *supra* note 18. *See also* Krawiec, *supra* note 59, at 69 (stating that the typical time commitment for sperm donors is nine months).

[64] Rene Almeling, *"Why Do You Want to Be a Donor?": Gender and the Production of Altruism in Egg and Sperm Donation*, 25 New Genetics & Soc'y 143, 144 (2006) [hereinafter Almeling, *Why Do You Want to Be a Donor*] (noting that men must sign a contract agreeing to "abstain[] from sexual activity for 48 hours before each visit"). *But see* Almeling, *Selling Genes, Selling Gender*, *supra* note 58, at 320 ("[M]en are paid only for samples deemed acceptable based on sperm count and quality, things that can be negatively affected by stress, sickness, or having abstained for fewer than 48 hours.").

[65] Almeling, *Why Do You Want to Be a Donor*, *supra* note 63, at 143.

[66] *Id*.

[67] *Id*. at 144 ("For these fees, women take fertility medications and undergo outpatient surgery, a process that is usually complete in about six weeks.").

[68] *See infra* note 84 and accompanying text.

[69] *See supra* note 1 and accompanying text.

[70] *See* Judith Daar, *Federalizing Embryo Transfers: Taming the Wild West of Reproductive Medicine?*, 23 Colum. J. Gender & L. 257, 262–63 (2012) (noting that CDC measures ART success by rates of pregnancies and live births).

[71] 21 C.F.R. § 1271.55 (2012) (outlining the records that must accompany a gamete donation).

[72] *See infra* notes 90–92 and accompanying text.

[73] *Our History and Mission*, Donor Sibling Registry, https://www.donorsiblingregistry.com/about-dsr/history-and-mission (last visited Nov. 5, 2013)

associated with the donor that the clinic shares with intended parents). The DSR "matches" children to their donors or their genetic half-siblings through the donor numbers. The DSR has over 41,600 members and has facilitated contact between more than 10,700 genetic relatives.[74] Participation in the DSR, a non-profit organization, is completely voluntary, so membership is not comprehensive, and depends on those who know that the DSR exists and are willing to pay the membership fee.[75] A national, mandatory registry is necessary to centralize donor gamete information to guarantee a unified system of the most essential information that clinics are mandated by law to collect and report to the FDA and CDC.

III. POLICY CONSIDERATIONS FOR A NATIONAL GAMETE DONOR REGISTRY

Academics and policymakers point to three justifications for a national, mandatory gamete donor registry: (1) to standardize information and requirements across states and the private industry, particularly regarding a nationwide limit on the number of gamete donations or resulting pregnancies per donor; (2) to increase access to donors' medical information beyond the snapshot provided at the time of donation; and (3) to recognize the benefits of knowing one's genetic origins, which include connecting with genetic half-siblings and preventing accidental incest. While scholars generally frame these three points around the child's perspective, they also acknowledge the privacy interests of the donors and parents. I will explore these points in greater detail below.

A. Standardizing Donor Information & Requirements Across States & Industry

The FDA's regulations on donor gametes and the CDC's requirements pursuant to the Fertility Clinic Success Rate & Certification Act (FCSRCA) are supplemented by state and industry regulation.[76] The Society for Assisted Reproductive Technologies (SART) requires that member clinics, which represent over 90% of U.S. fertility clinics,[77] adhere not only to state medical licensing requirements, but also to SART's ethics and practice

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[74] Donor Sibling Registry, *supra* note 16.

[75] The California Cryobank, one of the country's largest gamete banks, runs a similar registry for its clients. Participation is optional; those who enroll have access to half-siblings' profiles and contact information. *Sibling Registry*, Cal. Cryobank, http://www.cryobank.com/Services/Sibling-Registry/ (last visited Nov. 3, 2013). Genetisafe is another company that provides "donor profile storage, updated donor genetic and health information, and facilitated anonymous communication with the donor" if amenable. Genetisafe, LLC, http://genetisafe.com/frmAcceptAgreement.aspx (last visited Nov. 3, 2013).

[76] Prac. Comm., Am. Soc'y Reprod. Med. & Prac. Comm., Soc'y Assisted Reprod. Tech., Recommendations for Gamete and Embryo Donation: A Committee Opinion 2 (2012) ("In some instances, the federal [HCT/P] requirements may be less rigorous than those in the state in which an individual practice is located or than those recommended by ASRM and . . . SART.") [hereinafter Recommendations for Gamete and Embryo Donation]. *See also* Messing, *supra* note 14, at 440 ("Some of the major criticisms of the FDA regulations are: (1) the lack of a requirement for genetic testing; (2) the lack of limitations on the number of times one person can donate and a limitation on the number of live births per donor; and (3) the lack of a network for tracking the children actually conceived as a result of these donations.").

[77] Am. Soc'y Reprod. Med., Oversight of Assisted Reproductive Technology 9 (2010).

committee guidelines.[78] These guidelines encourage clinics to limit the number of pregnancies resulting from each donor; however, SART refrains from setting a firm limit given the regional variation in population and geography:

> It is difficult to provide a precise number of times that a given donor can be used because one must take into consideration the population base from which the donor is selected and the geographic area that may be served by a given donor. It has been suggested that in a population of 800,000, limiting a single donor to no more than 25 births would avoid any significant increased risk of inadvertent consanguineous conception. This suggestion may require modification if the population using donor insemination represents an isolated subgroup or if the specimens are distributed over a wide geographic area.[79]

Comparing the practices of the Fairfax Cryobank and the California Cryobank, two of the largest sperm banks in the United States,[80] demonstrates how sperm banks vary in their approach to limits on the number of pregnancies from a single donor. The Fairfax Cryobank limits sales of a donor's sperm when twenty-five children are born from that donor in the United States (though it will distribute further donations for "sibling pregnancies").[81] The California Cryobank, on the other hand, is more cryptic about its limitations, stating on its website that it "has taken steps to resolve concerns regarding the number of live births per sperm donor. Each donor is limited by the length of time he remains active in the program. Most donors remain in the program anywhere between 12 and 18 months."[82] Thus it is unclear exactly how California Cryobank limits a donor's sales, or whether there is even a limit of sales per live births at all.

A determined gamete donor could circumvent SART's non-binding guidelines[83] by donating to multiple clinics (as the sperm donor in the Slate column did).[84] The current regulatory scheme does not allow ART clinics to share information with each other about individual gamete donors.[85] A national, mandatory gamete donor registry would prevent this practice because each clinic would have access to that individual's donor history

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[78] *Id.*

[79] Recommendations for Gamete and Embryo Donation, *supra* note 75, at 53. Cahn warns that these advisory limits may not be sufficient given American mobility. Cahn, *Accidental Incest*, *supra* note 2, at 83.

[80] Gina Kolata, *Psst! Ask for Donor 1913*, N.Y. Times, Feb. 17, 2007, http://www.nytimes.com/2007/02/18/weekinreview/18kolata.ART.html?_r=0.

