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Potential National Voluntary Gamete Donor Registry Discussed at Recent Health Law Symposium

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26. *Id.* (*Levine v. Wyeth*), at 186 (Congress explicitly amended the FDCA to emphasize that it overruled state law only where there was a "direct and positive conflict" between state law and the FDCA).
27. See *Wyeth, granting cert., supra* note 4.
28. See *Riegel, supra* note 1, at 1008.
29. *Id.*
30. *Id.*, at 1010.
31. See *Federal Register, supra* note 2, at 3933-3934 (interpreting the FDCA to pre-empt state regulations dealing with safety, including state tort actions).
32. See *Wyeth, supra* note 16, at 188.
33. See generally *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), but see *Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (refusing to allow the FDA to regulate tobacco products after the agency had insisted for years that it lacked the authority to do so).
34. See *Riegel, supra* note 1, at 1009.
35. U.S. Government Accountability Office, *Drug Safety: Improvements Needed in FDA's Postmarket Decision-making and Oversight Process*, GAO-06-402, March 2006.
36. See Thornton, *supra* note 5, at 82.
37. *National Vaccine Injury Compensation Program*, 42 U.S.C. § 300aa-11 (2000).
38. L. Greenhouse, "Justices Shield Medical Devices from Lawsuits," *New York Times*, February 21, 2008.
39. *Id.*

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Despite exponential growth in the past decades, most aspects of the assisted reproductive technology (ART) industry remain largely unregulated; recently, pressure has been mounting for coordinated study and regulation of this developing industry.[1] On March 28, 2008, lawyers, health care professionals, representatives from sperm banks, consumers of ART services, and other stakeholders in ART industry gathered at DePaul University College of Law for its Health Law Institute's symposium titled "Tracking Change: The Feasibility of a Voluntary Gamete Donor Registry in the United States." The implementation of a registry would mark the first effort in the United States to centralize, maintain, and disseminate information about gamete donors by collecting and storing genetic and identifying information about egg and sperm donors.[2] Establishing a registry requires balancing the interests of donor-conceived individuals, their parents, gamete donors, health care professionals, and society as a whole, as well as ensuring the privacy and safety of all involved.[3] Further, the consideration of a voluntary registry invites debate about the desirability of a mandatory registry and increased systematic consideration and regulation of ART generally.

Background

Currently, it is impossible to know the exact number of donor-conceived individuals in the United States because no federal, state, or private agency tracks donor-conceived births.[4] The ART industry in the United States is regulated primarily by voluntary guidelines issued by organizations such as the American Society for Reproductive Medicine (ASRM); as these guidelines are advisory only, the extent to which they are followed is unclear.[5] There are few federal or state regulations, and those that do exist are not comprehensive.[6] Thus, the result is a decentralized, private industry that has yielded a norm of anonymous gamete donation, an absence of information about the intricacies of the market for gametes and the effects of ART, confusion about the legal consequences of gamete donation, inconsistent record keeping of births, and a dearth of resources for donor-conceived individuals in search of their biological progenitors.[7] Nowhere is this result more evident than in the realm of gamete donation: there are 26 sperm banks (five of which supply 75-80% of sperm distributed) and several hundred egg donor programs in the United States, most operating according to their own standards. An accurate estimate of the number of egg donor programs is impossible as no registration, licensing, or other requirements exist to track such entities.[8]

In contrast to the United States' model, many other countries heavily regulate ART, including mandating the non-anonymity of donors.[9] Historically, the United States' norm of donor anonymity and overall lack of regulation of ART reflected infertility's stigma, a national emphasis on personal autonomy and privacy, and a heated political debate over abortion.[10] Nevertheless, in recent years, the desirability of anonymous gamete donation has come into question, especially with regard to the interests of donor-conceived individuals (and their parents) in learning about their genetic origins.[11] Donors themselves also have advocated for open-identity donation, indicating an interest in knowing the outcome of their donation and a willingness to have contact with offspring.[12] This change in the perspective of ART participants has resulted in the following: (1) prompted the ASRM to promulgate guidelines advocating the collection and distribution of donors' genetic information upon request to donor-conceived individuals and their parents;[13] (2) led to the creation of Web sites dedicated to linking donor-conceived children with their genetic

half-siblings and donor "parents" if all parties are in agreement;[14] (3) encouraged sperm banks to establish open-identity donor programs that operate alongside anonymous donation programs;[15] and (4) fostered an increase in the ratio of open-identity to anonymous donors.[16]

Overall, there has been a trend toward open-identity donation, a term that describes gamete donors who agree to release their identifying information to their offspring when those offspring reach adulthood.[17] As noted at the symposium, there also has been a recognition that all participants in the gamete donation process may have an interest in the collection, maintenance, and disclosure of information about gamete donors. The confluence of these developments is why "Tracking Change" assembled key stakeholders in the ART industry to debate the creation of a national voluntary gamete registry.