[81] *Limitations on Donor Births*, Fairfax Cryobank, http://www.fairfaxcryobank.com/ReadFirst.shtml (last visited Nov. 3, 2013).

[82] *California Cryobank Policy of Openness*, Cal. Cryobank, http://www.spermbank.com/newdonors/index.cfm?ID=6 (last visited Nov. 3, 2013).

[83] Cahn, *Necessary Subjects*, *supra* note 7, at 213.

[84] Dennison, *supra* note 3, at 16.

[85] See *infra* Part III.B about federal regulation of protected health information. *Cf.* Nanette R. Elster & Andrea Braverman, *The Future Is Now: A Voluntary Gamete Donor Registry is Feasible*, 12 DePaul J. Health Care L. 195, 197 (2009) (noting that a centralized donor gamete registry "would enable ART programs to share information with one another about donors").

across all ART clinics.[86] Great Britain's Human Fertilisation and Embryology Authority requires that all ART clinics report information on all donor cycles, including a donor's identifying information and the outcome of any treatment.[87] A firmer, nationwide limit on gamete donations would lower the risk of accidental incest[88] and minimize disease transmission associated with a particular donor.[89]

B. Broader Access to Medical History

Intended parents have access to the medical history that the donor provides to the clinic. However, this information is not comprehensive because clinics cannot screen donors for "every known genetic condition,"[90] nor are they required to do so because FDA's authority over donor gametes is limited to preventing communicable disease transmission. Furthermore, donors' medical history is not necessarily updated after donation,[91] and clinics' recordkeeping practices vary widely.[92] ART clinics do not communicate with a donor's primary care doctor, and there is no mechanism in place that requires donors or resulting offspring to update the clinic when they discover new medical conditions that could impact their genetic relative(s).[93] Genetic history is becoming increasingly important in disease diagnosis and treatment.[94] A gamete donor registry could preserve donor medical information, allow donors to update their medical

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[86] Clinics could be required to collect social security numbers or other individually identifying information. *Cf.* Cahn, *Necessary Subjects*, *supra* note 7, at 218 ("A federal-level structure could more efficiently and effectively implement any large-scale collection of information and oversight of the process.").

[87] *Directions Given Under the Human Fertilisation & Embryology Act 1990 as Amended*, Hum. Fertilisation & Embryology Auth., http://www.hfea.gov.uk/docs/2009-06-03_GENERAL_DIRECTIONS_0005_Collecting_and_recording_information_for_the_HFEA_-_approved.pdf (last visited Nov. 3, 2013).

[88] Dennison, *supra* note 3, at 16.

[89] *See* Cahn, Cahn, *Accidental Incest*, *supra* note 2, at 102–03 (noting that five children in Michigan conceived by the same sperm donor share the "extremely rare disease of congenital neutropenia"). This limit would also mitigate the health risks associated with repeated egg donation. *Id*. at 99–100.

[90] Vardit Ravitsky, *"Knowing Where You Come From": The Rights of Donor-Conceived Individuals and the Meaning of Genetic Relatedness*, 11 Minn. J.L. Sci. & Tech 655, 672 (2010). *But see* Mary Crane, *Sperm for Sale*, Forbes, Feb. 9, 2007, http://www.forbes.com/2007/02/09/spermbank-fertility-fda-ent-manage-cx_mc_0209bizoflovesperm.html ("'I've been married to my wife for 38 years and she doesn't even know as much about me as parents know about their donors with our long-form medical history,' says Dr. Cappy Rothman, who founded the California Cryobank in 1976.").

[91] *See* Recommendations for Gamete and Embryo Donation, *supra* note 75, at 7 (noting that clinics "should" keep records on subsequent follow-up evaluations, and that clinics should "ideally" record the outcome of each clinical cycle to report any adverse outcomes or genetic diseases identified later on).

[92] Ravitsky, *supra* note 89, at 672.

[93] *See id.* at 673 (noting that most donors are young and healthy at the time of donation, but many donors fail to update the clinic with their medical history as they age and new conditions emerge); s*ee also* Benward et al., *supra* note 11, at 230 (reporting that there is no evidence that programs have a way to indefinitely main records, and concluding that the current system of tracking outcomes and maintaining information is deficient).

[94] Dennison, *supra* note 3, at 14.

history themselves after donation, allow children conceived with donor gametes to update relevant genetic information or medical history for the benefit of their donor or their genetic half-siblings, and ensure the availability of this information, even if individual clinics or providers terminate their practice or lose touch with the donors or clients.[95] In the case of egg donation, a registry could track the procedure's long-term health effects on the donor, which are still unknown.[96]

C. Psychological Benefits of Knowing Genetic Origins & Half-Siblings

Professor Vardit Ravitsky notes that the "first generation of donor-conceived offspring is now becoming young adults who are beginning to share their unique perspectives. Many are telling a story of psychological distress. They describe a strong need to know 'where they came from;' to know their genetic origins as an essential part of constructing their identities."[97] This emerging need to know one's genetic origins shares similarities with adopted children's' advocacy around liberalizing adoption records.[98]

In the gamete donor context, Professor Naomi Cahn has noted that the "need to know" has two parts: the need to know that one was conceived through donor gametes, and the need to know the donor's identity,[99] which is broader than a need to know for medical decisionmaking purposes.[100] Professor Ravitsky explains this need as follows:

> The biological aspect of our connection to our past provides a sense of continuity. As we develop a sense of personal identity we constantly refer to 'where we come from' as a way of grounding ourselves, establishing a sense of belonging, or our place in the world. Lack of knowledge about the donor as a person could thus create a gap or a void in the formation of personal identity, undermine a sense of continuity and grounding, and lead to troubling and disruptive feelings of completeness.[101]

However, even this "need to know" does not necessarily have to include a donor's identifying information. It could be at least partially satisfied by knowing a donor's physical and genetic traits, ethnic ancestry, and other facts, such as education, profession, and interests. In fact, most donor gamete banks already collect this information from donors, which intended parents use to decide which donor's gametes to purchase.[102]

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[95] Benward et al., *supra* note 11, at 230. *See also* Messing, *supra* note 14, at 455 ("A voluntary medical-update system would provide a happy medium for donor-conceived children with a need for the information and donors who still wish to remain anonymous.").

[96] Justine Durrell, *Women's Eggs: Exceptional Endings*, 22 Hastings Women's L.J. 187, 229 (2011).

[97] Ravitsky, *supra* note 89, at 665. *See also* Benward et al., *supra* note 11, at 232–34 (explaining the cultural importance of genetic ties for identity formation).

[98] Cahn, *Necessary Subjects*, *supra* note 7, at 206–10 (exploring the similarities and differences in secrecy in the adoption and ART contexts). Of course, no court has recognized a constitutional right to know one's genetic origins. Sauer, *supra* note 14, at 938.

[99] Cahn, *Necessary Subjects*, *supra* note 7, at 218–19.

[100] Ravitsky, *supra* note 89, at 674.

[101] *Id.* at 675.

[102] *Id.* at 676. *See also Donor Search*, Cal. Cryobank, http://www.cryobank.com/Search.aspx?listview=0# (last visited Nov. 3, 2013) (where one can search by height, eye color, hair color,

Given that intended parents value this information, it is unsurprising that resulting offspring do as well.[103]

This "need to know" is not limited to a child's genetic parent; the original purpose of the DSR was to connect genetic half-siblings that shared the same donor.[104] A donor gamete registry can allow half-siblings to connect without revealing a donor's identifying information. While mandating donor identity disclosure is controversial, the SART notes "it is widely agreed that such release is acceptable if all parties agree."[105]

D. Protecting Donors' and Parents' Privacy Rights & Choices

Various academics have noted that requiring parents to tell their children that they were conceived as a result of gamete donation would not only be difficult to enforce, but could also raise constitutional concerns regarding reproductive choice, family privacy, and child-rearing.[106] No jurisdiction in the world currently mandates that parents tell their children that they were conceived by donor gametes, so one's "need to know" only arises if parents disclose their use of donor gametes.[107] While SART recommends that parents of children born from donor gametes share the circumstances of their children's conception with them, SART recognizes that this is ultimately the parents' choice.[108] Prohibiting anonymous donation could overstate the role of genetics and discount the existing bonds between a child and his actual parents.[109] This emphasis would be particularly problematic for LGBT advocates working to minimize the legal importance of genetic connections to secure equal parenting rights and responsibilities for parents with no genetic or gestational connection to their children.[110] While a national donor gamete registry would clearly be beneficial for increasing access to medical history and

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hair texture, blood type, educational level, areas of study, ethnic origin, ancestry, religion, and celebrity "look-a-likes"). Fairfax Cryobank allows consumers to search by, among other factors, astrological sign, favorite subject, favorite pet, personal goals, talent, and "FaceMatch," which matches an intended parent's and a donor's facial features. *Donor Search*, Fairfax Cryobank, http://donorsearch.fairfaxcryobank.com/ (last visited Nov. 3, 2013).

103 Ravitsky, *supra* note 68, at 676. *See also* Dennison, *supra* note 3, at 17 ("It's hypocritical of parents and medical professionals to assume that biological roots won't matter to the 'products' of cryobanks' service, when the longing for a biological relationship is what brings customers to the banks in the first place." (quoting a teenager born from an anonymous sperm donor)).

104 *Our History and Mission*, Donor Sibling Registry, https://www.donorsiblingregistry.com/about-dsr/history-and-mission (last visited Nov. 3, 2013) ("The Donor Sibling Registry was founded in 2000 to assist individuals conceived as a result of sperm, egg or embryo donation that are seeking to make mutually desired contact with others with whom they share genetic ties.").

105 Ethics Comm., Am. Soc'y Reprod. Med., Informing Offspring of Their Conception by Gamete or Embryo Donation: A Committee Opinion 1, 2 (2013) [hereinafter Informing Offspring of Their Conception].

106 Cahn, *Necessary Subjects*, *supra* note 7, at 219; Ravitsky, *supra* note 89, at 683; Dennison, *supra* note 3, at 19.

107 Ravitsky, *supra* note 89, at 681.

108 Informing Offspring of Their Conception, *supra* note 83, at 45.

109 Sauer, *supra* note 14, at 940.

110 *See* Jennifer S. Hendricks, *Essentially a Mother*, 13 Wm. & Mary J. Women & L. 429, 477 (2007) (noting the "harm that exaltation of genetics works for families with adoptive, same-sex, or other non-traditional sets of parents"). *See also Legal Recognition of LGBT Families*, Nat'l Ctr.

knowing one's genetic origins, it should not cross the line of unnecessary state intrusion into health and family privacy.

IV. HHS RELIANCE ON ELECTRONIC HEALTH DATA & HEALTH PRIVACY OVERSIGHT

Just as the ART industry and its users are trending toward increasing openness, access to clinical trial and patient or product registry data has also become more publicly available.[111] Consequently, creating a national donor gamete registry would be a modest reform that fits into the current atmosphere of creating electronic systems that increase access to important health data. The rise of electronic health records and human subject research data means that the federal government already has the technical skills and systems necessary to safeguard the privacy of participants' protected health information.[112] Outside the ART context, federal involvement and regulation have joined this trend toward transparency. For example, the White House's Office of Science and Technology Policy issued a memorandum in February 2013 instructing agency heads to expand public access to data in federally funded projects.[113] In June of this year, the FDA published a notice and request for comment on a proposal to make available de-identified and masked clinical data from medical product applications.[114]

A national donor gamete registry brings many of the same benefits as those associated with increased access to clinical research data and product registries in general. Researchers and policymakers argue that public access to such data increases public confidence in clinical research, improves drug and product safety and effectiveness, advances scientific development and innovation, and mitigates individual participant risk.[115] However, increasing access to human subject research data also has its downsides: the difficulty of guaranteeing participants' privacy; the potential of poorly conducted, but widely publicized, data analyses that could mislead the public; the possible reduction of incentives for competition and innovation; and the potential to overwhelm regulators and increase costs associated with monitoring data systems.[116] HHS's participation in patient or product registries takes many forms, though it usually does not hold registry or study data exclusively, preferring to work with private or academic partners and

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Lesbian Rts., http://www.nclrights.org/wp-content/uploads/2013/07/Legal_Recognition_of_LGBT_Families.pdf (last visited Nov. 3, 2013).

111 Michelle M. Mello et al., *Preparing for Responsible Sharing of Clinical Trial Data*, 369 New England J. Med. 1651, 1651 (2013) ("Data from clinical trials, including participant-level data, are being shared by sponsors and investigators more widely than ever before.").

112 *Id.* at 1653 (noting that "a leading concern in expanding access to participant-level data is whether the privacy of research participants can be guaranteed").

113 Memorandum from John P. Holdren, Dir., Office Sci. & Tech. Policy, Exec. Office President, to Heads of Exec. Dep'ts & Agencies 1 (Feb. 22, 2013), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.

114 Availability of Masked & De-Identified Non-Summary Safety & Efficacy Data, 78 Fed. Reg. 33,421 (June 4, 2013).

115 Mello et al., *supra* note 110, Table 2.

116 *Id*. at 1653–54.

limiting its role to providing guidance or best practices.[117] I recommend a similar public-private collaboration for the national donor gamete registry, which can build on the best practices of patient and product registries.

A. Examples of HHS Involvement in Clinical Trials & Patient & Product Registries

The 1997 Food and Drug Modernization Act (FDAMA) was the first federal law mandating that the NIH "operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions."[118] The NIH must collect information about federally and privately funded clinical trials for experimental treatments (drug and biological products) for patients with serious or life-threatening diseases or conditions, including the purpose of each experimental drug, patient eligibility criteria, the location of clinical trial sites, and a point of contact for patients wanting to enroll in the trial.[119] The NIH and the FDA implemented this mandate by developing Clinicaltrials.gov, which debuted on February 29, 2000.[120] Clinicaltrials.gov represents a centralized approach to data management, where private researchers and companies are required to submit information to the federal government. I suggest a similar centralized system for a national donor gamete registry, where ART clinics would submit data to a unified government system.