Benefits, Drawbacks, and Feasibility of a Registry

One of the main impetuses to creating a national voluntary gamete registry is donor-conceived individuals' (or their parents') desire to access information about their genetic origins. However, a registry would not merely be a place for donor-conceived individuals to go in search of their genetic origins, but it would also be a central database of information for health care professionals, researchers, consumers of ART services, donors, and half-siblings. "Tracking Change" focused on the multi-directional flow of information that a registry would facilitate and provided a forum for the key stakeholders to discuss the benefits, drawbacks, and design of a voluntary registry.

The symposium's participants primarily examined how a registry might be designed to ensure that donor-conceived individuals' (or their parents') desire to access their biological progenitors might be advanced while protecting the interests of donors and parents. Even enabling this unidirectional exchange of information between donor-conceived individuals and their biological progenitors has the potential to generate benefits for many more stakeholders. Assuming donor-conceived individuals know they are donor conceived, accessing such information may advance their psychological well-being and sense of self. Similarly, if desired by all parties involved, the information could facilitate the connection and possible meeting of donors and genetic half-siblings, likewise improving the psychological well-being of donors and genetic half-siblings. A registry also could provide updated medical information about a donor's offspring and genetic half-siblings, which would provide an added medical — in addition to psychological — benefit for these parties.[18] Though medical information is routinely collected from donors at the time of donation, this information is rarely updated; medical history is almost never collected from donor-conceived individuals for use by their donors and genetic half-siblings.[19]

Moreover, the societal benefits that may accrue from such a registry are immense. For example, tracking gamete donation could address a concern about inadvertent consanguinity.[20] Beyond identifying genetically related individuals by following who is donating gametes where and when and the outcome of ART cycles using those gametes, health care professionals and researchers could draw upon information contained in a registry to generate data to better study the effects of ART on consumers of ART services, donors, and offspring. An improved understanding of ART may provide empirical grounds for the establishment of national standards for gamete donors and individuals undergoing ART procedures, limits on the number of children created by one individual's gametes, limits on how many times or how frequently one individual may donate gametes, and regulation of the solicitation and compensation of gamete donors. Further, a registry may increase society's confidence in and acceptance of gamete donation, while simultaneously recognizing its uniqueness as a means to facilitate procreation, thus responding to ethical arguments about the commodification that may accompany gamete donation and ART. This may in turn result in reduction of the stigma associated with infertility.[21]

Realizing these personal and societal benefits requires negotiating the potentially adverse interests of donors and the parents of donor-conceived individuals. Legally, donors may have

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a right to prevent disclosure of their identifying information, and disclosure may violate the recipient parents' privacy. Conflictingly, donor-conceived individuals may have a right to know information about themselves under certain circumstances. Though a gamete registry could be designed to address donors' privacy concerns by allowing the disclosure of donors' identifying information only upon their approval or precluding contact without their consent, donors' significant concerns about their parentage status remain. A majority of states do have laws relieving sperm donors of parental rights so long as the intended parent(s) have consented, but only a few states have enacted similar legislation addressing egg and embryo donation. Further, even if donors are willing to submit their information to a registry, the lack of well-established and tested regulations may dissuade participation.[22]

Disincentives from uncertain legal regimes is but one of a number of barriers to implementation of a registry. The tension between intended parents' privacy and the ability of donor-conceived individuals to access their genetic origins raises the question of how children might learn that they are donor-conceived in the first place, which was largely beyond the symposium's scope. Additionally, though a registry may provide health care professionals with greater information about how ART affects their patients, thereby allowing them to better inform and follow-up with patients, health care professionals note that a registry may intrude upon the practice of medicine. For example, it may increase the already high cost of ART, pricing more people out of these services; it may decrease the availability of gametes by reducing donations; and it may encourage international reproductive travel.[23]

Logistical implementation issues also must be resolved. Open questions include who will be responsible for gathering information and ensuring its protection, how data will be verified, and what should be done with outdated records.[24] Though no concrete proposal for a voluntary registry was discussed at the symposium, the three largest sperm banks in the United States have advocated for the creation of a voluntary registry run by a non-profit entity governed by a board of directors elected by its members, who will fund the non-profit and be comprised of sperm banks and egg donation programs.[25] Yet, funding sources are influential, which leads others to question the appropriateness of vesting regulation in the industry being regulated.[26]

Overall, symposium participants agreed that even if the implementation issues associated with a purely voluntary registry prevent the full realization of the potential societal and personal benefits discussed, the creation of a voluntary national gamete registry is a step in the right direction when compared with the status quo of sparsely regulated and sporadic record keeping.