The FDA's approach to pregnancy exposure registries has been more permissive. The agency defines a pregnancy exposure registry as "a **study that collects health information from women who take medicines or vaccines when they are pregnant."**[121] Its website contains a page titled "List of Pregnancy Exposure Registries," where users can search for registries by medical condition or by drug or vaccine. The FDA notes that the agency does not run any of these registries but invites companies that want their registry listed on the cite to contact the FDA Office of Women's Health. In 2002, the FDA released guidance on how to establish pregnancy exposure registries. This guidance notes that a sponsor is free to establish a pregnancy exposure registry on its own at any time; the FDA may also require that the sponsor establish such a registry "under an IND [investigational new drug procedure] before approval or, more typically, as part of a phase 4 commitment [a post-market study required by FDA as a condition of

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[117] M. Nielsen Hobbs, *Registries Rising: FDA Looking at TNF Inhibitors; AHRQ Updates Standards*, Pink Sheet, Aug. 24, 2009, at 8 (noting that disease-based registries are "usually public-private partnerships"). *See also* Agency for Healthcare Research & Quality, Registries for Evaluating Patient Outcomes: A User's Guide 1 (2d ed. 2010) (describing the purpose of the publication as "intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes").

[118] Food and Drug Modernization Act, P.L. 105-115, § 113, 111 Stat. 2296, 2311 (1997).

[119] *Id.*; *see also* Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions 2 (2002).

[120] *About This Cite*, ClinicalTrials.gov, http://clinicaltrials.gov/ct2/about-site/background; http://clinicaltrials.gov/ct2/about-site/history (last visited Nov. 3, 2013).

[121] *List of Pregnancy Exposure Registries*, FDA, http://www.fda.gov/scienceresearch/specialtopics/womenshealthresearch/ucm134848.htm (last visited Nov. 3, 2013).

drug approval]."[122] If the registry records a serious or unexpected adverse event where it is reasonably probable that the drug or product caused that event, the company must report that event to the FDA within fifteen calendar days.[123]

In other words, even if the FDA requires that a company establish a pregnancy exposure registry, the company still has discretion as to how the registry should be run. This approach is arguably already in place in the donor gamete registry realm, given that the Sibling Donor Gamete Registry, as well as other private registries run by individuals or sperm clinics, each runs separate systems that do not communicate with each other. This lack of communication is one of the obstacles that a single donor gamete registry would overcome, making it easier to enforce a nationwide limit on pregnancies per donor.

In addition to tracking particular drugs, other registries track medical devices. In 2011, the FDA shared the results of its internal review of breast implants and a possible association with anaplastic large cell lymphoma (ALCL). In its news release, the FDA announced that it is working with the American Society of Plastic Surgeons and others to create a breast implant registry to improve understanding of this association. In the meantime, the FDA encourages health care providers to report any confirmed ALCL cases. Even though two of the largest breast implant manufacturing companies support the idea of a registry, the FDA and the industry have not been able to agree on who will cover the costs of the registry, whether participation will be mandatory, and related privacy issues.[124] The delay in creating a breast implant registry demonstrates the need to carefully think through the cost, participation, and privacy implications of a donor gamete registry.

The NIH has had more success establishing DS-Connect, the Down Syndrome Registry that launched in September 2013. DS-Connect allows "people with Down syndrome and their family members, researchers, and parent and support groups to share information and health history in a safe, confidential, online database."[125] Users may choose to make their contact information available to researchers for participation in research studies but are not required to do so to create a DS-Connect profile.[126] The NIH de-identifies the data stored in the registry and only shares the data, with users' permission, with approved scientists, clinicians, and drug companies.[127] The NIH Down Syndrome Consortium, a coalition of government officials, researchers, and Down Syndrome advocates, recommended a national registry in 2007 as a vehicle to help achieve general

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[122] FDA Ctr. for Drug Evaluation and Research & Ctr. for Biologics Evaluation and Research, Guidance for Industry: Establishing Pregnancy Exposure Registries 4 (2002).

[123] *Id*. at 15 (citing 21 C.F.R. §§ 310.305(c)(1), 314.80(c)(2)(iii) and (e), 600.80(c)(1), (c)(2)(iii) and (e)).

[124] Anna Yukhananov, *Keeping Patients Safe: The Case for a Breast Implant Registry*, Atlantic, Jan. 5, 2012, http://www.theatlantic.com/health/archive/2012/01/keeping-patients-safe-the-case-for-a-breast-implant-registry/250709/.

[125] *DS-Connect Registry*, NIH Down Syndrome Consortium, http://downsyndrome.nih.gov/registry/Pages/default.aspx.

[126] *Id.*

[127] *Understanding Your Participation in DS-Connect,* NIH, https://dsconnect.nih.gov/en/about-ds-connect/faq.html#12 (last visited Nov. 6, 2013).

Down Syndrome research goals.[128] The NIH justified its authority to create DS-Connect by pointing to congressional directives in the FY2007 House and Senate Appropriations Committee Reports for Labor–HHS–Education.[129] While Down Syndrome advocacy organizations are generally supportive of DS-Connect, individuals have expressed skepticism about the potential for abuse and stigmatization of an already vulnerable population.[130] DS-Connect's experiences could be relevant for a national donor gamete registry, particularly regarding whether donors and offspring would want to make their data accessible to researchers. The social stigma surrounding infertility, single parenthood, and LGBT families is also something to keep in mind when considering opening this data to the public.[131]

Different agencies, along with states and non-profit organizations, can also jointly manage a registry. The NIH and CDC are working together to launch a Sudden Death in the Young Registry. This registry will not be limited to a particular condition; rather, its scope is broad to try to fill the knowledge gap around why sudden death occurs among infants and children.[132] State public health agencies will apply to participate, and the Michigan Public Health Institute will manage the data. Blood samples from a subset of cases will also be collected; the data will not contain personally identifiable information.[133] The collaboration between the CDC, the NIH, and a non-governmental third party provides a model for how the FDA and the CDC could partner with the ASRM to establish a donor gamete registry.

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128 NIH, Research Plan on Down Syndrome 42 (2007).

129 *Id*. at 24 (summarizing language encouraging the NIH to establish a strategic plan for Down Syndrome Research).

130 *See* MsAmericanPatriot, Comment to Shaun Heasley, *National Down Syndrome Registry Goes Live*, disabilityscoop, http://www.disabilityscoop.com/2013/09/09/national-ds-registry-live/18676/ (last visited Nov. 3, 2013) ("Boards like this should NOT be in existence. With Down Syndrome and Autism both demonized by the liberals, this would be used by them to hunt these individuals down. I see NO good come from boards like the one above. It would be abused and the cost could be people with Down or Autism lives. These boards just demonize and chastise us to no end. We should be allowed to live out our lives in PRIVATE and boards like that would NOT allow for it AT ALL."); *see also* Sharona Hoffman & Andy Podgurski, *Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research*, 65 SMU L. Rev. 85, 107–08 (2012) (explaining the potential for group stigmatization if research identifies a group of individuals pre-disposed to a particular illness or condition).

131 *See* Carrie Friese et al., *Older Motherhood and the Changing Life Course in the Era of Assisted Reproductive Technologies*, 22 J. Aging Stud. 65 (2008) (discussing how couples that use donor gametes negotiate identity and stigma associated with infertility); Movement Advancement Project et al, All Children Matter How Legal and Social Inequalities Hurt LGBT Families 2–3 (2011) (summarizing how stigma against LGBT families creates socioeconomic and health obstacles for children). *But see* Julia Medew, *Donor Sperm Families Just As Happy*, Age Nat'l, Dec. 4, 2012, http://www.theage.com.au/national/donor-sperm-families-just-as-happy-20121203-2arab.html (describing results of a study of "donor insemination families" that found that children born through sperm donation are just as psychologically healthy as those born as a result of typical conception).

132 Sudden death is not systematically reported, nor does it have established definitions or standards. Press Release, NIH, *NIH and CDC Launch Registry for Sudden Death in the Young* (Oct. 24, 2013, 9:00 a.m.), *available at* http://www.nih.gov/news/health/oct2013/nhlbi-24.htm.

133 *Id.*

Following FDAMA, Congress has continued to play a role in expanding access to clinical trial and health registry data. The Food and Drug Administration Amendments Act of 2007 (FDAAA) created a nationwide health care data network, the Sentinel Initiative, "to track the safety of drugs, biologics, and medical devices once they reach the market."[134] The Sentinel Initiative will allow FDA "to query multiple data environments" concerning potential product safety problems while effectively managing privacy and security to augment the agency's current surveillance capabilities."[135] However, the original owners will still hold and manage the data, and the FDA, through its contractors, will only able to access de-identified information.[136] Potential sources of this health data include the Centers for Medicaid and Medicare Services, the U.S. Department of Veterans Affairs, the healthcare exchanges created pursuant to the Affordable Care Act (ACA), private insurance companies, and state agencies, among others.[137] The sheer volume of available data that could be included in the Sentinel Initiative, along with the fact that the FDA will "engage private-sector companies to develop and operate the system infrastructure," has raised health privacy and security concerns that are also relevant to any decisions regarding the establishment of a national donor gamete registry.[138]

B. HIPAA Implications of Increased Patient & Product Surveillance

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established federal privacy protections for individually identifiable health information.[139] HHS implemented HIPAA by promulgating the Privacy Rule, which sets national protection standards for the "confidentiality, integrity, and availability of electronic protected health information" that bind health plans, health care clearinghouses, and health care providers.[140] Thus, the Privacy Rule covers health care research concerning human subjects and their medical records, and would apply to the medical information included in a national donor gamete registry.

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[134] FDA's Sentinel Initiative, FDA, http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm (last visited Sept. 30, 2014); *see also* Barbara J. Evans, *The Ethics of Postmarketing Observational Studies of Drug Safety Under Section 505(o)(3) of the Food, Drug, and Cosmetic Act*, 38 Am. J.L. & Med. 577, 582 (2012) (describing FDA's increased authority under Section 505(o)(3)) [hereinafter Evans, *Ethics of Postmarketing Observational Studies*]

[135] Janet M. Marchibroda, eHealth Initiative Foundation, Developing a Governance & Operations Structure for the Sentinel Initiative: A Report to the U.S. Food & Drug Administration 4 (2009).

[136] *Id.*

[137] *Id.* at 21.

[138] Barbara J. Evans, *Congress' New Infrastructural Model of Medical Privacy*, 84 Notre Dame L. Rev. 585, 589 (2009) [hereinafter *Evans*, Congress' New Infrastructural Model]; *cf.* Hoffman & Podgurski, *supra* note 129, at 85 (acknowledging the "tension between realizing societal benefits from medical research and granting individual preferences for privacy").

[139] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified at scattered sections of the U.S.C.).

[140] *Health Information Privacy,* HHS Office for Civil Rights, http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html (last visited Nov. 3, 2013). These three types are known as "covered entities." *Id.*

The Privacy Rule covers any patient information that is identifiable. That information is considered "protected health information,"[141] and patients must authorize its release for use in a research study.[142] The Privacy Rule does not cover de-identified health records.[143] Covered entities are in the "safe harbor" and patient records are considered "de-identified" if they remove eighteen specific items from patient records.[144] However, many experts acknowledge that de-identification procedures are not foolproof.[145] The national donor gamete registry would include protected health information, and thus would be subject to the Privacy Rule.

In addition to the Privacy Rule, HHS administers the HIPAA Security Rule for electronically stored health information.[146] The Security Rule requires a variety of safeguards, but only applies to health plans, clearinghouses, and providers, not to researchers.[147] The Security Rule does not cover de-identified records databases that meet the Privacy Rule's safe harbor standards.[148] Because the national donor gamete registry would be an online registry, it would be subject to the Security Rule in addition to the Privacy Rule.

Researchers can get around the general requirement for patient authorization of protected health information by requesting a waiver from an Institutional Review Board or privacy board (collectively referred to as "IRB").[149] Under the "research purposes" exception, an IRB may grant a waiver if protected health information is necessary for research purposes.[150] In addition, the use of protected health information cannot involve more than a "minimal risk to the privacy of individuals."[151] The "research purposes" exception would be relevant if a national donor gamete registry allowed users to make their identifying information available to approved researchers, similar to DS-Connect.

Another exception to the Privacy Rule that is relevant to donor gamete registries is the public health exception, which allows covered entities to disclose protected health information without a patient's authorization for "public health activities and purposes."

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141 45 C.F.R. § 160.103 (2012).

142 *Id.* § 164.508(b)(3)(i).

143 *Id.* § 160.103 (2012); *see also* Hoffman & Podgurski, *supra* note 129, at 94 ("Consequently, health care providers, including clinicians and medical facilities, can disclose de-identified data to researchers without obtaining patient consent or applying HIPAA's privacy safeguards to the de-identified data.").

144 45 C.F.R. § 164.514(b)(2)(i) (including names, geographic subdivisions smaller than a state, zip code information, relevant dates, telephone and fax numbers, e-mail addresses, social security numbers, medical and health plan numbers, account numbers, vehicle information, URLs, IP addresses, biometric identifiers, "full face" photographic images, and any other "unique identifying" information).

145 *See* Hoffman & Podgurski, *supra* note 129, at 104–107 (explaining the shortcomings of de-identification).

146 45 C.F.R. § 164.302-.318 (2010).