What Should Voluntary Mean, and Is a Mandatory Registry Desirable?

Questions about implementation led some participants to assert that a mandatory registry is necessary, although the symposium's participants only briefly discussed the relative merits of a mandatory versus a voluntary registry. Some time was spent considering the related question of what "voluntary" should mean. The medical or psychological benefits that donor-conceived individuals might experience could be undermined if parties opt-out at any one of several moments in a purely voluntary scheme. Some sperm banks and egg donor programs may decline to participate in the registry, and donors within a participating program may themselves decline to provide information or may choose to provide only partial information. For example, a donor-conceived individual would only be able to access her genetic information or connect with her biological relative(s) if her parents chose a fully participating donor from a participating program. Further, the larger societal benefits noted above have little chance of being realized without a guarantee that a threshold level of information will be collected and maintained.

A mandatory registry would ensure that donor-conceived individuals are able to access information about their biological origins while protecting the privacy of donors by including safeguards concerning when and how donors may be contacted. Moreover, a mandatory registry may prompt federal and state legislators to enact statutes to resolve legal issues surrounding ART. Finally, a mandatory registry would guarantee that health care professionals and researchers have robust information to consult when studying ART techniques.[27] However, given the United States' strong emphasis on personal autonomy and privacy, even if a mandatory registry is desirable, it may not be politically realistic.

Potential Impact on the Assisted Reproductive Technology Industry

As the first real national response to any consumer aspect of the ART industry, the mere proposal of a national registry has the potential to impact the ART industry far beyond providing for the needs of the donor-conceived individuals who initially motivated its suggestion, thus highlighting other aspects of the ART industry that invite systematic consideration and regulation. Although a discussion of these other aspects was almost entirely beyond the scope of "Tracking Change," it is interesting to hypothesize about some possible impacts of a registry on the ART industry that were only referenced in passing or not raised at the symposium.

In discussing the ART industry, commentators have focused on the consumers of ART services,[28] ART's corollaries with and effects on adoption,[29] and class inequalities in access to ART[30] as aspects of the industry that could benefit from increased regulation. Additionally, the need for counseling of all participants in the ART process was specifically mentioned at the symposium. But perhaps the most important consequence of increased discussion of ART is the potential to improve recognition of how most aspects of ART, especially egg donation, affect women. Egg donation is complicated, painful, and

potentially life-threatening.[31] With several hundred egg donor programs in the United States, it is virtually impossible to ensure that every woman who donates eggs is fully informed about the dangers of the procedure and that egg donation programs are taking the necessary safety precautions. Moreover, women themselves have become commercialized and sexualized apart from the eggs they donate, vastly more so than sperm donors.[32] Not only do select college students' eggs fetch upwards of $100,000,[33] an existing Web site offers the opportunity to bid on the eggs of the female models whose pornographic pictures members pay a monthly fee to view.[34] Such high monetary values placed on certain women's eggs engenders questions about the frequency with which some women donate eggs, which may bring both physical and mental health risks of its own.[35]

Further, little research has been conducted regarding the effects of multiple cycles of ART, multifetal pregnancies, and multifetal pregnancy reduction on a woman's body and psyche.[36] While a registry may provide a forum for data collection that will aid research into the effects of ART techniques, it has a much greater potential to highlight egg donation practices as purchasers of eggs consider obtaining eggs from a donor that participates in the registry, especially now that eggs can be frozen and the egg market increasingly resembles the impersonal sperm market.[37] Though there is a possibility that the conditions of egg procurement could become more obscured and worrisome, this transition to an impersonal market more likely will cause egg donor programs that participate in the national registry to be the primary places egg purchasers obtain open-identity donated eggs, a result that will encourage more uniform scrutiny and verification of the how those eggs were obtained.

Any sustained direct focus on how ART affects its many stakeholders has the potential to be extremely valuable. "Tracking Change" centered on the benefits of a national voluntary gamete registry to donor-conceived individuals in search of their biological origins and to other stakeholders who may access the information in the registry. Entwined in the discussion of how best to implement a registry to achieve those benefits is a broader debate about the regulation of the ART industry. The creation of a voluntary registry has the potential to advance the interests of donor-conceived individuals, their parents, gamete donors, and health care professionals, and in doing so, to highlight other aspects of the ART industry that are in need of systematic consideration at a time of rapid technological innovation.