147 Hoffman & Podgurski, *supra* note 129, at 137–138.

148 *Id*. at 138.

149 45 C.F.R. § 164.512(i).

150 *Id.* § 164.512(i)(1)(ii)

151 *Id.* § 164.512(i)(2)(ii)(A).

Cite? The public health exception includes reports for public health surveillance, investigations, interventions authorized by law, or at the direction of a public health authority.[152] This exception would potentially be relevant for any person on the registry who discovered a medical condition that could impact his genetic relatives. For example, if Ann Morriss's son was a user on a national donor gamete registry, he could report that his donor was a genetic carrier of MCADD, alerting the donor and any genetic half-siblings.[153] Covered entities rely on this exception to provide data to an FDA-regulated manufacturer.[154] Any national gamete donor registry will have to comply with the Privacy Rule and the Security Rule and not exceed the scope of the federal government's regulatory authority.

V. PROPOSAL: A TIERED GAMETE DONOR REGISTRY

To comply with the Privacy Rule and remain within the bounds of the federal government's existing regulatory authority, I propose a tiered gamete donor registry under the joint authority of the FDA and the CDC. Tier I will provide a mandatory floor for disclosure, but gamete donors may choose to share more information by participating in Tiers II through IV. This tiered approach complements the Society for Assisted Reproductive Technology (SART) Ethics Committee's categorization of gamete donor information sharing into four levels: (1) non-identifying information, (2) non-identifying contact for medical updates, (3) non-identifying personal information, and (4) identifying personal information.[155] Participation in the donor gamete registry would be limited to those who make donations through a gamete bank; the proposed registry would not require participation of those who donate gametes to a specific person because such donors already have relationships with their donees.

A. Tier I

Tier I would mandate that all ART clinics upload to the registry all donors' health and screening information that clinics already collect pursuant to FDA regulations. In addition, clinics would be obligated to disclose the number of times a donor's gametes are used for conception, as well as the conception and pregnancy outcomes. Tier I would prohibit any ART clinic from selling a donor's gametes after that donation resulted in a certain number of successful pregnancies.[156]

Each donor would have an individual code that clinics would share with intended parents. Children would be able to view the donor's registry profile and "link" to it to identify themselves as offspring to connect to their genetic half-siblings. Children could also update the profile by listing their own relevant medical information.[157] In addition, donors could decide whether their data could be used for research purposes, or

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[152] *Id.* § 164.512(b)(1)(i).

[153] *See supra* notes 4–6 and accompanying text.

[154] Evans, *Ethics of Postmarketing Observational Studies*, *supra* note 133, at 589.

[155] Ethics Comm., Am. Soc'y Reprod. Med., Interests, Obligations, and Rights of the Donor in Gamete Donation Table 1 (2008) hereinafter Donor Interests, Obligations, and Rights].

[156] I refrain from suggesting a specific numerical limit, preferring to defer to scientific authorities for the proper number.

[157] Parents would be authorized to create profiles on behalf of their children.

be only accessible to parents who purchased donor gametes and thus have their donor code. Data available for research purposes would not include individually identifiable information, and thus would not raise HIPAA compliance concerns.

Tier I's requirements would not extend much further than what is already required. The Fertility Clinic Success Rate & Certification Act (FCSCRA) mandates that ART clinics report conception and pregnancy outcomes for ART procedures using donated eggs and embryos. As mentioned earlier, the CDC already requires clinics to report more data than the specific categories mentioned in the statute. Furthermore, HHS already has the authority to amend the "pregnancy success rate" definition to include ART procedures using donated sperm.[158] The FDA's human cells, tissues, and cellular and tissue-based products (HCT/P) regulations already require gamete donors to undergo specific testing and screening procedures;[159] the only additional step would be that clinics would have to enter this data into a database that tracked donors across the country.

Professor Ravitsky notes that "drawing the policy line at the level of medical history and genetic information emphasizes the biomedical meaning of inheritability."[160] In other words, greater access to a donor's medical history is justifiable without the danger of essentializing the importance of genetic ties for other aspects of identity formation.[161] Furthermore, because donors are already required to disclose medical information to their individual clinic, pooling it with other clinics' records does not further intrude on donor privacy, but does limit the possibility of donors circumventing individual clinic donation limits and producing a large number of pregnancies.

B. Tier II

Tier II would allow donors the option of disclosing additional, non-medical history and physical characteristics. The largest sperm clinics already collect much of this information and disclose it to intended parents at various fee levels. This information includes a donor's race, education, and profession, as well as baby pictures, a recording of a donor's voice, and the clinic's impressions of a donor. If donors consented to sharing some or all of this information, the clinic would share this information with the registry along with the information mandated by Tier I. Again, sharing this information could satisfy some donor-conceived children's need for further information without compromising donor anonymity,[162] and it would relieve the individual clinic of being the steward of this information in perpetuity. Neither the FDA nor the CDC's current regulatory authority over ART extends to these characteristics, so this tier must remain

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158 FCSRCA § 8, Pub. L. No. 102-493, 106 Stat. 3146, 3151 (codified at 42 U.S.C. § 263a –7(2006) (defining ART to include "all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, *and such other specific technologies as the Secretary may include in this definition*, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency)" (emphasis added)).

159 21 C.F.R. § 1271.80.

160 Ravitsky, *supra* note 89, at 673.

161 *Id* at 673-74.

162 *Id.* at 677.

voluntary. Because this information is not protected health information that raises the risk of individual identification, it does not raise any HIPAA concerns.

C. Tier III

If donors chose to opt for Tier III, they would provide a more complete medical history beyond what the FDA currently collects to assess risk of communicable disease transmission. In addition, donors could update the registry with their health information and medical history post-donation. This would allow intended parents to make more informed choices when considering which donor gametes to purchase, and would let children conceived with donor gametes to stay continuously apprised of their donors' post-donation medical information even after donation occurred.

SART already recommends that donors provide medical updates when appropriate;[163] however, the FDA does not currently have the legal authority to mandate this information because its scope is limited to risk of communicable disease exposure and transmission prior to donation, and does not include authority over genetic disease prevention.[164] While the CDC already exercises considerable discretion under the FCSRCA by requesting more information that the statute requires, it is unlikely that this discretion could be reasonably interpreted to require individual donors to update their medical history post-donation because this information is not rationally related to the narrow definition of "pregnancy success rates." The purpose of mandating increased disclosure of medical information is not limited to the success of the pregnancies themselves, but rather focuses on the quality of life for the child that results from the pregnancy.

Because neither the CDC nor the FDA currently has the authority to mandate donors to update their information post-donation, this option must remain voluntary. Nonetheless, market forces could play a role in encouraging post-donation medical updates. Clinics could incentivize Tier III by providing higher compensation to or only accepting Tier III donors. The sperm bank industry is already engaged in a donor profile "arms race," where banks feel pressure to add more demographic information about the donor to keep up with the competition.[165] Again, providing medical history, without revealing individual identifying information, would not intrude on donor privacy or raise HIPAA concerns.

D. Tier IV

Tier IV, the highest level of disclosure, would allow the registry to make donors' identifying information available to any resulting offspring that requested it upon reaching eighteen. While neither the FDA nor the CDC has the current authority to require "open donation," this option is already becoming increasingly popular at sperm

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163 Donor Interests, Obligations, and Rights, *supra* note 154, at 4.

164 21 C.F.R. § 1271.1(a). *See* Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 Iowa L. Rev. 1399, 1455–56 (2013) (arguing that the PHSA should be amended to give FDA authority to regulate genetic material for disease diagnosis and treatment purposes).

165 Kolata, *supra* note 79 ("'One year someone adds a personality profile, the next year someone adds something else,' [Director of Fairfax Cryobank] says. 'If one of your competitors adds a service, you add a service.'").

and egg banks.[166] Given the regulatory limitations as well as the privacy policy concerns, this tier would need to be voluntary.

VI. LEGAL AUTHORITY FOR REGISTRY

As stated previously, my tiered proposal would be a modest step forward because only the first tier would be mandatory, and the federal government already imposes these requirements or has the authority to do so. While many advocate for more binding disclosure requirements, Tiers II through IV would be voluntary so that the FDA and CDC would not have to assert additional authority or wait for Congress to pass legislation to establish a donor gamete registry. Once the donor gamete registry was in use, if Tiers II through IV became popular and stakeholders advocated for these tiers to become binding, the executive or legislative branches could respond appropriately with incremental disclosure requirements.

A. Current FDA Jurisdiction

As previously described in Part II.B, the FDA currently has authority over donor gametes pursuant to its authority under Section 361 of the Public Health Service Act. Scholars note that while the FDA has broad discretion over how to pursue communicable disease prevention, the goal itself is narrow, and in the ART context, does not provide authority to regulate cloning or genetic diseases.[167] As such, FDA has looked beyond its powers to prevent communicable disease transmission to assert its authority over specific, cutting-edge ART procedures by classifying them as clinical drug investigations.

In 2001, the FDA asserted authority over "human cells used in therapy involving the transfer of genetic material by means other than the union of gamete nuclei" by deeming any such transfer a "clinical investigation" that required submission of an Investigational New Drug (IND) application.[168] This description included ooplasm transfer, where donor ooplasm (cytoplasm of an egg)[169] is injected into infertile eggs along with sperm to aid fertilization and embryonic development,[170] nuclear transfer, where doctors take nuclei from infertile eggs and transfer them to enucleated donor eggs and then fertilized

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166 Braverman, *supra* note 15, at 485.

167 Peter Barton Hutt et al., Food and Drug Law: Cases and Materials 949 (3d ed. 2007) (noting that while Section 361 "allows FDA to use virtually any means" to accomplish disease prevention, this authority "arguably limits the measures that FDA might adopt"); Merrill, *supra* note 44, at 61. *But see* Cahn, *Accidental Incest*, *supra* note 2, at 105 ("The existing federal regulation infrastructure thus provides an appropriate starting place. A new section could be added to the existing regulations which mandate safety tests for gametic material.").

168 Letter from Kathryn C. Zoon, Dir. of the Ctr. for Biologics Evaluation and Research, FDA, to Sponsors/Researchers, Human Cells Used in Therapy Involving the Transfer of Genetic Material by Means Other Than the Union of Gamete Nuclei (July 6, 2001), available at http://www.fda.gov/biologicsbloodvaccines/safetyavailability/ucm105852.htm. Investigational biologics are subject to IND requirements of Section 505(i) of the FD&C Act prior to their licensure for marketing. 21 C.F.R. § 312.2(a).

169 *Ooplasm Definition*, Merriam-Webster, http://www.merriam-webster.com/medical/ooplasm (last visited Nov. 3, 2013).

170 Kerry Lynn Macintosh, *Brave New Eugenics: Regulating Assisted Reproductive Technologies in the Name of Better Babies*, 2010 U. Ill. J. L. Tech & Pol'y 257, 271 (2010).

with sperm,[171] and reproductive cloning.[172] The FDA referred to earlier notice of its authority over somatic cells and gene therapy products to support its regulatory power over these transfers.[173] In that 1993 notice,[174] the FDA explained that somatic cellular therapies were biologics, subject to the product license application process, and drugs, subject to the new drug application process and current good manufacturing practices.[175] As for gene therapy, the FDA stated that products containing modified genetic material for therapeutic purposes are also biologics or drugs requiring product license or new drug applications.[176]

Scholars' reactions are mixed over the FDA's increasing involvement in the ART field. For example, Professor Macintosh argues that the FDA's analogy to its power over drugs, even biological drugs, is "extremely weak" because these transfers, unlike gene therapy, are not transferred "directly into patients," but rather into "unfertilized eggs that are not human beings."[177] Others advocate that the FDA should go even further and screen donor gametes for genetic disease as part of its mandate "to ensure the safety and efficacy of biologics" under Section 351 of PHSA.[178] While the debate over the FDA's legal authority to regulate cutting-edge ART procedures is beyond the scope of this article, the FDA's recent actions demonstrate that the agency is increasingly involving itself in ART procedures, and thus its collaboration in setting up a national donor gamete registry with the CDC and the American Society for Reproductive Medicine would not represent a novel incursion into the ART industry.[179] Furthermore, establishing a donor gamete registry is arguably less intrusive into the realm of the practice of medicine because a registry merely records data. Besides setting a limit on the number of pregnancies associated with each donor, the registry would not impose any other new requirements on ART clinical practices.

Of course, the most common donor gamete is sperm, and artificial insemination with donated sperm is actually the one of the most low-tech ART procedures[180] and does

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171 *Id*. at 269–70.

172 *Id.* at 271.

173 Letter from Kathryn C. Zoon, *supra* note 167. *See also* Macintosh, *supra* note 145, at 273 ("Such gene transfers have the same purpose and effect as drugs, making it plausible that the FDA has authority and can require an IND application.").

174 Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248 (Oct. 14, 1993).

175 *Id*. at 53,250.

176 *Id*. at 53,251.

177 Macintosh, *supra* note 145, at 169.

178 Held, *supra* note 23, at 291–95. *See also* Dolin, *supra* note 163, at 1455–56 (arguing that the PHSA should be amended to give FDA authority to regulate genetic material for disease diagnosis and treatment purposes).

179 *Cf.* FDA, Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs 3 (2011) ("FDA defines 'genetically engineered (GE) animals' as those animals modified by rDNA techniques, *including the entire lineage of animals that contain the modification*." (emphasis added)).

180 *See* Daniel Wikler & Norma J. Wikler, *Turkey-Baster Babies: The Demedicalization of Artificial Insemination*, 69 Milbank Q. 5, 8 (1991) ("Turkey basters, a common kitchen utensil, are adequate instruments, and, in any case, the physician's syringe is readily available.").

not require medical intervention.[181] Because the FDA cannot claim that artificial insemination is a clinical investigation or a new drug, the FDA does not have sufficient regulatory power to create a donor gamete registry on its own. For this reason, partnership with the CDC, which has broader authority over ART procedures, is necessary to establish the registry.