References

1. See D. L. Spar, *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception* (Boston: Harvard Business Press, 2005): at 31-67.
2. See N. Elster, "All or Nothing? The International Debate over Disclosure to Donor Offspring, Institute on Biotechnology and the Human Future," *available at* <http://www.thehumanfuture.org/commentaries/assisted_reproductive_technology/art_commentary_elster01.html> (last visited June 19, 2008).
3. *Id.*
4. *Id.*
5. See, e.g., American Society for Reproductive Medicine, *available at* <http://www.asrm.org> (last visited June 19, 2008).
6. See P. D'Orazio, Note, "Half of the Family Tree: A Call for Access to a Full Genetic History for Children Born by Artificial Insemination," *Journal of Health & Biomedical Law* 2 (2006): 249-276, at 258-61.
7. See Elster, *supra* note 2; H. M. Alvare, "The Case for Regulating Collaborative Reproduction: A Children's Rights Perspective," *Harvard Journal on Legislation* 40, no. 1 (2003): 1-63, at 7-32; N. Cahn, "Children's Interests and Information Disclosure: Who Provided the Egg and Sperm? Or Mommy, Where (and Whom) Do I Come From?" *Georgetown Journal of Gender & Law* 2 (2000): 1-27, at 3-4.
8. As noted by Dr. Charles Sims, co-founder of California Cyrobank. Arguments and observations are attributed to symposium participants in endnotes.
9. See Elster, *supra* note 2.
10. *Id.*
11. *Id.*
12. See R. Rowland, "The Social and Psychological Consequences of Secrecy in Artificial Insemination by Donor (AID) Programs," *Social Science & Medicine* 21 (1985): 391-396.
13. See *supra* note 5.
14. See, e.g., The Donor Sibling Registry, *available at* <http://www.donorsiblingregistry.com> (last visited June 19, 2008).
15. J. E. Scheib and R. A. Cushing, "Open-Identity Donor Insemination in the United States: Is It on the Rise?" *Fertility and Sterility* 88, no. 1 (2007): 231-232.
16. *Id.*
17. *Id.*
18. As discussed by Wendy Kramer, co-founder of the Donor Sibling Registry, Bette Galen, LCSW, Andrea Braverman, Ph.D, both of Reproductive Associates of New Jersey, and Jean Benward, LCSW, co-president of the Sperm Bank of California.
19. As discussed by Dr. Richard Scott, Director of Reproductive Medicine Associates of New Jersey.
20. *Id.*
21. Dr. David Adamson, President of the American Society of Reproductive Medicine, Dr. Scott, and Dr. Mark Hughes, founder of the Genesis Genetics Institute.
22. Professor Naomi Cahn and Susan Crockin, principal of the Crockin Law & Policy Group, discussed legal issues in donor registries and ART.
23. As discussed by Dr. David Adamson.
24. Dr. Charles Sims, Sean Tipton of the American Society of Reproductive Medicine, and Earl Furfine, founder of Cardinal Technologies, addressed feasibility and implementation issues.
25. As discussed by Dr. Charles Sims.
26. As noted by Ms. Wendy Kramer.
27. Professor Naomi Cahn, Ms. Susan Crockin, and Ms. Wendy Kramer noted the desirability of a mandatory national registry.
28. See R. F. Storrow, "The Bioethics of Prospective Parenthood: In Pursuit of the Proper Standard for Gatekeeping in Infertility Clinics," *Cardozo Law Review* 28 (2007): 2283-2320.
29. See P. J. Manning, "Baby Needs a New Set of Rules: Using Adoption Doctrine to Regulate Embryo Donation," *Georgetown Journal of Gender & Law* 5, no. 2 (2004): 677-721.
30. See G. Becker, *The Elusive Embryo: How Men and Women Approach New Reproductive Technologies* (Berkeley: University of California Press, 2000): at 19-21.
31. See K. Baum, "Golden Eggs: Towards the Rational Regulation of Oocyte Donation," *Brigham Young University Law Review* (2001): 107-166, at 116-19.
32. See Alvare, *supra* note 7, at 12-14.
33. See Spar, *supra* note 1, at 44-46.
34. Ron's Angels, *available at* <http://www.ronsangels.com> (last visited June 19, 2008).
35. See J. Schneider, "It's Time for an Egg Donor Registry and Long-Term Follow-Up," Center for Genetics and Society, *available at* <http://geneticsandsociety.

org/article.php?id=3820> (last visited June 19, 2008).

36. See Alvare, *supra* note 7, at 24-25; M. Malinowski, "Creating Life? Examining the Legal, Ethical, and Medical Issues of Assisted Reproductive Technologies: A Law-Policy Proposal to Know Where Babies Come From During the Reproductive Revolution," *Journal of Gender, Race & Justice* 9 (2006): 549-568, at 553-55; C. Strong, "Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities," *Journal of Law, Medicine & Ethics* 31, no. 2 (2003): 272-282, at 274.
37. S. Yuen, Comment, "An Information Privacy Approach to Regulating the Middlemen in the Lucrative Gamete Market," *University of Pennsylvania Journal of International Law* 29, no. 2 (2007): 527-562, at 537-540.