B. CDC Authority

Unlike the FDA, the CDC already has the necessary authority to establish a donor gamete registry and mandate the Tier I requirements. The Fertility Clinic Success Rate & Certification Act (FCSRCA) delegated to HHS the authority to amend the definition of ART through notice-and-comment procedures,[182] so the CDC could broaden this definition to include artificial insemination with anonymous donor sperm. Doing so would require that clinics performing these procedures would also have to report their pregnancy success rates.

As for the definition of "pregnancy success rates," the FCSRCA also allows HHS to amend this definition in consultation with ART consumer and professional organizations. Congress directed the Secretary to consider "the effect of success rates of age, diagnosis, and other significant factors."[183] Thus the CDC, in consultation with these stakeholders, could revise its regulations to include the Tier I requirements.[184] Scholars have already criticized the CDC's narrow definition of pregnancy success rates. For example, Professor Judith Daar notes the incongruity of the ART system: "while [ART procedures] are directed at patients, outcomes are measured by the well-being of any resulting children . . . the birth of a healthy ART child is not necessarily a sign of health in the ART system."[185] Thus, it is likely that stakeholders would support amending the definition of pregnancy success rates to enable the CDC to work with the FDA to gather more the Tier I data—donors' health and screening information, including the number of times a donor's gametes are used for conception and the donor's conception and pregnancy outcomes—and make this available to donors and families through a registry.

As stated earlier, the CDC's regulatory discretion does have its limits, especially concerning medical events following pregnancy, which is why only the first tier of the registry would be mandatory. These limits, especially when coupled with the FDA's regulatory authority over donor gametes that is limited to prevention of communicable

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[181] *See* Debora L. Spar, The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception 18 (2006) (noting that artificial insemination has been practiced for more than a century).

[182] FCSRCA § 8, Pub. L. No. 102-493, 106 Stat. 3146, 3151 (codified at 42 U.S.C. § 263a–7 (2006).

[183] *Id.* § 2(b)(2).

[184] *Accord* Naomi Cahn, *The New Kinship*, 100 Geo. L.J. 367, 412 (2012) ("The centers for Disease Control and Prevention already collect information on the success of ART procedures involving eggs and embryos; this collection could be expanded to include information about sperm as well as the number of children born."); *see also* Daar, *supra* note 69, at 290 (recommending that any mandatory reporting requirements for embryo transfer should "parallel or piggyback on the existing system used to collect data on ART outcomes under FCSRCA").

[185] Daar, *supra* note 69, at 262–63. *See also* Cahn, *Necessary Subjects*, *supra* note 7, at 223.

disease transmission, demonstrate the need for the FDA and the CDC to form a public-private partnership with an entity like SART to establish a donor gamete registry.

C. *National Donor Gamete Registry: A Public-Private Partnership*

While the FDA and CDC would only have to undertake modest regulatory revisions to create a donor gamete registry with Tier I requirements, their authority, even when considered jointly, does not extend past Tier I. If HHS stopped there and only created a donor gamete registry with these requirements, many of the policies justifying the registry would not be realized. For example, because neither FDA nor the CDC has authority once the donation or pregnancy occurs, parents and donor-conceived children would not be able to benefit from broader access to medical history. Tier IV would certainly not be an option because facilitating connections between donor-conceived children and their genetic relatives is outside the scope of the FDA's and the CDC's limited authority. Thus, creating a donor gamete registry solely within the bounds of current HHS regulatory authority would not be worth the effort.

However, if the FDA and CDC partnered with a private party like American Society for Reproductive Medicine (ASRM), and allowed donors and families to volunteer to higher tiers of disclosure, then the registry would be more comprehensive and have a better chance of achieving its policy goals. Partnering with ASRM would allow the joint-entity to use its power as a professional organization to encourage more disclosure than HHS is currently allowed to mandate, and would justify the creation of a registry that collects more information than the HHS can legally require.

Both the CDC and the FDA have a current practice of partnering with private professional organizations. The CDC already has an extensive partnership with ASRM and its partner organization, the Society for Assisted Reproductive Technology (SART) under the FCSRCA, where it allows clinics to report their data to SART directly. As for the FDA, it already has a practice of encouraging individuals to participate in pregnancy registries run by private parties by linking to them on the FDA website. Thus, establishing the donor gamete registry as a joint project between the FDA, the CDC, and ASRM would allow the entities to pool their authority to create the most comprehensive registry by encouraging participants to volunteer more information than the government is currently allowed to collect.

D. HIPAA Implications of a National Donor Gamete Registry

One of the biggest challenges to creating a successful donor gamete registry is ensuring the privacy of the participants. The donor gamete registry would contain protected health information because donors would be tracked across clinics through a social security number, insurance number, or some other individual identifiable information. As a result, the registry and its owner would be subject to the Privacy and Security Rules.[186] Donors, as well as children linked to donors, would have to authorize the release of their data for research purposes.[187] The donor gamete registry could follow the NIH's model in DS-Connect, where NIH stores all the data, but only releases de-

[186] 45 C.F.R. § 160.103 (2012).

[187] *Id.* § 164.508(b)(3)(i).

identified data to approved researchers.[188] This "sponsor review model" would, on the one hand, prevent inappropriate uses of sensitive information, but could also raise public distrust because then the registry would be owned by the government and the ASRM, not by the donors and children.[189]

The relatively small donor gamete community heightens existing concerns with privacy breaches.[190] Furthermore, even de-identifying this data does not necessarily mean that people's protected health information will be secure. Professor Barbara Evans, in her discussion of the Sentinel Initiative, recommends "segregating key functions that use identifiable health information as inputs, and sharply restricting the number of [entities] handling patients' sensitive health data" to prevent harmful disclosure.[191] These recommendations would apply to a gamete donor registry as well.

VII. CONCLUSION: HHS IS TRENDING TOWARD A DONOR GAMETE REGISTRY

Despite the very real privacy concerns that a donor gamete registry raises, it is undeniable that HHS has experience partnering with non-governmental entities to facilitate public access to data from post-market clinical trials and patient and product registries. The increasing post-market surveillance suggests that not only does the public support this trend, but also that the health and technology sectors have the necessary expertise to create secure systems. The rising use of donor gametes to create families, coupled with the success of the Donor Sibling Registry, suggests that it is an optimal time to create a national donor gamete registry.

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188 *See Understanding Your Participation in DS-Connect supra* note 127.

189 Mello et al., *supra* note 110, at 1656.

190 *See* Swink & Reich, *supra* note 17, for an example of how a child tracked down his sperm donor online even though the donation was supposed to be anonymous.

191 *Evans*, Congress' New Infrastructural Model, *supra* note 137, at 640–41.

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